UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

ASSOCIATION FOR MOLECULAR PATHOLOGY; AMERICAN COLLEGE OF MEDICAL GENETICS; AMERICAN SOCIETY FOR CLINICAL PATHOLOGY; COLLEGE OF AMERICAN PATHOLOGISTS; HAIG KAZAZIAN, MD; ARUPA GANGULY, PhD; WENDY CHUNG, MD, PhD; HARRY OSTRER, MD; DAVID LEDBETTER, PhD; STEPHEN WARREN, PhD; ELLEN MATLOFF, M.S.; ELSA REICH, M.S.; BREAST CANCER ACTION; BOSTON WOMEN'S HEALTH BOOK COLLECTIVE; LISBETH CERIANI; RUNI LIMARY; GENAE GIRARD; PATRICE FORTUNE; VICKY THOMASON; KATHLEEN RAKER,

09 Civ. 4515 (RWS)

v.

Plaintiffs,

UNITED STATES PATENT AND TRADEMARK OFFICE; MYRIAD GENETICS; LORRIS BETZ, ROGER BOYER, JACK BRITTAIN, ARNOLD B. COMBE, RAYMOND GESTELAND, JAMES U. JENSEN, JOHN KENDALL MORRIS, THOMAS PARKS, DAVID W. PERSHING, and MICHAEL K. YOUNG, in their official capacity as Directors of the University of Utah Research Foundation, ECF Case

DECLARATION OF ROBERT COOK-DEEGAN

Defendants.

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1. I am Director of the Center for Genome Ethics, Law & Policy of Duke's Institute for Genome Sciences and Policy. I am author of *The Gene Wars: Science, Politics, and the Human Genome.* I am also lead author of "Impact of Patents and Licensing Practices on Access to Genetic Testing for Inherited Susceptibility to Cancer: Comparing Breast and Ovarian Cancers to Colon Cancers" by Robert Cook-Deegan, Christopher DeRienzo, Julia Carbone, Subhashini Chandrasekharan, Christopher Heaney, and Christopher Conover. This is a case study on the impact of intellectual property on access to clinical genetic testing prepared for the Secretary's Advisory Committee for Genetics, Health and Society (SACGHS), a federal advisory committee. That case study was an input to the Committee's deliberations, and was one of eight such case studies made public, accompanying the Committee's separate "public comment draft report" in March 2009. A copy of my current *curriculum vitae* is attached.

Along with other experts in the field of human genetics, I looked at the Claim
of US Patent 5,747,282, which is one of those challenged by the plaintiffs in this case.
The structure of claims in the '282 patent came to my attention when preparing the
SACGHS case study noted above.

3. My co-authors and I wrote a paper on Claim 5 of the '282 patent, translating its form into a computational algorithm that was also empirically tested against DNA sequence data. That paper is attached as Exhibit 2. It has been submitted for publication. Our method of analysis is one used by experts in the field of genetics and our conclusions are fully supported by the data.

4. I circulated copies of the paper to counsel for all of the parties in this case on December 22, 2009.

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I declare pursuant to 28 U.S.C. §1746, under penalty of perjury under the laws of the United States that the foregoing is true and correct to the best of my knowledge and belief.

Robert Cook-Deegan

Executed this 7th day of January, 2010