

**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)

**DECLARATION OF WILLIAM G. GAEDE, III, IN SUPPORT OF  
BAYBIO, CELERA, THE COALITION FOR 21ST CENTURY MEDICINE,  
GENOMIC HEALTH, INC., QIAGEN, N.V., TARGET DISCOVERY, INC.  
AND XDX, INC.'S BRIEF FOR *AMICI CURIAE* IN SUPPORT OF DEFENDANTS'  
OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT**

I, William G. Gaede, III, declare as follows:

1. I am a partner with McDermott Will & Emery LLP and counsel for *Amici Curiae* BayBio, Celera, The Coalition for 21st Century Medicine, Genomic Health, Inc., QIAGEN, N.V., Target Discovery, Inc. and XDX, Inc. in the above-captioned matter.
2. I am submitting this declaration in support of *Amici Curiae*'s Brief in Support of Defendants' Opposition to Plaintiffs' Motion for Summary Judgment.
3. I have knowledge of the following, and if called as a witness, could and would testify competently to the contents herein.
4. Attached as Exhibit 1 is a true and correct copy of B. Spear, et al., *Clinical Application of Pharmacogenetics*, 7 TRENDS MOL. MED. 201 (2001).

5. Attached as Exhibit 2 is a true and correct copy of C. Kongkaew, et al., *Hospital Admissions Associated with Adverse Drug Reactions: A Systematic Review of Prospective Observational Studies*, THE ANNALS OF PHARMACOTHERAPY 42:1017 (2008).
6. Attached as Exhibit 3 is a true and correct copy of Guidance for Industry on Pharmacogenomic Data Submissions (2005).
7. Attached as Exhibit 4 is a true and correct copy of Drug-Diagnostic Co-Development Concept Paper (2005).
8. Attached as Exhibit 5 is a true and correct copy of President's Council of Advisors on Science and Technology, *2008 Report on Priorities for Personalized Medicine*.
9. Attached as Exhibit 6 is a true and correct copy of S. 3822, 109TH CONGRESS, 2ND SESSION (Aug. 3, 2006).
10. Attached as Exhibit 7 is a true and correct copy of the Opening Statement of Kathleen Sebelius, Senate Committee on Finance (April 2, 2009).
11. Attached as Exhibit 8 is a true and correct copy of the American Medical Association Ethics Opinion 2.105.
12. Attached as Exhibit 9 is a true and correct copy of BARFIELD & CALFEE, BIOTECHNOLOGY AND THE PATENT SYSTEM, The AEI Press (2007).
13. Attached as Exhibit 10 is a true and correct copy of Frank R. Lichtenberg, *Pharmaceutical Knowledge-Capital Accumulation and Longevity*, RESEARCH ON INCOME AND WEALTH/NATIONAL BUREAU OF ECONOMIC RESEARCH CONFERENCE ON MEASURING CAPITAL IN A NEW ECONOMY, FEDERAL RESERVE BOARD, WASHINGTON, D.C. (2002).
14. Attached as Exhibit 11 is a true and correct copy of Congressional Budget Office Research and Development in the Pharmaceutical Industry (2006).
15. Attached as Exhibit 12 is a true and correct copy of Sunil Kanwar & Robert E. Evenson, *Does Intellectual Property Protection Spur Technological Change?*, Economic Growth Center Yale University, Discussion Paper No. 831, 2001.

16. Attached as Exhibit 13 is a true and correct copy of Grabowski, *Patents, Innovation and Access to New Pharmaceuticals* 5(4) J. INT'L ECON. LAW 849 (2002).

17. Attached as Exhibit 14 is a true and correct copy of United States General Accounting Office, *Technology Transfer Agencies' Rights to Federally Sponsored Biomedical Innovations* (GAO-03-536 2003).

18. Attached as Exhibit 15 is a true and correct copy of Mark A. Lemley, *Distinguishing Lost Profits from Reasonable Royalties*, *William & Mary Law Review* 51:655 (2009).

19. Attached as Exhibit 16 is a true and correct copy of Judge Kimberly Moore, *Empirical Statistics on Willful Patent Infringement*, 14 Fed. Cir. B.J. 227 (2004).

20. Attached as Exhibit 17 is a true and correct copy of Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition (April 2007).

21. Attached as Exhibit 18 is a true and correct copy of Fed. Trade Comm'n, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003).

22. Attached as Exhibit 19 is a true and correct copy of H.R. 3967, 107TH CONGRESS, 2D SESSION (Mar. 14, 2002).

23. Attached as Exhibit 20 is a true and correct copy of H.R. 977, 110TH CONGRESS, 1ST SESSION (Feb. 9, 2007).

24. Attached as Exhibit 21 is a true and correct copy of S. 387, 103D CONGRESS, 1ST SESSION (Feb. 18, 1993).

I declare, under penalty of perjury, under the laws of the United States, that the foregoing is true and correct and that this Declaration was completed at New York, New York this 6th day of January 2010.



William G. Gaede, III