

Filed on behalf of: Guardant Health, Inc.
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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 Nos. IPR2022-00816, -00817
Patent No. 10,760,127

**CORRECTED PETITIONER'S EXPLANATION OF MULTIPLE
PETITIONS CHALLENGING PATENT NO. 10,760,127
AND RANKING OF PETITIONS**

I. INTRODUCTION

Pursuant to the November 2019 Consolidated Trial Practice Guide, Petitioner Guardant Health, Inc. provides this explanation of multiple petitions challenging U.S. Patent No. 10,760,127 (“the ’127 patent”). Petitioner brings two petitions, each of which presents a unique combination of challenges. As explained below, the multiple petitions are appropriate in this instance and Petitioner respectfully requests institution of both petitions.

II. DIFFERENCES BETWEEN THE PETITIONS AND WHY THE BOARD SHOULD INSTITUTE BOTH PETITIONS

Each claim of the ’127 patent requires the use of adapters in sequencing DNA. *E.g.* EX1001, claims 1, 22. The specification explains that the adapters may be either “Y-shaped” or “U-shaped,” and that prior art known sequence adapters are suitable for and are utilized in the disclosed “consensus sequencing” method. *Id.*, 6:4-53, 10:63-11:2 (“...As the sequence of the linker itself does not matter in the workflow, the published [U-shaped] linker sequences from either of these references would be adequate for use in the assay.”), 25:64-25:1 (“...ligation of Illumina TruSeq [Y-shaped] DNA sequencing adaptors, all by standard library preparation methods.”), *Twinstand Biosciences, Inc. v. Guardant Health, Inc.*, IPR2022-00746, Paper 2, 67 (identifying Craig’s prior art Y-shaped adapters as encompassed). The two petitions demonstrate that each of the two adapter types were indeed known in the art and recognized as enabling distinction of sequence

reads from each strand (top, bottom) of a duplex. As such, the claims of the '127 patent are broadly drafted to encompass two different types of prior art adapter sequences that are described in different literature references as utilized in consensus sequence approaches.

The Kinde Petition (IPR2022-00816): The Kinde Petition demonstrates that Y-shaped adapters were known in the art, and that it was obvious to use them as recited in the challenged claims. As explained in the Kinde Petition, claims 1-10 and 12-30 are unpatentable under 35 U.S.C. § 103 in view of Kinde (EX1006) and Craig (EX1007). Further, claim 11 is rendered obvious by Kinde and Craig, and further in view of NEB Expressions (EX1014).

The Travers Petition (IPR2022-00817): The Travers Petition demonstrates that U-shaped (hairpin) adapters were known in the art, and that it was obvious to use them as recited in the challenged claims. As explained in the Travers Petition, claims 1-10, 12, and 15-28 are unpatentable under 35 U.S.C. § 103 in view of Travers '075 (EX1018) and the Travers Paper (EX1021) (collectively, “the Travers Publications”). Claim 11 is rendered obvious by the Travers Publications and further in view of NEB Expressions (EX1014). Claims 13, 14, 29, and 30 are rendered obvious by the Travers Publications and further in view of McCloskey (EX1023).

As evidenced by the asserted grounds, there is no overlap in the prior art applied in the two petitions in the sense that they respectively focus on two different types of sequencing adaptors—Y- and U-shaped. The Kinde and Travers Petitions each challenge independent claims 1 and 22 with different prior art combinations. Both petitions cite NEB Expressions for dependent claim 11.

The Kinde and Travers petitions each present a strong showing that the claims of the '127 patent are unpatentable in view of prior art disclosing Y-shaped and U-shaped adapters, respectively. Thus, the two petitions are complementary at least in that they address the two different types of adapters contemplated by the '127 patent. Both petitions demonstrate that determining a “consensus” sequence read from redundant sequencing of a target polynucleotide was well-known in the art and that prior art methods utilized both types of sequencing adapters. Moreover, both petitions demonstrate that prior art consensus sequencing employed techniques relevant to the unpatentability challenge, such as amplification, redundant sequencing, and comparison to a reference to distinguish sequencing errors from true genetic mutations. Accordingly, because the '127 patent claims are broadly drafted to encompass two types of sequencing adapters described in different literature references and do not otherwise distinguish from prior art consensus sequencing approaches, the Board’s assessment of

unpatentability of the '127 patent claims would benefit from prior art presented and technical analysis provided in both petitions.

III. CONCLUSION

Accordingly, Petitioner respectfully requests that the Board consider both petitions and not exercise its discretion to deny institution. Should the Board nevertheless exercise its discretion to institute one petition but not the other, Petitioner elects the Kinde Petition (IPR2022-00816).

Respectfully submitted,

Dated: April 13, 2022

/ Michael T. Rosato /

Michael T. Rosato, Lead Counsel

Reg. No. 52,182

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(a), this is to certify that I caused to be served a true and correct copy of the foregoing Corrected Petitioner's Explanation of Multiple Petitions Challenging Patent No. 10,760,127 and Ranking of Petitions by overnight courier (Federal Express or UPS), on April 13, 2022, on the Patent Owner at the correspondence address of the Patent Owner as follows:

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Respectfully submitted,

Dated: April 13, 2022

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