

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

BOARD OF REGENTS, THE UNIVERSITY
OF TEXAS SYSTEMS, and TISSUEGEN,
INC.,

Plaintiffs,

v.

BOSTON SCIENTIFIC CORPORATION,

Defendant.

C.A. No. 18-392

Stamatios Stamoulis, STAMOULIS & WEINBLATT LLC, Wilmington, DE; Michael W. Shore, Chijioke E. Offor, Alex Q. Jacobs, THE SHORE FIRM, Dallas, Texas; Brian D. Melton, John P. Lahad, Corey M. Lipschutz, SUSMAN GODFREY L.L.P, Houston, Texas


Counsel for Plaintiffs

Brian E. Farnan, Michael J. Farnan, FARNAN LLP, Wilmington, DE; Michael P. Kahn, AKIN GUMP STRAUSS HAUER & FELD LLP, New York, NY; Rachel J. Elsby, AKIN GUMP STRAUSS HAUER & FELD LLP, Washington D.C; Chad Drown, Timothy E. Grimsrud, Katherine S. Razavi, Lauren J.F. Barta, Doowon R. Chung, N. Chethana Perera, FAEGRE DRINKER BIDDLE & REATH LLP, Minneapolis, MN; David J.F. Gross, FAEGRE DRINKER BIDDLE & REATH LLP, East Palo Alto, CA; Evan J. Kline-Wedeen, FAEGRE DRINKER BIDDLE & REATH LLP, Chicago, Illinois; Christopher J. Burrell, FAEGRE DRINKER BIDDLE & REATH LLP, Washington, D.C.

Counsel for Defendant

MEMORANDUM OPINION

June 5, 2024
Wilmington, Delaware


GREGORY B. WILLIAMS
U.S. DISTRICT JUDGE

After a bifurcated trial, the jury returned a verdict for Plaintiffs Board of Regents, the University of Texas Systems, and Tissuegen, Inc. (collectively, “Plaintiffs”), against Defendant Boston Scientific (“Defendant”). D.I. 332; D.I. 334. The jury found that Defendant directly and indirectly infringed U.S. Patent No. 6,596,296 (the “’296 patent”) and awarded Plaintiffs \$42 million in damages. *Id.* The jury also found that Defendant’s infringement was willful. *Id.* Now pending before the Court are Defendant’s Motions for a New Trial and Judgment as a Matter of Law (D.I. 345) and Plaintiffs’ Motion for Enhanced Damages and Pre- and Post-Judgment Interest (D.I. 349). Having reviewed the motions and all relevant briefing, the Court finds that: (1) Defendant’s Motion for a New Trial is DENIED; (2) Defendant’s Motion for Judgment as a Matter of Law is GRANTED as to willful infringement and is otherwise DENIED; (3) Plaintiffs’ Motion for Enhanced Damages is DENIED; (4) Plaintiffs’ Motion for Pre-Judgment Interest is GRANTED in the amount of \$7,436,328; and (5) Plaintiffs’ Motion for Post-Judgment Interest is GRANTED at a rate of 4.87% computed daily and compounded annually.

1. INTRODUCTION

On November 20, 2017, Plaintiffs initiated this litigation against Defendant alleging, among other things, infringement of the ’296 patent. D.I. 1. The ’296 patent, titled “Drug Releasing Biodegradable Fiber Implant” claims a biodegradable fiber format that can be used in the delivery of drugs. According to Plaintiffs, Defendant infringed the ’296 patent by producing and selling Synergy™ stents which, like Plaintiffs’ patented technology, utilized a biodegradable

polymer fiber to deliver drugs. D.I. 124, ¶¶ 65-66, 80. Plaintiffs asserted claims against Defendant for direct and induced infringement of claims 1, 11, 17, and 26 of the '296 patent (hereinafter, the "Asserted Claims"). *Id.* at ¶ 79. In response, Defendant alleged that one or more of the asserted claims of the '296 patent is invalid. D.I. 238 at 24-25.

On December 12, 2022, the Court issued an order to bifurcate trial into two phases. D.I. 260. Following the first phase of trial, the jury ruled in favor of Plaintiffs on infringement of the '296 patent and denied Defendant's claims of invalidity. D.I. 331. After phase two, the jury found for Plaintiffs on their claims that Defendants induced infringement of the '296 patent and that Defendant's infringement of Plaintiffs' patented technology was willful. D.I. 333. Finally, the jury found that Defendant's infringement entitled Plaintiffs to reasonable royalty damages totaling \$42 million. *Id.* at 4. Judgment was entered on February 15, 2023. D.I. 342.

Defendant now moves for a new trial under Rule 59(a) on the grounds that Plaintiffs engaged in improper conduct during their opening statements, introduced improper evidence and argument throughout the trial, and invited the jury to render a verdict based on improper considerations during closing. D.I. 345. Defendant also moves for judgment as a matter of law under Rule 50(b) on the grounds that the Asserted Claims are anticipated and lack written description as a matter of law; no reasonable jury could have found infringement based on the Court's constructions of "fiber" and "immiscible;" Plaintiffs failed to present sufficient evidence to support their damages theory; and no reasonable jury could have found willful infringement. *Id.*

Given the jury's finding of willful infringement, Plaintiffs seek enhancement of the jury's damages award under 35 U.S.C. § 284. D.I. 350. Additionally, Plaintiffs seek pre-judgment interest pursuant to the "de facto rule" of federal courts and post-judgment interest under 28

U.S.C. § 1961. *Id.* at 1. Defendant opposes Plaintiffs' motion for enhanced damages and contends that Plaintiffs' request for pre-judgment interest should be denied as premature or, alternatively, reduced. D.I. 355 at 2.

2. LEGAL STANDARD

a. Judgment as a Matter of Law

A court may enter JMOL against the non-moving party where it “finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on [an] issue.” FED. R. CIV. P. 50(a)(1). However, JMOL is appropriate “only if, viewing the evidence in the light most favorable to the nonmovant and giving it the advantage of every fair and reasonable inference, there is insufficient evidence from which a jury reasonably could find liability.” *Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1166 (3d Cir. 1993). Entry of JMOL is a remedy to be invoked only “sparingly.” *CGB Occupational Therapy, Inc. v. RHA Health Servs. Inc.*, 357 F.3d 375, 383 (3d Cir. 2004).

Following a jury trial, a renewed motion for JMOL under Rule 50(b) may be granted only if the movant demonstrates “that the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusion(s) implied [by] the jury's verdict cannot in law be supported by those findings.” *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1348 (Fed. Cir. 1998) (alteration in original) (internal quotation marks omitted). Substantial evidence requires such relevant evidence that a reasonable mind might accept it as adequate to support the finding under review. *See Enplas Display Device Corp. v. Seoul Semiconductor Co.*, 909 F.3d 398, 407 (Fed. Cir. 2018). In determining whether substantial evidence supports the jury verdict, the Court cannot make credibility determinations, weigh the evidence, or substitute its own conclusions for that of the jury where the record evidence supports multiple inferences. *See*

Lightning Lube, 4 F.3d at 1166. The standards that govern a Rule 50(b) motion, however, “vary according to whether the movant has the burden of proof.” *Fireman’s Fund Ins. Co. v. Videofreeze Corp.*, 540 F.2d 1171, 1177 (3d Cir. 1976).

To grant JMOL in favor of a party with the burden of proof, the court “must be able to say not only that there is sufficient evidence to support the finding [sought by the moving party] ... but additionally that there is insufficient evidence for permitting any different finding.” *Id.* (quoting 9 WIGMORE ON EVIDENCE § 2495 at 306 (3d ed. 1940)); *see also Amgen Inc. v. Hospira, Inc.*, 944 F.3d 1327, 1333 (Fed. Cir. 2019) (“[W]here the movant bears the burden of proof on an issue, JMOL is only granted where ‘there is insufficient evidence for permitting any different finding.’” (quoting *Fireman’s Fund*, 540 F.2d at 1177)); *Deere & Co. v. Agco Corp. et al*, C.A. No. 18-827-CFC, 659 F.Supp.3d 418 (D. Del. March 28, 2023).

b. Motion for New Trial

Under Fed. R. Civ. P. 59, “a new trial should only be granted when a ‘miscarriage of justice would result if the verdict were to stand,’ the verdict ‘cries out to be overturned,’ or the verdict ‘shocks the conscience.’” *Roche Diagnostics Corp. v. Meso Scale Diagnostics, LLC*, 503 F. Supp. 3d 156, 166 (D. Del. 2020); *see also Intellectual Ventures I, LLC v. Canon Inc.*, 104 F. Supp. 3d 629, 637 (D. Del. 2015) (“[T]he court should grant a new trial on the basis that the verdict was against the weight of the evidence only where a miscarriage of justice would result if the verdict were to stand.”).

3. DISCUSSION

For the reasons stated below, the Court (1) grants Defendant’s motion for judgment as a matter of law as to willfulness and denies Defendant’s motion for judgment as a matter of law as

to invalidity, infringement, and damages; (2) denies Defendant's motion for a new trial; (3) denies Plaintiffs' motion for enhanced damages; and (4) grants Plaintiffs' motion for pre- and post-judgment interest.

a. Judgment As a Matter of Law

- i. *Defendant is not entitled to JMOL on the issue of whether Song anticipates the asserted claims.*

Defendant contends that Song anticipates the asserted claims, and "there is no record evidence that supports the jury's finding otherwise." D.I. 364 at 12. For the following reasons, the Court disagrees.

"A single prior art reference anticipates a patent claim if it expressly or inherently describes each and every limitation set forth in the patent claim." *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed. Cir. 2002). While a single reference may expressly anticipate a claim where the reference explicitly discloses each and every claim limitation, the prior art need not be ipsissimis verbis (i.e., use identical words as those recited in the claims) to be expressly anticipating. *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716 (Fed.Cir.1984). "Instead, a reference may still anticipate if that reference teaches that the disclosed components or functionalities may be combined and one of skill in the art would be able to implement the combination." *Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1344 (Fed. Cir. 2016) (finding that "the reference anticipated the claims even without a particular disclosure of the specific combination recited in the disputed claims.").

The '296 patent claims "biodegradable polymer fibers capable of controlled delivery of therapeutic agents." '296 patent, Abstract. Claim 1 of the '296 patent, the only independent claim asserted by Plaintiffs, discloses "[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.” ’296 patent, claim 1. Song similarly describes “delivery systems for the gradual release of active agents and processes for making such systems and is particularly directed to delivery systems using heat sensitive active agents with biodegradable polymers and melt spinning processes for making such systems.” D.I. 347, Ex. 6 (hereinafter, “Song”), Abstract.

According to Defendant, Song anticipates claim 1 of the ’296 patent by “disclos[ing] that its ‘invention is a fiber having a support matrix’ [], ‘made up of wall material’ [] that ‘can be any spinnable synthetic or natural polymer’ [], including ‘biodegradable polymers’[]” and an “active agent [that] is dispersed throughout the support matrix.” D.I. 346 at 12-13 (internal citations omitted). Defendant notes that, just like claim 1, Song also asserts that “[t]he active agent and wall material . . . must be immiscible with each other.” *Id.* (internal citations omitted).

Plaintiffs, on the other hand, argue that claim 1 is not anticipated because “Song fails to disclose [the limitations of claim 1] **together in an enabled embodiment where the second phase is noncontiguous** (i.e., is composed of discrete regions) as claimed in the ’296 patent.” D.I. 354 at 6 (emphasis added). Specifically, Plaintiffs argue that “Song lacks any example of an embodiment involving a biodegradable polymer with drug in a noncontiguous phase.” *Id.* Plaintiffs also contend that “biodegradability” has a different meaning in Song than it does in the ’296 patent. Each argument is considered in turn below.

1. *Plaintiffs' Enablement Claims:*

According to Plaintiffs, the "'296 patent requires drug in a noncontiguous phase (i.e. discrete drug-containing regions) within a biodegradable polymer fiber." D.I. 354 at 6. During trial, Plaintiffs' expert, Dr. Pitt, testified that the asserted claims of the '296 patent disclose a fiber with discrete drug-containing regions dispersed throughout the fiber. *See* Tr. 900:2-901:12. Dr. Pitt explained that Song, on the other hand, does not disclose a fiber with discrete regions but instead "teaches that you have contiguous channels." *Id.* at 898:13-899:3. According to Dr. Pitt,

Contiguous means that you've got these regions that are touching each other, stretching out the length of this fiber, and when there's contact with the solution, which is water or saliva, this stuff just starts to dissolve and go out the ends. So that's not a discrete region."

Id. at 900:10-15. Because Song teaches a fiber with contiguous channels, Dr. Pitt noted that Song and the '296 patent disclosed fibers that differ in the way each releases drug particles. *Id.* at 901:3-8. Specifically, Dr. Pitt argued that Song delivers drugs from the fiber's "front end and [] back end" whereas, in the '296 patent, "you have a fiber, and it's biodegrading, and the drug is coming out in the radial direction instead of going out the ends. *Id.* Thus, according to Dr. Pitt, because Song does not disclose a biodegradable polymer with a non-contiguous drug phase, Song cannot anticipate the asserted claims. *Id.* at 901:9-12. Plaintiffs raise the same argument in response to Defendant's renewed motion for JMOL. *See* D.I. 354 at 5-6 (arguing that anticipation cannot be proven because "Song lacks any example of an embodiment involving a biodegradable polymer with drug in a noncontiguous phase").

According to Defendant, Dr. Pitt's testimony regarding the noncontiguous drug phases in the '296 patent cannot be used to distinguish the asserted claims from Song because the asserted

claims do not require that the fiber include drug-containing channels that are noncontiguous or discrete. D.I. 363 at 1-2. Thus, according to Defendant, Plaintiffs erred by introducing testimony on a feature not required by the claims. D.I. 363 at 2. The Court agrees.

Anticipation challenges “focus only on the limitations **actually recited in the claims.**” *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245, 1252-54 (Fed. Cir. 2014) (finding that asserted patent where “[b]oth the district court and DDR introduced a limitation found neither in the ’572 patent’s claims nor the parties’ stipulated construction.”) (emphasis added). “It is the claims that define the claimed invention[,] [a]nd it is claims, not specifications, that are anticipated.” *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1570-71 (Fed. Cir. 1988), *cert. denied*, 465 U.S. 1026, 104 S.Ct. 1284, 79 L.Ed.2d 687 (1984) (“A claim is anticipated only if each and every element **as set forth in the claim** is found, either expressly or inherently described, in a single prior art reference.”). Accordingly, a patentee cannot “avoid [an] anticipating disclosure” by “engage[ing] in a *post hoc* attempt to redefine the claimed invention by impermissibly incorporating language appearing in the specification into the claims.” *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994). While “it is entirely proper to use the specification to interpret what the patentee meant by a word or phrase in the claim,” the patentee cannot rely on “extraneous limitation appearing in the specification” *Id.* (internal quotations omitted). “[B]y ‘extraneous,’ the Federal Circuit meant ‘a limitation read into a claim from the specification wholly apart from any need to interpret ... particular words or phrases in the claim.’” *Id.* (internal quotations omitted).

In this matter, there is no dispute that claim 1 of the ’296 patent does not explicitly recite a fiber with “noncontiguous” phases and does not assert “dispersed discrete regions that release the drug.” Additionally, Plaintiffs did not allege that any terms in claim 1 of the ’296 patent

required a construction that would read the “noncontiguous” phase requirement into the claim, and the Court never adopted a construction requiring such a limitation. Thus, to the extent that Plaintiffs inject the “noncontiguous” phase limitation into the asserted claims from the specification’s description of the invention, the Court agrees with Defendant that the limitation cannot be used to differentiate the asserted claims from the prior art. D.I. 346, n. 2; *MobileMedia Ideas v. Apple*, 780 F.3d 1159, 1172 (Fed. Cir. 2015).

Because, as explained in more detail below, Defendant cannot challenge Plaintiffs’ arguments differentiating “biodegradable” polymers as asserted in the ’296 patent from “biodegradable” polymers in Song, Defendant is not entitled to JMOL on the issue of anticipation.

2. Plaintiffs’ Arguments on “Biodegradability”:

During his trial testimony, Dr. Pitt testified that Song also failed to anticipate the asserted claims because Song did not cover “biodegradable” polymers as asserted in the ’296 patent. Tr. 898: 5-11. According to Dr. Pitt, “even though biodegradable polymers are mentioned in passing [in Song],” Song is not “directed to biodegradability in the same manner as the ’296 patent.” *Id.* at 898:13-899:3. In making this argument, Dr. Pitt construed “biodegradable,” as used in the ’296 patent, to mean that the asserted fiber must “biodegrade [in order] to release the [drug] agent.” *Id.* at 899:2. Defendant contends that this testimony should be disregarded because: (1) Dr. Pitt “conceded that Song anticipates the asserted claims,” and (2) Dr. Pitt’s testimony improperly construed the term “biodegradable.” D.I. 346 at 13-14; D.I. 363 at n. 5. For the following reasons, the Court finds neither argument persuasive.

First, while Dr. Pitt testified that “claim 1 talks about a biodegradable polymer . . . [not] taught in Song,” Defendant argues that Dr. Pitt “later *recanted* that testimony after being impeached by his prior deposition testimony.” D.I. 346 at 13 (emphasis added). Specifically, Defendant highlighted during trial Dr. Pitt’s deposition testimony in which he explained that “one of [Song’s] examples is using a biodegradable polymer, and the second phase is solely and only the therapeutic agent.” Tr. 911:17-19. Defendant noted that Dr. Pitt also testified during his deposition that the second phase disclosed by the Song example “is [an] active agent [and] is immiscible with the [first] phase that is the wall material” and noted that the first phase, in turn, “is the polymer, and in some cases that could be biodegradable.” *Id.* at 912:17-23, 913:24-914:9. When faced with this deposition testimony during cross-examination, Dr. Pitt admitted to each statement and confirmed that he had no “problem with the jury relying on [his] sworn [deposition] answers.” *Id.* at 914:19-22. Thus, Defendant argues that Dr. Pitt “did not contradict” Defendant’s evidence of anticipation “on cross-examination or otherwise,” but instead admitted once more that Song discloses each limitation of the asserted claims. D.I. 346 at 13-14.

Dr. Pitt, however, *did* present testimony that countered Defendant’s anticipation claims by testifying during trial that, among other things, Song is not “directed to biodegradability in the same manner as the ’296 patent.” Tr. 899:4-6; *see also id.* at 897:24-899:3. While Defendant argues that Dr. Pitt “later recanted th[is] testimony on cross-examination,” Defendant cites an exchange in which counsel for Defendant sought to impeach Dr. Pitt by confronting him with his prior deposition testimony. D.I. 346 at 12 (citing Tr. 911:10-21, 912:16-23, 913:22-914:9). In seeking to impeach Dr. Pitt, however, Defendant asked whether Dr. Pitt was “asked [certain] question[s] and . . . g[a]ve [certain] answer[s] at your deposition” and limited Dr. Pitt’s response

by noting that “it’s really important right now that [Dr. Pitt] not inject anything new without approval from people.” Tr. 910:18-20, 911:10-11, 912:11-12, 912:16-17, 913:22-23. Thereafter, Dr. Pitt merely admitted to making certain statements during his deposition. *See, e.g.*, 911:20-21 (Q: “Did you give that testimony” A: Yes.”).

While Dr. Pitt also noted that the jury could rely on his deposition testimony, at no point did Dr. Pitt retract his prior inconsistent trial testimony. *See id.* at 914:19-22. For instance, Defendant cannot identify any testimony in which Dr. Pitt adopted his deposition testimony or alleged that his trial testimony was inaccurate. Indeed, Dr. Pitt was not asked whether he still agreed with his deposition testimony, and Defendant also did not permit Dr. Pitt to explain the discrepancies, if any, between his description of Song during his deposition and during trial. Thus, the Court agrees with Plaintiffs that Dr. Pitt did not concede his prior admissions, and the jury was entitled to “assess[] credibility” and disregard any or all of Dr. Pitt’s prior deposition testimony in favor of his testimony at trial. D.I. 354 at 6-7.

Second, Defendant argues that Dr. Pitt’s testimony on biodegradability should be disregarded because “the Court did not construe ‘biodegradable.’” D.I. 363, n. 5. According to Defendant, because claim construction is a question of law, “[w]hether a polymer ‘breaks down chemically and mechanically’ is [] irrelevant” and should be disregarded for purposes of determining anticipation. *Id.* While the Court notes that it is generally “improper for an expert witness to testify before the jury regarding claim construction when a claim has been construed by the Court,” “[t]here is no requirement that every term appearing in the claims must be specifically defined or used in the specification.” *Cirba Inc. v. VMware, Inc.*, No. CV 19-742-LPS, 2020 WL 5910112, at *8 (D. Del. Oct. 6, 2020) (internal citations omitted). Moreover, Defendant did not object to Dr. Pitt’s testimony on “biodegradability” during trial. By failing to

object to Dr. Pitt's construction of a claim term, Defendant "waived any challenge to the jury's finding of [no anticipation] based on this testimony." *See ATEN Int'l Co. v. Uniclass Tech. Co.*, 932 F.3d 1364, 1370 (Fed. Cir. 2019). Therefore, Defendant cannot claim that Dr. Pitt's construction of "biodegradable" was improper. *See id.* ("By failing to object, ATEN has waived any challenge to the jury's finding of infringement based on this testimony.").

Given the above—and because Defendant carried the burden of proof on anticipation—the Court cannot find that "there is insufficient evidence for permitting any finding" but JMOL. *See Amgen Inc. v. Hospira, Inc.*, 944 F.3d 1327, 1333 (Fed. Cir. 2019) (internal citations omitted). Defendant's motion for JMOL on anticipation is therefore DENIED.

ii. *Defendant is not entitled to JMOL on the issue of whether the Asserted Claims lack written description.*

In deciding a written description challenge to a patent, "[t]he primary consideration is factual and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure." *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976) (emphasis added). Where a jury decides the issue of written description, the Court may only review the jury's factual findings for substantial evidence. *See B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1423, 43 USPQ2d 1896, 1899 (Fed.Cir.1997).

Defendant argues that the claims lack written description support because the specification does not describe a fiber with two immiscible phases. D.I. 346 at 14; *see* '296 patent, claim 1 ("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...*") (emphasis added). Plaintiffs disagree and argue that the examples in the specification necessarily disclose the fabrication of fibers with the required immiscible phases.

D.I. 354 at 7. In response, Defendant contends that those examples do not provide written description support because the claimed phases must be immiscible in the fiber and those examples merely discuss whether the substances used to create the fiber are miscible. D.I. 363 at 3. Thus, Defendant argues that Plaintiffs have failed to show that the inventor was in possession of a fiber that contains two immiscible phases as of the filing date of the '296 patent. D.I. 346 at 14 (citing *Ariad Pharm. V. Eli Lilly*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc)). The Court disagrees.

Specifically, the Court finds that Plaintiffs presented sufficient evidence at trial to show that the specification discloses a fiber with two immiscible phases. Mr. Nelson, one inventor of the '296 patent, testified about the process of creating the fibers claimed in the '296 patent. Tr. 194:25-198:10. Mr. Nelson explained that, at a high level, the claimed fibers can be created using an emulsion of two solutions: an oily solution that consists of a polymer dissolved in an oily solvent, and a water solution that consists of water, a drug, and a stabilizing molecule. *Id.* According to Mr. Nelson, the emulsion is then extruded through a coagulating bath that extracts the oily solvent and leaves “a solidified polymer that had now trapped inside it these dispersed, discreet drug-loaded sites.” *Id.* at 197:8-21.

A reasonable juror could conclude that Mr. Nelson’s testimony describes a fiber with two immiscible phases, given Mr. Nelson’s testimony that the extrusion process results in a “polymer” (the first phase) that contains “dispersed, discreet drug loaded sites” (the second phase) *See* D.I. 90 at 1 (construing “first phase” as “the polymer portion of the fiber” and “second phase” as “the discrete drug-containing regions dispersed throughout the fiber”). A reasonable juror could also conclude that Mr. Nelson’s high-level explanation of the fiber-making process is disclosed in the specification, because Example 1 of the '296 patent mirrors

Mr. Nelson's testimony. '296 patent, 17:40-19:35, *see also id.* at 18:23-18:28 ("Because solvent (A) is highly miscible with coagulating bath solvent (B), it freely diffuses from the polymer solution stream, into the coagulating bath. The polymer, however, is not soluble in solvent (B), and therefore begins to precipitate upon itself, forming the outer sheath of a fiber and trapping virtually all of the dispersed aqueous phase of the emulsion within the forming fiber. In this way, the fiber is loaded with the drug or protein of interest."). Mr. Nelson's testimony was supported by Dr. Pitt who similarly explained that Examples 1, 4, and 15 disclose fabrication of a fiber with a first and second immiscible phase. Tr. 890:1-19, 891:6-22, 892:17-893:17.¹

Given the above, the Court finds that the jury's verdict was supported by "substantial evidence." *See B. Braun Med.*, 124 F.3d at 1423. Accordingly, the Court DENIES Defendant's motion for a new trial or JMOL regarding whether the claims of the '296 patent lack written description.

iii. *Plaintiffs presented sufficient evidence that the Synergy™ stent is a "fiber."*

Defendant argues that no reasonable jury could find that Defendant infringed the asserted claims because, (1) "[a]t trial, [], Plaintiffs employed their own unique constructions of 'fiber,' and otherwise relied on evidence unrelated to Synergy and therefore not relevant to infringement," and (2) "[Dr.] Pitt admitted that he never provided an opinion that the Synergy coating is thread-like[.]" D.I. 346 at 15-16 (cleaned up). For the following reasons, the Court disagrees with each of Defendant's arguments in support of JMOL.

As to Defendant's claim that Plaintiffs employed an improper construction of "fiber," Defendant highlights testimony from Dr. Pitt in which he distinguished between a film-like

¹ The Court agrees with Defendants that Dr. Pitt's description of example 5 does not describe a fiber with two immiscible phases because the second phase is outside of the fiber. *See* '296 patent at 21:1-22-15.

polymer and a fiber polymer. D.I. 346 at 16 (citing Tr. 615:3-6). This testimony was given after Defendant asked Dr. Pitt whether “the BSC coating is film-like.” Tr. 625:14-16. Dr. Pitt responded that it was not film-like “[b]ecause it has a long shape. It’s much longer than it is thick or wide, so that’s the definition of a fiber.” *Id.* at 625:23-626:4. However, during *Markman*, the Court construed the term “fiber” “as taking its plain and ordinary meaning to a person of ordinary skill in the art, which is a ‘thread-like structure of any length or shape.’” D.I. 256 (emphasis added). Defendant argues that, in doing so, the Court rejected Plaintiffs’ argument that “a ‘fiber’ is something with more length than width.” D.I. 346 at 16. Thus, according to Defendant, Plaintiffs erred by permitting Dr. Pitt to introduce a definition of “fiber” that, inconsistent with the Court’s construction, referenced the “rejected length-to-width characterization.” *Id.*

Typically, once the Court construes a term, “that legal determination governs for purposes of trial[,] [and] [n]o party may contradict the court’s construction to a jury.” *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1321 (Fed. Cir. 2009). Moreover, “[w]here an infringement verdict relies on incorrect construction of the disputed claim terms, this court may grant JMOL, or order a new trial to correct the error, depending on the degree of difference between the incorrect construction and the correct construction.” *Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1333 (Fed. Cir. 2008). In this matter, however, the Court is not persuaded that Dr. Pitt injected a new construction of the term “fiber.” Rather, the Court agrees with Plaintiffs that, when Dr. Pitt denied that BSC coating was film-like, he was merely “opin[ing] that the polymer structures [] satisfied the fiber limitation, [because] they were threadlike structures.” D.I. 354 at 10. Given that witnesses representing both parties testified to the

correlation between “thread-like” and the “length-to-width ratio,” the Court finds Plaintiffs’ argument to be most supported by the record.

Indeed, throughout his trial testimony, Dr. Pitt explained that the “length-to-width ratio characterization” is relevant to determining whether a fiber is “thread-like.” In describing how one determines whether a fiber is “thread-like,” for instance, Dr. Pitt cited testimony from Defendant’s Vice President of Clinical, Dr. Allocco, noting that “one thing that goes into the determination of whether a fiber is ‘thread-like’ is the presence of a ‘large aspect ratio’ as to the length and width of the polymer fiber.” Tr. 595:7-16; *see also id.* at 351:5-13 (Allocco testimony noting same). Dr. Pitt agreed with Dr. Allocco and adopted Dr. Allocco’s definition of “thread-like” to support his expert opinions. *Id.* at 595:11-16.

Further, Plaintiffs, “as [the] verdict winner[s],” must be given “the benefit of all logical inferences that could be drawn from the evidence presented” and must have “all conflicts in the evidence [resolved] in [their] favor.” *See Williamson v. Consol. Rail Corp.*, 926 F.2d 1344, 1348 (3d Cir. 1991). Thus, while Dr. Pitt later testified that the “definition of fiber” required a “long shape,” the Court will assume that the testimony highlighted by Defendant was not an attempt by Dr. Pitt or Plaintiffs to contradict the Court’s construction of “fiber,” given Dr. Pitt’s prior testimony associating the length-to-width ratio with “thread-like.”

Defendant argues, however, that even Dr. Pitt’s testimony describing “thread-like” as having a “large length and width ratio” is inconsistent with the Court’s *Markman* opinion. D.I. 346 at 16. Specifically, Defendant contends that the length and width limitation contradicts the Court’s finding that a fiber can have any length and width. *Id.* In construing the term “fiber,” however, the Court held that fiber could be “any length or width” in response to claims by Plaintiffs that “fiber” required “[a] volume of matter having a small cross section and a length at

least 100 times greater than its width or diameter[.]” D.I. 255 at 7 (citing D.I. 245 at 5). The Court rejected this argument and explained that it would not read a particular size or length requirement into the construction of “fiber” by requiring a specified minimum ratio. *Id.* at 12. As the Court noted, intrinsic evidence showed that the fiber could have a length that was not “at least 100 times greater than its width or diameter.” *Id.* For instance, “Figures 1, 2, and 3a [of the ’296 patent] display fibers of varying lengths.” *Id.* Thus, the Court held that “a construction that limits a fiber to a *particular . . . length* would be inconsistent” with the patent. *Id.* (citing ’296 patent at figs. 1, 2, 3a) (emphasis added). In doing so, the Court did not reject the argument that the length of a fiber would be longer than its width for the fiber to be “thread-like.” Accordingly, Dr. Pitt’s description of a “thread-like” fiber during trial does not warrant JMOL.

Defendant also contends that JMOL is warranted because “Plaintiffs failed to compare the actual features of ‘the accused device’ to the asserted claims,” choosing instead to raise several unrelated and improper infringement arguments. D.I. 346 at 16. For instance, Defendant claims that Plaintiffs improperly relied “on irrelevant Strickler and Weber applications—not the accused product— . . . to prove infringement.” *Id.* In response, Plaintiffs contend that the Strickler and Weber applications were introduced as “party opponent admissions as to what Defendant considered to be a polymer fiber before litigation.” D.I. 354 at 11. The Court agrees. In introducing the Weber application, Plaintiffs asked Dr. Pitt to highlight “what [Boston Scientific] describ[ed] as a fiber in the Weber application.” Tr. 603:12-13. Plaintiffs solicited similar testimony from Dr. Pitt regarding Strickler and explained that the testimony would “inform [the jury] as to what Boston Scientific, in a non-litigation context, referred to as a fiber.” *Id.* at 599:22-24, 601:5-6. During cross-examination, Defendant countered Dr. Pitt’s testimony by noting that the applications were “obviously not at issue in this case,” and Dr. Pitt agreed. *Id.*

at 638:6-9. Defendant's experts similarly testified that Strickler and Weber were not relevant to the accused products. *Id.* at 738:1-739:23. Considering this testimony and the totality of the circumstances, the Court does not believe that the jury was misled into relying on the Strickler and Weber applications over the accused products.

Defendant next argues that "Plaintiffs relied on evidence related to the 'shape' of a hypothetical 'particulate' that could break off from the Synergy coating, which has no bearing on whether the actual Synergy coating constitutes a fiber." D.I. 346 at 16. Yet, the Court agrees with Plaintiffs that nothing in the Court's claim construction prevented the jury from finding that the coating—"the polymer around the outside surface of the [] SYNERGY stent"—was a fiber. D.I. 354 at 11. Thus, the Court finds no support for Defendant's claim that the shape of the "particulate" had "no bearing on whether the actual Synergy coating constitutes a fiber." D.I. 346 at 16.

Defendant also contends that Plaintiffs "relied on mock-ups of 'what the polymer fiber *might look like* if it was removed from the Synergy stent[]" but failed to prove that "the unadulterated Synergy coating has a 'thread-like' structure." *Id.* at 16-17 (emphasis in original). While Defendant claims that Plaintiffs, through Dr. Pitt, "cut the models into pieces that he described as 'thread-like' shapes," *id.*, Dr. Pitt cut across a connector to access the fiber covering one serpentine loop around the stent and, in viewing the "scale model[] of one serpentine loop," found that the fiber met the characteristics of a "thread-like" fiber. Tr. 598:17-22. As Plaintiffs note, Dr. Pitt introduced the model as a demonstrative "during witness testimony to help the jury visualize admitted evidence—namely the dimensions and aspect ratios of the accused polymer structures." D.I. 354 at 12. Further, because Defendant does not claim that the model did not represent an accurate or full piece of fiber taken from a serpentine loop in a Synergy™ stent, the

Court disagrees with Defendant's description of the model as "altered." D.I. 346 at 17. Here again, while Defendant claims that Dr. Pitt failed to prove whether an unadulterated Synergy™ coating would constitute a "thread-like" structure, Defendant identifies no reason why the fiber would lose its "thread-like" properties merely when connected to the serpentine loop. *Cf. Drexelbrook Controls v. Endress-Hauser*, 989 F.2d 1201, *3 (Fed. Cir. 1993) (overturning rejection of JMOL where expert relied on "altered version of the accused product *with the rivet removed*") (emphasis added).

Finally, Defendant argues that "Plaintiffs presented only conclusory assertions by Pitt that the coating [of the accused product] is 'thread-like.'" D.I. 346 at 17 (internal citations omitted). Yet, Dr. Pitt testified extensively about his findings regarding the length, width, and height of the polymer around each ring of the Synergy™ stent and why the properties met the characteristics of a "thread-like" structure. Tr. 553:4-556:23. The Court agrees with Plaintiffs that Dr. Pitt showed that he "determined that each abluminal polymer structure adhered around the outside of a given ring of a Synergy™ stent was (1) three dimensional, (2) continuous, and had (3) a ratio of length to width greater than 160:1." D.I. 354 at 10 (internal citations omitted). Further, Plaintiffs introduced FDA documents in which Defendant described detached polymer particulates as "fibers" and "ribbon-like." Tr. 554:2-555:5. From these documents alone, the jury had sufficient reason to find that the Synergy™ stent includes a fiber. Therefore, the Court disagrees with Defendant's claim that such a finding by the jury was not supported by sufficient evidence. Accordingly, Defendant's motion for JMOL of no infringement for failure to show that the accused products contain a fiber is DENIED.

iv. *Plaintiffs presented sufficient evidence that the Synergy™ stent includes immiscible phases.*

According to Defendant, the jury erred by finding infringement because Plaintiffs failed to prove that the Synergy™ stents include “immiscible” phases. D.I. 346 at 17-18. Specifically, Defendant argues that Dr. Pitt opined “that the term ‘immiscible’ imposes a requirement that the first and second phases be incapable of forming,” which was contrary to the Court’s construction of the term “immiscible.” *Id.* Therefore, Defendant contends that the testimony must be disregarded. *Id.* Without the benefit of Dr. Pitt’s testimony on the issue of “immiscibility,” Defendant argues that “[t]he *only testing in the record* demonstrated that the materials in the purported first and second phases—PLGA and everolimus—were miscible,” thus warranting JMOL on the issue of infringement. *Id.* at 17 (emphasis in original). For the following reasons, the Court disagrees.

The Court construed the term “immiscible” to mean “incapable of dissolving into one another.” D.I. 90 at 1. While the Court’s construction did not impose an explicit “single phase” requirement, Dr. Pitt testified that, in order for the phases to be “capable of dissolv[ing] into one another,” the phases must be able to dissolve completely. Tr. 573:13-574:2 (testifying that, when phases “dissolve into one another,” “[t]here’s only one phase”). According to Dr. Pitt, there is “no such thing as slightly miscible [phases]” or partial dissolution of phases. *Id.* at 575:4-10. Rather, “phases [are either] miscible or immiscible.” *Id.* Thus, Dr. Pitt explained that, because the Synergy™ stent is described as having “separated drug- and PLGA-rich phases,” there was no argument that the phases did not dissolve into one another, thus making them immiscible. *Id.* at 577:13-17.

This testimony does not contradict the Court’s construction but rather describes the Court’s construction to the jury. *Id.* at 654:24-655:1 (noting that Dr. Pitt referenced “single

phase” in order “to explain” Court’s construction of “immiscible”). While Dr. Mooney disagreed with Dr. Pitt’s testimony and introduced his own explanation of the Court’s construction, Defendant did not object to this testimony during trial. *See id.* at 750:11-15 (testimony from Dr. Mooney explaining that “the term ‘immiscible’ is an absolute [and] means that they simply cannot dissolve in each other. If they can dissolve a little bit, they are not immiscible. If they can dissolve a lot, they are not immiscible”). Because Defendant failed to object, the Court will not address Defendant’s arguments challenging Dr. Pitt’s description of “immiscible phases” under the Court’s construction. *See Energy Transp. Grp., Inc. v. Sonic Innovations, Inc.*, No. CA 05-422 GMS, 2011 WL 2222066, at n.8 (D. Del. June 7, 2011), *aff’d sub nom. Energy Transp. Grp., Inc. v. William Demant Holding A/S*, 697 F.3d 1342 (Fed. Cir. 2012) (“If the defendants believed that ETG was attempting to introduce evidence based on something other than the court’s claim construction, they should have objected to the evidence.”).

Given Dr. Pitt’s testimony that “phases [are either] miscible or immiscible,” a reasonable jury could have found that the Synergy™ stent satisfied the “immiscible” phases limitation of the asserted claims of the ’296 patent. Accordingly, the Court DENIES Defendant’s motion for JMOL of no infringement for failure to show that the accused products satisfy the immiscible phases limitation of the asserted claims of the ’296 patent.

v. *Plaintiffs presented sufficient evidence to support their damages theory.*

Defendant next contends that “[m]ultiple critical defects invalidate Plaintiffs’ damages theory.” D.I. 346 at 18. Specifically, Defendant argues that Plaintiffs erred by presenting a damages case “focused solely on the value of the biodegradability of the fiber and [] silent on the value of the immiscibility of the fiber’s phases.” *Id.* According to Defendant, Plaintiffs’ damages expert, Mr. Garratt, improperly introduced “conclusory and speculative” apportionment

opinions to the jury and, without such improper testimony, Defendant contends that “no reasonable jury could have found sufficient evidence supporting Plaintiffs’ damages. *Id.* at 19.

“A jury award of damages is reviewed by [the district court] for substantial evidence. That award is entitled to deference.” *Honeywell Int’l, Inc. v. Universal Avionics Sys. Corp.*, 426 F.Supp.2d 211, 214 (D.Del.2006) (citation omitted). As the Federal Circuit has explained, “[t]he jury’s award should stand unless it is grossly excessive, not supported by evidence, or based on only speculation or guesswork.” *Fujifilm Corp. v. Benun*, 605 F.3d 1366, 1372 (Fed. Cir. 2010).

While Defendant claims that the award was based on speculation and guesswork, the Court finds that Plaintiffs’ damages expert, Mr. Lewis, established the “incremental profit” that the patented invention adds to the end product by subtracting the per unit profit Defendant earned from sales of the Promus PREMIER™ and Promus ELITE™ stents from the per unit profit Defendant earned from the accused Synergy™ stent. Tr. 1091:6-1093:19. As Plaintiffs note, in making his findings, “Mr. Lewis relied on the opinions of Plaintiffs’ technical and medical experts, Dr. Pitt and Dr. Garratt, that the only material difference between Defendant’s Synergy™ and Promus™ stents was the use of the claimed invention” as well as “Defendant’s sales training materials showing that the accused Synergy™ fiber structure was ‘the key differentiator’ between the Synergy™ and Promus™ products.” D.I. 354 at 12-13 (internal citations omitted); Tr. 1091:18-23 (noting that “Dr. Pitt and Dr. Garratt [] really weren’t able to find any material difference between Synergy and Primus that wasn’t related to the bioabsorbable coating”); Tr. 1092:3-7 (referencing Boston Scientific’s “training documents”). This evidence undermines Defendant’s claim that Mr. Lewis’ apportionment of at least 90% to 100% was conclusory and speculative.

Additionally, Defendant's claim that "Plaintiffs' damages case presented at trial focused solely on the value of the biodegradability of the fiber and was silent on the value of the immiscibility of the fiber's phases" is without merit. *See* D.I. 34 at 19. Mr. Lewis did not assign value to the polymer fiber merely because the fiber was biodegradable. Rather, Mr. Lewis recognized the jury's finding of infringement and sought to value the entire infringing Synergy™ polymer. *See* Tr. 1125:6-8 (recognizing the jury's finding that Synergy™ infringed the asserted claims). In doing so, Mr. Lewis compared the price of stents sold by Defendant that did not contain the infringing polymer fiber with the Synergy™ stent. *See* Tr. 1123:22-1126:13 (explaining Mr. Lewis's reliance on the Promus stent, which "does not infringe the '296 patent," to determine that "Promus made this much profit. SYNERGY made this much profit. And here's the amount that SYNERGY made more the incremental profit compared to Promus"). Like Plaintiffs, the Court finds no need for Mr. Lewis to "break up the value of the invention into pieces," given his testimony that Promus did not contain an infringing fiber. D.I. 354 at 13. The Court also agrees that Defendant failed to explain how or why Mr. Lewis's methodology could justify JMOL on damages. *Id.*

Accordingly, the jury's award will stand, and Defendant's request for JMOL is denied.

vi. *The record does not support a finding of willful infringement.*

Finally, Defendant contends that it is entitled to JMOL on willful infringement because "Plaintiffs presented no evidence that Boston Scientific has a specific intent to infringe the '296 [p]atent." D.I. 346 at 19. The Court agrees.

As the Supreme Court has explained, "[t]he 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.*,

Inc. v. Pulse Elecs., Inc., — U.S. —, 136 S. Ct. 1923, 1932, 195 L.Ed.2d 278 (2016). Indeed, a finding of willfulness is “generally reserved for egregious cases of culpable behavior.” *Id.* Thus, “[t]o establish willfulness, the patentee must show the accused infringer had a specific intent to infringe at the time of the challenged conduct.” *Bayer Healthcare LLC v. Baxalta Inc.*, 989 F.3d 964, 987 (Fed. Cir. 2021). The evidence must “transform simple ‘intentional or knowing’ infringement into egregious, sanctionable behavior.” *SRI Int’l, Inc. v. Cisco Sys., Inc.*, 930 F.3d 1295, 1308 (Fed. Cir. 2019) (internal citations omitted).

Plaintiffs contend that they satisfied this standard by presenting “compelling evidence that Boston Scientific copied the technology and ideas claims in the ’296 Patent.” D.I. 350 at 3. Specifically, Plaintiffs argue that “[t]he timeline of events establishes—nearly as a matter of law—that, led by its R&D team, Boston Scientific copied” the ’296 patent. *Id.* Included in this timeline was a presentation given by Boston Scientific to the FDA on or about October 1, 2008, in which Boston Scientific disclosed its initial plans for a “Drug-Eluting Biodegradable Polymer Coating on Metallic Stent.” *Id.* According to Plaintiffs, during this initial FDA presentation, Boston Scientific did not call their primarily-burst-release design “Evolution” and did not disclose any drug-to-polymer ratio or “suggest[] that immiscible, discrete (i.e. individually separate), drug-containing phase regions are dispersed throughout the abluminal continuous coating.” *Id.*

Plaintiffs’ timeline also cites to a meeting held on October 16, 2008 and a subsequent FDA presentation held in June 2009. *Id.* at 3-5. Plaintiffs note that, during the October 2008 meeting, a Boston Scientific employee, Dr. Nelson, presented to Mary Beth Moynihan, Boston Scientific’s VP of Research and Development, and Kevin Ballinger, Boston Scientific’s Vice President, on “TissueGen use[] [of] biodegradation, as well as polymer composition and format

to tune drug delivery” and TissueGen’s “Solid Patent Foundation,” including the ’296 patent. *Id.* at 4. According to Plaintiffs, shortly thereafter, “in the spring of 2009, Ms. Moynihan sought and received ‘additional information’ about the patented technology, promptly shared the information with multiple executives leading Boston Scientific’s research and development team, and confirmed that she and ‘Kevin Ballinger (VP, R&D)’ reviewed Dr. Nelson’s materials.” *Id.*

Finally, Plaintiffs noted that, in June 2009, during a second FDA presentation, Boston Scientific “provided far more detail and more specifics about a controlled extended-release design called ‘Evolution,’” which showed that Boston Scientific “settled on 85:15 PLGA polymer formulation using everolimus in a 45:55 drug to polymer ratio to be released over approximately 90 days at varying rates.” *Id.* at 4-5. According to Plaintiffs, during this second presentation, Boston Scientific described a polymer technology with many of the characteristics that “lie at the heart of the asserted claims of the ’296 Patent,” including immiscible, discrete (i.e. individually separate), dispersed drug-containing phase regions, where the “drug and polymer are not mixed” and the “flexible polymer and brittle drug phases coexist separately from each other.” *Id.* Plaintiffs argue that the jury’s finding of willful infringement was reasonable, given evidence that Defendant’s high-level employees “had knowledge of the ’296 Patent and TissueGen’s ‘Revolutionary’ technology during the exact period (Fall 2008–2009) when Boston Scientific’s FDA presentations “evolved” to include the patented features.” *Id.* at 6.

While Plaintiffs argue that Defendant failed to refute any of Plaintiffs’ evidence of copying, the Court, even accepting Plaintiffs’ evidence as true and weighing all logical inferences in Plaintiffs’ favor, finds that the record was insufficient to establish that Defendant’s “conduct rose to the level of wanton, malicious, and bad-faith behavior required for willful

infringement.” *SRI Int’l*, 930 F.3d at 1309. Specifically, the Court, like Defendant, finds that Plaintiffs have not presented sufficient evidence that Defendant acted with the specific intent to willfully infringe the asserted technology. D.I. 346 at 19.

The Federal Circuit’s holding in *Bayer Healthcare* is particularly illustrative. Just as in this matter, plaintiff in *Bayer* accused defendant of willfully infringing the asserted patent by “consciously redirect[ing] its own research . . . after learning about [plaintiff’s patented] invention.” *Bayer*, 989 F.3d at 987-88. In support of the claim that defendant acted willfully, plaintiff in *Bayer* relied on defendant’s “internal documents” which discussed the asserted patent. *Id.* Plaintiff in *Bayer* also highlighted two presentations made to the FDA by defendant describing the infringing product. *Id.* According to plaintiff, the first of the two presentations occurred before defendant reviewed the asserted patent and revealed defendant’s “initial approach with FVIII conjugates was random PEGylation.” *Id.* at 988. Plaintiff argued that the second presentation, which took place after defendant learned of plaintiff’s patent, revealed that defendant “switched to targeted, B-domain PEGylation,” just as claimed in the plaintiff’s technology. *Id.* at 980, 988. According to plaintiff, the inexplicable shift in defendant’s technology between the company’s initial and later approach proved that defendant “consciously redirected its own research . . . after learning about [plaintiff’s] invention” and justified a jury finding of willful infringement. *Id.* The Federal Circuit disagreed.

According to the Federal Circuit, the evidence presented by plaintiff revealed defendant’s knowledge of the asserted patent and supported plaintiff’s claim that defendant infringed plaintiff’s patented technology. *Id.* at 988. While “[k]nowledge of the asserted patent and evidence of infringement is necessary,” however, the court noted that “[such evidence was] not sufficient[] for a finding of willfulness,” which “requires deliberate or intentional infringement.”

Id. Thus, despite plaintiff's claims that defendant added infringing elements to the accused product only after learning about plaintiff's patented technology, the Federal Circuit found that plaintiff's evidence did not show that defendant acted with the necessary intent to willfully infringe the asserted patent. *Id.* Thus, the *Bayer* court overturned the jury's finding of willfulness. *Id.*

Similarly, in this case, while Plaintiffs contend that Boston Scientific redirected its technology after "review[ing] Plaintiffs' patented 'technology and ideas,'" such evidence is insufficient to establish that Defendant acted intentionally and deliberately to infringe on Plaintiffs' patent rights. Just as in *Bayer*, the internal Boston Scientific documents and FDA presentations highlighted by Plaintiffs are sufficient to support Plaintiffs' claims that Defendant had knowledge of and infringed the '296 patent but fall short of proving that Defendant acted with the requisite intent to willfully infringe. As such, Defendants' motion for JMOL on willful infringement is GRANTED.²

b. Plaintiffs' Motion for a New Trial

Defendant also moves for a new trial on the grounds that Plaintiffs' counsel engaged in misconduct that improperly influenced the jury's verdict. D.I. 346 at 2-11. Specifically, Defendant contends that Plaintiffs improperly referenced Defendant's decision not to file for *inter partes* reexamination of the '296 patent during Plaintiff's opening statements and continued to improperly reference Defendant's decision not to file an IPR during trial. *Id.* at 6-7. Defendant also contends that Plaintiffs' counsel improperly appealed to bias and emotion throughout the proceedings by, *inter alia*, (1) describing the "clear and convincing" standard for

² Given the Court's holding granting Defendant's JMOL on willful infringement, Plaintiffs' Motion to Amend the Judgment to Include Enhanced Damages (D.I. 349) is DENIED as moot.

proving invalidity as “the standard that we use if they want to involuntarily admit you to a psychiatric hospital”, or “to take your kids away”, (2) playing a video of a child lying to her parents and a baseball player lying about steroid use, and (3) telling the jury that that one Boston Scientific witness “told the truth” while another was a “paid witness to tell you that fiber doesn’t mean fiber”. D.I. 346 at 4-6 (citing Tr. 90:18-19, 91:2, 105:21-23, 106:6-9).

A new trial is proper with respect to such claims if Plaintiffs made prejudicial remarks and it is “reasonably probable” those prejudicial remarks influenced the jury’s verdict. *Draper v. Airco, Inc.*, 580 F.2d 91, 97 (3d Cir. 1978). Even if the Court agreed with Defendant that some of Plaintiffs statements at trial were prejudicial, when viewed in the context of the entire record and the Court’s curative instructions, the Court is not convinced that any of those statements had a reasonable probability of influencing the jury’s verdict.

Plaintiffs’ reference to the clear and convincing standard and comparison of that standard to the standard for taking away a child from a parent does not require a new trial. After Defendant objected to Plaintiffs’ characterization of that standard, the Court instructed the jury that “opening statements are not evidence and they are not instructions on the law. The Court will instruct you on the law later, this is just attorney argument.” Tr. at 106:2-5. The Court also instructed the jury that opening statements were not evidence in its Preliminary Instructions. See D.I. 316. And the Court once again instructed the jury on the clear and convincing standard during its Final Instructions. Tr. 1019:7-13 (explaining that “[c]lear and convincing evidence means evidence that is highly probable that a fact is true” and “[p]roof by clear and convincing evidence is a higher burden than proof by preponderance of the evidence”). The Court finds that the curative instruction and jury instructions were sufficient to remedy any prejudice from Plaintiffs’ statements. Specifically, the Court finds that this case is distinguishable from *Carrier*

Corp. v. Goodman Glob., Inc., 162 F. Supp. 3d 345, 368-369 (D. Del. 2016), where “both parties were aggressive litigators to the detriment of the trial record” such that “any gratuitous argument [was] sufficient to tip the balance for the wrong reason.” *Id.*

Likewise, Plaintiffs’ reference to Defendant’s decision not to institute IPR also does not require a new trial. The Court allowed some questioning on that issue after Defendant opened the door to such questioning by arguing that the trial was Defendant’s “only opportunity” to challenge the ’296 patent. *See* Tr. 155:18-156:22. During Plaintiffs’ closing statements, Plaintiffs argued that Dr. Mooney’s testimony that the ’296 patent would not have issued if the patent examiner had been aware of Song was not credible because Defendant had the opportunity to file an IPR but did not do so. Tr. 954:14-955:7. The Court found that Plaintiffs’ argument went beyond the scope of the limited questioning that the Court allowed. *See* Tr. 960:16-23. Accordingly, the Court issued a curative instruction informing the jury that “whether a party filed an IPR or not has no bearing on the issues you’re going to be asked to decide.” Tr. 962:1-3. The Court finds that this curative instruction was sufficient to remedy any prejudice from Plaintiffs’ statements regarding IPR.

The Court has also reviewed the remainder of the statements that Defendant contends improperly bolstered Plaintiffs’ counsel’s credibility or improperly appealed to bias and emotion. *See* D.I. 346 at 4-5; 9-10. The Court is not convinced that those statements were misconduct as opposed to aggressive advocacy, and none of the statements were prejudicial in the sense of affecting a substantial right in the context of the entire record. *Lucent Techs., Inc. v. Newbridge Networks Corp.*, 168 F. Supp. 2d 181, 261 (D. Del. 2001) (“In the case of alleged attorney misconduct, the party seeking a new trial must demonstrate that the attorney’s conduct constitutes misconduct, and not merely aggressive advocacy, and that the misconduct is

prejudicial in the sense of affecting a substantial right in the context of the entire trial record.”) Accordingly, viewing the record as a whole, and in light of the Court’s curative instructions, the Court cannot conclude that Plaintiffs’ arguments were “so egregious as to make it reasonably probable that the jury was improperly influenced” to warrant a new trial. *Id.*; *Snider v. Sterling Airways, Inc.*, 2017 WL 6336596, at *10 (E.D. Pa. Sept. 5, 2017) (“[A] litigant is entitled to a fair trial but not a perfect one, for there are no perfect trials.”).

c. Plaintiffs’ Motion for Pre-and Post-Judgment Interest

According to Plaintiffs, “[t]he law unequivocally compels, if not outright requires, an award of pre-judgment and post-judgment interest.” D.I. 350 at 17. Thus, Plaintiffs seek pre-judgment interest on the jury’s \$42 million damages award at the prime rate, compounded quarterly which, according to Plaintiffs, equates to \$10,947,425 of prejudgment interest through February 15, 2023, the date of the judgment on the verdict. Plaintiffs additionally seek post-judgment interest at 4.87% computed daily and compounded annually. *Id.* at 1. Defendant moves the Court to deny as premature or, alternatively, reduce Plaintiffs’ sought pre-judgment interest. D.I. 355 at 1. For the following reasons, the Court finds that Plaintiffs are entitled to pre- and post-judgment interest; however, Plaintiffs’ pre-judgment interest calculations are reduced to reflect interest on royalty payments.

i. Plaintiffs’ Request for Pre-Judgment Interest Is Not Premature.

“In cases of patent infringement, ‘prejudgment interest should be awarded [under 35 U.S.C. § 284] absent some justification for withholding such an award.’” *Tristrata Tech., Inc. v. Mary Kay, Inc.*, 423 F.Supp.2d 456, 471 (D. Del. 2006) (citing *GM Corp. v. Devex Corp.*, 461 U.S. 648, 657, 103 S.Ct. 2058, 76 L.Ed.2d 211 (1983)). As Plaintiffs’ note, “prejudgment

interest is the rule, not the exception.” D.I. 350 at 18 (citing *Schwendimann v. Arkwright Advanced Coating, Inc.*, 959 F.3d 1065, 1076 (Fed. Cir. 2020)). “As a general matter, prejudgment interest should ordinarily be awarded in patent cases to provide patent owners with complete compensation.” *LG Display Co. v. AU Optronics Corp.*, 722 F.Supp.2d 466, 475 (D. Del. 2010). According to the Federal Circuit, district courts have “‘great discretion’ when determining the applicable interest rate for an award of prejudgment interest.” See *Uniroyal, Inc. v. Rudkin–Wiley Corp.*, 939 F.2d 1540, 1545 (Fed. Cir. 1991).

Defendant contends, however, that Plaintiffs’ request for prejudgment interest should be denied because the request is premature given “there are considerable uncertainties due to the trial record and the disconnect between the evidence and the jury’s verdicts.” D.I. 355 at 17. However, as the Court noted above, the jury’s damages award of \$42 million was supported by the trial record, and the Court’s decision upholds the jury’s findings on all grounds but willfulness. See *supra* at 6-24. Thus, the Court disagrees with Defendant’s claims that there remains “significant issues with both the liability and damages evidence Plaintiffs presented at trial” and finds no reason to further postpone the award of prejudgment interest. See D.I. 355 at 17.

ii. *Plaintiffs’ Pre-Judgment Interest Calculations is Reduced to Reflect Interest on Royalty Payments.*

Alternatively, Defendant contends that Plaintiffs’ request for prejudgment interest should be reduced because (1) Plaintiffs are responsible for a two-year delay in litigation; (2) the jury’s damages award should be treated as a running royalty; and (3) prejudgment interest should be awarded under the Treasury Bill, not the higher Prime rate. D.I. 355 at 18. Each argument is considered in turn below.

1. *Defendant fails to prove that Plaintiffs' two-year delay resulted in any prejudice.*

According to Defendant, the Court should reduce Plaintiffs' prejudgment interest demand because "Plaintiffs initiated this case with a complaint in the Western District of Texas, an improper venue[,] [] and . . . [a]fter the Texas court dismissed the case, Plaintiffs then dedicated over two years to appealing the resulting transfer order, including a petition to the Supreme Court, while this case was stayed." *Id.* Thus, Defendant argues that Plaintiffs are not entitled to prejudgment interest before the stay was lifted on April 30, 2020. *Id.* at 18-19. While "undue delay" may justify a court's decision to deny or reduce prejudgment interest, our courts have held that, "[u]nless delay causes prejudice to the defendant, however, it does not support a denial of prejudgment interest." *Green Mountain Glass LLC v. Saint-Gobain Containers, Inc.*, 300 F. Supp. 3d 610, 627 (D. Del. 2018), *aff'd sub nom. Green Mountain Glass, LLC v. Saint-Gobain Containers, Inc.*, 773 F. App'x 619 (Fed. Cir. 2019); *see also Lummus Industries, Inc., v. D.M. & E. Corp.*, 862 F.2d 267, 275 (Fed. Cir. 1988). As Plaintiffs note, Defendant "does not even claim it suffered prejudice." D.I. 361 at 6. Additionally, Plaintiffs have presented some evidence that Defendant may have benefitted from the stay, given that Defendant "continued to sell and profit from infringing products" during that time. *Id.* at 6-7. Because Defendant failed to present evidence that it suffered prejudice, the Court denies Defendant's claim that "prejudgment interest should be awarded between April 30, 2020 (when stay was lifted) and February 15, 2023 (when judgment was entered)." D.I. 355 at 19.

2. *Pre-judgment interest will be awarded using the Prime rate.*

Additionally, Defendant contends that Plaintiffs' pretrial interest should be awarded "under the Treasury Bill rate (the rate set by statute for post-judgment interest under § 1961), as

opposed to the higher Prime rate requested by Plaintiffs” D.I. 355 at 20. The Court disagrees.

Courts in this district “have recognized that the prime rate best compensate[s] a patentee for lost revenues during the period of infringement because the prime rate represents the cost of borrowing money, which is ‘a better measure of the harm suffered as a result of the loss of the use of money over time.’” *IMX, Inc. v. LendingTree, LLC*, 469 F.Supp.2d 203, 227 (D. Del. 2007) (internal citations omitted). While Defendant argues against using the Prime rate because “there is no evidence that UTBOR was required to borrow any money due to Boston Scientific’s alleged infringement,” such evidence is not required. *See* D.I. 355 at 20. Indeed, “decisions of this District have used the prime rate even when there was no evidence that the patentee was borrowing money or experiencing a risk of non-payment.” *Idenix Pharms. LLC v. Gilead Scis., Inc.*, 271 F. Supp. 3d 694, 705 (D. Del. 2017). As Defendant presents no other reason to use the lower Treasury Bill rate, the Court will apply the Prime rate, as is “the most common practice in the District of Delaware.” *Id.*

3. *The jury’s damages award should be treated as a running royalty.*

Finally, Defendant argues that Plaintiffs’ prejudgment interest should be reduced because “neither party argued that damages should be calculated as a lump sum at trial; instead, both parties’ experts unambiguously applied a running royalty approach for calculating damages.” D.I. 355 at 19. Defendant contends that, by treating the jury’s award as a lump sum, Plaintiffs seek \$3.5 million of extra prejudgment interest. *Id.* Plaintiffs, on the other hand, argue that they are entitled to treat the jury award as a lump sum because “[t]he jury in this case awarded \$42 million in damages without any mention or indication of how the award was calculated.” D.I. 350 at 19-20. Plaintiffs contend that a royalty rate cannot be extrapolated from the record

because “[t]he jury was not instructed on a running royalty damages theory.” *Id.* The Court disagrees.

The trial record reveals that both Plaintiffs’ and Defendant’s damages experts utilized per unit royalties tied to the actual sales of Synergy™ to calculate damages. For instance, Plaintiffs’ expert, Mr. Lewis, explained that he used the number of Synergy™ units imported into the United States during the damages period and “multipl[ied] it times the incremental revenue or incremental profit that [Defendant] made per SYNERGY unit to get a total of the benefit achieved from selling SYNERGY.” Tr. 1095:8-16. Defendant’s expert, Mr. Hass, similarly offered testimony based on per unit royalties and the actual sales of Synergy™. *See id.* at 1232:1-7. As Defendant notes, “no expert provided any testimony about a lump-sum award at trial.” D.I. 355 at 19. Thus, this matter is comparable to *Trading Technologies International, Inc. v. IBG LLC*, where the court found that “[b]oth parties’ damages experts offered damages opinions based on the reasonable royalty IBG and TT would hypothetically negotiate at the start of the infringement period and their suggested award amounts were tied to actual use or access to the patented invention.” 2022 WL 103894, at *3 (N.D. Ill. Jan. 11, 2022). “Based on the damages testimony offered at trial,” the court in *Trading Technologies* found that “it [was] reasonable to conclude that the jury’s award most likely reflects a running royalty amount rather than a lumpsum payment.” *Id.* (“To treat the damages award as a lumpsum and charge interest on it over the course of the infringement period would overcompensate TT by awarding it interest on money it would not have yet received.”). This Court finds the same to be the case here.

Given the clear trial record, the Court finds that awarding pre-judgment interest on royalty payments offers the most accurate result and avoids overcompensating Plaintiffs by

awarding them interest they would not have yet received. Accordingly, the Court will award Plaintiffs prejudgment interest on a running royalty rate, which would yield \$7,436,328 in interest. As Defendant does not challenge Plaintiffs' request for post-judgment interest, the Court awards post-judgment interest to accrue at 4.87% computed daily and compounded annually.

4. CONCLUSION

For the foregoing reasons, the Court **GRANTS-IN-PART** and **DENIES-IN-PART** Defendant's Motions for a New Trial and Judgment as a Matter of Law (D.I. 345). Additionally, the Court **GRANTS-IN-PART** and **DENIES-IN-PART** Plaintiffs' Motion for Enhanced Damages and Pre- and Post-Judgment Interest (D.I. 349). An appropriate Order will follow.