IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NATERA, INC., Plaintiff, v. ARCHERDX, INC., ARCHERDX, LLC, and INVITAE CORP., Defendants.	C.A. No. 20-125-GBW (CONSOLIDATED) **UNSEALED 5/30/2023**

MEMORANDUM ORDER

Pending before the Court is Defendants ArcherDX, Inc.'s, ArcherDX LLC's, and Invitae Corp.'s (collectively, "ArcherDX" or "Defendants") motion to exclude portions of Dr. Paul T. Spellman's, Dr. John Quackenbush's, Mr. Robert Stoll's, Mr. Jerzy Wojcik, and Dr. Ryan Sullivan's testimony and opinions. D.I. 428; D.I. 430. Also pending before the Court is Plaintiff Natera, Inc.'s ("Natera" or "Plaintiff") motion to exclude portions of Mr. Nathan K. Kelley's and Dr. Gregory Cooper's testimony and opinions. *See* D.I. 431; D.I. 432. For the following reasons, Defendants' motion is DENIED and Plaintiff's motion is GRANTED-IN-PART and DENIED-IN-PART.[1]

I. LEGAL STANDARD

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 597 (1993), the Supreme Court held that Federal Rule of Evidence 702 creates "a gatekeeping role for the [trial] judge" in order to "ensur[e] that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." Rule 702 provides:

[1] The Court writes for the benefit of the parties and assumes their familiarity with this action. All D.I. citations refer to C.A. No. 20-125-GBW unless otherwise noted.

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. As the Third Circuit has explained,

> Rule 702 embodies a trilogy of restrictions on expert testimony: qualification, reliability and fit. Qualification refers to the requirement that the witness possess specialized expertise. We have . . . [held] that a broad range of knowledge, skills, and training qualify an expert. Secondly, the testimony must be reliable; it must be based on the methods and procedures of science rather than on subjective belief or unsupported speculation; the expert must have good grounds for his o[r] her belief. In sum, *Daubert* holds that an inquiry into the reliability of scientific evidence under Rule 702 requires a determination as to its scientific validity. Finally, Rule 702 requires that the expert testimony . . . must be relevant for the purposes of the case and must assist the trier of fact.

Schneider ex rel. Estate of Schneider v. Fried, 320 F.3d 396, 404-05 (3d Cir. 2003) (cleaned up); *Kuhar v. Petzl Co.*, C.A. No. 19-3900, 2022 WL 1101580, at *7 (3d Cir. Apr. 13, 2022) (noting the same trilogy).

Rule 702 "'has a liberal policy of admissibility[,]'" *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008) (citation omitted); *see also United States v. Scripps*, 599 F. App'x 443, 447 (3d Cir. 2015) (same), as "the question of whether the expert is credible or the opinion is correct is generally a question for the fact finder, not the court[,]" *Summit 6, LLC v. Samsung Elecs. Co., Ltd.*, 802 F.3d 1283, 1296 (Fed. Cir. 2015). "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596; *see Karlo v. Pittsburgh Glass Works, LLC*, 849 F.3d 61, 83 (3d Cir. 2017) (quoting *Daubert*, 509 U.S. at 596).

II. DISCUSSION

a. ArcherDX's *Daubert* Motions

i. ArcherDX's *Daubert* Motion to Exclude Dr. Spellman's Opinion Regarding the Faham Reference

ArcherDX seeks to exclude Dr. Spellman from testifying about United States Patent No. 8,748,103 ("Faham") because his opinions are "conclusory and irrelevant" and would be unhelpful to the jury. D.I. 430 at 36-37. The Court finds this reasoning unpersuasive. ArcherDX's *Daubert* motion is grounded in its general disagreement with Dr. Spellman's validity opinions. *Id.* But such disagreement does not warrant exclusion. Here, the Court finds that Dr. Spellman provides a detailed discussion of what the Faham reference discloses and why it does not anticipate or render obvious the asserted claims.[2] Specifically, Dr. Spellman explains that Faham is directed to "a completely different way of solving" the amplification bias problem. D.I. 443, Ex. 16 ¶¶ 131-35; *id.*, Ex. 3 at Tr. 167:19-172:1; *see also id.*, Ex. 3 at Tr. 161:20-165:8 (Dr. Spellman disagreeing with ArcherDX's expert's opinion because Faham requires that the universal "primer is not binding to a universal priming sequence in the adaptor, but is specific to a target sequence."). Dr. Spellman also offers a claim-by-claim analysis of why, in his opinion, the asserted claims are valid, and why a person of ordinary skill in the art would not be motivated to combine Faham with other prior art references. *See* D.I. 443, Ex. 16 ¶ 159; *see also id.* ¶¶ 131-32, 134, 160; *id.*, Ex. 3 at Tr. 167:19-172:1. Any deficiencies in Dr. Spellman's analysis are issues of weight and credibility—

[2] Natera alleges ArcherDX infringes the following patents: United States Patent No. 10,538,814 ("the '814 patent"), United States Patent No. 10,557,172 ("the '172 patent"), United States Patent No. 10,590,482 ("the '482 patent"), United States Patent No. 10,597,708 ("the '708 patent") and United States Patent No. 10,731,220 (the "'220 patent") (collectively, the "Asserted Patents"). D.I. 391 ¶ 1. The '814, '172, '482, and '220 patents are collectively referred to as the "cfDNA Patents."

which are issues squarely addressed by the jury—rather than admissibility. *See Masimo Corp. v. Philips Elec. N. Am. Corp.*, 62 F. Supp. 3d 368, 387-88 (D. Del. 2014) ("Where there is a logical basis for an expert's opinion testimony, the credibility and weight of that testimony is to be determined by the jury, not the trial judge.") (citation omitted); *see also Daubert*, 509 U.S. at 595 ("The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate."). ArcherDX can challenge Dr. Spellman's analysis of Faham and his specific disagreements with ArcherDX's expert through cross-examination and the presentation of contrary evidence. *See Daubert*, 509 U.S. at 596.

Accordingly, the Court denies ArcherDX's *Daubert* motion to exclude Dr. Spellman from testifying about Faham.

ii. ArcherDX's *Daubert* Motion to Exclude Dr. Spellman's and Dr. Quackenbush's Opinions on Which Patents the Signatera Product Practices

ArcherDX also seeks to exclude Dr. Spellman's and Dr. Quackenbush's opinions that Natera's Signatera product practices the claims of the '708 patent, arguing that these opinions are both unreliable and unsupported.[3] D.I. 430 at 37-39. The Court disagrees. Both Dr. Spellman's and Dr. Quackenbush's opinions are not unreliable because they are grounded in the factual record and the experts' respective experience. Specifically, Dr. Spellman properly applies the Court's claim construction and provides a detailed analysis of why, in his opinion, Natera's Signatera product practices the asserted claims of the '708 patent. *See* D.I. 443, Ex. 16 ¶¶ 194-99, 212. Dr. Spellman's report also notably incorporates Natera's Second Supplemental Responses to ArcherDX's Third Set of Interrogatories (No. 10), which provides a detailed claim chart showing,

[3] Based on Natera's representation that its "experts will not offer testimony on whether Signatera practices other Natera patents" besides the '708 patent, *see* D.I. 442 at 35 n.18, ArcherDX's *Daubert* motion as it relates to patents other than the '708 patent is moot.

on an element-by-element basis, how Natera's Signatera product practices the '708 patent's claims. *Id.* ¶ 212; *see also* D.I. 443, Ex. 9. Likewise, Dr. Quackenbush relies on his experience with Natera's Signatera product in opining that the Singatera product practices the asserted claims of the '708 patent. D.I. 443, Ex. 6 at Tr. 13:11-19 (Dr. Quackenbush testifying that he is familiar with and understands Natera's Signatera product); *see also id.*, Ex. 13 ¶¶ 331-423. The Court agrees with Natera that "Defendants' arguments go to the weight, not admissibility, of Dr. Spellman's [and Dr. Quackenbush's] opinions." *See Summit 6, LLC v. Samsung Elecs. Co.*, 802 F.3d 1283, 1299 (Fed. Cir. 2015) ("Where the methodology is sound and the evidence relied upon is sufficiently related to the case, disputes over the expert's credibility or over the accuracy of the underlying facts are for the jury."). ArcherDX can challenge Dr. Spellman's and Dr. Quackenbush's analysis of whether the Signatera product practices the asserted claims of the '708 patent through cross-examination and the presentation of contrary evidence. *See Daubert*, 509 U.S. at 596.

Accordingly, the Court denies ArcherDX's *Daubert* motion to exclude Dr. Spellman's and Dr. Quackenbush's opinions regarding whether Natera's Signatera product practices the asserted claims of the '708 patent.

iii. ArcherDX's *Daubert* Motion to Exclude Dr. Spellman's and Dr. Stoll's Opinions on Inventorship

ArcherDX further seeks to exclude Dr. Spellman and Mr. Stoll from offering rebuttal testimony related to inventorship because "[n]either expert performed any analysis of information regarding what the inventors actually worked on and whether this might have reflected a material contribution to the alleged inventions." D.I. 430 at 39. Specifically, ArcherDX contends that, because Dr. Spellman solely relies on inventorship oaths rather than reviewing "any material that may allow him to determine each inventor's contribution," Dr. Spellman must be precluded from

testifying as to inventorship. *Id.* (citing D.I. 434, Ex. B at Tr. 242:6-246:14). Similarly, ArcherDX argues that Mr. Stoll admits he "has no expertise in the technology of patents-in-suit" and, thus, has "no basis to attempt a proper analysis of whether any particular individual engaged in technical work that could constitute an inventive contribution to the patents." D.I. 430 at 39-40 (citing D.I. 434, Ex. JJ at Tr. 24:13-16, 101:20-23, 102:7-14). For the reasons stated below, the Court denies ArcherDX's *Daubert* to exclude Dr. Spellman and Mr. Stoll from offering rebuttal testimony related to inventorship.

Here, ArcherDX challenges the proper inventorship of the Asserted Patents. *See* D.I. 21. "Patent issuance creates a presumption that the named inventors are the true and only inventors." *Caterpillar Inc. v. Sturman Industries, Inc.*, 387 F.3d 1358, 1377 (Fed. Cir. 2004) (citing *Hess v. Advanced Cardiovascular Sys., Inc.*, 106 F.3d 976, 980 (Fed. Cir. 1997)). However, a party may rebut this presumption by proving, through clear and convincing evidence, that he or she is entitled to be named as an inventor and, thus, should have been included on the patent. *See Eli Lilly & Co. v. Aradigm Corp.*, 376 F.3d 1352, 1358 (Fed. Cir. 2004); *Checkpoint Systems, Inc. v. All–Tag Sec. S.A.*, 412 F.3d 1331, 1338 (Fed. Cir. 2005). Thus, ArcherDX bears the burden of proving, by clear and convincing evidence, that the Asserted Patents name improper inventors. In support of its inventorship challenge, ArcherDX's expert, Dr. Cooper, analyzes deposition testimony from various purported inventors to ascertain whether a given individual worked on "techniques for avoiding primer dimers in multiplex PCR." *See* D.I. 443, Ex. 11 ¶¶ 937-39. In direct response to Dr. Cooper's opinions, both Dr. Spellman and Mr. Stoll offer opinions relating to inventorship that are properly characterized as rebuttal testimony. That is, Dr. Spellman—based on his expertise in the field of genomic technologies for the analysis of cell-free DNA ("cfDNA"), *see* D.I. 443, Ex. 16 ¶¶ 1-8—criticizes Dr. Cooper's characterization of the Asserted Patents' cfDNA disclosures

and his analysis of selected deposition testimony rather than an analysis of the asserted claims. *Id.* ¶¶ 223-46. Similarly, Mr. Stoll, who has nearly thirty years of experience at the USPTO, *see id.*, Ex. 17 ¶¶ 5-18, refutes Dr. Cooper's conclusions on inventorship through detailed explanations "related to the ins and outs of internal PTO practices and procedures." *Id.* ¶¶ 42-45, 147-56; *see W.L. Gore & Assoc., Inc. v. C.R. Bard, Inc.*, C.A. No. 11-515-LPS, 2015 WL 12815314, at *3 (D. Del. Nov. 20, 2015); *see also Brigham & Women's Hosp. Inc. v. Teva Pharm. USA, Inc.*, C.A. No. 08-464, 2010 WL 3907490, at *1- 2 (D. Del. Sept. 21, 2010) (explaining that "[t]he law permits experts in patent cases to offer [] testimony" regarding "the practices and procedures of the PTO"). Mr. Stoll's opinions also include an explanation that the request to correct inventorship and signed statements by the named inventors complied with all of the relevant regulations and guidelines of the USPTO and were properly accepted as such, as is evidenced by the USPTO Director's issuance of the certificates of correction to inventorship. *See* D.I. 443, Ex. 17 ¶¶ 152-156.

Accordingly, the Court finds that both Dr. Spellman and Mr. Stoll offer proper rebuttal testimony to Dr. Cooper's inventorship analysis which would ultimately assist the trier of fact. *See Schneider*, 320 F.3d at 404-05. As such, the Court denies ArcherDX's *Daubert* motion seeking to exclude Dr. Spellman and Mr. Stoll from offering rebuttal testimony related to inventorship of the Asserted Patents.

iv. ArcherDX's *Daubert* Motion to Exclude Mr. Wojcik's Safe Harbor Opinions

ArcherDX seeks to exclude Mr. Wojcik's opinions related to whether 35 U.S.C. § 271(e)(1) (the "Safe Harbor Provision") covers certain uses of ArcherDX's products, arguing that Mr. Wojcik's opinions are "wholesale devoid of reliability" and incorrect as a matter of law. D.I. 430 at 40-45. Specifically, ArcherDX contends that, because Mr. Wojcik admitted that he had no experience with the Safe Harbor Provision, any opinion would be nothing more than a subjective

belief. *Id.* at 41 (citing *Willis v. Besam Automated Entrance Sys.*, C.A. No. 04-0913, 2005 U.S. Dist. LEXIS 26466, at *14 (E.D. Pa. Nov. 3, 2005)). Furthermore, in light of Mr. Wojcik's purported ignorance of the Safe Harbor Provision, ArcherDX argues that "many of his opinions are incorrect as a matter of law" and must be excluded. *Id.* Finally, ArcherDX asserts that "Mr. Wojcik's opinions should also be excluded because they are based on a misunderstanding and/or mischaracterization of the factual evidence." *Id.* at 44. For the reasons stated below, the Court denies ArcherDX's *Daubert* to exclude Mr. Wojcik's opinions related to the Safe Harbor Provision.

The Safe Harbor Provision exempts infringement if the infringing act was performed "solely for uses reasonably related to the development and submission of information" to the FDA. *See* 35 U.S.C. § 271(e)(1); *Amgen Inc. v. Hospira, Inc.*, 944 F.3d 1327, 1339 (Fed. Cir. 2019). In *Amgen Inc. v. Hospira, Inc.*, the Federal Circuit reaffirmed that the Safe Harbor Provision does not apply to all pre-approval activity:

> To the extent Hospira suggests the Safe Harbor exemption always applies in the pre-approval context . . ., we have previously rejected that reading of the statute. It is incorrect to 'assume[] that all otherwise infringing activities are exempt if conducted during the period before the regulatory approval is granted.'

See Amgen, 944 F.3d at 1339 n.2 (quoting *Amgen Inc. v. Int'l Trade Comm'n*, 565 F.3d 846, 852 (Fed. Cir. 2009)). Importantly, "[w]hether a 'use' falls within the Safe Harbor Exemption is a fact-based issue." *See Chang v. Biosucess Biotech Co.*, 76 F. Supp. 3d 1022, 1036 (C.D. Cal. 2014) (citing *Integra Lifesciences, Ltd. v. Merck KGaA*, 496 F.3d 1334, 1347 (Fed. Cir. 2007)).

Here, Mr. Wojcik properly examined each act of infringement and opined on whether the uses were "for uses reasonably related to submitting information to the FDA," *see, e.g.*, D.I. 443, Ex. 12 ¶¶ 70-114; *Amgen*, 944 F.3d at 1339, including whether, from a regulatory perspective, certain activities were required for an FDA submission. *See, e.g.*, D.I. 443, Ex. 12 ¶¶ 83-91 ("Such

retrospective studies are not type of uses that are reasonably related to FDA approval."). While ArcherDX takes issue with Mr. Wojcik's reliance on Natera's counsel for guidance on the law of the Safe Harbor Provision, *see* D.I. 430 at 41, ArcherDX ignores that expert witnesses are prohibited from rendering legal opinions because "it would usurp the District Court's pivotal role in explaining the law to the jury." *See Shire Viropharma Inc. v. CSL Behring LLC*, C.A. No. 17-414-MSG, 2021 WL 1227097, at *14 (D. Del. Mar. 31, 2021) (citing *Berckeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 217 (3d Cir. 2006)).

Further, contrary to ArcherDX's assertion, Mr. Wojcik's opinions are not based on a "fundamentally flawed foundation" of the law governing the Safe Harbor Provision. *See* D.I. 430 at 43. Rather, ArcherDX selectively quotes from Mr. Wojcik's report and deposition testimony in an effort to paint Mr. Wojcik's opinions as unreliable and contrary to the law. *Compare* D.I. 430 at 42 (citing D.I. 434, Ex. V at Tr. 75:8-76:4, 87:15-20, 91:21-93:18), *with* D.I. 443, Ex. 5 at Tr. 74:14-19, 87:22-88:2, 92:20-21; *compare* D.I. 430 at 42 (citing D.I. 434, Ex. V at Tr. 62:16-71:15), *with* D.I. 443, Ex. 5 at Tr. 68:4-16, 69:6-13; *compare* D.I. 430 at 42 (citing D.I. 434, Ex. V at Tr. 57:24-58:24; 71:17-72:21; 94:3-105:23; 108:17-111:11; 111:15-25; 116:5-10), *with* D.I. 443, Ex. 5 at Tr. 94:3-25; *see also* D.I. 442 at 43. However, when viewed in their full context, the Court cannot conclude that Mr. Wojcik's opinions related to the Safe Harbor Provision are based on a fundamental misunderstanding of the law. *See* D.I. 442 at 42-43. Moreover, the Court finds that Mr. Wojcik's application of the Safe Harbor Provision to certain uses of ArcherDX's products does not "erroneously exclude[] several types of product use that, on their face, are undeniably protected by the Safe Harbor [Provision]." *See id.* at 43-44. Indeed, Mr. Wojcik's opinions properly consider the factual context surrounding each category of activities prior to determining whether the Safe Harbor Provision applies. *See, e.g.*, D.I. 443, Ex. 12 ¶¶ 38-45, 68-79, 84, 114;

see Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 200 (2005) ("Each of the accused activities must be evaluated separately to determine whether the exemption applies."). Nor does ArcherDX's disagreement as to Mr. Wojcik's ***application*** of the factual evidence to the Safe Harbor Provision render his opinions unreliable. *See* D.I. 430 at 44-45. Because ArcherDX disputes the factual predicate underlying Mr. Wojcik's opinion, ArcherDX's objections go to the weight, not the admissibility, of Mr. Wojcik's opinion. *See f'real Foods, LLC v. Hamilton Beach Brands, Inc.*, C.A. No. 16-41-CFC, 2019 WL 1578259, at *1 (D. Del. Apr. 11, 2019). ArcherDX is "free to challenge those opinions on cross-examination of [Mr. Wojcik] at trial." *Id.* (citing Daubert, 509 U.S. at 596).

For the reasons stated above, the Court denies ArcherDX's *Daubert* motion to exclude Mr. Wojcik's opinions related to the Safe Harbor Provision.

v. ArcherDX's *Daubert* Motion to Exclude Dr. Sullivan's Opinions Regarding the BD-ArcherDX License Agreement

ArcherDX seeks to exclude Dr. Sullivan's royalty opinions based on the Becton-Dickinson license agreement (the "BD-ArcherDX License") because these opinions are allegedly based on a non-comparable license. D.I. 430 at 46. ArcherDX also seeks to exclude Dr. Sullivan's opinion on the basis that he fails to properly apportion for the incremental benefit of the use of (1) prior art molecular barcodes techniques, and (2) personalization of ArcherDX's products. *Id.* at 47-49. For the following reasons, the Court denies ArcherDX's *Daubert* to exclude Dr. Sullivan's royalty opinions based on the BD-ArcherDX License.

At the outset, the Court disagrees with ArcherDX's claim that Dr. Sullivan's reliance on the BD-ArcherDX License is improper because Dr. Quackenbush testified that the patents related to that agreement "have limited comparability with the Asserted Patents." D.I. 430 at 46. Although true that Dr. Quackenbush opined that there is "limited comparability" between the

patents covered in the BD-ArcherDX License and the Asserted Patents, Dr. Quackenbush did not testify that there is ***no*** comparability. *See* D.I. 443, Ex. 19 ¶¶ 58-59. Rather, as Dr. Sullivan explains, Dr. Quackenbush's limited comparability opinion rests on the technologies having a difference in scope even though both sets of patents relate to the library preparation process, not that the technologies are unrelated. *Id.* Indeed, Dr. Sullivan understands from Dr. Quackenbush that "the technology in the BD patents is sufficiently related to the technology in the patents-in-suit such that they can be compared." *Id.* Accordingly, Dr. Sullivan properly assessed whether the BD-ArcherDX License involves comparable technology, is economically comparable, and arises under comparable circumstances as the hypothetical negotiation. *See* D.I. 443, Ex. 14 ¶¶ 382-421; *see, e.g.*, *Bio-Rad Labs., Inc., v. 10X Genomics Inc.*, 967 F. 3d 1353, 1372-73 (Fed. Cir. 2020) (assessing a license's comparability requires considering whether the license involves "comparable technology, is economically comparable, and arises under comparable circumstances as the hypothetical negotiation"); *Commonwealth Sci. & Indus. Rsch. Org. v. Cisco Sys., Inc.*, 809 F.3d 1295, 1298, 1303 (Fed. Cir. 2015) (asserted patents "properly valued" with comparable licenses and then adjusted for differences and economics). Any disagreements as to the purported differences of the licenses "are factual issues best addressed by cross examination and not by exclusion." *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1333 (Fed. Cir. 2012).

Furthermore, the Court finds that Dr. Sullivan's methodology properly accounts for the incremental value of the patented use of molecular barcodes. *See* D.I. 430 at 47. Notably, when a patent claims a novel combination of conventional elements, "the question is how much new value is created by the novel combination, beyond the value conferred by the conventional elements alone." *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1339 (Fed. Cir. 2015). Here,

Dr. Sullivan properly addressed this question by attributing the benefits of the claimed novel use of molecular barcodes to the Asserted Patents. *See* D.I. 443, Ex. 1 ¶¶ 382-421. That is, Dr. Sullivan analyzed several factors, including: (1) the limited roles of molecular barcodes as covered in the Asserted Patents; (2) ArcherDX's proposal, as a non-infringing alternative, to drop the use of molecular barcodes; (3) ArcherDX's expert report submitted in another litigation asserting that "molecular barcodes do not play a critical role in the accused products," and (4) Natera's history of not licensing its patents. *Id.* ¶¶ 349, 382-421. Dr. Sullivan also properly relied on Dr. Quackenbush's opinions to establish the relatively low value of molecular barcodes concerning product pricing, *see Apple, Inc. v. Motorola, Inc.*, 757 F.3d 1286, 1321 (Fed. Cir. 2014) ("Consistent with [Federal Evidence] Rule 703, patent damages experts often rely on technical expertise outside of their field when evaluating design around options or valuing the importance of the specific, infringing features in a complex device."), thereby illustrating that the benefits of the Asserted Patents to the ArcherDX's products outweighs those of the patents in the BD-ArcherDX License. *Id.* Any disagreement as to Dr. Sullivan's methodology—which scales the royalty rate for a less valuable group of patents to reflect the appropriate royalty rate for the separate and more valuable group of Asserted Patents, D.I. 443, Ex. 14 ¶¶ 382-421, 503-507—is more properly addressed through cross-examination. *See Daubert*, 509 U.S. at 596.

Finally, the Court disagrees with ArcherDX's contention that Dr. Sullivan includes benefits from personalization of the accused products in his royalty rate determination. *See* D.I. 430 at 48-49. The evidence Dr. Sullivan relies upon does not indicate that personalization, either within ArcherDX's accused products or as a broad technology, improves the limit of detection. *See* D.I. 443, Ex. 14 ¶ 401. Instead, Dr. Sullivan discusses that the "Personalized Competition" data point refers to the limit of detection of a specific product, Natera's Signatera, with no indication that

personalization contributes to, or is responsible for, its limit of detection. *Id.* ¶¶ 401-03. Dr. Sullivan ultimately concludes that it is the accused AMP process itself that drives the limit of detection value and improvement—not personalization. *See, e.g.*, *id.* ¶¶ 95-117, 382-421; *see also id.*, Ex. 19 ¶ 73. Like ArcherDX's other disagreements with Dr. Sullivan's opinions, ArcherDX is "free to challenge [these] opinions on cross-examination of Dr. [Sullivan] at trial." *See f'real Foods*, 2019 WL 1578259, at *1 (citing *Daubert*, 509 U.S. at 596).

Accordingly, the Court denies ArcherDX's *Daubert* motion to exclude Dr. Sullivan's royalty opinions based on the BD-ArcherDX License.

b. Natera's *Daubert* Motions

i. Natera's *Daubert* Motion to Exclude Mr. Kelley's Opinion on Prosecution Laches

Natera seeks to exclude Mr. Kelley's opinion on prosecution laches because "it has nothing to do with PTO practices and procedures," and "is the product of unreliable principles and methods." D.I. 432 at 37. The Court agrees.

Courts in this District have recognized that "patent law experts are frequently permitted to testify about matters such as general practices and procedures employed by the PTO in examining . . . patents." *Sonos, Inc. v. D & M Holdings, Inc.*, 297 F. Supp. 3d 501, 511 (D. Del. 2017). Here, while Mr. Kelley calls on his eighteen years of experience working for the USPTO to detail the extensive prosecution history of the cfDNA Patents and related patent applications, *see* D.I. 433, Ex. 24 ¶¶ 3-4, Mr. Kelley fails to tether his opinions to the PTO's practices and procedures. In other words, Mr. Kelley simply interprets the facts of the case through ArcherDX's eyes and applies them to the legal framework for prosecution laches. *See Purewick Corp. v. Sage Prods., LLC*, C.A. No. 19-1508-MN, 2021 WL 2593338, at *1 (D. Del. June 24, 2021)) ("[L]egal testimony on substantive issues of patent law or Patent Office procedure improperly substitutes

the judgment of the expert for that of the Court."). However, "testimony of patent law experts that add a party's particular spin to disclosures in the prosecution or opine on how the Patent Office would have acted in certain circumstances have regularly been excluded." *Id.* (citing *Syngenta Seeds, Inc. v. Monsanto Co.*, C.A. No. 02-1331-SLR, 2004 WL 2106583, at *2 (D. Del. Sept. 8, 2004); *Ondeo Nalco Co. v. Eka Chem., Inc.*, C.A. No. 01-537-SLR, 2003 WL 1524658, at *3 (D. Del. Mar. 21, 2003)). This is particularly evident where Mr. Kelley offers opinions as to why Natera presented the Asserted Patent claims in 2019 rather than in 2011, why he believes this was unusual, and why Natera's purported delay was unreasonable and unexplained. *See* D.I. 433, Ex. 24 ¶¶ 111-25. In addition to being speculative, these opinions improperly delve into Natera's purported state of mind and motive for the alleged delay. *See, e.g., AstraZeneca UK Ltd. v. Watson Labs., Inc. (NV)*, C.A. No. 10-915-LPS, 2012 WL 6043266, at *2 (D. Del. Nov. 14, 2012) (noting that expert witnesses are not allowed to testify as to "intent, motive, or state of mind, or evidence by which such state of mind may be inferred"). Mr. Kelley's opinions related to prosecution laches effectively reads like an attorney's argument or brief, which is improper expert testimony and, thus, must be excluded. *See Brigham & Women's Hosp. Inc.*, C.A. No. 08-464, 2010 WL 3907490, at *2 (D. Del. Sept. 21, 2010) ("The law of this district is clear that experts in patent cases may not opine on whether a party engaged in inequitable conduct, discuss whether certain information was material to a pending patent application, or otherwise provide legal conclusions on substantive issues of patent law." (internal quotation marks and citation omitted)).

Accordingly, the Court grants Natera's *Daubert* motion to exclude Mr. Kelley's opinion on prosecution laches.[4]

ii. Natera's *Daubert* Motion to Exclude Dr. Cooper's Inventorship Opinions

Natera seeks to exclude Dr. Cooper from testifying as to the validity of the cfDNA Patents based on improper inventorship because Dr. Cooper does not undertake a proper inventorship analysis and usurps the role of the jury. D.I. 432 at 40. The Court disagrees and will, therefore, deny Natera's *Daubert* motion.

Here, Dr. Cooper relies on what Natera characterizes as the alleged invention covered by the asserted claims: a technique for avoiding unwanted side products in multiplex PCR. *See* D.I. 443, Ex. 11 ¶¶ 937-39; *see also* D.I. 353, Ex. 14 ¶¶ 49-58; D.I. 434, Ex. L at Tr. 150:4-13, 150:25-151:5; *id.*, Ex. A ¶¶ 201, 206-07. Dr. Cooper then explains how this issue is connected to claim 1 of each of the Asserted Patents, *see* D.I. 443, Ex. 11 ¶ 202, and identifies other specific features in the claims, in particular the requirement for "nested PCR." *Id.* at ¶ 203. Furthermore, Dr. Cooper analyzes the technical work each inventor was engaged in and whether, based on this work, the inventors could have made a contribution consistent with being named as an inventor. *See* D.I. 443, Ex. 11 ¶¶ 940-77. On its face, nothing about Dr. Cooper's analysis renders it an inappropriate inventorship analysis. Moreover, while Natera takes issue with Dr. Cooper predominately relying on inventor testimony, *see* D.I. 432 at 41, Natera ignores that ArcherDX also relies on other

[4] To be clear, this ruling does not preclude Mr. Kelley from walking through the prosecution history of the cfDNA Patents and those related patent applications, to the extent the testimony is rooted in facts and is not providing legal opinions. *See, e.g.*, D.I. 433, Ex. 24 ¶¶ 22-31, 36-37, 40-42, 44-46, 62-65, 71-83, 85; *see Purewick*, 2021 WL 2593338, at *1 ("It doesn't seem like an efficient use of limited trial time to use an expert for that given that the applications can be offered into evidence. That being said, if [ArcherDX] wants to use its trial time for that, it may."). However, Mr. Kelley is not permitted to testify as to ArcherDX's prosecution laches defense.

evidence which purportedly corroborates Dr. Cooper's improper inventorship analysis. *See, e.g.*, D.I. 434 at Ex. Y; Ex. Z; Ex. AA; Ex. UU; *see also* D.I. 441 at Section II.B.2.

Finally, the Court disagrees that Dr. Cooper's testimony would be "unhelpful to the trier of fact" because it is merely his interpretation of "cherry-picked testimonies of Natera's scientists." D.I. 432 at 42. There is no dispute that this case involves highly technical matters with complex technical testimony from experts. Dr. Cooper's testimony would certainly aid the trier of fact in interpreting this technical detail. *See Schneider*, 320 F.3d at 404-05. Natera's concern that Dr. Cooper's testimony "provide[s] a self-serving spin on witness testimony" can be adequately addressed through cross-examination and the presentation of contrary evidence. *See Daubert*, 509 U.S. at 596.

Accordingly, the Court denies Natera's *Daubert* motion to exclude Dr. Cooper from testifying as to the validity of the cfDNA Patents based on improper inventorship.

III. CONCLUSION

For the foregoing reasons, the Court denies Defendants' motion to exclude certain expert testimony. Further, the Court grants-in-part and denies-in-part Plaintiff's motion to exclude certain expert testimony.

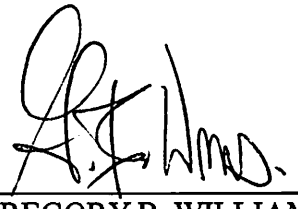
* * *

WHEREFORE, at Wilmington this 2nd day of May, 2023, **IT IS HEREBY ORDERED** that:

1. Defendants' Motion to Exclude Certain Expert Testimony and Opinions of Dr. Paul T. Spellman, Dr. John Quackenbush, Mr. Robert Stoll, Mr. Jerzy Wojcik, and Dr. Ryan Sullivan (D.I. 428) is denied as described herein; and

2. Natera's Motion to Exclude Certain Expert Testimony and Opinions of Mr. Nathan K. Kelley and Dr. Gregory Cooper (D.I. 431) is granted-in-part and denied-in-part as described herein.

3. Because the Memorandum Order is filed under seal, the parties shall meet and confer and submit a joint proposed redacted version no later than seven (7) days after the date of this Memorandum Order. In the absence of a timely request compliant with applicable standards, the Court will unseal the entire Order.



GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE