

Filed on behalf of: The Board of Trustees of the
Leland Stanford Junior University

Paper _____

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SEQUENOM, INC.
Petitioner,

v.

THE BOARD OF TRUSTEES OF
THE LELAND STANFORD JUNIOR UNIVERSITY
Patent Owner.

Case IPR2013-00390
Patent 8,195,415

DECLARATION OF HEI-MUN CHRISTINA FAN, PH.D.

The undersigned, Hei-Mun Christina Fan, Ph.D., does hereby declare and state that:

1. I make the following declaration based upon my knowledge and belief.

My educational and professional background

2. I am one of the named inventors on the above-identified patent by Hei-Mun Christina Fan and Stephen Quake, namely U.S. Patent No. 8,195,415, issued on June 5, 2012 (“the ‘415 patent”; **Ex. 2011**) from U.S. Application Serial No. 12/696,509, filed January 29, 2010 (“the ‘509 application”; **Ex. 2012**), which is a divisional of U.S. Application Serial No. 12/560,708, filed September 16, 2009 (“the ‘708 application”; **Ex. 2014**), which claims priority from U.S. Provisional Application No. 61/098,758, filed on September 20, 2008 (“the ‘758 provisional”; **Ex. 2015**).

3. I am currently employed as a Staff Scientist at Cellular Research, Inc. in Palo Alto, California. Prior to my current position, in 2011-2013, I was the Director of Technology Development at ImmunoMetrix LLC in Sunnyvale, California. In 2011, I was a postdoctoral scientist in the laboratory of Eddy Rubin at the Department of Energy Joint Genome Institute, Genomics Division, at the Lawrence Berkeley National Laboratory.

4. From 2006 to 2011, I was a graduate student in the laboratory of Stephen Quake in the Department of Bioengineering at Stanford University (Howard Hughes Medical Institute). During my time in Dr. Quake's laboratory, he and I conceived and reduced to practice the invention claimed in the '415 patent.

5. I am informed that a reduction to practice of an invention requires: (1) constructing an embodiment or performing a process meeting every limitation of the interference Count; and (2) demonstrating that embodiment or process operates for its intended purpose. I am also informed that reduction to practice may be an actual reduction or a constructive reduction to practice, which occurs when a patent application on the claimed invention is filed and that the filing of a patent application serves as conception and constructive reduction to practice of the subject matter described in the application.

The present interference

6. I understand that the '415 patent is involved in an interference with U.S. Application Serial No. 13/070,266, filed March 23, 2011 ("the '266 application"; **Ex. 2016**) by Yuk-Ming Dennis Lo, Rossa Wai Kwun Chiu and Kwan Chee Chan ("Lo").

7. I understand that the Count of an interference is the subject matter which is being contested in an interference.

8. I understand that the Count in the '922 interference is Fan claim 1, which recites: □

A method of testing for an abnormal distribution of a specified chromosome portion in a mixed sample of normally and abnormally distributed chromosome portions obtained from a subject, comprising:

(a) sequencing DNA from the mixed sample to obtain sequences from multiple chromosome portions, wherein said sequences comprise a number of sequence tags of sufficient length of determined sequence to be assigned to a chromosome location within a genome;

(b) assigning the sequence tags to corresponding chromosome portions including at least the specified chromosome by comparing the determined sequence of the sequence tags to a reference genomic sequence;

(c) determining values for numbers of sequence tags mapping to chromosome portions by using a number of windows of defined length within normally and abnormally distributed chromosome portions to obtain a first value and a second value therefrom; and

(d) using the values from step (c) to determine a differential, between the first value and the second value, which is determinative of whether or not the abnormal distribution exists.

9. I also understand the '415 patent is involved in an Inter Partes Review designated IPR2013-00390, filed by Sequenom, Inc.

10. Prior to filing the '758 provisional, Steve Quake and I filed an earlier provisional application, U.S. Provisional Application 60/764,420, filed on February 2, 2006 ("the '420 provisional"; **Ex. 2005**), and then U.S.

Application Serial No. 11/701,686, filed on February 2, 2007 (“the ‘686 application”); **Ex. 2004**), which issued as U.S. Patent No. 7,888,017, issued February 15, 2011 (“the ‘017 patent”; **Ex. 1046**). These applications disclosed the non-invasive diagnosis of fetal aneuploidy using digital PCR and massively parallel sequencing.

11. Toward the end of 2006 and through 2008, Steve Quake and I worked with Dr. Yair Blumenfeld in the Division of Maternal-Fetal Medicine in the Department of Obstetrics and Gynecology at Stanford University. Dr. Blumenfeld was interested in collaborating with us to provide us with maternal blood samples to use in optimizing our fetal aneuploidy diagnosis test. (**Ex. 2103, 2104, 2106**). Dr. Blumenfeld prepared the necessary protocol and consent forms for the Institutional Review Board (“IRB”) in order to collect the samples from patients. (**Ex. 2105, 2107, 2108**). The IRB consent listed Dr. Usha Chitkara, Dr. Louanne Hudgins, Dr. Yair Blumenfeld and Dr. Quake.

12. Throughout our studies and through the time we submitted our paper entitled “Noninvasive prenatal diagnosis of fetal chromosomal aneuploidy by massively parallel genomic sequencing of DNA in maternal plasma” (Proc. Natl. Acad. Sci. USA 105(51):20458-20643 [2008]; **Ex. 1036**)), on which I was a coauthor with Drs. Quake, Blumenfeld, Chitkara

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