

**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)

ECF

**MEMORANDUM OF LAW OF
BIOTECHNOLOGY INDUSTRY
ORGANIZATION IN SUPPORT OF
MOTION FOR LEAVE TO FILE
AMICUS CURIAE BRIEF**

Proposed *Amicus Curiae*, the Biotechnology Industry Organization (“BIO”), submit this memorandum of law in support of their motion for leave to file a brief *amicus curiae*.

I. INTRODUCTION AND INTERESTS OF PROPOSED *AMICUS CURIAE*

BIO is the country’s largest biotechnology trade association, representing over 1200 companies, academic institutions, and biotechnology centers in all 50 States. BIO members are involved in the research and development of biotechnological healthcare, agricultural, environmental and industrial products. BIO member companies range from start-up businesses and university spin-offs to large Fortune 500 corporations. The vast majority of BIO’s members are small companies that have yet to bring products to market and attain profitability. In many cases, gene-based patents are critical for a biotech company’s ability to attract the capital and investment necessary for the development of innovative diagnostic, therapeutic, agricultural and environmental products. Thus, the issues raised in this case are of great importance to the U.S. biotechnology industry.

BIO has reached out to the parties in this case seeking their consent to the filing of a brief *amicus curiae*. Counsel for Plaintiffs, Myriad Genetics, the Directors of the University of Utah

Research Foundation and the United States Patent and Trademark Office have consented to the filing of BIO's proposed *amicus curiae* brief.

BIO seeks leave to file their proposed *amicus curiae* brief, submitted herewith, in order to assist the Court with the complex and important issues raised by this case. Plaintiffs' unprecedented constitutional and statutory challenges to the patenting of isolated DNA molecules go far beyond the *BRCA1* and *BRCA2* genes at issue in this case; consequently, they are of tremendous concern to BIO, its membership, and society at large. As explained in more detail in the proposed brief, jurisprudence originating in this Court nearly a century ago has recognized the patent-eligibility of isolated substances that differ in kind, and not merely in degree of purity, from their natural counterparts. *Parke-Davis & Co. v. H. K. Mulford Co.*, 189 F. 95 (S.D.N.Y. 1911). For more than two decades, our courts and the United States Patent and Trademark Office have extended the wisdom of Judge Learned Hand to isolated nucleic acids and have approved the granting of thousands of patent claims to isolated DNA molecules comprising sequences derived from human, animal, plant and bacterial sources. From the mass production of life-saving medicines by cell cultures to the screening of our blood supply for life-threatening viruses, patented isolated DNA molecules have been put to countless uses that have benefited society -- uses not possible with the sequences as they exist in nature. Thus one purpose of the proposed brief *amicus curiae* is to highlight how such uses distinguish isolated DNA molecules in kind from their counterpart naturally occurring sequences, and compel their patent-eligibility.

Whether the goal is to identify a DNA molecule that can be used to develop a test that will predict if someone will develop a dangerous reaction to a specific drug, or to create a vaccine for the prevention of, e.g., cervical cancer, or to recombinantly produce a life-saving

therapeutic protein, the prospect of obtaining patents on isolated nucleic acid molecules provides an important incentive to BIO's membership, and to the research community at large, to expend the time, energy, and investment needed to translate basic scientific discoveries into real-world products that benefit patients, physicians, and consumers. Thus, another purpose of the proposed *amicus curiae* brief is to explain that the U.S. biotechnology industry dwarfs that of the rest of the world in large part because the U.S. patent system encourages investment in biotechnology research and development, and the DNA patenting incentives of the past 25 years have significantly contributed to making the United States the global leader in biotechnology innovation that it is today. Certainly, the constitutional objective of advancing the progress of science and the useful arts will not be served if important gene-based discoveries lie barren and are not developed for public use because patents on them will not be granted.

II. ARGUMENT

Federal District Courts are afforded broad discretion in allowing the filing of briefs *amicus curiae*. *United States v. Ahmed*, 788 F.Supp. 196, 198 n.1 (S.D.N.Y. 1992) ("District courts have broad discretion to permit or deny the appearance of amici curiae in a given case."). Amicus participation has been recognized by this Court as useful in situations where "participation will not prejudice any party and may be of assistance to the court." *Strougo v. Scudder, Stevens & Clark, Inc.*, No. 96-cv-2136, 1997 WL 473566, at *3 (S.D.N.Y. 1997). In particular, this Court has recognized the importance of granting leave for participation by *amicus curiae* when such participation may result in the advancement of policy arguments capable of illuminating the legal issues in dispute. *Id.* (granting leave for *amicus curiae* to participate when "the policy arguments advanced by the [*amicus curiae*] may illuminate the legal issues presented by this motion").

That this case involves fundamental questions regarding the scope of our patent laws cannot be overstated. Any decision impacting long standing expectations regarding the patent-eligibility of isolated substances will have enormous public health and economic implications. Given the complexity of the legal issues surrounding this case, as well as the underlying technical and policy issues, BIO submits that this Court will be well-served by exercising its discretion in allowing the filing of the proposed brief *amicus curiae* submitted herewith. The proposed brief *amicus curiae* is particularly relevant to the instant proceedings as it provides the technical and policy background necessary to understand how changes to such long standing expectations will impact the industry most closely connected to the claims at issue, the biotechnology industry.

III. CONCLUSION

In view of the foregoing, BIO respectfully request that this Court grant their Motion for Leave to File the proposed *amicus curiae* brief submitted herewith.

Dated: December 30, 2009

Respectfully Submitted:

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CERTIFICATE OF SERVICE

This is to certify that on December 30, 2009 a true and correct copy of the foregoing document has been served on registered counsel of record via the Court's ECF system.

Dated: December 30, 2009

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