

**IN THE UNITED STATES DISTRICT COURT  
IN AND FOR THE SOUTHERN DISTRICT OF NEW YORK**

ASSOCIATION FOR MOLECULAR  
PATHOLOGY, et al.,

Plaintiffs,

v.

UNITED STATES PATENT AND  
TRADEMARK OFFICE, et al.,

Defendants.

CASE NO. 09-CV-4515 (RWS)

**MEMORANDUM IN SUPPORT OF MOTION FOR LEAVE  
TO FILE BRIEF *AMICI CURIAE***

Proposed *Amici Curiae* BayBio, Celera Corporation, The Coalition for 21st Century Medicine, Genomic Health, Inc., QIAGEN, N.V., Target Discovery, and XDX, Inc. submit this memorandum of law in support of their motion to leave to file a brief *amici curiae*.

*Amici Curiae* seek leave to file their proposed brief *amici curiae*, submitted concurrently herewith, in order to assist the Court in understanding many of the important and complex issues concerning the patentability of human DNA sequences.

**I. INTRODUCTION AND INTERESTS OF PROPOSED *AMICI CURIAE***

Personalized medicine is universally acknowledged to hold enormous potential for treating diseases, improving the quality of patients' lives, decreasing health care costs by identifying patients most likely to benefit from particular therapies, and streamlining the drug discovery and development process. Molecular diagnostics allow patients to be classified into sub-categories based on correlations between genetic biomarkers and clinically useful disease characteristics, and to monitor the ongoing response to treatment. This evolving technology has

already delivered tremendous results for individual patients, and current research efforts and clinical trials promise significant future improvement in health care.

Molecular diagnostic companies are typically small and rely on private investment capital to sustain them through the lengthy and expensive research, development, and commercialization process. Also, there are increasing pressures from collaborative organizations to share ownership of any realized inventions in exchange for allowing access to the clinical samples and data necessary to validate these diagnostic correlations. For these reasons, most personalized medicine companies are highly dependent on their ability to protect their diagnostic tests through patents.

One of the *Amici Curiae*, Genomic Health Inc., is committed to improving the quality of cancer treatment decisions through genomics-based clinical laboratory services. Genomic Health currently offers an assay, which predicts the likelihood that a patient with early-stage, ER+ breast cancer will experience a recurrence within 10 years and whether that patient will benefit from adding chemotherapy to his/her hormonal therapy. Genomic Health has received multiple patents covering the methods and systems used to provide this valuable genomic information and is committed to making this assay available to patients and encouraging independent research in the area of oncology.

*Amicus Curiae* Celera Corporation is a manufacturer of diagnostic products that include DNA sequence-based products used in genetic testing. Celera has entered into agreements with the patent owners for non-exclusive licenses to the relevant patents, has obtained FDA clearance to commercialize a diagnostic product utilizing the patented DNA sequence-based technologies, and has become the worldwide leader of such cystic fibrosis testing products. Thus, these licensing arrangements have provided Celera access to critical DNA sequence-based patents for commercial development, and Celera's product has made cystic fibrosis testing widely available. It is the general public that has benefited because of the availability of this genetic testing.

*Amicus Curiae* QIAGEN, founded in 1984, is a leading provider of innovative sample and assay technologies and products which are considered standard for use in molecular

diagnostics, applied testing, and academic and pharmaceutical research and development. QIAGEN's products standardize workflows and enable customers to reliably and rapidly process samples from collection through purification and analysis of the target molecules. QIAGEN works closely with global health advocates and public health partners to select and serve appropriate recipient groups in the most effective manner. QIAGEN offers more than 500 consumable products and automated solutions, and announced a donation of one million of its HPV tests to bring cervical cancer screening to the world's developing nations to benefit the countries most in need.

*Amicus Curiae* Target Discovery discovers, validates, and utilizes protein isoforms to improve clinical diagnosis and management of disease. The company's initial products assist patients and doctors in making critical chemotherapy decisions in ovarian cancer and lung cancer. Outside of its cancer focus, Target Discovery collaborates with companies to develop its proprietary technology for assays in other diseases. The development of assays to determine patient-specific response profiles relative to drug efficacy or toxicology (Theranostics) is an area that holds great promise for personalized medicine.

*Amicus Curiae* XDx is a molecular diagnostics company focused on the discovery, development and commercialization of non-invasive gene expression testing in the areas of transplant medicine and autoimmunity. XDx has developed products for heart transplant patient management based on a proprietary method utilizing gene expression in blood. XDx is committed to supporting patients through the transplantation process. For example, the company sponsors "TransplantBuddies," a community support site, as well as a patient advocacy program that helps patients to resolve AlloMap billing-related issues. In addition, XDx offers financial aid to qualified patients.

*Amicus Curiae* BayBio is an independent, non-profit association serving the life science industry in Northern California. BayBio represents more than 330 companies involved in the research and development of treatments, cures and diagnostics. Of its life sciences members,

more than 30 organizations develop diagnostic services intended to improve health care outcomes.

*Amicus Curiae* The Coalition for 21st Century Medicine represents some of the world's most innovative diagnostic technology companies, clinical laboratories, researchers, physicians, venture capitalists, and patient advocacy groups -- all linked by a common mission to develop advanced diagnostics that improve the quality of healthcare for patients.

*Amici Curiae* seek to provide this Court with insights into the broader adverse effects of gene patents on society.

## II. ARGUMENT

Federal District Courts have broad discretion in granting the filing of briefs from *amicus curiae*. *Citizens Against Casino Gambling in Erie County v. Kempthorne*, 471 F.Supp.2d 295, 311 (W.D.N.Y.2007) (citing *United States v. Ahmed*, 788 F.Supp. 196 (S.D.N.Y. 1992), *aff'd*, 980 F.2d 161 (2d Cir. 1992)).

“The usual rationale for *amicus curiae* submissions is that they are of aid to the court and offer insights not available from the parties.” *Onondaga Indian Nation v. State of New York*, 97-CV-445, 1997 U.S. Dist. LEXIS 9168 at \*7 (N.D.N.Y. June 25, 1997) (quoting *United States v. El-Gabrowni*, 844 F. Supp. 955 (S.D.N.Y. 1994).

*Amicus* participation has been recognized by this Court in this case, and participation of the proposed *Amici Curiae* herein will not prejudice any party. The proposed *Amici Curiae* may provide timely and useful information which may be of assistance to the court in illuminating the legal issues presented by the parties' summary judgment briefing and providing insight not otherwise available from the parties. *See Community Ass'n for Restoration of Env't (CARE) v. DeRuyter Bros. Dairy*, 54 F. Supp. 2d 974, 975 (E.D. Wash. 1999); *Long Island Soundkeeper Fund, Inc. v. New York Athletic Club of the City of New York*, 1955 WL 358777, at \*1 (S.D.N.Y. 1995) (citing *Leigh v. Engle*, 535 F. Supp. 418, 420 (N.D. Ill. 1982); *Strougo v. Scudder, Stevens & Clark, Inc.*, No. 96-cv-2136, 1997 WL 473566 (S.D.N.Y. 1997); *Andersen v. Leavitt*, 2007

WL 2343572 (E.D. N.Y. 2007) (quoting *Ryan v. Commodity Futures Trading Comm'n*, 125 F.3d 1062, 1063 (7th Cir. 1997)).

An *amicus* brief should normally be allowed when a party is not represented competently or is not represented at all, when the *amicus* has an interest in some other case that may be affected by the decision in the present case (though not enough affected to entitle the *amicus* to intervene and become a party in the present case), or when the *amicus* has unique information or perspective that can help the court beyond the help that the lawyers for the parties are able to provide.

*Anderson*, 2007 WL 2343572 (quoting *Ryan v. Commodity Futures Trading Comm'n*, 125 F.3d 1062, 1063 (7th Cir. 1997)). Further, the Court may grant the filing of the amicus brief when no judgment has been entered and such filing will not delay Court's judgment. *Id.*; *Fluor Corp. v. United States*, 35 Fed. Cl. 284, 286 (Fed. Cl. 1996).

### III. CONCLUSION

In view of the foregoing, BayBio, Celera Corporation, The Coalition for 21st Century Medicine, Genomic Health, Inc., QIAGEN, N.V., Target Discovery, and XDX respectfully request that this Court grant their Motion for Leave to File the proposed *amici curiae* brief submitted herewith.

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Respectfully Submitted,

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