IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE JOHNS HOPKINS UNIVERSITY, Plaintiff, v. ALCON LABORATORIES, INC. and ALCON RESEARCH, LTD., Defendants.	)	Civil Action No. 15-525-SLR-SRF REDACTED VERSION [redacted]

REPORT AND RECOMMENDATION

I. INTRODUCTION

Presently before the court in this patent infringement action are the following motions: (1) the motion for summary judgment regarding U.S. Patent No. 7,077,848 ("the '848 patent"), filed by defendants Alcon Laboratories, Inc. and Alcon Research, Ltd. (together, "Alcon") (D.I. 196); (2) the motion for summary judgment on issues pleaded by defendants but not pursued or disclosed during discovery, filed by plaintiff The Johns Hopkins University ("JHU") (D.I. 199); (3) JHU's motions to exclude under Federal Rule of Evidence 702 and *Daubert* (D.I. 218); and (4) Alcon's *Daubert* motion to exclude certain opinions and testimony of JHU's experts Brian Napper and Charles Colby (D.I. 225). I recommend that the court grant-in-part each of the four pending motions for the following reasons.

II. BACKGROUND[1]

JHU filed this patent infringement action on June 23, 2015, alleging that Alcon infringes the '848 patent, entitled "Sutureless Occular Surgical Methods and Instruments for Use in Such

[1] Relevant facts pertaining to discrete issues raised in the parties' briefing are set forth in the court's analysis of the applicable motion.

Methods." (D.I. 1) The '848 patent involves an ocular surgery technique that allows a surgeon to perform vitreoretinal surgery without the use of traditional incisions and sutures. (*Id.* at ¶ 11) Instead, the surgery involves making openings in the eye for the placement of tubes, called cannulas, through which thin gauge instruments are inserted to perform the surgery. ('848 patent, col. 6:48-60) Following the procedure, the tubes are removed and the wounds self-seal. (*Id.*) The prior art method, known as 20-gauge surgery, was used for about twenty years before the technique claimed by the '848 was developed in 2002. Surgeons had to make multiple incisions in performing the 20-gauge surgery because that technique did not use cannulas. ('848 patent, col. 2:17-27)

JHU asserts that Alcon encourages performance of the patented surgical technique it calls "Micro-Incision Vitrectomy Surgery" ("MIVS") by making and selling certain surgical instruments (the "Accused Products"), including 23-gauge, 25-gauge, and 27-gauge products.[2] (D.I. 13 at ¶ 19) The list of Accused Products includes cannulas, instruments inserted and removed through the cannulas, other related items, and "Paks," which are kits containing the various tools. (3/29/16 Tr. at 14:6–15:1) The instruments included in the Accused Products can be sold individually, in pre-set Paks, or in customized Paks, and the instruments come in different sizes. (*Id.* at 15:1–21, 16:5-13)

III. LEGAL STANDARDS

A. Excluding Expert Testimony

In *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993), the Supreme Court explained that Federal Rule of Evidence 702 creates "a gatekeeping role for the [trial] judge" to

[2] Higher gauged products are smaller in size. Thus, the 23-gauge product is smaller than the 20-gauge product.

"ensur[e] that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." The rule requires that expert testimony "help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702(a). Expert testimony is admissible only if "the testimony is based on sufficient facts or data," "the testimony is the product of reliable principles and methods," and "the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(b)-(d). There are three distinct requirements for admissible expert testimony: (1) the expert must be qualified; (2) the opinion must be reliable; and (3) the expert's opinion must relate to the facts. *See generally Elcock v. Kmart Corp.*, 233 F.3d 734, 741-46 (3d Cir. 2000).

B. Summary Judgment

Pursuant to Rule 56(a) of the Federal Rules of Civil Procedure, "[t]he court shall grant summary judgment 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." The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 585-86 (1986). An assertion that a fact cannot be—or, alternatively, is—genuinely disputed must be supported either by citing to "particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials," or by "showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." Fed. R. Civ. P. 56(c)(1)(A) & (B). If the moving party has carried its burden, the nonmovant must then "come forward with specific facts showing that there is a genuine issue for trial." *Matsushita*, 475 U.S. at 587

(internal quotation marks omitted). The court will "draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence." *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000).

To defeat a motion for summary judgment, the nonmoving party must "do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita*, 475 U.S. at 586; *see also Podobnik v. U.S. Postal Serv.*, 409 F.3d 584, 594 (3d Cir. 2005) (stating that the party opposing summary judgment "must present more than just bare assertions, conclusory allegations or suspicions to show the existence of a genuine issue") (internal quotation marks omitted). The "mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment;" a factual dispute is genuine only where "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." *Id.* at 249-50 (internal citations omitted); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) (stating that entry of summary judgment is mandated "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial"). Thus, the "mere existence of a scintilla of evidence" in support of the nonmoving party's position is insufficient to defeat a motion for summary judgment; there must be "evidence on which the jury could reasonably find" for the nonmoving party. *Anderson*, 477 U.S. at 252.

IV. DISCUSSION

A. Alcon's *Daubert* Motions

1. Brian Napper

(a) Apportionment

In support of its *Daubert* motion, Alcon alleges that Mr. Napper's methodology for calculating a reasonable royalty is unreliable because the reasonable royalty base used by him applies the entire market value rule and includes 100% of Alcon's surgical product sales, despite the fact that the patented feature does not drive the demand for the entire product. (D.I. 226 at 2-11) Alcon contends that Mr. Napper failed to account for the value of Alcon's patent portfolio, Alcon's sales and marketing prowess, and Alcon's dominant market share in the industry resulting from its investment in independent research and development. (*Id.* at 4-5) According to Alcon, Mr. Napper's opinion is also based on his flawed assumption that the Accused Products directly infringe the '848 patent. (11/15/17 Tr. at 77:6-14, 79:16-22)

In response, JHU contends that Mr. Napper properly analyzed the *Georgia-Pacific* factors in this case, selecting a base consistent with the license agreements between JHU and Bausch & Lomb ("B&L"), which included both standalone instruments and instrument packs. (D.I. 233 at 3-4) JHU alleges that Alcon prices packs as a single product and markets them to be used together to perform a specific surgery, and argues that the cannulas drive the price of the packs. (*Id.* at 4) According to JHU, Mr. Napper's analysis reflects a base adjusted to account for alleged non-infringing uses, as well as Alcon's own contributions, such as marketing. (*Id.* at 5)

I recommend that the court deny Alcon's motion to exclude the opinions and testimony of Mr. Napper because Mr. Napper's method "is consistent with the Federal Circuit's approved methodology for valuing asserted patents based on comparable licenses." *Intel Corp. v. Future*

Link Sys., LLC, C.A. No. 14-377-LPS, 2017 WL 2482881, at *2 (D. Del. June 1, 2017) (citing *Commonwealth Sci. & Indus. Res. Org. v. Cisco Sys., Inc.*, 809 F.3d 1295, 1303 (Fed. Cir. 2015)). Mr. Napper's analysis focuses on the comparability of real-world license agreements between B&L and JHU to calculate a royalty on both standalone instruments and vitrectomy packs. (D.I. 227, Ex. 3 at 101) Specifically, Mr. Napper explains that B&L sells small-gauge standalone instruments comparable to Alcon's Accused Products, including 23-gauge and 25-gauge forceps, light pipes, aspirating picks, and soft tip cannulas, as well as procedure packs, including 23-gauge and 25-gauge posterior procedure packs containing high speed vitrectomy cutters, forceps, aspirating picks, and entry alignment systems. (*Id.* at n.415) Mr. Napper's damages analysis excludes other necessary components used to perform the claimed method, including consoles and certain supplies, consistent with the base identified in the 2016 agreement between B&L and JHU. (*Id.* at 101) However, because the 2016 agreement between B&L and JHU covers surgical packs as a whole, Mr. Napper identifies Alcon's vitrectomy packs to be royalty bearing in his damages analysis without isolating the individual components of the packs. (*Id.*)

Mr. Napper further apportioned damages in his analysis based on comparable benchmark agreements by accounting for non-infringing uses and ancillary items. For example, Mr. Napper applied a 5% reduction to the royalty rate to account for use of the accused Standard Paks in non-infringing methods such as the vit-buckle. (D.I. 227, Ex. 3 at 98) Moreover, Mr. Napper calculated that infringing components made up 86% of the total Standard Pak price, and accordingly subtracted 14% to account for non-infringing components included in the packs. (*Id.* at 105-06; 11/15/17 Tr. at 90:16-91:1) To the extent that Alcon alleges Mr. Napper failed to account for sales of its prior 20-gauge products, the record reflects that Mr. Napper considered

the sales of 20-gauge products, but ultimately credited evidence from Alcon employees indicating that those products have little to no value in light of the shift in the market to small-gauge products. (D.I. 227, Ex. 3 at 54-58; 11/15/17 Tr. at 98:1-11) Where, as here, "the methodology is sound, and the evidence relied upon sufficiently related to the case at hand, disputes about the degree of relevance or accuracy . . . may go to the testimony's weight, but not its admissibility." *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 856 (Fed. Cir. 2010).

Mr. Napper's methodology of calculating a reasonable royalty rate based on comparable licensing negotiations is an accepted methodology even in the absence of a separate apportionment analysis on the smallest salable patent-practicing unit. *See Intel*, 2017 WL 2482881, at *2 (citing *Commonwealth*, 809 F.3d at 1300-03). In addition, Mr. Napper presents the theory that the intended purpose of all Accused Products in the present case is to practice the patented method. (D.I. 227, Ex. 3 at 101) For example, claim 26 of the '848 patent suggests that other components are necessary to perform the claimed method in addition to the cannula, such as a light source and a high speed vitreous cutting/aspirating instrument. ('848 patent, col. 24:8-16) As a result, disputed issues of fact remain as to whether the cannula represents the smallest salable patent-practicing unit. *See AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1338 (Fed. Cir. 2015) ("[W]hile it is important to guard against compensation for more than the added value attributable to an invention, it is improper to assume that a conventional element cannot be rendered more valuable by its use in combination with an invention."). When "a multi-component product containing several non-infringing features with no relation to the patented feature" is itself the smallest salable unit, the Federal Circuit has held that "the patentee must do more to estimate what portion of the value of that product is attributable to the patented technology." *VirnetX, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1327 (Fed. Cir. 2014).

Mr. Napper's royalty calculation under the entire market value rule, which includes the entire surgical pack in the royalty base, should not be excluded because there is evidence to support Mr. Napper's conclusion that the accused small gauge devices form the basis of customer demand for the packs. (D.I. 227, Ex. 3 at 102-03) "[W]here the entire value of a machine as a marketable article is 'properly and legally attributable to the patented feature,'" it is appropriate to calculate the damages owed based on the entire market value of the product without apportionment. *Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1226 (Fed. Cir. 2014) (quoting *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1320 (Fed. Cir. 2011)). Mr. Napper points to record evidence demonstrating that the value of the packs is primarily attributable to the trocar cannulas and instruments, and ancillary components comprise only a small portion of the sale price.[3] (D.I. 227, Ex. 3 at 102) The record reflects that Alcon prices its vitrectomy packs as a single product because the contents of the packs are intended to be used together to perform the surgery, and any components of the packs not used in the surgery would be thrown away. (*Id.* at 101-02) Application of the entire market value rule is appropriate "when the accused product consists of both a patented feature and unpatented features . . . to account for the contribution of the patented feature to the entire product." *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1338 (Fed. Cir. 2015).

Factual issues regarding the proper valuation of the packs as a single unit should be left to the jury. *See Apple Inc. v. Motorola, Inc.*, 757 F.3d 1286, 1327 (Fed. Cir. 2014), *rev'd on other grounds*, *Williamson v. Citrix Online, LLC*, 792 F.3d 1339 (Fed. Cir. 2015) ("If a patentee's evidence fails to support its specific royalty estimate, the fact finder is still required to determine

[3] Mr. Napper's alternative apportionment analysis removes certain components of the packs from the royalty base which are not expressly mentioned in the '848 patent. (D.I. 227, Ex. 3 at 103-04)

what royalty is supported by the record."). The entire market value rule is an accepted methodology of calculating a royalty in cases involving a multi-component product where the value is attributable to the patented feature. *See Versata Software, Inc. v. SAP Am., Inc.*, 717 F.3d 1255, 1268 (Fed. Cir. 2013) ("A patentee may assess damages based on the entire market value of the accused product only where the patented feature creates the basis for customer demand or substantially creates the value of the component parts."). Mr. Napper has presented evidence suggesting that the trocar cannulas and instruments create the basis for customer demand. In these circumstances, the court "must be cautious not to overstep its gatekeeping role and weigh facts, evaluate the correctness of conclusions, impose its own preferred methodology, or judge credibility," as "these tasks are solely reserved for the fact finder." *Apple*, 757 F.3d at 1314.

Alcon contends that the facts before the Federal Circuit in *VirnetX* and *LaserDynamics* are analogous to the present case and, as a result, Mr. Napper's entire market value analysis should be excluded under *Daubert*. (D.I. 245 at 5-6) However, the patented features in those cases were small components of larger products, and there was no evidence to suggest that the patented components drove sales of the products. *See VirnetX*, 767 F.3d at 1328-29 (expert based the valuation of the patented software feature on the entire cost of the accused iOS devices, including the iPod Touch and iPhone 4S); *LaserDynamics, Inc. v. Quanta Computer, Inc.*, 694 F.3d 51, 67-68 (Fed. Cir. 2012) (expert used revenues from sales of entire laptop computers without establishing that the patented optical disc drives drove demand for sales of the entire laptop). The same is true of the facts before the court in *Sonos, Inc. v. D&M Holdings Inc.*, because the record revealed that only half of the accused product owners could use the claimed synchronization, group volume control, or pairing features in the accused speakers,

thereby undercutting the argument that the patented feature drove demand for the entire product. C.A. No. 14-1330-WCB, 2017 WL 4969328 (D. Del. Nov. 1, 2017). In the present case, Mr. Napper has presented evidence to support his position that every component of the surgical packs is necessary to perform the patented method, and the cannulas drive demand for sales of the surgical packs. (11/15/17 Tr. at 85:14-86:10) It is the province of the jury to determine whether this evidence is sufficient to support Mr. Napper's valuation in accordance with the entire market value rule.

(b) Parties to the hypothetical negotiation

Alcon further alleges that Mr. Napper improperly assumes that B&L would be present at the hypothetical negotiating table. (D.I. 226 at 11-13) In response, JHU contends that it is proper to include B&L in the hypothetical negotiation because B&L had an exclusive license to the '848 patent, and the party with the right to grant licenses at the time of the hypothetical negotiation must be considered in the hypothetical negotiation. (D.I. 233 at 9-12)

Alcon's motion to exclude on this basis should be denied. It is undisputed that B&L was the exclusive licensee of the '848 patent in 2006, at the time of the hypothetical negotiation. (D.I. 234, Ex. B at § 3) Mr. Napper notes that "JHU would necessarily have needed to convert its license grant to B&L to a non-exclusive license" as part of negotiating a license with Alcon. (D.I. 227, Ex. 3 at 39) The exclusive licensee of a patent "may sue for and collect damages as if [it] were the patent's owner." *Pentech Int'l, Inc. v. Hayduchok*, 931 F. Supp. 1167, 1172 (S.D.N.Y. 1996). Consequently, courts permit the inclusion of exclusive licensees at the hypothetical negotiation. *See id.* at 1174-75; *see also Brunswick Corp. v. U.S.*, 152 F.3d 946 at *3 (Fed. Cir. 1998).

Mr. Napper makes the reasonable presumption that the exclusivity of the license between JHU and B&L has economic value resulting in a higher royalty rate. (D.I. 227, Ex. 2 at 19:16-24) Although JHU had a pre-existing right under the license agreement to unilaterally convert the license to a non-exclusive license if B&L failed to achieve certain commercial targets, there is no evidence on the present record that B&L triggered the provision. (D.I. 227, Ex. 2 at 261:6-264:18; D.I. 234, Ex. B at § 5) Mr. Napper also properly considered B&L's expected lost profits from sublicensing a strong competitor in the marketplace. Although JHU had no express duty under the license agreement to reimburse B&L for lost profits, "expectant loss is an element to be considered in retroactively determining a reasonable royalty." *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1130 (S.D.N.Y. 1970) (quoting *Egry Register Co. v. Standard Register Co.*, 23 F.2d 438, 443 (6th Cir. 1928)). For these reasons, exclusion of Mr. Napper's hypothetical negotiation analysis is unwarranted on the present record.

(c) Effective rate calculation

On May 10, 2016, JHU sued B&L in Delaware state court for breach of contract of the 1999 License Agreement, alleging that B&L had failed to pay royalties. (D.I. 227, Ex. 6 at ¶ 1) [redacted] (D.I. 212, Ex. G32-33 at AA1299-1323) According to Alcon, Mr. Napper's royalty rate calculation [redacted] (D.I. 226 at 13-14) In response, [redacted] (D.I. 233 at 12-13)

I recommend that the court deny Alcon's motion to exclude Mr. Napper's expert testimony and opinion on the effective rate calculation. Evidence in the record supports Mr. Napper's position that JHU and B&L believed the recovery was limited to three years when they negotiated their settlement. (D.I. 234, Ex. G at 63:16-64:16) Moreover, the record reflects that JHU could not sue B&L for six years of patent infringement because B&L was licensed, and the dispute related only to the amount of royalties owed under the contract. (*Id.* at 19:2-11, 64:17-22) Purported weaknesses in Mr. Napper's analysis may be weighed by the jury.

2. Charles Colby

In an effort to discredit the expert report of Alcon's expert, Dr. Edwin Ryan, which relied on PAT Surveys and MarketScope Reports, *see* § IV.B.1 & 2, *infra*, JHU produced a supplemental expert report from survey expert Charles Colby. (D.I. 227, Ex. 9) By way of its *Daubert* motion, Alcon seeks to exclude the opinions of Mr. Colby as unreliable. (D.I. 226 at 16-20) Specifically, Alcon contends that Mr. Colby does not apply a scientific methodology to support his premise, and he never reviewed the actual survey questions or answer choices as they were presented to the survey respondents. (*Id.* at 16-18) In addition, Alcon alleges that Mr. Colby has no medical experience that would allow him to analyze the opinions of medical doctors. (*Id.* at 19-20)

In response, JHU contends that Mr. Colby does not require medical expertise to offer an opinion on the reliability of the surveys, and his opinion need not go beyond the materials relied upon by Dr. Ryan. (D.I. 233 at 15-18; 11/15/17 Tr. at 23:15-22) It is noteworthy that JHU's responsive brief focuses on purported deficiencies in the expert opinion of Dr. Ryan instead of the reliability of Mr. Colby's methodology. (D.I. 233 at 17-19)

I recommend that the court grant Alcon's motion to exclude the opinions and testimony of Mr. Colby. In his report, Mr. Colby represents that he engaged in "[e]xamination of the survey questions and permitted responses," which revealed "[m]ethodological flaws." (D.I. 227, Ex. 9 at ¶ 22) However, Mr. Colby revealed at his deposition that his review was limited to summary slide presentations of the survey data, as opposed to the survey questionnaires and underlying data. (*Id.*, Ex. 10 at 13:12-14:8, 15:14-16:11) Mr. Colby admitted that the presentation slides do not indicate "whether the actual question is provided in the slide heading or whether what is provided is a summary or paraphrasing of the question presented." (*Id.*, Ex. 9 at ¶ 54) Given that the purpose of Mr. Colby's opinion is to demonstrate the unreliability of the PAT Surveys and MarketScope Reports, Mr. Colby's admissions that he did not review the actual survey questions or answer choices in the questionnaire forms is dispositive. In light of the deficiencies in Mr. Colby's methodology, the court need not reach the issue regarding Mr. Colby's lack of medical experience in reviewing the opinions of medical doctors.

JHU's reliance on *Radiance Foundation, Inc. v. NAACP* does not alter the court's conclusion. In *Radiance*, the court concluded that the survey expert's opinion on the survey's design was admissible, while the expert's opinions on the substantive issues in the case regarding trademark dilution and likelihood of confusion were not. 27 F. Supp. 3d 671, 677 (E.D. Va. 2013) ("[T]he Court finds that Dr. Tuten may testify to the principles and methodologies of consumer surveys without offering her opinion on the survey's relationship to trademark dilution and likelihood of confusion."). The facts presently before the court are distinguishable because Mr. Colby did not evaluate the underlying data necessary to determine the reliability of the surveys, regardless of his qualifications to offer opinions on survey reliability.

For the foregoing reasons, I recommend that the court grant Alcon's motion to exclude the opinion of Mr. Colby.

B. JHU's *Daubert* Motions

1. PAT Surveys

Alcon's expert, Dr. Edwin Ryan, relies in part on Preferences and Trends Surveys ("PAT Surveys") to support Alcon's position that there are substantial non-infringing uses of the Accused Products, including their use in vit-buckle procedures, procedures involving suturing, and procedures that are not corrective procedures for the retina. (D.I. 224, Ex. 18 at ¶¶ 191-214) Since 1999, a professional society of over 3,000 retinal specialists known as the American Society of Retina Specialists ("ASRS") has annually surveyed its members on a range of surgical topics to collect the data compiled in the PAT Surveys. (D.I. 236, Ex. 17; D.I. 224, Ex. 18 at ¶ 88) Members of the ASRS must be Board-certified surgeons or fellows, and ASRS members include JHU's experts, Dr. Carl C. Awh and Dr. Julia A. Haller, as well as named inventor Dr. Eugene de Juan, Jr. (D.I. 236, Ex. 19 at 1; Ex. 20 at ALCONMIVS1025618; Ex. 21 at ALCONMIVS1025107; Ex. 22 at 13; 11/15/17 Tr. at 29:13-30:5)

The stated purpose of the PAT Surveys is to "provide[] a snapshot of retina practice patterns around the globe" by collecting multiyear data from practitioners showing how clinical preferences change over time. (D.I. 220, Ex. 7 at ALCONMIVS1025796) ASRS publishes the results of the PAT Surveys annually on the ASRS member website and at ASRS meetings, as well as in the *Retina Times* publication. (D.I. 220, Exs. 1-8; D.I. 224, Ex. 18 at ¶ 88; D.I. 236, Ex. 18) Retinal surgeons, including Dr. Awh and Dr. Haller, rely on the PAT Surveys as evidence of practice trends in the field. (11/15/17 Tr. at 30:19-31:2) For example, Dr. Haller cited the 2008 PAT Survey in a 2010 article entitled "Vitrectomy Outcomes in Eyes with

Diabetic Macular Edema and Vitreomacular Traction," observing that "[t]he surgical techniques recorded appear to mirror recent vitreoretinal surgical practice trends in North America, characterized by the increased use of smaller gauge vitrectomy systems . . . ." (D.I. 227, Ex. 12 at 6, 9) Dr. Awh referred to the 2007 PAT Survey in a January 1, 2008 article entitled "Why (and When) I Prefer 25-g Vitrectomy," noting that "[t]he most recent . . . [PAT] Survey found that 70% of vitreoretinal surgeons use 25-g technology occasionally and 25% of surgeons use 25-g vitrectomy for more than 75% of their cases." (D.I. 227, Ex. 13 at 1-2) Other surgeons also routinely rely on data in PAT Surveys when discussing surgical trends and preferences in publications. (D.I. 227, Ex. 11 at 1048; Ex. 14 at ALCONMIVS0686903; D.I. 236, Ex. 23 at 62; Ex. 24 at 735, 740; Ex. 25 at 139, 145; Ex. 26 at 1838; Ex. 27 at 1448; Ex. 28 at 975)

However, the PAT Survey guidelines provide that "[a]ll responses are retrospective opinion and are not based on accurate review of records by the respondents. There is no implication of any 'correct' or 'incorrect' responses, nor is there any establishment of 'clinical standard of care.'" (D.I. 220, Ex. 7 at ALCONMIVS1025793) The record reflects that only one out of every three ASRS members participated in the 2015 PAT Survey, which represented a record number of responses. (D.I. 220, Ex. 7 at ALCONMIVS1025798) Although the PAT Surveys present data regarding non-infringing uses, the data does not account for the low response rate and is not weighted for the number of surgeries performed by each respondent. (D.I. 220, Ex. 7 at ALCONMIVS1025851)

JHU moves to exclude the PAT Surveys, arguing that they lack the essential "fit" with the issues before the court because they do not address the Accused Products or asserted claims, and were not designed for the present litigation. (D.I. 219 at 9) Moreover, JHU alleges that the survey questions are vague and open to interpretation by Dr. Ryan. (*Id.* at 10) According to

JHU, the PAT Surveys are not based on scientifically accepted survey principles, and are therefore not quantitatively reliable as evidence of a substantial non-infringing use of the Accused Products. (D.I. 219 at 11-16)

Alcon does not dispute that the PAT Surveys were not designed to provide statistically accurate percentages regarding the number of vit-buckle or suture procedures performed in a given year. (D.I. 235 at 9-10) Instead, Alcon alleges that the PAT Surveys are qualitatively useful in confirming that the relevant surgical community evaluates general trends and preferences on an annual basis. (*Id.* at 8) According to Alcon, the ASRS would not survey the use of vit-buckles in particular surgical contexts if the procedures were unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental. (*Id.* at 8-9) To the extent that defects exist in the design or implementation of the PAT Surveys, Alcon contends that the fact finder should consider such factors in determining the weight attributed to the PAT Surveys. (*Id.* at 16-18)

I recommend that the court deny JHU's motion to exclude the PAT Surveys relied upon by Dr. Ryan to establish substantial non-infringing uses of the Accused Products.[4] A substantial non-infringing use is one that is "not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental." *Vita-Mix Corp. v. Basic Holdings, Inc.*, 581 F.3d 1317, 1327-29 (Fed. Cir. 2009). The PAT Surveys are relevant to this inquiry because they compile responses from retinal surgeons indicating that non-infringing procedures such as the vit-buckle are still

[4] To establish a cause of action for contributory infringement under 35 U.S.C. § 271(c), a plaintiff must show that, *inter alia*, the accused products sold or offered for sale have no substantial non-infringing uses. *See In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1337-38 (Fed. Cir. 2012) ("Where the product is equally capable of, and interchangeably capable of both infringing and substantial non-infringing uses, a claim for contributory infringement does not lie.").

used by practitioners. (D.I. 220, Ex. 4 at ALCONMIVS1025774; Ex. 5 at ALCONMIVS1026385; Ex. 6 at ALCONMIVS1025504; Ex. 7 at ALCONMIVS1025849; Ex. 8 at ALCONMIVS1025319); *see In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 745 (3d Cir. 1994) (observing that the standard of reliability under Rule 702 "is not that high," although it is "higher than bare relevance."). The PAT Surveys also provide evidence of suturing using small-gauge instruments in vitrectomies, which is another allegedly non-infringing use of the Accused Products. (D.I. 220, Ex. 1 at ALCONMIVS1026287-88; Ex. 5 at ALCONMIVS1026383; '848 patent, claim 30; 11/15/17 Tr. at 41:17-42:10)

Regardless of the accuracy of the numerical data set forth in the PAT Surveys, the decision by the ASRS to survey the use of these procedures each year is relevant to the question of whether the non-infringing procedures are unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental. (11/15/17 Tr. at 33:1-5) The body of retinal surgeons participating in the PAT Surveys supports the reliability of the data, as does the evidence on the record showing that ASRS members rely on the PAT Surveys when writing articles for medical publications. (D.I. 227, Ex. 12 at 6, 9; Ex. 13 at 1-2; Ex. 11 at 1048; Ex. 14 at ALCONMIVS0686903; D.I. 236, Ex. 23 at 62; Ex. 24 at 735, 740; Ex. 25 at 139, 145; Ex. 26 at 1838; Ex. 27 at 1448; Ex. 28 at 975)

JHU contests the "fit" of the PAT Surveys to the issue of substantial non-infringing uses because the PAT Surveys do not specifically inquire about the use of the Accused Products in retinal surgeries, nor do they distinguish between infringing and non-infringing uses of the vit-buckle procedure. (D.I. 219 at 9-11) Neither of these concerns warrants exclusion of the PAT Surveys. Although the PAT Surveys do not specifically identify the brand of products used in the non-infringing procedures, the parties do not dispute that Alcon's vitrectomy packs had a

market share between 71% and 78% during the damages period. (D.I. 277, Ex. 3 at 44-45) Given that the PAT Surveys are not being offered for numerical precision, the fact finder may consider retinal surgeons' use of non-infringing procedures in conjunction with the market share of Alcon's Accused Products to arrive at a conclusion regarding whether the use of the Accused Products during these non-infringing procedures is "substantial."

To the extent that the PAT Surveys did not ask respondents whether they performed vit-buckles with the accused small gauge products or the unaccused large gauge products, other evidence the record reflects that only 4% of vitrectomy procedures use the larger gauge products. (D.I. 236, Ex. 34 at ¶ 413; *see also* Ex. 31 at 149:18-25, 155:16-157:2; D.I. 220, Ex. 3 at ALCONMIVS1025940; Ex. 4 at ALCONMIVS1025759; Ex. 5 at ALCONMIVS1026377-79) In addition, the PAT Surveys' failure to distinguish between infringing and non-infringing uses of the vit-buckle procedure does not substantially diminish their relevance because the record consistently establishes that purportedly infringing vit-buckle procedures are extremely rare. (D.I. 236, Ex. 31 at 132:10-133:1; Ex. 35 at 74:12-75:13) The fact finder must therefore weigh the PAT Surveys in conjunction with the record as a whole to determine whether JHU has met its burden to prove the lack of substantial non-infringing uses. *See Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1363 (Fed. Cir. 2012).

Unlike the surveys deemed inadmissible in several cases cited by JHU, the PAT Surveys were not designed in response to this litigation. When a survey is created for litigation purposes, courts have articulated an expectation that the data will focus narrowly on the accused products with numerical precision. *See Parallel Networks Licensing, LLC v. Microsoft Corp.*, C.A. No. 13-2073-KAJ, D.I. 355 (D. Del. Feb. 22, 2017) (excluding a survey created for purposes of the litigation which did not adequately address the accused products); *Fractus, S.A. v. Samsung*,

2011 WL 7563820, at *1 (E.D. Tex. Apr. 29, 2011) (excluding two surveys commissioned for the litigation which were "not tied to the alleged advantageous technical characteristics of the patents-in-suit."). In contrast, this district has held that problems with survey data collected outside the context of litigation go to the weight of the evidence, not its admissibility. *See Intellectual Ventures I LLC v. Check Point Software Techs. Ltd.*, 215 F. Supp. 3d 314, 323-24 (D. Del. 2014) (admitting survey data not specifically designed for litigation, but instead comprised of open-ended comments provided by consumers regarding product satisfaction). Weaknesses in such survey data may be explored through cross examination and the presentation of competing evidence. *Id.* at 323; *see also Apple, Inc. v. Samsung Elecs. Co., Ltd.*, 2014 WL 794328, at *18 (N.D. Cal. Feb. 25, 2014). JHU's concerns about the "fit" of the PAT Surveys should therefore be weighed and resolved by the fact finder. *See Sentius Int'l, LLC v. Microsoft Corp.*, 2015 WL 331939, at *3 (N.D. Cal. Jan. 23, 2015); *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1326 (Fed. Cir. 2009).

The circumstances before the court in *Parallel Networks Licensing, LLC v. Microsoft Corp.* are distinguishable from the facts of the present case, and the court's holding in *Parallel Networks* does not alter the present analysis. C.A. No. 13-2073-KAJ, D.I. 355 (D. Del. Feb. 22, 2017). In *Parallel Networks*, Judge Jordan excluded a survey regarding customer usage of the accused products that was generated specifically for purposes of the litigation for two reasons: (1) the survey was not adequately linked to the asserted claims to aid in the infringement analysis, and (2) the survey respondents were not representative of the sample population, having been recruited through an internet survey panel. (C.A. No. 13-2073-KAJ, D.I. 355 at 4-10) In the instant case, the PAT Surveys specifically ask the survey respondents about their use of allegedly infringing vitrectomies and non-infringing vit-buckle procedures. (D.I. 220, Ex. 3 at

ALCONMIVS1025928-29; Ex. 4 at ALCONMIVS1025773-74; Ex. 5 at ALCONMIVS1026385; Ex. 6 at ALCONMIVS1025504; Ex. 7 at ALCONMIVS1025849-50; Ex. 8 at ALCONMIVS1025319-21) The PAT Surveys also question respondents regarding their use of sutures in small-gauge vitrectomies. (D.I. 220, Ex. 1 at ALCONMIVS1026287-88; Ex. 2 at ALCONMIVS1025416-17; Ex. 4 at ALCONMIVS1025759; Ex. 5 at ALCONMIVS1026383) The survey responses are therefore relevant to the question of whether vit-buckle procedures and/or sutures amount to a substantial non-infringing use. Dr. Ryan's expert opinion links the information in the PAT Surveys to the question of substantial non-infringing uses by analyzing the current trends and practices in retinal surgery as reflected in the PAT Survey responses, with a particular focus on the use of vit-buckles and sutures by retinal surgeons. (D.I. 224, Ex. 18 at ¶¶ 86-150; 191-214) Dr. Ryan does not use the PAT Surveys to prove infringement as in *Parallel Networks*, but instead relies on the PAT Surveys for the sole purpose of demonstrating substantial non-infringing uses, an inquiry which does not require numerical precision. (11/15/17 Tr. at 32:15-24)

JHU also alleges that the PAT Surveys are inadmissible because they were not conducted in accordance with generally accepted survey principles, citing *Parallel Networks* and two district court cases from other jurisdictions for the proposition that a survey must be based on a representative sample of respondents and the expert must demonstrate familiarity with the survey methodology, among other factors. *See Ways & Means, Inc. v. IVAC Corp.*, 506 F. Supp. 697, 704 (N.D. Cal. 1979); *Elliott v. Google, Inc.*, 45 F. Supp. 3d 1156, 1168-69 (D. Ariz. 2014). More recently, this court held that "[a] survey of the wrong 'universe' will be of little probative value in litigation," but "mere technical reliability goes to the weight accorded a survey, not its admissibility." *VeriFone, Inc. v. Poynt Co.*, 199 F. Supp. 3d 898, 906 (D. Del. 2016). Dr.

Ryan's concession that the surveys are not quantifiably representative of U.S. surgeons, and are not professional surveys, should therefore be weighed by the fact finder. (D.I. 224, Ex. 21 at 78:3-8; Ex. 20 at ¶ 35)

2. MarketScope Reports

Dr. Ryan also relies on the MarketScope Reports to support Alcon's position that there are substantial non-infringing uses of the Accused Products, including their use in vit-buckle procedures, procedures involving suturing, and procedures that are not corrective procedures for the retina. (D.I. 224, Ex. 18 at ¶¶ 262-269) The MarketScope Reports are annual comprehensive reports on the retinal surgical device market, compiled from surveys of and interviews with retina specialists, interviews with executives from retinal surgical device manufacturers, published medical research, and presentations at ophthalmic meetings. (D.I. 223, Ex. 15 at ALCONMIVS1023399) The MarketScope Reports are used by ophthalmic companies in annual reports, SEC filings, and investor presentations. (D.I. 223, Ex. 17 at JHU0022573)

In support of its *Daubert* motion seeking exclusion of the MarketScope Reports, JHU alleges that the MarketScope Reports are not quantitatively reliable, are not specific to Alcon's non-infringement defenses, and were not conducted in accordance with generally accepted survey principles. (D.I. 219 at 9-16) Specifically, JHU notes that any person can enter any data without verification on the internet survey, potentially skewing the survey results. (*Id.* at 13; 11/15/17 Tr. at 19:4-20:21) In response, Alcon observes that JHU's experts relied upon the MarketScope Reports as a basis for their opinions, prompting Dr. Ryan to respond to Dr. Haller's use of them and confirming their reliability. (D.I. 235 at 13)

I recommend that the court grant JHU's motion as it pertains to the MarketScope Reports. The MarketScope Reports provide the necessary fit regarding the question of

substantial non-infringing uses for the same reasons described above in connection with the PAT Surveys. However, the MarketScope Reports are not reliable. Specifically, the record reflects that the surveys incorporated into the MarketScope Reports may be taken by any individual on the internet, without verification of the individual's status as a retinal surgeon, and permit the entry of inconsistent data. (11/15/17 Tr. at 19:11-22:24) Consequently, the accuracy of the MarketScope Reports is questionable. (D.I. 224, Ex. 22 at 127:1-25)

Dr. Haller cited the MarketScope Reports in her expert report for the proposition that "repair of retinal detachment is the reason for approximately 20% of vitrectomy cases." (D.I. 201, Ex. F16 at ¶ 443) The record reveals that Dr. Haller subsequently questioned the reliability of the MarketScope Reports in her deposition testimony, describing the data as a "garbage in/garbage out assessment" "grouped in incomprehensible fashion for no apparent reason." (D.I. 236, Ex. 31 at 157:7-158:10) Regardless, the issue of JHU's reliance on the MarketScope Reports is moot because JHU has offered to strike all mention of the MarketScope Reports in Dr. Haller's expert report. (11/15/17 Tr. at 58:9-14)

JHU's damages expert, Dr. Napper, also relies on the MarketScope Reports for quantitative purposes in his expert report. (D.I. 227, Ex. 3 at 43-46) Specifically, Dr. Napper uses the MarketScope Reports to quantify market share in the global retinal surgical device market. (*Id.*) Dr. Napper expressly stated that, "[w]hile I recognize that exact sales figures may be inaccurate as reported by Market Scope, it is reasonable to rely on these reports for the limited purpose of providing 'directional' guidance in terms of company market share and size." (*Id.* at 46) Unlike the inquiry regarding substantial non-infringing uses, which requires a showing that a use is "not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental," *Vita-Mix*, 581 F.3d at 1327-29, determining market share for purposes of a damages analysis

cannot be so readily divorced from the accuracy of the underlying numerical data. Therefore, I recommend that the court grant JHU's motion to preclude the MarketScope Reports, as well as references to the MarketScope Reports in Dr. Haller's and Dr. Napper's expert reports.

3. Dr. D'Amico

I recommend that the court grant JHU's motion to exclude the invalidity testimony of Alcon's infringement expert, Dr. Donald J. D'Amico. (D.I. 219 at 17-18) In pertinent part, Dr. D'Amico's expert report states as follows:

> It is also my understanding that Alcon has taken the position that the surgical methods disclosed in the '848 patent were disclosed in the prior art. More specifically, Alcon has taken the position that the claimed method of allowing access within an eye using entry alignment devices was disclosed by Dr. Machemer in his 1985 publication, (Machemer 1985), and that the claimed transconjunctival, sutureless, small gauge method was disclosed by Dr. Robert Josephberg in his '363 patent, ('363 patent). I agree with this position.

(D.I. 224, Ex. 24 at ¶ 106) Furthermore, Dr. D'Amico testified that he was aware of the invalidity issues and was "in full agreement with the idea that this patent should not have been issued." (D.I. 224, Ex. 25 at 20:3-9; *see also* 20:10-25:16) Dr. D'Amico's opinion on this issue is not supported by an analysis or a demonstrated consideration of the applicable legal standard. *See M2M Solutions LLC v. Enfora, Inc.*, 167 F. Supp. 3d 665, 677-78 (D. Del. 2016) (concluding that "loose, vague allegations of technological comparability, without any explanation, are insufficient, and do not even provide a basis to meaningfully assess technological comparability."). The court's recommendation therefore excludes Dr. D'Amico's opinion on the ultimate invalidity issue at paragraph 106 of his expert report and his corresponding deposition testimony, but does not extend to Dr. D'Amico's opinion on the smallest salable unit for purposes of the infringement analysis.

4. Opinions Claiming Accused Products Practice Alcon's Patents

I recommend that the court deny JHU's motion to exclude opinions regarding whether the Accused Products practice Alcon's patents. JHU alleges that Alcon's expert opinions regarding whether the Accused Products are associated with Alcon's patents lack analytical support. However, under 35 U.S.C. § 287, patentees "may give notice to the public that the same is patented . . . by fixing thereon the word 'patent' . . . together with the number of the patent . . . ." Alcon has demonstrated that the Accused Products were marked with the numbers of its patents, establishing that the Accused Products were publicly identified as being covered by Alcon's patents. (D.I. 227, Ex. 2 at 68:5-17; 6/16/16 Tr. at 13:23-14:8) Consequently, JHU's motion to exclude is denied with respect to whether the Accused Products practice Alcon's patents.

C. Alcon's Motion for Summary Judgment of Non-Infringement

1. Direct infringement

A patent is infringed when a person "without authority makes, uses or sells any patented invention, within the United States . . . during the term of the patent." 35 U.S.C. § 271(a). To prove direct infringement, the patentee must establish, by a preponderance of the evidence, that one or more claims of the patent read on the accused device literally or under the doctrine of equivalents. *See Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc.*, 261 F.3d 1329, 1336 (Fed. Cir. 2001). "Direct infringement requires a party to perform each and every step or element of a claimed method or product." *BMC Res., Inc. v. Paymentech, LP*, 498 F.3d 1373, 1378 (Fed. Cir. 2007). "If any claim limitation is absent from the accused device, there is no literal infringement as a matter of law." *Bayer AG v. Elan Pharm. Res. Corp.*, 212 F.3d 1241, 1247 (Fed. Cir. 2000).

In support of its motion for summary judgment, Alcon contends that it does not directly infringe any of the asserted method claims because it is a medical device manufacturer. (D.I. 197 at 16-17) Alcon alleges that only a surgeon performing the claimed method can meet the standard for direct infringement in the present case, but there is no showing that doctors performing the claimed method have caused any actionable direct infringement harm to JHU. (*Id.* at 17-18) According to Alcon, doctors performing surgical procedures are immune from suit under 35 U.S.C. § 287(c) and, by extension, Alcon cannot be liable for indirect infringement stemming from the actions of surgeons immune from liability for direct infringement. (*Id.* at 17) In response, JHU asserts that "direct infringement harm" is not an element of a cause of action for direct infringement, and although § 287(c) shields medical practitioners from liability for infringement, their conduct still constitutes infringement under §§ 271 and 287(c). (D.I. 210 at 2-3)

I recommend that the court grant Alcon's motion for summary judgment as it pertains to JHU's allegations of direct infringement against Alcon. JHU's damages expert, Dr. Haller, testified that, to her knowledge, "there is no surgeon at Alcon performing this surgery." (D.I. 201, Ex. F18 at 70:8-18) The evidence cited by JHU in support of its theory of direct infringement by Alcon consists of deposition testimony and reports showing that Alcon doctors test the Accused Products in wet labs using porcine eyes. (D.I. 213, Ex. 2 at 119:19-120:15; Ex. 3 at 17:12-21, 145:2-10, 149:20-150:9, 154:10-15, 164:18-166:6; Ex. 4 at ALCONMIVS0299458; Ex. 6 at ALCONMIVS0461801-02; Ex. 7 at ALCONMIVS0681381) However, the testimony of Dr. Ryan establishes that the pig eyes and artificial eyes typically used in wet labs do not have a conjunctiva as required by the '848 patent. (D.I. 240, Ex. J1 at 277:20-278:12) Consequently, the evidence on the present record is inadequate to establish that

Alcon met each limitation of the patented method, which requires an entry aperture in the conjunctiva. ('848 patent at col. 23:63-24:7) Although Dr. Bruno Dacquay testified that cadaver eyes may also be used in wet labs, the evidence before the court does not indicate whether the conjunctiva has been removed from cadaver eyes used in wet lab procedures and, more importantly, Alcon's testing efforts relied upon by JHU uniformly cite the use of porcine eyes as opposed to cadaver eyes. (D.I. 213, Ex. 1 at 53:19-55:11)

In support of its claim for direct infringement against Alcon, JHU also refers to a clinical study performed by Alcon evaluating surgeons' use of the Accused Product in 2008. (D.I. 213, Ex. 5; Ex. 1 at 176:18-179:11) Unlike the other evidence cited by JHU in support of its cause of action for direct infringement against Alcon, the clinical study evaluated surgeries performed on human patients. However, the clinical study does not create a genuine issue of material fact for purposes of the court's summary judgment analysis because it was performed between May and July 2008. (*Id.* at ALCONMIVS0582966) A claim for direct infringement against Alcon based on the 2008 clinical study would be barred under the six-year statute of limitations applicable to patent infringement claims. 35 U.S.C. § 286; *see also SCA Hygiene Prods. Aktiebolag v. First Quality Baby Prods., LLC*, 137 S. Ct. 954 (2017).

JHU's discussion of its direct infringement claim against Alcon, relegated to a footnote in its answering brief, fails to identify evidence on the record sufficient to establish a genuine issue of material fact. (D.I. 210 at 5 n.3) The fact that JHU dropped its joint infringement theory from its final infringement contentions further illustrates JHU's tepid assertion of direct infringement by Alcon. (D.I. 212, Ex. G9 at AA1046-74; D.I. 240, Ex. J3 at AA1370-90) In view of the foregoing, I recommend that the court grant Alcon's motion for summary judgment with respect to JHU's cause of action for direct infringement by Alcon.

Turning to JHU's allegations of direct infringement by medical practitioners who use Alcon's Accused Products in performing the surgical method claimed in the '848 patent, I recommend that the court deny Alcon's motion for summary judgment. JHU does not contest Alcon's argument that the sale of the Accused Products alone cannot constitute the practice of the patented process even if those Accused Products are later used in the patented process. *See Standard Oil Co. v. Nippon Shokubai Kagaku Kogyo Co.*, 754 F.2d 345, 347 (Fed. Cir. 1985); *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311 (Fed. Cir. 2006) ("Method claims are only infringed when the claimed process is performed, not by the sale of an apparatus that is capable of infringing use."). However, genuine issues of material fact exist regarding whether doctors performing the patented method using Alcon's surgical instruments directly infringe the '848 patent.

The safe harbor provision at 35 U.S.C. § 287(c) does not preclude a finding of direct infringement by surgeons performing the claimed method as a matter of law. Section 287(c) states that, "[w]ith respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b), the provisions of sections 281, 283, 284, and 285 shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity." 35 U.S.C. § 287(c)(1). Although § 287(c) protects medical practitioners from liability for infringement, the language of the statute continues to define their activities as infringement under § 271.

In the instant case, the surgeons purportedly using Alcon's Accused Products to perform the claimed method of the '848 patent are not parties to the litigation. Consequently, the safe harbor provision in § 287(c)(1) does not apply to immunize them from suit because they are not being sued in the first instance. To the extent that the medical practitioners' activities

"constitute[] an infringement under section 271(a)," however, their direct infringement may supply the foundation for causes of action for indirect infringement by Alcon, regardless of their immunity from liability for their directly infringing activities. It is well-established that medical device and drug manufacturers may be liable for inducing or contributing to a medical practitioner's direct infringement of a patented method. *See Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 845 F.3d 1357, 1368 (Fed. Cir. 2017) ("[E]vidence that the product labeling that Defendants seek would inevitably lead some physicians to infringe establishes the requisite intent for inducement. The district court did not clearly err in concluding that Defendants would induce infringement of the asserted claims of the '209 patent."); *Warsaw Orthopedic, Inc. v. NuVasive, Inc.*, 824 F.3d 1344 (Fed. Cir. 2016) (affirming a finding of induced infringement of method claims for the sale of a medical device by the defendant device manufacturer where physicians directly infringed the method claims).

Moreover, JHU's reasonable royalty calculation based on Alcon's product sales, instead of harm from doctors practicing the patented method, finds adequate support in the record for the reasons previously discussed at § IV.C.4, *infra*, and § IV.A.1(a), *supra*. Establishing a reasonable royalty does not require proof of harm to the patentee because the inquiry focuses on the benefit to the infringer "for the use made of the invention by the infringer." 35 U.S.C. § 284. "[A] reasonable royalty compensates the owner not for the damage he suffered, but for the value of what was taken." *Warsaw Orthopedic, Inc. v. NuVasive, Inc.*, 778 F.3d 1365, 1377 (Fed. Cir. 2015); *see also AquaShield v. Inter Pool Cover Team*, 774 F.3d 766, 770 (Fed. Cir. 2014) ("The 'value of what was taken'—the value of the use of the patented technology—measures the royalty."). In accordance with this authority, both parties' experts adopted a damages model based on Alcon's product sales, as opposed to the harm suffered by JHU. (D.I. 198, Ex. E1 at

AA525-26; D.I. 213, Ex. 36 at 95-108) For these reasons, I recommend that the court deny Alcon's motion for summary judgment regarding JHU's cause of action for direct infringement by medical practitioners.

2. Contributory infringement

"[I]ndirect infringement requires knowledge of the underlying direct infringement—not merely the knowledge of the existence of the patent." *Unwired Planet, LLC v. Apple Inc.*, 829 F.3d 1353, 1364 (Fed. Cir. 2016) (citing *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 765-66 (2011); *Commil USA LLC v. Cisco Sys., Inc.*, 135 S. Ct. 1920, 1926 (2015)). "Contributory infringement imposes liability on one who embodies in a non-staple device the heart of a patented process and supplies the device to others to complete the process and appropriate the benefit of the patented invention." *Vita-Mix*, 581 F.3d at 1327. To establish contributory infringement, the plaintiff must prove: "(1) that there is direct infringement, (2) that the accused infringer had knowledge of the patent, (3) that the component has no substantial noninfringing uses, and (4) that the component is a material part of the invention." *Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1326 (Fed. Cir. 2010).

In support of its motion for summary judgment, Alcon focuses on the third requirement of JHU's cause of action for contributory infringement, alleging that JHU cannot prove the absence of a substantial non-infringing use under 35 U.S.C. § 271(c). (D.I. 197 at 18-19) Specifically, Alcon alleges that the Accused Products may be used in non-infringing procedures, including vit-buckles, procedures in which wounds are sutured, and non-corrective procedures for the retina. (*Id.* at 19-25) In response, JHU contends that the inquiry regarding substantial non-infringing uses is fact-intensive, and the present record reflects disagreement between the parties' experts regarding whether the uses are non-infringing and the frequency with which

those uses occur. (D.I. 210 at 9-17) Moreover, JHU argues that Alcon should be precluded from asserting the defense of substantial non-infringing uses because it failed to timely disclose the defense during discovery. (*Id.* at 18-20)

As a preliminary matter, I recommend that the court reject JHU's contention that Alcon should be precluded from asserting its substantial non-infringing use defense due to Alcon's purported failure to supplement its contentions throughout the discovery process. The record establishes that Alcon identified the vit-buckle procedure and procedures in which wounds are sutured in its discovery responses. Specifically, on April 1, 2016, Alcon served Request for Admission 19, asking JHU to "[a]dmit that a scleral buckle combined with vitrectomy is a use" of the Accused Products. (D.I. 240, Ex. J7 at AA1417) In January 2017, Alcon served its second set of requests for admission, seeking an admission "that the American Society of Retina Specialists 2013 Preferences and Trends ('PAT') Membership Survey reports that 8.1% of U.S. survey participants perform procedures involving sclerotomies that are not self sealing in 51-80% of 23-gauge vitrectomy cases." (*Id.*, Ex. J8 at AA1423) On February 22, 2017, Alcon further disclosed that scleral buckles and sutures were substantial non-infringing uses in its response to JHU's Interrogatory 19. (D.I. 202, Ex. 3 at 31-32) (asserting that "Alcon's products are routinely used in procedures that are not self-sealing or sealed without the use of sutures," and "are routinely used in procedures where the conjunctiva is pulled back, including, for example, scleral buckle procedures.") Given that JHU bears the ultimate burden of proving that there are no substantial non-infringing uses of the Accused Products to establish its cause of action for contributory infringement under § 271(c), Alcon's discovery responses should have been sufficient to place JHU on notice that Alcon intended to raise these procedures as

substantial non-infringing uses. *See Golden Blount, Inc. v. Robert H. Peterson Co.*, 438 F.3d 1354, 1363 (Fed. Cir. 2006).

JHU correctly contends that Alcon failed to identify non-corrective procedures for the retina as substantial non-infringing uses during the fact discovery period. The record reflects that Alcon raised this subject for the first time in Dr. Ryan's expert report dated June 6, 2017, which also proffered a proposed construction for the term "corrective procedure for the retina." (D.I. 198, Ex. B1 at ¶¶ 251-61) The record further demonstrates that JHU was able to supplement its expert reports to address the topic. (D.I. 201, Ex. F46 at ¶¶ 19-30; D.I. 213, Ex. 12 at ¶¶ 66-76) Given that both parties' experts were able to substantively address the topic, and no request for additional fact discovery was made to the court despite the disclosure of Dr. Ryan's expert report made less than a week after the close of fact discovery, the court declines to preclude Alcon's substantial non-infringing uses defense on timeliness grounds.

The court next turns to an analysis of whether a genuine issue of material fact exists regarding the surgical procedures identified by Alcon in the context of Alcon's substantial non-infringing use defense. A substantial non-infringing use is any use that is "not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental." *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1327 (Fed. Cir. 2009). Relevant considerations in assessing whether an asserted non-infringing use is substantial include the frequency of the non-infringing use, its practicality, the invention's intended purpose, and the intended market. *See i4i Ltd. P'ship*, 598 F.3d at 851.

(a) Vit-buckle

The parties do not dispute that the vit-buckle procedure may constitute a non-infringing use of the Accused Products because a surgeon performing a vit-buckle does not enter the eye

transconjunctivally as required by claims 25, 26, 30, 32, 36, 38, 39, 43, and 47 of the '848 patent. (D.I. 198, Ex. B1 at ¶¶ 51-56; D.I. 201, Ex. F18 at 132:2-133:1, 149:18-25, 155:16-23, 156:19-157:2; Ex. F19 at ¶ 21; D.I. 240, Ex. J4 at 151:22-152:2) Instead, the dispute centers on whether the use of this non-infringing procedure is substantial. I recommend that the court deny Alcon's motion for summary judgment on this subject because genuine issues of material fact remain as to whether the non-infringing uses of the vit-buckle procedure are substantial. *See Robocast, Inc. v. Microsoft Corp.*, 21 F. Supp. 3d 320, 331 (D. Del. 2014) (identifying the substantial non-infringing use inquiry as "a factual question reserved to the jury.").

A genuine issue of material fact exists regarding the frequency with which the non-infringing vit-buckle procedure is used. Alcon's expert, Dr. Ryan, calculates that approximately 15% of the uses of Alcon's Accused Products over the relevant time period were vit-buckles. (D.I. 198, Ex. B1 at ¶¶ 168-69) In contrast, JHU's expert, Dr. Haller, estimates that vit-buckles constitute between 2 and 8% of all vitrectomy cases.[5] (D.I. 201, Ex. F16 at ¶ 444; Ex. F18 at 213:14-20) Dr. Awh, who testified that he had not performed a vit-buckle in over a year, estimates that no more than 5% of all vitrectomy cases involve the use of a vit-buckle. (D.I. 213, Ex. 14 at 139:14-18; D.I. 201, Ex. F19 at ¶ 19) Dr. Ryan opined that the appropriate threshold for a substantial non-infringing use in this context would be a procedure performed "at least monthly." (D.I. 213, Ex. 11 at 60:5-11) A reasonable jury could conclude that vit-buckle rates

[5] The parties' experts agree that not every vit-buckle procedure is a non-infringing use of the Accused Products if: (1) the vitrectomy is performed using unaccused 20-gauge instruments (D.I. 213, Ex. 12 at ¶¶ 20, 26; Ex. 8 at ¶ 442; Ex. 11 at 162:10-16); or (2) the vit-buckle procedure is infringing because the vitrectomy is performed first, followed by the placement of the scleral buckle (D.I. 213, Ex. 16 at 150:1-21; Ex. 11 at 75:3-16). However, Dr. Haller indicated that her estimate accounted for these exceptions. (D.I. 213, Ex. 8 at ¶ 444)

at the levels presented by JHU demonstrate that the procedure is "occasional" and not substantial under the standard set forth in *Vita-Mix*. 581 F.3d at 1327.

Genuine issues of material fact also remain regarding the practicality of the vit-buckle procedure under the *Vita-Mix* standard. Dr. Awh opined that the continued use of vit-buckles is controversial. (D.I. 213, Ex. 12 at ¶¶ 19-25) Dr. Steve Charles and Dr. Donald D'Amico indicated that they do not use the vit-buckle procedure because the vitrectomy procedure without the added scleral buckle is sufficient. (D.I. 213, Ex. 13 at 59:6-9; D.I. 198, Ex. D1 at ¶ 301) Medical journals, textbooks, and other publications discussing vit-buckle procedures sometimes conclude that the vit-buckle procedure has no advantages over the vitrectomy procedure performed without a scleral buckle. (D.I. 201, Ex. F31 at AA814) (concluding that the scleral buckle offered no added benefit). In light of JHU's evidence supporting its position that scleral buckles are no longer a common treatment for retinal detachment since the advent of vitrectomy, as well as the evidence that vit-buckles do not have any clinical advantage over vitrectomy alone, a reasonable jury could conclude that the use of the vit-buckle procedure is not practical and therefore does not qualify as a substantial non-infringing use.

(b) Procedures in which wounds are sutured

The analysis regarding procedures where wounds are sutured is similar to the foregoing analysis regarding the vit-buckle procedure. The parties do not dispute that claims 30, 32, 39, and 47[6] of the '848 patent require a method in which the entry apertures are "sealed without the use of sutures," and that the use of sutures to seal wounds after vitrectomy procedures using Alcon's Accused Products is therefore non-infringing. (D.I. 201, Ex. F18 at 213:21-215:13,

[6] The parties dispute whether claim 43 of the '848 patent requires a sutureless sclerotomy. This dispute does not impact the court's analysis, as claims 30, 32, 39, and 47 undisputedly require that at least one sclerotomy must seal without the use of sutures.

219:17-220:3, 236:9-237:3; Ex. F49 at 103:20-105:19) However, disputes of fact remain regarding whether the use of sutures constitutes a substantial non-infringing use. JHU presents evidence suggesting that the use of sutures is rare in small-gauge surgeries because the wounds generally seal without the use of sutures, and using sutures is therefore unnecessary. (D.I. 213, Ex. 8 at ¶ 464; Ex. 9 at ¶¶ 12-15, 17) JHU also cites evidence that Alcon's expert, Dr. Ryan, identified small-gauge wounds as "typically unsutured." (D.I. 213, Ex. 19 at 2) While Dr. Ryan has suggested in this litigation that approximately 20% of procedures require sutures, JHU's expert, Dr. Gene de Juan, estimated that only one percent require sutures. (D.I. 213, Ex. 17 at 139:6-17; D.I. 240, Ex. J1 at 199:3-11) Resolving the issue of whether procedures where wounds are sutured constitute a substantial non-infringing use thus requires credibility determinations appropriately reserved for the jury. *See Robinson v. Pezzat*, 818 F.3d 1, 8 (D.C. Cir. 2016).

(c) Non-corrective procedures for the retina

Likewise, material issues of fact remain regarding whether procedures that are not "corrective procedures for the retina" constitute substantial non-infringing uses. Claims 25, 26, 30, 32, and 36 of the '848 patent recite a method including a "corrective procedure for the retina." This term was not construed during claim construction, and each party's expert has proposed a different construction.[7] The present record reflects a divergence of opinions among the experts, with Dr. Haller determining that each procedure identified by Dr. D'Amico and Dr. Ryan as a non-corrective procedure for the retina "is either an infringing use of the Accused Products, an insubstantial use of the Accused Products, or both." (D.I. 201, Ex. F46 at ¶¶ 19-30)

[7] This court defers to the District Judge as to whether a supplemental claim construction procedure on the term "corrective procedure for the retina" is necessary.

This issue therefore requires a weighing of the evidence and credibility determination by the jury.

The summary judgment cases relied upon by Alcon are distinguishable from the facts presently before the court. In *PolyVision Corp. v. Smart Technologies Inc.*, the district court granted summary judgment on substantial non-infringing uses after concluding that it would be "unlikely that a customer would spend thousands of dollars for these electronic interactive whiteboards for such simple purposes when much cheaper alternatives are available," rendering such uses "incidental to the primary use of the products." 501 F. Supp. 2d 1068, 1091 (W.D. Mich. 2007). In contrast, the record before the court in the present case contains factual data indicating that retinal surgeons actually use the accused small-gauge instruments in procedures that are non-infringing.

In *Toshiba Corp. v. Imation Corp.*, the Federal Circuit upheld the district court's ruling granting summary judgment on substantial non-infringing uses, concluding that the plaintiff failed to "put forth evidence showing that the use of unfinalized DVDs was not substantial." 681 F.3d 1358, 1363 (Fed. Cir. 2012). Unlike the circumstances presently before the court, the plaintiff in *Toshiba* "presented no survey, expert, or other evidence showing how frequently users choose not to finalize DVDs." *Id.* Instead, the plaintiff relied only on the DVD standards, which themselves recognized that users may record to DVDs without finalization. *Id.* In the instant action, JHU presents the PAT Surveys in addition to expert testimony from multiple experts opining on the frequency of use of the non-infringing procedures and the practicality of such use based on their own experiences as surgeons in the field. Drawing all reasonable inferences in favor of JHU as the nonmoving party, I recommend that the court deny Alcon's motion for summary judgment on the issue of substantial non-infringing uses.

3. Reasonable royalty

Section 284 permits the recovery of damages "adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer." 35 U.S.C. § 284. The measure of damages at issue in Alcon's motion for summary judgment is a reasonable royalty, which "seeks to compensate the patentee . . . for its lost opportunity to obtain a reasonable royalty that the infringer would have been willing to pay if it had been barred from infringing." *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1334 (Fed. Cir. 2015).

In support of its motion for summary judgment on the issue of a reasonable royalty, Alcon contends that the sale of an apparatus capable of performing the claimed process is not an infringement of the method and, consequently, JHU's reasonable royalty base should not be tied to Alcon's product sales. (D.I. 197 at 26) Moreover, Alcon alleges that JHU's royalty base is too broad because it is not limited to cannulas, which represent the smallest salable patent-practicing unit. (*Id.* at 27-28) In response, JHU argues that Alcon uses the patented invention heavily, as indicated by their MIVS product line named for the patented minimally invasive vitrectomy surgical method. (D.I. 210 at 34-36) According to JHU, a product royalty is the typical remedy for infringement of method claims, and the selection of an appropriate royalty base is a question of fact properly reserved for the jury. (*Id.* at 36-39)

I recommend that the court deny Alcon's motion for summary judgment as it pertains to reasonable royalty damages because issues of fact remain regarding the calculation of the royalty, as previously discussed at § IV.A.1, *supra*. *See i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 858 (Fed. Cir. 2010) ("Given the intensely factual nature of a damages determination and our deferential standard of review, we are not in a position to second-guess or substitute our

judgment for the jury's."). JHU demonstrates that Alcon named its entire product line "MIVS" to make use of the patented method for minimally invasive vitrectomy surgery. (D.I. 213, Ex. 37; Ex. 8 at ¶¶ 468-69) The record also reflects Alcon's extensive marketing efforts to convert customers from the prior art 20-gauge instruments to MIVS instruments. (D.I. 213, Ex. 38 at ALCONMIVS0368595; Ex. 39 at ALCONMIVS0126632; Ex. 40 at ALCONMIVS0300583; Ex. 41 at JHU0020833; Ex. 43 at 65; Ex. 44 at ALCONMIVS0324988) Drawing on this evidence, a reasonable jury could find that Alcon made use of the patented method.

Contrary to Alcon's contentions, and as discussed in more detail at § IV.C.1 & 2, *supra*, the sale of an apparatus capable of performing a claimed method may constitute infringement of the method if the record adequately establishes the elements of causes of action for direct and indirect infringement. *See i4i Ltd. P'ship*, 598 F.3d at 849-54 (concluding that the evidence presented at trial was sufficient to establish that the claimed methods were performed if customers used the accused Microsoft Word product to open, save, or edit an XML document). In such cases, a reasonable royalty is a permissible measure of damages to remedy the infringement. *Id.* at 852-57 (affirming a reasonable royalty award based on a calculation of Microsoft's product sales); *see also Fonar Corp. v. Gen. Elec. Co.*, 107 F.3d 1543, 1552-53 (Fed. Cir. 1997) (upholding a reasonable royalty based on the entire market value rule where the accused products were found to infringe the claimed method). The use of a reasonable royalty to measure damages for infringement of a method claim by an apparatus is further supported by both parties' damages experts, who adopted a hypothetical negotiation methodology to opine that a reasonable royalty rate should be calculated as a percentage of Alcon's product sales. (D.I. 198, Ex. E1 at AA525-26; D.I. 213, Ex. 36 at 95-108) Alcon's reliance on the Federal Circuit's decision in *Standard Havens Products, Inc. v. Gencor Industries, Inc.* is distinguishable from the

facts presently before the court because the plaintiff in *Standard Havens* failed to establish direct infringement by the foreign customer. 953 F.2d 1360, 1374 (Fed. Cir. 1991).

As discussed at § IV.A.1(a), *supra*, disputes of fact regarding whether cannulas constitute the smallest salable patent-practicing unit preclude limiting the royalty base to cannulas at this stage of the proceedings. *See Ericsson, Inc. v. D-Link Sys.*, 773 F.3d 1201, 1226 (Fed. Cir. 2014). Both parties' experts have testified that it would be impossible to perform the claimed method with just a cannula. (D.I. 213, Ex. 20 at ¶ 8; Ex. 11 at 190:19-22; Ex. 24 at 40:20-41:6, 102:12-15) In addition, claim 26 of the '848 patent identifies other components, such as a light source and a high speed vitreous cutting/aspirating instrument. ('848 patent, col. 24:8-16) As a result, the court cannot definitively conclude at this stage of the proceedings that the cannula represents the smallest salable patent-practicing unit. *See AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1338 (Fed. Cir. 2015) ("[W]hile it is important to guard against compensation for more than the added value attributable to an invention, it is improper to assume that a conventional element cannot be rendered more valuable by its use in combination with an invention.").

4. Willful infringement and enhanced damages

The willfulness inquiry asks whether a party has engaged in "conduct warranting enhanced damages" under 35 U.S.C. § 284, behavior the Supreme Court has described as "willful, wanton, malicious, bad-faith, deliberate, consciously wrongful, flagrant, or [] characteristic of a pirate." *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S. Ct. 1923, 1932 (2016).[8]

[8] JHU discusses the *Read* factors for enhanced damages set forth in *Read Corp. v. Portec, Inc.*, 970 F.2d 816 (Fed. Cir. 1992). However, the Federal Circuit recently observed that "the district court is not required to discuss the *Read* factors. When the Supreme Court articulated the current controlling test for decisions to award enhanced damages, it did not require the *Read* factors as part of the analysis." *Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 875 F.3d 1369,

Prevailing on a claim of either indirect or willful infringement requires a patentee to prove, among other things, that an accused infringer acted with a specific intent to infringe. *See id.* at 1933. Under 35 U.S.C. § 284, "the court may increase the damages up to three times the amount found or assessed."

In support of its motion for summary judgment on enhanced damages, Alcon stresses that it began making the Accused Products before the '848 patent issued, and obtained the advice of counsel after it issued to ascertain the risk of infringement. (D.I. 197 at 29-31) Alcon also points to its mitigation efforts to license the '848 technology from JHU in 2008 and 2009. (*Id.* at 32) In response, JHU alleges that willfulness and enhanced damages are two separate issues, and neither issue is appropriately resolved on summary judgment. (D.I. 210 at 29) According to JHU, there are issues of fact regarding whether Alcon continued to sell the Accused Products despite an obvious risk of infringement because the record reflects that Alcon executives were not confident in the opinions of counsel, and the claim constructions proposed by Alcon were rejected in the court's *Markman* decision. (*Id.* at 30-32)

I recommend that the court deny Alcon's motion for summary judgment on willfulness and enhanced damages. The court cannot properly reach the discretionary issue of enhanced damages until after a determination of willfulness. *See WesternGeco L.L.C. v. ION Geophysical Corp.*, 837 F.3d 1358, 1362-64 (Fed. Cir. 2016) ("[I]f willfulness is established, the question of enhanced damages must be left to the district court's discretion."); *see also Greatbatch Ltd. v. AVX Corp.*, C.A. No. 13-723-LPS, 2016 WL 7217625, at *6 (D. Del. Dec. 13, 2016) ("A finding

1382 (Fed. Cir. 2017). "The *Halo* test merely requires the district court to consider the particular circumstances of the case to determine whether it is egregious." *Id.* at 1383.

of willfulness may be a necessary—but is not a sufficient—condition to permit the Court to exercise its discretion" in awarding enhanced damages).

Issues of fact exist regarding the willfulness claim because the evidence cited by JHU suggests that certain Alcon employees questioned the opinions of counsel and continued to pursue licensing efforts regarding the '848 patent. Specifically, Mr. Barry Copeland, an Alcon attorney, recommended discontinuing sales of the 25-gauge products and transitioning to 23-gauge products both before and after obtaining the December 2006 and May 2007 opinions of counsel. (D.I. 198, Ex. A3 at AA4-5; D.I. 213, Ex. 26 at 4; Ex. 27 at 4) The record also reflects that the opinions of counsel were not shared with the Alcon employees most directly involved in the development of the Accused Products, including Mark Forchette, the former Vice President of Vitreoretinal Sales and Global Marketing, and Bruno Dacquay, the former Vice President of Surgical Instrumentation R&D. (D.I. 213, Ex. 35 at 166:10-168:4; Ex. 1 at 221:11-223:21; D.I. 198, Ex. A28 at AA372) Moreover, Alcon continued to pursue a license to the '848 patent after receiving the opinions of counsel that Alcon's 25-gauge products do not infringe the '848 patent. (D.I. 201, Ex. F11 at AA647-48; Ex. F12 at AA649-52; Ex. F17 at AA716-18) The trier of fact must weigh the evidence of Alcon's continued pursuit of a license while continuing to sell the Accused Products against evidence that JHU repeatedly failed to respond to Alcon's licensing efforts. (D.I. 201, Ex. F17 at AA715-18, AA720-23; Ex. F11 at AA647)

Alcon's failure to halt sales of the Accused Products following the issuance of the court's claim construction ruling on February 22, 2017 raises additional factual issues regarding whether Alcon willfully infringed. The claim construction order rejected each construction offered by Alcon, many of which were derived from the December 2016 opinion of counsel letter. (D.I. 151; D.I. 198, Ex. A7 at AA29-33) The Federal Circuit has held that willful infringement may

exist even when the defendant sought an opinion letter if there is evidence that "undermines [defendant's] alleged good faith reliance on the legal opinions." *See Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 435 F.3d 1356, 1365 (Fed. Cir. 2006). A reasonable jury considering the factual issues raised by JHU could determine that Alcon did not rely in good faith on the opinions of counsel given that it recommended discontinuing the 25-gauge products, pursued a license of the '848 patent from JHU, and continued to sell the Accused Products even after the court issued its claim construction decision rejecting Alcon's proposed constructions.

5. Induced infringement

Pursuant to 35 U.S.C. § 271(b), "[w]hoever actively induces infringement of a patent shall be liable as an infringer." Liability under § 271(b) "requires knowledge that the induced acts constitute patent infringement." *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060 (2011). "[I]nducement requires that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement." *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006). A finding of induced infringement requires the patentee to show both specific intent by the alleged infringer and actual inducement, which generally means "a successful communication between the alleged inducer and the third-party direct infringer." *Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1363 (Fed. Cir. 2012).

The parties' arguments regarding Alcon's motion for summary judgment of no induced infringement parallel their positions regarding willfulness and enhanced damages, as both require a showing that the accused infringer acted with a specific intent to infringe. (D.I. 197 at 34-37; D.I. 210 at 20-28) As previously discussed at § IV.C.4, *supra*, the facts surrounding Alcon's use of the opinions of counsel, Alcon's continued efforts to license the '848 patent, and Alcon's continued sales of the Accused Products following the court's rejection of its claim construction

positions give rise to factual issues regarding whether Alcon specifically intended to induce its customers to infringe the patented method. An accused infringer's good faith belief in non-infringement presents a factual question. *Smith & Nephew Inc. v. Arthrex, Inc.*, 603 F. App'x 981, 990 (Fed. Cir. 2015); *see also Vehicle IP, LLC v. AT&T Mobility LLC*, 227 F. Supp. 3d 319, 330 (D. Del. 2016). Consequently, the issue of Alcon's good faith intent in the present case presents a genuine issue of material fact to be presented to the jury. For these reasons, I recommend that the court deny Alcon's motion for summary judgment as it pertains to induced infringement.

D. JHU's Motion for Summary Judgment

1. Invalidity defenses other than obviousness

In March 2016, JHU served Interrogatory 11 on Alcon, asking for Alcon's positions on its invalidity defenses brought under §§ 101, 102, and 112. (D.I. 202, Ex. 2 at 11) Alcon objected to Interrogatory 11 without providing a substantive response. (*Id.*, Ex. 13 at 8-9) On July 18, 2016, the court entered a Memorandum Order highlighting Alcon's continuing obligation to supplement its interrogatory responses in accordance with Rule 26(e). (D.I. 67 at 9-12) However, in its third supplemental responses served on February 22, 2017, Alcon again failed to provide a substantive response to Interrogatory 11. (D.I. 202, Ex. 3 at 20) Alcon's invalidity expert, Dr. Stanley Chang, did not offer an opinion on Alcon's defenses under §§ 101 or 102. Alcon disclosed its § 112 theory in its final infringement contentions and Dr. Chang's expert report. (D.I. 212, Ex. G12 at AA1116-17; Ex. H1 at ¶ 341)

(a) Eligibility and anticipation under §§ 101 and 102

In support of its motion for summary judgment regarding Alcon's invalidity defenses under §§ 101 and 102, JHU contends that nothing on the record supports Alcon's § 101 defense

of unpatentable subject matter, and Alcon described the basis of its anticipation defense under § 102 for the first time in the summary judgment briefing, rendering the defense untimely. (D.I. 200 at 4-5; D.I. 237 at 4-6) In response, Alcon presents no arguments in support of its § 101 theory, but alleges that JHU's infringement allegations provide sufficient evidence for Alcon to prove anticipation under § 102. (D.I. 211 at 19-22)

I recommend that the court grant JHU's motion for summary judgment with respect to Alcon's § 101 defense. No theory regarding § 101 patentability is disclosed in Alcon's discovery responses, its final invalidity contentions, or Dr. Chang's expert report on invalidity. Alcon's answering brief mentions § 101, but only in the context of its argument regarding the mixing of statutory invention classes, which is an indefiniteness defense under § 112. (D.I. 211 at 19) Alcon likewise failed to address its § 101 defense during oral argument. Given that Alcon points to no genuine issue of material fact regarding its unarticulated § 101 theory, summary judgment is warranted on this defense.

In addition, I recommend that the court grant JHU's motion for summary judgment regarding Alcon's § 102 anticipation theory, which was raised for the first time in Alcon's answering brief.[9] Although Alcon argues that JHU's infringement allegations provide sufficient evidence of Alcon's § 102 theory, the fact remains that Alcon did not disclose its theory in response to JHU's infringement allegations during the discovery period. *See INVISTA N. Am. S.a.r.l. v. M & G USA Corp.*, C.A. No. 11-1007-SLR, 2013 WL 3216109, at *5 (D. Del. June 25, 2013) ("This defense alters the entire infringement and non-infringement landscape that was developed and vetted during fact and expert discovery."). Alcon's allegation that JHU's expert,

[9] Dr. Chang's expert report mentions anticipation of claim 39 of the '848 patent without further analysis. (D.I. 202, Ex. 4 at ¶ 304) At Dr. Chang's subsequent deposition, he testified that he did not know what anticipation means in the context of patent law. (*Id.*, Ex. 5 at 13:9-25)

Dr. Awh, first admitted that surgeons used prior art Machemer cannulas to cross both the conjunctiva and sclera after Alcon had submitted its final invalidity contentions is belied by the fact that Dr. Charles disclosed the prior art Machemer cannulas in his deposition on December 17, 2016. (D.I. 212, Ex. G17 at 253:17-25) Alcon's reliance on *Teva Pharm. Indus. Ltd. v. AstraZeneca Pharm. LP* is distinguishable from the circumstances presently before the court because in *Teva*, the defendant conceded infringement to advance its anticipation contentions. 661 F.3d 1378, 1381 (Fed. Cir. 2011). No such concession was made by Alcon in the present case.

(b) § 112 defenses

With respect to Alcon's § 112 defenses, JHU first alleges that Alcon's expert offered only contingent opinions on written description and enablement based on arguments JHU did not ultimately make. (D.I. 200 at 4) In response, Alcon argues that it disclosed its § 112 argument regarding the relationship between the need for sutures and the incision structure in its final invalidity contentions as well as in Dr. Chang's expert report and deposition testimony. (D.I. 211 at 34)

I recommend that the court deny JHU's motion for summary judgment regarding Alcon's enablement and written description defenses under § 112. Alcon's defense regarding prior art wound closure disclosures for sutureless surgery was properly disclosed in Alcon's final invalidity contentions, which assert that the '848 patent does not enable a person of ordinary skill in the art to create wounds that seal without the use of sutures. (D.I. 212, Ex. G12 at AA1116-17) Dr. Chang's expert report further supports Alcon's § 112 position regarding sutureless wound closure in the '848 patent by challenging a potential assertion by JHU that "the prior art does not teach a person of ordinary skill in the art the proper procedures to minimize the need for

sutures with instruments smaller than 20-gauge." (*Id.*, Ex. H1 at ¶ 341) JHU refuses to stipulate that the prior art disclosed surgical insertion methods resulting in sutureless wounds, giving rise to a genuine issue of material fact as to whether the prior art teaches surgical methods for creating sutureless wounds. (11/15/17 Tr. at 141:4-142:5)

For the first time in its answering brief, Alcon also seeks to assert indefiniteness under § 112 based on the improper mixing of statutory invention classes if the jury adopts JHU's theory that it possesses an exclusive right to all small-gauge surgical instrument products. (D.I. 211 at 19) In reply, JHU argues that Alcon's newly-raised § 112 theory was not disclosed in Alcon's discovery responses or invalidity contentions, nor was it identified in Alcon's expert report or deposition. (D.I. 237 at 6) JHU also challenges the legal basis for Alcon's § 112 theory regarding the mixing of two statutory invention classes. (*Id.*)

I recommend that the court grant JHU's motion for summary judgment on Alcon's § 112 indefiniteness defense regarding the mixing of statutory classes of invention.[10] Alcon did not identify this theory in its interrogatory responses or the expert report of Dr. Chang, and Dr. Chang did not endorse the theory in his deposition. Because the record is devoid of evidence supporting Alcon's newly-asserted § 112 theory, there is no genuine issue of material fact to be preserved for trial. *See INVISTA*, 2013 WL 3216109, at *5.

[10] Alcon relies on the Federal Circuit's decision in *IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377 (Fed. Cir. 2005), in support of its § 112 indefiniteness defense. In *IPXL*, the Federal Circuit held that a single claim reciting both an apparatus and a method of using that apparatus renders the claim indefinite under § 112. *Id.* at 1383-84. Alcon does not identify a claim in the '848 patent containing both a method and an apparatus, as in *IPXL*. Instead, Alcon seeks to expand *IPXL* to render indefinite a claimed surgical method when the accused product is an apparatus.

2. Prosecution history estoppel

During oral argument on JHU's motion for summary judgment, the parties agreed to drop the issue of prosecution history estoppel on the condition that JHU would not raise any arguments under the doctrine of equivalents at a later time. (11/15/17 Tr. at 114:18-115:1; 143:20-144:2) In light of JHU's representation on the record that it will not pursue any arguments under the doctrine of equivalents, I recommend that the court grant JHU's motion for summary judgment regarding prosecution history estoppel.

3. Laches

"The doctrine of laches is an affirmative defense . . . based on a party's unexcused delay that prevents that party from asserting a claim after too much time has passed." *Edge Sys. LLC v. Aguila*, 635 F. App'x 897, 906-07 (Fed. Cir. 2015). "[T]o invoke the laches defense, a defendant has the burden to prove two factors: (1) the plaintiff delayed filing suit for an unreasonable and inexcusable length of time from the time the plaintiff knew or reasonably should have known of its claim against the defendant, and (2) the delay operated to the prejudice or injury of the defendant." *A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020, 1032 (Fed. Cir. 1992), *rev'd on other grounds by SCA Hygiene Prods. Aktiebolag v. First Quality Baby Prods., LLC*, 137 S. Ct. 954 (2017).

In support of its motion for summary judgment, JHU contends that Alcon cannot prevail as a matter of law on its tenth defense under the doctrine of laches because JHU is not seeking damages beyond the statutory period under 35 U.S.C. § 286. (D.I. 200 at 7-8) In response, Alcon concedes that its laches defense does not apply to JHU's damages within the statutory period, but argues that JHU has identified allegedly infringing acts outside of the statutory

damages period. (D.I. 211 at 35; 11/15/17 Tr. at 150:10-151:3) Moreover, Alcon argues that its laches defense is not barred to the extent that JHU seeks injunctive relief. (D.I. 211 at 36)

I recommend that the court deny JHU's motion for summary judgment regarding Alcon's laches defense. The Supreme Court recently held that laches is no longer a defense to patent infringement where, as here, damages are sought only for the statutorily permitted period. *SCA Hygiene Prods. Aktiebolag v. First Quality Baby Prods., LLC*, 137 S. Ct. 954, 967 (2017). JHU filed its complaint on June 23, 2015, and seeks damages from June 23, 2009 forward in accordance with the statutory six-year period under § 286. (D.I. 1; D.I. 202, Ex. 8 at 97) The parties agree that Alcon's laches defense therefore does not apply to JHU's statutory damages.

However, Alcon is not barred from asserting its laches defense post-trial if JHU prevails on the merits and seeks injunctive relief. *See Bombardier Recreational Prods., Inc. v. Arctic Cat Inc.*, 2017 WL 5610220, at *2 (D. Minn. Nov. 20, 2017). The Supreme Court's recent decision in *SCA Hygiene* extends only to damages, and courts applying the Supreme Court's recent precedent have concluded that "laches may still bar injunctive relief." *Deckers Outdoor Corp. v. Romeo & Juliette, Inc.*, 2017 WL 2588065, at *6 (C.D. Cal. June 13, 2017); *Bombardier*, 2017 WL 5610220, at *2. JHU's amended complaint sets forth a request for a permanent injunction, JHU's response to Interrogatory 5 proposes that JHU has suffered irreparable harm, and Alcon represents that JHU has refused to stipulate that it will not demand injunctive relief. (D.I. 13 at 20; D.I. 212, Ex. G4 at AA1015-17; Ex. G30 at AA1295-96) Thus, Alcon should not be precluded from asserting its laches defense at the appropriate time to the extent that it pertains to injunctive relief.

4. Failure to mitigate

During oral argument on JHU's motion for summary judgment, the parties agreed to drop the issue of JHU's purported failure to mitigate damages. (11/15/17 Tr. at 116:7-117:4; 144:3-7) Consequently, I recommend that the court grant JHU's motion for summary judgment regarding JHU's purported failure to mitigate damages.

5. Waiver

During oral argument on JHU's motion for summary judgment, the parties agreed to drop the issue of waiver. (11/15/17 Tr. at 116:7-117:4; 144:3-7) Consequently, I recommend that the court grant JHU's motion for summary judgment as it pertains to waiver.

6. Estoppel

In a patent case, a party asserting equitable estoppel must prove three elements: (1) "[t]he patentee, through misleading conduct, leads the alleged infringer to reasonably infer that the patentee does not intend to enforce its patent against the alleged infringer;" (2) "[t]he alleged infringer relies on that conduct;" and (3) "[d]ue to its reliance, the alleged infringer will be materially prejudiced if the patentee is allowed to proceed with its claim." *See A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020, 1028 (Fed. Cir. 1992), *abrogated on other grounds by SCA Hygiene Prods. Aktiebolag v. First Quality Baby Prods., LLC*, 137 S. Ct. 954 (2017).

In support of its motion for summary judgment, JHU contends that Alcon was required to plead this defense with particularity under Rule 9(b) because it requires a showing of "misleading conduct." (D.I. 200 at 9-10) In addition, JHU alleges that Alcon failed to establish either the misleading conduct or reliance elements of the affirmative defense, noting that Alcon produced no discovery describing its development of the Accused Products dated before June

2009. (*Id.* at 10) According to JHU, evidence showing that Alcon attempted to obtain a license to the '848 patent in April 2009 proves that Alcon could not have relied on allegedly misleading conduct by JHU after June 2009. (*Id.* at 10-11)

In response, Alcon contends that Rule 9(b) does not apply to Alcon's estoppel defense because it is not based on fraud by JHU, and even if it did apply, Alcon gave JHU adequate notice of the claim. (D.I. 211 at 23) Moreover, Alcon argues that the record evidence supports Alcon's position that it relied on JHU's silence in response to Alcon's efforts to negotiate a license to the '848 patent. (*Id.* at 24-29)

I recommend that the court deny JHU's motion for summary judgment regarding Alcon's twelfth affirmative defense for equitable estoppel because material issues of fact remain with respect to Alcon's reliance on JHU's allegedly misleading conduct and silence. In the present case, Alcon presents evidence that neither JHU nor B&L, the exclusive licensee of the '848 patent, asserted infringement by Alcon in 2007, allowing Alcon to reasonably infer that JHU and B&L recognized the claims did not cover Alcon's Accused Products. (D.I. 198, Ex. A22 at AA331; Ex. A28 at AA372) At the same time, the record reflects that JHU purchased millions of dollars' worth of Accused Products from Alcon beginning in 2007 and extending through 2015, supporting Alcon's belief that JHU did not consider the Accused Products to be infringing. (D.I. 201, Ex. F13 at AA661; Ex. F18 at 88:14-89:22)

Moreover, Alcon presented evidence that the two licensing overtures made by Alcon employee Paul Hallen to JHU in 2008 were met with silence. (D.I. 201, Ex. F17 at 142:22-144:12, 148:17-152:4; Ex. F11 at AA647) The Federal Circuit has held that silence may lead to estoppel if it is "sufficiently misleading to induce the alleged infringer to reasonably infer that the patentee has abandoned his patent claims." *Meyers v. Brooks Shoe Inc.*, 912 F.2d 1459, 1464

(Fed. Cir. 1990). Viewing JHU's silence in combination with its continued purchase of Alcon's Accused Products, a reasonable jury could conclude that Alcon reasonably inferred JHU did not intend to pursue a cause of action for infringement of the '848 patent.

JHU stresses that in 2009, it responded to Mr. Hallen's licensing overtures by representing that B&L had a non-exclusive license, and JHU would confer with B&L regarding its license. (*Id.*, Ex. F17 at 186:10-188:7) Although Mr. Hallen testified that this response led him to believe the license was unavailable, he did not report his conversation or impressions to anyone else at Alcon, and JHU did not follow up on the conversation. (*Id.*) The evidence does not establish that JHU accused Alcon of infringement or threatened to assert the '848 patent against Alcon in response to Mr. Hallen's licensing inquiry. Consequently, this issue is appropriately reserved for the trier of fact.

7. Safe harbor

The "safe harbor" provision provides:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

35 U.S.C. § 271(e)(1). In support of its motion for summary judgment, JHU contends that no facts on the present record support Alcon's position that Alcon provided Accused Products to third parties within the damages period solely for uses reasonably related to the development and submission of information in accordance with § 271(e)(1). (D.I. 200 at 11-12) In response, Alcon alleges that JHU accuses its internal development and product testing of direct infringement, thereby bringing those activities within the scope of the safe harbor provision. (D.I. 211 at 37)

In view of the recommendation at § IV.C.1, *supra*, I recommend that the court grant JHU's motion for summary judgment regarding Alcon's eighth affirmative defense that JHU's claims are barred by 35 U.S.C. § 271(e)(1). Even if the court were to conclude that JHU has asserted a viable claim for direct infringement against Alcon, JHU concedes that it is not seeking damages for sales of the Accused Products before June 23, 2009. (D.I. 237 at 12) Moreover, Alcon fails to cite to facts in the record in support of its § 271(e)(1) defense.

8. Physician's immunity statute

Section 287(c) states that, "[w]ith respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b), the provisions of sections 281, 283, 284, and 285 shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity." 35 U.S.C. § 287(c)(1). In support of its motion for summary judgment, JHU contends that 35 U.S.C. § 287(c) does not apply to this case because Alcon is not a medical practitioner under the statute. (D.I. 200 at 12) In addition, JHU contends that § 287(c) does not relieve medical practitioners performing the claimed method from liability because the statute does not alter the practitioners' status as infringers. (*Id.* at 13) In response, Alcon argues that the statute is a complete immunity defense to patent infringement as opposed to a provision merely limiting damages. (D.I. 211 at 30-32) According to Alcon, JHU has not showed it suffered harm from doctors practicing the patented method on patients. (*Id.* at 32-33)

I recommend that the court grant JHU's motion for summary judgment with respect to Alcon's fourteenth affirmative defense under 35 U.S.C. § 287(c) as it pertains to claims of direct infringement against Alcon for the reasons set forth at § IV.C.1, *supra*. Even if the court were to conclude that a cause of action for direct infringement against Alcon should stand, Alcon's

activities within the relevant damages period are exempt under § 287(c)(3), which provides an exception for persons "engaged in the commercial development, manufacture, sale, importation, or distribution of a machine, manufacture, or composition of matter . . . regulated under the Federal food, Drug, and Cosmetic Act, the Public Health Service Act, or the Clinical Laboratories Improvement Act." 35 U.S.C. § 287(c)(3).

In addition, I recommend that the court grant JHU's motion for summary judgment to the extent that it applies to the surgeons performing the patented method for the reasons previously set forth at § IV.C.1, *supra*. Regardless of whether the court construes § 287(c) as a complete immunity defense to patent infringement or merely a limitation on damages,[11] the surgeons purportedly using Alcon's Accused Products to perform the claimed method of the '848 patent are not parties to the litigation. The express language of the statute characterizes the medical practitioners' actions as infringement under § 271, even if those medical practitioners are not subject to suit or liable for damages. 35 U.S.C. § 287(c)(1) ("With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b) . . ."). Nothing in the statutory language supports extending the immunity of directly infringing non-party medical practitioners to causes of action for indirect infringement by medical device manufacturers. For these reasons, I recommend that the court grant JHU's

[11] The parties have presented no precedential authority on whether § 287(c) is properly asserted as an affirmative defense in a case involving direct infringement of a surgical method by allegedly immunized non-party doctors using accused surgical devices. (11/15/17 Tr. at 136:9-137:6) JHU relies on the Federal Circuit's decision in *Bradford Co. v. Jefferson Smurfit Corp.*, 2001 WL 35738792, at *9 (Fed. Cir. 2001), for the assertion that limitations on damages are not defenses. However, *Bradford* discusses § 287 in the context of a previous decision in *Motorola, Inc. v. United States*, 729 F.2d 765, 769 (Fed. Cir. 1984), issued prior to the enactment of § 287(c) in 1996.

motion for summary judgment regarding Alcon's fourteenth affirmative defense under the physician's immunity statute at 35 U.S.C. § 287(c).

9. Unspecified additional defenses and counterclaims

During oral argument on JHU's motion for summary judgment, the parties agreed to drop the catch-all provision. (11/15/17 Tr. at 117:12-17; 144:11-17) Consequently, I recommend that the court grant JHU's motion for summary judgment regarding Alcon's seventeenth catch-all defense. (D.I. 17 at 13)

10. Obviousness

On April 11, 2016, Alcon served its responses to JHU's second set of interrogatories, offering a generic objection to Interrogatory 11's request for a detailed description of Alcon's invalidity contentions. (D.I. 202, Ex. 13 at 8-9) Shortly thereafter, on April 28, 2016, Alcon served its initial invalidity contentions identifying the prior art references relied upon in its obviousness defense in compliance with ¶ 1(c)(6) of the scheduling order. (D.I. 212, Ex. G11 at AA1072-81; D.I. 24 at ¶ 1(c)(6)) Specifically, Alcon's initial invalidity contentions referenced the '363 patent, the '831 patent, Chen 1996, and Machemer 1985, which are the four primary references identified by Alcon in support of its § 103 obviousness defense. (*Id.*; 11/15/17 Tr. at 131:12-19) However, Alcon's initial invalidity contentions did not set forth in detail which combinations of references rendered certain claims obvious.

JHU moved to compel a more detailed response to Interrogatory 11 in a letter submission filed on May 17, 2016. (D.I. 50 at 2-3) On July 18, 2016, the court issued a Memorandum Order addressing JHU's motion to compel, concluding that "[i]t would be premature to require Alcon to detail with specificity and finality the factual and legal bases for its claims in the early stages of discovery," but emphasizing Alcon's "continuing obligation to supplement its

discovery responses pursuant to Rule 26(e) as information becomes known." (D.I. 67 at 10-12) Alcon served its first supplemental initial disclosures on September 15, 2016, which identified Alcon's four primary references in a list of more than fifty prior art references. (D.I. 212, Ex. G8 at AA1040-42) On November 14, 2016, Alcon produced its December 15, 2006 opinion of counsel letter to JHU, which disclosed Alcon's obviousness theory regarding combinations of the Machemer 1985 reference, the '831 patent, and the '363 patent. (D.I. 198, Ex. A7 at AA36-38) Alcon served its third and final supplemental response to Interrogatory 11 on February 22, 2017, the last day of fact discovery. (D.I. 202, Ex. 3 at 20) Alcon's third supplemental response did not include a substantive response regarding its invalidity contentions. (*Id.*)

Alcon served its final invalidity contentions on March 30, 2017 in accordance with the scheduling order. (D.I. 212, Ex. G12) Alcon's final invalidity contentions identified combinations of the four primary prior art references which allegedly render the '848 patent obvious. (*Id.* at AA1095) (explaining that a combination of Machemer 1985 and the '363 patent renders claim 25 of the '848 patent obvious) On May 2, 2017, Dr. Stanley Chang issued his opening expert report, which identifies and relies upon thirty-nine prior art references, introducing nineteen new references in addition to the twenty references identified in Alcon's initial invalidity contentions. (D.I. 212, Ex. H1) Dr. Chang's deposition was taken on August 8, 2017. (D.I. 202, Ex. 5)

A patent is invalid if the differences between the invention and the prior art are such that the invention would have been obvious to one of ordinary skill in the art at the time of the invention. *See* 35 U.S.C. § 103. Obviousness is a question of law based on factual determinations, including: "(1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4)

evidence of secondary factors, known as objective indicia of non-obviousness." *Altana Pharma AG v. Teva Pharms. USA, Inc.*, 566 F.3d 999, 1007 (Fed. Cir. 2009).

In support of its motion for summary judgment, JHU contends that Alcon's obviousness defense should be excluded because Alcon failed to comply with this court's July 18, 2016 order by not supplementing its response to Interrogatory 11 in accordance with Rule 26(e). (D.I. 200 at 17-18; D.I. 237 at 15-17) At oral argument on November 15, 2017, JHU narrowed its requested relief by seeking only to limit Alcon to the prior art combinations disclosed in its expert report, as opposed to pursuing exclusion of Alcon's entire obviousness defense. (11/15/17 Tr. at 131:12-21) In response, Alcon alleges that it timely disclosed its obviousness defense in its invalidity contentions and expert report, and JHU cites no deficiencies in Alcon's final invalidity contentions. (D.I. 211 at 8-10)

In view of JHU's representations during the November 15, 2017 oral argument, I recommend that the court grant-in-part JHU's motion for summary judgment regarding Alcon's obviousness defense. Specifically, I recommend that the court deny the motion with respect to the four primary prior art combinations identified in Dr. Chang's expert report. *See Abbott Labs. v. Lupin Ltd.*, C.A. No. 09-152-LPS, 2011 WL 1897322, at *5 (D. Del. May 19, 2011) (holding that the "extreme sanction" of precluding invalidity defenses was not warranted because the defendant's failure to supplement its contention interrogatories was not unduly prejudicial to the plaintiff). I recommend that the court grant the motion with respect to the Packo reference identified as a primary reference for the first time during the deposition of Dr. Chang,[12] as well

[12] During the November 15, 2017 oral argument, Alcon's counsel represented that the Packo reference was disclosed in earlier contentions and was discussed in detail in Dr. Chang's report. (11/15/17 Tr. at 134:16-135:4) The record reflects that JHU's expert, Dr. Awh, discussed the Packo reference in his responsive expert report. (D.I. 212, Ex. G14 at AA1151-52) However,

as the secondary references for which no combination was identified in Dr. Chang's expert report. This ruling is consistent with the representations made by the parties on the record during the November 15, 2017 oral argument. (11/15/17 Tr. at 131:12-21)

JHU bases its request for relief on Rule 37(c)(1), which provides that, "[i]f a party fails to provide information . . . the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1). Courts in the Third Circuit apply five factors in considering whether to exclude evidence under Rule 37: "(1) the prejudice to or surprise of the party against whom the evidence is offered; (2) the ability of that injured party to cure the prejudice; (3) the likelihood of disruption of trial; (4) the bad faith or willfulness involved in not complying with the disclosure rules; and (5) the importance of the evidence to the proffering party." *Vehicle IP, LLC v. Werner Enters., Inc.*, C.A. No. 10-503-SLR, 2013 WL 4786119, at *1 (D. Del. Sept. 9, 2013).

Applying the *Pennypack* factors in accordance with Rule 37(c)(1) to Alcon's delayed disclosure of its reliance on the Packo reference in the expert deposition of Dr. Chang, the record shows that the first, second, and third *Pennypack* factors weigh in favor of granting JHU's motion for summary judgment. Specifically, Alcon's late disclosure of the Packo reference as a primary reference prejudiced JHU by denying it the opportunity to explore the asserted prior art combinations containing the Packo reference during fact or expert discovery. Instead, JHU was limited to cross-examining Dr. Chang without preparation during Dr. Chang's deposition. (11/15/17 Tr. at 133:17-23) JHU has no opportunity to cure the prejudice given that fact and

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Dr. Chang did not identify the Packo reference as a primary reference or specify prior art combinations including the Packo reference until his August 8, 2017 deposition.

expert discovery are closed, and trial is quickly approaching, and reopening this issue for further discovery would disrupt the trial schedule. The fifth factor does not weigh heavily in Alcon's favor, given that Alcon would have presumably advanced the Packo reference as a primary reference earlier in discovery if the reference was crucial to its obviousness defense.

Summary judgment may also be granted with respect to the numerous prior art references identified in Alcon's final invalidity contentions and Dr. Chang's expert report for which no combination was offered to support an obviousness defense. Alcon has not established the existence of a genuine issue of material fact in relation to its obviousness assertion with respect to these prior art references.

V. CONCLUSION

For the foregoing reasons, I recommend that the court dispose of the pending motions as follows:

1. **Alcon's *Daubert* Motion to Exclude Certain Opinions and Testimony (D.I. 225)**
    a. I recommend that the court **DENY** the motion with respect to the opinions and testimony of Mr. Brian Napper.
    b. I recommend that the court **GRANT** the motion with respect to the opinions and testimony of Mr. Charles Colby.
2. **JHU's Motions to Exclude Under F.R.E. 702 and *Daubert* (D.I. 218)**
    a. I recommend that the court **DENY** the motion with respect to the PAT Surveys.
    b. I recommend that the court **GRANT** the motion with respect to the MarketScope Reports.

c. I recommend that the court **GRANT** the motion with respect to Dr. Donald D'Amico's invalidity testimony.

d. I recommend that the court **DENY** the motion with respect to opinions claiming that the Accused Products practice Alcon's patents.

3. Alcon's Motion for Summary Judgment (D.I. 196)

a. I recommend that the court **GRANT** the motion with respect to JHU's claims of direct infringement by Alcon.

b. I recommend that the court **DENY** the motion with respect to JHU's claims of direct infringement by medical practitioners.

c. I recommend that the court **DENY** the motion with respect to contributory infringement.

d. I recommend that the court **DENY** the motion with respect to the reasonable royalty.

e. I recommend that the court **DENY** the motion with respect to willful infringement / enhanced damages.

f. I recommend that the court **DENY** the motion with respect to induced infringement.

4. JHU's Motion for Summary Judgment (D.I. 199)

a. I recommend that the court **GRANT** the motion with respect to Alcon's patent eligibility defense under 35 U.S.C. § 101.

b. I recommend that the court **GRANT** the motion with respect to Alcon's anticipation defense under 35 U.S.C. § 102.

c. I recommend that the court **DENY** the motion with respect to Alcon's written description / enablement defense under 35 U.S.C. § 112.

d. I recommend that the court **GRANT** the motion with respect to Alcon's indefiniteness defense based on statutory categories under 35 U.S.C. § 112.

e. I recommend that the court **GRANT** the motion with respect to Alcon's prosecution history estoppel defense.

f. I recommend that the court **DENY** the motion with respect to Alcon's laches defense.

g. I recommend that the court **GRANT** the motion with respect to Alcon's defense for failure to mitigate damages.

h. I recommend that the court **GRANT** the motion with respect to Alcon's waiver defense.

i. I recommend that the court **DENY** the motion with respect to Alcon's equitable estoppel defense.

j. I recommend that the court **GRANT** the motion with respect to Alcon's safe harbor defense under 35 U.S.C. § 271(e)(1).

k. I recommend that the court **GRANT** the motion with respect to Alcon's physician's immunity defense under 35 U.S.C. § 287(c).

l. I recommend that the court **GRANT** the motion with respect to Alcon's catch-all defense.

m. I recommend that the court **GRANT-IN-PART** with respect to Alcon's obviousness defense pursuant to 35 U.S.C. § 103. Specifically, I recommend that the court **DENY** the motion with respect to the four primary prior art

references relied upon by Alcon's invalidity expert, and **GRANT** the motion with respect to the fifth Packo reference and all other references for which no prior art combination was identified.

Given that the court has relied upon material that technically remains under seal, the court is releasing this Report and Recommendation under seal, pending review by the parties. In the unlikely event that the parties believe that certain material in this Report and Recommendation should be redacted, the parties should jointly submit a proposed redacted version by no later than **March 30, 2018**. The court will subsequently issue a publicly available version of its Report and Recommendation.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The objections and responses to the objections are limited to ten (10) pages each. The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the District Court. *See Sincavage v. Barnhart,* 171 F. App'x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

The parties are directed to the court's Standing Order for Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the court's website, http://www.ded.uscourts.gov.

Dated: March 1, 2018

Sherry R. Fallon
United States Magistrate Judge