

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GUARDANT HEALTH, INC.
Petitioner,

v.

UNIVERSITY OF WASHINGTON THROUGH ITS CENTER
FOR COMMERCIALIZATION,
Patent Owner.

Case No. IPR2022-00817
Patent No. 10,760,127

PETITIONER'S OBJECTIONS TO EVIDENCE

I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.64(b)(1), Guardant Health, Inc. (“Petitioner”) submits the following objections to the University of Washington Through Its Center for Commercialization’s, (“Patent Owner”) exhibits 2014-2017, 2019, 2021-2044, 2046-2048, 2050-2063, and 2065-2071.

Petitioner’s objections are made pursuant to the Code of Federal Regulations (“C.F.R.”) governing this proceeding, including without limitation 37 C.F.R. §§ 42.61-42.65 and § 42.6(a)(3). As required by 37 C.F.R. § 42.62, Petitioner’s objections below apply the Federal Rules of Evidence (“F.R.E.”).

II. OBJECTIONS

1. Declaration of Dr. Rahul Satija (Exhibit 2014)

Grounds for Objection: F.R.E. 401, 402 (Irrelevant Evidence Inadmissible); F.R.E. 403 (Excluding Evidence for Prejudice, Confusion, Waste of Time, Duplication, or Other Reasons); F.R.E. 701, 702, 703 (Expert Foundation and Opinions).

Exhibit 2014 is the declaration of Dr. Satija and is objected to in its entirety. Dr. Satija’s opinions are not the product of reliable principles and methods. For example, Dr. Satija opines on the patentability of the claims and on secondary considerations but his opinions lack the requisite foundation or support. Moreover,

Dr. Satija's opinions are based on unstated assumptions rather than on evidence including the Travers references.

Exhibit 2014 should be excluded as irrelevant, confusing, and a waste of time.

2. Briefing from different proceedings (Exhibits 2015, 2019, 2043, and 2044)

Grounds for Objection: F.R.E. 106 (Remainder of or Related Writings or Recorded Statements); F.R.E. 401 (Test for Relevant Evidence); F.R.E. 402 (General Admissibility of Relevant Evidence); F.R.E. 403 (Excluding Relevant Evidence for Prejudice, Confusion, Waste of Time, or Other Reasons).

Exhibits 2015, 2019, 2043, and 2044 are not evidence but are rather a selected subset of briefing filed in other cases. For example, exhibit 2015 is a complaint filed in a district court by Patent Owner, exhibit 2019 is briefing concerning an unrelated patent filed in a different jurisdiction, and exhibits 2043 and 2044 are briefing from other proceedings before the PTAB involving unrelated patents. None of exhibits 2015, 2019, 2043, and 2044 prove any fact relevant to resolution of this case. Further, to the extent any of exhibits 2015, 2019, 2043, and 2044 are deemed relevant, their admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that none of these exhibits can prove facts relevant to resolution of this case.

3. Institution decision from a different proceeding (Exhibit 2016)

Grounds for Objection: F.R.E. 106 (Remainder of or Related Writings or Recorded Statements); F.R.E. 401 (Test for Relevant Evidence); F.R.E. 402 (General Admissibility of Relevant Evidence); F.R.E. 403 (Excluding Relevant Evidence for Prejudice, Confusion, Waste of Time, or Other Reasons).

Exhibit 2016 is the Board's decision on institution of IPR2022-00816. Exhibit 2016 reflects only a partial record of another proceeding and does not prove any fact relevant to resolution of this case. Further, to the extent exhibit 2016 is deemed relevant, its admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that it does not establish any fact relevant to resolution of this case.

4. Exhibits 2017, 2021-2042, 2046-2048, 2054-2061, 2063, and 2066-2071

Grounds for Objection: F.R.E. 401 (Test for Relevant Evidence); F.R.E. 402 (General Admissibility of Relevant Evidence); F.R.E. 403 (Excluding Relevant Evidence for Prejudice, Confusion, Waste of Time, or Other Reasons); F.R.E. 701, 702, 703 (Expert Foundation and Opinions).

Exhibits 2017, 2021-2042, 2046-2048, 2054-2061, 2063, and 2066-2071 should be excluded because the probative value is minimal and is substantially outweighed by the risk of confusing the issues, wasting time, and needlessly presenting cumulative evidence. For example, exhibits 2017 and 2068 are cited for

the sole purpose of establishing that polymerases may incorporate errors in a manner not commensurate with the challenged patent or claims. Exhibits 2027, 2029, 2030, 2031, and 2063 are cited for the sole purpose of arguing the size of Traver's zero mode waveguides (ZMW). Argument and evidence regarding size of ZMWs, for example, is not commensurate with the challenged patent or claims. Exhibit 2047 is a reference describing the sequencing of "nanoballs." Nanoball sequencing and corresponding argument is not commensurate with the claims of the '127 patent. Exhibits 2025 and 2054 are cited for the sole purpose of establishing that eliminating amplification from a sample preparation method reduces amplification bias. This evidence and corresponding argument are not commensurate with the challenged patent or claims, or pertinent to the resolution of any contested issue. Exhibit 2067 is entitled "Biostatistics: A Guide to Design, Analysis, and Discovery" and is cited for the proposition that with sequencing according to Travers "the majority of potentially useable ZMW would be occupied by smaller DNA templates, without sufficient redundancy for resequencing," and for the proposition that a Poisson distribution is a way of describing random events. Exhibit 2067 is a general biostatistics reference, published before the Travers references, which includes no discussion of "ZMW." Thus, exhibit 2067 and argument is not commensurate with the challenged patent or claims and cannot be used to prove any fact material to resolution of this case. Exhibits 2069-2071

are computer-generated molecules produced by Dr. Satija. That is, exhibits 2069-2071 do not reflect content found in the prior art references and do not establish any fact relevant to resolution of this case. Additionally, exhibits 2069-2071 are not the product of reliable principles and methods.

5. Evidence of secondary considerations (Exhibits 2050-2053, 2062, and 2065)

Grounds for Objection: F.R.E. 401 (Test for Relevant Evidence); F.R.E. 402 (General Admissibility of Relevant Evidence); F.R.E. 403 (Excluding Relevant Evidence for Prejudice, Confusion, Waste of Time, or Other Reasons).

Exhibits 2050-2053, 2062, and 2065 are documents allegedly describing duplex sequencing. However, Patent Owner did not provide evidence linking the features of said duplex sequencing to the claims. Accordingly, exhibits 2050-2053, 2062, and 2065 do not establish any fact relevant to resolution of this case. Further, to the extent exhibits 2050-2053, 2062, and 2065 are deemed relevant, their admission would be unduly prejudicial, misleading, and a waste of time in view of the fact that these exhibits do not establish any fact relevant to resolution of this case.

III. CONCLUSION

The aforementioned exhibits were served on January 13, 2023. These objections are made within five business days of service pursuant to 37 C.F.R. § 42.64.

Respectfully submitted,

Dated: January 23, 2023

/ Michael T. Rosato /
Michael T. Rosato, Lead Counsel
Reg. No. 52,182

CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing Petitioner's Objections to Evidence was served on January 23, 2022, at the following electronic service addresses:

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Respectfully submitted,

Dated: January 23, 2023

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