

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FOUNDATION MEDICINE, INC.,
Petitioner,

v.

GUARDANT HEALTH, INC.,
Patent Owner.

Case IPR2019-00637
Patent No. 9,902,992

**PATENT OWNER'S PRELIMINARY RESPONSE
PURSUANT TO 37 C.F.R. § 42.107**

TABLE OF CONTENTS

I.INTRODUCTION	1
II.THE CHALLENGED CLAIMS	2
III.CLAIM CONSTRUCTION.....	4
A. Petitioner proposes constructions for claim terms not in dispute	4
B. The proposed constructions contradict claim interpretations adopted by Petitioner in related proceedings	5
IV.THE GROUNDS REFERENCES	6
A. Schmitt.....	6
B. Fan	7
C. Forshew	8
D. Kucera.....	8
E. Schwarzenbach.....	9
V.THE PETITION FAILS TO DEMONSTRATE THAT CLAIM 1 IS OBVIOUS.....	9
A. Schmitt does not disclose tagging any DNA with “at least 20%” tagging efficiency, much less cell-free DNA	10
B. Petitioner fails to establish that Schmitt discloses detecting “two or more different members selected from the group of members consisting of a single base substitution, a copy number variation (CNV), an insertion or deletion (indel), or a gene fusion”	15
(i) Schmitt’s disclosure of detecting a “single base substitution” is not prior art	15
(ii) Schmitt does not disclose detection of copy number variation....	17
(iii) Petitioner’s remaining arguments are insufficient	19
C. Petitioner fails to establish that Schmitt would be applicable to cell-free DNA	20
(i) The petition materials fail to establish motivation to apply the Schmitt method to cell-free DNA	21
(ii) The petition materials fail to establish that there would have been a reasonable expectation of success in applying Schmitt to cell-free DNA	24
VI.GROUND 1 FAILS	29
VII.GROUND 2 FAILS	30
VIII.GROUND 3 FAILS	32

IX.CONCLUSION.....33
X.APPENDIX.....35

I. INTRODUCTION

The Board should not institute *inter partes* review of claims 11, 12, 14, and 27-33 of U.S. Patent No. 9,902,992 (“the ’992 patent”) because Foundation Medicine, Inc. (“Petitioner”) fails to show that it has a reasonable likelihood of prevailing.

The ’992 patent is directed to and claims methods for detecting genetic aberrations in cell-free DNA (“cfDNA”). *E.g.*, EX1001, 1:61-2:40, claim 1. Detecting and analyzing cell-free DNA was known to be challenging for a number of reasons, including that it is highly fragmented and present in minute quantities in clinical samples. The ’992 patent filled the “need in the art for improved methods and systems for using cell-free DNA to detect and monitor disease” by disclosing methods for high efficiency conversion of cell-free DNA into non-uniquely tagged parent polynucleotides. *E.g., id.*, 1:55-57.

Despite the specific focus of the ’992 patent and challenged claims on cell-free DNA, each of the petition’s grounds of challenge rely on Schmitt as the primary reference. Schmitt has no applicable teachings for detecting rare mutation in cell-free DNA. Indeed, the petition concedes as much. Pet. 30 (“Schmitt focused on using well-characterized DNA instead of cfDNA from clinical samples.”). This defect in Petitioner’s primary reference is inescapable. Schmitt does not disclose any of the recited steps directed to cell-free DNA.

The petition is replete with additional defects. For example, the petition repeatedly points to disclosure that simply is not prior art. Furthermore, the petition fails to establish that multiple elements of claim 1 are found in the prior art such as “attaching tags comprising barcodes...to the cfDNA molecules to tag at least 20% of the cfDNA molecules,” and detecting “two or more different members selected from the group of members consisting of a single base substitution, a copy number variation (CNV), an insertion or deletion (indel), or a gene fusion.” Also lacking from Petitioner’s obviousness challenge is any substantiated assertion that a skilled artisan would have been motivated to apply the steps of Schmitt to cell-free DNA or would have had any expectation of success in doing so.

Petitioner fails to demonstrate that all elements of claim 1 are found in the prior art. While Petitioner does not challenge claim 1, the petition may be denied because all challenged claims depend from claim 1 and Grounds 1-3 fail to remedy any of the deficiencies associated with claim 1.

Accordingly, institution of *inter partes* review should be denied.

II. THE CHALLENGED CLAIMS

The petition challenges claims 27-33 as allegedly obvious over Schmitt in view of either Fan or Forshew, claims 11 and 12 over Schmitt in view of either Fan or Forshew, and further in view of Kucera, and claim 14 over Schmitt in view of either Fan or Forshew, and further in view of Schwarzenbach. Claims 11, 12, 14,

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.