

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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ASSOCIATION FOR MOLECULAR	:
PATHOLOGY et al.,	: 09-CV-4515 (RWS)
	:
Plaintiffs,	:
vs.	:
	: ECF
UNITED STATES PATENT AND TRADEMARK	:
OFFICE; et al.,	:
	:
Defendants.	:
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MEMORANDUM OF LAW OF MARCH OF DIMES FOUNDATION, CANAVAN FOUNDATION, CLAIRE ALTMAN HEINE FOUNDATION, MASSACHUSETTS BREAST CANCER COALITION, NATIONAL ORGANIZATION FOR RARE DISORDERS, AND NATIONAL TAY-SACHS & ALLIED DISEASES ASSOCIATION IN SUPPORT OF MOTION FOR LEAVE TO FILE BRIEF *AMICUS CURIAE*

Proposed *Amici Curiae* March of Dimes Foundation, Canavan Foundation, Claire Altman Heine Foundation, Massachusetts Breast Cancer Coalition, National Organization for Rare Disorders, and National Tay-Sachs & Allied Diseases Association (collectively “*Amici Curiae*”) submit this memorandum of law in support of their motion for leave to file a brief *amicus curiae*.

I. INTRODUCTION AND INTERESTS OF PROPOSED *AMICI CURIAE*

Amici Curiae seek leave to file their proposed brief *amicus curiae*, submitted concurrently herewith, in order to assist the Court in understanding some very important issues in this case. All Plaintiffs and Defendants have consented to the filing of an amicus brief by *Amici Curiae*, though as described below the extent of that consent differs among the Defendants.

This case concerns the patenting of DNA sequences of genes associated with hereditary forms of breast and ovarian cancer, and correlations between those sequences and the likelihood

of getting such cancers. Two *amici curiae*, the Canavan Foundation and the National Tay-Sachs & Allied Diseases Association previously brought suit against a patent holder that prevented low-cost genetic testing using patent claims similar to those in issue here. *Amici Curiae* have a substantial interest in the outcome of this case. They represent and support patients affected by, and susceptible to, diseases which are linked to a person's genetic code. *Amici Curiae* believe that Myriad's patent claims in issue here, and similar claims in other patents related to other genes and diseases, are unpatentable natural phenomena and laws of nature. *Amici Curiae* further believe that enforcement and restrictive licensing of patent claims like these cause real harm to scientific research and development into genetic-related diseases and, ultimately, and most importantly, to those susceptible to such diseases. As *Amici Curiae* explain in more detail in their proposed brief, unless patent claims such as Myriad's claims in issue here are ruled to be invalid as covering unpatentable subject matter – as Supreme Court precedent dictates they should be – then patients will continue to be harmed. The purpose of the proposed brief *amicus curiae* is to explain these extremely important issues in more detail to assist the Court.

Amici Curiae approached all of the parties last week seeking their consent to the filing of an amicus brief today. Last week all parties gave their consent without restriction. This morning, however, counsel for Defendants Myriad Genetics and the Directors of the University of Utah Research Foundation (“the Myriad Defendants”) contacted counsel for *Amici Curiae* to “clarify” their consent. Myriad's counsel stated that:

I would like to clarify the “consent to the filing of an amicus curiae brief on behalf of your identified clients” set forth in my August 20, 2009 e-mail below. In your e-mail on the preceding day requesting the consent (also set forth below), you indicated that the amicus brief would be filed in support of the plaintiffs and would be filed on “Wednesday, August 26, 2009, the same day that oppositions to the defendants' motions to dismiss are due.” The pending defendants' motions you referenced are a motion to dismiss the entire case under Rule 12(b)(1), F.R.Civ.P., for lack of “case or controversy” subject matter jurisdiction (i.e. lack

of standing) and a motion to dismiss as to the individual named defendants under Rule 12(b)(2), F.R.Civ.P., for lack of personal jurisdiction.

Our consent to the filing of an amicus brief on behalf of your identified clients was simply a consent to your filing of an amicus brief on the jurisdictional issues raised by the pending motions. We have subsequently learned that the plaintiffs, in addition to filing an opposition due today to our jurisdictional motions to dismiss, also plan on filing a summary judgment motion going to the merits of the issues raised in their complaint, namely, that certain claims in the seven patents identified in the complaint relating to the BRAC1 and BRAC2 genes are invalid and/or unconstitutional. We have notified the plaintiffs that if they do file such a summary judgment motion on the merits, we shall seek a stay of such a motion and all briefing with respect thereto until the Court decides our pending motions dealing with threshold jurisdictional issues. 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.

From this it appears that the Myriad Defendants still consent to the filing of an amicus brief on jurisdictional issues, but not – at this time – on substantive issues on the merits of the action.

The proposed brief of *Amici Curiae* to assist the Court addresses topics highly relevant to *both* the jurisdictional issue of standing as well as the substantive issue of patentability of the Myriad patent claims in dispute. That is because the harm caused by patents to unpatentable natural phenomena and laws of nature, such as those in issue in this case, directly affects patients with genetic diseases and those susceptible to such diseases. Several of the Plaintiffs are patients affected by or susceptible to genetic diseases, as are those represented by *Amici Curiae*. The patent claims in issue, and claims like them, restrict use of the patented genes in diagnosis and prevention of disease, they restrict research into new treatments and cures, and they prevent patients from getting second opinions. These are examples of harm caused by the patent claims in issue that are relevant to both the jurisdictional issues and the substantive patent issues.

To the extent the Myriad Defendants today have withdrawn their consent to the filing of a brief *amicus curiae* “in support of plaintiffs’ substantive position on the merits,” it appears that this is only a question of the timing of such brief. However, they still appear to consent to an amicus brief on matters relevant to the jurisdictional issues, which the proposed brief *amicus curiae* addresses. Plaintiffs and the USPTO have not changed their positions on the consent they gave last week.

II. ARGUMENT

“Federal courts have discretion to permit participation of amici where such participation will not prejudice any party and may be of assistance to the court.” *Strougo v. Scudder, Stevens & Clark, Inc.*, 1997 WL 473566, at *3 (S.D.N.Y. Aug. 18, 1997) (citing *Vulcan Society of New York City Fire Dep’t, Inc. v. Civil Service Comm’n*, 490 F.2d 387, 391 (2d Cir. 1973)). *See also Zell/Merrill Lynch Real Estate Opportunity Partners Ltd. P’ship III v. Rockefeller Center Properties, Inc.*, 1996 WL 120672, at *4 (S.D.N.Y. March 19, 1996) (granting leave to appear and argue, citing cases “uniform in support of a district court’s broad discretion to permit or deny amici appearances”); *United States v. Gotti*, 755 F.Supp. 1157, 1158 (E.D.N.Y. 1991) (holding amici can “provide supplementary assistance to existing counsel and insur[e] a complete and plenary presentation of difficult issues so that the court may reach a proper decision”). *See also The City of New York v. United States*, 971 F. Supp. 789, 791 n.3 (S.D.N.Y. 1997) granting leave to file a brief *amicus curiae* in relation to a motion for judgment on the pleadings.

This is an important case about the application of fundamental patent laws to complex scientific and health issues. It concerns the harm caused to patients and others by patents granted on unpatentable natural phenomena and laws of nature. It concerns the scope of patentable subject matter and raises significant constitutional issues concerning patent and First

Amendment rights. In light of this importance and complexity, and the substantial interests of patients and their supporters and advocates, such as *Amici Curiae*, it is appropriate for the Court to exercise its discretion to allow *Amici Curiae* to file the proposed brief *amicus curiae* to assist the Court in this case, especially given that Plaintiffs and the United States Patent and Trademark Office, one of the Defendants, do not oppose this. Furthermore, the Myriad Defendants do not oppose a brief *amicus curiae* at the present time addressing matters relevant to the jurisdictional issues, which the proposed brief does.

III. CONCLUSION

For the foregoing reasons, *Amici Curiae* respectfully request that the Court grant their Motion for Leave to File the proposed brief *amicus curiae* submitted concurrently herewith.

Dated: August 26, 2009

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