

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BAUSCH & LOMB INCORPORATED and
PF CONSUMER HEALTHCARE 1 LLC,

Plaintiffs,

v.

SBH HOLDINGS LLC,

Defendant.

Civil Action No. 20-1463-GBW

MEMORANDUM ORDER

On September 3, 2024, Plaintiffs¹ filed a Motion to Exclude Testimony of Dr. Matthew Kaser for Lack of Qualifications and Applying Incorrect Law (“Motion” or “Motion to Exclude”). D.I. 158. In their Opening Brief in Support of their Motion to Exclude, Plaintiffs made three arguments for exclusion. D.I. 165 at 32-42. Magistrate Judge Burke agreed with Plaintiffs’ first argument and therefore, on February 24, 2025, entered a Memorandum Order (“Memorandum Order”) granting Plaintiffs’ Motion to Exclude and not resolving the remaining arguments. D.I. 259. Pending before the Court is Defendant’s Objection (“Objection”) (D.I. 266) to the Memorandum Order, to which Plaintiffs have responded (D.I. 273). For the following reasons, the Court overrules Defendant’s Objection. The Court also considers in the first instance the remaining arguments in Plaintiffs’ Motion to Exclude.

¹ The Plaintiffs are Bausch & Lomb Incorporated and PF Consumer Healthcare 1 LLC (“Baush” or “Plaintiffs”). The Defendant is SBH Holdings LLC (“SBH” or “Defendant”).

I. BACKGROUND

The Court writes for the benefit of the parties and, as such, only briefly sets forth the facts and procedural history necessary for the discussion herein.

On February 20, 2024, Plaintiffs submitted the Opening Expert Report of Elizabeth J. Johnson. D.I. 166-1 Ex. 4. Therein, Dr. Johnson posited:

A POSA at the time of the inventions would typically have been a medical doctor, doctor of optometry (“O.D.”) or a person with a Masters or a Ph.D. degree in nutritional science, chemistry, biology, biochemistry, or a related discipline and a few years of practical experience in the nutritional supplement area, including an understanding of formulations that could be considered to prevent or treat visual acuity loss in patients diagnosed with AMD. Alternatively, a POSA at the time could have been a person with a Bachelor’s degree with a greater number of years of experience. The POSA would have, or would have access to, general information regarding AMD, the convenience and needs of patients who suffer from AMD, and background information.

D.I. 166-1 Ex. 4 ¶ 29.

On April 5, 2024, Defendant submitted the Rebuttal Expert Report of Matthew Kaser, D.Phil. to the Opening Expert Reports (“Dr. Kaser’s Opinion”). D.I. 166-1 Ex. 6.² Therein, Dr. Kaser similarly posited:

A POSA [i.e., a person of ordinary skill in the art] at the time of the inventions would be: a medical doctor, doctor of optometry (“O.D.”) or a person with a Masters or a Ph.D. degree in nutritional science, chemistry, biology, biochemistry, or a related discipline and experience in the nutritional supplement area, including an understanding of formulations that could be considered to prevent or treat visual acuity loss in patients diagnosed with AMD. Alternatively, a POSA at the time could have been a person with a Bachelor’s degree with a greater number of years of experience. The POSA would have, or would have access to, general information regarding AMD, the convenience and needs of patients who suffer from AMD, and background information.

D.I. 166-1 Ex. 6 ¶ 19.

² The title of Dr. Kaser’s Opinion is copied here verbatim.

As described above, Plaintiffs filed their Motion to Exclude on September 3, 2024. D.I. 158. In their first argument for exclusion, Plaintiffs correctly observe that the Federal Circuit does not permit experts to opine from the perspective of a person of ordinary skill in the art (“POSA” or “POSITA”) unless they are, in fact, a POSA. D.I. 165 at 33. Plaintiffs then assert, at least including on the basis of the parties’ experts’ proposed definitions of a POSA, that a POSA in this action, regardless of their level of education, must have experience in the nutritional supplement area. D.I. 165 at 34-38. Plaintiffs contend that Dr. Kaser does not have any experience in the nutritional supplement area and, consequently, does not constitute a POSA. D.I. 165 at 34-38. Plaintiffs therefore conclude that the Court should exclude all opinion and testimony from Dr. Kaser offered from the perspective of POSA. D.I. 165 at 38.

In its opposition brief, Defendant contends that “a person with a Masters or a Ph.D. degree in nutritional science, chemistry, biology, biochemistry” (like Dr. Kaser) constitutes a POSA regardless of whether that person has experience in the nutritional supplement area. D.I. 207 at 47-50. Defendants therefore conclude that the Court should not exclude Dr. Kaser’s Opinion and testimony offered from the perspective of POSA. D.I. 207 at 50.

On February 24, 2025, Magistrate Judge Burke entered the Memorandum Order agreeing with Plaintiffs’ first argument and excluding the Opinion and all corresponding testimony from Dr. Kaser offered from the perspective of POSA (which included essentially the entirety of Dr. Kaser’s Opinion). D.I. 259. On March 10, 2025, Defendant lodged its Objection to the Memorandum Order (D.I. 266) and, on March 24, 2025, Plaintiffs responded to Defendant’s Objection (D.I. 273). As to the Objection, the parties primarily dispute whether Dr. Kaser constitutes a POSA. As to the remaining arguments in Plaintiffs’ Motion to Exclude, the parties

dispute whether the Court should exclude opinion and testimony from Dr. Kaser regarding Dr. Kaser's theories on prosecution history estoppel and the doctrine of equivalents.

II. LEGAL STANDARD

28 U.S.C. § 636(b)(1)(A) provides that a “district court may refer a nondispositive motion to a magistrate judge ‘to hear and determine.’” *EEOC v. City of Long Branch*, 866 F.3d 93, 99 (3d Cir. 2017) (quoting 28 U.S.C. § 636(b)(1)(A)). Nondispositive motions include *Daubert* motions, like the underlying motion here. *Withrow v. Spears*, 967 F. Supp. 2d 982, 987 n.1 (D. Del. 2013) (“Our Court has treated *Daubert* motions as non-dispositive motions, which may be resolved by the Court pursuant to 28 U.S.C. § 636(b)(1)(A) and D. Del. LR 72.1(a)(2).”).

“Following a magistrate judge’s issuance of an order on a nondispositive matter, the parties may serve and file objections to the order within 14 days of being served with a copy of the order.” *Id.* (citing Fed. R. Civ. P. 72(a)). “If a party objects to a magistrate judge’s order regarding a nondispositive matter, the district court ‘must consider timely objections and modify or set aside any part of the order that is clearly erroneous or is contrary to law.’” *Id.* (quoting Fed. R. Civ. P. 72(a)); *see* 28 U.S.C. § 636(b)(1)(A) (providing that the district judge “may reconsider any pretrial matter” that has been designated to the magistrate judge under the same section “where it has been shown that the magistrate judge’s order is clearly erroneous or contrary to law”). “This standard requires the District Court to review findings of fact for clear error and to review matters of law *de novo*.” *EEOC*, 866 F.3d 93, 99 (quoting *Haines v. Liggett Grp. Inc.*, 975 F.2d 81, 91 (3d Cir. 1992)).

“There are also decisions that involve the exercise of discretion, and discretionary decisions are reviewed for abuse of discretion.” *Avaya Inc. v. SNMP Research Int’l Inc.*, No. 12-cv-191-RGA, 2016 U.S. Dist. LEXIS 10020, at *3 (D. Del. Jan. 28, 2016). “This deferential standard of review is ‘especially appropriate where the Magistrate Judge has managed this case from the outset

and developed a thorough knowledge of the proceedings.” *Id.* (quoting *Cooper Hospital/University Med. Ctr. v. Sullivan*, 183 F.R.D. 119, 127 (D.N.J. 1998)).

However, a “magistrate judge’s decision regarding a motion to exclude expert opinions,” like the one at issue here, “is subject to a ‘clearly erroneous and contrary to law’ standard of review.” *360Heros, Inc. v. GoPro, Inc.*, No. 17-cv-1302-MFK-CJB, 2022 U.S. Dist. LEXIS 96453, at *18 (D. Del. May 31, 2022).

III. DISCUSSION

Judge Burke’s Memorandum Order was neither clearly erroneous nor contrary to law for the reasons discussed herein and, as such, the Court overrules Defendant’s Objection. As described above, the Court also considers in the first instance the remaining arguments raised in Plaintiffs’ Motion to Exclude. Specifically, this Discussion includes the following Sections: (A) Judge Burke’s Memorandum Order was neither clearly erroneous nor contrary to law; and (B) even if the Court sustained Defendant’s Objection to the Memorandum Order, the Court would still exclude much of Dr. Kaser’s Opinion on other grounds asserted by Plaintiffs in their Motion to Exclude.

A. Judge Burke’s Memorandum Order Was Neither Clearly Erroneous Nor Contrary to Law

“Federal Rule of Evidence 702 governs the admissibility of qualified expert testimony, providing that an expert witness may testify 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.’” *Integra Lifesciences Corp. v. HyperBranch Med. Tech., Inc.*, No. 15-cv-819-LPS-CJB, 2018 WL 1785033, at *1-2 (D. Del. Apr. 4, 2018) (quoting Fed. R. Evid. 702).

“Rule 702’s requirements have been examined in detail by the Supreme Court of the United States in *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), and have been said to embody ‘three distinct substantive restrictions on the admission of expert testimony: qualifications, reliability, and fit.’” *Id.* (quoting *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000)).

Regarding the first substantive restriction (i.e., an expert’s qualifications), “Rule 702 requires the witness to have ‘specialized knowledge’ regarding the area of testimony.” *Elcock*, 233 F.3d 734, 741 (quoting *Waldorf v. Shuta*, 142 F.3d 601, 625 (3d Cir.1998)). “The basis of this specialized knowledge ‘can be practical experience as well as academic training and credentials.’” *Id.* (quoting *Waldorf*, 142 F.3d 601, 625). The Third Circuit has “interpreted the specialized knowledge requirement liberally, and [has] stated that this policy of liberal admissibility of expert testimony ‘extends to the substantive as well as the formal qualification of experts.’” *Id.* (quoting *Waldorf*, 142 F.3d 601, 625). “However, at a minimum, a proffered expert witness must possess skill or knowledge greater than the average layman.” *Id.* (cleaned up).

In patent cases, it “is true that an expert need not be a person of ordinary skill for the expert’s testimony to be admissible.” *Heron Therapeutics, Inc. v. Fresenius Kabi USA, LLC*, No. 22-cv-985-WCB, 2024 U.S. Dist. LEXIS 87435, at *9 (D. Del. May 15, 2024). “However, ‘[t]o offer expert testimony from the perspective of a skilled artisan in a patent case—like for claim construction, validity, or infringement—a witness must at least have ordinary skill in the art.’” *Id.* (quoting *Kyocera Senco Indus. Tools Inc. v. Int’l Trade Comm’n*, 22 F.4th 1369, 1376-77 (Fed. Cir. 2022)); *Osseo Imaging, LLC v. Planmeca USA Inc.*, 116 F.4th 1335, 1340 (Fed. Cir. 2024) (same). “Without that skill, the witness’ opinions are neither relevant nor reliable.” *Kyocera Senco Indus. Tools Inc.*, 22 F.4th 1369, 1377. “The opinions would not be based on any specialized knowledge, training, or experience that would be helpful to the fact-finder.” *Id.*

In this action, Dr. Kaser has offered expert testimony from the perspective of a POSA on the issue of infringement. Judge Burke correctly concluded that a POSA in this action must have “experience in the nutritional supplement area, including an understanding of formulations that could be considered to prevent or treat visual acuity loss in patients diagnosed with AMD.” D.I. 259 at 6. As described in Judge Burke’s Memorandum Order, there are at least three key reasons undergirding this conclusion.

First, this conclusion “better comports with a common sense understanding of what it means to be a person of skill in a relevant art.” D.I. 259 at 8. “To that end, both parties’ technical experts have explained that the asserted patents ‘relate to the art of nutritional supplement compositions for eye health and their methods of use.’” D.I. 259 at 8 (citations omitted). “Thus, it makes logical sense that to qualify as a person of ordinary skill in the art at the time of the invention, a person would need to have some familiarity with that art—i.e., some experience in the nutritional supplement area, including an understanding of formulations used to prevent or treat visual acuity loss.” D.I. 259 at 8 (citations omitted).

“Second, the actual wording of the POSITA definition [from Dr. Kaser] aligns with” Judge Burke’s conclusion. D.I. 259 at 8. “For example, [his] definition states that as an alternative to someone with an advanced degree, ‘a POS[IT]A at the time could have been a person with a Bachelor’s degree *with a greater number of years of experience.*’” D.I. 259 at 8 (citations omitted). “This additional language clearly conveys that the POSITA definition includes two types of requirements—a degree-related prong and an experience-related prong—and that it means to utilize a type of sliding scale approach as to how one can satisfy each of those prongs.” D.I. 259 at 8. “More specifically, the definition articulates that a POSITA with an advanced degree (i.e., a medical doctor, or an O.D., or a person with a Master’s or Ph.D. in certain fields) is also required

to have at least some number of years of experience in the nutritional supplement area.” D.I. 259 at 8-9. “But the definition goes on to explain that, alternatively, if the person has a lesser degree than the types of degrees referenced above (i.e., a Bachelor’s degree), then in order to qualify as a POSITA, the person will need to have a greater number of years of relevant experience in the field.” D.I. 259 at 9 (citations omitted).

“Third, Dr. Kaser’s testimony during his deposition” further supports the propriety of Judge Burke’s conclusion. D.I. 259 at 9. “During the deposition, Dr. Kaser was questioned about the experience prong of the POSITA definition.” D.I. 259 at 9. “In response, he did not take the position that a POSITA would not need to have any experience in the nutritional supplement field—so long as he or she was a medical doctor or doctor of optometry, or had an advanced degree in nutritional science, chemistry, biology or biochemistry.” D.I. 259 at 9 (citations omitted). “Instead, when asked ‘[w]hat type of experience in the nutritional supplement area would your [POSITA] possess?’ Dr. Kaser responded that he would expect the POSITA to have obtained experience through ‘a research program [in nutrition] at a university or clinically related’ program.” D.I. 259 at 9.

Since Dr. Kaser does not have the requisite experience (*see* D.I. 259 at 9-10),³ Dr. Kaser is not a POSA and, therefore, cannot testify from the perspective of a POSA on infringement. Thus, Judge Burke was correct to exclude Dr. Kaser’s Opinion and any corresponding testimony.

³ Defendant does not object to Judge Burke’s conclusion that Dr. Kaser lacks the requisite experience; rather Defendant objects to Judge Burke’s conclusion that such experience is required. *See, e.g.*, D.I. 266 at 2 (“Dr. Kaser’s understanding was that he, with a PhD in biochemistry, qualified as a POSITA.”), 3 (“Thus, Dr. Kaser’s PhD in biochemistry is sufficient to qualify him regardless of whether he qualifies under Judge Burke’s chosen definition of a POSITA.”). Nonetheless, the Court notes that Judge Burke is correct that Dr. Kaser lacks the requisite experience, as there is no evidence in the record to even suggest that Dr. Kaser had the requisite experience at either the time of the invention or by the time he provided his Opinion. As the Memorandum Order reflects, “Plaintiffs’ briefing reveals that the extent of Dr. Kaser’s experience

Defendant's arguments in its Objection are unavailing. *First*, Defendant contends that when "there are disputes over the qualification of an expert that has credentials that are relevant to the subject matter at issue, caselaw holds that an expert can be qualified." D.I. 266 at 3. However, that an expert *can* be qualified does not mean that the expert *must* be qualified. *Second*, Defendant contends that the jury should "evaluate" whether Dr. Kaser constitutes a POSA. D.I. 266 at 3; D.I. 266 at 4 ("At the very least there is a triable issue of fact as to what constitutes a POSITA."). However, the Federal Circuit and this Court routinely determine the level of ordinary skill in the art as part of the Court's gatekeeping function when in dispute. *See, e.g., Kyocera Senco Indus. Tools Inc.*, 22 F.4th 1369, 1377-78 (employing the definition of the "level of ordinary skill in the art" that was "adopted" by the lower court); *Astellas Pharma Inc. v. Lupin Ltd. Zydus Pharms.*

with the nutritional supplement area consists of: (1) '[p]erhaps two to three hours' of an undergraduate college lecture; (2) his mother having AMD and his understanding that she was taking supplements and was undergoing eye injections; and (3) a few months of working with scientists in order to draft a patent application." D.I. 259 at 11 n.8 (citing D.I. 166-1 Ex. 5 at 56-58, 60 (cited in D.I. 165 at 35-36)). "Plaintiffs' briefing also notes that Dr. Kaser could not identify anything that he learned about 'formulations that could be considered to prevent or treat visual acuity loss in patients diagnosed with AMD' beyond what he learned through his work as an expert in this case." D.I. 259 at 11 n.8. (citing D.I. 166-1 Ex. 5 at 61-62 (cited in D.I. 165 at 36)). As Judge Burke correctly observed, "Defendant did not even cite to any of this information in attempting to assert that Dr. Kaser had the requisite qualifications to be a POSITA in this case." D.I. 259 at 11 n.8. Indeed, in the October 17, 2024 Declaration that Dr. Kaser submitted to this Court regarding his purported qualifications as a POSA, which Dr. Kaser submitted *after* submitting his Opinion, Dr. Kaser failed to articulate that he had, at any point, developed any additional experience beyond those items referenced above. D.I. 204. In fact, in that Declaration, Dr. Kaser disclaimed the necessity of any such experience. *See* D.I. 204 at 2 ("I certainly would not agree that a POSA at the time of the invention involved in this lawsuit would have to be a person with experience in formulations aimed at preventing or treating visual acuity loss in patients diagnosed with AMD."). Moreover, as Judge Burke correctly concluded, "none of the above-referenced experience" rises to the level necessary to constitute a POSA in this action, including under the definitions proffered by the parties. *See* D.I. 259 at 11 n.8; *see, e.g., NorthMobileTech LLC v. Simon Prop. Grp., Inc.*, 11-cv-287-WMC, 2012 WL 12996205, at *3 (W.D. Wis. July 9, 2012) (finding that an expert did not qualify as a person of ordinary skill in the art with respect to marketing matters, where the record conveyed that he had "very little or no marketing experience").

USA Inc., No. 23-819-JFB-CJB, 2024 U.S. Dist. LEXIS 196689, at *15 (D. Del. Oct. 30, 2024) (“The Court agrees with Dr. Taft’s proposed definition of the POSA.”).

Third, Defendant contends that “Judge Burke simply favored an interpretation tendered by Plaintiffs without any verification from Plaintiffs’ expert as to what she meant by her definition.” D.I. 266 at 3. This argument is somewhat of a misdirection, however, since the briefing before Judge Burke included the parties’ interpretations of the proffered definitions. Moreover, Plaintiffs’ expert was not required to opine on how she would interpret her definition of a POSA for the purpose of Judge Burke’s ruling.

Fourth, Defendant contends that Judge Burke failed to apply the “rule of the last antecedent.” D.I. 266 at 4. However, Defendant waived this argument by not including it before Judge Burke. *See Financialapps, LLC v. Envestnet, Inc. & Yodlee, Inc.*, No. 19-cv-1337-JLH-CJB, 2024 U.S. Dist. LEXIS 174366, at *7 (D. Del. Sep. 26, 2024) (“[T]he record reflects that Envestnet never made the argument to the Magistrate Judge, and the Court will not consider arguments not previously raised.”). In addition, as Plaintiffs observe, “[t]he ‘rule of antecedent’ is a canon of statutory interpretation, which is not at issue here.” D.I. 273 at 6 (citing *Lockhart v. United States*, 577 U.S. 347, 351-52 (2016)). As Plaintiffs also observe (D.I. 273 at 6), the rule of antecedent is not “absolute” and can be “be overcome by other indicia of meaning.” *Lockhart*, 577 U.S. 347, 352. Here, Judge Burke thoughtfully and analytically considered the other indicia of meaning. D.I. 259.

Fifth, Defendant contends, on the basis of cherry-picked testimony, that Plaintiffs’ expert opined in a previous trial that a POSA does not require experience. D.I. 266 at 4-5. However, Defendant waived this argument as well by likewise not including it before Judge Burke. *See Financialapps, LLC*, 2024 U.S. Dist. LEXIS 174366, at *7 (not considering argument never made

to the Magistrate Judge). In any event, as Plaintiffs observe, the full scope of Plaintiffs' expert's previous testimony confirms that Plaintiffs' expert, in the prior trial, asserted that a POSA would have more than merely the requisite educational degree. D.I. 273 at 7-8.

Sixth, Defendant contends that “an expert is qualified if the witness has specialized expertise to aid the trier of fact” and underscores the liberal admissibility standard under the Third Circuit. D.I. 266 at 5. However, as discussed above, binding precedent on this Court provides that “[t]o offer expert testimony from the perspective of a skilled artisan in a patent case—like for claim construction, validity, or infringement—a witness must at least have ordinary skill in the art.” *Kyocera Senco Indus. Tools Inc.*, 22 F.4th 1369, 1376-77.

Seventh, Defendant takes issue with the *Kyocera* decision, contending that “the district court must apply the law of the Third Circuit” and not the Federal Circuit. D.I. 266 at 6. Defendant quotes *Treehouse Avatar LLC v. Valve Corp.*, 54 F.4th 709, 713 (Fed. Cir. 2022) for the proposition that the “grant or denial of motions to strike an expert report is not an issue unique to patent law” and therefore, the Federal Circuit “review[s] such issues under the law of the applicable regional circuit.” D.I. 266 at 6. While generally correct, when a motion to strike an expert report necessarily includes for resolution an issue that is unique to patent law, that issue that is unique to patent law is reviewed under the law of the Federal Circuit. *See, e.g., Fraunhofer-Gesellschaft Zur Förderung Der Angewandten Forschung E.V. v. Sirius XM Radio Inc.*, 940 F.3d 1372, 1380 (Fed. Cir. 2019) (“Moreover, we have applied Federal Circuit law in several circumstances where the interpretation of a contract is ‘intimately bound up’ with an issue of patent law.”). Here, the issue of whether Dr. Kaser constitutes a person of ordinary skill in the art is uniquely positioned within the province of patent law and, therefore, subject to the law of the Federal Circuit.

Eighth, Defendant contends that whether Dr. Kaser “is skilled in the art . . . is immaterial to his testimony” on “what effect increasing the amount of vitamin C above Plaintiffs’ claimed amount has on the eye.” D.I. 266 at 8. As stated repeatedly above, however, “[t]o offer expert testimony from the perspective of a skilled artisan in a patent case—like for claim construction, validity, or infringement—a witness must at least have ordinary skill in the art.” *Kyocera Senco Indus. Tools Inc.*, 22 F.4th 1369, 1376-77. Here, Defendant does not assert that Dr. Kaser is not presenting testimony from the perspective of a person with ordinary skill in the art.

Ninth, as Plaintiffs observe, Defendant’s “argument that Dr. Kaser meets the qualifications of a POSITA because he meets the alternate conditions of having a bachelor’s degree ‘with a greater number of years of experience’ is nonsensical” because “if Dr. Kaser lacks the experience needed to qualify as a POSITA in this case necessary for someone with a master’s or a Ph. D. degree (as Judge Burke [correctly] found), he clearly lacks the ‘greater number of years of experience’ necessary for a POSITA with a lesser degree.” *See* D.I. 273 at 10.

Tenth, Defendant contends that a person having or having access to “general information regarding AMD, the convenience and needs of patients who suffer from AMD, and background information” constitutes a POSA. D.I. 266 at 8. However, this is not what the parties stated in their proffered definitions of a POSA. Instead, they each stated that a “POSA would have, or would have access to, general information regarding AMD, the convenience and needs of patients who suffer from AMD, and background information.” D.I. 166-1 Ex. 4 ¶ 29; D.I. 166-1 Ex. 6 ¶ 19. In other words, the parties stated and, the Court agrees, that having or having access to such information is a necessary but not a sufficient condition to constituting a POSA. That Dr. Kaser has or has access to such information, therefore, does not automatically make him a POSA.

B. Even if the Court Sustained Defendant's Objection to the Memorandum Order, the Court Would Still Exclude Much of Dr. Kaser's Opinion on Other Grounds Asserted by Plaintiffs in Their Motion to Exclude

Even had the Court sustained Defendant's Objection, the Court still would have excluded much of Dr. Kaser's Opinion on the remaining grounds in Plaintiffs' Motion to Exclude. In those remaining grounds, Plaintiffs first contend that the Court should exclude the arguments of Dr. Kaser concerning prosecution history estoppel and the doctrine of equivalents because (1) "Dr. Kaser lacks an understanding of prosecution history estoppel and" the doctrine of equivalents and (2) "Dr. Kaser's prosecution history estoppel analysis is based entirely on arguments rejected by the Court." D.I. 165 at 38-39. Plaintiffs also contend that the Court should exclude Dr. Kaser's Opinion and testimony that relies on claim construction rejected by this Court. D.I. 165 at 41-42. Because Judge Burke did not resolve those arguments in the Memorandum Order, the Court considers each of those arguments for the first time below.

1. The Court Agrees-in-Part and Disagrees-in-Part with Plaintiffs' Contention that "Dr. Kaser Lacks an Understanding of Prosecution History Estoppel" and the Doctrine of Equivalents

Plaintiffs raise several arguments under this heading, which the Court will address in turn. *First*, Plaintiffs cursorily contend that Dr. Kaser's prosecution history estoppel testimony "is unreliable" because he "has never prepared an expert report on or testified concerning prosecution history estoppel," "did not review the entire file histories or even all the applicant responses to Examiner rejections," and "admitted he does not fully understand prosecution history estoppel." D.I. 165 at 38.

However, Plaintiffs are incorrect. The law does not require, for example, that an expert must have previously testified as an expert to be reliable (which would, of course, prevent any new experts from testifying). The law also does not require that a non-infringement expert comprehend every nuance of the doctrine on which he opines. Also, Plaintiffs fail to specify the degree to

which Dr. Kaser does not understand prosecution history estoppel. Plaintiffs likewise fail to specify the degree to which Dr. Kaser has not reviewed the file histories and applicant responses to Examiner rejections. *See ECB USA, Inc. v. Savencia, S.A.*, No. 19-cv-731-RGA, 2020 WL 5369076, at *4 (D. Del. Sept. 8, 2020) (“As a general prudential rule, courts only decide issues that are fairly and fully presented. Therefore, cursory arguments not fully developed by the parties are waived.”). For at least these reasons, the Court would reject Plaintiffs’ argument.

Second, Plaintiffs contend that “Dr. Kaser’s testimony is also unreliable because it is premised on an incorrect understanding of the law.” D.I. 165 at 38. Specifically, Plaintiffs contend that Dr. Kaser invokes the concepts of “tangentiality” and “foreseeability” in the context of argument-based estoppel, but that such concepts only apply to amendment-based estoppel. D.I. 165 at 38; D.I. 227 at 23. The cases upon which Plaintiffs rely, however, do not preclude parties from invoking the concepts of “tangentiality” and “foreseeability” in the context of argument-based estoppel; instead, Plaintiffs’ cases merely happen to discuss these concepts in the context of amendment-based estoppel. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 726 (2002) (cited, for example, in D.I. 227 at 23); *Conoco, Inc. v. Energy & Envtl. Int’l, L.C.*, 460 F.3d 1349, 1363-64 (Fed. Cir. 2006) (cited, for example, in D.I. 227 at 23) (explaining that “arguments to the examiner may have the same [estoppel] effect [as amendment]”). Thus, the Court would not exclude, on this basis, the portions of Dr. Kaser’s Opinion and any corresponding testimony concerning the concepts of “tangentiality” and “foreseeability.”

Third, Plaintiffs contend that Dr. Kaser “improperly assumes vitiation [in his Opinion] solely because the amount of vitamin C falls outside the claimed range.” D.I. 165 at 38 (citing D.I. 166-1 Ex. 6 ¶¶ 76-77). In addition, Plaintiffs correctly observe that the “vitiation test cannot be satisfied merely by noting that the equivalent substitute is outside the claimed limitation’s literal

scope.” D.I. 165 at 38 (citing *Cadence Pharms., Inc. v. Exela Pharma Scis., LLC*, No. 11-733-LPS, 2013 U.S. Dist. LEXIS 166097, at *66 (D. Del. Nov. 14, 2013)). Since Plaintiffs are correct that Dr. Kaser merely posits that the substitute is not within the literal scope of the claim limitation (D.I. 166-1 Ex. 6 ¶¶ 76-77), even if the Court sustained Defendant’s Objection to the Memorandum Order, the Court would also exclude the portions of Dr. Kaser’s Opinion and any testimony concerning vitiation on this basis.⁴

2. The Court Also Would Exclude Dr. Kaser’s Prosecution History Estoppel Analysis Because It is Based on Arguments Rejected by the Court

Plaintiffs contend: “Regarding prosecution history estoppel, Dr. Kaser argues (1) that the ’297 Patent Reexamination file wrapper suggests that the vitamin C term should be limited to a half an integer but no more than one integer below or above the RDA multiplier, i.e., 660 mg max; and (2) that the applicants’ arguments in the prosecution history over Gorsek and LaHaye support prosecution history estoppel.” D.I. 165 at 39.⁵ Plaintiffs contend that these arguments “are the same arguments SBH proposed during claim construction, and which were rejected by the Court.” D.I. 165 at 39.

Defendant does not deny that the Court previously rejected these arguments from Dr. Kaser. D.I. 207. Instead, the Defendant appears to contend that a party can present an argument at trial premised on prosecution history estoppel notwithstanding the Court’s previous rejection of

⁴ The Court also notes that Defendant fails to respond to this argument. *See In re Honeywell Int’l Inc. Consol. Stockholder Litig.*, No. 19-cv-898-CFC, 2024 U.S. Dist. LEXIS 22184, at *10 n.1 (D. Del. Feb. 8, 2024) (“When a party files an opposition brief and fails to contest an issue raised in the opening brief, the issue is considered waived or abandoned by the non-movant.” (citation omitted)).

⁵ Plaintiffs employ the terms “Gorsek” and “LaHaye” to reference U.S. Patent Nos. 6,103,756 and 5,075,116, respectively. *See* D.I. 165 at 5 n.1. RDA means “recommended dietary allowance.” *Bausch & Lomb Inc. v. SBH Holdings LLC*, No. 20-cv-1463-GBW-CJB, 2025 U.S. Dist. LEXIS 47858, *5 (D. Del. Mar. 17, 2025).

that same argument during claim construction. D.I. 205 at 51-52. Defendant, however, is incorrect. *See CAO Lighting, Inc. v. Gen. Elec. Co.*, Nos. 20-cv-681-GBW, 20-cv-690-GBW, 2023 WL 1930354, at *4 (D. Del. Jan. 30, 2023) (granting *Daubert* motion to exclude expert's opinions regarding a particular claim term because his opinion was based on "the very argument Defendants lost on claim construction and [he] should not be allowed to revive it before the jury"). Therefore, the Court would also exclude the portions of Dr. Kaser's Opinion and any corresponding testimony regarding these arguments because those opinions are based on arguments previously rejected by the Court.

3. The Court Agrees that Dr. Kaser's Testimony Regarding the Presence of Beta-Carotene Improperly Relies on a Claim Construction Rejected by this Court and Would Exclude Such Testimony

The Court construed "vitamin A in the form of beta-carotene, substituted or supplemented with lutein, zeaxanthine or a raw material combination thereof" in claim 19 of U.S. Patent No. 6,660,297 ("the '297 patent") patent to mean "lutein, zeaxanthine, or a raw material combination thereof, may be used instead of, or in addition to, vitamin A in the form of beta-carotene." D.I. 108 at 29 (recommending such construction); D.I. 189 at 12 (adopting such construction). Plaintiffs correctly observe that "Dr. Kaser's analysis relies on a [different] claim construction" requiring the presence of beta-carotene and argue, therefore, that such opinion and testimony "should be excluded." D.I. 165 at 41-42. The Court agrees and, thus, would also exclude, on this basis, all portions of Dr. Kaser's Opinion and any corresponding testimony contending, or relying on the contention, that claim 19 of the '297 patent requires the presence of beta-carotene. *See CAO Lighting, Inc.*, 2023 WL 1930354, at *4 (granting *Daubert* motion to exclude expert's opinions regarding a particular claim term because his opinion was based on "the very argument Defendants lost on claim construction and [he] should not be allowed to revive it before the jury").

IV. CONCLUSION

For the foregoing reasons, the Court OVERRULES Defendant's Objection.

* * *

WHEREFORE, at Wilmington this 3rd day of April 2025, **IT IS HEREBY ORDERED** that Defendant's Objection (D.I. 266) to Judge Burke's Order Dated February 12, 2025, Striking Disclosure-Dedication Arguments (D.I. 259) is **OVERRULED**.



GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE