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 Petition for a 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

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INTEREST OF *AMICI CURIAE*[1]

Amici Curiae AARP and the Public Patent Foundation respectfully submit this brief in support of petitioners Mayo Collaborative Services (d/b/a Mayo Medical Laboratories) and Mayo Clinic Rochester (collectively, "Mayo"), encouraging the grant of a writ of certiorari to review 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 the 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.

Amicus AARP is a nonpartisan, nonprofit organization dedicated to addressing the needs and

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[1] 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 have made a monetary contribution to the preparation or submission of this brief. Counsel of record for all parties received notice at least 10 days prior to the due date of the *amici curiae's* intention to file this brief. The parties have consented to the filing of this brief.

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. AARP works at the state and national levels for laws and policies that ensure greater freedom and competition in the healthcare marketplace. *See*, *e.g.,* Stephen Schondelmeyer and Leigh Purvis, *Rx Price Watch Report: Retail Prices for Widely Used Brand Name Drugs Increase Considerably Prior to Generic Competition*, AARP Public Policy Institute, Insight on the Issues 49, March, 2011, *available at* http://assets.aarp.org/rgcenter/ppi/health-care/i49-rx-2011.pdf. AARP supports Petitioners because patents that claim medical correlations prohibit diagnosis and treatment and discourage communication of medical information between a patient and physician.

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 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.

Amici support this petition for certiorari because of its interest in ensuring that laws of nature are not patented.

REASONS FOR GRANTING THE WRIT

I. This Court Previously Granted Certiorari On The Issue of Whether Medical Correlations Are Patentable, But Did Not Reach It For Procedural Reasons, Making This Case The Proper Vehicle To Address The Issue.

The issue in this case is effectively the same as that previously granted certiorari by this Court in *Lab. Corp. of Am. Holdings v. Metabolite Labs, Inc.*, 546 U.S. 999 (2005) which was:

> Whether a method patent directing a party simply to "correlat[e]" test results can validly claim a monopoly over a basic scientific relationship used in

> medical treatment such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result.

This Court ultimately did not reach the issue in *LabCorp*, because the writ of certiorari in that case was dismissed for having been improvidently granted. *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124 (2006). In dissenting from the dismissal of certiorari in *LabCorp*, Justices Breyer, Stevens, and Souter noted that, "those who engage in medical research, who practice medicine, and who as patients depend upon proper health care might well benefit from this Court's authoritative answer." The issue of whether medical correlations may be patented is one of supreme importance that merits this Court's attention.

To be sure, 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. *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*, 2009 U.S. Dist. LEXIS 101809 (S.D.N.Y. 2009) (owner of patents on medical correlations prevented patients from receiving medical services from physicians).

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 indicating they have an increased predisposition to those diseases. *Id.* at *16-17. Nature created the correlation between genetic mutations and predisposition for disease, not man. Thus, patents on the correlation between certain mutations and an increased risk of breast and ovarian cancer should not be patentable. But such patents are precisely what have been granted. *Id.*

In the years since *LabCorp*, the Federal Circuit has continued to blindly uphold medical correlation patents, without abiding by cases such as *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) where the Court prohibited 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. *See.*, *e.g.*, *Ass'n for Molecular Pathology*, 2009 U.S. Dist. LEXIS 101809 (involving patents claiming the correlation between mutated BRCA genes and an increased propensity for developing breast cancer). To be sure, under the Federal Circuit's decisions, including this case specifically, one could 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.

However, "correlation" patents like these violate the Court's long established precedent that prohibits the patenting of laws of nature.

Chakrabarty, 447 U.S. at 309 (citations omitted). 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) (Breyer, J., dissenting).

This Court has repeatedly rejected formulaic rules on issues in patent law, including particularly what constitutes patentable subject matter. *See Bilski v. Kappos*, 130 S. Ct. 3218 (2010) (rejecting the Federal Circuit's "machine or transformation" test for patent eligibility). Despite this, the Federal Circuit below again retreated to implement a formulaic rules-based analysis, finding as patentable subject matter anything that involves a transformation of matter, regardless whether that transformation is central to the patented invention or not. The "administering" step of the claims at issue here is of trivial importance, as there is no requirement that the amount of drug being administered cause any chemical change in the patient to whom the drug is administered. U.S. Patent No. 6,355,623 claim 1 (filed Apr. 8, 1999).

The Federal Circuit latched on to that triviality to uphold the patent as not being a law of nature. This was not a substantive analysis, but rather 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. This is wrong public policy and also directly in conflict with the Court's precedent.

Had the Federal Circuit correctly applied the pragmatic preemption analysis, 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, and that medical correlation is not an invention of the patentee. It is the result of nature's handiwork and to allow a patent on it, as the Federal Circuit has done, is to allow a patent that denies all use by others of a law of nature until the patent expires.

Now is the time and this is the case to declare that correlations based on laws of nature cannot be patented. The issue has been properly raised and all of the reasons justifying a grant of certiorari in *LabCorp* still exist today. In fact, the issue is perhaps of more importance today than it was several years ago, due to the increased rate at which the Patent Office has granted such patents.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

April 20, 2011 Respectfully submitted,

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