

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GUARDANT HEALTH, INC.
Petitioner,

v.

UNIVERSITY OF WASHINGTON,
Patent Owner.

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

**PATENT OWNER'S OPPOSITION TO
PETITIONER'S MOTION TO EXCLUDE**

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Patent Trial and Appeal Board
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I. INTRODUCTION

Patent Owner files this brief in opposition to Petitioner's motion to exclude EX2014 (Satija Declaration) and the exhibits used in cross examination of Guardant's two Reply witnesses included within EX2072 and EX2073 (deposition transcripts of Guardant's two reply witnesses).

II. ARGUMENT

A. Petitioner's Motion to Exclude the Satija Declaration (EX2014) Is Procedurally Deficient And An Improper Attempt at Substantive Briefing.

1. The Board should reject Petitioner's motion to exclude because Petitioner's motion is an improper attempt at additional briefing on the merits of the case.

The Board should reject Petitioner's Motion to Exclude outright because it is a blatant attempt to dispute the merits of Patent Owner's case, not an evidentiary motion. A motion to exclude is not an opportunity to refute the substantive arguments an opposing party raises in separate briefing. *See* CTPG (Nov. 2019), 78–79. Yet that is precisely what Petitioner has done.

Petitioner dedicates the majority of its motion to arguing that the Satija Declaration is inadmissible because it is “a frivolous attack on enablement based on alleged inoperability of [Travers '075's RCR] embodiment.” MTE, 4. This is so, according to Petitioner, because: (1) Travers '075 is entitled to a presumption of enablement; (2) this “[presumption] is not overcome by a mere showing that it is possible to operate within the disclosure without obtaining the alleged product;”

and (3) “[a]t best, Dr. Satija’s arguments demonstrate that a saboteur could contrive an experiment to obtain some useless data, not that . . . Travers [’075] is inoperable.” MTE, 7-8. These contentions have nothing to do with *admissibility* of evidence and everything to do with belated arguments on the merits of Petitioner’s obviousness theory. At best, Petitioner’s arguments go towards *weight* of evidence, not admissibility. And that is not enough for a motion to exclude. *Found. Med., Inc. v. Guardant Health, Inc.*, IPR2019-00652, FWD, 8-11 (PTAB Aug. 18, 2020). Moreover, Petitioner’s belated and improper briefing on the merits of its case still cannot overcome the fatal deficiencies in the Petition that Patent Owner identified in its POR and Sur-Reply.

Petitioner’s argument that Travers-075 should be presumed enabled is irrelevant, because any presumption of enablement is *rebuttable*. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1305 (Fed. Cir. 2006); *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1085 (Fed. Cir. 2008). Patent Owner and Dr. Satija presented extensive evidence showing that Travers-075’s RCR embodiment is indeed *not* enabled, thus overcoming any presumption of enablement. EX2014, ¶¶96-210; POR, 18-59; Sur-Reply, 16-27.

Petitioner now resorts to belatedly arguing the merits of the case under the guise of a *motion to exclude evidence*, claiming that Dr. Satija’s testimony is inadmissible because it amounts to “a legally erroneous attempt to sabotage the

prior art.” MTE, 8. But accusing an expert’s testimony of prior art “sabotage” *at most* goes to the weight of the testimony, not the admissibility. IPR2019-00652, 8-11. Moreover, Petitioner’s allegation is false. Dr. Satija’s testimony does nothing more than follow Petitioner’s embodiment as articulated in the Petition to show that Petitioner’s rolling circle replication embodiment would simply not work. EX2014, ¶¶113-210. This is not “sabotage.”

Petitioner’s implication that the Satija Declaration fails to rebut any presumption of enablement plainly goes to whether the Satija Declaration has proven a particular fact—namely, whether Petitioner’s RCR embodiment is inoperable and therefore not enabled. Again, this is not a proper basis for a motion to exclude because it attacks the *sufficiency*, not the admissibility, of the Satija Declaration. *See, e.g., Micro Chem., Inc. v. Lextron, Inc.*, 317 F.3d 1387, 1392 (Fed. Cir. 2003). While Petitioner is free to disagree with Patent Owner on the question of whether the Satija Declaration rebuts any presumption of enablement, a motion to exclude evidence is not the proper vehicle for voicing this disagreement.

Petitioner’s Motion also rehashes Petitioner’s arguments from its Reply regarding supposed “admissions” in the specification of the ’127 patent. Couching this additional briefing as relating to “admissibility,” Petitioner argues that the Satija Declaration is inadmissible because the challenged “claims rely on the very prior art technology it says lacks enablement to enable its own claims.” MTE, 6-7.

This recycled argument is premised on the same mischaracterizations of the '127 patent and Dr. Satija's deposition testimony Petitioner made in its Reply and thoroughly rebutted in Patent Owner's Sur-Reply. Sur-Reply, 2-6.

For example, Petitioner asserts that "the challenged claims are admittedly directed to amplification followed by PacBio sequencing, as disclosed in the Travers references." MTE, 5. Neither Patent Owner nor Dr. Satija have *ever* "admitted[]" that the challenged claims encompass PacBio sequencing. To the contrary, they have in fact stated repeatedly that while the '127 patent's specification teaches using a "suitable" sequencing method, a POSA would have concluded that the PacBio sequencing method disclosed in the Travers references was "*unsuitable*" for the claimed methods, *especially* Petitioner's proposed RCR embodiment. Sur-Reply, 5 (citing EX2014 ¶¶113-197, 215; EX1001, 15:33-39).

Petitioner next repeats its Reply argument that, by "testify[ing] that the claimed embodiment in Claim 10 is not limited to" the rolling circle replication embodiment in Travers '075, Dr. Satija somehow "admitted that the claims encompass" it. MTE, 6 (citing EX1037, 94:23-95:15); Reply, 3. As explained below, (and in Patent Owner's Sur-Reply) Petitioner cherry-picks excerpts from Dr. Satija's testimony to manufacture an "admission" that was never made.

At deposition, Dr. Satija explained that, *unlike* Petitioner's proposed RCR embodiment, claim 10's embodiment "is not limited to" using Travers '075's RCR

product with PacBio sequencing. EX1037, 108:5-14. Dr. Satija continued that a POSA reading the '127 patent could “do two things.” *Id.* First, instead of “sequenc[ing] directly after rolling circle replication,” the POSA could “further process[]” the “templates of the '127 patent.” EX2014, ¶215. This “downstream modification step[]” was disclosed in the '127 patent, *Id.*; EX1001, 11:15-18, but *not* in the Travers publications nor was it suggested in the Petition. EX2014, ¶215. Dr. Satija’s testimony thus refutes any suggestion that Dr. Satija “admitted” that the '127 patent and the Travers publications disclose the same technology. Second, a POSA—following the '127 patent’s disclosure could “us[e] any *suitable* [sequencing] method known in the art,” EX2014, ¶215; EX1001, 15:33-39. And Dr. Satija explained in detail in his declaration that a POSA “would have understood that rolling circle replication *was not suitable*” for use in PacBio sequencing as set forth in the Petition for the methods claimed in the '127 patent. *Id.* Petitioner turns a blind eye to this context.

Petitioner also rehashes its incorrect Reply argument that “the specification specifically instructs use of Travers’ adapters, amplification, and continuous loop sequencing as suitable for use with the disclosed methods.” MTE, 6; Reply, 7. The specification offers no such instructions for the claimed methods. As Patent Owner explained in its Sur-Reply (at 4), Petitioner ignores the disjunctive “or” in this statement (i.e., “*or* serve as the substrate”). The '127 patent’s statement that

“closed circles may . . . serve as the substrate for continuous loop sequencing” is an explicit reference to the PacBio SMRTbell sequencing method, which is not within the scope of the challenged claims at least because it does not use template amplification *after* ligation but *before* sequencing. Sur-Reply, 4-5.

Petitioner next raises rebuttal arguments to Dr. Satija’s opinions that a POSA would not have been motivated to combine Travers 2010 and Travers ’075. MTE, 8-10. According to Petitioner, this testimony is “inadmissible” because Travers 2010 and Travers ’075 disclose “all of the elements of the claimed invention” and a showing of motivation to combine is irrelevant under such circumstances. MTE, 4. First, Petitioner’s argument wrongly assumes that it is undisputed that the Travers references—alone or in combination—disclose all the elements claimed in the ’127 patent; this issue is hotly contested. *Id.*, 6-14; POR, 11-18. Second, Petitioner is wrong on the law. When a party asserts that a patent is invalid as obvious in light of a *combination* of prior art references (as Petitioner has done here, *see* Pet., 6, 19), “the PTAB must make a finding of a motivation to combine when it is disputed.” *In re Nuvasive, Inc.*, 842 F.3d 1376, 1382 (Fed. Cir. 2016). To hold otherwise “would essentially eliminate the motivation to combine requirement and . . . turn an obviousness analysis into an anticipation analysis.” *ProBatter Sports, LLC v. Sports Tutor, Inc.*, 680 F. App’x 972, 976 (Fed. Cir. 2017). Indeed, the only cases Petitioner cites in support of its assertions are

anticipation, not obviousness, cases. Dr. Satija’s testimony showing that a POSA would not be motivated to combine Petitioner’s references is squarely relevant (and admissible) here. Petitioner’s argument to the contrary is meritless.

2. Petitioner fails to identify any actual “legal error” in Dr. Satija’s claim construction determinations.

Petitioner asserts that Dr. Satija’s construction of the terms “barcode” and “first and second strand sequence reads” are “predicated on legal error” and are therefore inadmissible. MTE, 10. Petitioner never explains what the so-called *legal* error is. Rather, Petitioner spends this portion of its brief attempting to rebut Dr. Satija’s opinions. The Board should reject these arguments because they are, yet again, more improper substantive briefing. These arguments also fail on the merits.

Petitioner, for example, disagrees with Dr. Satija’s construction of the “barcode” to the extent that Dr. Satija’s construction would encompass “molecular barcode[s]” but not the “index or sample barcodes” disclosed in Travers ’075. MTE, 10. This is not a “legal error” by Dr. Satija; this merely Petitioner’s disagreement with Dr. Satija’s opinions. Moreover, Dr. Satija explained that claim 22 recites grouping sequence reads into families based on *barcode and DNA fragment-specific information*, which is fundamentally different from using “indexing or sample” barcodes that come from specific *sample sources*. EX2014, ¶84. As used in the claims, therefore, the claim 22’s barcode must be a molecular

barcode, not an index (sample) barcode. *Id.* Petitioner has ignored this family grouping requirement of claim 22 in attacking Dr. Satija's claim construction.

Petitioner then insists that, by concluding that the Travers references did not meet his construction of "first and sequence strand sequence reads," Dr. Satija has somehow adopted a "special definition" of this claim term that is "frivolous" and "has no basis." MTE, 11-12. But Dr. Satija, in fact, gave multiple bases in his Declaration for concluding that the "sequence reads" disclosed in the Travers references are a chain of contiguous *subreads* all *linked together* within a "raw" sequence read. *See, e.g.*, EX2014, ¶¶75-80. Travers 2010, for example, explicitly distinguished subreads from raw reads and described "identif[ying]" the former from the latter. *Id.* Petitioner has not and cannot demonstrate that Dr. Satija's analysis is based on legal error or that his testimony should be excluded.

3. Petitioner's motion to exclude the Satija Declaration violates 37 C.F.R. § 42.64(b)(1).

Even putting the foregoing improprieties of Petitioner's motion aside, the motion to exclude EX2014 fails procedurally under 37 C.F.R. § 42.64 because Petitioner failed to "identify the grounds for the objection with sufficient particularity." 37 C.F.R. § 42.64(b)(1). This alone is more than enough basis for rejecting a motion to exclude. *See Silicon Lab'sys, Inc. v. Cresta Tech. Corp.*, IPR2015-00626, FWD, 8-11 (PTAB Aug. 11, 2016).

Petitioner's objection to EX2014 merely stated in conclusory fashion that

the entire Satija Declaration is inadmissible and recited only boilerplate objections. Paper 35, 1-2. Petitioner's non-specific objections failed to "identify any particular portion of the [Satija Declaration] nor explain cogently *why* the" Satija Declaration is inadmissible. IPR2015-00626, 8-11 (emphasis added). The Board should deny Petitioner's motion for this additional reason. *Apple Inc. v. Achates Ref. Publ'g, Inc.*, IPR2013-00080, FWD, 52-53 (PTAB June 2, 2014).

B. Petitioner's Arguments for Excluding the Deposition Exhibits Attached to EX2072 and EX2073 Fail.

Patent Owner submitted with its Sur-Reply EX2072 and EX2073, each containing the complete records of the depositions of Petitioner's Reply witnesses, Drs. Larrea and Quackenbush. Because it would be unhelpful for the Board to consider Dr. Larrea's and Dr. Quackenbush's deposition transcripts in a vacuum, Patent Owner included alongside these transcripts the exhibits that Patent Owner used to test the direct testimony in each deposition. Petitioner's witnesses were presented with these documents during their depositions and had the full opportunity to respond to them; Petitioner insists that they constitute "new evidence" and asks the Board to exclude them in their entirety. Petitioner's argument relies on a number of federal evidentiary and regulatory rules—all of which either have no application here, have been found to be improper bases for a motion to exclude, or both. The Board should deny Petitioner's motion to exclude.

- 1. Each of the deposition exhibits were used during Dr. Larrea's and Dr. Quackenbush's depositions and they are highly relevant to evaluating their testimony.**

Exhibit 1 of EX2072 is a table of contents listing all of the documents in a binder that Dr. Larrea brought into the deposition room. EX2072, 90; *id.*, 7:23-22. It is relevant because it demonstrates the materials that Dr. Larrea brought into the deposition.

Exhibits 2-5 of EX2072: Exhibit 2 is a drawing taken directly from Travers-2010 and annotated by Dr. Larrea to show the polymerase binding sites on a SMRTbell template. Exhibits 3-5 of EX2072 are schematics depicting concatemers corresponding to the RCR products produced by Petitioner's RCR embodiment. During deposition, Dr. Larrea annotated the *many* polymerase binding sites present on these linear RCR products. Sur-Reply, 18-19. These exhibits impeach Dr. Larrea's declaration testimony regarding "Problem 1," and are highly probative of no enablement and no expectation of success of Petitioner's RCR embodiment. EX2072, 29:13-32:18, 91-94; Sur-Reply, 18-20. Petitioner's counsel made no objection to these exhibits during the deposition and therefore, objection is waived. 37 C.F.R. § 42.64(a).

Exhibit 6 of EX2072 is a PacBio Glossary that describes three categories of "productivity" from ZMWs and notes that multi-polymerase-occupied ZMWs are "not conducive to base calling," EX2072, 97. Patent Owner elicited testimony to

this effect from Dr. Larrea, *Id.*, 41:12-18 (testifying that “no useable data was generated from that ZMW” with multiple polymerases present). Sur-Reply, 21.

Exhibit 7 of EX2072 is the CHROMA SPIN Columns User Manual. (“Chroma User Manual”). As Dr. Larrea confirmed during deposition, the Chroma Spin User Manual discloses that ChromaSpin 100 columns remove DNA molecules “<300 bp” and retain all molecules “>1,350 bp” Sur-Reply, 24; EX2072, 50:18-519, 108. This demonstrates Petitioner’s Reply argument related to size selection would not work to remove the vast majority of concatemer products produced in an RCR reaction. Sur-Reply, 24.

Exhibit 8 of EX2072 is an academic article titled “Miniaturized gel electrophoresis system for fast separation of nucleic acids.” (Li). During his deposition, Dr. Larrea acknowledged Li’s disclosure that “gel electrophoresis” exposes DNA to intercalating dyes and ultraviolet radiation, undercutting Petitioner’s argument that a POSA would have used a “gel electrophoresis” as a viable size selection technique for use with PacBio sequencing because PacBio specifically warns *not* to expose DNA to UV light or DNA intercalating agents. EX2072, 52:8-53:15, 127; Sur-Reply, 24-25.

Exhibit 9 of EX2072 is a patent application (US2009/0024331 to “Tomaney”), which Travers ’075 cites and incorporates by reference. EX1018, ¶¶135, 141; EX2072, 56:20-59:3, 132-195. Tomaney teaches that ZMWs do “not

provide useful data” and should be excluded from analysis when “multiple[] polymerases are sequencing in [the] ZMW.” EX2072, 58:9-59:3, 189 (¶¶178, 181). This evidence undermines the enablement of Petitioner’s RCR embodiment which would result in many polymerases at the bottom of ZMWs. Dr. Larrea admitted he *never considered* Tomaney when formulating his opinions, EX2072, 57:8-13, which shows his prepared testimony should be given little weight.

Exhibits 1 and 2 of EX2073 are Dr. Quackenbush’s declaration and corresponding deposition transcript filed in concurrent district court litigation. In this testimony, Dr. Quackenbush testified that certain claim terms in the ’127 patent were indefinite, EX2073, 13:1-20:11, which is inconsistent with Dr. Quackenbush’s claim construction positions here. Sur-reply, 27 (citing EX2073, 274-278). Patent Owner elicited testimony from Dr. Quackenbush to this effect during his deposition, *id.* 13:1-20:11, and it goes directly to Dr. Quackenbush’s credibility as a witness.

Exhibit 3 of EX2073 is Dr. Quackenbush’s Declaration that Petitioner submitted in IPR2019-00652. In that Declaration, Dr. Quackenbush testified that a patent sharing the ’127 patent’s specification used a “family grouping” step as part of a “molecular barcoding approach,” which is consistent with disclosures in the ’127 patent and *inconsistent* with what is disclosed in the Travers references. EX2073, 93:11-95:19, 311 (¶33); Sur-Reply, 11.

Exhibit 4 of EX2073 is a public excerpt of a confidential expert report that Dr. Quackenbush submitted as part of the concurrent district court litigation. In that report, Dr. Quackenbush argued that the comparing, analyzing, and confirming steps disclosed in the '127 patent's claim 1 are "indefinite" for allegedly being step plus function elements, demonstrating that he has failed to construe claims consistently. Sur-Reply, 27; EX2073, 369 (¶298). Patent Owner elicited testimony from Dr. Quackenbush to this effect during his deposition, EX2073, 102:15-105:9, and it goes directly to Dr. Quackenbush's credibility as a witness.

* * *

Petitioner's counsel had ample opportunity on redirect to ask Drs. Larrea and Quackenbush questions regarding these exhibits. Indeed, Petitioner's counsel did during Dr. Larrea's deposition *after* conferring with Dr. Larrea *before* his redirect. EX2072, 59:12-61:9 (admitting during re-cross examination that he conferred with Petitioner's counsel about his testimony before re-direct).

2. Petitioner's arguments fail.

Petitioner argues that the deposition exhibits within EX2072 and EX2073 should be excluded because the transcript and exhibits *for the same deposition* cannot be filed together under 37 C.F.R. § 42.23(b). The Board has consistently rejected Petitioner's reading of § 42.23(b), finding instead that "if exhibits are introduced during a deposition for the purposes of testing the witness' testimony, *a party should be able to submit those exhibits with the transcript*, so the Board has

the full context available in order to evaluate the testimony.” *Ascend Performance Materials Operations LLC, v. Samsung SDI Co.*, IPR2020-00349, Paper 53, 12 (PTAB July 15, 2021); *see also Edwards Lifesciences Corp. v. Cardiovalve Ltd.*, IPR2021-00383, FWD, 87-89 (PTAB July 18, 2022).

Here, each and every one of the exhibits that Petitioner attached to EX2072 and EX2073 were used to impeach or otherwise test the declaration testimony of Drs. Larrea and Quackenbush. *See* EX2072, 14:5-6, 28:22-23, 30:1-2, 31:4-5, 30:23-24, 39:20-21, 49:12-13, 51:23-24, 57:17-18; EX2073, 7:25-8:3, 91:5-8, 93:6-8, 100:3-6. They are not Trojan horses, as Petitioner alleges. These exhibits are plainly relevant to the Board because they will serve “as an adjunct to reading and understanding the deposition transcript[s].” IPR2021-00383, 87-89. Admitting them as evidence, moreover, does not prejudice Petitioner, whose witnesses “had an opportunity to respond to the exhibits during [their] deposition[s].” *Id.*

Petitioner next argues for excluding the deposition exhibits within EX2072 and EX2073 under 37 C.F.R. § 42.6(a)(3), arguing that they constitute “combined documents.” Rule 42.6(a)(3) is not the proper basis for a motion to exclude because this provision does not relate to the *admissibility* of the challenged evidence. *Silicon Lab’s, Inc. v. Cresta Tech. Corp.*, IPR2015-00615, FWD, 8-11 (PTAB Aug. 11, 2016). Nor are EX2072 and EX2073 “combined documents” because both reflect the full record of the depositions. Petitioner’s objection under

37 C.F.R. § 42.63 fails for the similar reasons.

Petitioner also moves under FRE 106. But FRE 106 “is not properly the subject of a motion to exclude,” *Torrent Pharms. Ltd. v. Novartis Ag.*, IPR2014-00784 & IPR2015-00518, FWD, 53 (PTAB Sept. 24, 2015) because FRE 106 “provides a basis for including, rather than excluding, evidence,” *Mobile Tech, Inc. v. Invue Sec. Prods. Inc.*, IPR2016-00892, Paper 35, 68–69 (PTAB Sept. 28, 2017).

Petitioner’s argument that deposition exhibits included within EX2072 and EX2073 “lack foundation” under FRE 602 and 702 makes no sense. Petitioner cannot seriously argue that its *own* expert’s declarations, deposition testimony, and expert report “lack foundation, have no sponsoring witness, and were not affirmatively relied upon by any expert in this case.” As for the exhibits used in Dr. Larrea’s deposition, these exhibits are not even *subject* to FRE 702 because none of them contain testimony from any witness. *See* FRE 702. Petitioner’s FRE 602 argument fails because the Rule “expressly recites that it ‘does not apply to a witness’s *expert* testimony under Rule 703.’” *Apple Inc. v. Smartflash LLC*, CBM2015-00028, FWD, 30-31 (PTAB May 26, 2016).

Lastly, Petitioner’s argument under FRE 802 should be rejected because it fails to “explain th[is] objection” in violation of 37 CFR § 42.64(c). *See* MTE, 13 (stating in conclusory terms that “[t]he[] [deposition exhibits] also are and contain hearsay in violation of F.R.E. 802 for which PO has established no exception.”).

Respectfully submitted,

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CERTIFICATION OF SERVICE (37 C.F.R. § 42.6(e))

I certify that the above-captioned **PATENT OWNER'S OPPOSITION TO PETITIONER'S MOTION TO EXCLUDE** was served in its entirety on June 1, 2023 upon the following parties via electronic mail:

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