UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYRIAD GENETICS, INC., MYRIAD GENETIC LABORATORIES, INC., BIO-RAD LABORATORIES, INC., and RAINDANCE TECHNOLOGIES, INC.

Petitioners

v.

THE JOHNS HOPKINS UNIVERSITY

Patent Owner

U.S. Patent No. 7,824,889

Case No. *To be assigned*

DECLARATION OF MICHAEL L. METZKER, PH.D.

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I, Michael Metzker, hereby declare as follows.

1. I am over the age of eighteen (18) and otherwise competent to make this declaration.

2. I have been retained as an expert witness on behalf of Myriad Genetics, Inc., Myriad Genetic Laboratories, Inc. (together, "Myriad"), Bio-Rad Laboratories, Inc., and RainDance Technologies, Inc. in connection with the above-captioned requested *inter partes* review ("IPR"). I am being compensated for my time in connection with this IPR at my standard consulting rate, which is $750 per hour.

I. OVERVIEW AND SUMMARY OF OPINIONS

3. I understand that a petition for *inter partes* review has been filed regarding U.S. Patent No. 7,824,889 ("the '889 Patent") (MYR1001), which resulted from U.S. Application No. 11/709,742 ("the '742 Application"), filed on February 23, 2007, naming Bert Vogelstein and Kenneth W. Kinzler as inventors. I understand that the petition for *inter partes* review challenges claims 1, 4-9, and 12-22 of the '889 Patent as anticipated and/or obvious.

4. The '889 Patent originally issued on November 2, 2010, from the '742 application. The USPTO subsequently granted a petition for *ex parte* reexamination of the '889 Patent, finding substantial new questions of patentability for 22 claims. To overcome rejections over multiple prior art references during *ex*

parte reexamination, a number of claims of the '889 Patent were amended. The reexamination certificate issued October 31, 2014.

5. I note that although certain of the prior art that I discuss in this declaration as invalidating the '889 Patent (*e.g.*, Simmonds, Sykes, as defined below) was technically before the USPTO during the *ex parte* reexamination proceedings, the proceedings focused on different art and on different arguments from those that I advance below. *See* Simmonds, *Human immunodeficiency virus-infected individuals contain provirus in small numbers of peripheral mononuclear cells and at low copy numbers*. JOURNAL OF VIROLOGY 64:864-872 (1990) ("Simmonds") (MYR1012); Sykes *et al.*, *Quantitation of targets for PCR by use of limiting dilution*. BIOTECHNIQUES 13:444-449 (1992) ("Sykes") (MYR1013).

6. In particular, the *ex parte* reexamination proceedings focused on prior art involving distribution of single cells into compartments, rather than on distribution of isolated nucleic acids, and was overcome on that basis. The claims were amended to specify that the method involves "isolated" or "cell-free" nucleic acids rather than whole cells, in light of this art. MYR1008. While these amendments addressed the prior art discussed during the *ex parte* reexamination, they did nothing to address the Mullis chapter or other prior art references discussed in this petition for *inter partes* review. The prior art that I rely on here was never discussed by the USPTO during the *ex parte* reexamination proceedings

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