UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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ASSOCIATION FOR MOLECULAR PATHOLOGY;
AMERICAN COLLEGE OF MEDICAL GENETICS;
AMERICAN SOCIETY FOR CLINICAL PATHOLOGY;
[redacted]

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)

ECF Case

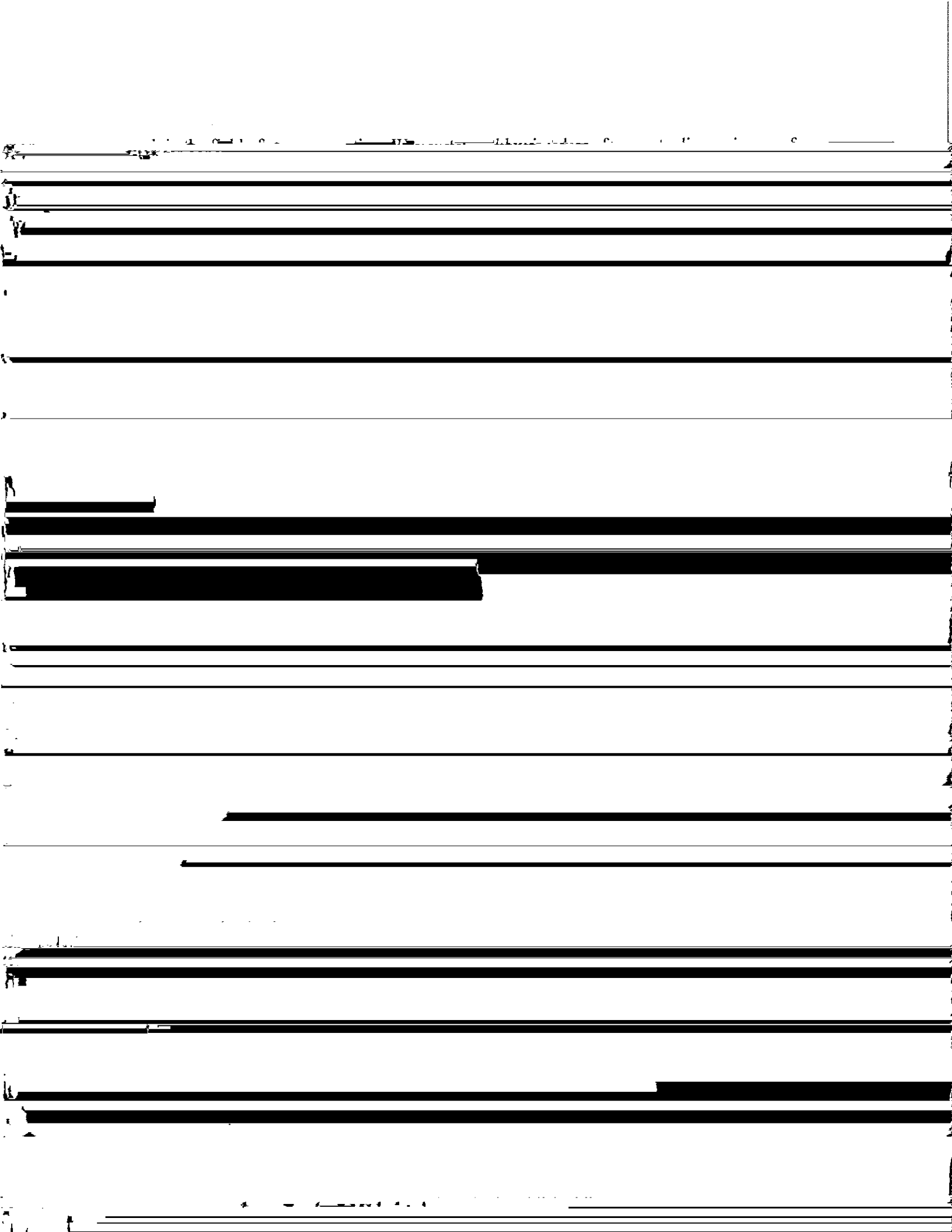
2. My laboratory is studying how ovarian cancer starts in order to determine better methods for prevention and early detection of ovarian cancer. I also study mechanisms of

6. I am currently an Associate Professor of Obstetrics and Gynecology at the University of Washington School of Medicine and an Adjunct Associate Professor in the

9. I am a leader and member of numerous professional organizations, as noted fully in my curriculum vitae. I serve on the Steering Committee for the Breast Cancer Information

focused on the use of platinum compounds to treat BRCA1/2-mutated carcinomas. Patients with

BRCA1/2-mutated ovarian cancer consistently have a better prognosis compared with



Committee. For that reason, the U.S. essentially does not provide any data regarding BRCA variants identified in Americans.

20. The patents granted on the genes allow one entity in the U.S. to exercise

full sequencing can miss large genomic rearrangements, where whole sections of the gene have been deleted or moved to a different part of the sequence.

24. A number of tests have been developed by researchers to better detect large rearrangements. The test that is now frequently relied upon is the multiplex ligation-dependent probe amplification (MLPA). MLPA was developed in Holland and can be applied to amplify any targeted gene sequence. MLPA is a high-resolution, simple, and relatively low cost test. It is used widely around the world and has been validated through numerous studies. MLPA kits for analyzing the BRCA1 and BRCA2 genes have been developed and are offered commercially. The difference between using full sequencing and a test like MLPA to analyze a gene is analogous to the difference between proofreading a page for single letter typos and for misplaced paragraphs.

25. In 2006, I co-authored a study examining the frequency and types of undetected cancer-predisposing mutations in BRCA1 and BRCA2 that was published in the Journal of the American Medical Association (JAMA).[1] The study focused on cancer patients with severe family histories of breast or ovarian cancer who had tested negative for BRCA mutations under Myriad's commercial full sequencing test. We used MLPA as one alternative mode of analysis.

26. The study concluded that genetic testing, as carried out in the United States by Myriad, did not provide all available information to women at risk. The data indicated that "12%

27. We recommended MLPA followed by confirmation of the points along the

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30. The BART test is not available to many women who should have access to it. Myriad has strict criteria – that Myriad determines – for which patients should receive concurrent BART testing. BART will be run concurrently, at no additional cost, for patients who have personally experienced breast cancer before the age of 50 years, ovarian cancer at any age, or male breast cancer at any age, but only if the patient has at least two relatives on the same side of the family who were diagnosed with breast cancer before age 50 or ovarian cancer at any age.[3] Patients who do not meet these criteria must pay an additional $650 to order BART. Many insurance policies will not cover BART including Medicare. Approximately one-third to one-half of my patients for whom I request genetic testing do not meet Myriad's criteria; yet, I think most should receive this additional testing.

31. One recent study examined Myriad's criteria for automatic BART testing.[4] Myriad provides automatic BART testing for people with an estimated risk of having a

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BRCA1/2 mutation of more than approximately 30%.[5] The study authors concluded that these criteria are too strict, and that large genomic rearrangement screening should be offered to all non-Ashkenazi Jewish women whose estimated risk of having a BRCA1/2 mutation is greater

[redacted]

result of the BRCA1/2 gene patents and the restrictions placed on genetic testing, this standard of

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care cannot be extended to patients in the United States. If the patents were invalidated, I have strong reason to believe that additional laboratories would offer large rearrangement BRCA1/2 testing, and I would order such testing for my patients.

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.

[redacted]