

COURTESY COPY

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

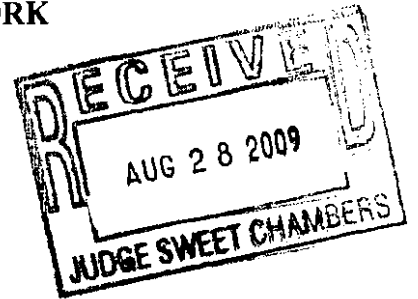
ASSOCIATION FOR MOLECULAR
PATHOLOGY, et al.,

Plaintiffs,

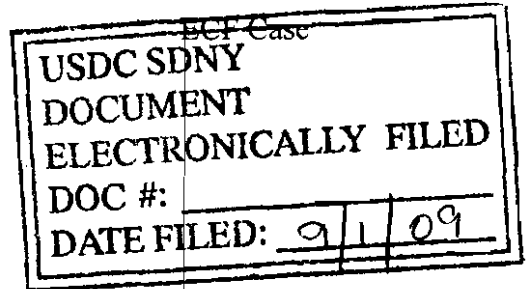
v.

UNITED STATES PATENT AND TRADEMARK
OFFICE, et al.,

Defendants.



09 Civ. 4515 (RWS)



NOTICE OF MOTION AND MOTION OF AMERICAN MEDICAL ASSOCIATION (AMA), AMERICAN SOCIETY OF HUMAN GENETICS (ASHG), AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS (ACOG), AMERICAN COLLEGE OF EMBRYOLOGY (ACE), AND THE MEDICAL SOCIETY OF THE STATE OF NEW YORK (MSSNY) FOR LEAVE TO FILE A BRIEF *AMICI CURIAE* IN SUPPORT OF PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTIONS TO DISMISS AND IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

PLEASE TAKE NOTICE that the American Medical Association, American Society of Human Genetics, American College of Obstetricians and Gynecologists, American College of Embryology, and the Medical Society of the State of New York, by their attorney Amy L. Katz, move for leave to file the accompanying brief in the above-captioned matter as *Amici Curiae* based upon reasons set forth below and in the accompanying brief. Proposed *Amici* are medical associations that seek to provide this Court with needed insight into the adverse effects on medical care and innovation caused by the threat of enforcement of gene patents in general and the breast/ovarian cancer gene patents at issue in this case in particular.

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Proposed *Amicus Curiae* American Medical Association (AMA) is a private, voluntary non-profit organization of 240,000 physicians and medical students, who practice in all states and all fields of medical specialization. From its inception, the AMA has maintained a Code of Medical Ethics, including a set of core Principles and a Code and Opinions applying those Principles. The Code has been cited by ethicists, legal scholars and courts of law, including, on numerous occasions, the U.S. Supreme Court. The AMA (with others) has issued numerous statements regarding the need to avoid having gene patents interfere with appropriate medical care and the development of better medical treatments and technologies, and declaring unethical any limitations on the dissemination of medical knowledge.

Proposed *Amicus Curiae* American Society of Human Genetics (ASHG) is a non-profit, tax-exempt organization that consists of over 8,000 professionals in the field of human genetics including researchers, clinicians, academicians, ethicists, genetic counselors, and nurses whose work involves genetic testing. ASHG has studied the gene patent issue since such patents were first granted and has found that patents on sequences and correlations interfere with research and medical care.

Proposed *Amicus Curiae* American College of Obstetricians and Gynecologists (ACOG) is a non-profit, tax-exempt organization that consists of over 51,000 health care professionals dedicated to providing quality health care to women. The patents at issue in this case interfere with ACOG's members' ability to provide health care and undertake research.

Proposed *Amicus Curiae* American College of Embryology (ACE) develops and maintains professional standards for embryologists. Patents on gene sequences and correlations have impeded embryologists' their ability to understand the complex cellular and genetic interactions related to organ development.

Proposed *Amicus Curiae* Medical Society of the State of New York (MSSNY) is a voluntary association of approximately 27,000 licensed physicians, medical residents, and medical students in all specialties in New York. The patents at issue in this case interfere with the purposes of MSSNY to enhance the delivery of medical care of high quality to all people and ensure that high quality medical care is available to the public.

The Plaintiffs have consented to the filing of this brief. Defendant U.S. Patent and Trademark Office has indicated that it does not object to the filing of this amicus brief. Defendants Myriad and Directors of the University of Utah Research Foundation have stated that they consent to the filing of an amicus brief, “but only to the extent it is limited to the jurisdictional issue[s] raised by our pending motions.” Defendants Myriad and Directors of the University of Utah Research Foundation have also stated, “While we have no objection to your filing an amicus brief in support of plaintiffs' substantive position on the merits in this action at an appropriate time, we do not consent to your filing of such a premature amicus brief at this time.”

A district court has broad discretion in allowing an appearance as *Amicus Curiae*. *Ester Sadowsky Testamentary Trust Derivatively ex rel. Home Loan Mortgage Corp. v. Syron*, 2009 WL 1285982, *3 (S.D.N.Y. May 6, 2009) (citing *United States v. Ahmed*, 788 F.Supp. 196, 198 n.1 (S.D.N.Y. 1992)). In *Strougo v. Scudder, Stevens & Clark, Inc.*, 1997 WL 473566, *3 (S.D.N.Y. Aug. 18, 1997), leave to participate amicus curiae was granted when the “parties have identified no prejudice arising from [*Amicus*’s] participation, and the policy arguments advanced by the [*Amicus*] may illuminate the legal issues presented by this motion.” *Id.* Moreover, “[t]he primary role of the *amicus* is to assist the Court in reaching the right decision in a case affected

with the interest of the general public.” *Ester Sadowsky Testamentary Trust Derivatively*, 2009 WL 1285982, *3.

This is a case of wide-ranging consequences and great public interest. The brief of *Amici* Medical Associations is relevant to the policy and legal issues raised by the Defendants’ Motion to Dismiss as well as to the Plaintiffs’ Motion for Summary Judgment. In addition, it will not prejudice any of the parties.

Specifically, the attached brief is relevant to the Court’s pending decision on the non-governmental motion to dismiss because it provides the necessary context for understanding the real and immediate adverse effects the Defendants’ actions have on physicians and researchers and how those actions cause such effects. The brief is relevant to the Court’s pending decision on the U.S. Government’s motion to dismiss because it explains why the patents at issue are unconstitutional and not authorized by the Patent Act. For the same reasons, the brief is relevant to the Plaintiffs’ motion for summary judgment.

The invalidity of gene sequence and correlation patents is of vital concern to proposed *Amici* Medical Associations and the general public. *Amici* submit this brief in order to explain why these patents are invalid and how these patents affect medical care and innovation, issues that are at the heart of the public interest. Permitting the filing of an *Amici* brief at this point in the proceedings should not prejudice any party because it is filed contemporaneously with Plaintiffs responses and motion and allows the Defendants to consider the full range of legal arguments raised by the motions to dismiss and by the summary judgment motion in any replies and responses, respectively. Further, this brief provides the Court with important and relevant facts and legal, policy, and ethical information that illuminate the legal issues presented by Defendant’s motion to dismiss and the Plaintiff’s motion for summary judgment.

WHEREFORE, AMA, ACOG, ASHG, ACE, and MSSNY hereby respectfully request that this Court accept for filing the accompanying brief.

Respectfully submitted,

Dated: August 27, 2009

s/Amy L. Katz

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