

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

BOSTON SCIENTIFIC CORPORATION)
and BOSTON SCIENTIFIC SCIMED, INC.,)

Plaintiffs,)

v.)

EDWARDS LIFESCIENCES)
CORPORATION,)

Defendant.)

EDWARDS LIFESCIENCES)
CORPORATION, EDWARDS)
LIFESCIENCES PVT, INC., and EDWARDS)
LIFE SCIENCES LLC,)

C.A. No. 16-275-SLR-SRF

UNDER SEAL

Counterclaim and Third-Party)
Plaintiffs,)

v.)

BOSTON SCIENTIFIC CORPORATION,)
BOSTON SCIENTIFIC SCIMED, INC., and)
SADRA MEDICAL, INC.,)

Counterclaim and Third-Party)
Defendants.)

MEMORANDUM ORDER

At Wilmington this **10th** day of **January, 2018**, the court having considered the parties' discovery dispute submissions and the arguments presented during the October 25, 2017 hearing (D.I. 275; D.I. 276; D.I. 277; D.I. 278; D.I. 279; 10/25/17 Tr.), IT IS HEREBY ORDERED THAT: (1) the motion to strike the invalidity contentions of Edwards Lifesciences Corporation,

Edwards Lifesciences PVT, Inc., and Edwards Life Sciences LLC (collectively, “Edwards”), filed by plaintiffs and counterclaim defendants Boston Scientific Corp. and Boston Scientific SciMed, Inc. and third-party defendant Sadra Medical, Inc. (collectively, “BSC”) is denied, and BSC is permitted to take additional limited discovery regarding the PVT prototypes; (2) BSC’s motion to strike Edwards’ expert opinions regarding the Sapien 3 Ultra device (“S3U”) is denied, and BSC is permitted to take additional discovery regarding the S3U in the form of document discovery, deposition discovery from a fact witness regarding the regulatory process, and deposition testimony from expert regulatory witnesses; and (3) BSC’s motion to strike the errata from the deposition of Mr. Assaf Bash is denied, for the reasons set forth below.

1. ***Motion to Strike Edwards’ Invalidity Contentions.*** In support of its motion, BSC contends that the court should strike Edwards’ invalidity contentions served on June 30, 2017, and any expert opinions that rely on those contentions, because Edwards delayed in identifying the additional references until the last day of fact discovery, denying BSC the opportunity to take discovery on the newly-cited prior art references. (D.I. 275 at 1-2) For the following reasons, BSC’s motion to strike is denied, and BSC is permitted to take additional limited discovery regarding the PVT prototypes in the form of documents and additional limited deposition testimony from Assaf Bash, Laksen Sirimanne, and Stan Rowe.

2. **Background.** Pursuant to the terms of the scheduling order in the above-captioned matter, Edwards was required to serve the final supplementation of its identification of invalidity references by April 7, 2017, and its final invalidity contentions were due on May 5, 2017. (D.I. 34 at ¶ 1(g)(3) & (h)) The record reflects that Edwards served a final supplementation of its invalidity references on April 7, 2017, identifying 153 written references

and 20 allegedly invalidating devices. (D.I. 139; D.I. 275, Ex. 1) Edwards subsequently served its final invalidity contentions on the May 5, 2017 deadline. (D.I. 169; D.I. 275, Ex. 2)

3. On May 26, 2017, BSC took the Rule 30(b)(6) deposition of Assaf Bash, an employee of Edwards. (D.I. 275, Ex. 8) At the Bash deposition, BSC's counsel marked as exhibits the photographs of prototypes produced by Edwards in November 2016. (D.I. 278, Exs. 16-19) BSC's counsel also inspected and asked questions about the prototypes themselves during the Bash deposition. (*Id.*, Exs. 20-28) Mr. Bash testified that Stan Rowe, another Edwards employee, had knowledge regarding certain other prototypes. (D.I. 275, Ex. 8 at 386:21-387:13)

4. On June 29, 2017, BSC took the deposition of Stan Rowe. (D.I. 278, Ex. 30) At the deposition, Mr. Rowe testified that he disclosed several of the Percutaneous Valve Technologies ("PVT") prototypes¹ in the United States in 2001 and 2002, and counsel for Edwards brought the prototypes to the Rowe deposition. (*Id.* at 109:13-112:23)

5. Fact discovery closed on June 30, 2017. (D.I. 153 at ¶ 1) On the same date, Edwards served its second supplemental invalidity contentions, purporting to add as prior art

¹ Percutaneous Valve Technologies was acquired by Edwards in January 2004. BSC's submission indicates that Edwards' untimely disclosure regarding its invalidity contentions included the disclosure of two prior art patents (the "Lambrecht References"), the PVT prototypes, and the Patriot prototypes. (D.I. 275 at 2) However, the Lambrecht References appear only in the background section of Edwards' expert reports, and Edwards has not affirmatively relied on the Lambrecht References as invalidating prior art. (D.I. 277, Ex. 1 at ¶ 130) Moreover, Edwards does not seek to strike the portion of Edwards' expert report relying on the Patriot program. (D.I. 277, Ex. 1 at 212-220) During the October 25, 2017 discovery dispute teleconference, the PVT prototypes were the focus of the dispute as the most critical of the late-disclosed prior art references. (10/25/17 Tr. at 6:8-14) This is consistent with the record before the court, which indicates that BSC seeks to strike the portions of Edwards' expert report pertaining to the PVT prototypes. (D.I. 277, Ex. 1 at 197-211)

references the Lambrecht References and several of the PVT prototypes identified by Mr. Rowe. (D.I. 278, Ex. 31)

6. On July 14, 2017, BSC notified Edwards of its intention to file a motion to strike in the event that Edwards' expert were to include any of the new prior art references in its expert reports. (D.I. 275, Ex. 4) The parties met and conferred on July 21, 2017, but on July 25, 2017, Edwards indicated its belief that its second supplemental invalidity contentions were proper, and expressed an intention to include the newly added prior art references in its expert reports. (*Id.*, Ex. 5)

7. On August 3, 2017, Edwards' expert, Dr. Nigel P. Buller, served his opening expert report on invalidity, which incorporated an analysis of the PVT prototypes introduced at Mr. Rowe's deposition. (D.I. 277, Ex. 1)

8. On August 31, 2017, BSC's expert, Dr. Stephen J.D. Brecker, inspected the PVT prototypes introduced at Mr. Rowe's deposition. (D.I. 278, Ex. 35) Dr. Brecker submitted his rebuttal expert report, which addressed the PVT prototypes, on September 21, 2017. (D.I. 279, Ex. 37 at 87-93)

9. **Legal standard.** Invalidity contentions are considered to be "initial disclosures" under Federal Rule of Civil Procedure 26(a). *See* United States District Court for the District of Delaware, *Default Standard for Discovery* § 4(d). A failure to disclose or supplement pursuant to Rule 26(a) or (e) "may lead to [the] exclusion of the materials in question" under Rule 37(c)(1). *Lambda Optical Solutions, LLC v. Alcatel-Lucent USA Inc.*, C.A. No. 10-487-RGA-CJB, 2013 WL 1776104, at *2 (D. Del. Apr. 17, 2013). Rule 37(c)(1) provides that "[i]f a party fails to provide information . . . as required by Rule 26(a) or (e), the party is not allowed to use

that information . . . 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).

10. Motions to strike invalidity contentions as untimely are reviewed in accordance with the “*Pennypack*” factors: (1) the prejudice or surprise to a party against whom the evidence is offered; (2) the ability of the injured party to cure the prejudice; (3) the likelihood of disruption of trial; (4) bad faith or willfulness involved in not complying with the disclosure rules; and (5) the importance of the evidence to the proffering party. See *Meyers v. Pennypack Woods Home Ownership Ass’n*, 559 F.2d 894, 904 (3d Cir. 1977). “Trial judges are afforded wide discretion in making rulings on the admissibility of evidence.” *Quinn v. Consol. Freightways Corp. of Del.*, 283 F.3d 572, 576 (3d Cir. 2002) (citations omitted).

11. “[T]he exclusion of critical evidence is an ‘extreme’ sanction, not normally to be imposed absent a showing of willful deception or ‘flagrant disregard’ of a court order by the proponent of the evidence.” *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 749 (3d Cir. 1994). Consequently, “evidence should be excluded sparingly and only in circumstances involving litigation conduct that is clearly unprofessional or inappropriate, and in circumstances creating prejudice to the party against whom the evidence is offered.” *Bridgestone Sports Co. Ltd. v. Acushnet Co.*, C.A. No. 05-132-JJF, 2007 WL 521894, at *4 (D. Del. Feb. 15, 2007). However, “[c]ourts applying the *Pennypack* factors in the case of sophisticated, complex litigation involving parties represented by competent counsel have been less indulgent in their application and more willing to exclude evidence without a strict showing that each of the *Pennypack* factors has been satisfied.” *Id.* (citing *Astrazeneca AB v. Mutual Pharm. Co.*, 278 F. Supp. 2d 491 (E.D. Pa. 2003)).

12. Analysis. As a preliminary matter, the court finds that the facts of the present case are distinguishable from the cases relied upon by BSC in its letter submission because Edwards supplemented its invalidity contentions within the fact discovery period. *Cf. Bridgestone Sports Co. Ltd. v. Acushnet Co.*, C.A. No. 05-132-JJF, 2007 WL 521894 (D. Del. Feb. 15, 2017) (granting motion to strike where invalidity contentions were due on August 11, 2006, fact discovery closed on October 10, 2006, and six prior art references were added to the invalidity contentions on December 14, 2006); *Praxair, Inc. v. ATMI, Inc.*, 231 F.R.D. 457 (D. Del. 2005) (granting motion to strike where fact discovery closed on April 15, 2005, and new prior art references were disclosed thereafter and relied on in the May 2, 2005 expert report); *see also Fairchild Semiconductor Corp. v. Power Integrations, Inc.*, C.A. No. 12-540-LPS, 2015 WL 1883960, at * (D. Del. Apr. 24, 2015) (granting motion to strike where fact discovery closed in December 2013 and invalidity contentions were supplemented in March 2014); *Intermec Techs. Corp. v. Palm Inc.*, C.A. No. 07-272-SLR, 2010 WL 2340228 (D. Del. June 7, 2010) (denying motion to strike where fact discovery closed on May 29, 2009 and invalidity contentions were supplemented on July 23, 2009). BSC also relies on *Intellectual Ventures I LLC v. AT&T Mobility LLC*, in which the defendant objected to the disclosure of a new infringement theory in the infringement contentions two weeks before the close of fact discovery as untimely. C.A. No. 13-1668-LPS, 2017 WL 658469, at *1 (D. Del. Feb. 14, 2017). In passing, the court in *Intellectual Ventures* characterized the newly-added infringement contentions as “legally deficient and untimely served,” but the analysis itself focused on the plaintiff’s failure to serve infringement contentions that applied the court’s claim construction. *Id.* at *2-3 (noting the untimeliness of the infringement contentions without specifying the date the contentions were served, the date the contentions were due, or the fact discovery deadline).

Given the lack of case authority supporting Edwards' motion to strike the invalidity contentions solely on the basis of untimeliness when those contentions were filed within the fact discovery period, the court declines to expand the ruling in *Intellectual Ventures*.

13. The court next turns to an evaluation of the *Pennypack* factors. The first factor, regarding the prejudice to the party against whom the evidence is offered, weighs in favor of granting BSC's motion to strike. BSC suffered prejudice from the untimely disclosure of the second supplemental invalidity contentions because the late production prevented BSC from being able to take its own discovery on the newly-produced prototypes. However, several considerations mitigate the prejudice suffered by BSC. First, BSC's expert, Dr. Brecker, was able to address the prototypes in his expert report after inspecting the prototypes following the close of fact discovery. (D.I. 279, Exs. 33-36; Ex. 37 at 87-93) Second, the prototypes were disclosed at the Bash deposition over a month prior to their inclusion in the invalidity contentions. (10/25/17 at 21:20-22:2; D.I. 275, Ex. 8 at 69:24-70:14) Counsel for BSC questioned both Bash and Rowe regarding the newly-disclosed prototypes during their respective depositions, raising questions seeking a similar level of detail to those asked about the previously-disclosed prototypes. (10/25/17 Tr. at 22:3-21; D.I. 275, Ex. 8 at 304:13-306:24, 367:2-397:15; D.I. 278, Ex. 30 at 109:13-112:23)

14. The court next evaluates whether the prejudice suffered can be cured. Edwards has indicated a willingness to comply with BSC's request for additional deposition testimony on the newly-produced prototypes. (10/25/17 Tr. at 24:25-25:8) BSC has suggested that additional limited depositions of Rowe, Bash, and Sirimanne could cure the prejudice in addition to the production of documents regarding the function and purpose of the material used in the

prototypes. (*Id.* at 9:8-13, 14:21-15:17) The court grants the requested relief.² Dr. Brecker, BSC's expert, was able to analyze the prototypes following the close of fact discovery, and incorporated his analysis of those prototypes into his expert report. If the additional document and deposition discovery reveal information critical to the expert analysis, the court will consider limited supplementation of the expert reports at the appropriate time.

15. Turning to the likelihood of disruption of the trial schedule, the court concludes that the trial schedule weighs in favor of granting the motion to strike. Trial is currently set to go forward on July 30, 2018. (D.I. 34) Awarding additional fact discovery at this late stage of the proceedings may result in the modification of subsequent scheduling order deadlines, up to and including trial. However, the additional discovery is limited in nature, and fact discovery pertaining to other issues is ongoing pursuant to the court's November 28, 2017 Memorandum Order permitting deposition discovery in accordance with the Hague Convention. (D.I. 285) Modifications may be made to the dispositive motion briefing schedule, currently set to conclude on March 30, 2018, as well as the pretrial conference date, currently scheduled for June 27, 2018, without necessarily resulting in a loss of the July 30, 2018 trial date. (D.I. 34)

16. The court's evaluation of whether the late disclosure of the prototypes was the result of Edwards' bad faith weighs against granting the motion to strike. Edwards produced documents and photographs relating to all prototypes earlier in the case. (D.I. 275, Ex. 8 at 70:11-14; D.I. 277, Exs. 2-5, 7-9) The record supports Edwards' assertion that it did not obtain the physical prototypes at issue in this dispute until the deposition of Stan Rowe on June 29, one

² In addition, the court entered a Memorandum Order on November 28, 2017 permitting limited deposition discovery under the Hague Convention regarding prototypes newly disclosed during the Bash deposition. (D.I. 285)

day prior to the close of fact discovery. (D.I. 278, Ex. 30 at 109:13-112:23) These facts are inconsistent with allegations that Edwards intentionally tried to avoid disclosing the prototypes.

17. The final factor of the *Pennypack* analysis weighs against granting the motion to strike because the parties agree that the prototypes are relevant to the validity of the patents and are therefore important to the case. (10/25/17 Tr. at 21:15-19)

18. In summary, the court concludes that the *Pennypack* factors support denial of BSC's motion to strike. Although the delayed production of the prototypes prejudiced BSC, the prejudice suffered was minimal and is easily cured. The loss of the July 30, 2018 trial date is speculative at this stage of the proceedings, and other recent developments in fact discovery separate from the present dispute may cause delays in the scheduling order regardless of whether the court grants or denies the present motion. BSC presents no compelling evidence that Edwards acted in bad faith. For these reasons, BSC's motion to strike Edwards' invalidity contentions is denied, and BSC is instead permitted to take limited document and deposition discovery regarding the newly-disclosed prototypes to cure any prejudice suffered as a result of the late disclosure of those prototypes.

19. ***Motion to Strike Edwards' Expert Opinions Regarding the Sapien 3 Ultra.*** In support of its motion, BSC seeks to strike Edwards' expert opinions regarding the SAPIEN 3 Ultra ("S3U") because Edwards disclosed its theory that the S3U is a non-infringing alternative to the accused SAPIEN 3 ("S3") for the first time in its damages rebuttal expert report, preventing BSC from conducting the fact and expert discovery necessary to disprove Edwards' assertions. (D.I. 275 at 2-5) For the following reasons, BSC's motion is denied, and the court will instead permit limited additional discovery regarding the S3U.

20. Background. Edwards conceived of the S3U's outer skirt on or about February 8, 2017, and built prototypes of the S3U, performed feasibility testing on it, chose a design for it, and created CAD models of the skirt on or about February 13, 2017. (D.I. 275, Exs. 14-15) By April 20, 2017, Edwards had designed, developed, and tested the delivery system and applied for regulatory approval. (D.I. 275, Exs. 16-17) Paravalvular leak ("PVL") testing was performed on May 10, 2017. (D.I. 279, Ex. 43)

21. The deadline to serve written discovery requests in the present matter passed on April 21, 2017. (D.I. 34 at ¶ 1(e)(4)) On June 6, 2017, when the S3U design was final, Edwards produced thirty-three design and regulatory documents regarding the S3U, including skirt assembly instructions and PVL testing documents. (D.I. 279, Exs. 41-43) BSC took the deposition of Edwards employee Larry Wood on June 13, 2017, which disclosed the S3U as a replacement for the S3. (D.I. 275, Ex. 9 at 265:12-272:12) On June 20, 2017, BSC took the deposition of Laksen Sirimanne, which included questioning on the S3U, M-Dock, Apogee, and Intuity devices. (D.I. 275, Ex. 11 at 107:2-123:25)

22. Fact discovery closed on June 30, 2017. (D.I. 153 at ¶ 1) On the same day, Edwards served its supplemental responses to BSC's interrogatories, identifying "the ready availability of acceptable alternatives" to the S3, including the S3U. (D.I. 278, Ex. 32 at 26)

23. On July 12, 2017, counsel for BSC emailed counsel for Edwards, indicating BSC's intent to have its expert rely on the S3U device. (D.I. 279, Ex. 48) Edwards produced a sample of the S3U device on July 18, 2017. On August 3, 2017, BSC's damages expert, Michael E. Tate, submitted an opening expert report, in which he acknowledged that he was aware of the S3U, but declined to offer opinion or analysis. (D.I. 279, Ex. 51 at 22) ("I understand from counsel that, late in the fact discovery proceedings of this case, Edwards first disclosed an

alleged design-around.”). Edwards produced additional documents regarding the S3U on August 17, 2017 and September 6, 2017. (D.I. 275 at 3)

24. BSC alleges that it first became aware of Edwards’ contention that the S3U was a non-infringing alternative when Edwards served its damages rebuttal expert report on September 21, 2017. (D.I. 275 at 3)

25. Analysis. BSC’s motion to strike Edwards’ expert opinions regarding the S3U is denied. The timing of the S3U’s development and the regulatory process for approval of the S3U are not within the control of Edwards’ counsel for purposes of discovery in this litigation. The record reflects that Edwards disclosed documentary evidence regarding the S3U in a timely manner as it became available. Specifically, Edwards produced documents regarding the S3U shortly after the product was developed, and BSC received deposition testimony from Laksen Sirimanne on June 20, 2017, prior to the close of fact discovery. (D.I. 275, Ex. 11) Moreover, Edwards disclosed its theory regarding the S3U as an acceptable alternative to the S3 in its responses to BSC’s interrogatories, served on June 30, 2017, which was the fact discovery deadline. (D.I. 278, Ex. 32 at 26)

26. On July 12, 2017, BSC’s counsel sent an email to Edwards’ counsel, which indicated that, “should Boston Scientific be unable to obtain samples of the Sapien 3 Ultra in time for its experts to properly test the device, we will reserve all rights, including the possibility of moving to exclude the device.” (D.I. 279, Ex. 48) In response, Edwards produced a sample of the S3U on July 18, 2017, prior to the exchange of expert reports on August 1, 2017. (D.I. 275 at 3) The record reflects that substantial discovery regarding the S3U has occurred, and earlier discovery on the device would have been difficult, if not impossible, due to its recent development.

27. Despite Edwards' good faith efforts to disclose discovery regarding the S3U as it becomes available, BSC has articulated the prejudice it suffered, including its inability to effectively examine fact witnesses or retain a regulatory expert, as a result of the late disclosure of the S3U discovery. Consequently, the court will grant limited additional discovery regarding this subject in lieu of precluding Edwards' expert opinions regarding the S3U. Specifically, the court will permit additional document discovery limited to the production of regulatory submissions, internal regulatory documents, underlying testing data, and marketing documents to the extent that such documents have not already been produced.³ In addition, BSC may depose one regulatory fact witness for purposes of identifying when and if the S3U product would be approved, and the parties may each retain and depose a regulatory expert, consistent with the parties' discussions during the meet and confer process. (10/25/17 Tr. at 47:5-14)

28. ***Motion to Strike the Errata of Mr. Assaf Bash's Deposition Transcript.*** In support of its motion to strike the errata of Mr. Bash's deposition, BSC alleges that the errata fail to meet the requirements set forth in Rule 30(e). (D.I. 275 at 6) For the following reasons, BSC's motion to strike the errata from the Bash deposition is denied.

29. **Background.** On May 16, 2017, BSC deposed Mr. Bash. (D.I. 275, Ex. 8) The deposition transcript contained a certification by the reporter indicating that reading and signing was neither requested nor waived. (*Id.*) Edwards timely served errata in accordance with Rule

³ Edwards represents that the requested documents have already been produced, explaining that the production is smaller because it relates to a modification to the scope of the product on a fast-track timeline, as opposed to a complete redesign of the valve. (10/25/17 Tr. at 41:12-22; 46:12-20) Edwards cannot be compelled to produce that which has already been produced. To the extent that the requested documents have already been produced, Edwards shall make a representation as to the completeness of the production in writing.

30(e) on July 17, 2017. (D.I. 279, Ex. 52) However, the errata list did not contain the required explanation as to why the changes to the transcript were necessary. (*Id.*)

30. Subsequent changes to the errata to conform to the requirements of Rule 30(e) were made at BSC's request. (D.I. 279, Exs. 53-55) On September 6, 2017, counsel for BSC sent an email to counsel for Edwards, indicating that BSC considered the corrected errata untimely under Rule 30(e), and submitting a narrowed list of eight changes that BSC sought to have withdrawn. (D.I. 275, Ex. 28)

31. Legal standard. Rule 30(e) provides that, “[o]n request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which (A) to review the transcript or recording; and (B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.” Fed. R. Civ. P. 30(e)(1). Although Rule 30 permits a deponent to make changes to the “form or substance” of his deposition testimony, and “does not flatly prohibit an erratum that contradicts prior deposition testimony, a minority of courts refuses to allow contradictory errata in certain circumstances.” *Alcon Research Ltd. v. Barr Labs. Inc.*, C.A. No. 09-318-LDD, 2011 WL 13135574, at *2 (D. Del. Oct. 25, 2011). The majority rule, followed by courts in the Third Circuit, maintains that “a deponent may ‘make changes that contradict the original answers given, even if those changes are not supported by convincing explanations, as long as the deponent complies with the instructions provided within the rule itself for making such changes.’” *Id.* (quoting Wright and Miller, Federal Practice and Procedure, § 2118; and *Aetna Inc. v. Express Scripts, Inc.*, 261 F.R.D. 72, 75 (E.D. Pa. 2009)). “Under this broader interpretation of the rule, all of the deponent’s answers, including old and

new, remain a part of the record, and Defendants are free to cross-examine the witness at trial on his contradictory answers.” *Express Scripts*, 261 F.R.D. at 75.

32. The Third Circuit has suggested the application of a “flexible approach” to account for different policy considerations depending on the stage of the litigation. *See EBC, Inc. v. Clark Building Sys., Inc.*, 618 F.3d 253, 267-68 (3d Cir. 2010). Specifically, the Third Circuit has posited that “requiring trial judges in all cases to permit contradictory alterations could risk the defeat of summary judgment in a large swath of cases for which a Rule 56 disposition otherwise would be appropriate. Preservation of the original testimony for impeachment at trial serves as cold comfort to the party that should have prevailed at summary judgment.” *Id.* Consequently, the Third Circuit held that “when reviewing a motion for summary judgment, a district court does not abuse its discretion under Rule 30(e) when it refuses to consider proposed substantive changes that materially contradict prior deposition testimony, if the party proffering the changes fails to provide sufficient justification,” while leaving open the door for discretionary allowance of contradictory changes “as the circumstances may warrant.” *Id.* at 268.

33. **Analysis.** As noted by BSC, courts in other jurisdictions have determined that corrections to an errata sheet must be made within the thirty day window provided under Rule 30(e) to be considered timely. *See E.I. du Pont de Nemours & Co. v. Kolon Indus., Inc.*, 277 F.R.D. 286, 295-96 (E.D. Va. 2011). BSC has cited no binding precedent from the Third Circuit in support of this proposition. Viewing the facts specific to the present record, the court declines to strike the corrections to the errata as untimely. The record reflects that the original errata sheet was timely filed, and BSC and Edwards made efforts to reach a compromise regarding the purported deficiencies in the errata after the deadline set forth in Rule 30(e) had expired. (D.I.

275, Ex. 28) Imposing an obligation on Edwards to anticipate challenges to the errata, and to build sufficient time into the thirty-day window to resolve those challenges despite the unknown variables which may arise during the process, is unreasonable in the present case. The timely filing of the original errata sheet was sufficient to meet the timeliness requirement of Rule 30(e) in this instance, and Edwards' subsequent modifications were promptly made in response to BSC's complaints. Dismissing the subsequent changes as untimely would elevate form over substance under the facts of this case.

34. BSC further contends that the errata include a certain number of substantive changes to Mr. Bash's testimony which are being sought to create an issue of fact in an effort to preclude summary judgment on the prior use defense. (10/25/17 Tr. at 53:14-56:18) BSC specifically objects to eight⁴ proposed clarifications identified in its correspondence with Edwards during the meet and confer process. (D.I. 275, Ex. 28) Upon review of the disputed clarifications in conjunction with the Bash deposition transcript, the court concludes that the proposed substantive changes do not materially contradict prior deposition testimony, and Edwards has provided sufficient justification for the changes.

35. The majority of the proposed errata are intended to correct typographical errors and are not subject to dispute. Consequently, BSC's motion to strike is denied with respect to all modifications not identified in the list of seven disputed changes at Exhibit 28 of BSC's October 18, 2017 letter. (D.I. 275, Ex. 28)

⁴ BSC identifies page 262, line 12 of the Bash deposition as containing an objectionable modification. (D.I. 275, Ex. 28) However, the attached errata sheets do not identify any changes to this page. (D.I. 275, Exs. 21, 25, 27) Consequently, the court limits its analysis to the subsequent seven disputed changes.

36. BSC's motion to strike is denied with respect to the change proposed at page 321, line 6 of the Bash deposition transcript. In response to a question regarding whether "Dr. Cribier had the original idea and helped develop the procedure for the heart valve described in the '133 patent," Mr. Bash answered with an affirmative "Yes." (D.I. 275, Ex. 8 at 321:2-6) Edwards seeks to add a narrative response reiterating the phraseology of the question itself, citing consistent prior deposition testimony. (D.I. 275, Ex. 27 at 4) To the extent that the proposed correction seeks to reiterate the language of the question answered, it is repetitive in its confirmation of the original affirmative answer, but it does not contradict prior deposition testimony by Mr. Bash. (D.I. 275, Ex. 8 at 43:25-45:8, 320:15-321:1) As a result, the proposed modification does not run the risk of creating a genuine issue of material fact sufficient to preclude summary judgment on the prior use defense when compared with the original deposition testimony. *Cf. EBC*, 618 F.3d at 267-68 (holding that "requiring trial judges in all cases to permit contradictory alterations could risk the defeat of summary judgment in a large swath of cases for which a Rule 56 disposition otherwise would be appropriate."). For these reasons, the fact finder should be permitted to consider both the original and modified versions of Mr. Bash's testimony with respect to this passage.

37. BSC's motion to strike the errata is also denied with respect to the proposed substantive changes on page 336 of the Bash deposition. Edwards' proposal to change "We are not aware of" to "I do not recall" does not constitute a material contradiction of the prior deposition testimony, which supports Edwards' assertion that Mr. Bash did not remember the details of whether PVL was an issue at the time the patent was drafted in 2012. (D.I. 275, Ex. 8 at 336:3-6) Specifically, Mr. Bash previously testified that he "remember[ed] talking about the issue of PVL," and while he did not "know how to link this topic for [his] historical memory at

the moment to this specific discussion or to the design [they] had at the time; but, yeah, it was an issue.” (*Id.* at 82:22-83:2) Mr. Bash stressed that, “with all due respect, we are talking about 14 years back to say exactly what happened then. I remember there was an issue I don’t know if it was enough to drive any conclusion on the design and how this impact, but definitely, there was an issue around PV leak came from the physician.” (*Id.* at 86:10-17) Given the consistency of this prior deposition testimony with the representations on page 336, the risk that Edwards “may attempt to manufacture sham factual disputes through . . . contradictory testimony to defeat otherwise proper summary judgment motions” is minimal at best, and any alleged contradiction may be explored at trial through examination of the deponent or reading the original deposition testimony into the record. *See Alcon Research*, 2011 WL 13135574, at *3.

38. Several of the remaining proposed modifications to the Bash deposition transcript involve the insertion of the word “explicit” or “explicitly” before the words “reference,” “discussed,” and “description.” (D.I. 275, Ex. 27 at 5; Ex. 8 at 336:4; 336:15; 365:4; 366:16) These additions do not materially contradict Mr. Bash’s prior deposition testimony and, although the changes are substantive in nature, they do not drastically alter the meaning of the cited testimony. The changes are unlikely to create a factual issue in circumstances in which a Rule 56 disposition would otherwise be appropriate. Consequently, BSC’s motion to strike the errata with respect to these portions of the Bash deposition transcript is denied, and the parties may address further concerns regarding discrepancies between the original testimony and the errata at trial through examination of the deponent or reading the original deposition testimony into the record.

39. The final proposed modification is the deletion of the word “clean” from page 352, line 24 of the Bash deposition transcript, which Edwards characterized as a typographical

correction. (D.I. 275, Ex. 27 at 5) For context, the original sentence in the transcript reads as follows: “As we said in our discussion before, the attempts we did were always the issue of clean profile and delivery system that couldn’t hold it, the diameter that we wanted.” (D.I. 275, Ex. 8 at 352:22-25) Nothing on the present record suggests that this is anything other than a typographical error. BSC has offered no insight into how this presents a substantive change which could alter the landscape of a ruling on the prior use defense at summary judgment. Therefore, BSC’s motion to strike the errata with respect to this change is also denied.

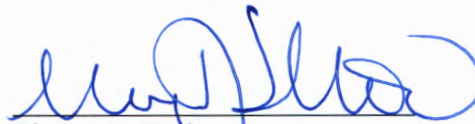
40. Conclusion. For the foregoing reasons, (1) BSC’s motion to strike Edwards’ invalidity contentions is denied, and BSC is permitted to take additional limited discovery regarding the PVT prototypes; (2) BSC’s motion to strike Edwards’ expert opinions regarding the S3U is denied, and BSC is permitted to take additional discovery regarding the S3U in the form of document discovery, deposition discovery from a fact witness regarding the regulatory process, and deposition testimony from expert regulatory witnesses; and (3) BSC’s motion to strike the errata from the Bash deposition is denied.

41. Given that the court has relied upon material that technically remains under seal, the court is releasing this Memorandum Order under seal, pending review by the parties. In the unlikely event that the parties believe that certain material in this Memorandum Order should be redacted, the parties should jointly submit a proposed redacted version by no later than **January 24, 2018**. The court will subsequently issue a publicly available version of its Memorandum Order.

42. This Memorandum Order is filed pursuant to 28 U.S.C. § 636(b)(1)(A), Fed. R. Civ. P. 72(a), and D. Del. LR 72.1(a)(2). The parties may serve and file specific written objections

within fourteen (14) days after being served with a copy of this Memorandum Order. Fed. R. Civ. P. 72(a). The objections and responses to the objections are limited to ten (10) pages each.

43. 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, www.ded.uscourts.gov.



Sherry R. Fallon
United States Magistrate Judge