UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

ASSOCIATION FOR MOLECULAR PATHOLOGY, et al.,

Plaintiffs,

v.

09 Civ. 4515 (RWS)

UNITED STATES PATENT AND TRADEMARK OFFICE, et al.,

ECF Case

Defendants

NOTICE OF MOTION AND MOTION OF GENETIC ALLIANCE FOR LEAVE TO FILE A BRIEF AMICUS CURIAE IN OPPOSITION TO CERTAIN POSITIONS OF THE PLAINTIFFS

PLEASE TAKE NOTICE that the Genetic Alliance, by its counsel, moves for leave to file the accompanying brief in the above-captioned matter as Amicus Curiae based upon reasons set forth below.

Proposed Amicus Curiae Genetic Alliance is a not-for-profit, tax-exempt health advocacy organization founded in 1986 (as the Alliance for Genetic Support Groups). Genetic Alliance brings together diverse stakeholders that create novel partnerships in advocacy. By integrating individual, family, and community perspectives to improve health systems, we seek to revolutionize access to information to enable translation of research into services and individualized decision-making. Proposed amicus seeks to provide this court with insight into the importance of so-called "gene patents" not only for genetic testing but also for the development and manufacture of potential treatments for genetic diseases.

A district court has broad discretion to allow an appearance as amicus curiae. *Esther 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), *aff'd*, 980 F.2d 161 (2d Cir.1992)). The privilege rests in the discretion of the court, which may grant or refuse leave based upon whether it views the proffered information timely, useful, or otherwise. *Long Island Soundkeeper Fund, Inc. v. New York Athletic Club*, 1995 WL 358777, * 1 (S.D.N.Y. 1995) (citing *Leigh v. Engle*, 535 F. Supp. 418, 420 (N.D.III. 1982)). Leave to participate as *amicus curiae* has been granted when the parties have identified no prejudice arising from participation of amicus, and policy arguments advanced by the amicus may illuminate legal issues presented by the motion. *Strougo v. Scudder, Stevens & Clark, Inc.*, 1997 WL 473566, at *3 (S.D.N.Y Aug. 18, 1997). 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." *Esther Sadowsky Testamentary Trust Derivatively*, 2009 WL 1285982, at *3.

This case concerns the validity of patent claims relating to isolated DNA molecules. The outcome of the case may have broad and profound consequences affecting not only genetic research and testing, but also the future of genetic health services available to the public, the discovery and development of treatments for genetic diseases, and biotechnology in general. The brief of amicus Genetic Alliance is relevant to the policy and legal issues raised by the Plaintiffs' Motion for Summary Judgment. Amicus believes that the wholesale changes in the patent law advocated by plaintiffs are inappropriate vehicles for remedying the harms of which the plaintiffs complain. Amicus further believes that these wholesale changes would be detrimental to the development of diagnostics and therapies critical to alleviate disease burden. These changes would delay or prevent advances in biotechnology that would be beneficial to

patients. Indeed, with the right policies, patents on isolated DNA molecules related to genetic diseases facilitate access to reliable testing and therapies. The discussion of substantive patent law presented in the attached memorandum of law may be particularly helpful to the court because a defendant with special expertise in patent law, the United States Patent and Trademark Office, will be responding only to Constitutional arguments and not to other questions of substantive patent law. This brief will not prejudice any of the parties. We believe that it will assist the Court by providing important information on basic patent law principles and on the scientific and social consequences of prohibiting patenting in a critical area of biological technology of great importance to patients.

Representatives of plaintiffs (ACLU) and defendants (Myriad et al.) have consented to filing of an amicus brief, but the undersigned has been unable to reach all parties today.

Respectfully Submitted,

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