IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOARD OF REGENTS, THE UNIVERSITY OF TEXAS SYSTEM and TISSUEGEN, Inc.

Plaintiffs,

v.

BOSTON SCIENTIFIC Corp.

Defendant.

Civil Action No. 18-392-GBW

MEMORANDUM ORDER

Plaintiffs TissueGen, Inc. (TissueGen) and the Board of Regents, The University of Texas System (collectively, "UT") allege that Defendant Boston Scientific Corp.'s ("BSC") "Synergy" brand coronary stents (the "Accused Products") infringe claims 1, 11, 12, 17, and 26 (the "Asserted Claims") of U.S. Patent No. 6,596,296 ("the '296 patent"). D.I. 124 ¶¶ 1–3, 79. Pending before the Court are BSC's Motion for Summary Judgment of No Willful Infringement (D.I. 197) and Motion for Summary Judgment of Noninfringement (D.I. 198). The Court has reviewed BSC's briefing, statements of fact, and response to statements of fact, D.I. 200; D.I. 201; D.I. 202; D.I. 220; D.I. 221, and UT's briefing, statement of facts, and responses to statements of fact, D.I. 213; D.I. 214; D.I. 216; D.I. 217. The Court will deny both Motions because there are genuine issues of material fact in dispute between the parties. No hearing is necessary. The Court writes for the benefit of the parties and assumes familiarity with the case.

I. LEGAL STANDARD

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed.

R. Civ. P. 56(a). "A genuine issue of material fact is one that could lead a reasonable jury to find in favor of the nonmoving party." *Bletz v. Corrie*, 974 F.3d 306, 308 (3d Cir. 2020). "The court must review the record as a whole, draw all reasonable inferences in favor of the nonmoving party, and must not 'weigh the evidence or make credibility determinations.'" *Id.* (citation omitted). The Court must enter summary judgment if the non-moving party "fails to make a showing sufficient to establish the existence of an element essential to [its] case, and on which [the non-moving] party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *see also SodexoMAGIC, LLC v. Drexel Univ.*, 24 F.4th 183, 204 (3d Cir. 2022) (quoting *Celotex*, 477 U.S. at 322). The Federal Circuit "reviews a district court's grant of summary judgment under the law of the regional circuit, here the Third Circuit." *Acceleration Bay LLC v. 2K Sports, Inc.*, 15 F.4th 1069, 1075 (Fed. Cir. 2021).

II. DISCUSSION

BSC argues that the Court must grant summary judgment of noninfringement because (1) the "biodegradable polymer coating" it applies to its stent is not "thread-like" or "filamentous" and lacks "a common orientation of the polymer molecules"; (2) the coating's drug and polymer are not "immiscible"; and (3) the drug-rich and polymer-rich regions of its stent overlap. D.I. 200 at 11–12. UT disputes each of BSC's arguments, D.I. 214 at 3, and the parties dispute the proper construction of the term "polymer fiber," D.I. 200 at 11; D.I. 214 at 3. BSC further argues that the Court must grant summary judgment of no willful infringement because "[t]he record does not contain any evidence even remotely meeting" the "high standard" needed to show willful infringement. D.I. 200 at 32. UT argues that its evidence of willful infringement is "sufficient" to send the issue to a jury. D.I. 214 at 18. The Court finds for UT as to both summary judgment motions. The Court will reschedule trial and hold a separate hearing to construe the disputed term.

A. Non-Infringement

The Court considers each of BSC's three arguments for summary judgment of non-infringement in turn.

1. Whether the Accused Products Contain a "Fiber" or "Polymer Fiber"

The Court finds that, regardless of the claim construction adopted, the parties have a genuine dispute of material fact as to whether the Accused Products contain a "fiber" or "polymer fiber."

The parties' disputes relate to Claim 1 of the '296 patent:

> A composition comprising at least one biodegradable polymer fiber wherein said fiber is composed of a first phase and a second phase, the first and second phases being immiscible, and wherein the second phase comprises one or more therapeutic agents.

D.I. 1-1 at 27:54–58. On April 15, 2021, the Court construed "fiber" to "have its plain and ordinary meaning." D.I. 90 at 1. The Court explained that the '296 patent uses the term "fiber" "according to its plain and ordinary meaning." D.I. 90 at 5. "[I]t seemed like the real dispute," the Court explained, "is not over whether a fiber is threadlike . . . but rather whether the term 'fiber' can encompass what [BSC] says is a coating," which, the Court said, "is an issue of fact as to whether a coating that covers some structure can itself be a fiber that must also meet the other requirements of the claim fiber." D.I. 90 at 5–6. BSC could, the Court explained, reraise the issue at summary judgment if "that really is a claim construction dispute . . . ." D.I. 90 at 6.

BSC now asks the Court to reconsider its construction of "fiber" and to construe the term "polymer fiber." D.I. 200 at 13. BSC asserts that a "polymer fiber" is "a thread-like or filamentous polymer structure that at least includes common orientation of the polymer molecules." D.I. 200 at 12. Thus, BSC argues, "[UT's] claims fail as a matter of law because no evidence shows that the polymer in the Synergy coating has, for example, a thread-like or

filamentous structure or that the polymer molecules have a common orientation." D.I. 200 at 12. UT argues that, even if "the Court adopts [BSC]'s proposed construction of 'polymer fiber,' which it should not, summary judgment is still unwarranted." D.I. 214 at 17. In particular, UT argues that its expert, Dr. William G. Pitt, will testify that "the ultrathin biodegradable polymer on the serpentine rings of the Synergy stent is a fiber formed by a dynamic process involving rotation and shearing." D.I. 214 at 17. BSC responds that "Dr. Pitt's new opinions, disclosed for the first time in opposition to summary judgment, are untimely, extremely prejudicial, and should not be considered." D.I. 220 at 8. Further, BSC argues that Pitt's declaration "confirms that the final coating on the Synergy Stent does not have polymers with a common molecular orientation, which means [BSC] is entitled to summary judgment." D.I. 220 at 9.

First, the Court rejects BSC's argument that Pitt's new declaration is prejudicial. The parties' scheduling order recites—under the heading "Expert Report Supplementation"—that the parties "**will** permit expert declarations to be filed in connection with motions briefing (including case-dispositive motions)." D.I. 47 ¶ 8(f)(ii) (emphasis in original). The parties have reset scheduling order deadlines multiple times, D.I. 70; D.I. 164; D.I. 179, but they have never amended the aforesaid provision. Therefore, the Court will consider Pitt's new declaration.

Second, a genuine dispute of material fact would remain even if the Court adopted BSC's proposed claim construction. BSC asserts the following facts:

> 16. A person of ordinary skill would understand "polymer fiber" to mean a thread-like or filamentous structure made of polymers that have a common molecular orientation.
>
> 17. The amorphous 85:15 PLGA polymer used to form the Synergy coating has randomly oriented polymer molecule chains and would be unable to spontaneously form a fiber without undergoing a spinning and/or extrusion process to draw or stretch the polymer chains into a common molecular orientation.

> 18. Boston Scientific's roll-coating process does not involve spinning and/or extrusion to draw or stretch the polymer chains into a common molecular orientation.
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> 19. Dr. Pitt did not perform any testing to assess whether the Synergy coating has independent structural integrity or a common molecular orientation of polymer molecules.

D.I. 202 ¶¶ 16–19 (citations omitted). UT disputes each asserted fact with reference to Pitt's new declaration. D.I. 217 ¶¶ 16–19. Pitt explains that BSC's process to coat the Accused Products "lead[s] to orientation of the polymer chains"; "orients polymer chains"; "caus[es] polymer chain orientation"; and "results in the forming of fiber that meets the other limitations of the claims on the serpentine rings of each stent." D.I. 215-4 at PA0980, PA0982. While the Court did not find any reference to a thread-like structure in the relevant section of Pitt's new declaration, BSC does not challenge the sufficiency of Pitt's declaration on those grounds. *See* D.I. 220 at 8–9. *But see* D.I. 220 at 9 (arguing that UT's briefing "fails to offer evidence from which a jury could find that the coating . . . is 'thread-like'").

BSC raises for the first time in its Reply brief that Pitt's declaration supports BSC's argument that the final, dry coating on the Synergy stent is not oriented. D.I. 220 at 9.[1] However, Pitt declares that, "in my opinion, even under [BSC's] misguided construction, BSC's roll-coating process results in the forming of fiber that meets the other limitations of the claims on the serpentine rings of each stent." D.I. 215-4 at PA0982. Pitt's discussion of BSC's process

[1] The Court does not have the benefit of UT's answer to BSC's argument, and the Federal Circuit has expressed concern about arguments raised for the first time in reply precisely because the Court lacks responsive analysis. *See SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1319 (Fed. Cir. 2006) ("Our law is well established that arguments not raised in the opening brief are waived."); *Novosteel SA v. U.S., Bethlehem Steel Corp.*, 284 F.3d 1261, 1274 (Fed. Cir. 2002) ("[T]he non-moving party ordinarily has no right to respond to the reply brief, at least not until oral argument. As a matter of litigation fairness and procedure, then, we must treat this argument as waived.").

to coat the Accused Products shows that his statement has sufficient factual support such that a reasonable juror could credit his declaration. BSC's argument that a different portion of Pitt's new declaration supports its argument goes to the weight that the jury should assign to Pitt's testimony, and not to whether a genuine dispute exists as to a material issue of fact. *See BASF Corp. v. SNF Holding Co.*, 955 F.3d 958, 963 (Fed. Cir. 2020) ("[A]t the summary judgment stage the judge's function is not himself to weigh the evidence . . . ." (internal quotation marks and citation omitted)).

The jury must be left to decide the parties' factual disputes. Thus, even if the Court were to adopt BSC's proposed construction that a "polymer fiber" is "a thread-like or filamentous polymer structure that at least includes common orientation of the polymer molecules[,]" D.I. 200 at 12 (internal quotation marks omitted), a genuine dispute of material fact remains as to whether BSC's production process would create a common orientation of the polymers.

Third, UT's definition would not change the result here. BSC argues that its "coating does not have a 'large' aspect ratio[,]" so the Accused Products would not infringe even if "fiber" were defined "by a 'large ratio of length to a characteristic width or thickness' . . . ." D.I. 200 at 20. UT proposed that definition as an alternative to plain and ordinary meaning prior to claim construction. D.I. 80 at 8. UT replies that Pitt properly opines that the Accused Products' "ultrathin biodegradable polymer is a fiber that meets the other limitations of the claims." D.I. 214 at 14. Indeed, Pitt's April 1, 2022 expert report specifies, for various examples of the Accused Product, that the length-to-width ratios of the stents are sufficiently large to "indicat[e] a biodegradable polymer fiber format." D.I. 215-4 at PA1016–17. Thus, the parties have a genuine dispute of material fact as to whether the aspect ratio of the Accused Products is

sufficiently large to constitute a "fiber" or "polymer fiber." BSC does not allege the lack of a genuine dispute of material fact as to a plain and ordinary meaning construction.

Since the parties have a genuine dispute of material fact regardless of how the Court would construe the term "fiber" or "polymer fiber" in Claim 1 of the '296 patent, the Court denies the motion for summary judgment of noninfringement on that ground. The Court left open the possibility that BSC could re-raise the construction of the term "fiber" at a later point. *See* D.I. 90 at 6. Since BSC continues to insist that the Court's prior claim construction of plain and ordinary meaning was incorrect, the Court will treat BSC's briefing here as a motion for claim construction as to the term "polymer fiber."

To prepare the Court to hold a mini-*Markman* hearing on an accelerated timeframe, the parties shall provide joint claim construction briefing to the Court. BSC shall serve, but not file, its opening brief, not to exceed 1,000 words, by 12:00 PM on October 12, 2022. UT shall serve, but not file, its answering brief not to exceed 1,500 words, on October 18, 2022. BSC shall serve, but not file, its reply brief, not to exceed 1,000 words, on October 21, 2022. UT shall serve, but not file its sur-reply brief, not to exceed 500 words, on October 25, 2022. No later than October 26, 2022, the parties shall file a Joint Claim Construction Brief. The parties shall copy and paste their unfiled briefs into one brief, with their positions on each claim term in sequential order, in substantially the following form: 1. BSC's Opening Position; 2. UT's Answering Position; 3. BSC's Reply Position; 4. UT's Sur-Reply Position. If there are any materials that would be submitted in an appendix, the parties shall submit them in a joint appendix. The parties shall submit two (2) courtesy copies of the joint brief and appendix thereto. Further, the Court requests that the parties file each exhibit included in the joint appendix in CM/ECF as a separate exhibit, if possible (e.g., similar to how the exhibits to the

Declaration filed at D.I. 222 were filed). The Court will hold the mini-*Markman* hearing on November 7, 2022 at 4:00 PM in place of the scheduled pre-trial conference. If the parties are available for a hearing on November 16 and/or 17, 2022, the parties may submit a new proposed briefing schedule that results in submission of the joint brief no later than November 7, 2022.

2. Whether the Accused Products' Coating Meets the "Immiscible" Limitation

The Court finds that the parties have a genuine dispute of material fact as to whether the Accused Products' coating meets the "immiscible" limitation in Claim 1 of the '296 patent.

Claim 1 of the '296 patent requires that the Accused Product's "polymer fiber" be composed of "a first phase and a second phase, the first and second phases being immiscible . . . ." D.I. 1-1 at 27:54–58. On April 15, 2021, the Court announced the parties agreed-upon constructions for "immiscible" as "incapable of dissolving into one another"; "first phase" as "the polymer portion of the fiber"; and "second phase" as "the discrete drug-containing regions dispersed throughout the fiber . . . ." D.I. 90 at 1. The polymer in the Accused Products is "poly-lactic-co-glycolic acid ('PLGA')" and the drug in the Accused Products is "everolimus." D.I. 200 at 9; D.I. 214 at 8. The Accused Products are a metal stent with a biodegradable coating; the coating includes both PLGA and everolimus. D.I. 200 at 9, 11; D.I. 214 at 8.

BSC and UT disagree as to whether BSC's documentation that sought Food and Drug Administration (FDA) approval of the Accused Products supports "slight miscibility" or immiscibility. *See* D.I. 200 at 22; D.I. 214 at 10. BSC argues that UT misconstrues the issue, because UT argues that the *phases* of the polymer fiber are immiscible, but the real question is whether the *substances* that the phases contain (i.e., PLGA and everolimus) are immiscible. D.I. 220 at 11. BSC similarly argues that immiscibility must mean something other than having separate phases if the immiscibility limitation is to retain meaning separate from the requirement to have "a first phase and a second phase." *See* D.I. 200 at 28–29. However, BSC's prior

briefing focused on phases, not on substances. BSC explained in the joint claim construction brief that (1) a claim limitation—"the first and second phases being immiscible"—is indefinite because "two phases in a solid composition cannot 'dissolve into one another[,]'" D.I. 80 at 40, and (2) the specification of the '296 patent would leave a skilled artisan confused as to whether the "two phases" had to be immiscible in a liquid or solid state at various points in the fiber production process, D.I. 80 at 50. The parties agreed upon their construction of the claim term "immiscible," D.I. 90 at 1, and BSC understood that "immiscible" referred to phases (rather than substances). The Court will not allow BSC to change the object of the miscibility inquiry.[2]

Thus, the existence of a genuine dispute of material fact is evident. UT asserts that each of the Accused Products contains "everoliumus-rich domains and [] PLGA polymer-rich domains" that "are incapable of dissolving into one another . . . ." D.I. 213 ¶ 3. BSC "disputes" that assertion. D.I. 221 ¶ 3. Further, the parties dispute the facts underlying their respective positions. *See, e.g.*, D.I. 202 ¶ 36 (suggesting "molecular interaction between PLGA and everolimus"); D.I. 217 ¶ 36 ("[d]isput[ing]" that factual assertion). Neither party contends immiscibility is immaterial. To the extent BSC contends that the record discredits UT's factual assertions, D.I. 220 at 14, the Court finds that a reasonable juror could credit Pitt's reasoned

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[2] BSC raises for the first time in its Reply Brief that there is no material dispute of fact as to immiscibility because "everolimus" and "PLGA" are synonymous with the phases that contain those substances. D.I. 220 at 12. First, BSC was clear in its opening brief that "the evidence of *phase* separation, in and of itself, would not permit a reasonable jury to conclude that two *substances* are immiscible." D.I. 200 at 29 (emphases added). The Court will not credit BSC's attempt to equate phases and substances for the first time in its reply brief. *See SmithKline Beecham*, 439 F.3d at 1319. Second, even if the Court credited BSC's new argument, UT disputes as a factual matter that the miscibility of PLGA and everolimus results in the miscibility of the phases that contain PLGA and everolimus. *See* D.I. 217 ¶ 28. Thus, a material fact would remain in dispute as to the miscibility of the phases. BSC's arguments to the contrary, *see* D.I. 220 at 13 ("PLGA and everolimus are literally the only substances in the Synergy coating."), go to the weight that the jury should assign to the parties' evidence.

opinions, *see* D.I. 215-4 at PA1013–15 (discussing evidence of immiscibility). Therefore, the Court denies the motion for summary judgment of noninfringement as to the immiscibility limitation.

3. Whether the Regions of the Accused Products' Coating are "Discrete"

The Court finds that the parties have a genuine dispute of material fact as to whether the Accused Products contain discrete drug-containing regions within the polymer fiber. According to BSC, "[t]he undisputed facts show that" (1) the coating of the Accused Products does not contain everolimus that is "'discrete' from the PLGA polymer" because "the PLGA-rich domain includes at least some everolimus . . . ." D.I. 200 at 30. Also, they show that (2) "the PLGA-rich domains . . . are not solely made of polymer . . . ." D.I. 200 at 31. In response, UT asserts Pitt's testimony that the Accused Products contain discrete "everolimus-rich domains" within the "polymer rich domain . . . ." *See* D.I. 214 at 10.

At its core, the parties' dispute whether the everolimus and PLGA must be entirely separate from one another in order to satisfy the requirements of Claim 1 of the '296 patent. Claim 1 requires "a first phase and a second phase, the first and second phases being immiscible," D.I. 1-1 at 27:54–58, and the parties agreed that "'first phase' means 'the polymer portion of the fiber'" and that "'second phase' means 'the discrete drug-containing regions dispersed throughout the fiber[.]'" D.I. 90 at 1. The parties agreed that the "discrete" regions must be "drug-containing," not that such regions must include *only* the drug. One definition of "contain" is "to consist of wholly or in part" and another is "to have capacity for [or] be able to hold . . . ." *Contain*, Merriam Webster's Unabridged Dictionary (Accessed Sept. 29, 2022), https://unabridged.merriam-webster.com/unabridged/contain. The '296 patent uses contain in this manner. For example, Claim 21 of the '296 patent claims a fiber comprised of polymer layers that "optionally contain one or more therapeutic agents." D.I. 1-1 at 28:63–67. Claim 23

is "the composition of Claim **1**, wherein the fiber contains more than one therapeutic agent . . . ." D.I. 1-1 at 29:4–5. Neither the polymer layers of Claim 21 nor the fiber of Claim 23 could be entirely comprised of the therapeutic agents, even though the therapeutic agents are "contained" therein. Thus, the parties did not agree upon a purity requirement.

UT asserts that the Accused Products have "everolimus-rich domains and the PLGA polymer-rich domains[,]" D.I. 213 ¶ 3, and Pitt will provide testimony that supports UT's assertion, *see, e.g.*, D.I. 215-4 at PA1010 ("Figure 2.A.F5 illustrates the phase separated morphology of the SYNERGY coating, with discrete everolimus-rich domains dispersed throughout the PLGA polymer matrix."). Thus, a reasonable juror could find that the Accused Products have "a first phase and a second phase," D.I. 1-1 at 27:54–58, where "'first phase' means 'the polymer portion of the fiber'" and "'second phase' means 'the discrete drug-containing regions dispersed throughout the fiber[.]'" D.I. 90 at 1. Therefore, the Court must deny BSC's motion for summary judgment of noninfringement as to the discrete regions limitation of Claim 1.

Since there remain genuine disputes of material fact as to noninfringement, the Court will deny BSC's Motion for Summary Judgment of Noninfringement.

B. Willfulness

The Court finds that the parties have genuine disputes of material fact as to willfulness.

"The subjective willfulness of a patent infringer, intentional or knowing, may warrant enhanced damages . . . ." *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 579 U.S. 93, 105 (2016). "Knowledge of the patent alleged to be willfully infringed continues to be a prerequisite to enhanced damages." *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1341 (Fed. Cir. 2016). However, "pre-suit knowledge alone is not sufficient to support a finding of willful infringement." *Intell. Ventures I LLC v. Symantec Corp.*, 234 F. Supp. 3d 601, 612 (D. Del.

2017), aff'd, 725 F. App'x 976 (Fed. Cir. 2018). "The sort of conduct warranting enhanced damages has been variously described in our cases as willful, wanton, malicious, bad-faith, deliberate, consciously wrongful, flagrant, or—indeed—characteristic of a pirate." *Halo Elecs.*, 579 U.S. at 103–04. However, "the concept of willfulness requires a jury to find no more than deliberate or intentional infringement." *SRI Int'l, Inc. v. Cisco Sys., Inc.*, 14 F.4th 1323, 1330 (Fed. Cir. 2021) (internal quotation marks and citation omitted). The Court is mindful that willfulness is often a jury issue. *See Exmark Mfg. Co. Inc. v. Briggs & Stratton Power Prod. Grp., LLC*, 879 F.3d 1332, 1353 (Fed. Cir. 2018).

According to BSC, UT cannot show that BSC had knowledge of the '296 patent prior to this suit, nor can UT show "that [BSC] took any action based on purported knowledge of the '296 patent, such as copying, reverse engineering, or the like." D.I. 200 at 33, 37. Further, UT "also fail[s] to show . . . willfulness" after this suit was filed in November 2017. D.I. 1; D.I. 200 at 39. In response, UT asserts six pieces of evidence that it says show willful infringement. D.I. 214 at 18–24.

First, Mary Beth Moynihan—now the chief marketing officer of BSC—testified that she—then the vice president of business development at BSC—and Kevin Ballinger—then the vice president of research and development at BSC—met with Dr. Kevin Nelson—the chief scientific officer of TissueGen—at an industry conference about TissueGen's technology. D.I. 215-1 at PA0004–07. Moynihan testified that she requested from Nelson and received follow-up information on April 24, 2009, and Moynihan testified that she "sometimes" opens attachments sent to her. D.I. 215-1 at PA0006–0009, PA0013.

Second, Nelson received an email from Moynihan on May 26, 2009 that said Moynihan and Ballinger "ha[d] reviewed your material" and that BSC would not invest in TissueGen; the

"material" consisted of an "executive summary and PowerPoint presentation . . . ." D.I. 215-4 at PA1153. Third, the PowerPoint presentation specified that TissueGen was developing a "peripheral vascular stent" rather than a "[c]oronary drug eluting stent[]"; asserted a "[s]olid [p]atent [f]oundation" based on four patents, one of which was the '296 patent that was "[e]xclusive[ly] license[d] to TissueGen"; explained that the stent contained a "biodegradable polymer" and a coil with "[f]ully [t]unable [d]rug [d]elivery"; and pointed to "future product[]" opportunities. D.I. 215-1 at PA00017–18, PA0020–22, PA0029–30, PA0036.

Fourth, Dr. Yen Lane Chen testified that BSC began the project that resulted in the "Synergy Stent" in 2006; that BSC first used the "Synergy Stent" in humans in 2009 and did so in the United States in 2012; that all "Synergy Stents" sold by BSC from 2015 through2020 had the same "coating formulation"; that the coating has a "drug rich domain . . . dispersed in the polymer rich domain"; and that BSC "realize[d]" the existence of the drug-rich and polymer-rich domains in 2008 or 2009. D.I. 215-1 at PA0090–91, PA0095–96, PA0098, PA0101–02. As explained above, Claim 1 of the '296 patent requires that the Accused Product have two phases, D.I. 1-1 at 27:54–58, one of which is a "polymer portion of the fiber" and the other of which is "discrete drug-containing regions dispersed throughout the fiber[,]" D.I. 90 at 1.

Fifth, Pitt declares (i) that, based on his review of one patent that a BSC scientist obtained, "individuals at BSC recognized they could cover, the abluminal surfaces of serpentine rings of a bare metal stent with fibers" in 2006 and (ii) that another BSC patent publication—filed in 2007—describes a fiber "not dissimilar from the fiber that BSC has disposed on the abluminal surface of the stent in the SYNERGY family of products." D.I. 215-4 at PA0986–87. Further, Pitt asserts in his expert report that, "[i]n my opinion, the concepts explained in the [presentation that Nelson provided to Moynihan] are indistinguishable from the concepts set

forth the SYNERGY Developer's video . . . ." D.I. 215-4 at PA1023. Sixth, UT points to BSC's failure to secure an opinion of counsel regarding potential infringement or invalidity of the '296 patent and failure to bring any challenge to the patent. D.I. 214 at 23.

Unsurprisingly, UT's evidence did little to sway BSC. As to UT's allegation of pre-suit willfulness, BSC argues that UT cannot show BSC's knowledge of UT's technology, since the presentation relates to a peripheral—not a coronary—stent and because Moynihan does not "say that she actually read the patent." D.I. 220 at 17–18. Further, BSC asserts that UT offers no evidence that could connect Moynihan's "purported knowledge to either (1) any appreciation of infringement or (2) any actions taken by [BSC]." D.I. 220 at 18. Finally, BSC argues that "none of these activities have anything to do with actions by someone at [BSC] who knew of the '296 patent and knew of an infringement risk." D.I. 220 at 19.

The Court finds that a rational juror could credit UT's evidence, discredit BSC's evidence, and conclude that UT both knew of BSC's technology and intentionally persisted in its use prior to this lawsuit. *See ArcherDX, LLC v. QIAGEN Sciences, LLC*, 2022 WL 4597877, at *9 (D. Del. Sept. 30, 2022) ("The jury was entitled to assess credibility and infer willfulness from the evidence presented . . . ."). A rational juror could find that Moynihan and Ballinger opened and read Nelson's PowerPoint presentation based on Moynihan's statement that she and Ballinger "reviewed [Nelson's] material." D.I. 215-4 at PA1153. A rational juror also could find that the PowerPoint presentation's discussion of a stent that contained a "biodegradable polymer" with "[f]ully [t]unable [d]rug [d]elivery" and that mentioned by name the '296 patent was sufficient to put a reviewer on notice of the patented technology. D.I. 215-1 at PA00017, PA0020, PA0029–30. Next, a rational juror could credit Pitt's report that the concepts Nelson presented to Moynihan and Ballinger were "indistinguishable" from those in the Accused

Products. D.I. 215-4 at PA1023. Additionally, a rational juror could credit Pitt's and Chen's combined testimony to conclude that BSC was using this "indistinguishable" technology that met limitations specified in the '296 patent as early as 2006. *See* D.I. 215-1 at PA0091, PA0101–02; D.I. 215-4 at PA0986–87. Finally, since executives at BSC knew of the patented technology and since the patented technology was similar to the technology BSC was developing, testing, marketing, and (eventually) selling, a rational juror could infer that BSC acted despite the knowledge that it infringed. *See Extang Corp. v. Truck Accessories Grp., LLC*, 2022 WL 607868, at *3 (D. Del. Feb. 18, 2022) (finding that "the alleged many similarities between the parties' products" supported denial of summary judgment of no willfulness). BSC tellingly argues that, "given the remarkable differences between the peripheral, fully biodegradable stent technology in the presentation sent to Ms. Moynihan and the coronary, metal Synergy stent, no rational juror could [conclude] that Ms. Moynihan or anyone else would have appreciated any infringement risk and taken action with that knowledge." D.I. 220 at 19 (citations omitted). However, whether such differences were "substantial" is a fact question for the jury, not for the Court, to resolve.

As to post-suit willfulness, BSC argues that "[UT] cannot demonstrate any post-suit conduct that goes beyond typical alleged infringement . . . ." D.I. 220 at 20. As an initial matter, "willfulness requires a jury to find no more than deliberate or intentional infringement." *SRI Int'l*, 14 F.4th at 1330 (internal quotation marks and citation omitted). There is no dispute that, once the lawsuit was filed, BSC knew of the '296 patent. *See* D.I. 1 ¶ 26 (accusing BSC of infringement). The question for the Court is whether UT has proffered sufficient evidence to demonstrate *intentional* or *deliberate* infringement. While BSC has consistently denied that it infringed the '296 patent, *see* D.I. 1 ¶¶ 26–28; D.I. 40 ¶¶ 26–28, UT has proffered expert

testimony that the Accused Products and the '296 patent are quite similar, *see* D.I. 215-4 at PA1023, and can point to Chen's testimony to show that BSC recognized many of the elements of the patented technology that were present in the Accused Products, *see* D.I. 215-1 at PA0091, PA0101–02. Based on this evidence, "a rational juror could find BSC knew of the '296 patent . . . and knew it was coating stents with fibers that infringed the '296 patent claims" and continued to do so anyway. D.I. 214 at 23.[3]

In summary, UT has advanced evidence sufficient for a rational juror to conclude that both before and after this suit was filed, BSC knew about and intentionally infringed the technology in the '296 patent. The Court is skeptical that UT has promulgated evidence sufficient to support enhanced damages, but "the concept of willfulness requires a jury to find no more than deliberate or intentional infringement." *SRI Int'l*, 14 F.4th at 1330 (internal quotation marks and citation omitted); *see id.* ("Although willfulness is a component of enhancement, 'an award of enhanced damages does not necessarily flow from a willfulness finding.'" (citation omitted)).

Therefore, the Court denies BSC's motion for summary judgment of no willfulness. No later than October 21, 2022, the parties shall meet and confer to determine whether to bifurcate infringement and invalidity from damages and willfulness and try this case in two phases to a

[3] UT's evidence of post-suit willfulness is limited. For example, the Court agrees with BSC, D.I. 220 at 20, that the failure to get an opinion of counsel is not evidence of willful infringement. *See* 35 U.S.C. § 298 ("The failure of an infringer to obtain the advice of counsel with respect to any allegedly infringed patent . . . may not be used to prove that the accused infringer willfully infringed the patent . . . ."). Further, BSC was (and is) under no obligation to challenge the '296 patent's validity, since BSC may (and, based on its assertions before this Court, does) believe that it has not infringed. Finally, UT failed to distinguish between its evidence in support of pre-suit and post-suit willfulness; while UT's evidence appeared directed primarily at pre-suit conduct, *see, e.g.*, D.I. 214 at 23 ("BSC knew of the '296 patent since 2009 . . . ."), BSC does not argue for waiver, D.I. 220 at 20, and the Court need not rule on that issue.

single jury. The Court recognizes the potential value of bifurcation where, as here, the issue of willfulness is close at summary judgment. The Court instructs the parties to consider what evidence may be limited to a willfulness/damages phase. After the parties meet and confer, either party may file—no later than October 31, 2022 and consistent with Local Rule 7.1.2—a motion to bifurcate that describes what evidence should be limited to a willfulness/damages phase.

III. CONCLUSION

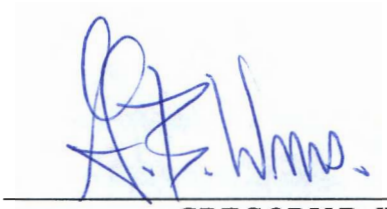
The Court finds that the parties have genuine disputes of material fact as to whether the Accused Products contain a fiber, two immiscible phases, and a discrete drug-containing region. The Court also finds that the parties have a genuine dispute of material fact as to whether BSC's infringement, if it occurred, was willful. Therefore, the Court denies both of BSC's motions for summary judgment.

WHEREFORE, at Wilmington this 6th day of October, 2022, **IT IS HEREBY ORDERED** that:

1. BSC's Motion for Summary Judgment of Noninfringement (D.I. 198) is **DENIED**;
2. BSC's Motion for Summary Judgment of No Willful Infringement (D.I. 197) is **DENIED**;
3. Trial in this case is rescheduled for the 25th, 26th, 27th, 30th, and 31st of January, 2023, and the pre-trial conference is rescheduled for January 12, 2023, at 3:00 PM;
4. The parties shall appear on November 7, 2022 at 4:00 PM for a claim construction hearing as to the term "polymer fiber." Each party is allocated up to thirty (30) minutes for its arguments;

5. The parties shall submit a joint claim construction brief in the form and based on the schedule discussed herein; and

6. The parties shall meet and confer no later than October 21, 2022 on the issue of whether to bifurcate the trial and may file a motion to bifurcate no later than October 31, 2022.



GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE