

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 YAIR BLUMENFELD, M.D

The undersigned, Yair Blumenfeld, M.D., does hereby declare and state that:

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

2. I am currently an Assistant Professor of Obstetrics and Gynecology (Maternal Fetal Medicine) at the Stanford University Medical Center.

3. In 2008, I was a fellow in the Department of Obstetrics and Gynecology (Maternal Fetal Medicine) at the Stanford University Medical Center.

4. I have been asked to testify about events associated with providing blood samples to Christina Fan and Stephen Quake related to their performing experiments to non-invasively diagnose fetal aneuploidy by quantifying DNA fragments in the blood of a pregnant patient, which DNA fragments can be aligned to particular chromosomes, and certain of which exist at an elevated level when the fetus is aneuploid, and my role as a co-author on a paper we published on that collaboration.

5. I have reviewed **Exhibits 2103-2108, 2111, 2112, 2127, 2129, and 2131**, which I understand are being submitted in this patent interference

proceeding, and they refresh my recollection as to those events and the dates on which they occurred.

6. Toward the end of 2006 and through 2008, I collaborated with Stephen Quake and Christina Fan to provide them with patient blood samples for optimizing their fetal aneuploidy diagnosis test. (**Ex. 2103, 2104, 2106**). I 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. Quake and me.

7. Throughout these 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, Fan, Chitkara and Hudgins, I corresponded by email with Drs. Quake and Fan to keep updated on the progress of their research.

8. On May 28, 2008, Christina Fan sent a graph of the preliminary analysis of a full sequencing run to Dr. Quake and me, which included four trisomy 21 samples and three normal samples. She noted that we should

“pay attention to the distribution of chr21,” and I responded that the results were “awesome.” (Ex. 2127).

9. On June 19, 2008, Dr. Fan sent to Stephen Quake and me a “rough draft of the non-invasive study,” (Ex. 2111, 2113) which was based on their first Solexa sequencing run and was to be submitted to the journal *Proceedings of the National Academy of Sciences, USA*, which ultimately published as the article “Noninvasive diagnosis of fetal aneuploidy by shotgun sequencing DNA from maternal blood,” Proc. Natl. Acad. Sci. USA (2008) **105(42)**:16266-16271 (“first draft of the PNAS manuscript”; Ex. 2113). I was listed as an author on that paper, along with Christina Fan, Usha Chitkara, Louanne Hudgins and Stephen Quake.

10. On July 1, Dr. Fan sent a graph including new data points (3 Down syndrome [P2, P7, P14] and 2 normal males [P19, P31]) to Dr. Quake and me. (Ex. 2129).

11. On July 7, 2008, Drs. Quake, Fan and I discussed revisions to the PNAS manuscript. (Ex. 2112, 2131).

12. The PNAS manuscript was received for review on July 13, 2008, communicated on August 22, 2008, and published on October 21, 2008. (Ex. 1036).

13. In signing this declaration, I understand that the declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I acknowledge that I may be subject to cross-examination in the case and that cross-examination will take place within the United States. If cross-examination is required of me, I will appear for cross-examination within the United States during the time allotted for cross-examination.

14. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true. I also declare that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

5/7/14

Date



Yair Blumenfeld, M.D.