

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*

**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 7,824,889
UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. §§ 42.1-.80, 42.100-.123**

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I. STATEMENT OF THE PRECISE RELIEF REQUESTED AND THE REASONS THEREFOR (37 C.F.R. § 42.22(A))

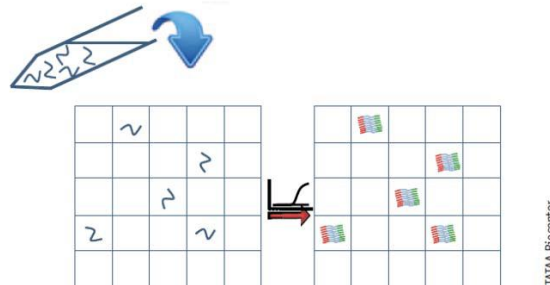
Myriad Genetics, Inc., Myriad Genetic Laboratories, Inc. (collectively, "Myriad"), Bio-Rad Laboratories, Inc., and RainDance Technologies, Inc. (collectively, "Petitioners") respectfully petition for *Inter Partes* Review, and seek cancellation of claims 1, 4-9, 12-22 of USPN 7,824,889 (the "'889 patent") (MYR1001) as unpatentable for anticipation and/or obviousness. The '889 patent is assigned to The Johns Hopkins University (hereinafter "Patent Owner").¹

II. OVERVIEW

Claims 1, 4-9, and 12-22 of the '889 patent should be canceled as anticipated and/or obvious. MYR1002, ¶¶20-22. Independent claims 1 and 19 recite a method that the Patent Owner calls "digital PCR." MYR1002, ¶¶10-19. The figure below shows the basic steps of the method, which involve distributing a DNA sample into compartments such that each compartment contains, ideally, one or zero molecules of DNA from the sample, carrying out PCR in each compartment, and then

¹ Petitioners note that the Ex Parte Reexamination Certificate for the '889 patent lists the NIH and DHHS as assignees, rather than JHU. Nonetheless, in litigation asserting the '889 patent against Myriad, JHU stated, "The '889 patent is assigned to and owned by JHU." MYR1031, ¶114.

analyzing the resulting amplified DNA molecules, to determine how many compartments contain each different template DNA molecule



MYR1018, 541.

The steps comprising what the Patent Owner calls "digital PCR" were well known in the art before the earliest possible priority date for the '889 patent.² MYR1002, ¶11. In the prior art, this method was often called "limiting dilution analysis" or "limiting dilution PCR" ("LDPCR") because the sample is diluted down to the point at which some compartments will be "positive," i.e., contain a

² The earliest application to which the '889 patent claims priority is provisional application 60/146,792, filed 8/2/1999. MYR1011. Given that, Petitioners rely almost exclusively on prior art under 35 U.S.C. §102(b), they are not aware of any claim to an earlier priority date that would affect any of the arguments set forth herein. Petitioners reserve the right to respond should Patent Owner allege an earlier priority date.

PCR-amplified product, and some will be "negative," i.e., contain no PCR-amplified product. *Id.* For LDPCR, terms such as "assay samples," "replicates," "compartments," "sample chambers," "wells," or "microreactors" all represent the same functional element – a separate space where a diluted single template molecule can undergo PCR without cross-contamination, and produce pure or homogeneous amplified product. *Id.* As discussed in detail below, Patent Owner did nothing more than add a snappy name to the prior art method of LDPCR.

By 1994, Kary Mullis, the Nobel Prize winning inventor of PCR, had edited a book on PCR (MYR1014) that included a chapter on quantitative PCR, the use of PCR to quantitate amounts of nucleic acids in a sample. The Mullis chapter discloses and discusses the work of multiple groups of scientists at the time who were carrying out and publishing work involving LDPCR. MYR1002, ¶15. A common feature of this work is that it involved diluting and distributing nucleic acids down to the single molecule level in assay samples or compartments, amplifying the single molecule templates using PCR, and counting or otherwise analyzing the amplified templates in the assay samples or compartments. As the Mullis chapter disclosed in 1994

The principle of limiting dilution can also be called on to achieve absolute DNA quantitation. It is based on the use of a qualitative all-or-none endpoint and on the premise that one or more targets in the reaction mixture give rise to a positive endpoint. . . . *Accurate*

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