

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 GROUP INCORPORATED and)	
COOK MEDICAL LLC,)	
)	
Defendants.)	

Order on Motions for Summary Judgment and Motion to Preclude

This is a patent infringement case. Before the Court is Defendants' Motion to Preclude Evidence and Untimely Theory Relied on by Plaintiffs in their Motion for Summary Judgment (hereafter, "Motion to Preclude"). (ECF No. 634.) Additionally, the Court will address Plaintiffs' and Defendants' Cross-Motions for Summary Judgment. (ECF Nos. 620 & 630.)

I. Background¹

Plaintiffs/Counterclaim Defendants Boston Scientific Corporation ("BSC") and Boston Scientific Scimed, Inc. ("BSSI") (collectively "Plaintiffs" or "Boston Scientific") brought this patent infringement action against Defendants/Counterclaim Plaintiffs Cook Group Incorporated ("CGI") and Cook Medical LLC (collectively with CGI,

¹ The Court finds that Plaintiffs' brief is not deficient. While Defendants correctly note that Plaintiffs' Statement of Material Facts is rather sparse, (ECF No. 633 at 20), Plaintiffs' brief cited to the record extensively for the Court. The Court will not dismiss Plaintiffs' summary judgment motion on this ground.

"Defendants" or "Cook"), in the District of Delaware in October of 2015. (ECF No. 1.) The three asserted patents are U.S. Patent No. 8,685,048 ("048 patent"), U.S. Patent No. 8,974,371 ("371 patent"), and U.S. Patent No. 9,271,731 ("731 patent") (collectively, the "Asserted Patents" or "patents-in-suit"). (ECF Nos. 451-2, 451-4, 451-5.) In 2016, Defendants filed several *Inter Partes* review ("IPR") petitions directed to the Asserted Patents. (ECF Nos. 74, 254.) In August of 2017, the District of Delaware granted Defendants' request to stay the case pending the IPRs. (ECF No. 304.) While stayed, the case was transferred to this Court. (ECF No. 316.)

Plaintiffs and Defendants are both major competitors in the medical device industry. The Asserted Patents are directed toward a reversibly closeable endoscopic hemostatic clip. (See ECF No. 451-2 at 2.) Such clips are used for treating gastrointestinal bleeding. (*Id.* at 39.) Plaintiffs assert seven claims across their three patents-in-suit against two of Defendants' products: (1) the Instinct and (2) the Instinct Plus (each an "Accused Product" and collectively the "Accused Products"). The following is a summary of the remaining claims asserted against the Accused Products: (1) Claims 3, 4, 7, and 14 of the '048 patent are asserted against both the Instinct and the Instinct Plus; (2) claim 13 of the '371 patent is asserted against both the Instinct and the Instinct Plus; and (3) claims 5 and 19 of the '731 patent are asserted against only the Instinct Plus. The parties have brought many arguments; the Court will address each in turn.

II. Defendants' Motion to Preclude Evidence

The Court will first address Defendants' Motion to Preclude, (ECF No. 634), in order to determine the scope of evidence that is available at the summary judgment stage. Defendants ask the Court to exclude from consideration on summary judgment the following: (1) Mr. Leinsing's opinions on cumulateness; (2) Mr. Lhymn's opinions on IPR estoppel; and (3) Plaintiffs' reliance on a "new" infringement theory for the "link" required by claims 3, 4, 7, and 14 of the '048 patent.

A. Mr. Leinsing's Opinions on Cumulateness

Defendants seek to exclude Leinsing's opinions regarding cumulateness between certain prior art devices and printed publications provided in support of Plaintiffs' arguments relating to IPR estoppel, arguing the opinions are untimely in violation of the Court's Case Management Plan and Fed. R. Civ. P. 26(a). (Defs.' Mot. to Preclude, ECF No. 636 at 9.) Per the Court's Case Management Plan, "[t]he party with the burden of proof as to any liability issue . . . shall serve the report required by Fed. R. Civ. P. 26(a)(2) on or before **January 11, 2022.**" (ECF No. 468 at 1, ¶ II.C.) "If a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was *substantially justified or is harmless.*" Fed. R. Civ. P. 37(c)(1). The arguments in this section can therefore be broken down into three parts: (1) whether Plaintiffs had the burden of proof on cumulateness (therefore requiring service by January 11, 2022) and, if so, (2)

whether their untimely expert report written by Leinsing was substantially justified or (3) harmless.

1. Burden of proof as to cumulateness

Plaintiffs and Defendants agree that Plaintiffs bear the ultimate burden of proof on Plaintiffs' IPR estoppel argument under 35 U.S.C. § 315(e). (ECF No. 636 at 10 (citing *Clearlamp LLC v. LKQ Corp.*, No. 12 C 2533, 2016 WL 4734389, at *9 (N.D. Ill. Mar. 18, 2016)); Pls.' Resp., ECF No. 672 at 13 (same).) Therefore, Plaintiffs needed to serve any expert reports related to their IPR estoppel argument by January 11, 2022. Rather than dispute this requirement, Plaintiffs instead attempt to distinguish cumulateness from IPR estoppel and suggest that they did not bear the burden of proof as to this issue. (ECF No. 672 at 13.)

The Court can quickly dismiss two arguments. First, Plaintiffs argue that Defendants' reliance on *Clearlamp* is inappropriate because that case did not address the issue of cumulateness of prior-art systems. (*Id.*) This is not correct. *See Clearlamp*, 2016 WL 4734389, at *8–10 (discussing cumulateness at length). Second, Plaintiffs argue that Leinsing "first needed to know the **particular structures** of the prior-art systems on which Nicosia was relying" before rendering an opinion on whether those structures were disclosed in a printed publication subject to IPR estoppel. (ECF No. 672 at 13 (emphasis in original).) But this argument has nothing to do with the burden of proof; rather, as Plaintiffs themselves seem to realize, it is more appropriate in determining whether the delay in serving the report

was *justified*. (See ECF No. 672 at 13–14 (discussing why Leinsing could not feasibly address cumulateness in his initial report until reading Nicosia's report).)

Plaintiffs' attempt to distinguish cumulateness from IPR estoppel fails; cumulateness is not a separate doctrine from IPR estoppel. Rather, cumulateness is one avenue that a party can use to argue IPR estoppel. IPR estoppel, codified under 35 U.S.C. § 315(e)(2), states that a "petitioner in a post-grant review of a claim in a patent . . . may not assert . . . in a civil action arising in whole or in part under section 1338 of title 28 . . . that the claim is invalid on any ground that the petitioner raised or reasonably could have raised during that post-grant review." In other words, the IPR estoppel doctrine seeks to prevent a defendant from making the same invalidity arguments they previously made (or reasonably could have made) in a prior IPR proceeding. Cumulateness is the idea that a "petitioner cannot put forth invalidity arguments in litigation that rely solely upon patents or printed publications that could have been raised in the IPR, and then claim that IPR estoppel does not apply because these printed materials reflect or represent a prior art product." *Medline Indus., Inc. v. C.R. Bard, Inc.*, No. 17 C 7216, 2020 WL 5512132, at *5 (N.D. Ill. Sept. 14, 2020) ("The IPR petitioner in that situation is improperly attempting to disguise a ground that could have been raised during the IPR as one that could not have been raised."); *see also Vaporstream, Inc. v. Snap Inc.*, No. 2:17-cv-00220-MLH (KSx), 2020 WL 136591, at *23 (C.D. Cal. 2020 Jan. 13, 2020) (citation omitted) ("[I]f a patent challenge is simply swapping labels for what is otherwise a patent or printed publication invalidity ground in order to "cloak" its prior art ground and "skirt"

estoppel,' then § 315(e)(2) estoppel still applies."). Thus, because cumulateness is a way for a patentee to show that a petitioner is estopped from presenting certain invalidity arguments at the district court based on prior art systems and devices, cumulateness and IPR estoppel are inextricably linked, and as such, the burden of proof is on the patentee (here, Plaintiffs).

Therefore, per the Court's Case Management Plan, Plaintiffs had to serve any report with arguments on cumulateness on or before January 11, 2022. They did not. The Court must next determine whether this delay was justified or harmless.

2. Whether the delay in serving Leinsing's report was justified

Plaintiffs argue that the delay in Leinsing's report was justified because Defendants' invalidity contentions, served on December 27, 2021, "failed to identify the structures of the prior-art systems upon which [Defendants] would rely." (ECF No. 672 at 13–14.) This, too, is incorrect.

The Court fails to find, nor have Plaintiffs pointed to, any examples of "particular structures" that Nicosia identified in his report that were not likewise identified in Defendants' earlier invalidity contentions. (*See id.*) Plaintiffs repeatedly assert that Defendants' contentions lacked references to these "particular structures," and Leinsing himself makes a general and vague claim that the contentions "often do not identify the particular features or structure of the device" upon which Defendants rely for their invalidity arguments. (Leinsing Report, ECF No. 621-77 at 19.) Plaintiffs thus argue that Leinsing "needed to know" the specific structures Nicosia would be relying on in order to analyze whether those structures were disclosed in a

printed publication subject to IPR estoppel; in other words, he simply could not have provided his cumulativeness opinion based on Defendants' invalidity contentions alone. (ECF No. 672 at 13–14.)

Upon examining the opinion ultimately given by Leinsing and the structures in fact relied on in support, the Court fails to see how this is the case. As an example, an analysis of Leinsing's very first argument on cumulativeness, the Marlow Nu-Tip, is illustrative. Defendants rely on the Marlow Nu-Tip to allegedly invalidate the '371 and '731 patents. For instance, they argue that claim 13 of the '371 patent would have been obvious in view of the Marlow Nu-Tip in combination with the Adams '245 patent. (Defs.' Contentions, ECF No. 548 at 94.) Leinsing then argues that each of the Marlow Nu-Tip features relied on by Defendants is cumulative of features described in printed publications that are estopped. (*See* ECF No. 621-77 at 19–20.) Leinsing cites to both Nicosia's report *and* Defendants' contentions for this opinion. (*Id.*) But BSSI points to no evidence supporting its assertion that Leinsing could not have reached his conclusions without Nicosia's report. In his report, Leinsing defines the particular features that Defendants rely on (which he argues are all cumulative) as the "handle, push rod, capsule, clip assembly, control element, sheath, ball and socket, end effector designed to detach, and insertion and expanded configurations." (*Id.* at 19.) But these features were *not* missing from Defendants' contentions. It is true that Nicosia's report discloses these features. (Nicosia Report, ECF No. 584-1 at 338–39.) However, so do Defendants' contentions. In fact, Defendants' contentions provide the exact features that Leinsing discusses in his cumulativeness opinion.

(*See, e.g.*, ECF No. 548 at 94 (discussing the Marlow Nu-Tip comprising "a capsule, and a clip assembly housed within the capsule for movement between an insertion configuration and an expanded configuration); ECF No. 548 at 95 (displaying a diagram and discussing the features of "a control element removably connected to the clip assembly via a ball-and-socket connection, and a sheath extending from a proximal to a distal end and covering a portion of the control element").) This analysis holds true for Leinsing's cumulativeness opinions on other references as well. (*E.g., compare* ECF No. 621-77 at 25–26 *with* ECF No. 547 at 56–58 *and* ECF No. 584-1 at 116–20 (showing Leinsing's conclusion that features of the Olympus HX-2, relied on by Defendants, are cumulative, wherein said features (such as a covering tube, coil pipe, lock sleeve, etc.), are fully disclosed in Defendants' contentions).)

Thus, the Court sees no reason that Leinsing could not have provided his cumulativeness opinion on January 11, 2022, by relying solely on Defendants' contentions. Plaintiffs have not explained, nor has the Court found, a reason that Nicosia's report would be needed for Leinsing's opinion; the delay in serving Leinsing's opinion is therefore unjustified.

3. Whether the delay in serving Leinsing's report was harmless

"The determination of whether a Rule 26(a) violation is justified or harmless is entrusted to the broad discretion of the district court." *Mid-Am. Tablewares, Inc. v. Mogi Trading Co., Ltd.*, 100 F.3d 1353, 1363 (7th Cir. 1996). In determining whether a party's failure to comply with a discovery deadline under Fed. R. Civ. P. 37 is harmless, the Seventh Circuit considers four factors: "(1) the prejudice or surprise to

the party against whom the evidence is offered; (2) the ability of the party to cure the prejudice; (3) the likelihood of disruption to the trial; and (4) the bad faith or willfulness involved in not disclosing the evidence at an earlier date." *David v. Caterpillar, Inc.*, 324 F.3d 851, 857 (7th Cir. 2003). In examining these factors, the Court finds that Plaintiffs' delay was harmless.

Plaintiffs argue that Defendants are not prejudiced because Leinsing's report was served on February 8, 2022, more than a month before the close of liability discovery on March 11, 2022, and almost three months before Defendants' opening dispositive motion was due. (ECF No. 672 at 15.) Arguably, however, any prejudice to Defendants arises from the fact that Leinsing's cumulativeness opinion was not presented until the last possible day for service of expert reports; thus, Defendants could not respond with a rebuttal expert report of its own within the original Case Management Plan. (See ECF No. 468 at 1.) But Defendants still had the opportunity to move for a supplemental round of expert reports and could still depose Leinsing in any event. See *Uncommon, LLC v. Spigen, Inc.*, 926 F.3d 409, 419 (7th Cir. 2019) (applying the *Caterpillar* factors) ("Rule 37 . . . provides recourse for parties actually harmed by a litigant's noncompliance with disclosure obligations. It does not safeguard a party's decision to sense an error, seize on it, and then, when it is resolved, claim incurable harm in the face of apparent remedies.")

In fact, Defendants did depose Leinsing on March 4; yet they did not ask Leinsing a single question about his cumulativeness opinion. (See Defs.' Reply, ECF No. 704 at 13–15.) Even if deposing Leinsing by itself is not a complete "cure" for any

prejudice, (*id.* at 15), it would be a start. *See, e.g., Endotach LLC v. Defendants Med. Inc.*, No. 1:13-cv-01135-LJM-DKL, 2017 WL 3873693, at *9 (S.D. Ind. Sept. 5, 2017). Also, Defendants, in early March, *did* move for a supplemental round of expert reports, albeit for a different issue, which Plaintiffs did not oppose and which the Court granted. (ECF No. 613.) Yet, Defendants did not file any motions or make any arguments to the Court or Plaintiffs as to their disapproval of Leinsing's cumulativeness opinion until this Motion to Preclude was filed on May 6. (ECF No. 634.) Defendants knew they could move for a supplemental round of expert reports, and they could have addressed the untimely report during Leinsing's deposition, but instead made no attempts to address their issues with Leinsing's opinions at all until this stage. In any event, and arguments concerning burden shifting notwithstanding², (ECF No. 704 at 14), any prejudice was not only within Defendants' ability to cure but was harmless upon consideration of the other *Caterpillar* factors. *See Uncommon*, 926 F.3d at 419 ("There was no surprise to [the prejudiced party] and no delay in the proceedings, and while there was likely some prejudice, it was neither unforeseeable nor incurable—even if the cure was not [the prejudiced party]'s strategic preference.").

² Defendants cite to several cases stating that the non-compliant party has the burden of showing that their violation was justified or harmless; in other words, the non-compliant party has the burden of showing that the *Caterpillar* factors weigh in their favor. (*Id.*) This is all accurate; however, Defendants then make an erroneous logical jump, stating that because this burden is on the non-compliant party, it is the non-compliant party that has the burden to cure the prejudice. (*Id.*) That is simply not the case. The non-compliant party has the burden to show that the prejudiced party *had an ability to cure the prejudice*; the non-compliant party is not expected to cure the prejudice themselves.

The third and fourth *Caterpillar* factors likewise favor a finding that Plaintiffs' delay was harmless. Turning to the "likelihood of disruption to the trial" factor, Leinsing's opinion was served a year before trial, which, as noted, provided ample time both to seek an additional round of expert reports and to depose Leinsing on the subject without disrupting the trial.

As to the fourth *Caterpillar* factor, there is no evidence of "bad faith or willfulness" on Plaintiffs' part. Concepts of "willfulness" and "bad faith" usually require "intentional or reckless behavior." *Uncommon*, 926 F.3d at 418 (citing *Brown v. Columbia Sussex Corp.*, 664 F.3d 182, 191 (7th Cir. 2011)). Rather, Defendants argue that Plaintiffs must have known that their expert opinions related to IPR estoppel had to be served by January 11 because their other report related to IPR estoppel (Lhymn's report on skilled searcher opinions) was properly served on that date. (ECF No. 704 at 15.) While perhaps true, Plaintiffs' conduct does not rise to intentional or reckless behavior. Plaintiffs have had issues with Defendants' contentions well before this Motion to Preclude, and they reasonably reached out to Defendants regarding their concerns. (ECF No. 573-7 at 9–12.) When confronted about their contentions, Defendants told Plaintiffs that Nicosia's report would "clarify" their concerns. (*Id.* at 2.) Plaintiffs' decision to wait for Nicosia's report before supplying Leinsing's cumulativeness opinion, while perhaps not free from fault does not rise to the level of intentional or reckless behavior considering the surrounding circumstances and communications between the parties.

In considering all of the *Caterpillar* factors, the Court finds that Plaintiffs' delay in providing Leinsing's cumulativeness opinion was harmless. Accordingly, Defendants' Motion to Preclude, (ECF No. 634), as to Leinsing's cumulativeness opinion is **denied**.

B. Mr. Lhymn's Opinions on IPR Estoppel

Defendants next seek to preclude Lhymn's opinions regarding IPR estoppel. Specifically, they ask the Court to exclude (1) opinions regarding Defendants' purported knowledge of the prior art and (2) opinions regarding what a skilled searcher "could" possibly find. The Court will address these requests in turn.

1. Lhymn's opinions on Defendants' knowledge of the prior art

Defendants argue that Lhymn's opinions on Defendants' purported knowledge of certain prior art constitute inadmissible "state of mind" testimony. (ECF No. 636 at 13.) Expert testimony is appropriate where "scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue." *Huey v. United Parcel Serv., Inc.*, 165 F.3d 1084, 1087 (7th Cir. 1999) (quoting Fed. R. Evid. 702). In Plaintiffs' own words, Mr. Lhymn is an expert on "prior-art invalidity searches." (ECF No. 672 at 19.) Accordingly, the Court finds that his "knowledge, skill, experience, training, or education," Fed. R. Evid. 702, does qualify him to opine on what prior art is and what has previously been identified as prior art, either in the entity's own related prosecution histories or in its invalidity contentions. This is pure knowledge, though. Such knowledge does not cross over into state of mind, which might be, for example, why a piece of prior art known to an

entity is not disclosed to the USPTO during prosecution or to the PTAB during an IPR. That being said, the court does not need such expert testimony to determine this knowledge because it is clear from the record and the law. *See Litton Sys., Inc. v. Honeywell, Inc.*, 140 F.3d 1449, 1465 (Fed. Cir. 1998) ("[T]he prosecution history is objective evidence of what knowledge the applicant has of the art."); *Wi-LAN Inc. v. LG Elecs., Inc.*, 421 F. Supp. 3d 924, 925 (S.D. Cal. 2019) ("Several district courts have held that the identification of prior art in invalidity contentions generated prior to the filing of the IPR petition is sufficient to establish as matter of law that the accused infringer knew of those prior art references."); *see also Avenatti v. Gree USA, Inc.*, No. 2:20-cv-00354-JPH-MJD, 2022 WL 3134425, at *2 (S.D. Ind. Aug. 5, 2022) (citation omitted) ("The 30(b)(6) designee 'must not only testify about facts within the corporation's knowledge, but also its subjective beliefs and opinions,' as well as the organization's 'interpretation of documents and events.'"). Also, armed with the knowledge of the references cited in Defendants' related prosecution histories, for example, a skilled searcher such as Lhymn can opine as to what he would consider to be related art in order to develop a prior art search strategy. (ECF No. 672 at 19; ECF No. 621-33 at 14–15, 70-71.) Namely, he is qualified to address under 35 U.S.C. § 315(e)(2) whether a piece of prior art was one which "a skilled searcher conducting a diligent search reasonably could have been expected to discover." *Wi-LAN Inc. v. LG Elecs., Inc.*, 421 F. Supp. 3d 911, 924 (S.D. Cal. 2019) (citations omitted). Still, Defendant's motion to exclude is granted to the extent the court will not consider any state of mind opinions. *See Lanard Toys Ltd. v. Anker Play Prods., LLC*, CV 19-4350-

RSWL-AFMx, 2020 WL 6873647, at *7 (C.D. Cal. Nov. 12, 2020) (citations omitted) ("Courts routinely exclude as impermissible expert testimony as to intent, motive, or state of mind.").

To be clear, the Court is merely excluding Lhymn's opinions that Defendants "knew" of the existence of certain prior art; the remainder of Lhymn's opinion (i.e., his conclusions as to what a diligent searcher reasonably could have found) remains admissible. Accordingly, Defendants' Motion to Preclude is **granted** to this extent.

2. Lhymn's skilled searcher standard

Defendants next object that Lhymn relied on an incorrect legal standard for the "skilled searcher" prong of IPR estoppel; therefore, Defendants argue that his opinion is unreliable and will not assist the trier of fact. (ECF No. 636 at 16.)

Defendants and Plaintiffs agree on the same *overarching* legal standard. To review, IPR estoppel prevents a petitioner in a post-grant review from asserting in a civil action that a patent claim is "invalid on any ground that the petitioner raised or *reasonably* could have raised during that post-grant review." 35 U.S.C. § 315(e)(2) (emphasis added). In interpreting the word, "reasonably," in relation to the discovery of prior art, many district courts have adopted the standard articulated in *Clearlamp*. There, relying on the legislative history of § 315(e)(2), the court stated: "Adding the modifier 'reasonably' ensures that could-have-raised estoppel extends *only to that prior art which a skilled searcher conducting a diligent search **reasonably could have been expected to discover.***" *Clearlamp*, 2016 WL 4734389, at *8 (emphasis added); *see also Pavo Sols., LLC v. Kingston Tech. Co.*, No. 8:14-cv-01352-JLS-KES,

2020 WL 1049911, at *4 (C.D. Cal. Feb. 18, 2020) (adopting the same standard). The Court also finds this standard persuasive.

However, Defendants argue that Lhymn then applied this "skilled searcher" standard improperly. Specifically, Defendants assert that Lhymn relied on an improper reasonableness standard when considering what a skilled searcher "reasonably could" have been expected to discover. (ECF No. 636 17–18.) In this context, Defendants state that *Clearlamp's* standard uses "would" rather than "could." (*Id.* (citing *Clearlamp*, 2016 WL 4734389, at *9 (emphasis added) ("One way to show what a skilled search **would** have found would be (1) to identify the search string and search source that **would** identify the allegedly unavailable prior art and (2) present evidence, likely expert testimony, why such a criterion **would** be part of a skilled searcher's diligent search."))).) Defendants argue that "would" crucially and properly contemplates the reasonableness standard embedded within the phrase, "reasonably could have been expected to discover." This argument was explained in *Palomar*, a case on which Defendants chiefly rely:

To be clear, the standard cannot be that a reasonable search could have, or might have, discovered the disputed reference. It is almost always possible to construct a search scenario—particularly with the benefit of hindsight—under which a skilled searcher could locate a reference with a relatively small number of steps. Instead, the standard must account for the fact that the relevant databases are huge, the technology is often complex, and there are almost infinite ways to construct a search. The touchstone is reasonableness, not perfection. Accordingly, the appropriate standard for the objective prong is one of probability, not possibility: that is, whether it is more probable than not that a skilled searcher conducting a diligent search reasonably could have been expected to discover the disputed reference.

Palomar Techs., Inc. v. MRSI Sys., LLC, No. 18-10236-FDS, 2020 WL 2115625, at *3 (D. Mass. May 4, 2020). Defendants then direct the Court's attention to Lhymn's report, wherein he states the following:

I further understand from counsel that one way of showing a skilled searcher's diligent search is to identify the relevant search string and search source that **could** identify the allegedly unavailable prior art and explain why such a criterion **could** be part of a skilled searcher's diligent search.

ECF No. 621-33 at 12 (emphasis added) (noting the difference between Lhymn's articulation compared to the court in *Clearlamp*). And therein lies Defendants' principal grievance. Defendants urge that Lhymn's misstatement of the *Clearlamp* standard verbatim (namely, "could" vs. "would") renders the standard inaccurate and results in an unreliable and useless report written by Lhymn. The Court cannot agree.

The Court is not minimizing Defendants' argument. But Defendants' emphasis on this distinction is not as significant as they suggest. First, Defendants assert that Plaintiffs make misleading arguments regarding the use of "could" because they point back to the "overarching language of the estoppel statute," (ECF No. 704 at 19); in other words, Defendants argue that Plaintiffs are relying on the following phrase out of § 315(e)(2) to support their "could" standard: "invalid on any ground that the petitioner raised or *reasonably could have* raised during that post-grant review." This, of course, would not be proper as this is the principal estoppel standard; but this is not what Plaintiffs do. Rather, Plaintiffs (and Lhymn) cite to the *Clearlamp* standard, which applies the IPR estoppel statute to prior art references. (ECF No. 672 at 24 (emphasis in the original) ("IPR estoppel applies to references that were

known to the petitioner or *reasonably could have been discovered by a skilled searcher conducting a diligent search.*"); *see also* ECF No. 621-33 at 12 (stating this same standard.) Clearly, this standard uses a "reasonably *could*" term.

Defendants' argument is best explained by the passage cited to above from *Palomar*. *See* 2020 WL 2115625, at *3 ("To be clear, the standard cannot be that a reasonable search could have, or might have, discovered the disputed reference. It is almost always possible to construct a search scenario—particularly with the benefit of hindsight—under which a skilled searcher could locate a reference."). It would make no sense for IPR estoppel to preclude the use of any prior art that "could" have been discovered with a diligent search. As the court in *Palomar* notes, this would preclude *every* reference. But the *Clearlamp* standard takes this into account by adding the term "*reasonably*" before "could." This, by itself, limits the inquiry to searches that would have been "reasonable" to make. Defendants are placing too much weight on *Clearlamp*'s subsequent two-part inquiry regarding "one [of the] way[s]" to show what a skilled searcher "would have found." *Clearlamp*, 2016 WL 4734389, at *9. The court there does not emphasize any distinction between the overarching standard and their sudden use of the word "would." In fact, contrary to Defendants' argument, the court in *Clearlamp* uses "would" and "could" interchangeably. For example, a deep dive into the very paragraph where the court briskly provides their two-part skilled search inquiry (that uses "would") is illustrative. There, the court begins the paragraph by stating, "[i]n accordance with the § 315(e)(2) standard, the [relevant prior art reference] can be used in civil

litigation only if it **could** not have been found by a skilled searcher performing a diligent search." *Id.* The court did not say "reasonably could" nor did it say "would." After stating the overarching standard (which includes "reasonably could" within it), the *Clearlamp* court did not need to rearticulate the standard verbatim throughout its opinion. Reasonableness is clear on the face of the standard.

The explanatory passage from *Palomar* also supports this conclusion. After going through their discussion of the *Clearlamp* standard and emphasizing the importance of reasonableness, the *Palomar* court concludes with the following: "Accordingly, the appropriate standard for the objective prong is one of probability, not possibility: that is, whether it is more probable than not that a skilled searcher conducting a diligent search reasonably **could** have been expected to discover the disputed reference." *Palomar*, 2020 WL 2115625, at *3 (emphasis added). The *Palomar* court even implicitly equates "reasonably could" with "would." First, the court adopts and describes *Clearlamp*'s standard as one of two prongs: a subjective prong, i.e., "(1) the IPR petitioner actually knew of the reference" and an objective prong, i.e., "(2) a skilled searcher conducting a diligent search reasonably **could** have been expected to discover the reference." *Palomar*, 2020 WL 2115625, at *3 (emphasis added). But only a few sentences later, the court refers to the objective prong inquiry as follows: "**would** a reasonable search have discovered the reference?" *Id.* (emphasis added). Ultimately, what is clear is that the standard must contemplate a *reasonable* search. It is not dispositive whether the standard uses "could" or "would." The overall standard uses "reasonably could," and so long as an expert's opinion is legitimately

considering the reasonableness and probability of a prior art search occurring, the expert is relying on the proper legal standard; on the other hand, if the expert merely opines that a prior art reference could possibly be found and provides little to no support showing why this search would be reasonable, then the opinion relies on an incorrect standard and is impermissible.

Defendants' arguments to the contrary notwithstanding, their cited cases do not take heed of a "would" vs. "could" distinction. To summarize this analysis in different terms, when courts use "could," they are implicitly referring to "*reasonably* could" from the *Clearlamp* standard. *See, e.g., Clearlamp*, 2016 WL 4734389, at *9. While "would" likewise properly considers this reasonableness requirement, it is not a necessary term for the standard.

Examining Lhymn's report, the Court can confirm that Lhymn relied on the proper legal standard for his opinion. First, in his "Legal Standards" section, Lhymn begins by properly referencing the IPR estoppel statute under §315(e)(2). (ECF No. 621-33 at 12.) Next, Lhymn outlines the proper *Clearlamp* standard that he must use in his analysis. (*Id.* (emphasis added) ("I further understand from counsel that a petitioner reasonably could have raised a ground and/or reference during *inter partes* review when . . . a skilled searcher conducting a diligent search ***reasonably could have been expected to discover the ground and/or reference.***".)) Finally, Lhymn refers to one of the ways that an expert can show a skilled searcher's diligent search. (*Id.* ("[O]ne way of showing a skilled searcher's diligent search is to identify the relevant search string and search source that could identify the allegedly unavailable

prior art and explain why such a criterion could be part of a skilled searcher's diligent search.".) As discussed, it is this paragraph that has drawn Defendants' objection because Lhymn says "could" rather than "would" as is otherwise stated in *Clearlamp*. But for the reasons discussed above, the Court will not dispose of Lhymn's entire opinion for this turn of phrase; the proper legal standard was already articulated in his report, and more importantly, Plaintiffs have shown that Lhymn was making his findings based on what a diligent searcher "*reasonably* could" find. The Court will do the same. Lhymn did not make unsupported, barebones assertions that a prior art reference could be found by a diligent searcher. Rather, Lhymn identified numerous reasonable and commonplace techniques that would be used by skilled and diligent searchers to discover prior art references. (*See* ECF No. 621-33 at 13–21.) Throughout his opinion, Lhymn used clear language indicating the reasonableness and probability of his methods. (*See, e.g., id.* at 23 (emphasis added) ("[A] skilled searcher during the Timeframe could have *readily* identified [the prior art]."); *id.* at 48 (emphasis added) ("A skilled searcher could *easily* complete this search."); *id.* at 81 (emphasis added) ("Olympus is a *well-known and prolific* assignee in the endoscope arts.")) These were not mere opinions of "possibility" as Defendants would suggest; Lhymn provided an account of what a diligent searcher "reasonably could" find, and that is all that is required.

Defendants take issue with the type of search terms, sources, claims, and classifications used by Lhymn in support of his opinion, (*see* ECF No. 704 at 23–24), but as the Court just discussed, Lhymn adequately considers reasonableness in his

report as required by the standard; the report's level of persuasiveness is not at issue at this stage. The Court will not exclude an entire expert opinion simply because the opposing party disagrees with its conclusions or did not want to "waste resources" deposing the expert. (*Id.* at 25.)

For the aforementioned reasons, the Court **denies** Defendants' Motion to Preclude, (ECF No. 634), with regards to Mr. Lhymn's skilled searcher opinions.

C. Plaintiffs' Allegedly New "Link" Infringement Theory

Defendants next argue that Plaintiffs present a new and improper argument about how the Accused Products meet the "link" limitation of claim 1 of the '048 patent. (ECF No. 636 at 21.) Specifically, Defendants argue that Plaintiffs, in their summary judgment brief, assert that "***the driver alone***" constitutes claim 1's "link." (*Id.* (emphasis in original); *see also* ECF No. 622 at 16–17.) The language Defendants refer to from Plaintiffs' brief is the following: "The proximal end of the driver . . . includes a socket formed by two driver legs, which is a link that couples the end of the drive wire to the clip." (ECF No. 622 at 16.) Defendants argue that Plaintiffs' previous contentions and expert report identified the "link" as being formed by the "junction" or "coupling" of "***both the drive wire and driver***" rather than just the driver alone. (ECF No. 636 at 22 (emphasis in original).)

Plaintiffs disagree, asserting that the infringement theory in their summary judgment motion was disclosed both in their infringement contentions (2017 and 2021) and in Leinsing's infringement reports (2017 and 2022). (ECF No. 672 at 28-

31.) They further argue that Defendants' contention is "belied by Nicosia's deposition testimony." (*Id.* at 23.)

While Plaintiffs have perhaps been inconsistent in their theory throughout the long pendency of this case—(*compare, e.g.,* Pls.' Contentions, ECF No. 544-1 at 42 (emphasis added) ("The [Accused Product] has a link (*e.g.,* the *coupling* of the distal hook of the 'drive wire' and the 'driver legs' of the 'driver')."); Leinsing Report, ECF No. 621-4 at 77 (emphasis added) ("This *junction* between the drive wire and proximal end of the driver operates as a link.") *with, e.g.,* ECF No. 621-4 at 101 (emphasis added) ("Accordingly, *the link (the proximal end of the driver)* is not integral with the control wire (drive wire) or the clip (jaws)."); ECF No. 544-1 at 48 ("Q: Is it correct for me to say that the driver of the [Accused Product] links the drive wire . . . to the jaw . . . prior to deployment of the clip? A: Yes.))—this does not rise to the level of a new theory much less an ambush as Defendants allege. (*See* ECF No. 636 at 22 (citing *Rowe Int'l Corp. v. Ecast, Inc.*, 586 F. Supp. 2d 924, 934 (N.D. Ill. 2008)).) Indeed, Defendants' own expert, Nicosia, noted the inconsistency: "[T]he term 'link' itself is not very clear. . . . '[L]ink' has been applied as a junction between two components. . . . Mr. Leinsing has applied it also as a structure. At least that's my understanding of [Leinsing's] opinion, is that . . . the driver is the link, and then, in other places, the link is the junction." (ECF No. 671-6 at 15–16.).

Defendants' frustration with Plaintiffs' sometimes confusing descriptions of "link" aside, referring to the driver as the "link" *by itself* is not a "new" infringement theory. In short, Defendants have not been ambushed by a new theory that they have not

before encountered (indeed, their own expert at times interpreted Plaintiffs' theory to designate the driver alone as the "link"). Accordingly, Defendants' Motion to Preclude, (ECF No. 634), is **denied** as to Plaintiffs' new "link" infringement theory. The Court will consider Plaintiffs' argument on this issue at the summary judgment stage.

D. Summary

For the reasons discussed above, Defendants' Motion to Preclude, (ECF No. 634), is **granted in part and denied in part**.

Defendants' Motion as to Leinsing's cumulativeness opinions is **denied**. The Court will consider these opinions as part of the record when ruling on summary judgment.

Defendants' Motion as to Lhymn's opinions concerning Defendants' state of mind is **granted**. Any such opinions will not be considered on summary judgment.

Defendants' Motion with regards to Mr. Lhymn's skilled searcher opinions is **denied**. The Court will consider these opinions as part of the record when ruling on summary judgment.

Defendants' Motion as to Plaintiffs' new "link" infringement theory is **denied**. The Court will consider Plaintiffs' argument on this issue.

III. Motions for Summary Judgment

Plaintiffs and Defendants have both filed motions for summary judgment on several issues including claim limitations. (ECF Nos. 620 & 630.) The Court will address these issues and claim limitations in turn.

A. Legal Standards

1. Summary Judgment

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A dispute about a material fact is genuine only "if the evidence is such that a reasonable jury could return a verdict" for the non-moving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). If no reasonable jury could find for the non-moving party, then there is no "genuine" dispute. *Scott v. Harris*, 550 U.S. 372, 380 (2007). The Court views the evidence "in the light most favorable to the non-moving party and draw[s] all reasonable inferences in that party's favor." *Zerante v. DeLuca*, 555 F.3d 582, 584 (7th Cir. 2009) (citation omitted). The Court need consider only materials cited by the Parties but may also consider other materials in the record. Fed. R. Civ. P. 56(c)(3). "An infringement issue is properly decided upon summary judgment when no reasonable jury could find that every limitation recited in the properly construed claim either is or is not found in the accused device either literally or under the doctrine of equivalents." *Gart v. Logitech, Inc.*, 254 F.3d 1334, 1339 (Fed. Cir. 2001). The Court may grant summary judgment on each claim limitation independently of other limitations. Fed. R. Civ. P. 56(g); *see also Riddell, Inc. v. Kranos Corp.*, 319 F. Supp. 3d 1071, 1088 (N.D. Ill. 2018) (granting summary judgment on some claim limitations but not others).

When reviewing cross-motions for summary judgment, all reasonable inferences are drawn in favor of the party against whom the motion at issue was made. *Valenti*

v. Lawson, 889 F.3d 427, 429 (7th Cir. 2018) (citing *Tripp v. Scholz*, 872 F.3d 857, 862 (7th Cir. 2017)). The existence of cross-motions for summary judgment does not imply that there are no genuine issues of material fact. *R.J. Corman Derailment Servs., LLC v. Int'l Union of Operating Engineers, Local Union 150, AFL-CIO*, 335 F.3d 643, 647 (7th Cir. 2003). The Court will consider each party's motion individually to determine whether that party has satisfied the summary judgment standard. *Blow v. Bijora, Inc.*, 855 F.3d 793, 797 (7th Cir. 2017) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 324 (1986)).

2. Patent Infringement

The plaintiffs in a patent suit bear the burden of proving infringement by a preponderance of the evidence. *See Bayer AG v. Elan Pharm. Rsch. Corp.*, 212 F.3d 1241, 1247 (Fed. Cir. 2000). A patent can be infringed in two ways: either (1) literally or (2) under the doctrine of equivalents. *Id.* "Literal infringement requires the patentee to prove that the accused device contains each limitation of the asserted claim." *Id.* (citation omitted). "If any claim limitation is absent from the accused device, there is no literal infringement as a matter of law." *Id.* "If an asserted claim does not literally read on an accused product, infringement may still occur under the doctrine of equivalents if there is not a substantial difference between the limitations of the claim and the accused product." *Id.* One way to determine equivalence is through the function-way-result test, wherein the plaintiff would have to show that the allegedly equivalent element in the accused device "'does substantially the same thing in substantially the same way to get substantially the same result' as the claim

limitation." *Toro Co. v. White Consol. Indus., Inc.*, 266 F.3d 1367, 1370 (Fed. Cir. 2001) (citation omitted).

B. The '048 Patent

The Court begins with the '048 patent. The asserted claims of the '048 patent are claims 3, 4, 7, and 14. Claims 3, 7 and 14 each depend from claim 1, the base claim, of the '048 patent. Further, claim 4 depends from claim 3. Therefore, to infringe, the Accused Products must first meet all claim limitations in claim 1. The Accused Products will also need to meet the additional pertinent limitations found in the asserted claims to find infringement of those respective claims.

1. Claim 1 (Unasserted Base Claim)

Claim 1 of the '048 patent is reproduced below, with the disputed limitations in bold:

1. A medical device, comprising:
 - a clip having first and second clip legs;
 - a control wire being operable both to open the clip legs and to close the clip legs;
 - a sheath enclosing the control wire;
 - a link coupling the control wire to the clip, the link being movable from a coupled configuration in which the clip is coupled to a distal end of the control wire to a released configuration **in which first and second arms of the link are configured to move radially outward at an area of the sheath to release the control wire from the clip;**
 - and
 - an actuator coupled to the control wire, the control wire engageable by the actuator to move the control wire to open and close the clip legs and to move the link from the coupled configuration to the released configuration.

('048 Patent, ECF No. 451-2 at 38 (emphasis added).)

i. The disputed "sheath" limitation

Plaintiffs argue that the driver legs of the Accused Products are the claimed "link arms" that move radially outward at an area of the sheath. (ECF No. 622 at 17.) Both parties agree that "at an area of the sheath" means "within the lumen or wall of the sheath." (ECF No. 68.) Defendants do not dispute that the driver legs expand outward within the lumen of the Accused Products' "housing." (ECF No. 633 at 36.) Rather, Defendants argue that the "housing" is *not* part of the "sheath." (*Id.*) Thus, the Accused Products would not literally meet the claim limitation described in claim 1 (i.e., that the arms of the link move outward "at an area of the *sheath*"). The central question, therefore, is whether the "housing" of the Accused Products is part of the "sheath."

The District of Delaware, from where this case was transferred, construed "sheath" to mean "one or more components *of the delivery device* that enclose the control wire." (ECF No. 80 at 35 (emphasis added).) There is no doubt that the Accused Products' "housing" encloses the control wire; but Defendants argue that the housing is not a component of the *delivery device*, and thus, cannot be a part of the "sheath." (ECF No. 633 at 37–38.) The Court agrees.

The undisputed facts indicate that the "housing" is not a component of the delivery device and therefore not a part of the "sheath"; accordingly, the Court finds that claim 1 of the '048 patent is not literally infringed by the Accused Products. First, Plaintiffs' own corporate designee, Kevin Wilcox, a Research and Development Engineer at Boston Scientific tasked with studying the Accused Products and breaking them apart to understand how they work, (ECF No. 632-8 at 5, 7), unequivocally stated

that the "housing" (which he called a "capsule") was not a component of the delivery device, (*id.* at 18). Plaintiffs' sole counterargument to this testimony is that their corporate designee was a "lay witness" who was not shown the '048 patent or the claim constructions and thus potentially used "other terminology." (ECF No. 679 at 30 (citing ECF No. 674-5 at 12).) But, as designated by Plaintiffs themselves, Wilcox provided factual testimony on the structure and function of the Accused Products based on what he learned in his role at Boston Scientific. *See Teashot LLC v. Green Mountain Coffee Roasters, Inc.*, 595 F. App'x 983, 986 (Fed. Cir. 2015) (affirming summary judgment of no literal infringement because the plaintiff's admissions showed that a claim limitation was not met in the accused product). Further, there is no confusion with the "terminology" that Wilcox used. Wilcox labeled images of the Instinct Plus indicating that his term, "capsule," clearly referred to the "housing." (*See* ECF No. 632-16 at 2, 11.) And his testimony leaves no doubt that the capsule "is not a component of the delivery system," which, by the Court's construction, it would need to be if it were a component of the sheath. (ECF No. 632-8 at 18.)

Plaintiffs attempt to create a genuine dispute of fact by pointing to both their expert's report and Defendants' expert's testimony. Plaintiffs cite generally to ten pages of Leinsing's (Plaintiffs' expert) report in support of the assertion that the housing is part of the "delivery device." (ECF No. 622 at 16 (citing ECF No. 621-4 at 22–32).) However, Plaintiffs do not point to any passage where Leinsing actually states such an opinion. Upon examining Leinsing's opinion, the Court likewise fails to see any affirmation from Leinsing that the housing is a component of the delivery

device. Leinsing goes into considerable detail discussing how the coil spring, coil cath, and cath attach are components of the delivery system. (*See, e.g.*, ECF No. 621-4 at 28–29.) The housing is discussed in this section as well. (*Id.*) Because of this, Plaintiffs argue that Leinsing is opining that the housing is another component of the delivery system. This is not the case. To the extent that the housing is mentioned by Leinsing with regards to the delivery system, it is only in reference to its deployment from the cath attach; Plaintiffs themselves acknowledge this. (ECF No. 679 at 30 (citing to the record to show that the cath attach decouples from the housing during deployment).) But this is not evidence that the housing is part of the *delivery system*. The housing is designed to be left behind in the body with the clips; it inevitably *must* decouple from the cath attach. But this does not mean that it is a part of the delivery system comprised of the coil spring, coil cath, and cath attach (the components "delivering" the housing and the clips). Importantly, the Court is *not* saying that "the patents require the limitation that no part of the sheath may ever remain with the clip at the target site." (*See* ECF No. 622 at 16 (citing ECF No. 80 at 32–35).) Portions of the sheath theoretically *can* remain behind in the body. The housing is not a part of the sheath *not* because it remains in the body, but rather, because Plaintiffs have not presented evidence that it is a component of the *delivery device*, as is required by this Court's construction of "sheath." (ECF No. 80 at 35; *see also* ECF No. 451-2 at 33 ('048 patent specification stating that the "delivery device . . . can be removed while leaving the clip 101 (with lock sleeve 113) in place,"

suggesting that the lock sleeve (which Plaintiffs later analogize to the Accused Products' housing) is not part of the delivery device.)

Plaintiffs' reliance on Defendants' expert is likewise unpersuasive. Plaintiffs argue that Defendants' expert, Nicosia, stated that a component "is part of the delivery device . . . if it is involved in the function of delivering the clip." (ECF No. 679 at 30.) Of course, if this is true, then the housing is "involved" in delivering the clips to a target site; after all, as discussed above, the cath attach deploys from the housing (which is connected to the clip), leaving (i.e., "delivering") the housing and clip to the target. However, this is not exactly what Nicosia stated. When asked to define what is meant by a delivery component, Nicosia did not say that it was any component involved in the delivering of a *clip*; instead, he stated that the component would be involved with "[d]elivering the *payload*." (ECF No. 621-10 at 28 (emphasis added).) This distinction is not trivial. As Defendants note, the housing is a part of the payload. (ECF No. 706 at 15.) Logically, the housing cannot be involved in the delivery of itself (otherwise, anything being delivered would also be a component of its respective delivery device). Nicosia's testimony only further supports the Court's conclusion that the undisputed facts show that the housing is part of what is *delivered*; it is not itself a component of the delivery system and thus cannot be a part of the sheath. (See also ECF No. 632-4 at 51–55 (Nicosia explaining and illustrating in intricate detail the differences between the "delivery device" (comprised of the handle, coil spring, coil cath, cath attach, and drive wire) and the housing/clip).)

Because there is no literal infringement of this claim limitation, the Court next examines whether there is a genuine dispute of fact as to infringement under the doctrine of equivalents. The Court finds that such a dispute exists.

Defendants make several arguments attempting to show that no genuine dispute exists as to whether the pertinent claim limitation is infringed under the doctrine of equivalents. First, Defendants suggest that Plaintiffs have no equivalents analysis on this limitation. (ECF No. 633 at 40.) That simply is not the case. Plaintiffs' expert, Leinsing, extensively opined that the "housing" (along with the coil spring, coil cath, and cath attach) of the Accused Products is not substantially different from the claimed "sheath" and further stated that these components together perform substantially the same function as the claimed sheath in substantially the same way. (ECF No. 621-4 at 74–76.) Defendants respond that Plaintiffs have mischaracterized their equivalents analysis; specifically, Defendants state that "Plaintiffs misidentify the issue here as whether the Accused Products include an equivalent to a 'sheath.'" (ECF No. 706 at 16.) But Plaintiffs do not simply search for any equivalent to the sheath; rather, they assert that the *housing* is insubstantially different from other components of the claimed sheath. (ECF No. 679 at 31.) This is significant because the parties all agree that the driver legs of the Accused Products move radially outward at an area of the *housing*. (ECF No. 633 at 19.) Thus, if the housing is substantially the same as the sheath (and therefore an equivalent for infringement purposes), then the legs of the Accused Products effectively move radially outward at an area of the "sheath," as required by the patent claim. This is, in fact, exactly what

Leinsing opines in his report. Leinsing states that "[t]he difference between the claimed sheath and the Instinct's coil spring, coil cath, cath attach, and *housing* is insubstantial." (ECF No. 621-4 at 74 (emphasis added).) Leinsing then breaks down the three functions of the claimed sheath: (1) acting as a housing for the control wire, (2) acting as a means for rotating the clip, and (3) acting as a component of the clip release mechanism. (*Id.*) Finally, Leinsing explains why the coil spring, coil cath, cath attach, and *the housing* of the Accused Products together perform each of these same functions in substantially the same way to achieve substantially the same result. (*Id.*; see also *Toro*, 266 F.3d at 1370.) This is Plaintiffs' central equivalents analysis and argument. If Leinsing's expert opinion is credited, then even if the housing is not literally a component of the sheath, it is substantially the same as the sheath, acting in concert with the remaining sheath components, the coil spring, coil cath, and cath attach, to achieve the same results in substantially the same way as the claimed sheath. This would yield a conclusion that the link arms of the Accused Products move radially outward "at an area of the sheath," in satisfaction of claim 1 of the '048 patent.

Defendants' reliance on *Sage Products, Inc. v. Devon Industries, Inc.*, 126 F.3d 1420 (Fed. Cir. 1997), is not dispositive at this stage. (*See* ECF No. 706 at 16.) In that case, the court affirmed a district court's finding that there was no infringement under the doctrine of equivalents in part because the patent claims required a "precise arrangement of structural elements that cooperate in a particular way to achieve a certain result," and though the accused products in the case achieved

similar results, they did so using a different arrangement of elements. *Sage*, 126 F.3d at 1425. But the claims in *Sage* are not quite like the claims here. In *Sage*, the patent claims provided specific positional directions for the different elements of the invention. Namely, the elements at issue were claimed to be "at the *top* of the container body" or "*over*" a particular slot. *Id.* at 1422 (emphasis added). The accused products in that case were configured in a completely different order (e.g., the pertinent elements were well within the container rather than on top) such that no reasonable jury could possibly find the element to be equivalent to what was claimed. *Id.* at 1424–25. The same is not true here. This is not a case of claim 1 of the '048 patent requiring a "precise arrangement of structural elements." Rather, the entirety of the issue here is whether the housing of the Accused Products is an equivalent of a sheath component such that the link arms that move radially outward within it satisfy the pertinent claim. Leinsing's expert opinion, already discussed at length above, serves as evidence in the record that the housing is indeed an equivalent to a sheath component. In contrast, Defendants' expert, Nicosia, provided a report that suggests the exact opposite. (ECF No. 632-4 at 152 (discussing the substantial difference of having arms move radially outward at an area of a delivery device as opposed to an area not within a delivery device).) With this genuine factual dispute in mind, the Court cannot rule for either party on whether the housing of the Accused Products infringes claim 1 of the '048 patent under the doctrine of equivalents. *See Leggett & Platt, Inc. v. Hickory Springs Mfg. Co.*, 285 F.3d 1353, 1360 (Fed. Cir. 2002) ("Because infringement under the doctrine of equivalents often presents difficult

factual determinations, a summary conclusion that a reasonable jury could not find infringement is often illusive.").

ii. The limitation of a link "to release the control wire from the clip"

Defendants' argument of no literal infringement on this claim limitation hinges on whether the driver of the Accused Products is part of the "control wire" referred to in the '048 patent. (See ECF No. 633 at 41–43.) Plaintiffs do not appear to dispute that this inquiry is central to determining whether the Accused Products meet this claim limitation. If the driver is a part of the control wire, then this claim limitation cannot be met because the driver is not released from the clip; in other words, a portion of the control wire (the driver) remains attached to the clip, in contrast to the patent requiring a link "to release the control wire from the clip." Defendants argue that the driver *is* part of the control wire. But, Plaintiffs identify solely the drive wire as the control wire of the Accused Products; therefore, they argue, the claim limitation is literally met because the driver (the "link") releases the drive wire (the "control wire") from the clip. (ECF No. 679 at 32–33.) The Court finds that there is no genuine dispute that the driver is not a part of the "control wire." Accordingly, Plaintiffs are entitled to summary judgment that the Accused Products literally meet this claim limitation.

The intrinsic evidence of the '048 patent makes it clear that the driver of the Accused Products would meet the separate "link" limitation claimed in the patent, rather than merely being a part of the separately claimed "control wire." Indeed, the patent claims a separate structure, a link, that couples the control wire of the invention to the clip. The link can be integral with the control wire, but it still must

be a separate element. (*See, e.g.*, ECF No. 451-2 at 4 (FIG. 1 depicting the control wire 108 coupled to the clip 101 through a distinct though integral frangible link (j-hook) 107); *id.* at 33 (stating at col. 6, ll. 29-30 that frangible link or "J-Hook 107 is formed on the distal terminal end of control wire 108."). *But cf. id.* at 38 (claim 14 requiring that the link *not* be integral with the control wire).) The patent also discloses an embodiment of the invention with a control wire that is analogous to the drive wire of the Accused Products and where that control wire is coupled to the clip via a separate link that is not integral with the control wire. (*See* ECF No. 451-2 at 30 (depicting the control wire 2104 coupled to the clip 2101 via a separate link 2105).) The driver of the Accused Products includes the claimed link, which couples the drive wire of the Accused Products to the clip as claimed; this means that the driver, while related to the drive wire (which both parties agree is analogous to the control wire), is *not* itself merely a part of the control wire. For the reasons that follow, Defendants' arguments to the contrary are not persuasive.

First, Defendants argue that the '048 patent states that the control wire "acts as a means of actuating the clip . . . between the open and closed position." (ECF No. 633 at 41 (citing ECF No. 451-2 at 33).) Therefore, the driver, which also helps actuate the clip, must be a part of the control wire. (*Id.*) But the '048 patent is not defining "control wire" as *all* components that actuate the clip. Rather, the patent simply states that the control wire is a distinct component that has this function. Stated differently, the control wire actuates the clip; but not all components that are involved in actuating the clip are a control wire. Other elements of the invention can also play

a role in actuating the clip without being labeled a part of the control wire. (*See, e.g.*, ECF 451-2 at 33, 37 (describing the roles of various non-control wire components such as the frangible link 107, the sheath 111, and the breakable link 2105 in actuating the clips).) Additionally, Defendants urge that "a 'control wire' may be made up of 'a two (or more) piece wire so that certain sections of the wire have different material properties or geometries'". (ECF No. 451-2 at 37.) Thus, the argument goes, the driver is part of the control wire and infringement cannot be found. Yes, the control wire of the Accused Products *can* be made of different materials and geometries, but this does not mean that the link (here, the driver), that couples the control wire to the clip becomes part of the control wire simply because it is connected to the wire and is made of a different material or geometry.

Second, Defendants argue that Plaintiffs are not credible because they define the "control wire" one way when analyzing the '048 patent and another way when analyzing the '371 patent. (ECF No. 706 at 17.) But this is not exactly true. As has already been seen in the discussion on the Motion to Preclude, the parties engage in some inconsistent and often confusing phrasing. However, the Court does not find that Plaintiffs are inconsistently defining the "control wire" in their '371 analysis. This is because Defendants' argument implicitly equates "control element" (used in the '371 patent) with "control wire" (used in the '048 patent). Defendants argue that, when analyzing the '371 patent, Plaintiffs define "control element" as the driver *and* drive wire of the Accused Products, in contrast with how they define "control wire" here (i.e., as only the drive wire). However, Defendants do not explain why "control

element" in the '371 patent is necessarily equivalent to "control wire" in the '048 patent. The language of the '371 patent would actually suggest that "control element" is a different limitation than "control wire." There, the patent claim, in relevant part, reads "a control element *including a connector element*." (ECF No. 451-4 at 40 (emphasis added).) Defendants' "a-ha" evidence comes from Plaintiffs' expert report, wherein Leinsing states, "The control element of the Instinct includes the *drive wire and the driver*." (ECF No. 621-4 at 172 (emphasis added).) Thus, Defendants argue, because Plaintiffs have defined the "control element" as both the driver and drive wire, they must also define "control wire" in this way. But "control element," by definition, includes a secondary "connector element." The control wire in the '048 patent is not described in this way. (*See generally* ECF No. 451-2; *see also* ECF No. 679 at 25–26 ("[T]he distal end of the control element (drive wire) is removably connected to the clip assembly via the connector element (driver), and the control element (drive wire) detaches from the connector element (driver).").) The Court will not equate "control element" of the '371 patent to the "control wire" of the '048 patent; the fact that the driver may be the "connector element" that is included within the "control element" of the '371 patent does not mean it is a part of the "control wire" here.

Third, Defendants argue that Plaintiffs are "stuck" with the position they argued during the IPR for the '731 patent. Specifically, Defendants point to Plaintiffs' arguments as to what constituted a "control wire" in the Sackier prior art. (ECF No. 706 at 16–17.) In that proceeding, Plaintiffs argued that the prior art did not disclose

a clip coupled to a control wire via a separable link because shaft 158 is part of the control wire and remains attached to the clip. (ECF No. 631-12 at 41–42.) Additionally, Plaintiffs stated that shaft 158 was part of the control wire in part because it was "one of the structures involved in actuating the jaws." (*Id.* at 42.) Defendants thus seem to think that Plaintiffs stated that shaft 158 (which is, according to Defendants, analogous to the driver) "must be treated" as a part of the control wire because it is involved in actuating the jaws. (ECF No. 706 at 17.) Therefore, relying on *Aylus Networks, Inc. v. Apple Inc.*, 856 F.3d 1353 (Fed. Cir. 2017), Defendants argue that Plaintiffs are stuck with this position from the IPR. (ECF No. 706 at 16.) The Court cannot agree. In *Aylus*, the court rejected Aylus' arguments that directly contradicted statements it had made to the Board during IPR proceedings. *Aylus*, 856 F.3d at 1363. The court stated that Aylus' statements during IPR were a "clear and unmistakable surrender of [claim] methods" that "represent an unequivocal and unambiguous disavowal" of a particular claim construction. *Id.* This is not the case here. Plaintiffs did not unequivocally state that the Accused Products' driver is a part of the control wire; their argument pertained to the shaft 158 of the Sackier prior art during an IPR proceeding on a separate claim of a separate patent. Further, even within this argument, Plaintiffs did not unequivocally state that shaft 158 is part of the control wire *solely* because it is involved in actuating the jaws. Rather, Plaintiffs argued that shaft 158 acts as an "extension" of the inner shaft 58a when the clamp applicator engages the clamp. (ECF No. 631-13 at 24, 50.) The intrinsic evidence of the '048 patent is the most pertinent evidence here, and as discussed

above, a component is not automatically a "control wire" simply because it may help actuate the clip legs. Thus, while Defendants describe shaft 158 as an analog to the Accused Products' driver, (ECF No. 633 at 42), the Court is not convinced this is the case. The driver has additional functional and structural features (besides actuating the jaws) as compared to both shaft 158 and the drive wire, rendering it as not a mere "extension" of the drive wire. For instance, the driver has legs that lock the clip in a closed configuration, central ribs that engage teeth at the proximal end of the clip legs to help the clip open and close, and an end portion that couples a nitinol strip that acts as a spring to return the clip to an open position. (ECF No. 621-4 at 14–20, 37–45; *see also* ECF No. 621-10 at 23 (Nicosia conceding that the drive wire is part of the delivery device while the driver is not); ECF No. 633 at 18 (Defendants describing the role of the driver ribs in engaging the proximal end of the jaws to form a rack-and-pinion mechanism).) These are all functions that are not performed by the drive wire of the Accused Products nor by the shaft 158. Nor does it appear, aside from its position on the device, that the shaft 158 is structurally equivalent to the driver. This is not to say that the driver has to have *identical* functions to the drive wire in order to be considered part of the control wire, but Defendants have not described in any detail why the driver is a direct analog to the shaft 158 of the Sackier prior art. And even if they had done so, the Court does not read Plaintiffs' argument as an unequivocal concession that *any* component that remains attached to the clip and that helps actuate the clip legs is automatically deemed a part of the control wire.

In summary, the Court **grants** Plaintiffs' summary judgment motion as to whether the Accused Products literally contain the '048 patent claim 1 limitation requiring a link to "release the control wire from the clip." The driver is the "link" of the Accused Products, and it is distinct from the "control wire." The control wire (the drive wire) is therefore fully released from the clip, as required by the patent.

2. Claims 3 and 4 (Asserted Claims)

Defendants present the same argument as to why their Accused Products do not infringe claims 3 and 4 of the '048 patent. The Court therefore will analyze both claims concurrently.

Claim 3 reads "The medical device of claim 1, ***further comprising a lock sleeve*** surrounding a part of the clip so that, as the clip is drawn proximally thereinto, the clip legs are drawn toward one another, wherein the lock sleeve radially surrounds part of the first and second clip legs." (ECF No. 451-2 at 38 (emphasis added).) Claim 4 depends from claim 3. (*Id.*) Plaintiffs identify the housing of the Accused Products as the "lock sleeve" limitation in claims 3 and 4. (ECF No. 622 at 18–19.) In response, Defendants make a single argument as to why their Accused Products cannot infringe claims 3 and 4 as a matter of law. Namely, Defendants argue that, if the housing is to be considered part of the "sheath" (in order to satisfy the "at an area of the sheath" limitation of claim 1 discussed previously), the housing cannot *also* be the "lock sleeve." (ECF No. 633 at 44.) The Court agrees with Defendants. As analyzed in the section discussing claim 1, there is no genuine dispute of fact as to whether the housing of the Accused Products literally infringes claim 1 of the '048 patent because

the housing is *not* a part of the delivery device and thus is *not* a literal component of the sheath. Therefore, as Plaintiffs alternatively argued, for claim 1 to be infringed, the housing would need to be deemed an equivalent of a component of the sheath to satisfy the claim limitation. (See ECF No. 679 at 31 (stating Plaintiffs' equivalents argument for claim 1).) The Court found there was a genuine dispute of fact as to whether the housing constituted such an equivalent. Thus, if the finder of fact deems the housing as an equivalent of the sheath under a doctrine of equivalents theory, Defendants argue that there would still be no infringement of claims 3 and 4 because there is no dispute of fact that the housing is not *also* the lock sleeve as required by the claims.

There is a presumption that "[w]here a claim lists elements separately, 'the clear implication of the claim language' is that those elements are 'distinct component[s]' of the patented invention." *Becton, Dickinson & Co. v. Tyco Healthcare Grp., LP*, 616 F.3d 1249, 1254 (Fed. Cir. 2010) (quoting *Gaus v. Conair Corp.*, 363 F.3d 1284, 1288 (Fed. Cir. 2004); see *Kyocera Senco Indus. Tools Inc. v. Int'l Trade Comm'n*, 22 F.4th 1369, 1382 (Fed. Cir. 2022) (citing *Becton* as support for a presumption that separately listed elements are distinct components from one another). Claim 3 in this case (from which claim 4 depends), unequivocally lists a "lock sleeve" as a separate element of the invention. (ECF No. 451-2 at 38 (emphasis added) ("The medical device of claim 1, **further comprising a lock sleeve.**")). Therefore, there is a presumption that the lock sleeve is a distinct component (and therefore separate from the distinctly listed sheath); Plaintiffs' arguments fail to overcome this presumption.

Plaintiffs first argue that "further comprising" is "merely an open-ended transitional phrase indicating that the dependent claim includes additional limitations." (ECF No. 679 at 34.) Exactly right. The additional limitation in this case, a "lock sleeve," is listed separately from the other elements of the medical device; therefore, the Court presumes it is a distinct component of the device. Plaintiffs state that the use of this phrase "does not *compel* the conclusion that the housing may not be both the lock sleeve and part of the sheath," (*id.* (emphasis added)), but the law presumes that the two components are distinct from one another.

Plaintiffs next try to distinguish the cases relied on by Defendants, namely, *Becton* and *Engel Indus., Inc. v. Lockformer Co.*, 96 F.3d 1398 (Fed. Cir. 1996). (ECF No. 679 at 34.) In *Becton*, the pertinent claims were "a hinged arm" and "spring means connected to said hinged arm." *Becton*, 616 F.3d at 1254. The Federal Circuit held that the "hinged arm" had to be distinct from the "spring means" in part because the alternative would be a physical impossibility; in other words, the hinged arm would have to be connected to itself. *Id.* at 1255. Plaintiffs rely on this reasoning in distinguishing their case because it would not be impossible for the sheath and the lock sleeve to be the same component. But this is not a rule. Just because two elements could *possibly* be represented by the same structural component, does not mean this is enough to overcome the *Becton* presumption that separately listed elements are distinct components from one another. The principal analysis requires reliance on the language of the patent claims and specification. This is in fact what the court in *Becton* first did. *Id.* at 1254–55 (discussing that the patent specification

confirms that the "spring means" is a separate element from the "hinged arm" and that the only elements disclosed in the specification as "spring means" are separate structures from the "hinged arm"). Simply put, the fact that it would not be "physically impossible" for the lock sleeve and sheath to be the same component does not mean that the Plaintiffs have overcome the clear presumption, based on the language of the claims and the patent specification, that they are in fact separate components.

Plaintiffs' attempted distinguishing of *Engel* is likewise unpersuasive. In *Engel*, the Federal Circuit held that the claimed "second portion" and "return portion" of a duct could not be the same component because the "second portion" was described in the specification as "bent rearwardly" whereas the "return portion" was described as "bent forwardly." *Engel*, 96 F.3d at 1405. Again, Plaintiffs are implying that the specification must make it *physically impossible* for two elements to be represented by the same component in order for the element to be viewed as distinct. (See ECF No. 679 at 34.) But again, this is not how the presumption operates, and Plaintiffs seem to know it. Plaintiffs state that in *Engel*, "[t]here was also substantial intrinsic evidence supporting a construction of separate and distinct elements." (*Id.* (citing *Engel*, 96 F.3d at 1405).) Plaintiffs think this is a distinguishing feature from their case, but this argument is wrong. Actually, the intrinsic evidence found in the '048 patent *only* shows the lock sleeve as a separate and distinct component from the sheath. First, the Court has already noted that the patent claim lists the lock sleeve as an additional separate limitation of the "medical device of claim 1" (which had

already included a distinct sheath). (ECF No. 451-2 at 38.) Further, the specification consistently shows and describes the lock sleeve as separate from the sheath. (*See, e.g., id.* at 34 (describing the lock sleeve as a separate component); *id.* at 4 (showing lock sleeve 113 in Figure 1 as a separate component from sheath 111); *id.* at 7 (showing a blown-up image of the lock sleeve 113 on its own as an individual component); *id.* at 37 (describing an embodiment in Figure 21 where the lock sleeve is eliminated and therefore the sheath would have to deploy from another component).) The Court has not found, nor have Plaintiffs pointed to any, intrinsic evidence in the '048 patent that would suggest that the lock sleeve and sheath are (or can be) the same component of the invention. The only evidence that Plaintiffs point to in support is this Court's claim construction of "sheath," wherein the Court defined "sheath" as "one or more components of the delivery device that enclose the control wire." (ECF No. 80 at 35.) But this evidence is not on point. Yes, the sheath can include more than one component of the *delivery device*. As discussed previously, the Court acknowledges that the facts not in dispute show that the Accused Products' coil cath, cath attach, and coil spring are all part of the sheath. But this does not show that the lock sleeve is (or even can be) a component of the sheath. Plaintiffs have introduced no evidence to suggest that the lock sleeve is a component of the delivery device (in order for the lock sleeve to qualify under the definition for "sheath"). Moreover, "lock sleeve" is different from other potential components of the sheath (like the coil cath and cath attach) because it is a *separately listed element in the patent claim*. Plaintiffs have simply not overcome the *Becton* presumption.

Plaintiffs' reliance on *Powell v. Home Depot U.S.A., Inc.*, 663 F.3d 1221 (Fed. Cir. 2011), also falls short. Plaintiffs claim that "it is black-letter law that a single element (housing) can satisfy two claim limitations (sheath and lock sleeve)." (ECF No. 622 at 19.) But as already discussed at length, that is not the law, and *Powell* is consistent with this Court's understanding of the law. In *Powell*, the plaintiff was able to overcome the *Becton* presumption, which the *Powell* court duly cited at the start of its analysis. *Powell*, 663 F.3d at 1231. Specifically, the Federal Circuit referenced numerous pieces of intrinsic evidence *from the specification* of the relevant patent showing that the pertinent claim elements could indeed be represented by the same structural component. *Id.* at 1231–32; *see also id.* (distinguishing *Becton* by stating that the claim language in that case did not suggest that the two elements could be the same structure). The intrinsic evidence in this case makes no suggestion whatsoever that the lock sleeve and sheath can be the same structure. Accordingly, Plaintiffs have not overcome the *Becton* presumption.

For the aforementioned reasons, even if the housing is deemed an equivalent of a component of the sheath (in order satisfy claim 1 of the '048 patent), there is no genuine dispute of fact that the Accused Products do not contain separate structures corresponding to the claimed housing and the claimed lock sleeve respectively, and thus, as a matter of law, the housing is not *also* the lock sleeve of asserted claims 3 and 4. Therefore, the Court finds that Defendants are entitled to summary judgment on literal infringement of claims 3 and 4 of the '048 patent as a matter of law.

The Court likewise finds that there is no genuine dispute of fact as to infringement of claims 3 and 4 under the doctrine of equivalents. "[A]n element of an accused product or process is not, as a matter of law, equivalent to a limitation of the claimed invention if such a finding would entirely vitiate the limitation." *Freedman Seating Co. v. Am. Seating Co.*, 420 F.3d 1350, 1358 (Fed. Cir. 2005). Defendants argue that allowing "lock sleeve" to be a component of the "sheath" would render the "lock sleeve" limitation meaningless. (ECF No. 633 at 46.) The Court agrees, and Plaintiffs do not dispute this argument.

Defendants also argue that Plaintiffs cannot dispute that there is no infringement under the doctrine of equivalents for claim 4 because of prosecution history estoppel. (*Id.*) Specifically, Defendants point to the amendments Plaintiffs made to claim 49 of their '494 application (an identical claim to claim 4 of the '048 patent). (*Id.*) There, Plaintiffs initially had a claim identical to claim 4, except that rather than claim a "lock sleeve," the limitation pertained to the "sheath." (ECF No. 632-7 at 17–18.) After having the claim rejected, Plaintiffs amended the claim by adding a "lock sleeve" limitation such that the claim became identical to claim 4 of the '048 patent. Plaintiffs are therefore estopped from arguing that the housing, an equivalent of a sheath component, is also an equivalent of the lock sleeve. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 344 F.3d 1359, 1366–67 (Fed. Cir. 2003) (discussing estoppel of arguing equivalents when plaintiff had amended a claim to narrow its scope in the prosecution history).

Therefore, the Court **grants** Defendants' summary judgment motion for noninfringement of claims 3 and 4 of the '048 patent as to both literal infringement and infringement under the doctrine of equivalents.

3. Claim 7 (Asserted Claim)

Claim 7, which depends from claim 1, adds the limitation "wherein ***the clip legs are separated from one another by a spring member*** positioned therebetween and biased to urge the first and second clip legs away from one another." (ECF No. 451-2 at 38 (emphasis added).) Plaintiffs identified the nitinol strip of the Accused Products as the "spring member." (ECF No. 622 at 20–21; *see also* ECF No. 621-4 at 95–100.) Defendants argue that this claim limitation recites three distinct requirements for the "spring member": it must (1) separate the clip legs, (2) be positioned between the clip legs, and (3) urge the clip legs away from one another. (ECF No. 633 at 46.) Plaintiffs do not dispute that the claim 7 limitation has the second and third requirements, and Defendants concede that the nitinol strip meets these requirements; thus, the parties only dispute the first "requirement," if such a requirement exists at all. (ECF No. 679 at 35; ECF No. 706 at 20.)

Plaintiffs and Defendants disagree about what it means for a spring member to "separate the clip legs from one another." There is no genuine dispute of fact as to the basic properties of the nitinol strip nor as to the location of the strip on the Accused Products. The real issue here is a question of law pertaining to claim construction. *Tempo Lighting, Inc. v. Tivoli, LLC*, 742 F.3d 973, 977 (Fed. Cir. 2014) ("Claim construction is a question of law."). Defendants argue that the clip legs are

not separated by the nitinol strip; rather, they are separated by the driver. (ECF No. 633 at 46.) Specifically, Defendants argue that the "separated" requirement means that the clip legs must be "spaced apart from one another." (ECF No. 633 at 46; *see also* ECF No. 632-4 at 173 (Nicosia opining that, based on the patent claim language, "[t]he 'separated' requirement refers to the use of the spring member to separate the 'clip legs' in space from one another").) Plaintiffs argue that no "spaced apart from one another" requirement exists. (ECF No. 679 at 35.) The Court agrees with Plaintiffs.

Defendants and their expert, Nicosia, attempt to create a dispute as to the meaning of "separate" through clever argument. But "[t]he words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art *when read in the context of the specification and prosecution history.*" *SkinMedica, Inc. v. Histogen Inc.*, 727 F.3d 1187, 1195 (Fed. Cir. 2013) (emphasis added). While extrinsic evidence *can* be useful in deciphering the meaning of claim terms, "[e]xpert testimony, in particular, is less reliable because it 'is generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence.'" *Id.* (citation omitted); *see also Hockerson-Halberstadt, Inc. v. Converse Inc.*, 183 F.3d 1369, 1374 (Fed. Cir. 1999) ("Proper claim construction . . . demands interpretation of the entire claim in context, not a single element in isolation.").

In this case, Defendants and Nicosia argue that "separate" *must* require the spring member to "space apart" the clip legs from one another because claim 7 has two

additional requirements (namely, (1) that the spring member be "positioned therebetween" the clip legs, and (2) that the spring member is "biased to urge the first and second clip legs away from one another") and the "separated from one another" clause must therefore mean something different than those limitations; therefore, Defendants conclude, the only explanation is that "separated from" requires the clip legs to be "spaced apart" from one another. (ECF No. 706 at 20; ECF No. 632-4 at 173.) But Defendants' argument is unconvincing. First, Defendants point to no evidence in the specification or prosecution history that suggests the spring member must "space apart" the clip legs from one another, other than through the biasing action, which is a separate requirement. In examining the '048 patent specification and figures, the Court likewise is unable to find any teaching of a "gap" or "space" between the clip legs. (*See generally* ECF No. 451-2; *see id.* at 4–5 (Figures 1 and 2 showing an embodiment of the invention where the clip legs are separated from one another at the distal end, but still in contact, not "spaced apart," at the proximal end); *id.* at 16 (Figures 10A and 10B showing an embodiment with a flexible linkage 1002 between the clip legs, but where the clip legs are not "spaced apart" at the proximal end regardless of whether the clip is open or closed).) Second, Defendants' and Nicosia's reliance on the claim language is also unpersuasive. The Court does not read "wherein the clip legs are separated from" as a distinct claim limitation for the spring member. Claim 7, interpreted within its ordinary meaning (as was correctly done by Leinsing in his report, (*see* ECF No. 621-4 at 95–100)), clearly indicates that the spring member separates the clip legs from one another (1) *by being positioned*

therebetween the clip legs and (2) by urging the clip legs away from one another. It seems quite clear to the Court that there is no distinct "separation" requirement; rather, the positioning of the spring member therebetween, which alone is enough to separate the clip legs, as well as its function of urging the clip legs away from one another, "separates" the clip legs. *Cf. Multimatic, Inc. v. Edscha Auto. Mich., Inc.*, 19-12598, 2020 WL 6054693, at *6 (E.D. Mich. Oct. 14, 2020) (differentiating between brackets that are "separate" but still in contact as compared to brackets that are "spaced apart" with a "gap in between").

The Court finds that there is no genuine dispute of fact on this claim limitation. As Defendants concede, the nitinol strip is the spring member of the Accused Products, it is positioned in between the clip legs, and it is biased to urge the first and second clip legs away from one another. (ECF No. 621-17 at 71 (Nicosia, on a separate issue, admitting that the nitinol strip applies an outward force on the clip legs); *see also* ECF No. 621-10 at 37; ECF No. 621-24 at 24 (Defendants' documentation indicating that the nitinol strips ensure clip opening).) Thus, based on the '048 patent specification and the ordinary meaning of the terms in claim 7, there is no dispute that the nitinol strip "separates" the clip legs from one another by being positioned in between the legs to urge them away from one another. Accordingly, the Accused Products literally infringe the limitation added in dependent claim 7 of the '048 patent; Plaintiffs are entitled to summary judgment as to this claim limitation. Plaintiffs' Motion, (ECF No. 620), is **granted** to this extent, with ultimate

infringement of the claim falling to the jury's determination regarding the doctrine of equivalents issue.

4. Claim 14 (Asserted Claim)

Claim 14, which depends from claim 1, requires that "the link is not formed integrally with the control wire or the clip." (ECF No. 452-1 at 38.) As discussed previously, Plaintiffs have identified the driver of the Accused Products as the "link" that couples the drive wire (the "control wire") to the clip. (ECF No. 622 at 21.) There is no dispute that the driver is not integral with the drive wire. (ECF No. 621-10 at 54–55 (Nicosia conceding that the driver is not integral with the drive wire).) Instead, Defendants essentially have two arguments in support of a finding of no infringement here. Defendants' first argument can be resolved expeditiously. Defendants again rely on their argument that the driver is part of the control wire, and therefore, if the driver is the "link," then it actually is formed "integrally" with the control wire. (ECF No. 706 at 21.) For the reasons discussed above in Section III.B.1.ii., the Court finds that the driver is *not* part of the control wire; this argument therefore is rejected.

In the alternative, Defendants' second argument involves the identification of the "link." Defendants argue that the driver cannot be the link because Plaintiffs themselves identify the link as another component of the Accused Products. (ECF No. 633 at 42–43.) This has also already been briefly discussed regarding the Motion to Preclude, where the Court found that Plaintiffs did *not* present an untimely and new theory of infringement at the summary judgment stage. (*See supra* Section II.C.) To reiterate, Defendants contend that rather than identifying the driver as the "link"

of the Accused Products, Plaintiffs identify the "coupling or junction of the driver and drive wire" as said "link." (*Id.*) Thus, they argue, even if the driver is not a control wire, the link would at least still partially be "integral" with the control wire because the drive wire (which all parties agree is a control wire) is part of the link. (ECF No. 633 at 47.) The Court cannot agree with this interpretation, and finds that no reasonable jury would agree with this interpretation either.

There is no genuine dispute as to the role of the driver of the Accused Products. The driver is the link that couples the control wire (the drive wire) to the clip. The "link" referenced in the '048 patent "reads on the accused product exactly." *See Jeneric/Pentron, Inc. v. Dillon Co., Inc.*, 205 F.3d 1377, 1382 (Fed. Cir. 2000) (discussing literal infringement). As has been analyzed at length, the intrinsic evidence of the patent makes clear that the "link" is a separate element that couples the control wire of the invention to the clip. (*See* ECF No. 451-2 at 4 (depicting the control wire 108 coupled to the clip 101 through a distinct frangible link (j-hook) 107); *id.* at 33 (discussing the role of the frangible link (j-hook) 107 in coupling the control wire 108 to the clip 101).) In fact, there is a presumption that the link is a separate component of the invention because the patent claim lists the link as a distinct element. *Kyocera*, 22 F.4th at 1382 (citing *Becton* for the presumption). This is the very same presumption that Defendants rely on to argue that the "lock sleeve" must be a separate structure from the sheath. (*See supra* Section III.B.2.) The Court agreed with Defendants there, and the same rule applies here. The "link" of claim 14 references the "link" originally discussed in claim 1, wherein it was listed as a distinct

element of the claim. (ECF No. 451-2 at 38.) The driver of the Accused Products, as identified by Plaintiffs, is the distinct structural component that serves as the "link" of the products.

Plaintiffs do not identify the "link" as the "coupling or junction of the driver and drive wire." Plaintiffs could have been more precise in their analysis. For example, in certain portions of their infringement contentions, Plaintiffs state that the Accused Products have a "link (*e.g.*, the coupling of the distal hook of the 'drive wire' and the 'driver legs' of the 'driver') coupling the control wire (*e.g.*, 'drive wire') to the clip (*e.g.*, 'jaws')." (*See, e.g.*, ECF No. 544-1 at 42.) In Plaintiffs' expert report, similar language is used by Leinsing. (*See, e.g.*, ECF No. 621-4 at 77 ("This junction between the drive wire and proximal end of the driver operates as a link that couples the drive wire to the jaws.")) But this language does not create a genuine dispute as to what component of the Accused Products the '048 patent's "link" limitation reads upon. The proximal end of the distinct *driver* couples the drive wire to the clip, acting as the "link" referenced in the '048 patent is meant to do. Furthermore, Plaintiffs do correctly identify the driver as the "link," and based on their arguments in other sections, the only rational component of the Accused Products that serves as the "link" is the driver. For example, in the very same infringement contentions on which Defendants rely, Plaintiffs point to deposition testimony unequivocally identifying the driver as the "link." (ECF No. 544-1 at 48.) And when discussing the "arms of the *link*" that "move radially outward at an area of the sheath," Plaintiffs identify and analyze the "'driver legs' of the 'driver'" as the pertinent components of the

Accused Products. (*Id.* at 58.) Leinsing likewise consistently referred to the *driver* of the Accused Products as the "link." (ECF No. 621-4 at 101 ("[T]he link (the proximal end of the driver) is not integral with the control wire (drive wire) or the clip (jaws)."); *id.* at 144 (same); *see also id.* at 77 ("[T]he drive wire couples to the clip legs by way of the socket formed by the driver legs."); ECF No. 671-6 at 15–16 (Nicosia interpreting Leinsing's report, at least in part, as referring to the driver as the "link").)

The intrinsic evidence of the '048 patent makes it clear what the "link" element entails. There is no genuine dispute that the "link" of the '048 patent reads directly onto the *driver* of the Accused Products. The parties agree that the driver is not integral with the drive wire. Accordingly, this claim limitation of claim 14 is literally infringed. Plaintiffs' Motion for Summary Judgment is **granted** to this extent, with ultimate infringement of the claim hinging on the jury's determination regarding the doctrine of equivalents issue.

C. Infringement of the '371 Patent

The Court next examines the '371 patent. The lone asserted claim of the '371 patent is claim 13. Claim 13 depends from claim 11 of the patent. As before, the Court finds the claim limitations to which Defendants present no argument to be literally met by the Accused Products as also asserted by the Plaintiffs. (*See, e.g.*, ECF No. 622 at 21–22 (discussing literal infringement of uncontested claim limitations and citing to the record in support).) The Court therefore addresses the claim limitations in dispute.

1. Claim 11 (Unasserted Base Claim)

Claim 11 states the following:

An apparatus for applying clips to tissue within a living body, comprising:

a capsule;

a clip assembly housed within the capsule for movement between an insertion configuration in which first and second arms of the clip assembly are drawn toward one another and an expanded configuration in which the first and second arms are separated from one another to receive tissue therebetween;

a control element including a connector element, extending between a proximal end which, during use, remains outside the body accessible to a user **and a distal end removably connected to the clip assembly via the connector element**, wherein the control element detaches from the connector element via a frangible link; and

a sheath extending from a proximal to a distal end and covering a portion of the control element, wherein the distal end of the sheath is releasably coupled to the capsule.

(ECF No. 451-4 at 40 (emphasis added).) The language in bold is the central limitation in dispute between Plaintiffs and Defendants. Plaintiffs identify the "drive wire plus driver" of the Accused Products as the "control element including a connector element," where the drive wire is the "control element" and the driver is the "connector element." (ECF No. 679 at 25.) There is no dispute that the claim requires the control element to detach from the connector element via a frangible link, and Defendants do not dispute that the drive wire of the Accused Products detaches from the driver via a frangible link, as required by the claim. (ECF No. 633 at 32.) Rather, the issue here is whether the claim also requires the connector element to detach from the clip assembly. (*Id.* at 33.) Despite Plaintiffs' arguments to the contrary, there is such a requirement.

There is no dispute that the driver (the connector element) of the Accused Products is not detachable from the clip assembly; thus, if the claim indeed requires the connector element to detach from the clip assembly, the Accused Products cannot literally infringe the patent. For the following reasons, the Court holds that in light of the claim, the specification, and Plaintiffs' own unequivocal statements during the pertinent IPR proceeding, claim 11 of the '371 patent requires that the connector element be detachable, or "removably connected" to, the clip assembly. (*See* ECF No. 631-1 at 18 (noting that "releasably coupled" and "removably connected" both mean the same thing, namely, "coupled and capable of being released/removed within the body").) Because there is no dispute that the driver of the Accused Products is not removably connected to the clip assembly, the Court finds that the Accused Products do not meet this claim limitation of claim 11 and therefore do not literally infringe the sole asserted claim of the '371 patent, claim 13, which depends from claim 11.

The Court first looks to the claim language in light of the specification. The claim here distinctly lists a "a control element ***including*** a connector element." "As a patent law term of art, 'includes' means 'comprising.'" *SanDisk Corp. v. Memorex Prods., Inc.*, 415 F.3d 1278, 1284 (Fed. Cir. 2005). Thus, the connector element is a subpart of the control element. Plaintiffs do not disagree with this construction. (*See* ECF No. 622 at 23 (arguing that the connector element is not separate and distinct from the control element because the control element "includes" a connector element).) As the District of Delaware properly construed, the control element and connector element do not need to be a single, unitary structure. (*See* ECF No. 80 at

35 (stating that "a control element including a connector element" should be afforded its plain and ordinary meaning and that the two elements did not need to be a single structure).) No doubt, these elements ultimately separate from one another, as the '371 patent discloses. But the connector element is a subpart of the control element based on the plain and ordinary meaning of the claim term, "including." It would stand to reason then, that the "proximal end" and "distal end" limitations apply to the distinctly listed "control element including a connector element" of the claim. The "distal end" limitation states that the distal end of the "control element including a connector element" must be "removably connected to the clip assembly via the connector element." In the Accused Products, the distal end of the "control element including a connector element" would have to logically be the distal end of the "drive wire plus driver," which is, in effect, the distal end of the driver. (ECF No. 632-4 at 229 (discussing the fact that the driver does not separate from the clip assembly, which Plaintiffs do not dispute); *see also* ECF No. 621-4 at 94 (image of the Accused Products wherein it is clear that the driver is the distal end of the "drive wire plus driver").) This distal end (the driver) does not detach from the clip assembly and therefore does not literally infringe the claim.

Plaintiffs contend that this interpretation is incorrect. Plaintiffs argue that the claim only requires the "control element to detach from the clip assembly, not necessarily the connector element." (ECF No. 679 at 26.) Plaintiffs' interpretation is that the "distal end," which is "removably connected to the clip assembly *via the connector element*," refers to the distal end of the control element only, and the

control element is what is removably connected to the clip assembly through the connector element. (ECF No. 679 at 26.) Thus, the argument goes, the drive wire (the control element) is removably connected to the clip assembly via the driver (the connector element) as is required by the claim. (*Id.*) But the language of the claim, as Plaintiffs themselves noted, states that the control element *includes* the connector element, and this entire phrase is the separately listed element of the invention, set off from its pertinent "distal end" limitation. *See Kyocera*, 22 F.4th at 1382 (citing *Becton* for the presumption that separately listed elements are distinct components). Thus, until such time as the connector element detaches from the control element via the separately recited limitation of a frangible link, these two elements share the recited distal end.

Additionally, and perhaps more convincingly, the specification of the '371 patent supports the Court's interpretation. To understand the evidence within the specification in context, it is important to first be familiar with two additional terms: (1) the "yoke" and (2) the "tension member." Plaintiffs, when analyzing dependent claim 13 (which additionally requires a "yoke"), identified a portion of the Accused Products' driver as the "yoke." (ECF No. 679 at 27 (identifying the proximal portion of the driver as the "yoke"); *id.* at 28 (Plaintiffs stating that "the Delaware Court [where this case was transferred from] already held that the specification describes an embodiment in which the yoke is part of the connector element).) This is key because while "connector element" and "control element" is not language used in the specification, the "yoke" which Plaintiffs identify as a portion of the driver (the

connector element), is discussed throughout the disclosure. Additionally, the "tension member" is a *component of the clip assembly* located at the base of the clip legs. (See ECF No. 451-4 at 11 (depicting the tension member 206); *id.* at 35 (discussing how the clip arms go "over the tension member"); *id.* at 34–35 (identifying the tension member as a component of the clip assembly); *id.* at 35 (explaining that the operator can "fully deploy the clip" by adding pressure to "separate the yoke 204 from the tension member 206).) Thus, if a component is detaching from the tension member, it is, by definition, detaching from the base of the clip legs.

With these terms in mind, the Court can turn to the language and disclosure of the '371 patent. The entirety of the '371 patent consistently emphasizes the multi-stage deployment of the invention as a distinction of the invention over the prior art. In the very first section summarizing the invention, the patent discloses that the yoke is "***releasably coupled*** to the tension member." (ECF No. 451-4 at 32 (emphasis added).) Importantly, the yoke is *also* separately detachable from the control element. (*Id.* (discussing the yoke having a cavity that receives the ball connector of the control element).) The limitations of the asserted claim 13 as disclosed in the specification read directly on the Accused Products' components. The driver, which the Plaintiffs call the connector element and which they state also includes the yoke, has a socket that accepts the distal hook of the drive wire (which Plaintiffs call the control element), much like the disclosed yoke accepts the ball connector of the control element. The Accused Products' yoke, represented by a portion of the driver, must then also be "releasably coupled" to the clip, just as the disclosed yoke is releasably

coupled to the tension member (which as discussed, is at the base of the clip legs). (See *id.* at 36 (discussing Figure 24 which depicts the condition where the yoke is no longer connected to the base of the clip legs nor connected to the control element)).) This feature of the invention is reiterated throughout the '371 specification. (See, e.g., *id.* at 35 (explaining the process wherein the clip is deployed by separating the yoke from the tension member); *id.* at 32 (stating that the control element is frangible so that it can ***detach the yoke from the delivery device to provide a second user feedback, and wherein the release of the yoke from the tension member (i.e., the base of the clip) provides a third user feedback***). Compare *id.* at 9 (Figures 9 and 10 displaying an embodiment of the invention where the control element is coupled to the yoke, which itself is coupled to the tension member of the clip assembly) with *id.* at 15 (Figures 16 and 17 showing an embodiment of the invention where the control element remains coupled to the yoke but where the yoke is detached from the clip assembly) and *id.* at 19 (Figure 24 showing an embodiment of the invention where the yoke is decoupled from *both* the control element and the clip).) Thus, based on the specification and figures, the disclosure of the '371 patent is clear: the invention contains a connector element (which includes a yoke) that not only is releasably coupled to a control element via a frangible link, but is *also* removably connected from the clip. The connector element, represented by the yoke, must be detachable in *two locations*: it must be (1) detachable from (removably coupled to) the control element *and* (2) detachable from (removably connected to) the clip assembly. Plaintiffs' interpretation that the connector element need not be detachable from the

clip assembly is not supported by the specification, and Plaintiffs have failed to adduce evidence in the specification supporting their interpretation of the asserted claim. (See ECF No. 679 25–26.)

Plaintiffs' statements during the IPR proceeding on the '371 patent likewise support the Court's interpretation. As discussed in previous sections, plaintiffs are held to arguments they made during IPR proceedings if their arguments represented "unequivocal and unambiguous" claim interpretations. *Aylus*, 856 F.3d at 1363. Unlike the discussion of Plaintiffs' statements regarding whether the driver was part of the control wire, (*see supra* Section III.B.1.ii), in this context, Plaintiffs' statements were clear. In construing claim 11 of the '371 patent, Plaintiffs argued that "the express language of claim 11 requires the capability to release the capsule from the sheath ***and remove the connector element from the clip assembly.***" (ECF No. 631-1 at 19 (emphasis added); ECF No. 631-2 at 14 (same).) Plaintiffs argue that their IPR position has been mischaracterized and that their argument during the IPR proceeding is the same as their argument here. (ECF No. 679 at 26.) But the Court fails to see how this is the case based on the cited language concerning the "connector element." The entire issue of this claim limitation turns on whether the connector element must be "removably connected" to the clip. Plaintiffs are bound by their unequivocal interpretation of the claim forwarded during the IPR. The Court need go no further.

Plaintiffs' reliance on *Cook Group Inc. v. Boston Scientific Scimed, Inc.*, 809 F. App'x 977 (Fed. Cir. 2020) is misplaced. In that case, Cook Group Inc., Cook Medical

LLC, and Boston Scientific SciMed, Inc. appealed decisions of the PTAB regarding claims of the '371 patent. Particularly relevant for the issue here, the Federal Circuit held that "the Board erred in its construction of claim 11's 'connector element' when it determined that the element could not be a part of the clip arms." *Id.* at 983. Plaintiffs here now urge that the Federal Circuit "held that the connector element could be a part of the clip ***that does not separate from the clip.***" (ECF No. 679 at 26.) But the Federal Circuit's holding did not go that far. Not only do those words not appear in the court's opinion, but the issue the Court analyzes today was not on appeal. The Federal Circuit did not opine whatsoever on whether the connector element needed to be "removably connected" to the clip; rather, all that was at issue was whether the connector element could be located on the clip. *Cook*, 809 F. App'x at 983 ("Defendants argue that the Board erred in concluding that the connector element could not be located on the clip."). The Federal Circuit held that the connector element *can* be part of the clip assembly. *Id.* But again, this says nothing about the type of connection that the connector element has with the clip assembly, or that it is not also a part of the control element until such time as it detaches from one or both of the control element or the clip assembly. After all, as Plaintiffs themselves contend, the connector element is a part of the control element, yet it detaches from the control element via a frangible link. (ECF No. 622 at 23 (discussing the fact that the control element "includes" the connector element).) Simply because the connector element of claim 11 may or may not be a part of the clip assembly says nothing about the claim limitation requiring it to be "removably connected" to the clip

assembly (and removably coupled to the control element). For instance, as disclosed in the '371 patent and discussed above, the connector element can be on the clip assembly but can detach within the assembly from the base of the clip legs when the appropriate user pressure is applied via the control element. (See ECF No. 451-4 at 35 (discussing the separation of the yoke from the tension member).) The Federal Circuit's holding as to claim 11 is inapposite here.

For the aforementioned reasons, the Court finds that there is no genuine dispute that the claim 11 "control element including a connector element" limitation is not found in the Accused Products. Because claim 13 depends from claim 11, the lone asserted claim of the '371 patent is found not to be literally infringed. The driver of the Accused Products, which serves as the connector element, is not removably coupled to the clip assembly as required by the claim.

There is also no genuine dispute that there is no infringement under the doctrine of equivalents. Because Plaintiffs argued that the claim only required a single detachment, they did not identify an equivalent detachment in the Accused Products, nor could they. As discussed extensively, the driver (the connector element) is not removably connected to the clip assembly, and there is no such equivalent connection that could meet this limitation. Plaintiffs have presented no evidence in support of infringement on this claim limitation under the doctrine of equivalents. *InTouch Techs., Inc. v. VGO Commc'ns, Inc.*, 751 F.3d 1327, 1338 (Fed. Cir. 2014) ("The patentee bears the burden of proof for infringement."). Ignoring this claim limitation or finding some other "equivalent" would render the limitation meaningless.

Freedman Seating Co. v. Am. Seating Co., 420 F.3d 1350, 1358 (Fed. Cir. 2005) ("[A]n element of an accused product or process is not, as a matter of law, equivalent to a limitation of the claimed invention if such a finding would entirely vitiate the limitation."). No doubt, here, a key feature of the invention is the ability of the connector element (a portion of which is the "yoke") to detach from the clip assembly. This is a key element that cannot be eliminated. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997) ("It is important to ensure that the application of the doctrine, even as to an individual element, is not allowed such broad play as to effectively eliminate that element in its entirety.").

The Accused Products do not infringe the lone asserted claim of the '371 patent, claim 13 (which depends from claim 11), either literally or under the doctrine of equivalents. Accordingly, the Court dismisses all claims against Defendants as to the '371 patent. The Court therefore need not discuss other arguments as to invalidity.

Alternatively, the Court notes that even if the claim limitations of claim 11 are found in the Accused Products, the lone asserted claim 13 would still not be infringed either literally or under the doctrine of equivalents. Claim 13, which depends from claim 11, adds the following limitation: "wherein the clip assembly includes a yoke slidably received in the capsule and removably coupled to the control element." (ECF No. 451-4 at 40.) Plaintiffs identify the proximal portion of the driver of the Accused Products as the "yoke." (ECF No. 622 at 24.) Yet, the driver, as discussed above, also serves as the "connector element" of claim 11. Plaintiffs urge the Court to consider the District of Delaware's (the court of transfer) order wherein that court held that

"the yoke may constitute at least a part of the connector element." (ECF No. 80 at 9.) But that order did not pertain to claim 13 nor the construction of the term "yoke." Instead, it discussed the "yoke" referenced throughout the '371 specification.

Here, with claim 13, the "yoke" is listed as a distinctly separate claim limitation in the invention. *See Becton, Dickinson & Co. v. Tyco Healthcare Grp., LP*, 616 F.3d 1249, 1254 (Fed. Cir. 2010) (cleaned up) ("Where a claim lists elements separately, the clear implication of the claim language is that those elements are distinct components of the patented invention."). Simply put, Plaintiffs urge the Court to identify the driver as the "connector element" limitation of claim 11 that "detaches from the [control] element via a frangible link" **and** as the "yoke" limitation of claim 13 that is "removably coupled to the control element." Such a finding would be nonsensical and render the added claim limitation of claim 13 superfluous. *See Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1370 (Fed. Cir. 2007) (citation omitted) (discussing claim differentiation and stating that the "doctrine is based on 'the common sense notion that different words or phrases used in separate claims are presumed to indicate that the claims have different meanings and scope," and that "to the extent that the absence of such difference in meaning and scope would make a claim superfluous, the doctrine of claim differentiation states the presumption that the difference between claims is significant"). There could also be no finding of infringement under the doctrine of equivalents because Plaintiffs simply cannot identify an "equivalent" of a "yoke" in the Accused Products. *See Kustom Signals Inc. v. Applied Concepts, Inc.*, 264 F.3d 1326, 1333 (Fed. Cir. 2001) ("No

claimed element, or an equivalent thereof, can be absent if the doctrine of equivalents is invoked.").

D. Infringement of the '731 Patent

1. Claims 1 and 12

Plaintiffs assert that the Instinct Plus infringes claims 5 and 19 of the '731 patent. Plaintiffs do not allege that the Instinct infringes the '731 patent. Claim 5 depends from claim 1, while claim 19 depends from claim 12. (ECF No. 451-5 at 38.) The first two clauses of claims 1 and 12 recite identical claim limitations. Claims 1 and 12 state, in relevant part, the following:

A medical device, comprising:

a clip including first and second clip arms, ***the clip being movable between an open tissue receiving configuration in which the first and second arms are separated from one another by a distance selected to receive tissue therebetween and a closed configuration in which the first and second arms are moved inward to capture the tissue received therebetween;***

an opening element engaging inner walls of the first and second clip arms, the opening element urging the first and second clip arms away from one another into the open tissue-receiving configuration, wherein the opening element is movable between an expanded configuration and a retracted configuration to correspond to a movement of the clip between the open tissue receiving configuration and the closed configuration

(ECF No. 451-5 at 38 (emphasis added).)

Claim 12 recites the following additional limitation in a separate clause introduced by an "and" following "configuration" in the immediately preceding clause: "[; and] a control wire coupled to the proximal end of the clip and operable to move the clip between the open and closed configurations." (*Id.*) This additional recitation found

in claim 12 is not disputed. Therefore, the Court finds that the Instinct Plus meets this additional limitation.

Plaintiffs identify the nitinol strip of the Instinct Plus as the "opening element" referenced in the '731 patent. (ECF No. 622 at 25.) The parties dispute whether the nitinol strip urges the clip arms "into the open tissue-receiving configuration." Plaintiffs argue that the opening element merely needs to apply any outward force on the clip legs as they move into the open tissue-receiving configuration, even if the opening element itself is no longer applying any force on the clip legs as the clip enters the final configuration. (ECF No. 679 at 37 (arguing that the opening element only needs to urge the clip arms by pressing outwardly on them "for a portion of the arms' travel during opening").) On the other hand, Defendants argue that the nitinol strip does not urge the first and second clip arms away from one another into the open tissue-receiving configuration because the nitinol strip's purpose is to exert an outward force on the clip arms during closing, and the nitinol strip plays no role in helping the clip transition to the open tissue-receiving configuration. (ECF No. 633 at 48.) The Court agrees with Plaintiffs' claim interpretation and finds that there is no genuine dispute of fact as to whether the Instinct Plus literally infringes this limitation; the nitinol strip urges the clip arms of the Instinct Plus away from one another *into the open tissue-receiving configuration* as required by claims 1 and 12 of the '731 patent. This is so even if the strip's intended purpose in the Instinct Plus is to exert an outward force on the clip arms during closing so long as they also urge the clip arms outwardly during opening as claimed. The former does not preclude the

latter. Also, if the strip exerts outward force beyond that claimed, this does not immunize the device from infringing based on practicing the claimed "urging" force.

As previously stated, the words of a patent claim are generally given their ordinary meaning in light of the claim language and the patent specification, *SkinMedica*, 727 F.3d at 1195; here, the language of claims 1 and 12 clearly indicates that the opening element must urge the clip arms "***into the open tissue-receiving configuration.***" (ECF No. 451-5 at 38.) "A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so." *Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005). The Court agrees with Defendants' contention; simply exerting any outward force on the clip arms is not enough to satisfy the claim limitation here. If that were the case, the "into the open tissue-receiving configuration" clause would be rendered superfluous (i.e., the claim would have instead simply stated that the opening element urges the clip arms away from one another). Clearly, the opening element must help urge the clip arms into this final configuration.

Yet, with the above construction in mind, the Court finds that there is no genuine dispute of fact as to whether the nitinol strip of the Instinct Plus comports with the claim limitation. The evidence shows that the nitinol strip, at least minimally, urges the clip arms into the open tissue-receiving configuration. Defendants' arguments and evidence to the contrary are not persuasive.

Defendants first argue that a separate component, dubbed the "rack-and-pinion mechanism" formed between the jaws and the driver, is the component that actually

opens the clip arms into the requisite configuration. (ECF No. 633 at 48.) The proximal ends of the clip arms of the Accused Products engage the driver's rib structure so that the movement of the driver causes the clip arms to open and close. (ECF No. 632-4 at 58–63; ECF No. 621-4 at 17–20.) But the fact that the rack-and-pinion mechanism also urges the clip arms into the open tissue-receiving configuration is not dispositive here. The Court is even inclined to believe that the rack-and-pinion mechanism is the core component that opens the clip arms. But the claims do not say that the opening element is the *only* component that can urge the clip arms into the requisite configuration, and the opening element certainly does not need to be the main component completing this function. The claim only requires the opening element to urge the clip arms into the open tissue-receiving configuration; whether there is another component of the Accused Products that also urges the clip arms into the open tissue-receiving configuration is inapposite.³ *See In re Crish*, 393 F.3d 1253, 1257 (Fed. Cir. 2004) (cleaned up) (“[I]t is well-established that

³ Leinsing and Nicosia have a similar debate in their expert reports. In their reports, Nicosia and Leinsing conduct similar experiments in support of their opinions. They manually closed the clip arms of the Instinct Plus and then released them. Leinsing conducted the experiment with the nitinol strip; Nicosia conducted it without the nitinol strip. When the clip arms were released, the clip would return to the open tissue-receiving configuration. Of relevance here is that the clip would return to the open tissue-receiving configuration *both when the nitinol strip was present and after it was removed*. (ECF No. 621-4 at 142; ECF No. 632-4 at 195.) Drawing on this, Nicosia concluded that the rack-and-pinion mechanism, not the nitinol strip, urged the clip arms into the open tissue-receiving configuration. (ECF No. 632-4 at 195.) But this conclusion is incomplete. Again, just because the rack-and-pinion mechanism can urge the clip open by itself does not mean that the nitinol strip does not assist in this process as well. In fact, Leinsing's report compares the opening of the clip with the nitinol strip to the opening of the clip without the nitinol strip. When he opened a clip (which did not have a nitinol strip) by moving the driver distally, he observed that while the clip still opened, the opening was delayed and less controlled (ECF No. 621-4 at 142.) Thus, even if the rack-and-pinion mechanism is the main component that urges the clip arms into the open tissue-receiving configuration, the nitinol strip certainly provides a supporting force outward on the clip arms that also helps urge them into the open tissue-receiving configuration.

'[c]omprising' is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.").

Defendants next point to Plaintiffs' own animation, where the nitinol strip is shown to not even be in contact with the clip arms as the arms reach the open tissue-receiving configuration (thus, they argue, it would be impossible for the nitinol strip to exert any force on the clip arms at that stage). (ECF No. 633 at 48 (citing ECF No. 621-42 at 0:09).) But the animation and images that Defendants point to in order to show that the nitinol strip is not in contact with the clip arms when they are in the open tissue-receiving configuration all relate to the *Instinct product, not the Instinct Plus*. Plaintiffs are not alleging that the Instinct infringes the '731 patent. Defendants' arguments are completely irrelevant here. In the Instinct Plus, the relevant accused product for this claim limitation, there is no question that the nitinol strip is in contact with the clip arms throughout the opening process all the way into the open tissue-receiving configuration. (*Compare* ECF No. 632-4 at 61 *with* ECF No. 632-4 at 73 (Nicosia breaking down the Instinct clip first, where the nitinol strip does not touch the clip arms in the final configuration, with the Instinct Plus clip, where the nitinol strip clearly does); *see also* ECF No. 621-4 at 142, 151 (Leinsing showing detailed images of the Instinct Plus clip reaching the open tissue-receiving configuration, where the nitinol strip clearly still contacts the clip arms); *see also* ECF No. 621-42 at 0:01 (title of the animation as "Instinct" rather than "Instinct Plus").)

Further, the nitinol strip naturally exerts an outward force on the clip arms because it has a natural tendency to return to its expanded configuration, and this is not in dispute. (*See, e.g.*, ECF No. 621-10 at 39 (Nicosia admitting that the nitinol strip exerts an outward force on the clip arms when it is deformed and in contact with the clip arms); ECF No. 632-4 at 195 (Nicosia arguing that the nitinol strip does not "urge" the clip arms into the requisite configuration even though it "exerts an outward force.")) Therefore, the nitinol strip "urges" the clip arms into the open tissue-receiving configuration, as required. *See Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1316 (Fed. Cir. 2003) (stating that the ordinary meaning of "urge" is either "to press or to push" or "to cause to move, hasten, or gather speed"). But Nicosia's report, like Defendants' brief, argues that the rack-and-pinion mechanism opens the clip into the open tissue-receiving configuration, that the claim requires more than simply urging the clip arms away from one another, and that Leinsing provided no evidence that the nitinol strip urges the clip into the required configuration. (ECF No. 632-4 at 194–95.) These arguments are not persuasive. First, again, the fact that the rack-and-pinion mechanism may indeed be the major component urging the clip into the open tissue-receiving configuration says nothing about the opening element, the nitinol strip. Second, as all parties agree, the nitinol strip applies an outward force on the clip arms while in contact with them (which, in the Instinct Plus, is throughout the entirety of the opening process); this inevitably means it applies an outward force on the clip arms "urging" them into the open tissue-receiving configuration. Third, Leinsing *does* provide evidence further showing that

this force, even if it is small, is not negligible. (*See* ECF No. 621-4 at 142 (discussing how, while the clip still opens without the nitinol strip, the opening is delayed and less controlled).)

Defendants next point to Leinsing's testimony in a separate proceeding. There, when asked about the spring member of the Accused Products (here, the nitinol strip), Leinsing stated that such components are used for stability to prevent jamming during the clip's closing and that devices such as the "Defendants' device" do "not *need* them for any kind of opening." (ECF No. 632-14 at 6 (emphasis added).) Defendants rely on this testimony to argue that the nitinol strip clearly is not an *opening* element. But this testimony does nothing to change the Court's analysis here. As noted, just because the nitinol strip is not "needed" for opening does not mean that the nitinol strip does *not* help urge the clip arms into the open tissue-receiving configuration as claimed. Indeed, Defendants' product documentation is consistent with this conclusion. (*See* ECF No. 621-24 at 24 (stating that one of the functions of the nitinol strip is to "ensure clip opening").) As already discussed above, the Court is aware that the clip can open without the nitinol strip; but the nitinol strip still provides an outward force that urges the clip arms into the open configuration. Thus, even accepting Defendants' contention that the nitinol strip's *purpose* is for stability and to prevent jamming during *closing*, the undisputed evidence shows that it does urge the clip into the open configuration as claimed, and this is enough.

The Instinct Plus has a nitinol strip that engages the inner walls of the clip arms and applies an outward force on the clip arms, urging the clip arms, alone or in combination with the rack-and-pinion mechanism, into the final open tissue-receiving configuration as claimed. Accordingly, the Court finds that the Instinct Plus literally infringes this claim limitation. Plaintiffs' Motion for Summary Judgment is **granted** to this extent.

2. Claims 5 and 19

Claims 5 and 19, which depend from claims 1 and 12, respectively, add the same exact limitation. Both claims recite the following: "wherein a distal end of the control wire includes an increased width portion formed to removably engage the clip." (ECF No. 451-5 at 38.) Defendants' only argument here is that Plaintiffs misidentify the control wire as just the drive wire, when it should have been identified as both the drive wire and driver. (ECF No. 633 at 50.) The Court has already addressed this argument at length above, (*see supra* Section III.B.1.ii). The drive wire of the Instinct Plus is the control wire; the driver is not part of the control wire. The drive wire has a distal end with an increased width portion that is removably engaged with the clip (as is required of the control wire in the claim); therefore, the Court finds that the Instinct Plus literally infringes the claim limitations added by claims 5 and 19 of the '731 patent. Thus, the Instinct Plus literally infringes claims 5 and 19 of the '731 patent and the Plaintiffs' are entitled to summary judgement accordingly.

E. Infringement Under 35 U.S.C. §§ 271(b) and (c)

Plaintiffs have conceded that they will not assert indirect infringement claims. (ECF No. 679 at 41–42.) Accordingly, the Court **grants** Defendants' Motion for Summary Judgment as to indirect infringement under 35 U.S.C. §§ 271(b) and (c).

F. Cook Group Incorporated

Defendants argue that CGI, the parent company of Cook Medical LLC, is not liable for direct infringement. (ECF No. 633 at 51–52.) Plaintiffs do not dispute that CGI does *not* make, use, sell, offer to sell, or import the Accused Products as is required for direct infringement under 35 U.S.C. § 271(a). Rather, Plaintiffs argue that CGI is vicariously liable for the infringing activity of its subsidiary, Cook Medical LLC. (ECF No. 679 at 17 (arguing that CGI can be held liable as the parent of Cook Medical because it has a direct financial interest in the infringing activity and is able to direct and supervise its subsidiary).)

Defendants counter that any direct infringement liability on a parent corporation for the infringing activity of its subsidiary can only be accomplished by "piercing the corporate veil," and because Plaintiffs do not make a "piercing the corporate veil" argument here, CGI should be entitled to summary judgment and dismissed from the case. (ECF No. 706 at 24.) The Court agrees.

Generally, a parent is liable for a subsidiary's direct infringement "only if the evidence reveals circumstances justifying disregard of the status of [the entities] as distinct, separate corporations." *A. Stucki Co. v. Worthington Indus., Inc.*, 849 F.2d 593, 596 (Fed. Cir. 1988). In determining whether to disregard the corporate status

of separate entities, the Federal Circuit draws on the general principles relating to piercing the corporate veil. *See id.* (citing *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1579 (Fed. Cir. 1986)). "Corporate separateness is an issue of regional-circuit law." *Celgene Corp. v. Mylan Pharms. Inc.*, 17 F.4th 1111, 1125 (Fed. Cir. 2021). In the Seventh Circuit, "[e]fforts to 'pierce the corporate veil' are governed by the law of the state of incorporation." *Stromberg Metal Works, Inc. v. Press Mech., Inc.*, 77 F.3d 928, 933 (7th. Cir. 1996) (citation omitted). Because Defendants are an Indiana corporation and an Indiana limited liability company, Indiana law applies. Under Indiana law, to succeed in piercing the corporate veil, the party seeking to pierce the veil must "[1] prove that the corporate form was so ignored, controlled or manipulated that it was merely the instrumentality of another and [2] that the misuse of the corporate form would constitute a fraud or promote injustice." *Reed v. Reid*, 980 N.E.2d 277, 301 (Ind. 2012) (citation omitted).

Plaintiffs have cited no facts that would justify a piercing of the corporate veil as it relates to CGI. Instead, Plaintiffs argue that CGI and Cook Medical LLC have significant overlap in officers/directors; that CGI provides support, oversight, and control over Cook Medical LLC; and that patent law supports a finding of direct infringement liability on a parent corporation under these circumstances. (ECF No. 679 at 40–41.) Plaintiffs' citations to the record and the law fall short at best. Nothing in the record suggests that Cook Medical LLC is an "alter ego" of CGI and nothing in the record suggests that treating Cook Medical LLC as a separate corporate entity would promote fraud or injustice; Plaintiffs are not suggesting this

is the case anyway. Rather, Plaintiffs argue that patent law attributes direct infringement liability on a parent if the parent had significant control over the infringing subsidiary. Notwithstanding, as set forth in *Orthokinetics*, that patent law does not supplant or alter black letter law concerning general principles relating to piercing the corporate veil, this is inaccurate in any event. Plaintiffs first cite to *Autronic Plastics, Inc. v. Apogee Lighting, Inc.*, No. 19-CV-6268 (MKB), 2021 WL 5965715, (E.D.N.Y. Dec. 16, 2021), for the proposition that "[a]n actor may be held liable for direct infringement based on another entity's actions where that actor directs or controls the other entity's performance." *Id.* at *4. But that court's reasoning is not persuasive nor binding on this Court and is inapposite in any case. In that case, the court relied on a family of Federal Circuit cases all stemming from *Akamai Technologies, Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020 (Fed. Cir. 2015). But *Akamai* and its progeny do not stand for a rule that a party can be liable for direct infringement any time it directs or controls the infringing activity of a subsidiary. Rather, these cases apply to a particular context that is not relevant here: when the patent claim allegedly infringed is a *method* claim and more than one party is performing the pertinent steps. *See Akamai*, 797 F.3d at 1022 (emphasis added) (discussing vicarious liability applicability for direct infringement and stating that "[w]e will hold an entity responsible *for others' performance of method steps* in two sets of circumstances: (1) where that entity directs or controls others' performance, and (2) where the actors form a joint enterprise"); *see also Travel Sentry, Inc. v. Tropp*, 877 F.3d 1370, 1378 (Fed. Cir. 2017) (citing to *Akamai* and stating that one actor may

be liable for direct infringement of a method claim if it directed or controlled another entity to perform certain steps). Plaintiffs attempt to transplant this language into the apparatus claim context and argue that a parent entity can be liable for direct infringement when it directs a subsidiary entity to make, use, sell, offer to sell, or import an infringing product; *Akamai* did not go this far. Moreover, even if it did, there is no assertion that CGI practiced any part of the claimed invention. So, it is not even the case that the party being held liable practiced some but not all of the claimed invention. Here, only Cook Medical LLC practices the claimed inventions.

Plaintiffs' reliance on *Streck, Inc. v. Research & Diagnostic Systems, Inc.*, No. 8:06CV458, 2010 WL 3926059, (D. Neb. Sept. 30, 2010), is likewise unpersuasive. The court in *Streck*, relying on *Stucki*, held that a parent company could be liable for direct infringement based on its subsidiary's products if there is a "substantial and continuing relationship" between the two companies. *Id.* at *9. But this interpretation of *Stucki* not only does not comport with either Seventh Circuit or Indiana law, which controls such matters, but misconstrues even Federal Circuit precedent, which requires a piercing of the corporate veil before direct infringement liability can attach to a parent. As discussed above, the language and analysis in *Stucki* was clearly done in the context of piercing the corporate veil. The reasoning and analysis of the court in *Aspex*, for instance, is much more in line with this Court's reading of the law. In that case, the court analyzed the holding in *Stucki* and how it has been characterized by the Federal Circuit. *Aspex*, 361 F. Supp. 2d at 216–17. The court concluded that "the clearest statement from these cases suggests that the

standard for piercing the corporate veil must be met before a parent may be held liable for the acts of its subsidiary." *Id.* at 217 (comparing *Stucki* with *Tegal Corp. v. Tokyo Electron Co.*, 248 F.3d 1376 (Fed. Cir. 2001) and reasoning that a parent's control over a subsidiary is a factor to consider in the context of an overarching piercing the corporate veil analysis); *see also FloodBreak, LLC v. Art Metal Indus., LLC*, No. 3:18-cv-503 (SRU), 2020 WL 5300250, at *9 (D. Conn. Sept. 3, 2020) (citing to *Aspex* and stating that, for the corporate veil to be pierced, the plaintiff must offer evidence showing that recognizing a parent and its subsidiary as separate corporate entities would permit the parent to commit fraud and illegitimately escape direct infringement liability). A mere "substantial and continuing relationship" is not enough. This conclusion also makes sense in light of the causes of action available in the patent system. Rather than holding a parent liable for *direct infringement* under 35 U.S.C. § 271(a), a party can seek damages from a parent that induces infringement under § 271(b) or contributes a component to an infringing product under § 271(c). This is, in fact, what the Federal Circuit suggests in its case law. For example, in analyzing whether a parent company could be held liable for *direct infringement* for its subsidiary's activity, the Federal Circuit stated that "[d]irect infringement . . . requires more than mere control; direct infringement requires making, using, offering to sell, or selling a patented invention. . . . Induced infringement, on the other hand, requires 'actively and knowingly aiding and abetting another's direct infringement.' . . . Thus, control may indeed serve as a predicate for induced infringement under

appropriate circumstances." *Hockerson-Halberstadt, Inc. v. JSP Footwear, Inc.*, 104 F. App'x 721, 724 (Fed. Cir. 2004) (emphasis added) (citation omitted).

But here, Plaintiffs have chosen to relinquish claims of induced or contributory infringement. (ECF No. 633 at 52.) Absent any evidence justifying a piercing of the corporate veil, CGI is entitled to summary judgment as a matter of law. CGI is not liable for direct infringement as a separate and distinct legal entity that does not make, use, sell, offer to sell, or import the Accused Products, and is not otherwise the alter ego of Cook Medical LLC.

G. IPR Estoppel

"The petitioner in an inter partes review of a claim in a patent . . . that results in a final written decision . . . may not assert either in a civil action arising in whole or in part under section 1338 of title 28 . . . that the claim is invalid on any ground that the petitioner *raised or reasonably could have raised* during that inter partes review." 35 U.S.C. § 315(e)(2) (emphasis added). The Federal Circuit holds that "estoppel applies not just to claims and grounds asserted in the petition and instituted for consideration by the Board, but to all grounds not stated in the petition but which reasonably could have been asserted against the claims included in the petition." *Cal. Inst. of Tech. v. Broadcom Ltd.*, 25 F.4th 976, 991 (Fed. Cir. 2022).⁴ Against this backdrop, the parties break down their arguments regarding IPR

⁴ The Federal Circuits *Cal. Tech.* decision thus definitely settles the parties' dispute over the meaning behind "reasonably could have raised." (See ECF No. 633 at 59; ECF No. 679 at 42.) Defendants' arguments to the contrary are without merit. In interpreting § 315(e)(2), the Federal Circuit overruled *Shaw Industries Group, Inc. v. Automated Creel Systems, Inc.*, 817 F.3d 1293 (Fed. Cir. 2016), a case on which Defendants rely.

estoppel by prior art type, namely, (1) printed publications/patents and (2) commercial product prior art. The Court will address each of these in turn.

1. Prior Printed Publications and Patents

i. References that Defendants knew about before the IPR

As discussed above with regard to the Motion to Preclude, courts interpret the "reasonably could have raised" phrase in § 315(e)(2) to mean "any patent or printed publication that a petitioner actually knew about or that 'a skilled searcher conducting a diligent search reasonably could have been expected to discover.'" *Wi-LAN Inc. v. LG Elecs., Inc.*, 421 F. Supp. 3d 911, 924 (S.D. Cal. 2019) (citations omitted).

There is no dispute that Defendants knew of the following twelve patents and printed publications prior to the IPR because these references were included in Defendants' 2016 invalidity contentions: U.S. Patent No. 3,958,576 ("Komiya '576"), U.S. Patent No. 5,373,854 ("Kolozsi '854"), U.S. Patent No. 5,423,857 ("Rosenman '857"), U.S. Patent No. 5,542,432 ("Slater '432"), U.S. Patent No. 5,569,274 ("Rapacki '274"), U.S. Patent No. 5,749,881 ("Sackier '881"), U.S. Patent No. 5,766,189 ("Matsuno '189"), U.S. Patent No. 5,776,075 ("Palmer '075"), U.S. Patent No. 5,843,000 ("Nishioka '000"), Japanese Unexamined Patent App. Pub. No. S60-103946 ("Shinozuka '946"), U.S. Patent No. 4,733,664 ("Kirsch '664"), and U.S. Patent No. 7,094,245 ("Adams '245"). (See ECF No. 621-33 at 22–44; see also ECF No. 621-34 at 5–7; ECF No. 621-35 at 5–7; ECF No. 621-36 at 5–8; see also *Wi-LAN*, 421 F. Supp. 3d at 925 ("Several district courts have held that the identification of prior art in

invalidity contentions generated prior to the filing of the IPR petition is sufficient to establish as matter of law that the accused infringer knew of those prior art references.") The dispute as to these *known* references is to what extent they can be used in light of IPR estoppel. Plaintiffs argue that Defendants are estopped from asserting these references at all. (ECF No. 622 at 28.) But this is a bridge too far.

The language of the pertinent statute precludes Defendants from raising "any **ground** that [they] raised or reasonably could have raised" during the IPR proceeding. 35 U.S.C. § 315(e)(2) (emphasis added). A "ground" is not necessarily equivalent to a reference. (See ECF No. 633 at 62.) Rather, "[c]ourts have clarified that an invalidity 'ground' before the PTAB is 'the basis or bases on which a petitioner challenges a claim.'" *Cal. Inst. of Tech. v. Broadcom Ltd.*, No. CV 16-3714 GW (AGRx), 2018 WL 7456042, at *4 (C.D. Cal. Dec. 28, 2018) (citation omitted). Thus, Defendants are estopped from arguing any invalidity ground that rests *solely* on the previously known references listed above; however, Defendants are permitted to raise grounds (e.g., obviousness) that rely on these known references in combination with other references that Defendants did *not* know about and that a skilled searcher conducting a diligent search reasonably could *not* have found. For example, Defendants are estopped from arguing invalidity based on *solely* the Sackier '881 patent (which Defendants asserted in their 2016 contentions). Defendants would also be estopped from asserting invalidity grounds based on Sackier '881 in combination with any other references that Defendants knew about or that a skilled searcher reasonably could have discovered. On the other hand, if Defendants wish to make an

obviousness invalidity argument that combines Sackier '881 with a reference that Defendants did *not* know about prior to IPR and that a skilled searcher could *not* reasonably have discovered, they are permitted to do so. This would, after all, be a new and unique *ground* that Defendants could *not* have reasonably raised during the IPR.

Accordingly, the Court concludes that Defendants are estopped from raising any invalidity grounds that rely on any of the following references (either solely or in any combination with one another): U.S. Patent No. 3,958,576 (“Komiya ‘576”), U.S. Patent No. 5,373,854 (“Kolozsi ‘854”), U.S. Patent No. 5,423,857 (“Rosenman ‘857”), U.S. Patent No. 5,542,432 (“Slater ‘432”), U.S. Patent No. 5,569,274 (“Rapacki ‘274”), U.S. Patent No. 5,749,881 (“Sackier ‘881”), U.S. Patent No. 5,766,189 (“Matsuno ‘189”), U.S. Patent No. 5,776,075 (“Palmer ‘075”), U.S. Patent No. 5,843,000 (“Nishioka ‘000”), Japanese Unexamined Patent App. Pub. No. S60-103946 (“Shinozuka ‘946”), U.S. Patent No. 4,733,664 (“Kirsch ‘664”), and U.S. Patent No. 7,094,245 (“Adams ‘245”). However, Defendants may rely on the aforementioned references in combination with other prior art that they did not know of or that they could not have reasonably discovered with a diligent search.

ii. References that Defendants reasonably could have discovered with a diligent search

Plaintiffs argue that Defendants are estopped from asserting the following eleven prior art references because a skilled searcher reasonably could have been expected to discover them with a diligent search: U.S. Patent No. 5,645,075 (“Turturro ‘075”), U.S. Patent No. 5,967,997 (“Turturro ‘997”), International Patent App. No. WO

99/15089 (“Cosgrove ‘089”), U.S. Patent No. 5,636,639 (“Turturro ‘639”), U.S. Patent No. 4,896,678 (“Ogawa ‘678”), U.S. Patent No. 5,172,700 (“Bencini ‘700”), U.S. Patent No. 5,211,655 (“Hasson ‘655”), U.S. Patent No. 5,368,606 (“Marlow ‘606”), U.S. Patent No. 5,782,748 (“Palmer ‘748”), U.S. Patent No. 5,797,957 (“Turturro ‘957”), and U.S. Patent No. 6,077,290 (“Marini ‘290”). (ECF No. 622 at 29–30.) The Court finds that, based on the overwhelming evidence in the record, no reasonable jury could find in favor of Defendants here. A skilled searcher conducting a diligent search reasonably could have found all of the aforementioned references; accordingly, Defendants are estopped from arguing invalidity on any grounds that rely on these references on their own, or in combination with other previously known references.

First, the Turturro '075, Turturro '997, Turturro '639, and Cosgrove '089 references were included in Defendants' June 2017 contentions, served six months after the IPR petition was filed, (ECF No. 573-3 at 4–6; ECF No. 573-4 at 4–6); a few months after that, in their December 2017 supplemental contentions, Defendants included the remaining references (i.e., Ogawa '678, Bencini '700, Hasson '655, Marlow '606, Palmer '748, Turturro '957, and Marini '290). (ECF No. 548 at 8–10; ECF No. 549 at 8–10.) In other words, within one year of their IPR petition, Defendants were able to find all the aforementioned references. The discovery of references such a short time after the IPR petition, when there is no evidence that the same search could not have been conducted before the petition, suggests the references reasonably could have been discovered with an earlier diligent search.⁵

⁵ Defendants argue that such an inference means “the only references a skilled searcher could not find are those that were never found.” (ECF No. 633 at 28.) That is not so. For instance, there may be

Nothing else had changed. Defendants could have presented evidence explaining why their subsequent discovery of the pertinent references required exceptional circumstances or strategies that would not have been used by a skilled searcher conducting a reasonably diligent search; but they did not. *See, e.g., Wi-LAN*, 421 F. Supp. 3d at 926 (noting that the patent challenger had pointed to no barriers or difficulties that would cause the prior art search conducted after the IPR petition to produce different results than one conducted before the IPR petition). Other courts have relied on evidence of subsequent reference discovery to find that a diligent search could have reasonably discovered the references prior to the IPR petition. *See, e.g., id.* ("Evidence that LG discovered these references through a prior art search is clear evidence that LG reasonably could have discovered these references through a diligent search."); *Sioux Steel Co. v. Prairie Land Mill Wright Servs.*, No. 16-cv-2212, 2022 WL 4132441, at *11 (N.D. Ill. Sept. 12, 2022) ("Because these references were 'found in a later prior art search, there is a reasonable inference that [they] could have been found earlier by a skilled searcher."); *Trustid, Inc. v. Next Caller Inc.*, No. 18-172 (MN), 2021 WL 3015280, at *1 (D. Del. July 6, 2021) ("[T]he fact that Defendant included Goldman in its invalidity contentions filed just several months after the IPR petition confirms that a skilled searcher likely would have been able to find the reference.").

references that a skilled searcher could not have found that are later found using new search strategies, improved databases, and years of painstaking search. But those factors are not present here.

Second, Plaintiffs' expert Lhymn provides a substantial report detailing various methods that a skilled searcher could have used to reasonably discover the references in question, including examples of search strings that a searcher could have used to reasonably find the prior art. (ECF No. 621-33 at 19–20.) Lhymn's analysis explained why the terms used in the search terms are *reasonable* in light of the Asserted Claims. (*Id.* (discussing where the search terms or their related synonyms can be found in the patent abstract, claims, and specification).) Lhymn used prevalent terms present in the relevant patents (e.g., tissue, clip, sheath, lock, actuate, handle, clamp, etc.), and used a related synonym prevalent in the art ("effector") to develop some of the search strings. (ECF No. 621-33 at 19–20.)

Third, the various references at issue here were closely related to references that Defendants knew about. Four references, Turturro '075, Turturro '997, Turturro '639, and Turturro '957, all share a common inventor, Vincent Turturro, with the '048 and '731 patents. (*See* ECF No. 621-40 at 30 (Defendants' expert, Davis, acknowledging that one method of discovering prior art is to search for prior art by the inventors listed on the patent).) The Palmer '748 reference (in addition to the Turturro references just mentioned), is owned by Plaintiffs through its predecessor, Symbiosis Corp. (ECF No. 621-46; *see also* ECF No. 621-40 at 27–28 (Davis acknowledging the use of assignees as a tactic in prior art searches); ECF No. 621-33 at 73 (Lhymn discussing how a skilled searcher could use Patbase to find prior art assigned between Symbiosis and Plaintiffs).) Five more references, Turturro '075, Ogawa '678, Hasson '655, Marlow '606, and Palmer '748 were cited throughout the prosecution of

Defendants' own patents directed to the same technical field, an area that would have been readily examined by a skilled searcher conducting a diligent search. (See ECF No. 621-33 at 52, 63, 67, 71, 74.) Six more references, Turturro '997, Turturro '639, Ogawa '678, Bencini '700, Hasson '655, and Marlow '606, are cited by or cite to prior art references included in Defendants' 2016 invalidity contentions. (ECF No. 621-44 at 2; ECF No. 621-45 at 2; ECF No. 621-52 at 2; ECF No. 621-53 at 3; ECF No. 621-54 at 2; *see also Wi-LAN*, 421 F. Supp. 3d at 926 (finding that certain references could have been found with a reasonably diligent search because the reference was cited to in prior art contained in the patent challenger's invalidity contentions served before the IPR petition).) And every reference shares at least one classification with the Asserted Patents (and all but one share multiple): Turturro '075 (IPC A61B 17/00, 17/28, and 19/00 and CPC A61B 2017/292), Turturro '997 (IPC A61B 17/00 and 17/28 and CPC A61B 2017/003), Cosgrove '089 (IPC A61B 17/00, 17/12, 17/28, 17/122, and 17/128 and CPC A61B 17/122, 17/1285, and 2017/292), Turturro '639 (IPC A61B 17/00, 17/28, and 19/00), Ogawa '678 (IPC A61B 17/28 and 19/00 and CPC A61B 90/03 and 2017/292), Bencini '700 (IPC A61B 17/00 and 17/28), Hasson '655 (IPC A61B 17/28 and CPC A61B 2017/292), Marlow '606 (IPC A61B 1/00, 17/00, 17/28, and 19/00), Palmer '748 (IPC A61B 1/00, 17/00, and 17/28 and CPC A61B 2017/292), Turturro '957 (IPC A61B 17/28), and Marini '290 (IPC A61B 17/00 and 17/28 and CPC A61B 2017/292). (ECF Nos. 621-62–75). Courts have looked at the shared classifications between prior art references and asserted patents to conclude that a diligent search reasonably could have discovered said references. *See, e.g., Trustid*,

2021 WL 3015280, at *1. *Cf. Palomar*, 2020 WL 2115625, at * 16 (finding that two references likely could not be discovered from a reasonable search in part because there was a "lack of overlap in classifications").

Taken together, these three arguments mean no reasonable jury would find for Defendants here. Accordingly, because a skilled searcher conducting a diligent search reasonably could find all of the remaining asserted references, Defendants are estopped from asserting them individually or in combination with one another.

2. Systems and Devices

Plaintiffs ask the Court to apply IPR estoppel to Defendants' prior art systems and devices and to therefore preclude Defendants from using the following devices in their invalidity arguments: (1) the Olympus Endoclips, (2) Plaintiffs' Radial Jaw Device, (3) Plaintiffs' Multibite Device, (4) Marlow's Nu-Tip Device, and (5) the Switch-Blade Device.

The party asserting estoppel bears the burden to show that estoppel applies. *Wi-LAN*, 421 F. Supp. 3d at 925; *CliniComp Int'l, Inc. v. Athenahealth, Inc.*, No. A-18-CV-00425-LY, 2020 WL 7011768, at *2 (W.D. Tex. Oct. 28, 2020) ("The moving party bears the burden of showing IPR estoppel."). IPR estoppel precludes a patent challenger from asserting that a claim is "invalid on any ground that the petitioner raised or reasonably could have raised *during . . . inter partes review.*" 35 U.S.C. § 315(e)(2) (emphasis added). "[C]ourts have interpreted ['ground'] in the IPR estoppel context to mean the 'specific pieces of prior art' that are 'the basis or bases on which a petitioner challenges a claim.'" *Medline*, 2020 WL 5512132, at *3. But a petitioner

in an IPR can request to cancel a claim as unpatentable "only on the basis of prior art *consisting of patents or printed publications.*" 35 U.S.C. § 311(b) (emphasis added). Thus, a petitioner is statutorily prohibited from raising physical prior art devices and systems at the IPR. IPR estoppel, then, at least *generally*, does not apply to physical device prior art because such prior art "could not have been raised" during the IPR. *CliniComp*, 2020 WL 7011768, at *2 ("Estoppel does not extend to other types of prior art, such as prior-art devices."); *SPEX Techs. Inc. v. Kingston Tech. Corp.*, No. SACV 16-01790 JVS (AGRx), 2020 WL 4342254, at *15 (C.D. Cal. June 16, 2020); *IOENGINE, LLC v. PayPal Holdings, Inc.*, No. 18-452-WCB, 2022 WL 2800861, at *31 (D. Del. June 15, 2022) (citation omitted) ("In general, IPR estoppel does not apply to device art, because 'a petitioner cannot use an IPR to challenge the validity of a patent claim . . . based on prior art products or systems.'").

Plaintiffs ask the Court to depart from this general rule and allow IPR estoppel to apply to physical devices in particular situations. The Court will address each in turn.

i. Analysis Under Medline

Plaintiffs argue that *Medline Industries, Inc. v. C.R. Bard, Inc.*, No. 17 C 7216, 2020 WL 5512132 (N.D. Ill. Sept. 14, 2020), allows IPR estoppel of devices when the defendant relies on estopped patents or printed publications to show how the prior art devices worked. But the *Medline* court's holding was very narrow: an IPR petitioner will avoid estoppel "if the invalidity ground it pursues in litigation *actually* relies upon a product or some other product-related evidence that could not have been

introduced in an IPR proceeding as a prior art reference." *Id.* at *5 (emphasis in the original). Stated differently, "the petitioner cannot put forth invalidity arguments in litigation that rely *solely* upon patents or printed publications that could have been raised in the IPR, and then claim that IPR estoppel does not apply because these printed materials reflect or represent a prior art product." *Id.* (emphasis added). The Court agrees with this narrow holding. A patent challenger cannot rely *solely* on otherwise estopped printed publications or patents to describe how a physical device works and then argue that they are actually relying on a physical device. Rather, the patent challenger must, at least in part, substantively rely on the actual physical specimen to escape IPR estoppel. As will be discussed, this rule goes hand in hand with the standard under *Wasica*; in other words, the physical device must provide a substantive difference to the challenger's invalidity argument that would not have been available by solely relying on the patents and publications describing the device.

In this case, Defendants do not rely solely on patents or printed publications to describe how the various physical devices work. While Defendants certainly rely on some printed publications and patents, at least some portions of Defendants' invalidity arguments rely substantively on the physical specimens themselves. (*See, e.g.*, ECF No. 632-7 at 30–35 (discussing features of the Olympus Endoclip physical device through specimen testing and physician testimony); *id.* at 36–37 (explaining, through inspection and testing of the physical Radial Jaw device, relevant pinching features of the device); *id.* at 38–39 (same as to the Multibite device).)

Accordingly, the Court finds that Defendants are not relying *solely* on estopped documents to describe how their asserted physical devices work; Plaintiffs have not met their burden under *Medline*.

ii. Analysis Under Wasica

Plaintiffs also rely on *Wasica Finance GmbH v. Schrader International, Inc.*, 432 F. Supp. 3d 448 (D. Del. 2020) to argue that IPR estoppel of physical devices is allowed when the defendant relies on devices themselves that are described in estopped patents or printed publications. *See Wasica*, 432 F. Supp. 3d at 455; *IOENGINE*, 2022 WL 2800861, at *31 (citing cases including *Wasica* and stating that "some courts have estopped defendants from asserting device art when 'the physical product is entirely cumulative' of the prior art raised in the IPR, i.e., when the product is "materially identical" to the prior art reference raised in the IPR"). Of course, *Wasica* is not binding on this Court or other courts across the country, and some courts have expressly rejected *Wasica*'s reasoning based on statutory interpretation. *See, e.g., Chemours Co. FC, LLC v. Daikin Indus., Ltd.*, No. 17-1612 (MN), 2022 WL 2643517, at *2 (D. Del. July 8, 2022) (declining to apply *Wasica* absent guidance from the Supreme Court or the Federal Circuit). This Court, however, finds *Wasica* persuasive and holds that a patent challenger will be estopped from using a physical device to argue invalidity if all of the material limitations of that device were disclosed in a patent or printed publication that the patent challenger either knew about or reasonably could have discovered with a diligent search prior to the IPR. Despite

opposition from some courts, the reasoning in *Wasica* is not without its support from the statutory language as well:

35 U.S.C. § 312(a)(3) identifies as separate requirements to be included in an IPR petition "the **grounds** on which the challenge to each claim is based, and the **evidence** that supports the grounds for the challenge to each claim." . . . In this way, the Patent Act distinguishes between grounds and evidence. Since the estoppel provision, § 315(e)(2), applies to **grounds**, a petitioner is estopped from proceeding in litigation on those **grounds**, even if the **evidence** used to support those grounds was not available to be used in the IPR.

Wasica, 432 F. Supp. 3d at 454 (emphasis in the original). In other words, if the patent challenger is relying on a physical device at the district court that is *fully* disclosed in an estopped patent or publication, then there is truly no substantive difference between the ground to be argued before the district court and the ground that was or reasonably could have been argued at the IPR. This is true even if the patent challenger could not have used the physical device at the IPR.⁶ As the court in *Wasica* notes, though, the reference that discloses the limitations of the physical device must be "materially identical" to the physical device. If reliance on the physical device discloses *any* substantive additional limitation that was not present in the reference, the physical device will not be estopped. Thus, to meet its burden, a plaintiff must show that each and every material limitation present in the physical

⁶ As a simple example, assume Patent A discloses claim limitations 1, 2, and 3, and Patent B discloses claim limitations 4, 5, and 6. At the IPR for Patent C, a patent challenger could present an argument that Patent C is invalid as obvious in light of Patents A and B. Now assume that this argument is rejected. Additionally, assume Physical Device A discloses the same claim limitations 1, 2, and 3 that were disclosed in Patent A. If this Court declines to follow *Wasica*, then a patent challenger could argue that Patent C is invalid as obvious in light of Physical Device A and Patent B. But this would be irrational, curb the efficiency purposes of IPR estoppel, and allow the patent challenger to make an *identical* challenge at the district court based on the exact same *ground* as that made at the IPR (i.e., based on the exact same limitations under the same invalidity theory with essentially the same pieces of prior art).

device is disclosed in the estopped reference; the burden then shifts to the defendant. If the defendant, in response, points to a material limitation that is disclosed in the physical device that is *not* disclosed in the estopped reference, then the burden shifts back to the plaintiff to show why said limitation is (1) either *not* material or (2) is in fact specifically disclosed in the estopped reference. *See CliniComp*, 2020 WL 7011768, at *2 ("The moving party bears the burden of showing IPR estoppel."). Only then will the Court extend IPR estoppel to a physical device.⁷

iii. Application to Defendants' Asserted Prior Art Devices

The Court will address the application of IPR estoppel to each physical device in turn.

Upon review of the patents and publications that Plaintiffs have identified, the Court finds that the physical Olympus Endoclips are not materially identical to any

⁷ Additionally, it is important that this application of IPR estoppel is not abused. Again, the point of IPR estoppel is to preclude a patent challenger from arguing the same *ground* that it raised or reasonably could have raised at the IPR. A plaintiff cannot bring numerous estopped references, each disclosing a few limitations of the physical device, and then argue that the physical device as a whole must be estopped. Combining one reference (call it Reference A) with numerous other references (References B through E) that each independently disclose some limitations is certainly not the same "ground" as combining Reference A with a physical device that by itself discloses all of the material limitations of References B through E. If all of the material features of the device are not fully disclosed in a *single* reference, then the physical device cannot be estopped. After all, showing that all material features of a patent claim are disclosed in an infinite number of references is typically not enough to prove invalidity under an obviousness theory; rather, the patent challenger must show a *motivation to combine* these references. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (discussing the motivation to combine inquiry in the obviousness context). The motivation to combine Reference A with References B through E is certainly a different inquiry than the motivation to combine Reference A with a singular physical device. This single reference requirement aligns with other courts' application of IPR estoppel to physical devices as well. *See Wasica*, 432 F. Supp. 3d. at 455 (finding IPR estoppel as to the physical ZR-1 Sensors because all of the material elements were disclosed in a single 1990 prior art publication); *SPEX*, 2020 WL 4342254, at *15 ("The Court finds that the reliance on some printed publications in an overall collection of documents being used to describe a system invalidity theory should not lead to estoppel of the overall system invalidity theory itself, nor piecemeal exclusion of the printed publications underlying that system invalidity theory.").

one of these estopped references. Plaintiffs compare annotated images of the Olympus Endoclips (taken from Nicosia's report) to figures disclosed in various patents, (ECF No. 622 at 39 (comparing Komiya '576 and Shinozuka '946)), to show that some features of the Olympus Endoclips are disclosed in the references. (*See, e.g., id.* (discussing the figure-8 clip, hook member, control wire, and sleeve).) But not all the material features of the Olympus Endoclips are disclosed in these references. Even in comparing the Komiya '576 disclosure to the Shinozuka '946 disclosure, for example, the Court is not convinced that these references even describe the same clip. The clip in Komiya '576 links to the control wire via a base whose shape completely closes. (ECF No. 621-59 at 4.) On the other hand, the Shinozuka '946 clip links to the control wire via a hook at the base of the clip. (ECF No. 674-30 at 5.) This difference is not immaterial, as Plaintiffs themselves have previously noted. (*See* ECF No. 631-5 at 68–69 (discussing the significance of this difference in shape).) Plaintiffs then move to the Matsuno '189 patent to show that it discloses a link that is not integral with the control wire or clip, a feature that Defendants point to with the Olympus Endoclips. (ECF No. 622 at 40.) But again, the clip in Matsuno '189 appears to have a link and control wire that are shaped differently and connect differently than the clips in the other references. (*Compare* ECF No. 621-61 at 4, 6–7 *with* ECF No. 621-59 at 4 *and* ECF No. 674-30 at 5.) Additionally, Plaintiffs are erroneously relying on multiple patents which each purportedly disclose particular limitations of the Olympus Endoclips. These references in combination would not present the same *ground* as the Olympus Endoclips by themselves. Further,

Plaintiffs' reliance on the Olympus Endoclips Instructions for Use as an estopped printed publication that fully discloses all material limitations of the Olympus Endoclips is insufficient. (*See* ECF No. 622 at 40.) The Instructions for Use document does not disclose that the Olympus devices are capable of reversibly opening and closing, which is a key claimed feature in the Asserted Patents here.⁸ (ECF No. 633 at 25; *see generally* ECF No. 674-7 at 222; ECF No. 674-8 at 57; ECF No. 674-9 at 3.)

Plaintiffs' estoppel arguments as to the Radial Jaw device and the Multibite device suffer from similar deficiencies. With both devices, Plaintiffs list an assortment of references which they claim disclose all material limitations of the physical devices. (*See* ECF No. 622 at 41–42.) Plaintiffs support this argument by relying on Leinsing's cumulativeness opinion. However, the analysis presented is insufficient as the Court fails to see where Leinsing (or Plaintiffs in their brief) shows how any *single reference* discloses all of these material features. (*See, e.g.*, ECF No. 621-77 at 36.) In fact, Leinsing's cumulativeness opinion as a whole is not helpful at all and only offers conclusory testimony on the issue. (*See id.* (concluding in broad strokes that the asserted physical devices are cumulative and offering burdensome citations to full documents in support).) In any case, none of the references that Plaintiffs point to discloses the fact that the physical Radial Jaw or Multibite clips can "pinch tissue without cutting." (ECF No. 633 at 25.) This is not a negligible difference. Plaintiffs themselves have discussed the importance of this limitation. (*See* ECF No. 631-25 at 27–30 (discussing that "the claimed clip must be capable of 'pinching', which is a

⁸ As far as the Court can tell, none of the other patents and printed publications disclose this feature either.

compression force" and differentiating biopsy forceps which apply a shear force and therefore do not constitute a "clip".) In order to ascertain this feature, Defendants tested physical specimens of the Radial Jaw and Multibite. (ECF No. 632-7 at 36–39.) In other words, this feature was not derived from any estopped patent or printed publication. Accordingly, the Radial Jaw device and the Multibite device are not materially identical to any single estopped reference.

Plaintiffs have more success with the Marlow Nu-Tip device. Defendants and their expert, Nicosia, rely almost exclusively on the Marlow '606 patent in describing the Nu-Tip device and how it works. (*See, e.g.*, ECF No. 674-18 at 116–22 (relying on figures from the Marlow '606 patent to identify all key limitations of the device, such as an "opening element").) Importantly, all of the limitations that Defendants identify in the device (the opening element, the open and closed configurations, the clip, the linkage mechanism with pins engaging the inner walls, the separable link, the control wire, etc.) are disclosed in the Marlow '606 patent. (ECF No. 621-37 at 3–4 (showing figures used by Defendants, which were later annotated to include all material elements).) Because the Court has already found that the Marlow '606 patent is estopped prior art, (*see supra* III.G.1.ii.), and because the Marlow '606 patent is materially identical to the Marlow Nu-Tip physical device, Defendants are estopped from using the device to argue invalidity.

Finally, the Court finds that the Switch-Blade device is not materially identical to any estopped reference produced by Plaintiffs. Plaintiffs argue that all material limitations of the Switch-Blade are disclosed in the Furnish '290 patent and,

alternatively, in the device's brochure and instruction card. The Court disagrees. First, the Furnish '290 patent discloses very little about the clip portion of the device, focusing almost exclusively on the actuating portion of the device. (*See* ECF No. 621-78 at 3.) The specification only mentions the "surgical tool 23" a few times and only states that it is connected to the distal end of the device's shaft. (*Id.* at 6.) There is no indication at all that this surgical tool (which Defendants argue is analogous to a "clip") is detachable from the device (similar to the claimed linkage feature of the invention here). Plaintiffs point to no evidence in the patent to suggest otherwise. The brochure/information card of the Switch-Blade likewise does not disclose all material features of the physical device; specifically, these documents provide no detail about the surgical tool (i.e., clip) whatsoever. (*See generally* ECF No. 674-70.) To ascertain key features of the Switch-Blade clip, such as the "opening element engaging inner walls of first and second clip arms," Defendants had to rely on the device's 510(k) application. (*See* ECF No. 632-7 at 70–71.) The estopped references that Plaintiffs point to do not disclose these features. Therefore, Defendants are not estopped from relying on the physical Switch-Blade device.

H. Collateral Estoppel

During the IPR of the '731 patent, the PTAB found, and the Federal Circuit affirmed, that the asserted claims of the '731 patent were not rendered invalid by the prior art patents and printed publications asserted therein. Defendants want now to argue that the claims are in fact invalid. Plaintiffs wish to defend against such a challenge. But Defendants argue that Plaintiffs are collaterally estopped from doing

so. (ECF No. 633 at 52.) The Court first recaps important background information germane to this issue. Claims 5 and 19 of the '731 patent, the Asserted Claims, depend from claims 4 and 12, respectively. (ECF No. 451-5 at 38.) Claims 5 and 19 add an identical limitation: "wherein a distal end of the control wire includes an increased width portion." (*Id.*) In the IPR, the Patent Office held claims 4 and 12 unpatentable as anticipated by Sackier but claims 5 and 19 were found to *not be obvious* over Sackier. (ECF No. 345-7 at 86.) Because the only difference between claim 4/claim 12 and claim 5/claim 19 is the "increased width" limitation, Defendants urge the Court to find that the same invalidity "issue" has already been litigated at the IPR and thus Plaintiffs should be collaterally estopped from disputing invalidity here.

"Collateral estoppel protects a party from having to litigate issues that have been fully and fairly tried in a previous action and adversely resolved against a party-opponent." *Ohio Willow Wood Co. v. Alps South, LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013). "If the differences between the *unadjudicated* patent claims and adjudicated patent claims do not materially alter the question of invalidity, collateral estoppel applies." *Id.* (emphasis added). Regional circuit precedent guides the general principles of collateral estoppel, but Federal Circuit precedent is applied "to those aspects . . . that involve substantive issues of patent law." *Id.*; *see also Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335, 1341 n.1 (Fed. Cir. 2012) ("[T]he question whether a particular claim in a patent case is the same as or separate from

another claim has special application to patent cases, and we therefore apply our own law to that issue.").

In the Seventh Circuit, collateral estoppel has the following elements: "(1) the issue sought to be precluded is the same as an issue in the prior litigation; (2) the issue must have been actually litigated in the prior litigation; (3) the determination of the issue must have been essential to the final judgment; and (4) the party against whom estoppel is invoked must have been fully represented in the prior action." *Adams v. City of Indianapolis*, 742 F.3d 720, 736 (7th Cir. 2014) (citation omitted). The parties dispute only the first element—whether the "increased width" limitation materially alters the issue of validity.

Defendants present an interesting issue of first impression before the Court. The law on this issue is varied and relatively sparse; no case is directly analogous. In *Intellectual Ventures I, LLC v. Lenovo Group Ltd.*, 370 F. Supp. 3d 251, 256–57 (D. Mass. 2019), the court held that collateral estoppel precluded assertion of *unadjudicated* claims that do not "materially alter the question of invalidity." However, this conclusion fails to account for the different burdens at the IPR and district court. *See, e.g., Papst Licensing GmbH & Co., KG v. Samsung Elecs. Co.*, 403 F. Supp. 3d 571, 602 (E.D. Tex. 2019) (finding no "binding precedent addressing whether a finding of invalidity under the preponderance of the evidence standard in an IPR collaterally estops invalidity arguments for separate, unadjudicated claims under the clear and convincing standard in a district court") (citing *B & B Hardward, Inc. v. Hargis Indus., Inc.*, 575 U.S. 138, 148 (2015)); *United Therapeutics Corp. v.*

Liquidia Techs., Inc., No. 20-755-RGA-JLH, 2022 WL 823521, at *4 (D. Del. Mar. 18, 2022) (declining to apply collateral estoppel and stating that "the problem for Liquidia is that the PTAB made its findings on a preponderance of the evidence standard, and Liquidia must prove invalidity in this case by clear and convincing evidence"). Defendants successfully showed that claims 4 and 12 were unpatentable as obvious by a preponderance of the evidence at the IPR. (ECF No. 345-7 at 86.) But here, to show that claims 5 and 19 are invalid, they must do so by the more stringent clear and convincing standard. *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1376 (Fed. Cir. 2009). The Court is reluctant to apply collateral estoppel in this situation.

Furthermore, the facts here present a unique situation that does not warrant collateral estoppel. Unlike the circumstances in *Intellectual Ventures*, claims 5 and 19 here, which Defendants allege to be "materially identical" to the prior invalidated claims 4 and 12, *actually were adjudicated in the prior IPR*. *Cf. Intellectual Ventures*, 370 F. Supp. 3d at 256–57. Defendants sought to invalidate those claims as obvious in view of the Sackier prior art but were unsuccessful. (ECF No. 345-7 at 86.) Now, they wish to preclude Plaintiffs from even disputing the invalidity of claims 5 and 19 because the claims depend from the now-invalidated claims 4 and 12 and because claims 5 and 19 do not add a limitation that would materially alter the invalidity analysis. The Court struggles to see how such an application of the collateral estoppel doctrine would be just, particularly because it cannot be said that claims 5 and 19 were "unadjudicated." Plaintiffs should not be precluded from disputing invalidity

here when they successfully did so at the IPR, even if the invalidity challenge was on a different ground (i.e., Sackier alone rather than Sackier with other prior art). This conclusion only means that Plaintiffs are not precluded from *disputing invalidity*. Defendants can still argue invalidity using prior art that is not estopped, such as through some of the physical devices previously discussed.

Accordingly, the Court will not collaterally estop Plaintiffs from disputing invalidity as to the '731 claims.⁹

I. Summary

The Court **grants in part and denies in part** both parties' Motions for Summary Judgment. (ECF Nos. 620 & 630.)

As to infringement of the '048 patent, the Court finds that the only surviving claims are claims 7 and 14. All that remains is a genuine dispute as to whether the housing of the Accused Products is an equivalent of a component of the "sheath" of independent claim 1. The remaining claim limitations of claims 7 and 14 (and claim 1 on which they depend) are found in the Accused Products. For the remaining claims of the '048 patent, summary judgment is **granted** in favor of Defendants.

⁹ Even if collateral estoppel applied, the Court would find that Defendants had not met their burden of showing no genuine dispute as to materiality of the increased width limitation. While the evidence weighs in favor of concluding that the increased width limitation is immaterial, Plaintiffs have presented at least some genuine dispute as to materiality that precludes summary judgment. The differentiation between Defendants' own devices suggests that there is some beneficial purpose to a control wire with an increased width at the distal end. Namely, while the Instinct did not have a control wire with an increased width portion, the Instinct Plus did; the '731 claims are thus only asserted against the Instinct Plus. (*Compare* ECF No. 621-3 at 21 (Instinct Plus) *with* ECF No. 621-42 (Instinct).) Defendants' arguments that the Instinct Plus and Instinct are not "materially different" are not enough to extinguish a genuine dispute here. (See ECF No. 706 at 25.) The Instinct Plus is, by all accounts, at the least a small improvement on the Instinct. Additionally, Defendants' own documentation attributes some significance to the increased width of the control wire. (See ECF No. 674-65 at 9–11 (noting that the width of the drive wire will help keep the "drive wire and driver engaged regardless of lateral movement").)

As to infringement of the '371 patent, the Court **grants** Defendants' Motion for Summary Judgment. All claims against Defendants asserted under the '371 patent are **dismissed**.

As to infringement of the '731 patent, the Court **grants** Plaintiffs' Motion for Summary Judgment. The Court finds that all pertinent limitations of claims 5 and 19 of the '731 patent are literally infringed by the Instinct Plus.

As to infringement under 35 U.S.C. §§ 271(b) and (c), the Court **grants** Defendants' Motion for Summary Judgment.

As to infringement by Cook Group Incorporated, the Court **grants** Defendants' Motion for Summary Judgment.

As to IPR estoppel, the Court finds that Defendants are **estopped** from using any of the printed publications or patents listed in Section III.G.1.i and III.G.1.ii. Additionally, Defendants are **estopped** from using the Marlow Nu-Tip physical device to argue invalidity. Defendants may rely on any of the other asserted devices.

The Court **denies** Defendants' Motion for Summary Judgment as to collateral estoppel. Plaintiffs may dispute invalidity of the '731 patent.

IV. Conclusion

A. Motion to Preclude

For the reasons discussed above, Defendants' Motion to Preclude, (ECF No. 634), is **granted in part and denied in part**.

Defendants' Motion as to Leinsing's cumulativeness opinions is **denied**.

Defendants' Motion as to Lhymn's opinions that Defendants "knew" of the existence of certain prior art is **granted**.

Defendants' Motion with regards to Mr. Lhymn's skilled searcher opinions is **denied**.

Defendants' Motion as to Plaintiffs' new "link" infringement theory is **denied**.

B. Motions for Summary Judgment

The Court **grants in part and denies in part** both parties' Motions for Summary Judgment. (ECF Nos. 620 & 630.)

As to infringement of the '048 patent, the Court finds that the only surviving claims are claims 7 and 14. All that remains is a genuine dispute as to whether the housing of the Accused Products is an equivalent of a component of the "sheath" of independent claim 1. The remaining claim limitations of claims 7 and 14 (and claim 1 on which they depend) are found in the Accused Products. For the remaining claims of the '048 patent, summary judgment is **granted** in favor of Defendants.

As to infringement of the '371 patent, the Court **grants** Defendants' Motion for Summary Judgment. All claims against Defendants asserted under the '371 patent are **dismissed**.

As to infringement of the '731 patent, the Court **grants** Plaintiffs' Motion for Summary Judgment. The Court finds that all pertinent limitations of claims 5 and 19 of the '731 patent are literally infringed by the Instinct Plus.

As to infringement under 35 U.S.C. §§ 271(b) and (c), the Court **grants** Defendants' Motion for Summary Judgment.

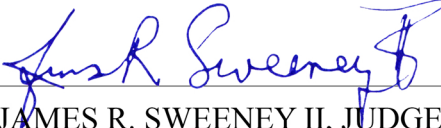
As to infringement by Cook Group Incorporated, the Court **grants** Defendants' Motion for Summary Judgment. The Clerk is ordered to **terminate** Cook Group Incorporated from the case.

As to IPR estoppel, the Court finds that Defendants are **estopped** from using any of the printed publications or patents listed in Section III.G.1.i and III.G.1.ii. Additionally, Defendants are **estopped** from using the Marlow Nu-Tip physical device to argue invalidity. Defendants may rely on the remaining physical devices.

The Court **denies** Defendants' Motion for Summary Judgment as to collateral estoppel. Plaintiffs may dispute invalidity of the '731 patent.

SO ORDERED.

Date:01/31/2023



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

Distribution to registered counsel of record via CM/ECF.