

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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FOUNDATION MEDICINE, INC.,  
Petitioner,

v.

GUARDANT HEALTH, INC.,  
Patent Owner.

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Case IPR2019-00636  
Case IPR2019-00637  
Patent 9,902,992 B2<sup>1</sup>

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Before TINA E. HULSE, JOHN E. SCHNEIDER, KRISTI L. R. SAWERT,  
*Administrative Patent Judges.*

HULSE, *Administrative Patent Judge.*

DECISION

Denying Petitioner's Request on Rehearing of Decision Denying Institution  
*37 C.F.R. § 42.71(d)*

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<sup>1</sup> The Petitions in both proceedings challenged the '992 patent, in which claim 1 is the only independent claim. Because both Petitions turned on the same issue regarding claim 1, we exercised our discretion and issued a single Decision Denying Institution in both proceedings. Petitioner has filed a single Rehearing Request in both proceedings. We, therefore, enter a single Decision on the Rehearing Request. For the sake of convenience, and unless stated otherwise, paper and exhibit numbers refer to those filed in IPR2019-00636. Similar papers and exhibits were filed in IPR2019-00637.

## I. INTRODUCTION

Foundation Medicine, Inc. (“Petitioner”) filed a Request for Rehearing (Paper 11, “Reh’g Req.”) of our Decisions Denying Institution of *Inter Partes* Review, holding that Petitioner had failed to establish a reasonable likelihood that it would prevail in showing that claims 1–33 of U.S. Patent No. 9,902,992 B2 (Ex. 1001, “the ’992 patent”) are unpatentable. Specifically, in IPR2019-00636, we denied institution as to claims 1–11, 13, and 15–26 of the ’992 patent. IPR2019-00636, Paper 10 (“Dec.”). And in IPR2019-00637, we denied institution as to claims 11, 12, 14, and 27–33 of the ’992 patent. IPR2019-00637, Paper 10.

Petitioner requests a rehearing of our decision, arguing that we (1) misapprehended Petitioner’s obviousness argument and improperly required Petitioner to meet an inherency standard; and (2) overlooked Petitioner’s express identification of motivation to improve ligation efficiency. Reh’g Req. 3–12.

For the reasons stated below, Petitioner’s request is *denied*.

## II. STANDARD OF REVIEW

The party requesting rehearing has the burden to show that the decision should be modified. Under 37 C.F.R. § 42.71(d), the request for rehearing must identify, specifically, all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, or a reply. When rehearing a decision on a petition, we review the decision for an abuse of discretion. 37 C.F.R. § 42.71(c). An abuse of discretion may arise if a decision is based on an erroneous interpretation of law, if a factual finding is not supported by substantial evidence, or if an unreasonable judgment is made in weighing relevant factors. *In re Gartside*, 203 F.3d 1305, 1315-16 (Fed. Cir. 2000).

### III. ANALYSIS

Petitioner argues that we erroneously applied an inherency standard to Petitioner's argument that a person of ordinary skill in the art would have understood Schmitt<sup>2</sup> to teach tagging "at least 20% of the cfDNA molecules," as required by the claims. Reh'g Req. 3 (citing Pet. 39–41). According to Petitioner, we erred because "the absence of an express disclosure of a claim limitation by a prior art reference in an obviousness analysis does not necessarily result in reliance on an inherency theory." *Id.* at 5. Petitioner asserts that it never made an inherency argument and that we were led to erroneously apply an inherency standard because of Patent Owner's mischaracterization of its obviousness argument. *Id.* Petitioner asserts that we overlooked the evidence in the Petition that demonstrated a person of ordinary skill in the art, with knowledge of the state of the art, would have understood Schmitt to teach a 10–20% or higher ligation efficiency. *Id.* at 6–9.

We are not persuaded that we misapprehended or overlooked Petitioner's argument. It is Petitioner's burden to demonstrate that all claimed limitations are disclosed in the prior art, either alone or in combination with other prior art. *See PAR Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1194 (Fed. Cir. 2014). The claims require tagging "at least 20% of the cfDNA molecules." Petitioner admits that "Schmitt does not explicitly recite tagging 'at least 20%' of the cfDNA molecules by ligation." Pet. 39. Petitioner argues, however, that Schmitt teaches "using state of the art ligation techniques, which a [person of ordinary skill in the

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<sup>2</sup> Schmitt et al., US 9,752,188 B2, issued Sept. 5, 2017 ("Schmitt," Ex. 1011).

art] would have understood to result in at least a 10–20% yield of tagged DNA fragments.” *Id.* To support its argument, Petitioner relies on various prior art references and the testimony of its expert, which largely parrots the language in the Petition. *Compare* Ex. 1002 ¶¶ 131–135 *with* Pet. 39–41.

In our Decision, we considered and addressed Petitioner’s arguments. In the Petition, Petitioner admits that Schmitt does not explicitly teach the “at least 20%” claim limitation. Pet. 39. Petitioner now asserts that it did not argue Schmitt inherently teaches the claim limitation. Rather, Petitioner argues that “the Petition provided sufficient evidence that a [person of ordinary skill in the art], with knowledge of the state of the art, would understand the method of Schmitt to achieve a 10–20% or higher ligation efficiency.” *Reh’g* Req. 9. Even if Petitioner did not expressly make an inherency argument, it was not erroneous to explain why Schmitt does not inherently teach the claim limitation, as argued by Patent Owner. *Prelim. Resp.* 9–11. The Decision establishes that even if a person of ordinary skill in the art would have understood that the ligation techniques in Schmitt would result in a 10–20% yield of tagged DNA fragments, that understanding does not teach a yield of “at least 20%,” either expressly or inherently. *Dec.* 13–14.

Our analysis, however, did not stop there. Once we found that Schmitt does not expressly or inherently teach “at least 20%” ligation efficiency, we then addressed Petitioner’s argument that the claim limitation would have been obvious. *Id.* at 14–15. Thus, contrary to Petitioner’s assertion, we did not “hold Petitioner to the inherency standard” without considering its obviousness argument. *See Reh’g* Req. 3–9. We considered Petitioner’s obviousness arguments and evidence, but we were not persuaded that Petitioner had met its burden to institute trial. *Id.*

Petitioner argues that we overlooked its express identification of motivation to improve ligation efficiency. *Id.* at 10–12. Specifically, Petitioner asserts that it explained that “[t]he relevance of ligation efficiency was well-known to the [person of ordinary skill in the art], which was to improve the sequencing library’s diversity or representation of the genome by optimizing one or more steps of sample preparation.” *Id.* at 10 (quoting Pet. 39). Petitioner contends that this statement sufficiently explains why a person of ordinary skill in the art would have been motivated to improve ligation efficiency according to techniques known in the art. *Id.*

We did not overlook Petitioner’s evidence or argument of improving ligation efficiency. Indeed, we expressly acknowledged it. *See* Dec. 14 (noting Petitioner’s argument that “tagging ‘at least 20% of the cfDNA molecules’ would have been obvious because ligation efficiency ‘could be improved using a variety of techniques’”). After reviewing Petitioner’s evidence and argument, however, we were not persuaded that it was sufficient. *Id.* Even if the relevance of ligation efficiency was well known to a person of ordinary skill in the art for the reasons stated by Petitioner, the Petition still fails to provide a specific motivation to modify Schmitt. As explained in the Decision, “even if techniques were known that *could* have improved ligation efficiency, Petitioner has not shown sufficiently why a person of ordinary skill in the art *would* have modified Schmitt to tag ‘at least 20%’ of the DNA molecules.” Dec. 15; *see also Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015) (“[O]bviousness concerns whether a skilled artisan not only *could have made* but *would have been motivated to make* the combinations or modifications of prior art to arrive at the claimed invention.”). That is, Petitioner’s motivation is “generic and bears no relation to any specific combination of prior art elements.”

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