

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

BOSTON SCIENTIFIC CORP. and)
BOSTON SCIENTIFIC SCIMED, INC.,)
)
)
Plaintiffs,)
)
v.) No. 1:17-cv-03448-JRS-MJD
)
COOK MEDICAL LLC,)
)
Defendant.)

Order on Motions to Exclude Expert Testimony

This is a patent infringement case. Before the Court are Defendant's following motions: (1) Motion to Exclude Plaintiffs' Technical Expert, Karl Leinsing, (ECF No. 735); (2) Motion to Exclude Plaintiffs' Patent Law Expert, Stephen Kunin, (ECF No. 740); and (3) Motion to Exclude Plaintiffs' Damages Expert, John Bone, (ECF No. 760). Additionally, the Court will address Plaintiffs' Motion to Exclude Defendant's Expert, Vincent A. Thomas, (ECF No. 752).

I. Legal Standard for Expert Testimony

"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 part of its "gatekeeping" responsibility, "[i]t is the district court's role to ensure that expert testimony is both relevant and reliable." *Bielskis v. Louisville Ladder, Inc.*, 663 F.3d 887, 893 (7th Cir. 2011) (citing *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993)). "In performing this role, the district court must engage in a three-step analysis, evaluating: '(1) the proffered expert's qualifications; (2) the reliability of the expert's methodology; and (3) the relevance of the expert's testimony.'" *Kirk v. Clark Equip. Co.*, 991 F.3d 865, 872 (7th Cir. 2021) (quoting *Gopalratnam v. Hewlett-Packard Co.*, 877 F.3d 771, 779 (7th Cir. 2017)). The proponent of the expert bears the burden of demonstrating the admissibility of the expert's testimony. *Lewis v. CITGO Petroleum Corp.*, 561 F.3d 698, 705 (7th Cir. 2009). "[T]he district court's role as gatekeeper does not render the district court the trier of all facts relating to expert testimony. . . . The jury must still be allowed to play its essential role as the arbiter of the weight and credibility of expert testimony." *Stollings v. Ryobi Techs., Inc.*, 725 F.3d 753, 765 (7th Cir. 2013) (citations omitted).

II. Plaintiffs' Technical Expert, Karl Leinsing

Defendant makes three challenges in its Motion to Exclude Karl Leinsing: (1) Leinsing's opinions that contradict "findings from the IPR proceedings" should be excluded under the doctrine of collateral estoppel, (ECF No. 738 at 9); (2) Leinsing's "conclusory" testimony is cumulative, (*id.* at 19); and (3) Leinsing's written description opinions are "legally-flawed", (*id.* at 24). The Court addresses these arguments in turn.

A. Collateral Estoppel of Leinsing's "Contradictory" Opinions

Defendant seeks to preclude three opinions that contradict arguments and issues raised and decided during the *Inter Partes Review* ("IPR") conducted before the Patent Trial and Appeal Board ("PTAB") of the U.S. Patent and Trademark Office ("USPTO" or "Patent Office"): (1) opinions regarding the relevance of prior art biopsy forceps to the asserted patents, (ECF No. 738 at 9); (2) opinions regarding the scope and content of Nishioka's prior art biopsy forceps, (*id.* at 13); and (3) opinions regarding the scope and content of Sackier's prior art clamps, (*id.* at 14).

Collateral estoppel, also called issue preclusion, "bars successive litigation of an issue of fact or law actually litigated and resolved in a valid court determination essential to the prior judgment, even if the issue recurs in the context of a different claim." *Dexia Credit Loc. v. Rogan*, 629 F.3d 612, 628 (7th Cir. 2010). Collateral estoppel applies if "(1) the issue sought to be precluded is the same as that involved in the prior action; (2) the issue was actually litigated; (3) the determination of the issue was essential to the final judgment; and (4) the party against whom estoppel is invoked was fully represented in the prior action." *Id.* Seventh Circuit law determines the general procedural question of whether collateral estoppel applies; Federal Circuit law applies on issues of collateral estoppel that implicate substantive patent law, or issues of collateral estoppel that implicate the scope of previous Federal Circuit decisions. *Soverain Software LLC v. Victoria's Secret Direct Brand Mgmt., LLC*, 778 F.3d 1311, 1314 (Fed. Cir. 2015).

Defendant chiefly relies on *XY, LLC v. Trans Ova Genetics* in support of its argument. 890 F.3d 1282 (Fed. Cir. 2018). In that case, the Federal Circuit

considered two appeals on the same patent claims: first, the Federal Circuit affirmed a finding of invalidity by the PTAB as to certain claims challenged in the IPR; based on this affirmance, the Federal Circuit dismissed the subsequent appeal from the district court that invalidated those same claims. *XY*, 890 F.3d at 1294–95. After affirming the PTAB's decision, the Federal Circuit dismissed the appeal of the district court decision as moot and held that "an affirmance of *an invalidity finding*, whether from a district court or the Board, has a collateral estoppel effect on all pending or co-pending actions." *Id.* at 1294 (emphasis added). From this, Defendant wishes to preclude Plaintiffs (and Leinsing, in particular) from making any arguments that contradict *any* "findings" made by the Patent Office at the IPR. For the following reasons, this is an overbroad reading of *XY*.

In *B & B Hardware, Inc. v. Hargis Industries, Inc.*, the Supreme Court stated that because issue preclusion "can be challenging to implement," the Court "regularly turns to the Restatement (Second) of Judgments for a statement of the ordinary elements of issue preclusion." 575 U.S. 138, 148 (2015). Continuing, the Court stated that, per the Restatement, "subject to certain well-known exceptions, the general rule is that '[w]hen an issue of fact or law is actually litigated and determined by a valid and final judgment, and the determination is essential to the judgment, the determination is conclusive in a subsequent action between the parties, whether on the same or a different claim.'" *Id.* (citing Restatement (Second) of Judgments § 27, p. 250 (1980)). One such exception to issue preclusion provided in the Restatement is when "the adversary [seeking preclusion] has a significantly heavier burden than

he had in the first action." Restatement (Second) of Judgments § 28(4) (1980). The Supreme Court has applied this principle frequently. *See, e.g., Grogan v. Garner*, 498 U.S. 279, 284–85 (1991). Importantly in the patent context and relevant to the parties' arguments here, the burden of proof to show invalidity in an IPR is much less stringent than the burden of proof required at the district court. *See Celgene Corp. v. Peter*, 931 F.3d 1342, 1362 (Fed. Cir. 2019) ("IPRs use a preponderance of the evidence burden of proof rather than the district court's clear and convincing evidence burden of proof."). Despite this, in *XY*, the Federal Circuit did not apply the exception articulated in the Restatement and instead issued its holding quoted above that an affirmance of an *invalidity finding* can have a preclusive effect on all pending actions. But this holding is a narrow one: namely, if there is an affirmance of an IPR's finding of *invalidity*, then the patentee is precluded from disputing that invalidity finding in all other pending actions. There is nothing in *XY* that suggests all findings and arguments resolved at the IPR are then also precluded at the district court.

Not only does it make sense to preclude a patentee from later disputing the invalidity of claims (or materially identical claims) that were found invalid at the IPR, but to find otherwise would neuter IPR proceedings. Indeed, the foundation underlying the holding in *XY* can be stated as follows: By having his claims invalidated at the IPR, the patentee effectively has no leg left to stand on; the *cause of action* as to those invalidated claims dies. *See Fresenius USA, Inc. v. Baster Int'l, Inc.*, 721 F.3d 1330, 1340 (Fed. Cir. 2013) ("[W]hen a claim is cancelled, the patentee loses any cause of action based on that claim, and any pending litigation in which the

claims are asserted becomes moot."); *see also Intell. Ventures I, LLC v. Lenovo Grp. Ltd.*, 370 F. Supp. 3d 251, 256 (D. Mass. 2019) (citation omitted) ("The holding in *XY* is necessitated by the IPR statutory scheme because if the PTAB finds that a claim is unpatentable during an IPR proceeding, 'the PTO is required to issue a certificate cancelling the claim.' . . . Thus, 'the patent holder may no longer assert that claim in litigation or otherwise.'"). This is precisely what Federal Circuit Judge Bryson, sitting by designation at the District of Delaware, explained in *IOENGINE, LLC v. PayPal Holdings, Inc.*: "The Federal Circuit in *XY* reached a result roughly equivalent to the result it reached in *Fresenius*, as the court in *XY* dismissed the appeal from the district court litigation over certain [claims] after upholding the PTAB's decision invalidating those same claims. To be sure, the court in *XY* granted that relief *before the PTO had formally canceled the claims*. Perhaps for that reason, the Federal Circuit in *XY* treated its decision as being based on collateral estoppel rather than on a direct application of *Fresenius*." No. 18-452-WCB, 2022 WL 2800861, at *14 (D. Del. June 15, 2022) (emphasis added). Like the defendant in *IOENGINE*, Defendant here "ignores the special circumstances in which [*XY*] arose" and attempts to broaden its holding such that "any issue decided by the PTAB in addressing invalidity has collateral estoppel effect in subsequent district court litigation notwithstanding the differences in the standard of proof between the two forums." *Id.*

While both parties try to paint this issue as one of "settled law," district courts have reached different conclusions in interpreting *XY*. Defendant's citations to many of these district court cases are unpersuasive. First, most of these citations are to

cases interpreting *XY* much as the Court does today, applying issue preclusion only to *findings of invalidity* at the IPR. *See, e.g., Cisco Sys., Inc. v. Capella Photonics, Inc.*, No. 20-cv-01858-EMC, 2020 WL 7227153, at *4 (N.D. Cal. Dec. 8, 2020) (citing to both *XY* and *Fresenius* and applying collateral estoppel to preclude subsequent litigation over the validity of claims that had already been *invalidated* at the IPR); *Fellowes, Inc. v. Acco Brands Corp.*, No. 10 cv 7587, 2019 WL 1762910, at *3–7 (N.D. Ill. Apr. 22, 2019) (applying collateral estoppel to preclude the plaintiff from asserting patent claims that were materially identical to claims invalidated at the IPR); *Intell. Ventures*, 370 F. Supp. 3d at 256–57 (same). As discussed in this Court's order on the parties' motions for summary judgment, (ECF No. 962), issue preclusion *could* potentially apply in situations where one patent claim is invalidated at an IPR, and another "materially identical" claim (which was *not* challenged at the IPR), is asserted at the district court. But Defendant is not asking the Court to apply collateral estoppel to preclude Plaintiffs from asserting a specific patent claim that was either previously invalidated at the IPR or that is materially identical to a previously invalidated claim. Instead, Defendant wishes to estop Plaintiffs from making any of the arguments (e.g., opinions on scope, content, and relevance of prior art) they previously made in the IPR and which were unsuccessful in that proceeding. The one case Defendant cites that stretches the holding in *XY* this far, *University of Pennsylvania v. Eli Lilly & Co.*, conducts no meaningful analysis of the *XY* opinion, and this Court finds its reasoning unpersuasive. *See* No. 15-6133, 2022 WL 3973276, at *5–6 (E.D. Pa. Jan. 14, 2022). This Court's conclusion aligns with the reasoning

in *IOENGINE*. See 2022 WL 2800861, at *14 ("To read *XY* that broadly would mean that the Federal Circuit, without saying so, has created an exception to the general rule of the law of judgments that collateral estoppel does not apply in circumstances in which the standard of proof that the party asserting collateral estoppel is more exacting in the second forum than in the first.").

For the aforementioned reasons, the Court declines to apply collateral estoppel to Leinsing's opinions that "contradict" arguments resolved at the IPR. Defendant's Motion is **denied** to this extent.

B. "Conclusory" Cumulativeness Testimony

Defendant next argues that Leinsing's cumulativeness opinions should be excluded because they are conclusory and thus unreliable and/or unhelpful to the trier of fact. (ECF No. 738 at 18–24.) Because the Court considered Leinsing's opinion and fully resolved the issue of cumulativeness at the motion for summary judgment stage, there are no longer any cumulativeness issues remaining for trial; accordingly, Defendant's Motion is **denied as moot**; Leinsing will not be allowed to testify concerning cumulativeness at trial.

C. Leinsing's Written Description Testimony

Defendant next argues that Leinsing's testimony as to whether the '048 and '731 patents adequately meet the written description requirement of 35 U.S.C. § 112 should be excluded at trial because he applies the wrong legal standard in reaching his conclusions, thus making his testimony unreliable. (ECF No. 738 at 24–25.) For the following reasons, the Court agrees.

A patent specification is required to have a written description. 35 U.S.C. § 112(a). To satisfy the written description requirement, "the description must 'clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.'" *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (citation omitted). "In other words, the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Id.* Importantly, the Federal Circuit has also made clear that while the specification need not "recite the claimed invention *in haec verba*, a description that merely renders the invention obvious does not satisfy the requirement." *Id.* at 1352 (citing *Lockwood v. Am. Airlines*, 107 F.3d 1565, 1571–72 (Fed. Cir. 1997)). The claimed invention must be disclosed in the specification "as an integrated whole rather than as a collection of independent limitations." *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1349 (Fed. Cir. 2013). A patentee cannot use "an amalgam of disclosures plucked selectively" from the specification to meet the written description requirement. *Id.* Stated differently, "[a] patent owner cannot show written description support by picking and choosing claim elements from different embodiments that are never linked together in the specification." *Flash-Control, LLC v. Intel Corp.*, 2020-2141, 2021 WL 2944592, at *4 (Fed. Cir. July 14, 2021). Further still, the key question is not whether the claimed invention is obvious in hindsight, but whether it is actually fully disclosed; thus, *boilerplate language in the specification* teaching a person of ordinary skill in the art that the scope of the

invention includes various combinations and permutations of the disclosure is not helpful nor sufficient for the written description requirement. *See D Three Enters., LLC v. SunModo Corp.*, 890 F.3d 1042, 1050–51 (Fed. Cir. 2018) (stating that such boilerplate language is not sufficient to show adequate disclosure of the actual combinations pertinent to the claimed invention).

As an initial matter, some of Leinsing's testimony as to the written description requirement is sufficiently reliable and will not be excluded. For example, as to the '048 patent, Leinsing argues that Figures 12A and 12B represent the embodiments disclosing all of the pertinent claim limitations at issue. For the claim limitation of independent claim 1 requiring a control wire that is "operable both to open the clip legs and to close the clip legs," which Defendant challenges as not adequately described in the specification, Leinsing points to various passages in the specification that discuss the importance of the "reversibly closable" feature of the clip and then states that, based on this, one of ordinary skill in the art would understand that the control wire of Figures 12A and 12B is operable to both open and close the clip as required by the asserted claim. (ECF No. 737-1 at 48–49.) While Leinsing's analysis is rather sparse, the Court will not exclude this testimony. Leinsing offers at least some explanation and reasonable reliance on the specification to explain why one of ordinary skill in the art would understand Figures 12A and 12B to disclose an embodiment with the required control wire; whether this testimony is convincing will be left to the finder of fact.

However, Leinsing's testimony as to certain other claim limitations is more problematic. For instance, claim 7 of the '048 patent requires a "spring member" positioned between the clip legs and "biased to urge the first and second clip legs away from one another." (ECF No. 451-2 at 38.) Leinsing admits that the embodiment depicted in Figures 12A and 12B does not include a spring member positioned between the clip legs. (ECF No. 736-11 at 5.) Instead, Leinsing argues that the written description requirement is still met as to this limitation because a different disclosed embodiment, the embodiment of Figure 8A, contains the requisite spring member, and a person of ordinary skill in the art would know that the Figure 8A embodiment could be combined with the embodiment of Figures 12A and 12B. (ECF No. 736-1 at 56–57.) But this is precisely the hindsight obviousness analysis that the Federal Circuit stated does not satisfy the written description requirement. *See Ariad Pharms.*, 598 F.3d at 1352. Leinsing has not shown what links these embodiments together in the specification. Plaintiffs argue that Leinsing is not stating what would be "obvious" to a person of ordinary skill; rather, he is stating what would actually be *disclosed* to a person of ordinary skill. (ECF No. 751 at 23.) But to make this argument, Plaintiffs point to the portions of Leinsing's report where he relies on boilerplate language from the '048 patent. (*Id.*) Namely, Leinsing states that the patent adequately discloses the combination of the Figure 8A and Figures 12A/12B embodiments to a person of ordinary skill because of the final paragraph of the specification, which states that "[i]t will be obvious to those skilled in the art, having regard to this disclosure, that other variations on this invention beyond those

specifically exemplified here may be made." (ECF No. 451-2 at 38; *see also* ECF No. 737-1 at 57 n.81 (Leinsing quoting the aforementioned language as his sole support of why a person of ordinary skill would be led to combine the embodiments).) But this boilerplate language is directly analogous to the boilerplate language rejected by the Federal Circuit in *D Three* as adequate support for the written description requirement. Such language does nothing to disclose combinations of embodiments to one of ordinary skill in the art. And Leinsing makes these same arguments as to other limitations.¹ (ECF No. 737-1 at 57–58.)

The Court will handle the testimony related to the '731 patent in the same way as the testimony related to the '048 patent. Where Leinsing argued that a single embodiment disclosed all the relevant features of the claimed invention, the Court will allow the testimony. (*See, e.g.*, ECF No. 737-1 at 84 (discussing how the embodiment of Figures 15A-D discloses all of the pertinent limitation).) However, where he opined that one of ordinary skill in the art would know to combine various embodiments of the specification based on boilerplate language, the Court will exclude the testimony. (*See, e.g., id.* (relying solely on boilerplate language to support a showing that one with ordinary skill in the art would combine the embodiments of Figures 8A, 10A, and 10B with those of Figures 11, 12A, and 12B).)

¹ The Court notes that in his August 2017 report, Leinsing made slightly different arguments as to this claim limitation. Rather than argue a combination of embodiments, he argues that one of ordinary skill in the art would understand that the embodiment of Figure 12A and 12B in fact *does* contain a link not integral with the control wire. (*See* ECF No. 737-2 at 61–62.) Such an argument is appropriate in the written description context and will therefore not be excluded pursuant to this Order.

Leinsing's expert opinion testimony that relies solely on boilerplate language as support to combine disclosed embodiments of the asserted patents would go against Federal Circuit written description precedent and not be helpful or reliable to a finder of fact. To avoid confusing the jury, the Court **grants** Defendant's motion to this extent.

D. Conclusion

For the foregoing reasons, Defendant's Motion to Exclude Plaintiffs' Technical Expert, Karl Leinsing, (ECF No. 735), is **granted in part and denied in part**.

The pertinent portions of Leinsing's testimony to be excluded are the following: paragraphs 16, 19, 255 through 264, and 384 of his February 2022 report, (ECF No. 737-1); and paragraph 555 of his August 2017 report, (ECF No. 737-2).

III. Plaintiffs' Patent Law Expert, Stephen Kunin

Defendant intends to assert a prosecution laches defense, an equitable issue that both parties agree is for the Court, not the jury, to decide. In support of their counterargument, Plaintiffs plan to present the testimony of Stephen Kunin. Defendant seeks exclusion of this testimony on three grounds, arguing that: (1) Kunin improperly issues opinions on *legal standards*, a domain that is reserved for the Court; (2) Kunin offers opinions on issues for which he is not qualified; and (3) Kunin's testimony regarding USPTO practices and procedures is not relevant and will not assist the trier of fact. (ECF No. 743 at 6–7.)

A. Opinions on Legal Standards

Defendant first argues that Kunin is providing impermissible opinions on legal standards. The Court is not persuaded.

Undoubtedly, "[a]s a general rule, . . . an expert may not offer legal opinions." *Jimenez v. City of Chicago*, 732 F.3d 710, 721 (7th Cir. 2013). However, there is a difference between opining on a legal issue and simply relying on legal standards to produce a proper, admissible expert opinion. *See id.* (differentiating between legal opinions as opposed to opinions that merely have "direct implications for applying legal standards"); *see also Medicines Co. v. Mylan Inc.*, No. 11-cv-1285, 2014 WL 1257943, at *2 (N.D. Ill. Mar. 27, 2014) ("In the course of offering his opinions on commercial success, [the expert] references the legal standard upon which he bases his economic analysis and opinions. Contrary to TMC's assertions, [the expert] is not offering an impermissible legal opinion. Instead, he is merely setting forth his understanding of the legal standards upon which he relies for his opinions. This reference is appropriate and puts his testimony in context.").

In the Court's view, Kunin does not provide an impermissible legal opinion. Rather, based on his extensive experience with the USPTO, (*see* ECF No. 741-1 at 4–10 (discussing experience which includes reviewing the work of patent examiners, serving as Deputy Commissioner for Patent Examination Policy, and more)), he provides an opinion as to whether there was any unreasonable delay in the prosecution of the asserted patents. This "unreasonable delay" inquiry is derived from established legal standards that Kunin summarized and properly relied on in his report. (*See id.* at 20–26 (summarizing the applicable prosecution laches legal standards); *see also Symbol Techs., Inc. v. Lemelson Med.*, 277 F.3d 1361, 1363 (Fed. Cir. 2002) (“[T]he equitable doctrine of prosecution laches may be applied to bar

enforcement of patent claims that issued after an unreasonable and unexplained delay in prosecution”).) And Kunin did not *admit* he would opine on the *law*. (ECF No. 770 at 5–6.) The entirety of Kunin's report, and the crux of his conclusions, centers on whether the prosecution of the asserted patents was unreasonably delayed. (ECF No. 741-1 at 55–64.) Kunin's deposition testimony likewise supports this conclusion. While Defendant asserts that it caught Kunin in an admission, (ECF No. 770 at 5–6), Kunin's deposition, which involved him conducting some mental gymnastics around Defendant's clearly pointed questions, does nothing more than reiterate his intention to opine on unreasonable delay, *not the law*. (See ECF No. 742-1 at 7 (Kunin stating that he referenced case law only as a foundation for his opinion and his opinion was confined to whether there was an unreasonable delay in prosecution).) Kunin's outlining of relevant legal standards is quite similar to the legal framework sections of Defendant's own experts, except Kunin's report contained citations and quotations from caselaw; the Court does not understand how Defendant's experts engaged in "simple recitation of the legal standards informing their opinions" whereas Kunin did not. (ECF No. 770 at 7; *see also* ECF No. 747-2 at 3–5 (Nicosia outlining a legal framework as foundation for his opinion).) And Defendant's citations to cases where experts were excluded for providing legal opinions are inapposite here; unlike the case here, those cases involved experts actually opining on how to interpret statutes or contract terms. *See, e.g., United States v. Lupton*, 620 F.3d 790, 799 (7th Cir. 2010) (excluding testimony of expert who offered interpretations of Wisconsin statutes and the parties' contract, despite

conceding that he had absolutely no personal experience with the statutes he was interpreting). In short, the Court views Kunin's report as one based on extensive USPTO experience that opines on whether Plaintiffs unreasonably delayed the prosecution of their patents; Kunin has provided useful expert opinions on this issue before and his opinion here, though it implicates legal standards, does not opine on legal issues or conclusions. *See Hyatt v. Hirshfeld*, 998 F.3d 1347, 1357 (Fed. Cir. 2021) (discussing Kunin's expert testimony, including the factors he discussed in support, in analyzing the patentee's unreasonable delay during prosecution).

To the extent that Defendant takes issue with Kunin's particular citations or interpretations of some caselaw, their concerns have no weight here. (*See, e.g.*, ECF No. 743 at 10–12 (arguing that some of Kunin's legal standards are not supported by the cases he cites, like *Kingsdown*, or are supported by cases/journal articles not binding on this Court).) The Seventh Circuit has made clear that while *Daubert* requirements still apply in a bench trial, "the court in a bench trial need not make reliability determinations before evidence is presented" as "the usual concerns of the rule—keeping unreliable expert testimony from the jury—are not present in such a setting." *Metavante Corp. v. Emigrant Sav. Bank*, 619 F.3d 748, 760 (7th Cir. 2010); *see also Medicines*, 2014 WL 1257943, at *3 (citing to *Metavante* and assuring the parties that "[t]he Court is fully aware of the law of obviousness and commercial success" and that it "will not construe [the expert's] comments or his understanding of the law on which he bases his commercial success opinions as any type of expert opinion on the law"); *United States v. Brown*, 415 F.3d 1257, 1269 (11th Cir. 2005)

("There is less need for the gatekeeper to keep the gate when the gatekeeper is keeping the gate only for himself."). While the case here is not a bench trial, the issue on which Kunin opines is one that will be decided by the Court. There is no risk of exposing a jury to unreliable expert testimony. The Court will determine the law of prosecution laches and will apply it accordingly. Kunin's testimony will not be construed as an opinion on the law, and to the extent that his opinion misconstrues or misapplies a legal standard, the Court will disregard it.

B. Kunin's Alleged Lack of Experience or Expertise

Defendant next argues that portions of Kunin's testimony should be excluded because he lacks any expertise or experience to render it reliable.

First, Defendant asks the Court to exclude Kunin's opinions pertaining to patent prosecution *in the medical device field*. The Court agrees that these opinions are unreliable. In his report, Kunin opines that "the prosecution of the patents-in-suit was *typical of patents in the medical device field*." (ECF No. 741-1 at 61 (emphasis added).) He then states that patent families with prosecutions spanning more than a decade are "quite common in the medical device field," and he references multiple Cook patent families in support. (*Id.* at 62–63.) This portion of Kunin's opinion is unreliable and is of no value to the Court. By Kunin's own admission, he is "not an expert in the medical device field." (ECF No. 742-1 at 20.) When asked about his statement that it is "quite common" for prosecutions to span more than a decade in the medical device field, he responded that this was an understanding he "obtained from counsel from Boston Scientific." (*Id.*) And as for the Cook patent families he

cites in support, Kunin admits that he did not find these patent families himself either and that they were "provided to [him]." (*Id.* at 21.)

Plaintiffs argue that "Kunin need not have personally prosecuted medical device patents to make informed observations on whether he observed strategies during prosecution of the Patents-in-Suit that resulted in unreasonable delays." (ECF No. 748 at 15.) The Court does not disagree with this assertion. Kunin is qualified to opine, based on his *general* experience with patent prosecution before the USPTO, whether the prosecution of certain patents in this case was unreasonably delayed; the Court is not excluding these opinions. It is Kunin's opinions on prosecution practice in the *medical device field* specifically that are unsupported and unreliable. These opinions are not based on Kunin's expertise; it is unhelpful to the Court in considering the evidence and will be excluded. Accordingly, the Court excludes paragraphs 216 through 218 of Kunin's report.

Second, Defendant asks the Court to exclude Kunin's opinions related to the prosecution of claims *to exclude competitors*. Again, the Court finds that Kunin, by his own admission, lacks the expertise to provide a reliable opinion on this particular issue. Defendant plans to argue that Plaintiffs obtained certain patent claims after learning of the Instinct clip. (ECF No. 741-1 at 59–60.) In response, Plaintiffs hope to have Kunin testify that this conduct is not improper and that "it is actually quite common for clients to target their competitor's products by filing claims directed to those competitor products." (*Id.* at 63.) However, Kunin lacks experience to provide such an opinion. (ECF No. 748 at 19–20.) As the Court has already noted, Kunin

clearly *does* have the expertise to provide opinions on whether or not certain delays in the timeline of the asserted patents' prosecution were generally "unreasonable," or whether there were unusual gaps or suspect events in the prosecution history of the pertinent patents. But his expertise does not stretch so far as to allow him to opine specifically on whether patent *clients* commonly target their competitor's products. In fact, Kunin admits that while working in private practice, he did not perform any work in patent prosecution or preparation. (ECF No. 742-1 at 5.) When asked about the number of instances he is aware of where clients targeted their competitors' products, Kunin testified that he had not "personally . . . interacted with a client" and had "only heard anecdotally from other attorneys in the firm in terms of things that they have done." (*Id.* at 12.) Continuing, he stated that he has not been "personally involved in those discussions with a client" or with "preparing that type of an opinion." (*Id.*) The Court sees no reason to admit Kunin's testimony on this issue; paragraph 219 of Kunin's report is therefore excluded.²

C. Whether Kunin's Opinion Assists the Trier of Fact

Defendant next seeks to exclude the entirety of Kunin's testimony because it will not assist the trier of fact, which in this case is the Court. (ECF No. 743 at 16.) The Court has already analyzed this argument in the context of matters tried to the

²The Court would not rely on this section of Kunin's report anyway. Kunin did not give an opinion on anything that would not have been commonly known or discoverable. Prospective patentees naturally prosecute claims directed at excluding particular competitor products, and the Federal Circuit has acknowledged as much. *See Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 874 (Fed. Cir. 1988) ("[T]here is nothing improper, illegal or inequitable in filing a patent application for the purpose of obtaining a right to exclude a known competitor's product from the market; nor is it in any manner improper to amend or insert claims intended to cover a competitor's product the applicant's attorney has learned about during the prosecution of a patent application.").

bench. That analysis applies here. Defendant's arguments go to the weight of Kunin's testimony; because the Court is deciding this issue itself and there is no risk of influencing a jury improperly, the Court will give Kunin's testimony whatever weight it deserves. *See Metavante*, 619 F.3d at 760. There is no reason to exclude the entirety of Kunin's testimony at this stage.

Defendant relies on cases excluding expert testimony about "procedures at the PTO" that are not binding or relevant here. (*See* ECF No. 743 at 17.) In *AstraZeneca UK Ltd., IPR v. Watson Labs., Inc.*, the expert was offered as a "legal expert" to opine on how a chemical patent practitioner would read the patent's claims. No. 10–915–LPS, 2012 WL 6043266, at *1 (D. Del. Nov. 14, 2012). Such is not the case here. *Corning Inc. v. SRU Biosystems* is likewise inapposite as the expert in that case provided opinions that were primarily on ultimate issues of law. No. 03–633 JJF, 2004 WL 5523178, at *1 (D. Del. Nov. 5, 2004). As stated, Kunin is not providing legal opinions.

Defendant also argues that Kunin's testimony about the United States patenting process and the prosecution histories of the patents-in-suit are not helpful because (1) prosecution laches is an equitable issue for the Court to decide and (2) because the Federal Circuit has stated that prosecution laches "*may* be applied to bar enforcement of a patent that issued after unreasonable and unexplained delay in prosecution, even though the patent applicant complied with pertinent statutes and rules." *In re Bogese*, 303 F.3d 1362, 1367 (Fed. Cir. 2002) (emphasis added). But experts can still be helpful on equitable issues. *See, e.g., Hyatt*, 998 F.3d at 1357 (relying on Kunin's

testimony for the same issue). Of course, Defendant is correct that "the Court is fully capable of understanding the parts of a patent application, the statutes and rules governing the patenting process itself, and what occurred during the prosecution of the patents-in-suit." (ECF No. 743 at 17.) But this does not mean that testimony from an expert on whether there was "unreasonable delay" in the prosecution of a patent is unhelpful, particularly when the expert has had decades of experience with the USPTO and with the intricacies of patent prosecution procedure. Finally, just because the prosecution laches defense "may" still apply despite full compliance with USPTO rules and procedures does not mean that expert testimony on the subject is rendered completely useless; laches may still apply, but full compliance with the rules and procedures at least provides circumstantial evidence on the matter.

Defendant further takes issue with Kunin's reliance on patent term adjustment ("PTA") data, arguing that his analysis requires no special knowledge or expertise. (ECF No. 743 at 18.) This argument, too, goes to the weight of Kunin's testimony rather than his methodology. Kunin relied on the data to interpret, based on his experience with prosecution procedure before the USPTO, whether the delays were "unreasonable" or "unexplained." (*See, e.g.*, ECF No. 741-1 at 34.) This testimony could be helpful to the Court in this regard. Defendant will be able to cross examine Kunin and provide its argument on this issue; ultimately, the weight of his opinion may end up negligible, but his testimony should not be excluded for this reason.

D. Conclusion

For the foregoing reasons, Defendant's Motion to Exclude Plaintiffs' Patent Law Expert, Stephen Kunin, (ECF No. 740), is **granted in part and denied in part**.

Due to a lack of expertise on the issues, paragraphs 216 through 219 of Kunin's report are **excluded**. The remainder of Kunin's testimony is admissible.

IV. Plaintiffs' Damages Expert, John R. Bone

Defendant asks the Court to exclude Plaintiffs' damages expert, John R. Bone, because (1) his lost profits analysis is unreliable and (2) his reasonable royalty analysis is unreliable. (ECF No. 762 at 10–11.)

A. Lost Profits

Both parties rely on the same legal test for calculating lost profits, a four-factor test derived from *Panduit Corp. v. Stahl Bros. Fibre Works, Inc.*, 575 F.2d 1152 (6th Cir. 1978). "Under [*Panduit*], a patentee is entitled to lost profits if it can establish four things: (1) demand for the patented product, (2) absence of acceptable, non-infringing alternatives to the patented product, (3) manufacturing and marketing capability to exploit the demand for the patented product, and (4) that the patentee would have made a profit if it had made the infringer's sales." *TEK Glob., S.R.L. v. Sealant Sys. Int'l, Inc.*, 920 F.3d 777, 789–90 (Fed. Cir. 2019) (citation omitted).

Defendant makes several arguments as to why Bone's lost profits analysis is improper or unreliable, none of which is persuasive. Bone's analysis utilized the proper legal standards discussed above and is reliable; his credibility and conclusions are to be weighed by the jury. Bone's expert report properly goes through an analysis of the *Panduit* factors one by one to provide an opinion on lost profits damages. (See ECF No. 761-33 at 37.)

As to the first *Panduit* factor, Bone assessed demand for the patented *product*. But Defendant takes issue with some of Bone's focus on the "open/close" feature of

the claimed invention, first arguing that the claimed invention does not cover such a feature, and in any case, arguing that Bone's reliance on this "faulty premise" renders his overall opinion unreliable. (ECF No. 762 at 23.) While the Court need not determine on this Motion what exact features the Asserted Patents cover, it notes there is some evidence that the patents do in fact cover an open/close feature of a hemostatic clip. (See ECF No. 451-2 at 32 (discussing the key advantage of the device being its ability to reopen and close); *id.* at 38 (requiring an actuator coupled to a control wire to open and close the clip legs).) And Bone properly relied on Plaintiffs' technical expert in assessing the features of the claimed invention. (See, e.g., ECF No. 761-33 at 27–28 (citing to Leinsing's expert report in support of the open/close capability *via the control wire* of the claimed invention).) Additionally, the Federal Circuit has made clear that the first factor of *Panduit* requires analysis of demand of the patented *product*, not of a patented *feature*. *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1330 (Fed. Cir. 2009) (citation omitted) ("All that the first factor states, and thus requires, is 'demand for the patented product.' . . . This factor does not require any allocation of consumer demand among the various limitations recited in a patent claim. Instead, the first *Panduit* factor simply asks whether demand existed for the 'patented product,' i.e., a product that is 'covered by the patent in suit' or that 'directly competes with the infringing device.'"). Any allocation of the particular patented features is encompassed in the second *Panduit* factor discussed below. As for this first factor, Bone properly considered demand for the patented *product*. (ECF No. 761-33 at 38–40.)

Within the first factor, Defendant also took issue with Bone's consideration of Defendant's activities prior to the 2014 issuance of the asserted patents. (*See* ECF no. 762 at 29–30.) But argument on this issue was sparse, and the Court fails to see where Defendant's examples of Bone's pre-issuance considerations actually affected his conclusions as to lost profits. Also, the Federal Circuit itself has considered the effect of pre-issuance activities on lost profits damages calculations in various circumstances. *See, e.g., Brooktree Corp v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1579–81 (Fed. Cir. 1992). More importantly, Defendant's cited examples do not show any flaw in Bone's methodology. The first example, where Bone states that "BSC began to lose market share after Cook's Instinct hemoclip was introduced in 2011," is a statement made in the background section of Bone's opinion discussing the evolution of the hemoclip market. (*See* ECF No. 761-33 at 33.) There is no indication that this vague contextual statement influenced any lost profits calculations. Defendant's second example, Bone's reliance on correspondence from 2012, is likewise proper. Bone relied on this internal BSC correspondence (as well as numerous other *post-2014* documents³) to help determine whether an adjustment was necessary to BSC's relative market share *during the damages period*. (*Id.* at 57–61.) Even though Defendant was not infringing in 2012 prior to the asserted patents' issuance, Bone was permitted to rely on correspondence and documentation from this time period to help determine BSC's appropriate relative market share during the

³ The other documents that Bone relied on, all of which were describing post-2014 activity, independently supported Bone's conclusions as to market share, whether or not he considered the 2012 document.

alleged infringing period. The Court has not found, nor has Defendant pointed to, any law that prohibits such analysis and that would render Bone's opinion inherently unreliable.

Bone's analysis of the second *Panduit* factor is likewise proper. In *State Industries, Inc. v. Mor-Flo Industries, Inc.*, the Federal Circuit endorsed a market shares analytical framework for the second *Panduit* factor in situations where, as here, the market consisted of more than just two suppliers. 883 F.2d 1573, 1577 (Fed. Cir. 1989). Under this framework, a patentee can recover lost profits based on the market share of the various suppliers, assuming the infringer was not in the market (i.e., in the "but for" world where the infringement did not occur). See *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 185 F.3d 1341, 1350 (Fed. Cir. 1999) ("Within this framework, trial courts, with this court's approval, consistently permit patentees to present market reconstruction theories showing all of the ways in which they would have been better off in the 'but for world,' and accordingly to recover lost profits in a wide variety of forms."). Bone properly applied this framework to the second *Panduit* factor in devising his expert opinion. (ECF No. 761-33 at 56–61.) Any disagreement with Bone's conclusions that Defendant may have is not to be resolved in this Motion to Exclude.

Defendant also takes issue with Bone's opinions regarding non-infringing alternatives (also relevant for the second *Panduit* factor). Namely, Defendant argues that Bone's analysis for the '731 patent is unreliable because it does not consider

Defendant's own Instinct clip as a non-infringing alternative.⁴ (ECF No. 762 at 27.) But Plaintiffs and Bone provided ample explanation as to why the Instinct was not considered a non-infringing alternative for the '731 patent. Namely, Plaintiffs pointed to evidence that considered Defendant's own perspective (rather than the customer perspective) in marketing and selling the Instinct clip; because the Instinct clip was more expensive to manufacture, Bone testified that, based on Cook's interrogatory responses, Cook itself would not have considered the Instinct as a non-infringing alternative because of its higher cost. (See ECF No. 761-36 at 20–21.) Bone was entitled to develop his opinion relying on this evidence in the record. As explained, he is relying on the correct legal standard and assessing the second *Panduit* factor accordingly; a disagreement with his conclusions (e.g., what he did or did not consider a non-infringing alternative) is to be resolved at trial.

Slimfold Manufacturing Co. v. Kinkead Industries, Inc., 932 F.2d 1453 (Fed. Cir. 1991), also cited in support of Defendant's argument on the second *Panduit* factor, is not pertinent here. In that case, the Federal Circuit affirmed the denial of lost profits damages because the district court was *not clearly erroneous* in finding that the patentee had failed to establish a lack of acceptable non-infringing alternatives. *Id.* at 1458. Specifically, the Federal Circuit concluded that the patentee in that case not only failed to make *any* showing of a lack of acceptable non-infringing alternatives, but the evidence in the record strongly suggested the opposite conclusion. *Id.* That

⁴ Plaintiffs only asserted the '731 patent against the Instinct Plus and not the Instinct.

is not the case here, where Bone conducted an analysis of non-infringing alternatives to include the Defendant's own TriClip. (ECF No. 761-33 at 41.)

And Defendant's argument that Bone's analysis fails to properly "apportion" value attributable to the asserted patents is likewise unpersuasive. (See ECF No. 782 at 12.) The Federal Circuit has made clear that analysis under the second *Panduit* factor inherently results in the necessary apportionment for lost profits. See *Mentor Graphics Corp. v. EVE-USA, Inc.*, 851 F.3d 1275, 1288 (Fed. Cir. 2017) ("*Panduit's* requirement that patentees prove demand for the product as a whole and the absence of non-infringing alternatives ties lost profit damages to specific claim limitations and ensures that damages are commensurate with the value of the patented features.>").

Bone's analysis of the third *Panduit* factor, the manufacturing/marketing capacity to exploit the demand for the patented product, was also based on proper methods and legal standards. Defendant's chief concern is that Bone's analysis is "speculative" and comprised of "guesswork." (ECF No. 762 at 34 (citing cases for the general proposition that projections of lost profits cannot be based on speculation or guesswork).) But Defendant's only reasoning in support of Bone's analysis as "speculative" is that his opinion never confirms whether Plaintiffs' *suppliers* had the capacity to sell additional clip components to Plaintiffs. (*Id.*) Defendant cites to no law suggesting that this purported deficiency warrants exclusion of Bone's testimony, and the Court has not found any either. In any case, Bone's analysis was not "guesswork" at all; he relied on Plaintiffs' documentation as well as the deposition testimony of various Boston Scientific employees in order to assess, in detail,

Plaintiffs' capacity during two distinct manufacturing periods (which consisted of (1) the Freudenberg period and (2) the Costa Rica period). (See ECF No. 761-33 at 61–64; see also *Sprint Commc'ns Co. LP v. Charter Commc'ns, Inc.*, No. 17-1734-RGA, 2021 WL 982732, at *10 (D. Del. Mar. 16, 2021) (refusing to exclude expert testimony on manufacturing capacity under *Panduit* factor 3 because the expert relied on deposition testimony and interviews with company executives, and such evidence was the same type used by the Federal Circuit in *TEK Global, S.R.L. v. Sealant Systems International, Inc.*, 920 F.3d 777, 790 (Fed. Cir. 2019), to conclude that a jury could infer manufacturing capacity).) Defendant further complains, though, about certain considerations missing from Bone's analysis, such as the effect that the COVID-19 pandemic would have on Plaintiffs' capacity or whether Plaintiffs would have access to the requisite *materials* to make their clips. (See ECF No. 782 at 21–22.) But these arguments do not go to the issue of whether Bone used proper methodology or relied on appropriate legal standards in producing his opinion; rather, they go to the *weight* of the evidence at trial. See *Smith v. Ford Motor Co.*, 215 F.3d 713, 718 (7th Cir. 2000) ("The soundness of the factual underpinnings of the expert's analysis and the correctness of the expert's conclusions based on that analysis are factual matters to be determined by the trier of fact.").

Bone's analysis under the fourth factor of *Panduit* is also sufficient to avoid exclusion at this stage. Defendant's objection to Bone's testimony in this section revolves around one central issue: whether it was appropriate for Bone to calculate damages on behalf of BSC, the parent company of BSSI, rather than BSSI itself, the

patentee. When Defendant filed this Motion to Exclude, the Court had not yet ruled on Defendant's Motion to Dismiss BSC for Lack of Jurisdiction. The Court has now denied that Motion, (*see* ECF No. 914), as well as its associated Motion for Reconsideration, (*see* ECF No. 958), and concluded that BSC *does* have standing in the present action. Accordingly, Defendant's argument on the fourth *Panduit* factor is moot. Bone properly relied on the finances of BSC. (*See* ECF No. 761-33 at 70–71.) He calculated the revenue BSC would have received from the infringing sales, (*id.*), and relied on BSC's financial statements to deduct variable costs associated with the goods, (*id.* at 66–68).

For the foregoing reasons, Defendant's Motion to Exclude Plaintiffs' Damages expert, John Bone, (ECF No. 760), is **denied** as to Bone's lost profits opinions.

B. Reasonable Royalty

Both parties, and the Federal Circuit, rely on the fifteen factors articulated in *Georgia-Pacific Corp. v. United States Plywood Corp.* in making a reasonable royalty determination. 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970) (listing the factors); *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1324–26 (Fed. Cir. 2009) (relying on *Georgia-Pacific*).

Defendant complains that Bone's reasonable royalty opinions are inadmissible. For context, Bone provided two alternative reasonable royalty opinions (assuming that infringement is found). The first scenario is if the jury were to award Plaintiffs lost profits damages. In that scenario, Defendant would be expected to compensate Plaintiffs for the lost profits that Plaintiffs would have obtained had Defendant not been selling an infringing product during the damages period; additionally, because

not *all* of Defendant's infringing sales would go to Plaintiffs in this scenario, Defendant would also have to compensate Plaintiffs with a reasonable royalty for the fraction of the "infringing sales" that third-party competitors would have made. The second, alternative scenario is if the jury determines that the *Panduit* factors are not met and therefore does not award lost profits damages. In that scenario, Defendant would still have to compensate Plaintiffs with a reasonable royalty, but it would be based on all infringing sales made by Defendant and the third-party competitors. Here, Bone opines that there would be a shift in the hypothetical negotiating power of the parties under the fifteenth *Georgia-Pacific* factor that would result in an increased reasonable royalty rate. (*Compare* ECF No. 761-33 at 103–08 (scenario where lost profits are awarded) *with id.* at 112–14 (scenario where no lost profits are awarded).)

Troubled by this increase in royalty rate under the second scenario, Defendant cites to *SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 926 F.2d 1161 (Fed. Cir. 1991) to argue that, like the patentee in that case, Bone here has simply taken the lost profits damages Plaintiffs would have received in the first scenario and baked them into the increased royalty rate of the second scenario. (ECF No. 762 at 37.) Thus, they continue, Bone's opinion should be disregarded like the one in *SmithKline*. *See* 926 F.2d at 1165–68. But this is not what Bone did here. Bone's *Georgia-Pacific* analysis does not simply "translate" the lost profits figure into the reasonable royalty rate like the expert in *SmithKline*. (*See* ECF No. 761-33 at 9–11 (concluding that there would be about \$165 million in damages in the lost profits plus reasonable

royalty rate scenario while the damages would amount to approximately \$43 million in the scenario where no lost profits are awarded.) Rather, Bone adjusted his analysis of the factors under this scenario, (*see id.* at 112–14); and nothing indicates that he simply baked in the lost profits of the first scenario into the reasonable royalty increase of the second scenario (for if he did, the two damages figures would be much more similar to one another as was the case in *SmithKline*).

Defendant next seeks exclusion of Bone's opinions because they argue that his reliance on four surveys was fundamentally flawed. Bone relied on surveys produced by both Plaintiffs and Defendant, as well as a survey produced by a third party, (ECF No. 761-33 at 97–99), in support of his opinion that Plaintiffs are entitled to a price premium in their reasonable royalties. Defendant argues that Bone does not "hold himself out as a survey expert" and that his interpretations of the surveys are flawed. But Bone does not need to be a survey expert. To the extent Defendant disagrees with the particular data points that Bone relies on from the surveys, such disagreements go to the *weight* of the evidence. *See Summit 6, LLC v. Samsung Electronics Co.*, 802 F.3d 1283, 1297-99 (Fed. Cir. 2015) (stating expert need not be a survey expert to testify about information used from surveys to form opinions and concluding that "[t]o the extent [the expert's] credibility, data, or factual assumptions have flaws, these flaws go to the weight of the evidence, not to its admissibility).

Finally, Defendant's issues with the populations that were surveyed similarly go to weight rather than admissibility.⁵ (*See* ECF No. 762 at 39.)

⁵ The surveys polled physicians and asked them about the relative importance of different features in the hemostatic clips; while the physicians indicated that the ultimate purchasing decisions were

Defendant finally argues that Bone's reasonable royalty opinions are unreliable because he fails to consider the circumstances of a hypothetical negotiation for a license to only the '731 patent. (ECF No. 762 at 40–41.) Specifically, Defendant argues that the price premium analysis under *Georgia-Pacific* factor 13 would be different if only the '731 patent is found to be infringed. But Defendant does not directly attack Bone's analysis under factor 13. (See ECF No. 761-33 at 92–102.) Bone relied on consumer survey data, hemoclip market data, and other evidence to render his opinion on the reasonable royalty; this was proper. To the extent that Defendant believes Bone erred by not considering a unique circumstance in one particular infringement scenario (namely, that the Instinct Plus alone, and not the Instinct, is the product accused of infringing the '731 patent), they may undermine and challenge Bone's testimony on cross examination; at this time, the Court finds Bone's testimony to be rooted on reliable legal standards and methods to survive a motion for exclusion. See *Gayton v. McCoy*, 593 F.3d 610, 616 (7th Cir. 2010) ("Determinations on admissibility should not supplant the adversarial process; 'shaky' expert testimony may be admissible, assailable by its opponents through cross-examination.").

C. Conclusion

For the foregoing reasons, Defendant's Motion to Exclude Plaintiffs' Damages Expert, John Bone, (ECF No. 760), is **denied**.

heavily influenced by other groups (such as purchasing administrators), (ECF No. 761-44 at 11), this alone does not render the survey sample unreliable. Of course, other groups may influence the purchasing decision. But the end user of these hemostatic clips, the physicians, will undoubtedly have a major, if not the most significant, role in choosing which clips to purchase.

V. Motion to Exclude Defendant's Damages Expert, Vincent Thomas

Plaintiffs seek exclusion of Defendant's Damages Expert, Vincent Thomas, for three reasons: (1) Thomas improperly analyzed the first *Panduit* factor, rendering his testimony on the factor unreliable; (2) Thomas's analysis under the second *Panduit* factor is unreliable due to speculation; and (3) Thomas's analysis under the first *Georgia-Pacific* factor improperly relies on licensing agreements that are not economically comparable to this case, rendering his testimony unreliable.

A. *Panduit* Factor One

Plaintiffs argue that Thomas's opinion as to the first *Panduit* factor, demand for the patented product, relies on the wrong legal standard. Specifically, they point to Thomas's rebuttal expert report as exemplary of the deficiency in his testimony. In that report, Thomas begins by correctly outlining the four factors of the *Panduit* test, and explicitly as to factor one, he correctly states that it consists of the demand for the patented *product*. (ECF No. 784-1 at 5–6.) The section is then broken down into four subsections, with each section seeming to correspond to each *Panduit* factor. (*Id.* at 6–11.) However, the first section, corresponding to the first *Panduit* factor, is titled "Demand for the Patented *Features*." (*Id.* at 6 (emphasis added).) And the ensuing paragraphs focus on the demand of patented features, namely an "open/close capability" (which Thomas argues is not a patented feature at all). (*See, e.g.*, ECF No. 753-1 at 8 (discussing Bone's "failure" to properly target his analysis to the patented aspects of the patents-in-suit).)

As the Court has already noted, when it comes to *Panduit* factor one, the Federal Circuit has squarely rejected Thomas's premise. *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1330 (Fed. Cir. 2009) (citation omitted) ("All that the first factor states, and thus requires, is 'demand for the patented product.' . . . This factor does not require any allocation of consumer demand among the various limitations recited in a patent claim."). Defendant acknowledges this, and rather than dispute the law, argues that this section of Thomas's rebuttal was actually dealing with the *second Panduit* factor. (See ECF No. 772 at 9.)

Accepting Defendant's proposition about Thomas's report as true, this means that no section of the report rebuts Bone's analysis of the first *Panduit* factor. And in any event, Thomas has already effectively admitted that the first *Panduit* factor favors Plaintiffs. When asked whether there has been demand for the Instinct since it launched in the market, Thomas responded affirmatively. (See ECF No. 753-2 at 11.) He did the same when asked about demand of the Instinct Plus. (*Id.* at 13.) Further, contrary to Defendant's understanding of the law, the Instinct and Instinct Plus, as the alleged infringing devices, qualify as the "patented product" under *Panduit* factor one based on Federal Circuit precedent. *DePuy Spine*, 567 F.3d at 1330 (quoting *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1548–49 (Fed. Cir. 1995)) ("[T]he first *Panduit* factor simply asks whether demand existed for the 'patented product,' i.e., a product that is 'covered by the patent in suit' or that 'directly competes with the infringing device.>"). The Instinct and Instinct Plus meet this definition.

Thus, Because Defendant now argues that Thomas's "patented features" section of his report actually corresponded to the second *Panduit* factor, and because Thomas himself concedes demand for the patented product at all relevant times, the Court **excludes** Thomas's testimony as to *Panduit* factor one.

B. *Panduit* Factor Two

Plaintiffs also argue that a portion of Thomas's *Panduit* factor two analysis is conclusory and unhelpful and should therefore be excluded. Defendant responds that the burden for the issue was on Plaintiffs' expert, Bone. Because Defendant misinterprets the law, the pertinent portions of Thomas's testimony are excluded.

Panduit factor two requires a showing of an absence of acceptable non-infringing substitutes. Defendant is correct that the burden is *initially* on the *patentee* to make this showing. (See ECF No. 754 at 8.) But, once the patentee analyzes the possible substitutes *on the market* and finds that none are available non-infringing alternatives for the alleged infringer, an inference of unavailability of an acceptable non-infringing alternative arises; the burden then shifts to the accused infringer to overcome this inference of unavailability:

When an alleged alternative is not on the market during the accounting period, a trial court may reasonably infer that it was not available as a non-infringing substitute at that time. . . . The accused infringer then has the burden to overcome this inference by showing that the substitute was available during the accounting period. . . . Mere speculation or conclusory assertions will not suffice to overcome the inference.

Grain Processing Corp. v. Am. Maize-Prods. Co., 185 F.3d 1341, 1353 (Fed. Cir. 1999) (citations omitted); *see also id.* (emphasis added) ("Acceptable substitutes that the infringer proves were available during the accounting period can preclude or limit

lost profits; substitutes only *theoretically possible* will not."); *DePuy Spine*, 567 F.3d at 1331 ("However, because Medtronic [the accused infringer] did not actually have a non-infringing substitute 'on the market' during the relevant accounting period, it was Medtronic that bore the burden of overcoming the inference of unavailability.").

In this case, Bone properly met his initial burden for the second *Panduit* factor; it is Thomas's rebuttal that is conclusory and unhelpful to the trier of fact, therefore warranting exclusion. Bone analyzed available alternatives *on the market* that could be available to Defendant and concluded there were none. (*See generally* ECF No. 761-33 at 40–56.) Specifically, he focused on Defendant's early generation product, the TriClip, and discussed why he did not believe it was an acceptable non-infringing alternative. (*Id.*) To the extent there is an alternative that is not on the market, the Court, per Federal Circuit precedent, may infer that it is *not* an available, non-infringing alternative for Defendant. Defendant then bears the burden of overcoming this inference.

But in his report, Thomas does next to nothing to overcome this inference. He spends a paragraph discussing how Defendant has, in the past, made design changes in as little as several months, (ECF No. 753-1 at 11–12), without providing any analysis on why this means a non-infringing alternative design was available to Defendant. Thomas then points to other competitor products on the market (from some competitors that Plaintiffs have also sued and settled with) as an indication that having an alternative non-infringing design is feasible; but this opinion is not helpful on this issue. Thomas does not indicate how these other designs would be

available to Defendant or why some of these designs are even non-infringing; any analysis of the second *Panduit* factor is missing. Simply put, Thomas fails to identify any specific alternative designs that would have been *available* to Defendant, stating in conclusory fashion that "[i]t is reasonable to assume Cook Medical would reenter the market with a non-infringing alternative product as well." (*Id.* at 12.) An assumption is not enough. Experts of accused infringers in district court cases where *Panduit* factor two is at issue regularly identify *specific* alternative designs, as Thomas needed but failed to do here. *See, e.g., LaserDynamics, Inc. v. Quanta Comput., Inc.*, No. 2:06–CV–348, 2011 WL 197869, at *1 (E.D. Tex. Jan. 20, 2011) (noting that the defendant's expert identified four prior-art patents that disclose alternative designs); *AU New Haven, LLC v. YKK Corp.*, 15-CV-3411 (GHW)(SN), 2019 WL 1254763, at *20 (S.D.N.Y. Mar. 19, 2019) (noting that the defendant's expert identified three specific zippers as alternative non-infringing designs).

Without identifying any alternative design in response to Bone's proper analysis, the jury would have no way of determining whether an alternative non-infringing design was available to Defendant during the damages period; Thomas's testimony is unhelpful and **excluded** on this issue. Specifically, the Court **excludes** paragraphs 80 and 81 of Thomas's Supplemental Rebuttal Expert Report.⁶ (ECF No. 753-1.)

⁶ Plaintiffs also seek exclusion of paragraphs 69–79 of the report (which the Court had discussed in the section on *Panduit* factor one) because Defendants had essentially argued that these paragraphs actually related to *Panduit* factor two. (ECF No. 785 at 18.) However, Plaintiffs provide no further explanation as to why the testimony in these paragraphs is inadmissible, and the Court finds that the subject matter (demand for patented *features*) is indeed relevant and useful in analyzing *Panduit* factor two. *See Mentor Graphics Corp. v. EVE-USA, Inc.*, 851 F.3d 1275, 1285–86 (Fed. Cir. 2017). These portions of Thomas's testimony are not excluded.

C. *Georgia-Pacific* Factor One

Plaintiffs lastly ask the Court to exclude a portion of Thomas's reasonable royalty analysis under factor one of *Georgia-Pacific*. Specifically, they argue that Thomas's reliance on BSC intracompany R&D agreements from 1998 (the "1998 Agreements") is unreliable and should be excluded. (ECF No. 754 at 19.)

The first *Georgia-Pacific* factor considers "[t]he royalties received by the patentee for the licensing of the patent in suit, proving or tending to prove an established royalty." *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970). In other words, parties often look to previous licensing agreements involving the patents-in-suit (or the claims-in-suit) to help inform the fact finder about a reasonable royalty rate in the present hypothetical negotiation (in this case, a hypothetical negotiation in 2014). The Federal Circuit has "stressed that comparisons of past patent licenses to the infringement must account for 'the technological *and economic differences*' between them." *Wordtech Sys., Inc. v. Integrated Networks Sols., Inc.*, 609 F.3d 1308, 1320 (Fed. Cir. 2010) (emphasis added) (quoting *ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 873 (Fed. Cir. 2010)). Plaintiffs argue that while Thomas may have provided a baseline *technological* comparison between the 1998 Agreements and the pertinent 2014 hypothetical negotiation, there was no analysis of any *economic* comparison between these scenarios; in other words, they argue that Thomas has provided no reason why R&D agreements between a parent company and its subsidiaries from 1998 would be considered as a "starting point" for reasonable royalty determinations in a

hypothetical licensing negotiation between that company and a competitor in 2014. The Court agrees; without any meaningful analysis on this front at all, Thomas's opinion on this issue is unreliable and must be excluded.

Defendant's reliance on *Bio-Rad Laboratories, Inc. v. 10X Genomics Inc.* for the proposition that the "degree of comparability [between the licensing agreement and the hypothetical negotiation] is a factual issue best addressed through cross examination" is unpersuasive. 967 F.3d 1353, 1374 (Fed. Cir. 2020) (citation omitted). Defendant is correct that the *degree* of comparability is a factual issue that should not bar admissibility. However, as the court in *Bio-Rad* noted, the district court in that case concluded that the expert had made a showing of "baseline comparability." *Id.* It is here that Defendant's expert, Thomas, has critically erred. Thomas has made a showing of "baseline comparability" as to *technological comparison*. (See ECF No. 753-1 at 16–17 (discussing how the agreements either involved the same products as those pertinent to the patents-in-suit or dealt with the research and development of those same products).) However, Thomas conducts no analysis whatsoever on *economic* comparability, instead simply making conclusory assertions that "[t]hese amounts [i.e., the rates from the 1998 Agreements] would have been considered by the parties during the hypothetical negotiation" without explaining why they would have been considered in a radically different situation between different parties almost twenty years later in 2014. (*Id.* at 19.) Relying on the Federal Circuit precedent discussed above, other district courts have excluded expert testimony in almost identical circumstances. *DataQuill Ltd. v. High Tech*

Comput. Corp., 887 F. Supp. 2d 999, 1023 (S.D. Cal. 2011) (excluding expert report where the expert had sufficient factual support for technological comparability but where the report appeared "to have no analysis at all of the economic differences between the 'significant patent agreements' and the license reached at the hypothetical negotiation."); *IP Innovation L.L.C. v. Red Hat, Inc.*, 705 F. Supp. 2d 687, 691 (E.D. Tex. 2010) (Rader, J.) (excluding expert testimony for relying on non-comparable licenses); *see also Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1316 (Fed. Cir. 2011) (citation omitted) (noting that when conducting an analysis under the first *Georgia-Pacific* factor, one cannot "rely on license agreements that were 'radically different from the hypothetical agreement under consideration' to determine a reasonable royalty"). Relying on the same law, the Court must exclude Thomas's testimony on this issue here as unreliable.

For the aforementioned reasons, the Court **excludes** the testimony found in paragraphs 128 through 135 of Thomas's Supplemental Rebuttal Expert Report, (ECF No. 753-1).

D. Conclusion

Plaintiffs' Motion to Exclude Defendant's Damages Expert, Vincent A. Thomas, (ECF No. 752), is **granted in part and denied in part**.

The Court **precludes** Thomas from testifying as to *Panduit* factor one. Further, the Court **excludes** the testimony found in paragraphs 80–81 and 128–35 of Thomas's Supplemental Rebuttal Expert Report, (ECF No. 753-1).

VI. Summary

Defendant's Motion to Exclude Plaintiffs' Technical Expert, Karl Leinsing, (ECF No. 735), is **granted in part and denied in part**. The pertinent portions of Leinsing's testimony to be **excluded** are the following: paragraphs 16, 19, 255–64, and 384 of his February 2022 report, (ECF No. 737-1); and paragraph 555 of his August 2017 report, (ECF No. 737-2).

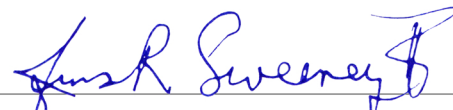
Defendant's Motion to Exclude Plaintiffs' Patent Law Expert, Stephen Kunin, (ECF No. 740), is **granted in part and denied in part**. Due to a lack of expertise on the issues, paragraphs 216–19 of Kunin's report are **excluded**.

Defendant's Motion to Exclude Plaintiffs' Damages Expert, John Bone, (ECF No. 760), is **denied**.

Plaintiffs' Motion to Exclude Defendant's Damages Expert, Vincent A. Thomas, ECF No. 752), is **granted in part and denied in part**. The Court **precludes** Thomas from testifying as to *Panduit* factor one and **excludes** the testimony found in paragraphs 80–81 and 128–35 of Thomas's Supplemental Rebuttal Expert Report, (ECF No. 753-1).

SO ORDERED.

Date:02/02/2023



JAMES R. SWEENEY II, JUDGE
United States District Court
Southern District of Indiana

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