No. 09-490

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

DANIEL B. RAVICHER
PUBLIC PATENT FOUNDATION
BENJAMIN N. CARDOZO SCHOOL OF LAW
55 Fifth Avenue
New York, NY 10003
(212) 796-0570

STACY CANAN*
AARP FOUNDATION LITIGATION

MICHAEL SCHUSTER
AARP

601 E Street, NW
Washington, DC 20049
(202) 434-2060

**Counsel of Record for Amici Curiae*

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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 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.

Amicus AARP is a nonpartisan, nonprofit membership organization of nearly 40 million persons age 50 or older. It is dedicated to addressing the needs

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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 written consents of the parties to the filing of this brief have been filed with the Clerk of the Court pursuant to Supreme Court Rule 37.3.

and interests of older Americans. As the country's largest membership organization, AARP has a long history of advocating for access to affordable health care and for controlling costs without compromising quality. Affordable health care is particularly important to the older population because of its higher rates of chronic and serious health conditions. For example, persons over sixty-five, although only thirteen percent of the population, account for thirty-four percent of all prescriptions dispensed and forty-two cents of every dollar spent on prescription drugs. Families USA, Cost Overdose: Growth in Drug Spending for the Elderly, 1992-2010 at 2 (July 2000). 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.*, AARP, Rx Watchdog Report, Apr. 2009, Vol. 6, Issue 3, *available at* http://assets.aarp.org/www.aarp.org_/cs/health/rx_watchdog_apr09.pdf. 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 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 re-examine 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 this petition for certiorari because of its interest in ensuring that laws of nature are not patented.

REASONS FOR GRANTING THE WRIT

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. of Am. Holdings v. Metabolite Labs, Inc., et al.*, 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 did not, however, 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." We could not agree more that 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 do nothing more than express 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, et al. 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, owners of medical correlation patents have used them to prevent patients contemplating prophylactic breast and ovary removal from getting independent verification that they have a

genetic mutation indicating an increased predisposition to those diseases. *Id.* at 16-17.

In the years since *LabCorp*, the Federal Circuit has continued to blindly uphold medical correlation patents. 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., id.* (involving patents claiming the correlation between mutated BRCA genes and an increased propensity for developing breast cancer).

However, such patents violate 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 explained repeatedly 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).

Thus, *Amici* respectfully submit that now is the time and this is the case to declare that medical correlations 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 four years ago, due to the increased rate at which the Patent Office has granted such patents.

CONCLUSION

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

November 25, 2009

Respectfully submitted,

Daniel B. Ravicher
Public Patent Foundation
Benjamin N. Cardozo School of Law
55 Fifth Avenue
New York, NY 10003
(212) 790-0442

Stacy Canan*
AARP Foundation Litigation

Michael Schuster
AARP

601 E Street, NW
Washington, DC 20049
(202) 434-2060

*Counsel of Record for *Amici Curiae*