IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

SOFREGEN MEDICAL INC., a Delaware Corporation; and SOFREGEN MEDICAL IRELAND LIMITED, an Irish Private Limited Company, Plaintiffs/Counterclaim-Defendants, v. ALLERGAN SALES, LLC, a Delaware Limited Liability Company; and ALLERGAN PHARMACEUTICALS HOLDINGS (IRELAND), an Irish Incorporated Private Unlimited Liability Company, Defendants/Counterclaim-Plaintiffs.	)	C.A. No.: N20C-03-319 EMD CCLD

DECISION AFTER TRIAL

Brian M. Rostocki, Esquire, Benjamin P. Chapple, Esquire, Anne M. Steadman, Esquire, Reed Smith LLP, Wilmington, Delaware. *Attorneys for Defendants/Counterclaim-Plaintiffs Allergan Sales, LLC and Allergan Pharmaceuticals Holdings (Ireland).*

Thomas A. Uebler, Esquire, Kathleen A. Murphy, Esquire, Adam J. Waskie, McCollom D'Emilio Smith Uebler LLC, Wilmington, Delaware. *Attorneys for Plaintiffs/Counterclaim-Defendants Sofregen Medical Inc. and Sofregen Medical Ireland Limited*.

DAVIS, J.

I. INTRODUCTION

This is a breach of contract and fraudulent inducement action assigned to the Complex Commercial Litigation Division of this Court. In November 2016, Plaintiffs Sofregen Medical Inc. and Sofregen Medical Ireland Limited (collectively, "Sofregen") purchased from Allergan Sales, LLC and Allergan Pharmaceuticals Holdings (Ireland) (collectively, "Allergan") certain "silk biomaterial surgical mesh" ("SERI") products for use in reconstructive surgeries.[1] The purchase occurred via an asset purchase agreement (the "APA") between Sofregen and Allergan.[2] Sofregen conducted due diligence prior to the execution of the APA.[3] However, after the APA was executed, Sofregen allegedly discovered for the first time that Allergan omitted troubling, material clinical studies from the documents it shared with Sofregen.[4] Further, Sofregen discovered that some of the inventory allegedly covered by the APA was missing.[5] As a result, Sofregen filed this action on March 31, 2020.[6]

II. PROCEDURAL BACKGROUND

Sofregen filed a Second Amended Complaint on July 23, 2020, against Allergan for (1) breach of representations and warranties, (2) breach of contract, and (3) fraudulent inducement.[7] Allergan asserted counterclaims on May 3, 2021, for a declaratory judgment and two breaches of contract.[8] One counterclaim relates to Sofregen's alleged failure to consult with Allergan in related litigation, which was required by the APA.[9] Another relates to Sofregen's failure to pay

[1] Second Amended Complaint ("Second Am. Compl.") ¶ 1. D.I. No. 20.
[2] *Id.*
[3] *See id.* ¶¶ 32-33.
[4] *Id.* ¶ 34.
[5] *Id.* ¶ 50.
[6] Original Complaint ("Compl."). D.I. No. 1.
[7] *See* Second Am. Compl.
[8] Defendants' Counterclaims ("Defs.' Countercls."). D.I. No. 46.
[9] *Id.* ¶¶ 109-15.

Allergan its share of sale proceeds as required by the APA.[10] The final counterclaim is for a declaratory judgment.[11]

Allergan filed a motion to dismiss all three counts in the Second Amended Complaint.[12] The Court denied the motion.[13] Later, the parties stipulated to a dismissal of Count I (breach of representations and warranties).[14] Allergan moved for summary judgment on Sofregen's remaining claims and Allergan's counterclaims (the "Motion").[15] The Court heard argument on the Motion on December 6, 2022. The Court denied the Motion on February 3, 2023.[16]

III. THE TRIAL

The Court held a bench trial from June 5, 2023, through June 8, 2023 (collectively, the "Trial"). After Trial, the parties engaged in post-trial briefing.

A. THE WITNESSES

During the Trial, the Court heard from and considered testimony from the following witnesses:

Dr. Anh Hoang Lindsay
Philippe Schaison
Christopher White
Howard Weisman
Daniel Huff
Dr. Jedediah Kaufman
Peter D. Wrobel
Kevin Green
Dr. Karen M. Decker
Carrie Strom
William G. Krieger

[10] *Id.* ¶¶ 116-22.
[11] *Id.* ¶¶ 98-108.
[12] Defendants' Second Motion to Dismiss ("Defs.' Second Mot. to Dismiss"). D.I. No. 23.
[13] *Sofregen Medical Inc. v. Allergan Sales, LLC*, 2021 WL 1400071 (Del Super. Apr. 1, 2021). D.I. No. 38.
[14] Order entered on Sept. 6, 2022. D.I. No. 145.
[15] Defendants' Motion for Summary Judgment ("Defs.' Mot. for Summ. J."). D.I. No. 146.
[16] Sofregen Medical Inc. v. Allergan Sales, LLC, 2023 WL 2034584 (Del. Super. Feb. 3, 2023).

The expert witnesses for Sofregen were Peter D. Wrobel and Dr. Jedediah Kaufman. Allergan's expert witnesses were Dr. Karen M. Decker and William G. Krieger.

All the witnesses testified on direct and were available for cross-examination. Normally, the Court would list the witnesses in the order they testified, and which party called the witness; however, because the Trial was a bench trial, the Court took witnesses out of order and used Rule 611 of the Delaware Rules of Evidence to allow for examination of the witness for both parties cases-in-chief.

B. CREDIBILITY OF WITNESSES

Here, the Court is the sole judge of each witness's credibility, including the parties.[17] The Court considers each witness's means of knowledge; strength of memory; opportunity to observe; how reasonable or unreasonable the testimony is; whether it is consistent or inconsistent; whether it has been contradicted; the witnesses' biases, prejudices, or interests; the witnesses' manner or demeanor on the witness stand; and all circumstances that, according to the evidence, could affect the credibility of the testimony.[18]

The Court finds that—based on their testimony at the Trial and the factors listed above—the witnesses that testified were generally credible. All witnesses had some form of relationship to the parties and the Court accounted for that bias. The Court, however, believes that the witnesses were not evasive, nor did they provide testimony that was not somehow supported by other evidence. While the Court finds that the witnesses were generally credible, the Court gave more weight to some testimony based on evidence supporting that testimony. As discussed below, some witnesses' testimony was less helpful based on lack of memory or alike—e.g.,

[17] *See* Superior Court Civil Pattern Jury Instruction 23.9.
[18] *Id.*

testimony regarding a July 8, 2016, due diligence meeting at Allergan. The Court cannot give as much credibility to such testimony.

C. Exhibits

The parties submitted an extensive number of exhibits on June 9, 2023. Most of these exhibits were admitted without objection. The parties provided the Court with the exhibits in the form of joint exhibits ("JX") and range from JX1 to JX507.[19]

IV. FACTUAL FINDINGS

A. THE PARTIES

Plaintiff Sofregen Medical Inc. is incorporated in Delaware and has its principal place of business in Medford, Massachusetts.[20] Sofregen Medical Inc. is "an early stage commercial biotechnology company focused on developing natural biomaterial medical products for medical aesthetics and reconstructive surgery."[21] At the time of filing this action, Sofregen Medical Inc. raised a total of around $22.3 million in funding.[22] Plaintiff Sofregen Medical Ireland Limited was "an Irish private limited company" when the APA closed in November 2016.[23]

Defendant Allergan Sales, LLC is a Delaware limited liability company with revenues exceeding $16 billion in 2019.[24] Defendant Allergan Pharmaceuticals Holdings (Ireland) is an "Irish incorporated private unlimited liability company."[25]

[19] One reason for the delay in issuing this decision related to the Court's difficulty in reconciling the Court's record of exhibits with those used by the parties in briefing.
[20] Second Am. Compl. ¶ 10.
[21] *Id.*
[22] *Id.*
[23] *Id.* ¶ 11.
[24] *Id.* ¶ 12.
[25] *Id.* ¶ 13.

B. SERI

SeriScaffold and SeriPliable (collectively, "SERI") are surgical meshes for soft-tissue support.[26] SERI is composed of purified silk that has been knit into a weave.[27] Allergan acquired SERI for $70 million in 2010.[28] The FDA approved SERI for use "as a transitory scaffold for soft-tissue support and repair to reinforce deficiencies where weakness or voids exist that require the addition of material to obtain the desired outcome."[29] Allergan interpreted the FDA's approval to include any type of soft-tissue support, such as in the abdomen for a tummy tuck or in the breast for reconstruction.[30]

Allergan employed approximately 100 salespeople to market and sell SERI to doctors, surgeons, and hospitals.[31] Allergan's salespeople brought samples of SERI while meeting with potential customers ("Trunk Stock").[32] The evidence at Trial demonstrated that Allergan did not carefully track the Trunk Stock carried by its salespeople.[33]

The FDA requires medical-device companies to track complaints about their devices.[34] Allergan tracked SERI-related complaints using software called TrackWise, which generates a computerized spreadsheet listing each complaint (the "SERI Complaint Report").[35] The SERI Complaint Report consists of data compiled into a list of every complaint relating to SERI on a worldwide basis.[36] Each SERI procedure is assigned a case number.[37] The SERI Complaint

[26] June 5, 2023 Tr. 12:14-13:1.
[27] June 5, 2023 Tr. 12:14-13:1.
[28] JX 4 at 4.
[29] JX 34 at 1; JX 4 at 4.
[30] JX 403 at 7 (24:17-21).
[31] June 8, 2023 PM-Tr. 10:4-7.
[32] June 8, 2023 PM-Tr. 19:19-3.
[33] *Id.* at 39:14-17; JX 403 at 19 (71:14-24) ("I think the reps had a lot of stock in their car trunk of Seri. We did not have a good system in place to know exactly how much was still with the reps because … we were not tracking everything at that time.")
[34] June 5, 2023 AM-Tr. 40:12-15.
[35] *Id.* 40:6-11.
[36] June 7, 2023 AM-Tr. 123:13-23, 124:9-13.
[37] June 5, 2023 AM-Tr. 40:16-41:6.

Report provides a separate entry for each complaint associated with that procedure.[38] There could be multiple entries for different complaints from a single procedure.[39] The SERI Complaint Report can reveal patterns of adverse events or safety signals but the information is insufficient to determine the cause of any specific adverse event.[40]

The FDA expects that certain adverse events be reported with the Manufacturer and User Facility Device Experience (MAUDE) database.[41] The MAUDE database homepage provides that "[c]onfirming whether a device actually caused a specific event can be difficult based solely on information provided in a given report" and that "[e]stablishing a cause-and-effect relationship is especially difficult if circumstances surrounding the event have not been verified or if the device in question has not been directly evaluated."[42]

C. SERI CLINICAL TRIALS AND USE

Allergan sponsored a number of Phase 4 clinical studies for SERI, including the SURE clinical studies after purchasing SERI.[43] Allergan had the first clinical trial started in the United States on October 22, 2010 (the "SURE-001 Study").[44] The SURE-001 Study explored the use of SERI for tissue support and repair in breast reconstruction.[45] According to Dr. Hoang-Lindsay, a study sponsor must obtain permission from the FDA, known as an investigational device exemption ("IDE") before an experimental device may be used with human subjects.[46]

---

[38] June 5, 2023 AM-Tr. 40:16-41:6.
[39] June 5, 2023 AM-Tr. 40:16-41:6.
[40] June 5, 2023 AM-Tr. 42:5-8; June 7, 2023 AM-Tr. 124:1-21.
[41] June 5, 2023 AM-Tr. 43:19-44:2; *see also* JX 495.
[42] JX 495 at 1.
[43] JX 452 at 5 (definition of "Study Phase"); Clinicaltrials.gov defines Phase 4 clinical trials as "[a] phase of research to describe clinical trials occurring after FDA has approved a drug [or device] for marketing …. These trials gather additional information about a drug's [or device's] safety, efficacy, or optimal use." https://clinicaltrials.gov/study-basics/glossary.
[44] JX 25 at 1.
[45] *Id.* at 1-2.
[46] June 5, 2023 AM-Tr. 35:15-22.

Allergan failed to obtain an IDE for the SURE-001 Study, so the FDA required Allergan to obtain the IDE retroactively in 2013.[47]

The SURE-001 Clinical Study Report (the "SURE-001 CSR") results were promising and indicated that SERI was safe and effective in breast reconstruction.[48] The SURE-001 CSR reflected an explant rate of less than 10% and the reasons for explantation were not attributed to SERI.[49] As explained at Trial, explant rate relates to the need to remove SERI from the body during a subsequent surgery. Only 5.3% of the adverse events were related to SERI and all were considered mild.[50] The investigators did not find any serious adverse events related to SERI.[51] All reported statistics were within an acceptable range for a surgical mesh.[52] The SURE-001 CSR reflected a high satisfactory rating for SERI with doctors and patients.[53]

The SURE-001 Study was completed on April 25, 2014.[54] Allergan finalized the SURE-001 CSR on December 24, 2014, seven months after the study was completed.[55] In February 2015, data for the SURE-001 Study was published in *Plastic and Reconstructive Surgery*, the journal of the American Society for Plastic Surgeons.[56]

During Allergan's ownership of SERI, reports of adverse events associated with SERI in breast reconstruction increased "drastically."[57] Philippe Schaison, the former head of U.S. Medical for Allergan, learned from physicians, key opinion leaders ("KOL"),[58] and Allergan

[47] JX 25 at 1; *see also* June 5, 2023 AM-Tr. 38:14-23.
[48] June 7, 2023 AM-Tr. 122:7-15.
[49] JX 25 at 5; JX 429 at 8.
[50] June 7, 2023 AM-Tr. 120:19-121:3.
[51] June 7, 2023 AM-Tr. 122:1-6.
[52] June 7, 2023 AM-Tr. 118:20-121:15.
[53] JX 25 at 4-5.
[54] *Id.* at 2, 71.
[55] *Id.* at 2, 71.
[56] JX 429 at 6.
[57] June 5, 2023 Tr. 268:23-269:15.
[58] Key Opinion Leaders are clinicians that are early adopters and users of SERI that share their experience with their colleagues. *See* June 5, 2023 Tr. 270:5-7.

salespeople of increasing rates of adverse events and side effects, including seroma and removal of SERI.[59]

Allergan commenced a second study of SERI—the "SURE-002 Study"—in Europe on June 21, 2011, to examine the use of SERI for tissue support and repair in direct-to-implant breast reconstruction.[60] Dr. Carolin Nestle-Kräming and Dr. R. Douglas MacMillan were the principal investigators for the SURE-002 Study. The results reflected in drafts of the SURE-002 Clinical Study Report ("SURE-002 CSR") differed from the SURE-001 Study.[61] Allergan's then-Vice President of Regulatory Affairs, Constance Garrison, noted that "it was determined that a deep dive was required into the data to understand why the results from SURE-002 are so different from SURE-001 …."[62]

Addressing the differences in results, Allergan proposed drafting a white paper (the "White Paper") that would accompany the final SURE-002 CSR.[63] In 2014, Allergan's Vice President of Global Regulatory Affairs, Bruce Krattenmaker, commissioned an assessment of the SURE-002 Study to be completed by October 2014.[64] During the drafting process, Allergan addressed ways to explain the rates of adverse events reflected in the SURE-002 Study data.[65] Mr. Krattenmaker commented on a later draft of the White Paper that "[i]t reads very poorly to me and I think their rationale for justifying [adverse event] rates wouldn't hold much support externally or by a regulatory agency …."[66]

[59] *Id.* 268:22-269:8.
[60] JX 469 at 2.
[61] JX 37.
[62] *Id.* at 37.
[63] JX 45 at 1; JX 46 at 1.
[64] JX 471.
[65] JX 46 at 1.
[66] JX 55 at 1.

On May 27, 2015, an email circulated within Allergan with the subject line "Douglas Macmillan – URGENT."[67] Dr. MacMillan (one of the SURE-002 Study investigators) advised Allergan that "he and some colleagues will shortly be publishing some data [sic] on SERI which he said is not favorable."[68] Dr. MacMillan explained that a manuscript about to published identified that 18% of patients "developed a significant 'inflammatory reaction' to Seri" that appears approximately six weeks post-surgery.[69] At Trial, this inflammatory reaction was defined as Red Breast Syndrome. Dr. MacMillan promised to share a copy of the final manuscript with Allergan.[70] This email chain was eventually forwarded to Dr. William Daunch, Ph.D., an Allergan consultant, and Dr. Joseph Purpura, Allergan's Senior Medical Director, Head of Device Safety.[71]

In September 2015, Dr. Mark Jewell advised Allergan of a link between SERI and Red Breast Syndrome.[72] Dr. Jewell, a paid Allergan consultant, contacted Allergan's then-Vice President of Sales and Marketing, Carrie Strom, to a presentation given by Dr. MacMillan regarding the SURE-002 Study and post-operative Red Breast Syndrome.[73] Dr. Jewell informed Ms. Strom that "[w]e will need to be vigilant about this, as I think that [Dr.] MacMillan and the Sure-002 group may try to publish something on their own about this issue."[74]

As such, Allergan was on notice of the data collected in drafts of the SURE-002 CSR drafts. Allergan had a "final" SURE-002 CSR by June 2015 (a year and a half before the APA).[75] In December 2015 (a year before the APA), Mr. Smith, Allergan's director of regulatory affairs,

[67] JX 35.
[68] *Id.* at 4.
[69] *Id.* at 1.
[70] *Id.*
[71] *Id.* Dr. Daunch and Dr. Purpura were identified by Allergan as individuals with knowledge in the APA. JX 147 at 1.
[72] JX 40 at 1.
[73] *Id.*
[74] *Id.*
[75] JX 36.

represented that the SURE-002 CSR "is being completed now and will probably be final in January '16."[76] Results from the SURE-002 Study were due to the FDA by December 2015 but Allergan requested an extension until August 2016.[77]

Mr. Smith and Mr. Krattenmaker paused work on both the SURE-002 CSR and White Paper so Allergan could "wait and see the results of business development," *i.e.*, the sale of SERI to Sofregen.[78] In March 2016, Mr. Smith instructed Allergan employees to continue to "hold for a little while more …" on completion of the SURE-002 CSR.[79]

The SURE-002 Study concluded on February 5, 2015. Allergan did not sign SURE-002 CSR until December 7, 2016—a time just after the sale of SERI to Sofregen.[80] On August 10, 2016, an Allergan employee sent an internal email indicating that the SURE-002 CSR was "e-signed and ready for publishing."[81] The SURE-002 CSR subsequently was revised and the SURE-002 CSR "version 2.0" was finally signed by Allergan on December 7, 2016[82] The signed SURE-002 CSR concluded that "[t]he use of SERI in this study provided an adequate and acceptable safety profile, a favorable risk-benefit ratio ... and high levels of breast satisfaction by surgeons and subjects."[83]

Ms. Garrison inquired why the draft SURE-002 CSR "has a seroma rate of 30%, tissue necrosis of 21%, and explant rate of 25% with a conclusion that the device is safe and effective. (!)."[84] Mr. Krattenmaker did not think that "the results in SURE 002 should be viewed positively and that they support safe and effective use in the patient population enrolled (and procedures

[76] JX 135 at 2.
[77] JX 474 ("results were due Dec 2015 and we are requesting a new due date of August 2016").
[78] JX 472 at 2; June 7, 2023 AM-Tr. (Green) 79:2-9.
[79] JX 473 at 1.
[80] JX 157 at 1, 69.
[81] JX 124.
[82] JX 156.
[83] JX 157 at 68.
[84] JX 36.

used) in SURE 002."[85] Mr. Krattenmaker believed that the "FDA isn't going to buy any of it."[86] Mr. Krattenmaker acknowledged:

> We have been concerned about regulatory implications, but in the end, this isn't Regulatory Affairs responsibility to release a CSR or assure that it is defendable. If it comes back to haunt whoever owns Seri going forward, then they can seek out our CMO or Safety people to defend it.[87]

The SURE-002 CSR signed by Allergan reported surgeon satisfaction as an 8 of 10 and subject satisfaction as a 4.4 of 5.[88]

The SURE-006 clinical study began on July 1, 2013, exploring the use of SERI for soft-tissue support and repair in breast reconstruction with and without radiation (the "SURE-006 Study" and together with the SURE-002 Study, the "SURE Studies").[89] Dr. Scheflan was the principal investigator on the SURE-006 Study.[90] The SURE-006 Study was designed to analyze eighty patients but only fifteen patients were enrolled.[91] Allergan halted the SURE-006 Study early.[92] Five of the fifteen of them had SERI explanted.[93]

As with the SURE-002 CSR, the final SURE-006 clinical study report (the "SURE-006 CSR" and together with the SURE-002 CSR, the "SURE CSRs") provided that the investigator satisfaction with SERI was "a mean of 9.2 out of 10."[94] The SURE-006 CSR further provided that "Allergan halted enrollment in this study because it was determined that the enrollment criteria needed to be more restrictive."[95] An internal Allergan email provided that the SURE-006

[85] JX 45.
[86] *Id.*
[87] JX 475 at 1 (emphasis added).
[88] JX 469 at 4, 61.
[89] JX 128 at 1-2.
[90] *Id.* at 2.
[91] *Id.*
[92] JX 370 at 1-2.
[93] *Id.* at 5.
[94] JX 128 at 5.
[95] *Id.* at 2.

Study was "stopped due to high SAE rates."[96] Testimony at Trial demonstrated that the inclusion and exclusion criteria for the SURE-006 Study were consistent with the SURE-001 Study and SURE-002 Study.[97] The testimony also indicated that the SURE-006 Study likely was stopped because of high rates of adverse events and not because of the patient enrollment criteria.[98]

The SURE-006 CSR was signed on September 19, 2016, approximately six months after the study ended and two months before the APA was signed.[99]

On June 5, 2016, Drs. MacMillan, Nestle-Krämling, Scheflan, and two other physicians, submitted a manuscript for publication to the *Journal of Plastic, Reconstructive & Aesthetic Surgery* (the "Rolph Paper").[100] The Rolph Paper is a study that summarizes the authors' clinical experience with SERI.[101] The Rolph Paper addressed a complication with SERI described as "a delayed hypersensitivity reactions," or "Red Breast Syndrome."[102] Red Breast Syndrome apparently causes the patient to have an immune response that attacks the mesh.[103]

The authors of the Rolph Paper submitted the paper publication while Allergan still owned SERI and approximately five months before the APA was signed.[104] The authors disclosed the consultancy fees and payment received from Allergan for conducting clinical trials.[105]

[96] JX 370 at 1-2.
[97] June 7, 2023 AM-Tr. 134:10-135:10.
[98] *Id*.
[99] JX 128 at 47.
[100] JX 299 at 6.
[101] June 7, 2023 AM-Tr. 139:1-22, 140:4-11.
[102] *Id.* 140:22-141:3, 143:5-147:20.
[103] *Id*.
[104] JX 299 at 6.
[105] JX 299 at 12.

D. ALLERGAN DECIDES TO DIVEST SERI

SERI does not appear to be a commercial success for Allergan.[106] The record indicates a number of reasons for this. On May 29, 2015, the FDA issued a warning letter (the "Warning Letter") to Allergan addressing Allergan's untested use of SERI in breast-surgery applications in combination with a secondary device, like an implant or expander.[107] Although contested at Trial, surgeons also began having problems with SERI similar to those reflected in the SURE-002 CSR and the Rolph Paper, including seroma and poor tissue integration, requiring explantation of SERI.[108] Surgeons became reluctant to use SERI and Allergan salespeople stopped promoting SERI as the rates of adverse events increased.[109] Mr. Schaison testified that Allergan noticed a correlation between the decline of SERI's reputation among surgeons and lower sales of SERI.[110]

Allergan decided in mid-2015 to stop promoting SERI.[111] Allergan did this for a number of reasons. The Warning Letter instructed Allergan that using SERI in "breast reduction applications" would require additional FDA clearance.[112] Substantially all of Allergan's sales of SERI stemmed from breast surgery applications.[113] Moreover, as already discussed, there were increasing incidents of adverse events. These combined reasons led Allergan to divest SERI.[114]

In November 2015, Sofregen, through its CEO Howard Weisman, expressed interest in acquiring SERI to Mr. Schaison.[115] Sofregen was developing its own silk-derived material that

[106] June 5, 2023 Tr. 264:5-7.
[107] JX 34; June 5, 2023 AM-Tr. 57:4-12.
[108] June 5, 2023 Tr. 268:16-269:13.
[109] *Id.* 264:8-265:12.
[110] *Id.* 271:12-272:4.
[111] JX444.
[112] JX34.
[113] June 8, 2023 PM-Tr. 10:22-11:14.
[114] *Id.* 272:5-15.
[115] PTO ¶ 29.

originated from the same lab and shared similar technology as SERI.[116] When Sofregen contacted Allergan about acquiring SERI, Sofregen knew that Allergan had been promoting SERI with its breast implant and tissue expander business.[117] Sofregen also knew about the Warning Letter.[118] Because SERI was otherwise performing well in the market, Sofregen saw the Warning Letter as an opportunity.[119] Sofregen would use SERI as its only commercial product and leverage its understanding of silk technology to show surgeons the value of SERI.[120] Moreover, Sofregen believed it would have an easier time navigating promotional issues with the FDA because it was a smaller company.[121] Allergan had apparently had confidence in Sofregen's ability to manage SERI despite Sofregen's smaller size and sales force.[122]

Allergan's Executive Director of Development, Kevin Green, oversaw due diligence for Allergan.[123] On December 18, 2015, Mr. Green emailed individuals with the most knowledge of SERI, including Dr. Daunch, Mr. Krattenmaker, Ms. Strom, Mr. Smith, and Dr. Purpura, to gather diligence materials to share in a data room on Box.com.[124] Mr. Green instructed them to "[t]hink about the types of things you would want to see if you were conducting diligence on this asset."[125] Allergan entitled the shared folder in Box.com as "Sofregen—Project Silver Oak—Allergan R&D."[126]

[116] June 6, 2023 AM-Tr. 83:11-19.
[117] *Id.* 84:10-23.
[118] *Id.*
[119] *Id.* 86:13-87:1-10.
[120] *Id.* 87:16-88:1-2.
[121] *Id.* 87:11-15; June 8, 2023 PM-Tr. 58:17-59:1-9.
[122] JX 140; June 8, 2023 PM-Tr. 58:9-16.
[123] JX 52 at 1; June 5, 2023 Tr. 22:12-16.
[124] JX 52 at 1.
[125] *Id.*
[126] JX64.

Dr. Hoang-Lindsay,[127] Sofregen's then-Chief Science Officer, coordinated due diligence with a team of five or six Sofregen employees and consultants.[128]

In February 2016, Dr. Hoang-Lindsay, Sofregen's co-founder and chairman, Howard Weisman, and Sofregen's then-Chief Financial Officer, Milan Kofol, attended an in-person diligence meeting at Allergan's offices in Irvine, California.[129] Allergan's attendees included Ms. Strom, Mr. Smith, and Dr. Daunch.[130]

At that meeting, Allergan gave a PowerPoint presentation that purported to represent SERI's clinical performance and reputation among surgeons.[131] One slide, titled "Perceptions of SERI have significantly improved on several attributes compared to 2014," provided that surgeons perceived that there was rapid tissue integration, well-vascularized tissue, and minimal seroma after SERI was implanted.[132] Allergan represented to Sofregen that the perception of SERI among surgeons had only grown more positive from 2014 to 2015.[133] Another slide, titled "SERI Continues to Make Strides with Plastic Surgeons," claimed that surgeons perceived SERI as performing as well as, or better than, biologically sourced surgical meshes.[134] Allergan explained SERI's "regulatory position" after receiving the Warning Letter.[135] The presentation contained unit forecasts for SERI for periods before and after receipt of the Warning Letter.[136] Allergan projected lower financial projections for SERI after the Warning Letter.[137]

---

[127] Dr. Hoang-Lindsay earned her Ph.D. in interdisciplinary material science from Vanderbilt University and completed a fellowship at Harvard University Medical School in biomedical engineering within the Center of Engineering for Medicine. June 5, 2023 Tr. 9:19-10:1-16. The Court did not understand that Dr. Hoang-Lindsay to be experienced with respect to due diligence in asset acquisition.
[128] PTO ¶ 33.
[129] JX444.
[130] June 5, 2023 Tr. 15:16-21; JX 79 at 1.
[131] June 5, 2023 Tr. 15:7-13.
[132] JX 79 at 22; June 5, 2023 Tr. 18:4-13.
[133] June 5, 2023 Tr. 18:16-19:1.
[134] JX 79 at 24; June 5, 2023 Tr. 19:9-20:1-4; June 5, 2023 Tr. 268:22-269:8.
[135] JX65
[136] JX79.
[137] Id.

Due diligence began in early 2016 and consisted of regular conference calls, requests for information, and follow-up questions that continued until shortly before closing.[138] Dr. Hoang-Lindsay took notes during the conference calls summarizing key takeaways and shared her notes with Sofregen's management team.[139]

Shortly after due diligence started, Allergan added a folder to the data room titled "SERI Phase IV," devoted to the SERI-related Phase 4 clinical trial data (*i.e.* the SURE studies).[140] Allergan provided the SURE-001 Study data in the "SERI Phase IV" folder, and that data had also been published and was available on ClinicalTrials.gov.[141] Allergan and Sofregen conferred regarding the SURE-001 Study data extensively during due diligence and Sofregen was impressed with the results.[142] The low rates of seroma, skin necrosis, and explant were consistent with other FDA-approved surgical meshes and indicative that SERI carried a low liability risk.[143] Mr. Smith and Dr. Hoang-Lindsay discussed using the SURE-001 Study clinical data to support Sofregen's future application to the FDA to obtain clearance for the use of SERI in breast reconstruction.[144]

Afterwards, Dr. Hoang-Lindsay and Mr. Smith talked regarding the retroactive IDE that Allergan obtained for the SURE-001 Study.[145] Mr. Smith, followed up with Dr. Hoang-Lindsay to further clarify SERI's "complex [regulatory] situation."[146] Mr. Smith explained that the "FDA continues to be concerned over [SERI's use] in conjunction with a breast implant or tissue expander" based on the "new questions of safety and effectiveness" associated with SERI's use

[138] PTO ¶ 31; June 5, 2023 AM-Tr. 20:16-21:11.
[139] June 5, 2023 AM-Tr. 21:6-11.
[140] JX 64; June 5, 2023 Tr. 245:17-246:1-2.
[141] June 5, 2023 Tr. (Hoang-Lindsay) 245:13-246:22; JX 401 at 3.
[142] June 5, 2023 Tr. (Hoang-Lindsay) 32:12-19 and 245:14-246:22.
[143] *Id.* 33:20-34:19.
[144] JX 118; June 5, 2023 Tr. 60:2-6.
[145] JX 25 at 1; June 5, 2023 Tr. 38:14-17.
[146] JX65.

"in proximity to expanding tissue."[147] Mr. Smith also noted that "any procedure involving a breast implant" was "definitely not within [SERI's] cleared intended use."[148] Mr. Smith opined that, if Sofregen wanted to market SERI for any non-implant-based breast applications, Sofregen would need to provide a pre-market "submission for those applications."[149] A consultant apparently also advised Sofregen that SURE-001 could not be used to "support a future marketing application for any use of SERI in the breast … [because] it lacked a control group and effectiveness endpoint."[150]

As part of the application process, Dr. Hoang-Lindsay understood that Allergan would have provided all relevant SERI clinical data to the FDA so the FDA could evaluate the benefits and risks of SERI.[151] Dr. Hoang-Lindsay believed that would have included any clinical SURE Studies data for the use of SERI in the breast or with an implant.[152] Dr. Hoang-Lindsay thought that any other SERI related clinical data was either consistent with the SURE-001 Study data or was not otherwise concerning because the FDA approved Allergan's retroactive IDE application.[153]

On July 8, 2016, Dr. Hoang-Lindsay emailed an updated due-diligence list to Mr. Green titled "AGN-Sofregen Pre-Closing Activity" (the "July 2016 Due Diligence Request").[154] The July 2016 Due Diligence Request asked for: (i) Allergan's FDA regulatory files regarding SERI, (ii) the SERI Complaint Report and medical-device report, and (iii) contact information for SERI KOLs.[155] The July 2016 Due Diligence Request also included a request for "Allergan to provide

[147] *Id*.
[148] *Id*.
[149] *Id*.
[150] JX63.
[151] June 5, 2023 Tr. 38:1-13.
[152] *Id.*
[153] June 5, 2023 Tr. 39:4-17.
[154] JX 95; June 5, 2023 Tr. 23:3-8.
[155] JX 95 at 2, 4; June 5, 2023 Tr. 23:12-26:1-7.

information of any on-going sponsored clinical studies ….”[156] Mr. Green testified that the July 2016 Due Diligence Request sought copies of the SURE Studies.[157]

Allergan provided the FDA communications, the SERI Complaint Report, medical-device report, and KOL list prior to closing on the APA.[158] Allergan does not appear to have provided the data from the SURE Studies until after the APA.[159]

On July 27, 2016, Dr. Hoang-Lindsay, Mr. Weisman, and Christopher White (Sofregen's future president), traveled to Allergan's offices for a second in-person due diligence meeting (the "Second Due Diligence Meeting").[160] Dr. Hoang-Lindsay requested to "review any clinical data" regarding SERI prior to the Second Due Diligence Meeting.[161]

The Sofregen team was scheduled to meet with different Allergan representatives throughout the day; however, testimony regarding the Second Due Diligence Meeting was not overly helpful as Dr. Hoang-Lindsay, Mr. Smith, and Mr. Weisman do not recall who exactly attended what meeting.[162] For example, Mr. White took notes ("White's Notes") but Mr. White cannot recall any details other than those in his notes.[163] White's Notes indicate that the Sofregen representatives met with Ms. Strom, Mr. Smith, and Dr. Purpura.[164]

Apparently, Allergan made a presentation on the SURE-001 Study, SURE-002 Study, and SURE-006 Study.[165] Mr. Smith reviewed three "Seri+ secondary device clinical trials."[166] The White Notes indicate that Mr. Smith also discussed the status of their accompanying "clinical

[156] JX 95 at 4.
[157] *Id.*; June 7, 2023 AM 89:3-17.
[158] June 5, 2023 Tr. 24:4-26:7.
[159] *Id*.
[160] *Id.* 27:14-28.
[161] JX 96.
[162] June 5, 2023 Tr. 28:1-7; June 6, 2023 AM-Tr. 91:14-92:4; June 6, 2023 AM-Tr. 10:17-11:10.
[163] JX 109; June 6, 2023 AM-Tr. 11:23-24:4.
[164] JX 109 at 1, 4, 6.
[165] *Id.* at 4-5.
[166] JX100.

study reports [CSRs],"[167] Mr. Smith first addressed SURE-001, disclosing: (i) this study involved "2 stage breast" reconstruction using a "[t]issue expander followed by [an] implant"; and (ii) the SURE-001 CSR was "available."[168] Mr. Smith also discussed SURE-002 and SURE-006, two studies which (unlike SURE-001) involved "direct to implant" breast reconstruction.[169] Mr. Smith made disclosures about SURE-002 and SURE-006: (i) SURE-002 involved "direct to implant surgery" in "breast cancer patients" and "[n]o tissue expander was used"; (ii) the SURE-002 CSR was "not done but really close" and "should be finished in 1 or 2 months"; (iii) SURE-006 involved "direct to implant" surgery in "[p]atients who had received radiation"; (iv) SURE-006 was "[h]alted … because enrollment [was] not strict enough"; and (v) the SURE-006 CSR was not yet finished.[170]

White's Notes reflect, and Dr. Hoang-Lindsay recalled attending, a meeting with Dr. Purpura regarding SERI's safety profile where Dr. Purpura represented that there had not been "any events for failures that were unusual or causes of concern" and that "[o]therwise, what was found is what you'd expect."[171]

The Sofregen representatives did not recall learning anything during the Second Due Diligence Meeting that gave them cause for concern regarding SERI.[172]

Around the time of the Second Due Diligence Meeting, Mr. Smith provided Dr. Hoang-Lindsay with the SERI Complaint Report.[173] After comparing the number of complaints listed with the approximate number of SERI units that Allergan had sold, Sofregen concluded that the

[167] JX109.
[168] *Id*.
[169] *Id*.
[170] *Id*.
[171] *Id.* at 6; June 5, 2023 Tr. 30:6-16.
[172] June 5, 2023 Tr. 30:17-31:1-5; June 6, 2023 AM-Tr. 92:23-93:1-11.
[173] JX 107.

percentage of SERI-related complaints was in the low single digits.[174] During a follow-up call between Dr. Hoang-Lindsay and Allergan's Brian Dunstan,[175] Allergan represented that its analysis of this data did not reveal any safety signals or patterns of adverse events related to SERI.[176]

On July 31, 2016—just days after the July Meeting—Dr. Hoang-Lindsay prepared and circulated (internally) a list of transitional services that contemplated obtaining a "complete report" from Mr. Smith about SURE-001, SURE-002, and SURE-006 post-Closing.[177] At Trial, Dr. Hoang-Lindsay admitted that she was aware of both SURE-002 and SURE-006 months pre-Closing.[178]

Dr. Hoang-Lindsay noted that the SERI Complaint Report recorded adverse events in foreign territories and inquired further.[179] Allergan informed Dr. Hoang-Lindsay that Allergan ran the SURE-006 Study in Israel with Dr. Scheflan and that the study was terminated because "AEs were unacceptable."[180] Dr. Hoang-Lindsay then followed up with Allergan's Medical Affairs Director, Dr. Jason Hammer.[181] On August 9, 2016, Dr. Hoang-Lindsay called with Dr. Hammer to discuss the SURE-006 Study and SERI generally.[182] Dr. Hammer explained that the high rates of adverse events reflected in the SURE-006 Study were the result of Dr. Scheflan refusing to follow the patient-enrollment criteria and called Dr. Scheflan a "cowboy."[183]

[174] June 5, 2023 AM-Tr. 41:11-22.
[175] JX 147 at 1.
[176] June 5, 2023 AM-Tr. 42:5-43:1-5.
[177] JX505.1; June 5, 2023 Tr. 171:5-11; June 5, 2023 Tr. 172:9-15.
[178] June 5, 2023 Tr. 157:5-16.
[179] *Id.* 44:3-6; JX 477 at 2.
[180] JX 477 at 1.
[181] *Id.* at 1; June 5, 2023 Tr. (Hoang-Lindsay) 46:3-22.
[182] JX 123.
[183] June 5, 2023 Tr. 47:14-48:22.

Dr. Hammer stated that SERI was well received by plastic surgeons and that, while Allergan had envisioned that SERI would be used in two-stage breast reconstruction, surgeons were finding success in direct-to-implant procedures.[184] Dr. Hammer also discussed a study conducted by Dr. Dan Mills, the president of the American Society of Plastic Surgery, examining the effect of radiation on SERI that showed positive results.[185] This was consistent with what Dr. Hoang-Lindsay had learned during an earlier due-diligence call that exposure to radiation did not alter the performance of SERI.[186] On August 5, 2016, Dr. Hoang-Lindsay sent a follow-up email to Dr. Hammer asking, "[i]s there any other study that is outstanding (results not published, approved by Allergan but not initiated, or in the midst of study)?"[187] Dr. Hammer never responded.[188]

The record indicates that Sofregen made three requests for all SURE clinical data.[189] However, the record also indicates that Allergan never made a representation that additional studies did not exist or that Allergan had produced all studies in due diligence.

E. SOFREGEN ACQUIRES SERI

On November 10, 2016 ("Closing"), Sofregen and Allergan executed the APA.[190] Sofregen acquired all the existing SERI inventory, including the Trunk Stock for an initial payment of $3 million.[191] The parties also executed a "Transition Services Agreement" under which Allergan would render services to Sofregen post-Closing.[192]

[184] JX 123 at 1; June 5, 2023 Tr. 49:6-19.
[185] June 5, 2023 Tr. 48:7-13.
[186] JX 94; June 5, 2023 Tr. 21:12-22:11.
[187] JX 481.
[188] June 5, 2023 Tr. 53:13-16.
[189] June 5, 2023 Tr. 53:21-54:1-3.
[190] JX 146 ("APA").
[191] *Id.*, §2.2(a)(iv)); JX 147 at 31; June 6, 2023 PM-Tr. (Huff) 97:19-98:8.
[192] *Id.*, §1.1; June 5, 2023 Tr. 170:5-9.

The APA included assumption of liabilities provisions.[193] Under the APA, Sofregen assumed liabilities for SERI sold by Allergan.[194] Sofregen agreed to assume liabilities for SERI implanted after the execution of the APA even if sold prior to the signing of the APA.[195]

In the APA, the parties agreed Allergan would provide the "Transferred Ancillary Documents" to Sofregen post-Closing.[196] The APA defines Transferred Ancillary Document to include "all of [Allergan's SERI-related] … clinical study reports, product complaints and adverse events records, … [and] research and development data and records,"[197] Sofregen understood "that there was outstanding data … from the studies that [Sofregen] was aware of [*e.g.*, SURE-002, SURE-006]."[198] Sofregen expected to receive this outstanding data (including CSRs and clinical trial data) post-Closing.[199]

The APA sections relevant to the remaining claims in this civil action are set out here.

Section 2.2(a)(iv) of the APA governs the transfer of SERI units. It is titled "Transfer of Assets" and states:

> (a) "Acquired Assets" means all of [Allergan's] right, title and interest, as of the Effective Date, in and to [its] respective assets exclusively related to the Business and/or [SERI] Product, wherever located, including without limitation the following: . . . (iv) (A) all finished product inventory of [SERI], including the finished product inventory set forth on Schedule 2.2(a)(iv)(A) (such finished product inventory, the "Finished Product Inventory"), (B) all silk spools held for use solely to manufacture [SERI] set forth on Schedule 2.2(a)(iv)(B) (the "Spools"), and (C) the packaging materials used or held for use exclusively with respect to [SERI] set forth on Schedule 2.2(a)(iv)(C) (such packaging materials, together with the Finished Product Inventory and Spools, the "Product Inventory").[200]

[193] JX146, §2.3(a)(iii), §5.7.
[194] JX 126.
[195] JX146, at 17.
[196] *Id*., §2.5(b).
[197] *Id*., §1.1.
[198] June 5, 2023 Tr. 197:7–15.
[199] June 5, 2023 Tr. 198:13–18.
[200] JX146, § 2.2(a)(iv).

Schedule 2.2(a)(iv)(A) lists 15,767 units of Finished Product Inventory in total.[201] Both parties agree this was the total Finished Product Inventory under the Schedule,[202] but they disagree over the number of unaccounted for units and the price of those missing units.[203]

Section 2.3(a)(iii) of the APA is titled "Assumption of Liabilities," and it states:

> (a) As of the Effective Date, [Sofregen] shall assume and pay, discharge, perform or otherwise satisfy the following liabilities and obligations of every kind and nature, whether known or unknown, express or implied, primary or secondary, direct or indirect, absolute, accrued, contingent or otherwise and whether due or to become due, of [Allergan's] arising out of, relating to or otherwise in respect of the Acquired Assets and/or Business (the "Assumed Liabilities"): . . . (iii) subject to any applicable reimbursement obligations of [Allergan] in Section 5.7, (A) all liabilities and obligations for warranty claims, complaints and product liability, and the other liabilities assumed by [Sofregen] pursuant to Section 5.7, including all Actions relating to such liabilities, and (B) all liabilities and obligations for refunds, adjustments, allowances, repairs, exchanges, recalls and returns or similar claims, arising out of or relating to [SERI] Product, arising after the Effective Date, whether relating to any [SERI] Product sold prior to, on or after the Effective Date.[204]

Section 5.7(a)(ii) of the APA is titled "Product Responsibility," and it states in pertinent part:

> (a) From and after the Effective Date: . . . (ii) Without limiting the foregoing, (A) [Sofregen] shall promptly notify [Allergan] of any complaints, requests, investigations, reports or pending or threatened Actions with respect to any Previously Sold Product; (B) [Sofregen] shall regularly consult in advance with [Allergan] on all material actions to be taken relating to such complaints, requests, investigations, reports or Actions relating to any Previously Sold Product; (C) [Sofregen] shall in good faith incorporate into its response(s) to any such complaints, requests, investigations, reports or Actions any input of [Allergan] on such matters; and (D) [Allergan] shall be entitled to participate, at its cost, in any Action related thereto. [Sofregen] shall diligently conduct the defense of any such Action. . . . [Sofregen] shall be financially responsible for all such actions required to be taken by it under this clause (ii); provided, that if (1) any such complaint, request or investigation shall result in an Action relating to Previously Sold Product, (2) [Sofregen] has complied with the foregoing terms of this Section 5.7(a)(ii), and (3) the final and non-appealable holding in such Action is that [Sofregen] is liable

[201] JX146, Ex. 38 at 31 (showing a table of Finished Product Inventory as of November 7, 2016).
[202] *See id.* at 22; Pls.' Answering Br. at 44.
[203] *See* Defs.' Mot. for Summ. J. at 22, Ex. 51; Pls.' Answering Br. at 22, Ex. 65. Sofregen believes that, using Allergan's own pricing, the price of the missing units totals approximately $467,000. *See* Pls.' Answering Br. at 22, Ex. 66. Allergan disagrees with the damages calculation. *See* Defs.' Reply Br. at 20.
[204] JX146, § 2.3(a)(iii).

> for damages resulting, in whole or in part, from Non-Conforming Product (or such a determination is made in any appealable holding or settlement, consented to by [Allergan], such consent not to be unreasonably withheld, conditioned or delayed), then [Allergan] shall be responsible for its *pro rata* share . . . of the reasonable out-of-pocket costs and expenses actually incurred by [Sofregen] in connection with such Action, including damages required to be paid by [Sofregen] relating thereto, but solely to the extent that such reasonable out-of-pocket costs and expenses and other Losses are attributable to the use, sale, manufacture or distribution of Non-Conforming Product.[205]

Allergan brought Counterclaim I against Sofregen for breach of the above APA Sections because Allergan believes Sofregen failed to assume liabilities and obligations in connection to certain lawsuits discussed below.

Sofregen's post-acquisition plan was to promote SERI, within FDA guidelines, for soft-tissue reconstruction in a few, high performing markets.[206] Sofregen increased its sales force by hiring six or seven salespeople experienced with surgical devices.[207] Using Allergan's sales data by territory, Sofregen designed its sales strategy around the largest SERI customers in the best-selling territories.[208] Sofregen expected that sales of SERI in these territories would remain consistent post-Closing.[209] Because Sofregen acquired a set quantity of SERI and it would be a few years before Sofregen could manufacture SERI, Sofregen's plan was to maintain, but not increase, SERI sales.[210] Allergan dismantled its own SERI manufacturing facility post-Closing which meant that Sofregen constructed its own facility.[211]

During due diligence, Allergan provided Sofregen with its historical SERI sales data that Sofregen used for its own financial projections for SERI.[212] Dan Huff, Sofregen's Chief

[205] *Id.*, § 5.7(a)(ii).
[206] June 6, 2023 AM-Tr. 93:17-94:1-3.
[207] *Id.* 97:8-98:8.
[208] *Id.* 98:14-99:1-7.
[209] *Id.* 99:4-7.
[210] *Id.* 94:4-21.
[211] *Id.* 94:22-95:1-7.
[212] June 6, 2023 PM-Tr. 69:3-8.

Financial Officer, presented the Sofregen board with updated post-Closing financial projections during a February 2017 board meeting.[213] By 2019, Sofregen projected SERI sales to generate more than $20 million.[214]

F. POST-CLOSING RECEIPT OF THE SURE-002 STUDY DATA AND SURE-006 STUDY DATA

On December 12, 2016, Mr. Smith directed Allergan personnel to provide the SURE CSRs to Sofregen.[215] On December 22, 2016, Dr. Hoang-Lindsay received an email from Allergan indicating that additional documents had been uploaded to the Box.com data room.[216] Dr. Hoang-Lindsay testified that she did not immediately review the uploaded information because she did not expect to receive any new data post-Closing that was materially different from, or contradicted, what was shared during due diligence.[217]

After reviewing the data, Dr. Hoang-Lindsay believed that the SURE-002 Study data was new and felt it was concerning.[218] Dr. Hoang-Lindsay testified that the rates of necrosis, seroma, and explant were double, if not triple, the rates reflected in the SURE-001 CSR.[219] Dr. Hoang-Lindsay stated that this concerned Sofregen because patients that had SERI explanted were more likely to bring a lawsuit.[220] Sofregen had been especially sensitive to explant rates during due diligence.[221]

The SURE-002 CSR concluded that SERI was safe and effective and reflected high levels of surgeon and patient satisfaction.[222] Dr. Hoang-Lindsay was confused by this conclusion

---

[213] *Id.* 62:10-77:10; JX 189 at 25.
[214] JX 189 at 25.
[215] JX 159 at 3.
[216] JX 164.
[217] June 5, 2023 AM-Tr. 70:7-71:1-4.
[218] *Id.* 71:5-12.
[219] JX 157 at 55, 60; June 5, 2023 Tr. 71:19-72:18.
[220] June 5, 2023 Tr. 72:19-73:1-14.
[221] *Id.*
[222] JX 157 at 68.

because the complication and explantation rates were outside the acceptable range for surgical meshes.[223] In January 2017, Dr. Hoang-Lindsay contacted Robert Carnevale at Allergan asking to schedule a call with the head of the SURE-002 Study to discuss the data.[224] Dr. Hoang-Lindsay also asked Dr. Daunch for more information, but neither Mr. Carnevale nor Dr. Daunch could explain why Sofregen had not received the data during due diligence.[225] Dr. Hoang-Lindsay testified that she never received an explanation as to why the SURE-002 Study data was not shared during due diligence and never received a point of contact for the SURE-002 Study.[226]

Allergan provided written responses to Sofregen about SURE-002 and SURE-006 in February 2017.[227]

Sofregen contends that had it known about the SURE-002 Study data, the SURE-006 Study data, or the Rolph Paper prior to November 10, 2016, it never would have agreed to purchase SERI or signed the APA.[228]

G. SERI SALES DECLINE

For the first few months after the acquisition, sales of SERI remained consistent with historical performance and Sofregen's projections.[229] SERI sales dropped at the end of the first quarter of 2017 and declined throughout 2017.[230] Sales declined even in territories where SERI previously sold well.[231] Mr. Schaison testified that SERI was a commercial failure for

[223] June 5, 2023 Tr. 73:19-74:1-12.
[224] JX 184.
[225] June 5, 2023 Tr. 78:12-79:1.
[226] June 5, 2023 Tr.79:2-21.
[227] JX209.
[228] June 6, 2023 AM-Tr. 116:20-117:15; June 5, 2023 Tr. 82:8-83:23.
[229] June 6, 2023 AM-Tr. 99:8-17.
[230] *Id.* 99:8-20.
[231] *Id.* 99:21-100:1.

Sofregen.[232] Mr. Schaison contends that this failure could not have anticipated because of Allergan's purported concealment of the SURE CSRs.[233]

H. SERI TRUNK STOCK

Allergan did not have a tracking system to know how much inventory was in the possession of its salespeople.[234] Allergan stored its aesthetics inventory, including SERI, with Kuehne and Nagel ("K&N"), a third-party vendor in Texas.[235] K&N kept records by serial number of the SERI inventory.[236]

Allergan provided Sofregen with an inventory of the SERI trunk stock ("Trunk Stock") as of October 18, 2016, prior to Closing.[237] Sofregen realized that units of Trunk Stock were missing sometime in 2017.[238] In January 2018, Sofregen provided Allergan with a reconciliation of the Trunk Stock inventory received from Allergan prior to closing with an updated inventory list from K&N.[239] This reconciliation demonstrates that 140 units of SERI remained missing.[240]

The outstanding Trunk Stock concerned Sofregen because it meant there were potentially 140 individuals with implanted SERI and Sofregen had no idea who those patients were or how to monitor potential adverse events.[241] Allergan conceded that 140 units of Trunk Stock could not be located.[242] Mr. Schaison testified at Trial that, after Sofregen's acquisition of SERI, he heard directly from salespeople that representatives were offering free samples of SERI to physicians to encourage the purchase of Allergan breast implants.[243]

---

[232] June 5, 2023 Tr. 263:20-265:1-12.
[233] *Id*.
[234] JX 403 at 19; June 8, 2023 PM-Tr. 39:14-17.
[235] June 6, 2023 AM-Tr. 101:14-23.
[236] *Id.* 102:4-9.
[237] JX 274; June 6, 2023 AM-Tr. 104:12-105:1-8.
[238] June 6, 2023 AM-Tr. 106:10-15.
[239] JX 274; June 6, 2023 AM-Tr. 105:1-106:1.
[240] *Id*.
[241] June 6, 2023 AM-Tr. 106:2-9.
[242] JX 281 at 1.
[243] June 5, 2023 Tr. 274:21-275:1-12.

Sofregen continued trying to locate the missing Trunk Stock and, after an additional reconciliation, Sofregen still showed 131 units of Trunk Stock missing.[244] Sofregen never located these 131 units of Trunk Stock.[245] At no time did anyone at Allergan represent to anyone at Sofregen that the APA did not obligate Allergan to provide all the Trunk Stock.[246]

The Court finds that Sofregen has proved that Allergan is responsible to Sofregen for 131 units of Trunk Stock.

I. POST-CLOSING LAWSUITS

A number of SERI-related lawsuits were filed after Closing. Each case involved a direct-to-implant procedure that resulted in explantation and, in certain cases, it was noted that SERI had failed to fully integrate into breast tissue:

- On November 28, 2016, Wendy Knecht filed suit in California.[247] Knecht underwent a direct-to-implant breast reconstruction on February 24, 2015.[248] During follow-up visits, it was noted that Knecht had developed seroma and the SERI was explanted in two separate surgeries.[249]

- On April 2, 2018, Dwyn Harben filed suit in Pennsylvania.[250] Harben underwent a direct-to-implant breast reconstruction on January 29, 2015, and the SERI was explanted on December 28, 2016.[251] During the explantation procedure, the SERI was still visible and palpable (i.e., had not integrated)[252]

- On July 27, 2018, Gianna Krstic filed suit in Massachusetts against Sofregen and Allergan.[253] Krstic underwent breast augmentation surgery on July 16, 2014, and, after her surgeon determined that the SERI "had not biodegraded as Allergan had represented it would do," he removed the SERI.[254]

- On March 24, 2020, Jennifer Hasso filed suit in California.[255] Hasso underwent

[244] June 6, 2023 AM-Tr. 107:3-108:8; JX 281 at 1.
[245] June 6, 2023 AM-Tr. 107:22-108:8.
[246] *Id.* 109:1-7.
[247] JX 169 at 15.
[248] *Id.* at 25, ¶ 56.
[249] *Id.* at 25-26, ¶¶ 59-60, 68.
[250] JX 289.
[251] *Id.* at 3, ¶¶ 2, 26, 92.
[252] *Id.* at 26, ¶ 92.
[253] JX 323.
[254] *Id.* at 5, ¶¶ 19, 23.
[255] JX 374.

> a direct-to-implant breast reconstruction on February 4, 2014, and experienced significant complications, including seroma.[256] The SERI was explanted in March 2020.[257]

V. APPLICABLE LAW

The Court will be applying the following general legal principles:

A. GOVERNING SUBSTANTIVE LAW

Delaware law applies here. The parties have relied on Delaware law and the Court is unaware of any reason why Delaware law does not apply to the claims asserted by the parties.

B. FRAUDULENT INDUCEMENT

To establish a claim for fraudulent inducement, a party must prove:

> (1) a false representation of material fact; (2) the defendant's knowledge of or belief as to the falsity of the representation or the defendant's reckless indifference to the truth of the representation; (3) the defendant's intent to induce the plaintiff to act or refrain from acting; (4) the plaintiff's action or inaction taken in justifiable reliance upon the representation; and (5) damage to the plaintiff as a result of such reliance.[258]

Element (2) is often referred to as "scienter."[259]

Fraud does not merely consist of overt misrepresentations.[260] Fraud may also occur when someone deliberately conceals facts important to a transaction, causing the other party to rely on the concealment to that party's detriment.[261] A party's concealment can occur through silence in the face of a duty to disclose the facts or by some action taken to prevent the other party from discovering the facts important to the transaction.[262]

---

[256] *Id.* at 12, ¶¶ 63, 65.
[257] *Id.* at 13, ¶ 69.
[258] *Chapter 7 Tr. Constantino Flores v. Strauss Water Ltd.*, 2016 WL 5243950, at *7 n.34 (Del. Ch. Sept. 22, 2016) (internal quotation marks omitted) (citing *Duffield Assocs., Inc. v. Meridian Architects & Eng'rs, LLC*, 2010 WL 2802409, at *4 (Del. Super. July 12, 2010)).
[259] *See ITW Glob. Invs. Inc. v. Am. Indus. P'rs Cap. Fund IV, L.P.*, 2017 WL 1040711, at *6 (Del. Super. Mar. 6, 2017).
[260] *Gaffin v. Teledyne, Inc.*, 611 A.2d 467, 467 (Del. 1992).
[261] *Id*.
[262] *Id*.; *see also* Superior Court Civil Pattern Jury Instruction 16.3.

If a party is aware of the true facts of the transaction, even if the facts were concealed, then there is no fraud.[263]

C. BREACH OF CONTRACT

Under Delaware law, to prove a breach of contract claim, a party must show: "(1) a contractual obligation; (2) a breach of that obligation; and (3) resulting damages."[264] A party harmed by a breach of contract is entitled to compensation that will place that party in the same position that the party would have been in if the other party had performed under the contract.[265]

The standard remedy for breach of contract is based upon the reasonable expectations of the contracting parties.[266] Expectation damages are measured by determining "the amount of money that would put the promisee in the same position as if the promisor had performed the contract."[267] "Damages for a breach of contract must be proven with reasonable certainty. Recovery is not available to the extent that the alleged damages are uncertain, contingent, conjectural, or speculative."[268]

"Delaware adheres to the 'objective' theory of contracts, *i.e.*[,] a contract's construction should be that which would be understood by an objective, reasonable third party."[269] "Contract terms themselves will be controlling when they establish the parties' common meaning so that a reasonable person in the position of either party would have no expectations inconsistent with the contract language."[270]

---

[263] *See Merrill v. Crothall-American, Inc.*, 606 A.2d 96, 100 (Del. 1992) (knowledge negates fraud); see also Superior Court Civil Pattern Jury Instruction 16.4
[264] *Interim Healthcare, Inc. v. Spherion Corp.*, 884 A.2d 513, 548 (Del. Super. 2005).
[265] *See E.I. DuPont de Nemours and Co. v. Pressman*, 679 A.2d 436, 445-46 (Del. 1996).
[266] *See Duncan v. Theratx, Inc.*, 775 A.2d 1019, 1022 (Del. 2001).
[267] *Id*.
[268] *Lee-Scott v. Shute*, 2017 WL 1201158, at *7 (Del. Com. Pl. Jan. 30, 2017).
[269] *Osborn ex rel. Osborn v. Kemp*, 991 A.2d 1153, 1159 (Del. 2010) (citing *NBC Universal v. Paxson Commc'ns*, 2005 WL 1038997, at *5 (Del. Ch. Apr. 29, 2005)).
[270] *Eagle Indus., Inc. v. DeVilbiss Health Care, Inc.*, 702 A.2d 1228, 1232 (Del. 1997).

D. BURDEN OF PROOF

In a civil case, the burden of proof is by a preponderance of the evidence. Proof by a preponderance of the evidence means proof that something is more likely than not. This means that certain evidence, when compared to the evidence opposed to it, has the more convincing force and makes the Court believe that something is more likely true than not. If the evidence on any particular point is evenly balanced, the party having the burden of proof has not proved that point by a preponderance of the evidence, and the Court must find against the party on that point.[271] While in some jurisdictions fraud must be shown by clear and convincing evidence, the burden of proof in a fraud case in Delaware is by a preponderance of the evidence.[272]

In deciding whether any fact has been proved by a preponderance of the evidence, the Court may consider the testimony of all witnesses regardless of who called them, and all exhibits received into evidence regardless of who produced them.

In this particular case, Sofregen carries the burden of proof on Counts II and III of its Second Amended Complaint. Allergen carries the burden of proof on the Counterclaims.

E. EVIDENCE EQUALLY BALANCED

If the evidence tends equally to suggest two inconsistent views, neither has been established. That is, where the evidence shows that one or two things may have caused the breach/damages—one for which a party was responsible and one for which a party was not—the Court cannot find for the party carrying the burden of proof if it is just as likely that the breach/damages was caused by one thing as by the other.[273]

---

[271] Superior Court Civil Pattern Jury Instruction 4.1.
[272] *See In re IBP, Inc., Shareholders Litigation*, 789 A.2d 14, 15, 54 (Del. Ch. 2001).
[273] Superior Court Civil Pattern Jury Instruction 4.2.

VI. DISCUSSION[274]

A. SECOND AMENDED COMPLAINT COUNT I—THE MISSING SERI UNITS

APA Section 2.2(a)(iv) governs the transfer of SERI units. It is titled "Transfer of Assets" and states:

> (a) "Acquired Assets" means all of [Allergan's] right, title and interest, as of the Effective Date, in and to [its] respective assets exclusively related to the Business and/or [SERI] Product, wherever located, including without limitation the following: . . . (iv) (A) all finished product inventory of [SERI], including the finished product inventory set forth on Schedule 2.2(a)(iv)(A) (such finished product inventory, the "Finished Product Inventory"), (B) all silk spools held for use solely to manufacture [SERI] set forth on Schedule 2.2(a)(iv)(B) (the "Spools"), and (C) the packaging materials used or held for use exclusively with respect to [SERI] set forth on Schedule 2.2(a)(iv)(C) (such packaging materials, together with the Finished Product Inventory and Spools, the "Product Inventory").[275]

Allergan had a contractual obligation to turn over the Trunk Stock within 30 days of closing.[276] Schedule 2.2(a)(iv) of the APA identified the SERI Product Inventory that Allergan was obligated to transfer to Sofregen.[277]

At Trial, Sofregen carried its burden and proved Allergan breached its contractual obligation under APA Section 2.2(a)(iv). Allergan failed to accurately account for and turn over its Trunk Stock. In the spring of 2017, Sofregen realized that a number of Trunk Stock units remained outstanding.[278] Sofregen prepared and provided Allergan with a reconciliation of the inventory of Trunk Stock it received from Allergan with an updated list of inventory it received from K&N, noting that 140 units remained unaccounted for.[279] After additional reconciliation,

[274] To the extent that the Court does not provide a citation of a finding of fact in this Section, the Court incorporates by reference the findings in Section IV above.
[275] JX 146, § 2.2(a)(iv).
[276] *Id*., §§ 2.1, 2.2 and 2.5.
[277] *Id*., at 31.
[278] June 6, 2023 AM Tr. 106:10-15.
[279] JX 274.

131 units of Trunk Stock were still unaccounted for, without explanation.[280] Allergan never recovered the missing Trunk Stock.[281]

Allergan's witnesses confirmed Allergan's breach when Ms. Strom testified that Allergan did not have a tracking system to determine the location of all SERI product,[282] and Mr. Schaison further testified that he heard from Allergan salespeople and managers that they were offering free samples of SERI to physicians to encourage the purchase of Allergan breast implants.[283]

The Court also finds that Sofregen has met its evidentiary burden as to damages. Sofregen has been damaged by not receiving the SERI inventory as was contractually agreed to by Allergan and Sofregen. Because Allergan failed to account for and provide Sofregen all of the Trunk Stock, Sofregen was not able to identify and track the adverse events that patients experienced, as required by the FDA because Allergan failed to account for and provide all of the SERI Trunk Stock.[284]

Sofregen's inability to meet FDA requirements was a liability concern.[285] Further, Sofregen was unable to market or sell the Trunk Stock that Allergan failed to provide.[286] Using Sofregen's average sales price of $3,000 per unit[287] multiplied by 131 units of Trunk Stock,[288] The Court awards Sofregen damages in the amount of $393,000, plus prejudgment interest.

B. SECOND AMENDED COMPLAINT COUNT III—FRAUDULENT INDUCEMENT

To establish fraudulent inducement, Sofregen must prove:

> (1) a false representation of material fact; (2) the defendant's knowledge of or belief as to the falsity of the representation or the defendant's reckless indifference to the

[280] JX 281 at 1; JX 486.
[281] June 6, 2023 PM Tr. 99:22-100:3.
[282] June 6, 2023 PM Tr. 39:14-17; *see also* JX 270 at 1.
[283] June 5, 2023 Tr. 274:21-275:12.
[284] June 6, 2023 AM Tr. 103:19-104:5.
[285] June 6, 2023 AM Tr. 103:19-104:5.
[286] June 6, 2023 PM Tr. 97:1-98:1-13.
[287] *Id.* 94:7-8; *see also* JX 189 at 8.
[288] June 6, 2023 PM Tr. 98:9-13; *see also* JX 282.

> truth of the representation; (3) the defendant's intent to induce the plaintiff to act or refrain from acting; (4) the plaintiff's action or inaction taken in justifiable reliance upon the representation; and (5) damage to the plaintiff as a result of such reliance.[289]

Element (2) is often referred to as "scienter."[290]

Fraud does not merely consist of overt misrepresentations.[291] Fraud may also occur when someone deliberately conceals facts important to a transaction, causing the other party to rely on the concealment to that party's detriment.[292] A party's concealment can occur through silence in the face of a duty to disclose the facts or by some action taken to prevent the other party from discovering the facts important to the transaction.[293]

Sofregen must prove these elements by a preponderance of the evidence.[294]

Allergan argues: (a) it did not conceal material facts; (b) it did not act with scienter; and (c) Sofregen cannot establish justifiable reliance. Sofregen argues: (a) Allergan intentionally hid harmful SERI studies and remained silent in the face of a duty to disclose the studies; (b) Allergan acted with at least reckless indifference; (c) Allergan concealed with the intent to induce Sofregen into the APA; and (d) Sofregen justifiably relied on Allergan's due diligence disclosures.

After hearing all of the evidence and considering the post-trial briefing, the Court finds that Sofregen failed to carry its burden of proof at Trial. Because Sofregen failed to carry its burden on the essential elements, the Court will not address the issue of whether Sofregen suffered damages.

---

[289] *Chapter 7 Tr. Constantino Flores*, 2016 WL 5243950, at *7 n.34.
[290] *See ITW Glob. Invs. Inc.*, 2017 WL 1040711, at *6.
[291] *Gaffin*, 611 A.2d at 467.
[292] *Id*.
[293] *Id*.
[294] *See In re IBP, Inc., Shareholders Litigation*, 789 A.2d at 54.

1. Sofregen Cannot Prove that Allergan Knowingly Made False Statement or Concealed the Truth from Sofregen.

Sofregen cannot demonstrate that Allergan concealed information regarding SERI. Sofregen did not establish that Allergan failed to disclose the SURE-001 CSR pre-Closing. The record does demonstrate that Allergan did disclose information about SURE-002 and SURE-006 months pre-Closing, including that SURE-006 was halted due to "unacceptable" adverse events. Sofregen elected not to request the data from SURE-002 or SURE-006 pre-Closing. In addition, Sofregen failed to establish justifiable reliance in light of Allergan's pre-Closing disclosures and the provisions of the APA.

Sofregen can only prevail on its fraud claim if it demonstrates concealment of material information.[295] Sofregen claims Allergan engaged in concealment by: (i) not disclosing the SURE-002 and SURE-006 data and CSRs pre-Closing; (ii) selectively disclosing the SURE-001 CSR post-Closing; (iii) repeatedly representing that there were no issues with SERI's clinical performance but failing to disclose SURE-002's and SURE-006's high rates of serious adverse events; and (iv) not disclosing the Rolph Paper or the link between SERI and RBS.

Sofregen has not provided evidence that Allergan took steps to conceal the SURE-002 and SURE-006 CSRs or underlying data prior to Closing. The Court notes that: (i) Allergan disclosed the study design and status of the SURE-002 and SURE-006 studies during the Second Due Diligence Meeting;[296] and (ii) Allergan disclosed SURE-006 was halted because of "unacceptable" adverse events just days after the Second Due Diligence Meeting.[297] The evidence shows that Sofregen failed to specifically request or, if there was a request, follow up to obtain the CSRs or data for either SURE-002 or SURE-006 pre-Closing.

[295] JX 385 at 10-11.
[296] JX 109 at 4–5.
[297] JX 120 at 1.

Allergan's post-Closing disclosure of the SURE-002 and SURE-006 CSRs is not evidence of concealment, because this disclosure was expressly contemplated by the APA. There, the parties agreed Sofregen would receive "clinical study reports" post-Closing (along with "adverse events records" and "research and development data").[298]

Sofregen contends that Allergan concealed high rates of adverse events in connection with SURE-002 and SURE-006 while also representing there were no issues with SERI's clinical performance. Sofregen points to (i) survey results reported within slides entitled "Perceptions of SERI" that were presented at the February Meeting;[299] (ii) a purported representation regarding a trend analysis of the Complaints Report;[300] and (iii) representations by Dr. Hammer during a call with Dr. Hoang-Lindsay,[301] which Dr. Hoang-Lindsay claims was organized to discuss the SURE-006 study.[302]

The "Perceptions of SERI" slides do not constitute representations that there were no issues with SERI's clinical performance. Allergan reported the results of a June 2015 survey of plastic surgeons.[303] The survey results do not describe SERI's efficacy and, instead, convey information regarding how SERI was perceived by the surveyed plastic surgeons.[304] The Court does not find that the slides would not cause a reasonable person to believe SERI had "rapid tissue integration, well vascularized tissue, and minimal seroma," because the majority of surveyed surgeons did not even perceive SERI as having these characteristics.[305]

[298] JX 146 § 2.5(b); JX 146 § 1.1.
[299] JX 79 at 22, 24.
[300] June 5, 2023 Tr. 42:5–43:5.
[301] June 5, 2023 Tr. 49:6–19.
[302] June 5, 2023 Tr. 47:5–9.
[303] JX 79 at 22, 24.
[304] *Id*. at 22.
[305] *Id*. at 22 and 24.

Sofregen contends that Mr. Dunstan represented that an analysis of the Complaints Report did not reveal any safety signals or patterns of adverse events related to SERI. The record does not wholly support that contention.

First, the support for this representation is Dr. Hoang-Lindsay's trial testimony.[306] The Court was not presented with any additional or corroborating evidence to support the testimony. Sofregen also did not present any trial or deposition testimony from Mr. Dunstan to support Sofregen's burden of proof. Second, the purported statement is not a representation that SERI has "no issues." Moreover, Sofregen does not dispute the accuracy of Mr. Dunstan's representation regarding the Complaints Report.[307] Third, Sofregen possessed "the means of knowledge" regarding any safety signals or patterns in the Complaints Report because Sofregen analyzed the report months pre-Closing.[308] Sofregen could not have reasonably relied on Mr. Dunstan's purported assessment.[309] Finally, Sofregen could not have reasonably relied on Mr. Dunstan's purported representation because Sofregen elected not to obtain "AE trend reports for SERI" until post-Closing (instead of independently analyzing the trend reports pre-Closing).[310]

Sofregen describes Dr. Hoang-Lindsay's August 5, 2016,[311] call with Dr. Hammer as scheduled in response to Mr. Green's disclosure regarding "unacceptable" adverse events in SURE-006.[312] Sofregen's position is based on Dr. Hoang-Lindsay's trial testimony, and it also ignores her deposition testimony that she was unaware of SURE-006 pre-Closing.[313]

---

[306] June 5, 2023 Tr. 42:5-43:5.
[307] JX 410 at 114:19–23 ("[The] complaints that [Allergan was] monitoring were pretty consistent and very low single digits.").
[308] *Universal Enter. Grp., L.P. v. Duncan Petroleum Corp.*, 2013 WL 3353743, at *43 (July 1, 2013); *see also* JX107; JX 116; JX 117.
[309] *Universal*, 2013 WL 3353743, at *43.
[310] JX158 at 1.
[311] Sofregen identifies that call having occurred on August 9. OB at 26; *but see* JX123 at 1.
[312] JX 120.
[313] JX 410 at 65:12–18, 121:11–17, 13:10–15.

The Court notes that some evidence demonstrates that, as of July 31, 2016 (a time prior to Mr. Green's SURE-006 email), Dr. Hoang-Lindsay already had a call scheduled to discuss "sponsored research studies" with Dr. Hammer.[314] About a week before the call, Allergan identified Dr. Hammer as the appropriate contact for Allergan-sponsored "IITs" (*i.e.*, investigator-initiated trials) which would not have included the sponsor initiated SURE-006 study.[315] Dr. Hammer was also identified as a point of contact for a specific IIT initiated by Dr. Mills.[316] After the August 5 call, Dr. Hoang-Lindsay confirmed that it had been "recommended by [Strom]" and was for the purpose of discussing "sponsored research studies." [317]

Dr. Hoang-Lindsay's email summary of the Dr. Hammer call also does not reflect any discussion of SURE-006 or the "unacceptable" adverse events Green disclosed.[318] The email summary also does not mention either Israel (the location of SURE-006) or Dr. Scheflan (SURE-006's principal investigator), despite identifying other clinicians by name (including Dr. Mills).[319]

To the Court, other evidence undermines Sofregen's claim that Dr. Hammer made misrepresentations to Dr. Hoang-Lindsay to prevent inquiry into SURE-006. At Trial, the Court understood that Dr. Hoang-Lindsay knew about SURE-006 and, for some reason, elected not to inquire about it during a previously scheduled call with Dr. Hammer unrelated to that study. Even with all this, and without further inquiry, Sofregen proceeded to iron out the details of the acquisition.

[314] JX 505 at 1; see also JX505.1 at C23.
[315] JX 113 at 1.
[316] JX 109 at 3.
[317] JX 478 at 1; see also JX479 at 1 (call was scheduled "some time ago").
[318] JX 123 at 1–2.
[319] *Id*.

The Court also does not find that Allergan concealed information about the "possible" publication of the Rolph Paper and any link between SERI and Red Breast Syndrome. For example, Sofregen, during Trial, did not identify due diligence requests that would have included the Rolph Paper. Additionally, during due diligence, Allergan disclosed the involvement of Dr. Scheflan in a the SURE-006 study that was halted due to "unacceptable" adverse events.[320] Dr. Scheflan is a co-author of the Rolph Paper. This disclosure seems inconsistent with Sofregen's theory that Allergan actively concealed the possible publication of the Rolph Paper.

As for Red Breast Syndrome, Allergan provided Sofregen with the Complaints Report, which contains the phrase "red breast" 76 times[321] and the phrase "red breast syndrome" 46 times.[322] The Complaints Report's entries also relate to patients treated by Dr. Macmillan—another co-author of the Rolph Paper.[323] Allergan also disclosed in the APA a pending product liability lawsuit, *Goulet v. Allergan*, Cause No. DC-16-3808 (Tex. Dist. Ct.).[324] The complaint there included specific allegations regarding red breast issues. These disclosures refute Allergan actively concealing any connection between SERI and Red Breast Syndrome.

The Court finds that, with this factual record, Sofregen cannot carry its burden on concealment by Allergan or that Allergan knowing made false statements. The Court, therefore, finds that Sofregen cannot meet this element of its fraudulent inducement claim.

[320] JX 120 at 1.
[321] JX 107.1 at AP558–72, AP632–44, AP829–30, AP834–41, AP1052–56, AP1063–64, AP1077, AP1126, AP1128–29, AP1145–46, AP1174–78, AP1196–97, AP1241, AP1294–95, AP1704–09, AP1735, AP1858–65.
[322] JX 107.1 at AP558–72, AP632–44, AP1052–56, AP1128–29, AP1145–46, AP1196–97, AP1294–95, AP1704–08.
[323] JX 107.1 at AP558–72, AP632–44.
[324] JX 147 at 36.

2. Sofregen Cannot Meets its Burden on Justifiable Reliance.

The Court also finds that Sofregen did not carry its evidentiary burden as to justifiable reliance. As such, Count III fails for the independent reason that Sofregen satisfy the element of justifiable reliance.

To support justifiable reliance, Sofregen claims it: (i) specifically requested the SURE-002 and SURE-006 data "multiple times" pre-Closing so it reasonably believed Allergan had shared all of the clinical trial data available; (ii) reasonably believed the SURE-002 and SURE-006 data was consistent with the positive data from the SURE-001 study showing SERI was safe and effective; and (iii) reasonably relied on Allergan's purported representations regarding SERI's positive clinical performance.

However, Sofregen expressly disclaims any such reliance in the APA. Accordingly, the Court cannot agree with Sofregen's arguments regarding reliance on extra-contractual representations and the incompleteness of information regarding SERI disclosed pre-Closing based on the APA.

Sofregen's reliance arguments are also unsupported by the evidence, which demonstrates that Sofregen knew, prior to Closing, that data from SURE-002 and SURE-006 was available (including data regarding "unacceptable" adverse events). However, Sofregen elected not to specifically request the data or CSRs for either study prior to Closing. Given these (and other) undisputed facts, Sofregen cannot establish justifiable reliance.

The Court has held APA "Sections 4.5(b) and 6.7 do not disclaim fraud by concealment;"[325] however, this Court has not yet examined how the APA's provisions impact the "fact-intensive inquiry" into whether Sofregen can establish justifiable reliance. Sofregen's

[325] JX 385 at 11.

claimed justifiable reliance cannot be squared with the promises and representations it expressly made in the APA.

First, Sofregen's argument that it reasonably believed Allergan provided complete responses to Sofregen's pre-Closing information requests cannot be reconciled with Sofregen's unambiguous disclaimer that Allergan had not made "any representation … as to the accuracy and completeness of any information" provided during due diligence.[326] Second, Sofregen expressly agreed that (except as expressly set forth in Article III of the APA) Allergan made no "representation or warranty of any kind … relating to the … design, performance, value, merchantability or fitness for any particular purpose of" SERI.[327] This unambiguous provision—together with APA Sections 4.5(b) and 6.7—directly refutes Sofregen's argument that it reasonably relied on Allergan's purported extra-contractual representations about SERI's performance.[328] Third, Sofregen's purported reliance on extra-contractual representations is undermined by the exclusive-remedies provision in APA Section 2.4(h) of the APA which provides the remedies in APA Section 2.4 are exclusive for any claim related to the APA except for one "based upon fraud … with respect to a representation contained in this Agreement."[329] APA Section 2.4(h) requires Sofregen to premise its claimed reliance on an express representation in the agreement. [330] Fourth, the APA expressly contemplated Sofregen would receive "clinical study reports" post-Closing (along with all "research and development data").[331]

[326] JX 146 § 4.5(b); see RAA Mgmt., LLC v. Savage Sports Hldgs., Inc., 45 A.3d 107, 116 (Del. 2012).
[327] JX 146 § 3.10.
[328] *Great Lakes Chem. Corp. v. Pharmacia Corp.*, 788 A.2d 544, 556 (Del. Ch. 2001); *see also Infomedia Grp., Inc. v. Orange Health Sols., Inc.*, 2020 WL 4384087, at *22 (July 31, 2020) ("The language in the [APA] unambiguously defines the universe of information on which [Sofregen] relied in deciding to purchase [SERI].").
[329] JX 146 § 2.4(h).
[330] *Novipax Hldgs. LLC v. Sealed Air Corp.*, 2017 WL 5713307, at *31–32 (Nov. 28, 2017) (finding that anti-reliance and exclusive-remedies provisions, read together, "preserved a fraud claim [but limited that fraud claim] to written representations in the APA").
[331] JX 146 § 1.1; see id. § 2.5(b).

The Court finds that this express agreement regarding the post-Closing disclosure forecloses Sofregen's belief that Allergan "had shared all [available] clinical trial data" prior to Closing.

The Court notes that Sofregen's claims of reliance must include recognition that Sofregen's due-diligence team was sophisticated and professional.[332] "[J]ustifiable reliance has a personalized character. It is measured by reference to the plaintiff's capabilities and knowledge; [and] a plaintiff's sophistication may affect a court's judgments about what dangers were fairly considered obvious."[333]

The Court finds that the evidence demonstrates Sofregen knew (pre-Closing) it had not received all available clinical trial data prior to Closing and could not reasonably have concluded that the SURE-002 and SURE-006 data—which Sofregen consciously elected not to request—were consistent with SURE-001. Sofregen's failure to specifically request the SURE-002 and SURE-006 data is fatal to its ability to establish justifiable reliance.

During the Second Due Diligence Meeting, Allergan made several key disclosures that alerted Sofregen to the two studies—and the necessary existence of their underlying clinical data. At that point in time, Sofregen knew that: (i) both SURE-002 and SURE-006 (unlike SURE-001) investigated SERI's use in one-stage, direct-to-implant breast reconstruction; (ii) the SURE-002 study was complete and the SURE-006 study had been halted; and (iii) Allergan already had a near-final draft of the SURE-002 CSR, which Allergan planned to finalize within "1 or 2 months."[334] Based on these disclosures, Sofregen knew (or, at the very least, was on inquiry notice), prior to Closing, that Allergan had not provided the SURE-002 and SURE-006 data.[335]

---

[332] Dr. Hoang-Lindsay, aided by a team of experts led Sofregen's technical diligence in connection with the potential acquisition. June 5, 2023, Tr. 13:23–14:6, 107:15–108:5; JX410 at 75:23–76:6. Also, Mr. Weisman, Mr. White, and Mr. Kofol were sophisticated individuals who had prior experience with complex transactions. JX408 at 95:13–16, 96:4–25.
[333] *Arwood v. Arwood*, 2022 Del. Ch. LEXIS 57, at *41 (Mar. 9, 2022) (citation omitted).
[334] JX 109 at 5.
[335] JX 410 at 119:14–18; *Vichi v. Koninklijke Philips Elecs, N.V.*, 85 A.3d 725, 796 (Del. Ch. 2014).

Dr. Hoang-Lindsay testified, based on previous disclosures, that SURE-002 data was available as of the July Meeting.[336] The Court is unaware of any evidence indicating Allergan told Sofregen any data or CSR (draft or otherwise) for SURE-002 or SURE-006 was unavailable.

After the Second Due Diligence Meeting, Dr. Hoang-Lindsay and the rest of Sofregen's management team (*i.e.*, Mr. Weisman, Mr. White, and Mr. Kofol) knew Allergan was in possession of negative clinical trial data for "unacceptable" adverse events.[337] At the time, Dr. Hoang-Lindsay knew Sofregen had not received a "complete report" from Mr. Smith about SURE-002 or SURE-006.[338] Dr. Hoang-Lindsay testified that she was not "too concerned" about adverse events in SURE-006 "[b]ecause the numbers were statistically not meaningful." [339] Despite its knowledge, Sofregen elected not to request the SURE-002 and SURE-006 data after the Second Due Diligence Meeting and prior to Closing. [340]

On these facts, the Court cannot find that Sofregen has satisfied the element of justifiable reliance.[341] Sofregen knew or should have known that Allergan had the SURE-002 and SURE-006 data in its possession no later than the Second Due Diligence Meeting during their in-person meeting. Sofregen consciously proceeded to Closing without reviewing the clinical data (or the CSRs) for SURE-002 and SURE-006. Sofregen now claims it relied on extra-contractual representations despite agreeing in the APA that it had not done so. However, the Court finds that Sofregen appears an neglectful buyer that fails to ask for or otherwise follow-up on available records that would have been useful.

---

[336] JX 410 at 119:14–18.
[337] JX 120 at 1.
[338] June 5, 2023 Tr. 172:6-15; JX505.1 at C31.
[339] Day 1 at 49:3–5; see also id. at 48:1–3.
[340] JX 410 at 121:21–122:6; June 5, 2023 Tr. 172:6-15, 178:13–20, 181:21–182:1, 184:19–185:1. Dr. Hoang-Lindsay also testified at Trial that she made a conscious decision not to request the SURE-006 data. June 5, 2023 Tr. 48:23–49:5.
[341] See, e.g., *Homan v. Turoczy*, 2005 Del. Ch. LEXIS 121, at *60–61 (Aug. 12, 2005).

C. COUNTERCLAIM I—DECLARATORY JUDGMENT

Allergan is seeking a declaration, pursuant to APA Section 2.3 and 5.7, that Sofregen assumed all liabilities and obligations relating to Previously Sold Products under APA Section 2.3(a)(iii).[342] Moreover, Allergan seeks a declaration that Allergan is not responsible for reimbursing Sofregen for any damages or costs associated with warranty claims and product liability unless and until there is a final and non-appealable holding that Sofregen was liable for damages resulting, in whole or in part, from a Non-Conforming Product and, even then, only if Sofregen has satisfied the conditions precedent in APA Section 5.7(ii).[343]

Delaware's Declaratory Judgment Act[344] "provides a means for securing judicial relief in an expeditious and comprehensive manner."[345] The Act permits the Court to construe a contract and provide to a party a declaration of rights thereunder.[346] To consider a controversy suitable for declaratory judgment: "1) the controversy must involve a claim of right or other legal interest of the party seeking declaratory relief; 2) the [claim] must be asserted against" a party with "an interest in contesting the claim; 3) the conflicting interests must be real and adverse; and 4) the issue must be ripe for judicial determination."[347]

The parties previously agreed that Counterclaim I was justiciable. The parties disagreed as to the meaning of APA Section 2.3(a)(ii) and 5.7(a)(ii). The Court has already ruled on the language of APA Section 2.3(a)(ii) but will set out the reasoning again in this Decision after Trial. [348]

---

[342] Defs.' Countercls. ¶ 108.
[343] *Id.*
[344] 10 *Del. C.* § 6502.
[345] *Weiner v. Selective Way Ins. Co.*, 793 A.2d 434, 439 (Del. Super. 2002). "The Act is entitled to liberal application." *Id.* (citing *Stabler v. Ramsay*, 89 A.2d 544 (Del. 1952)).
[346] *See* 10 *Del. C.* § 6502.
[347] *Weiner*, 793 A.2d at 439 (citing *Rollins Int'l Inc. v. Int'l Hydronics Corp.*, 303 A.2d 660, 662 (Del. 1973)).
[348] *Sofregen Medical Inc.*, 2023 WL 2034584, at *15-18.

Sofregen argues that the plain language of the APA shows that Sofregen "did not assume any liability for SERI *implanted* prior to the execution of the APA, only SERI *sold* prior to the APA that is implanted after." Sofregen contends that is the correct interpretation because APA Section 2.3(a)(iii) contains the language, "arising after the Effective Date."

APA Section 2.3(a)(iii), titled "Assumption of Liabilities" states:

> (a) As of the Effective Date, [Sofregen] shall assume and pay, discharge, perform or otherwise satisfy the following liabilities and obligations of every kind and nature, whether known or unknown, express or implied, primary or secondary, direct or indirect, absolute, accrued, contingent or otherwise and whether due or to become due, of [Allergan's] arising out of, relating to or otherwise in respect of the Acquired Assets and/or the Business (the "Assumed Liabilities"): . . . (iii) subject to any applicable reimbursement obligations of [Allergan] in Section 5.7, (A) all liabilities and obligations for warranty claims, complaints and product liability, and the other liabilities assumed by [Sofregen] pursuant to Section 5.7, including all Actions relating to any such liabilities, and (B) all liabilities and obligations for refunds, adjustments, allowances, repairs, exchanges, recalls and returns or similar claims, arising out of or relating to the Seri Product, arising after the Effective Date, whether relating to any Seri Product sold prior to, on or after the Effective Date.[349]

APA Section 5.7(a)(ii), titled "Product Responsibility" states:

> (a) From and after the Effective Date: . . . (ii) Without limiting the foregoing, (A) [Sofregen] shall promptly notify [Allergan] of any complaints, requests, investigations, reports or pending or threatened Action with respect to any Previously Sold Product; (B) [Sofregen] shall regularly consult in advance with [Allergan] on all material actions to be taken relating to such complaints, requests, investigations, reports or Actions relating to any Previously Sold Product; (C) [Sofregen] shall in good faith incorporate into its response(s) to any such complaints, requests, investigations, reports or Actions any input of [Allergan] on such matters; and (D) [Allergan] shall be entitled to participate, at its cost, in any Action related thereto. . . . [Sofregen] shall be financially responsible for all such actions required to be taken by it under clause (ii); provided, that if (1) any such complaint, request or investigation shall result in an Action relating to Previously Sold Product, (2) [Sofregen] has complied with the foregoing terms of this Section 5.7(a)(ii), and (3) the final and non-appealable holding in such Action is that [Sofregen] is liable for damages resulting, in whole or in part, from Non-Conforming Product . . . then [Allergan] shall be responsible for its *pro rata* share . . . of the reasonable out-of-pocket costs and expenses actually incurred by [Sofregen] in connection with such Action, including damages required to be paid by [Sofregen] relating thereto but solely to the extent that such reasonable out-of-

[349] JX 146, § 2.3(a)(iii).

> pocket costs and expenses and other Losses are attributable to the use, sale, manufacture or distribution of Non-Conforming Product.[350]

"Previously Sold Product" is defined as "any SeriScaffold sold and distributed in interstate commerce by [Allergan] or any of its Affiliates prior to the Effective Date."[351] "Non-Conforming Product" is defined as:

> [A]ny SeriScaffold sold and distributed in interstate commerce by [Allergan] or its Affiliates prior to the Effective Date, the manufacture of which failed to conform in all material respects to the Laws then applicable to the manufacture of SeriScaffold, . . . as finally determined (i) [in writing by the parties], (ii) [final judgment of a court], or (iii) [any of means the parties agree to].[352]

Allergan argues that "Section 2.3(a)(iii) consists of a sub-part (A) and (B) and the former does not include the 'arising after the Effective Date' language." APA Section 2.3(a)(iii) is subject to only one reasonable interpretation, and Allergan's interpretation is not reasonable. The only reasonable interpretation of APA Section 2.3(a)(iii) is to read the "arising after the Effective Date" language as relating to both sub-part (A) and (B). To read sub-part (A) without this limiting language would render other liability provisions meaningless because it would operate as a general liability clause. Such a construction is inconsistent with the way Sections 2.3(a)(i)-(ii) are drafted. Further, the plain language of APA Section 5.7(a) states that Sofregen is financially responsible for Previously Sold Products "[f]rom and after the Effective Date," not generally as Allergan argues.[353]

Therefore, APA Section 2.3(a)(iii) is subject to only one reasonable interpretation, and that interpretation is inconsistent with Allergan's interpretation underlying its requested declaration.

---

[350] *Id.*, § 5.7(a)(ii).
[351] *Id.*, § 1.1.
[352] *Id.*
[353] *See id.*, § 5.7(a).

While the Court already addressed the issue of what APA Section 2.3(a)(iii), and APA Section 5.7(a)(ii) mean, the Court denied summary judgment.[354] The reason the Court denied summary judgment on Counterclaim I had to do with Count III of the Second Amended Complaint. The Court has ruled on Count III so the holding on what is the meaning of APA Section 2.3(a)(iii), and APA Section 5.7(a)(ii) is law of the case. Moreover, as discussed below, the Court finds that Allergan has failed to prove that Sofregen breached APA Section 5.7.

D. COUNTERCLAIM II—BREACH OF CONTRACT (APA SECTIONS 2.3 AND 5.7).

In Counterclaim II, Allergan contends that Sofregen breached APA Sections 2.3 and 5.7. In post-Trial briefing, Allergan makes the following legal and factual arguments regarding Counterclaim II:

> Sofregen failed to "diligently conduct the defense" and "regularly consult" with Allergan regarding Actions relating to Previously Sold Products, including the Knecht, Hasso, Harben, and Krstic Actions. JX146 § 5.7(a)(ii). Sofregen has not identified any credible evidence demonstrating it regularly consulted with Allergan with respect the foregoing post-Closing Actions relating to Previously Sold Products. Allergan has incurred significant expenses as a result of Sofregen's failure to comply with Section 5.7. Day 3 (Morning) at 61:12–62:22.

Allergan relies exclusively on the APA Agreement and brief Trial testimony on June 7, 2023.[355] Allergan seemingly places the burden of proof on Sofregen to show that Sofregen complied with APA Sections 2.3 and 5.7. Allergan misstates the law on this point. Allergan carries the burden on each and every element as to Counterclaim II. The Court finds that, on this

[354] *Sofregen Medical Inc.*, 2023 WL 2034584, at *18.
[355] June 7, 2023 AM Tr. 61:12–62:22.

record, Allergan has failed to meet its burden of proof that Sofregen breached APA Sections 2.3 and 5.7. Accordingly, the Court finds in favor of Sofregen on Counterclaim II.

E. COUNTERCLAIM III—FAILURE TO PAY EARN-OUT PAYMENTS

APA Section 2.8(b) involves "Earn-Out Payments."[356] Section 2.8(b) states that "[Sofregen] shall pay to [Allergan] earn-out payments equal to five percent (5%) of Net Sales of [SERI] Products sold directly or indirectly by [Sofregen and related parties] during the Earn-Out Term (the 'Earn-Out Payments') in accordance with Section 2.8(b)."[357] The APA defines "Earn-Out Term" as "the period commencing on the Effective Date and ending on the first to occur of (i) the 10th anniversary of the Effective Date; and (ii) the expiration of the last-to-expire patent covering SeriScaffold or SeriPliable."[358]

Sofregen failed to provide Earn-Out Reports and pay Earn-Out Payments after Q3 2017. Allergan alleges that Sofregen's failure to pay from Q4 2017 to Q4 2018 entitles Allergan to damages. Sofregen's failure to pay relates to its belief that Allergan breached the APA. Sofregen does not dispute that it breached the earn-out obligations under Section 2.8(b) of the APA.

The Court has already found that Sofregen failed to carry its burden as to Count III. The APA therefore is enforceable. The Court has found Allergan breached the APA in Count II as to the return of SERI Trunk Stock. No party has argued that Allergan's breach would excuse the performance of Sofregen under APA Section 2.8(b). Accordingly, Allergan is entitled to judgment in its favor on Counterclaim III in the amount of $102,033, plus pre-judgment interest.

[356] *See* JX 146, § 2.8(b).
[357] *Id.* (underlining in original). Under Section 2.8(b)(ii), Earn-Out Payments for a specific quarter were due within sixty (60) days after the end of each quarter. *See id.*, § 2.8(b)(ii).
[358] *Id.*, § 1.1 (Definitions).

VII. CONCLUSION

The Court enters judgment in favor of Sofregen on Count II in the amount of $393,000, plus prejudgment interest and costs.

The Count enters judgment in favor of Allergan on Count III.

The Court enters judgment on Counterclaim I consistent with its early decision on the meaning of APA Sections 2.3 and 5.7.

The Court enters judgment in favor of Sofregen on Counterclaim II.

The Court enters judgment in favor of Allergan on Counterclaim III in the amount of $102,033 plus pre-judgment interest and costs.

IT IS SO ORDERED.

September 26, 2024
Wilmington, Delaware

/s/ Eric M. Davis
Eric M. Davis, Judge

cc: File&ServeXpress