Paper No. ___
Filed: July 19, 2019

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

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

TABLE OF CONTENTS

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,

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