

Paper No. _____
Filed: May 25, 2023

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

PETITIONER'S MOTION TO EXCLUDE
37 C.F.R. §42.64(c)

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I. INTRODUCTION

Petitioner (Guardant) requests exclusion of Patent Owner (PO)'s EX2014, "Exhibits" 1-9 in EX2072, and "Exhibits" 1-4 in EX2073 for violation of the Federal Rules of Evidence (FRE). 37 C.F.R. §42.64(c).

II. REASONS FOR EXCLUSION

A. EX2014 – Satija Declaration

Guardant timely objected to EX2014 under FRE 402, FRE 403, and FRE 702-703. Paper 23, 1-2. Guardant moves to exclude EX2014 because Dr. Satija's proffered opinions are frivolous and are not "the product of reliable principles" and methods "reliably applied" to the facts of this case. F.R.E. 702, 402, 403; *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589 (1993). Expert testimony is neither relevant nor reliable, and is therefore inadmissible, when it is predicated on an erroneous legal standard. *See, e.g., U.S. Gypsum Co. v. Lafarge N. Am. Inc.*, 670 F. Supp. 2d 737, 745 (N.D. Ill. 2009) ("Having applied the incorrect legal standard ..., Davis will not be permitted to testify on that topic."). Here, Dr. Satija's declaration testimony is predicated on erroneous legal standards for challenging the operability of a prior art embodiment and regarding certain claims terms. Accordingly, his testimony should be excluded.

1. Erroneous Legal Standard For Challenging Operability

The bulk of Dr. Satija's declaration is spent arguing that the Travers embodiment employing amplification prior to sequencing, while admittedly disclosed, is inoperable and thus a POSA would have been dissuaded from doing it, allegedly undermining motivation to combine. *See, e.g.*, EX2014, ¶100 ("Dr. Quackenbush provides no explanation of why a POSA would have been motivated to combine Travers '075's rolling circle replication embodiment with the SMRT sequencing applications disclosed in Travers 2010....[F]our problems would have rendered Travers '075's rolling circle replication embodiment unworkable and requiring undue experimentation. Thus, a POSA would have been dissuaded from considering such an embodiment.). But Dr. Satija's motivation arguments are legally irrelevant because he ignores the law that no additional motivation is required for an embodiment that is already disclosed in the prior art. *See, e.g.*, *Upsher-Smith Labs. v. Pamlab, LLC*, 412 F.3d 1319, 1322-23 (Fed. Cir. 2005) (reference disclosing optional inclusion of a particular component teaches compositions that both do and do not contain that component); *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361 (Fed. Cir. 1998) (prior art anticipated the claims even though it taught away from the claimed invention); Paper 14 at 19.

Dr. Satija already acknowledges that the Travers amplification and sequencing embodiment is disclosed. Dr. Satija first concedes, as he must, that Travers '075 and Travers 2010 disclose the same SMRT sequencing method. *See, e.g.*, EX2014, ¶¶39 (“Dr. Quackenbush admits that Travers '075 discloses the same SMRT sequencing methods and SMRTbell template molecules disclosed in Travers 2010.”), 47 (“Dr. Quackenbush explains that Travers 2010 is authored ‘by scientists employed by PacBio (including inventors of Travers '075) and describes applications of the sequencing method described in Travers '075.’”), 108 (discussing “the SMRT sequencing of Travers'075 and Travers 2010”), 110 (“the SMRT sequencing of Travers '075 and Travers 2010”), 112 (“the SMRT sequencing method disclosed in Travers '075 and Travers 2010”), 113 (“the SMRT™ sequencing of Travers '075 and Travers 2010”), 171 (“The SMRT™ sequencing platform disclosed in Travers '075 and Travers 2010”), 193 (“the SMRT sequencing of Travers '075 and Travers 2010”). Because the two references admittedly disclose the very same SMRT sequencing method, there is no additional motivation required for combining their descriptions of that method.

Second, Dr. Satija admits that Travers '075 teaches an embodiment in which the Travers sequencing method includes an amplification step before sequencing. *E.g.*, EX2014, ¶110. Dr. Satija's arguments about motivation to combine are thus irrelevant because he has already acknowledged that amplification before

sequencing is a disclosed embodiment. No further showing of motivation to practice a disclosed embodiment is required. Though the Travers sequencing method can be performed directly on template without prior amplification, amplification followed by sequencing was useful for providing sequencing redundancy as disclosed by Travers, including when there was low sample volume, when it was desirable to increase the number of reads and depth of coverage, or when it was desirable to target specific loci in particular applications. EX1018, ¶122; EX2073, 21:19-22:5, 68:3-17. It is beyond reasonable dispute that the amplification embodiment of the Travers method anticipates or at least discloses all of the elements of the claimed invention. EX2073, 23:19-24:8, 27:4-9, 108:8-109:3. In such circumstances, a preference for one over the other is irrelevant.

Dr. Satija's argument essentially collapses into a frivolous attack on enablement based on alleged inoperability of this disclosed embodiment. *See, e.g.*, EX2014, ¶¶21 ("Travers '075's rolling circle replication embodiment would produce a set of linear molecules that are ***incompatible*** with the SMRT sequencing workflow"),¹ 22 ("Travers '075's rolling circle replication embodiment would ***not*** have been expected to ***produce any useable sequencing data at all***"), 22 (multiple polymerases would "render this multi-complex ***unsequenceable*** on the ZMW

¹ All emphases added unless otherwise indicated.

arrays for SMRT sequencing”), 23-24 (“**would not result in usable sequencing data**”), 25 (“the narrow diameter of ZMWs would have **precluded** the large concatemer molecules from physically fitting into the wells”), 27 (“functional **incompatibilities**”), 99 (“would **not have expected to achieve useful sequencing reads**”), 100 (four problems “would have rendered Travers ’075’s rolling circle replication embodiment **unworkable**”), 112 (“**fundamentally incompatible** with the SMRT sequencing method disclosed in Travers ’075 and Travers 2010”), 123 (“**unreadable** sequencing data”), 128 (“**unable to be sequenced** on the ZMWs”), 130 (“producing **useless** data”), 134 (“the ZMW array **would not have been able to** sequence”), 134 (“**unreadable**”), 146 (“**could not be usefully sequenced**”), 157 (“not provide **useful sequencing data**”), 169 (not “achieve a **useable sequencing readout**”), 209 (“not have even fit into the ZMWs”) ; *see also id.*, ¶¶113-216 (discussing the four “problems”). These frivolous arguments are legally erroneous.

Dr. Satija’s arguments are legally erroneous at least because the challenged claims are admittedly directed to amplification followed by PacBio sequencing, as disclosed in the Travers references. We know this is true because claim 1 plainly encompasses use of U-shaped adapters and rolling circle amplification, and broadly encompasses sequencing on the Pacific Biosciences sequencing platform. See EX1001, claims 10, 13. Dr. Satija specifically testified that the claims are not limited to Illumina sequencing (i.e., are not limited to using flow cells or y-shaped

adapters). EX1037, 77:8-17. He also admitted that the claims encompass “Travers’s ’075 rolling circle replication embodiment” when he testified that the “claimed embodiment in Claim 10 is not limited to” it. EX1037, 94:12-95:15. Moreover, the specification specifically instructs use of Travers’ adapters, amplification, and continuous loop sequencing as suitable for use with the disclosed methods. EX1001, 10:63-11:15, 15:29-39; *see also* EX2014, ¶214; EX1037, 94:24-95:15; EX1039, ¶7; EX1037, 26:9-17, 76:10-14, 77:14-17; *see also* EX1039, ¶9. There can thus be no reasonable dispute that the claims encompass the prior art Traverse amplification and sequencing embodiment.

It is legally improper to argue a different standard for enablement of the specification as compared to the prior art. *See In re Paulsen*, 30 F.3d 1475, 1481 n.9 (Fed. Cir. 1994) (noting the specification would not be enabling if held to the same standard urged for the reference); *In re Epstein*, 32 F.3d 1559, 1568 (Fed. Cir. 1994) (noting appellant’s specification lacks the same detail urged as making the reference inadequate); *SRI Int’l, Inc. v. Internet Sec. Sys.*, 511 F.3d 1186, 1192-94 (Fed. Cir. 2008) (finding unpersuasive arguments that the prior art was not enabling where the disclosure between the prior art and challenged patent were highly similar). A patentee asserting a reference is inoperative therefore must distinguish the claims from the alleged inoperative reference’s disclosure. *In re Crosby*, 157 F.2d 198, 200 (CCPA 1946). Here, PO cannot do so because PO’s

claims rely on the very prior art technology it says lacks enablement to enable its own claims. Dr. Satija's inoperability arguments are thus legally erroneous.

Dr. Satija's arguments also are legally erroneous because they are predicated on sabotaging the prior art. Regardless of the forum, prior art patents and publications enjoy a presumption of enablement and the patentee has the burden to show facial non-enablement for such prior art. *In re Antor Media Corp.*, 689 F.3d 1282, 1287-88 (Fed. Cir. 2012); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1355 (Fed. Cir. 2003). Absent a demonstration of facial **inoperability**, the prior art is "self-enabling." *Raytheon Techs. v. GE Co.*, 993 F.3d 1374, 1376 (Fed. Cir. 2021). "When the reference relied on expressly anticipates or makes obvious all of the elements of the claimed invention, the reference is presumed to be operable." MPEP §2121. Proof of efficacy is not required. *Impax Labs. Inc. v. Aventis Pharm. Inc.*, 468 F.3d 1366, 1383 (Fed. Cir. 2006).

The presumption that a prior art process used by one skilled in the art will produce the product or result described therein is not overcome by a mere showing that it is possible to operate within the disclosure without obtaining the alleged product. *In re Weber*, 405 F.2d 1403, 1407 (CCPA 1969). Instead **skilled** workers must be presumed to make adaptations within the skill of the competent worker, as needed. *In re Michalek*, 162 F.2d 229, 231-32 (CCPA 1947). Any failures of experimenters who have no interest in succeeding (*e.g.*, Dr. Satija's hypotheticals)

should not be accorded great weight. *Id.* At best, Dr. Satija’s arguments demonstrate that a saboteur could contrive an experiment to obtain some useless data, not that the amplification plus sequencing embodiment of Travers is nonoperative. Accordingly, Dr. Satija’s arguments are baseless and irrelevant.

Dr. Satija’s “four problems” are nothing more than a legally erroneous attempt to sabotage the prior art method based on unrealistic assumptions. The prior art expressly describes templates with more than one primer/polymerase binding sites wherein only the polymerase bound to the bottom of the ZMW is detected. EX1018, ¶¶17, 14, 67. EX1018, ¶¶103, 105, 144, Figure 7; EX1021, 3; EX1035, 34; EX2021, 1, 4, Figs. 4, 6; *see also* EX1036, 12-13; EX1037, 117:19-24. EX1033, ¶¶8-18; EX1039, ¶28. Loading of multiple templates is easily mitigated and the method routinely generated useable sequence reads. EX1035, 39; EX1033, ¶¶19-20. Dr. Satija’s “problem” 1 improperly attempts to sabotage the very same SMRT sequencing method that the patent itself relies upon.

Dr. Satija’s “problems” 2 and 3 (EX2014, ¶¶139-163, 165-169) attempt to sabotage the prior art by unreasonably assuming that POSAs would ignore known and routine methods to address diffusion bias. EX1037, 40:2-5 (“there were size selection methods that were known in the art.”). This assumption is baseless. *E.g.*, EX1018, ¶¶145, 150 (“ChromaSpin 1000”); EX1021, Figure 3 (gel electrophoresis of amplified concatemers); EX1035, 3, 24, 27, 35, 38, 48; EX1036, 12 (“AMPure

XPTM”); EX1037, 43:16-45:3; EX1033, ¶¶21-24; EX1039, ¶29; EX2072, 43:1-45:15, 47:18-48:8, 59:23-60:6 (protocols routinely adjusted to remove different targets, including by varying concentration of the beads), 48:21-49:8, 50:19-51:9, 60:12-24 (Chromas Spin column protocols varied to remove different targets), 51:11-22, 59:15-23 (Gel Electrophoresis is so easy high school students can do it).

Finally, Dr. Satija’s fourth “problem” attempts to sabotage the prior art by imagining hypothetical concatemer products of a particular shape that he says would not fit in the ZMWs, when the literature was clear that molecules of similar and even larger size were routinely sequenced and that there was no evidence of an “intrinsic limit in the size of template.” EX1021, 1, 5, Fig. 4B; EX1018, ¶¶83, 85, 144, 150; EX1033, ¶¶29-34; EX1039, ¶30; EX1035, 6, 35; EX1037, 124:6-14, 125:21-126:3, 126:24-127:1 (confirming size of hypotheticals), 120:15-18 (confirming DNA shape in solution would not be rigid). Dr. Satija’s contrived selection of circumstances tries to maximize as many opportunities to sabotage the Travers method as possible. But POSAs don’t try to sabotage.

Even under these unreasonable selections by Dr. Satija, these arguments still do not render the method inoperable. Even if some templates might sometimes produce “unusable” sequencing data, this is legally deficient for establishing inoperability, as discussed above. Dr. Satija’s inoperability arguments are “fallacious” and unreliable. EX2073, 37:25-38:1, 60:8-14. Accordingly, Dr.

Satija's frivolous declaration testimony about the Travers amplification plus sequencing embodiment should be excluded. F.R.E. 702, 401, and 403.

2. Legally Erroneous Constructions

Dr. Satija provides testimony that hinges on legally erroneous arguments about the terms "barcode" and "first and "second strand sequence reads." For example, Dr. Satija argues that when claim 22 uses the word "barcode" without limitation that this term should be narrowed to mean "molecular barcode" and to exclude index or sample barcodes. *See, e.g.*, EX2014, ¶¶16, 81-87.

But claim 22 generically recites "barcode" without any "molecular" modifier. Dr. Satija's argument ignores the broad plain language of the claims and the disclosure in the specification. EX1037, 92:23-93:13 (acknowledging the '127 patent discloses multiple different types of barcodes), 86:15-87:10 (confirming "barcode" broadly includes both molecular barcodes and index barcodes). Indeed, the only usage of the term "barcode" in the specification of the '127 patent is in connection with an index barcode. EX1001, 20:34-39; *see also* EX1037, 59:8-16 (arguing a nucleotide sequence can be considered a barcode even when not used for identification purposes), 90:25-91:13 (confirming the '127 patent only mentions "barcode" once); EX1039, ¶¶15, 16. The '127 patent never uses the term "molecular barcode" and neither do the claims. Because Dr. Satija's testimony

regarding claim 22 is predicated on this erroneous construction, the testimony is legally irrelevant, has no basis, and should be excluded. F.R.E. 702, 401, 403.

Dr. Satija's testimony regarding claim 1 also is legally erroneous. Dr. Satija construes "sequence read" to mean "a contiguous set of DNA nucleotides that correspond to the output of a DNA sequencing reaction[.]" EX2014, ¶60. Dr. Satija then asserts that "multiple, distinct sequencing reactions" are indicated by the act of "sequencing the first and second strand copies to obtain first and second strand sequence reads." EX2014, ¶61; *see also* EX2014, ¶¶15, 62-65, 75-80. But Travers specifically describes obtaining first and second strand **sequence reads**. EX1018, ¶61 ("[A] consensus is first established for **one sequence read**, e.g., a sense strand, and another consensus sequence is established for **another read**, e.g., the an[ti]sense strand."); *see also id.*, ¶¶55, 62. Those reads meet Dr. Satija's own definition of what constitutes a sequence reads. Drs. Larrea and Quackenbush both confirmed, the Travers strand sequence reads are sequence reads under the plain and ordinary meaning. EX2072, 60:25-61:5; EX1039, ¶¶10, 11-13; EX1002, ¶¶80-82. Dr. Satija provided no support for narrowing the claims by adopting a special definition. Instead, he offered a definition under which he frivolously asserted that the Travers first and second strand sequence reads are not sequence reads. His arguments amount to sophistic linguistic acrobatics that ignore the disclosure of the Travers references. Because Dr. Satija's testimony regarding claim 1 is frivolous

and is predicated on legal error, the testimony is legally irrelevant, has no basis, and should be excluded. FRE 702, 401, 403.

B. EX2072 and EX2073 – (“Exhibits” 1-9 and “Exhibits” 1-4).

Guardant timely objected to EX2072 and EX2073 under F.R.E. 106, 402-403, 602, 702, and 802, and 37 C.F.R. §§42.6, 42.23, 42.63. Paper 35, 1-5.

Guardant moves to exclude EX2072 and EX2073 because PO in each instance improperly combined multiple documents into a single exhibit, which is “not permitted,” as a guise for an untimely submission of multiple exhibits it then attempts to rely upon substantively in its Sur-Reply. 37 C.F.R. §§42.6, 42.23; *see also* Consolidated Trial Practice Guide (Nov. 2019) at 73-74 (“The sur-reply may not be accompanied by new evidence other than deposition transcripts of the cross-examination of any reply witness.”). EX2072 and EX2073 are labeled as deposition transcripts but are a combination of deposition transcripts and additional documents (“Exhibits” 1-9 and “Exhibits” 1-4, respectively). “Exhibits” 1-9 (within EX2072) include various schematics presumably drawn by PO’s counsel, among other materials. “Exhibits” 1-4 (within EX2073) include incomplete portions of documents from proceeding other than the instant IPR.

In many cases, PO failed even to ask the deponent substantive questions about the documents. Even where PO asked questions, PO generally only asked the witness merely to read the documents into the record. Throughout the depositions,

PO studiously avoided asking Drs. Larrea and Quackenbush questions about their submitted declarations. PO is now using their deposition transcripts as a Trojan Horse to pepper the record with untimely and improperly submitted exhibits it seeks to use for their substance. Because new evidence may not be submitted in sur-reply (37 C.F.R. §42.23), vast swaths of EX2072 and EX2073 (“Exhibits” 1-9 and “Exhibits” 1-4, respectively) are not relevant to resolution of this case and their admission would be unduly prejudicial, misleading, and a waste of time. The Board should therefore exclude them under F.R.E. 402-403.

As a direct result of PO’s failure to submit “Exhibits” 1-9 and 1-4 with PO’s declarant’s testimony when they submitted the POR, “Exhibits” 1-9 and 1-4 lack foundation, have no sponsoring witness, and were not affirmatively relied upon by any expert in this case. F.R.E. 602, 702. They also are and contain hearsay in violation of F.R.E. 802 for which PO has established no exception.

“Exhibits” 1-4 within EX2073 reflect only a partial record from another proceeding which, if considered at all, should in fairness be considered only together with entirety of the record. “Exhibit” 4 within EX2073 is an incomplete document. Because these documents are submitted after the close of evidence, Guardant has no opportunity to complete the record. F.R.E. 106. PO’s withholding from the Board of the full content of “Exhibit” 1 and the context of “Exhibits” 1-4

additionally justifies their exclusion because any probative value is substantially outweighed by undue prejudice, confusion and waste of time. F.R.E. 402-403.

PO's multiple violations of the F.R.E. discussed above flow directly from their brazen violation of Board rules against using deposition transcripts as a vector for submitting new evidence with the Sur-Reply. Board rules prohibit filing "combined documents" and differentiate between "transcripts of depositions" and "documents," each of which "must be filed in the form of **an** exhibit." 37 C.F.R. §§42.6(3), 42.63(a), (d). All PO exhibits "must be uniquely numbered sequentially" in the range of "2001-2999," and labeled with the party's name, the unique exhibit number, and the names of the parties and the trial number. 37 C.F.R. §§42.63(c), (d)(1)(ii). When the exhibit is a paper, each page must be uniquely numbered in sequence and the exhibit label must be affixed to the lower right corner of the first page of the exhibit without obscuring it. 37 C.F.R. §42.63(d)(2)(i)-(ii). The PO's exhibit list must describe each exhibit. 37 C.F.R. §§42.63(e). PO violated all of these rules to further its attempt to make an end-run around the Board's rules against submitting new evidence in a sur-reply. "Exhibits" 1-9 within exhibit 2072 and "Exhibits" 1-4 within exhibit 2073 are neither properly numbered nor properly labeled as required by section 42.63. Accordingly, the exhibits should be excluded.

III. CONCLUSION

Neither Petitioner nor the Board is required to sort through Dr. Satija's nearly 250 paragraphs of testimony to try to find some admissible nugget from among its frivolous arguments. Nor should they be required to sort through the conglomerations PO created in EX2072 and EX2073 to determine which, if any, of the individual documents might be admissible. Accordingly, each of EX2014, "Exhibits" 1-9 within EX2072, and "Exhibits" 1-4 within EX2073 should be excluded in its entirety; if not excluded, it should be restricted to minimize prejudice so far as possible or given no weight. FRE 105.

Respectfully submitted,

Dated: May 25, 2023

/ Michael T. Rosato /
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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing Petitioner's Motion to Exclude was served on May 25, 2023, at the following electronic service addresses:

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Respectfully submitted,

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