

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

Stamatios Stamoulis, STAMOULIS & WEINBLATT LLC, Wilmington, Delaware; Michael W. Shore, Alfonso G. Chan, Chijioke E. Ofor, SHORE CHAN DEPUMPO LLP, Dallas, Texas; Brian D. Melton, John P. Lahad, Corey M. Lipschutz, SUSMAN GODFREY LLP, Houston, Texas

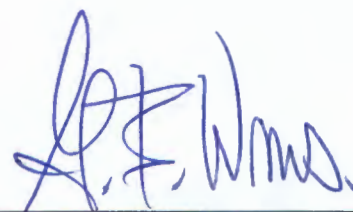
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MEMORANDUM OPINION

November 17, 2022
Wilmington, Delaware



GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE

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. Before the Court is BSC’s renewed request for claim construction as to “polymer fiber.” D.I. 200 at 13; D.I. 243 at 7. The Court has considered the parties’ joint claim construction brief, D.I. 245, and held a *Markman* hearing on November 7, 2022 (“Tr. __”). For the reasons below, the Court declines to construe “biodegradable polymer fiber”; construes “fiber” rather than “polymer fiber”; and construes “fiber” as having its plain and ordinary meaning to a person of ordinary skill in the art (“POSA”), which is “a thread-like structure of any length or shape.”

I. BACKGROUND

On November 20, 2017, UT filed suit against BSC for infringement of the ’296 patent and an additional patent no longer at issue. D.I. 1 at 1; D.I. 56 at 1. On April 15, 2021, the Court announced four agreed upon constructions (*) and two disputed constructions:

Term	Construction	Citations (’296 Patent)
“first phase”*	“the polymer portion of the fiber”	Claims 1, 11, 12, 16, 17, & 26
“second phase”*	“the discrete drug-containing regions dispersed throughout the fiber”	<i>Id.</i>
“immiscible”*	“incapable of dissolving into one another”	<i>Id.</i>
“fiber”	plain and ordinary meaning	<i>Id.</i>
“the first and second phases being immiscible”	not indefinite; plain and ordinary meaning	<i>Id.</i>
“radioactive agent”*	“an agent that pertains to, exhibits, or is caused by an element that spontaneously emits radiation resulting from changes in the nuclei of atoms of the elements”	Claim 12

D.I. 90 at 1–2. As to the “fiber” term, the Court provided the following explanation of its ruling:

I agree with [UT] that “fiber” need not be construed beyond its plain and ordinary meaning. The patent uses the term fiber repeatedly throughout and used the term according to its plain and ordinary meaning. The fibers described can be different lengths including very short. [(*See, e.g.*, D.I. 1-1 at 6:63–7:14, 7:24–32; *id.* at Figs. 1, 2, 3A, 3B, 6, 7).] They may be, but need not be, woven into support structures[,] [(*See, e.g., id.* at 8:41–45)][,] and may be used as drug delivery reservoirs with metal stents, [(*See, e.g., id.* at 22:40–51 (ex. 7)))][,] or they may be attached directly to vessel walls or tacked down in the eye[,] [(*See, e.g., id.* at 23:31–54 (ex. 10))]. These fibers may be made by various solvent exchange methods. [(*See, e.g., id.* at 17:36–19:36 (ex. 1), 19:37–20:5 (ex. 2), 20:6–36 (ex. 3), 25:13–31 (ex. 15), 25:32–49 (ex. 16)).]

[BSC] does not disagree with any of that. Instead, [BSC] contends that I should construe fiber because the parties have raised a dispute regarding the scope of the claim. As I probed the issue today during argument, it seemed like the real dispute is not over whether a fiber is threadlike as in [BSC]’s proposed construction, but rather whether the term “fiber” can encompass what [BSC] says is a coating. As I understand the issue based on what I have before me, that does not appear to be an issue of claim construction but rather 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. If, however, it turns out that I’m wrong about that and[,] as the record develops[,] [it] really is a claim construction dispute, [BSC] can raise the issue again in connection with summary judgment briefing to the extent appropriate.

D.I. 90 at 5–6.

On September 17, 2021, UT filed the operative complaint, UT’s First Amended Complaint for Patent Infringement (D.I. 124, the “Complaint”). On August 30, 2022, BSC filed its Answer to the Complaint, denied UT’s infringement allegations, and asserted defenses and counterclaims of invalidity for, among others, lack of written description. D.I. 238 at 23–25.

On June 14, 2022, BSC filed a Motion for Summary Judgment of Noninfringement. D.I. 198. In its briefing on that motion, BSC argued that “the developed record . . . has clearly revealed that there is a dispute between the parties as to the meaning of the term ‘polymer fiber’ and not just its factual application.” D.I. 200 at 13 (cleaned up). UT argued that the Court need not construe “fiber” because “[b]oth parties agree that a fiber must have a high aspect ratio and a

small cross-section” and because BSC was asking “the Court to import new limitations” into the definition of “polymer fiber.” D.I. 214 at 15. On October 6, 2022, the Court denied BSC’s summary judgment motion because “the parties have a genuine dispute of material fact regardless of how the Court would construe the term ‘fiber’ or ‘polymer fiber’” D.I. 243 at 7. However, the Court explained, “[s]ince 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.’” D.I. 243 at 7.

BSC argued in its summary judgment briefing that

[t]he accused [BSC] Synergy stents are composed of (1) a platinum chromium metal stent having a number of linked, serpentine rings, and (2) a drug-eluting biodegradable coating that is applied to the outside (abluminal) surface of the metal stent. The biodegradable coating includes a polymer (poly-lactic-co-glycolic acid (“PLGA”)) and a drug (everolimus). As shown, the coating applied to the Synergy stents includes “PLGA-rich domains” and “drug-rich domains.” When it is applied to the metal stent, the coating solution includes the drug everolimus, the polymer PLGA, and solvents.

D.I. 200 at 9 (citations omitted). UT did not dispute that description. D.I. 214 at 8 (explaining that “there is no true dispute” regarding those characteristics of the Accused Products).

“Polymer fiber” and “biodegradable polymer fiber” appear only in Claim 1 of the Asserted Claims:

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, and wherein the second phase comprises one or more therapeutic agents.

D.I. 1-1 at 27:54–29:14 (emphases added).

BSC argues that a POSA “would understand the claimed ‘polymer fiber’ to have its ordinary and customary meaning of “a thread-like or filamentous polymer structure that at least includes common orientation of the polymer molecules.” D.I. 245 at 1. UT responds that “[a]

[POSA] reading the '296 patent in 1999 would have understood the claimed 'biodegradable polymer fiber' means 'a fiber capable of releasing drug slowly, in a controlled manner over time as the polymer breaks down chemically and mechanically in animal or human tissue.'" D.I. 245 at 5. UT adds that a "fiber" is "a three-dimensional format having a small cross section and length much greater than its width." D.I. 245 at 15. BSC responds that the Court should decline to construe "fiber" or "biodegradable polymer fiber" because UT's request failed to comply with the Court's order as to this *Markman* hearing. D.I. 245 at 13.

II. LEGAL STANDARDS

"[T]he claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (citation omitted); *Aventis Pharms. Inc. v. Amino Chemicals Ltd.*, 715 F.3d 1363, 1373 (Fed. Cir. 2013) (same). "[T]here is no magic formula or catechism for conducting claim construction." *Phillips*, 415 F.3d at 1324. The Court is free to attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." *Id.* The ultimate question of the proper construction of a patent is a question of law, although "subsidiary factfinding is sometimes necessary." *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 326–27 (2015) (citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996)).

"The words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the context of the specification and prosecution history."¹ *Thorner v. Sony Comput. Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed.

¹ "Strictly speaking, the specification includes both the written description and the claims. In common parlance, however, 'specification' is used to refer only to the written description component of a patent." Tun-Jen Chiang & Lawrence B. Solum, *The Interpretation-Construction Distinction in Patent Law*, 123 Yale L.J. 530, 538, n.17 (2013). The Court will endeavor to use "written description" where intended in the "Discussion" section of this Memorandum Opinion.

Cir. 2012) (citing *Phillips*, 415 F.3d at 1312–13); *Unwired Planet, LLC v. Apple Inc.*, 829 F.3d 1353, 1358 (Fed. Cir. 2016) (similar). The “only two exceptions to this general rule” are (1) when a patentee defines a term or (2) disavowal of “the full scope of a claim term either in the specification or during prosecution.” *Thorner*, 669 F.3d at 1365 (citation omitted).

The Court “first look[s] to, and primarily rel[ies] on, the intrinsic evidence,” which includes the claims, written description, and prosecution history and “is usually dispositive.” *Personalized Media Commc’ns, LLC v. Apple Inc.*, 952 F.3d 1336, 1340 (Fed. Cir. 2020) (citation omitted). “[T]he specification ‘ . . . is the single best guide to the meaning of a disputed term.’” *Akzo Nobel Coatings, Inc. v. Dow Chem. Co.*, 811 F.3d 1334, 1340 (Fed. Cir. 2016) (citation omitted). “[T]he specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess.’ When the patentee acts as its own lexicographer, that definition governs.” *Cont’l Cirs. LLC v. Intel Corp.*, 915 F.3d 788, 796 (Fed. Cir. 2019) (quoting *Phillips*, 415 F.3d at 1316). However, “[the Court] do[es] not read limitations from the embodiments in the specification into the claims.” *MasterMine Software, Inc. v. Microsoft Corp.*, 874 F.3d 1307, 1310 (Fed. Cir. 2017) (citation omitted). The specification “is not a substitute for, nor can it be used to rewrite, the chosen claim language.” *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004).

The Court “should also consider the patent’s prosecution history, if it is in evidence.” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), *aff’d*, 517 U.S. 370; *Cont’l Cirs.*, 915 F.3d at 796 (same). The prosecution history may “demonstrat[e] how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution” *SpeedTrack, Inc. v. Amazon.com*, 998 F.3d 1373, 1377 (Fed. Cir. 2021) (quoting *Phillips*, 415 F.3d at 1317).

The Court may “need to look beyond the patent’s intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period.” *Teva*, 574 U.S. at 331. “Extrinsic evidence consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Markman*, 52 F.3d at 980; *Phillips*, 415 F.3d at 1317 (same). Extrinsic evidence may be useful, but it is “less significant than the intrinsic record in determining the legally operative meaning of claim language.” *Cont’l Cir.*, 915 F.3d at 799 (internal quotation marks and citations omitted). However, “[p]atent documents are written for persons familiar with the relevant field Thus resolution of any ambiguity arising from the claims and specification may be aided by extrinsic evidence of usage and meaning of a term in the context of the invention.” *Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1119 (Fed. Cir. 2002); see *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 899 (2014) (explaining that patents are addressed “to those skilled in the relevant art”).

III. CONSTRUCTION OF DISPUTED TERMS

The Court construes “fiber” rather than “polymer fiber.” The Court finds that “fiber” takes its plain and ordinary meaning to a POSA, which is “a thread-like structure of any length or shape.” The Court declines UT’s request that it construe “biodegradable polymer fiber” as untimely and unnecessary.

A. Construction of “Fiber”

BSC argues that “polymer fiber” is “a term of art with a well understood meaning.” D.I. 245 at 11. UT counters that the invention describes a “fiber format” and that “‘polymer fiber’ is not a term of art” D.I. 245 at 5. The Court finds that it should construe “fiber.”

Claim 1 claims a “composition comprising at least one biodegradable polymer *fiber* where said *fiber* is composed” D.I. 1-1 at 27:54–55 (emphases added). Claim 2 claims the

composition of Claim 1 wherein the “second phase is derived from . . . a hydrogel or polymer[.]” and Claims 3 and 4 claim the composition of Claim 1 “where said fiber” either “forms a scaffold” or “is woven . . . with other fibers” D.I. 1-1 at 27:59–65. The claims, thus, clarify that the relevant structure is a “fiber,” while “polymer” describes a material used to create a “fiber.” *See* D.I. 1-1 at 29:15–30:7 (independent claims with “fibers,” not “polymer fibers”).

The written description supports this understanding. The ’296 patent regularly invokes a “biodegradable polymer fiber.” *See, e.g.*, D.I. 1-1 at 2:44, 4:33, 4:59, 5:13–14, 5:23–25. It also separately defines “biodegradable” as “over time it will break down both chemically and mechanically.” D.I. 1-1 at 1:49–51. Thus, the patent modifies “fiber” with “biodegradable,” a term with its own meaning in the art. The patent uses “biodegradable,” *see, e.g.*, D.I. 1-1 at 1:10–11 (implants), 4:52 (polymer), 10:5–6 (polymer matrices), and “polymer,” *see, e.g.*, D.I. 1-1 at 1:42 (scaffold), 2:23 (matrix), 3:50 (layers), similarly, to modify nouns aside from “fiber.” Thus, “polymer” also has an independent meaning in the art. *See also* D.I. 1-1 at 9:64–10:9 (giving “examples of a class of biodegradable polymer matrices that may be used in this invention”). Lastly, the ’296 patent clarifies that polymer fibers’ capability for “the controlled delivery of therapeutic agents” over time, D.I. 1-1 at 2:44–45, is not a characteristic of the “polymer fiber,” but, rather, follows from the use of different polymer types, therapeutic agents, and coatings in the invention, *see, e.g.*, D.I. 1-1 at 2:63–65 (controlling “[t]emporal distribution” with “polymer composition”), 9:10–35 (using polymer coatings with different release kinetics).

The Court finds that it should construe “fiber.” UT asks that the Court construe “fiber” to take its ordinary meaning. UT first argues that the ordinary meaning of “fiber” is “[a] volume of matter having a small cross section and a length at least 100 times greater than its width or diameter[.]” D.I. 245 at 5. However, after BSC explained that UT’s expert, Dr. William Pitt,

contradicted UT's proposal, D.I. 245 at 13; *see also* D.I. 246-22 ¶ 31(e) (opining that, where the "length-to-width ratio" exceeds "50[,] the "polymeric compositions fit the definition of fiber, in the plain and ordinary definition"), UT argued that "'fiber' is a term of art understood as a three-dimensional format having a small cross section and length much greater than its width[,] D.I. 245 at 15. BSC takes issue with any "meaning of polymer fiber limited to a single characteristic of shape" D.I. 245 at 13. For the reasons below, the Court finds that the plain and ordinary meaning of fiber to a POSA is "a thread-like structure of any length or shape."³

i. Intrinsic Evidence

The Court "'first look[s] to, and primarily rel[ies] on, the intrinsic evidence . . . , which is usually dispositive.'" *Personalized Media Commc'ns*, 952 F.3d at 1340 (citation omitted).

While the '296 patent describes some thread-like embodiments, it does not define "fiber."

BSC argues that "[t]he '296 patent consistently describes a polymer fiber as being a 'strand,' a 'filament,' or a 'monofilament.'" D.I. 245 at 2 (citing D.I. 1-1 at 8:51–58, 17:55–57). The written description explains that one illustrative embodiment is a "Three Dimensional Fiber Matrix." D.I. 1-1 at 8:32. To make the matrix, "therapeutic agents are encapsulated into individual fibers of the matrix"; in that embodiment, "filaments could be formed into a unique scaffold that provides a growth substrate for tissue repair" and "it is possible to incorporate strands that will induce the formation of blood vessels into the fabric." D.I. 1-1 at 8:51–58. The nouns "filament" and "strand" do not appear in the specification outside of this single

³ UT has previously conceded the potential advantages of a construction of "fiber" as "thread-like." During the first *Markman* hearing, the Court proposed to construe "fiber" as "threadlike, but . . . [it] is not imputing any particular size, length" D.I. 89 at 8:13–16. UT, by way of its counsel, responded that the Court's proposal "would make sense" but expressed concern that the Court was reading an unnecessary "limitation into the claims." D.I. 89 at 8:17–21; *see also* D.I. 89 at 10:12–15 ("[The Court's proposed definition of "threadlike"] does give . . . a vision of the structure that you're looking at. . . . [But] we do not believe that it is an accurate depiction.").

embodiment. In one of 17 examples of “preferred embodiments of the invention[,]” the written description explains that a POSA should create an “aqueous emulsion” of two solutions, and it gives a specific ratio that is “most typical for monofilament [poly(L-lactic acid)] fibers.” D.I. 1-1 at 17:26, 17:55–57. The word monofilament does not recur anywhere else in the specification. Additionally, the word thread appears nowhere in the ’296 patent.

BSC further points out that “[t]he figures of the ’296 patent [] show polymer fibers as thread-like or filamentous structures, where the fibers are labeled numerals 21–28[.]” D.I. 245 at 2. BSC points in its briefing to Figures 1, 2, and 3a. D.I. 245 at 2. The written description explains that each figure shows fibers arranged either in scaffolding or so as to support a “tubular body,” such as an artery or vein. D.I. 6:63–7:14. The figures show the fibers as independent thread-like strands:

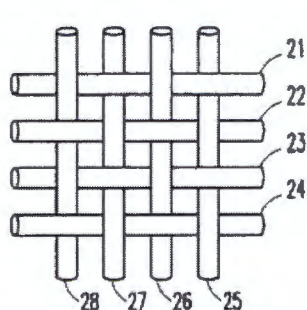


FIG. 1

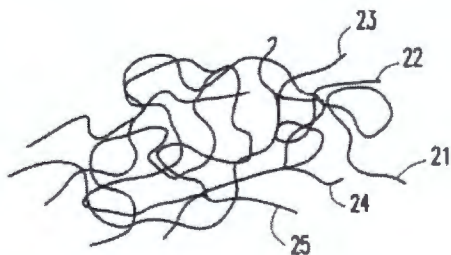


FIG. 2

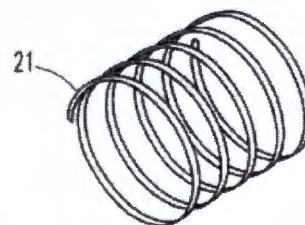


FIG. 3a

D.I. 1-1, figs. 1, 2, 3a. UT argues that Figure 4 rejects a “thread-like” requirement because it shows “discrete drug-containing phase regions . . . dispersed in the cross section of a polymer of a fiber [] formed by ‘coating’ the outside of a core fiber” rather than a fiber that “look[s] like a thread.” D.I. 245 at 9 (citations omitted). Figure 4 “shows that a fiber may have multiple component coatings, with each component loaded with different therapeutic agents.” D.I. 1-1 at 7:15–19. The written description further teaches that “fibers can be coated, forming co-axial fibers as shown in FIG 4. Each coating can be of a different polymer material The coating

can also be physically divided into multiple sections” D.I. 1-1 at 9:10–19. However, the patent clarifies that such a “coated fiber” is only one fiber, not multiple fibers. *See* D.I. 1-1 at 9:23–26. Thus, Figure 4 fails to support the assertion that a fiber need not be thread-like.

UT pointed to Example 3 at oral argument as evidence that the ’296 patent affirmatively disclaims any requirement that a fiber be thread-like. *See* Tr. at 44:7–45:11. Example 3 explains that a single fiber may have “concentric coatings” applied to it that are made of different polymers and that contain different therapeutic agents. D.I. 1-1 at 20:10–36. It nowhere suggests that the coatings, themselves, are polymers. *See* D.I. 1-1 at 20:31–32 (distinguishing between “the core fiber” and “the coating polymers”). Example 3 explains that an artisan may form “fibers with any desired cross-sectional shape[,]” D.I. 1-1 at 20:29–32, and the Court agrees with UT, Tr. at 44:7–19, that the Court should clarify for jurors that a “fiber” can take any shape. However, Example 3 fails to support the assertion that a fiber need not be thread-like.

The written description and claims of the ’296 patent both would support a thread-like structure and do not disclaim a requirement that a fiber be thread-like. However, the ’296 patent does not define fiber, *see* D.I. 1-1 at 2:50–4:51 (defining terms), and it does not answer whether a “fiber” must be thread-like, which is the real dispute between the parties, *see* D.I. 245 at 4 (asserting that a “fiber” must be “thread-like”), 8 (arguing that nothing “in the art or record require[s]” that a “fiber” be thread-like or a filament). Here, “resolution of [the] ambiguity arising from the claims and specification may be aided by extrinsic evidence of usage and meaning of a term in the context of the invention.” *Verve*, 311 F.3d at 1119.

The intrinsic evidence does not support that a “fiber” must have common orientation of the polymer molecules. UT argues that the patent’s process for “making polymer fibers . . . necessarily provide[s] molecular orientation of the polymers.” D.I. 245 at 3. The ’296 patent

does not include the words “common” or “orientation” and does not include the phrase “polymer molecules.” *See* D.I. 1-1. However, the parties’ equally-credible experts disagree as to whether any of the ’296 patent’s embodiments lack common molecular orientation. *Compare* D.I. 246-9 ¶ 32 (“Example 1 of the ’296 patent depicts the synthesis of a fiber without any sort of orientation introduced in the formation process.”), *with* D.I. 246-18 ¶ 22 (“I disagree with Dr. Pitt’s ultimate opinion In my opinion, the ’296 Patent Examples uniformly describe processes that draw or stretch the polymer during the formation of the fiber, which would then necessarily impart common molecular orientation. . . .”).

The Court also considers the prosecution history. BSC argues that it would be appropriate to read restrictions in Example 1 of the ’296 patent into Claim 1. BSC asserts that

the [written description] describes making polymer fibers using standard extrusion processes that, through drawing and stretching, necessarily provide molecular orientation of the polymers. [(Citing BSC’s expert)]. Example 1 of the ’296 patent—which the patentee identified as the *only* written description support for Claim 1 [(citing the prosecution history)]—describes a process in which a polymer is “drawn” and “extruded” into a fiber [(citation omitted)]. Indeed, the patent’s “apparatus for fabrication of polymer fibers” illustrated in Figure 8 shows polymers being extruded and drawn

D.I. 245 at 3 (emphasis in original); *see* D.I. 246-6 at 32–36 (including the text of Example 1 on pages 27–31); D.I. 246-6 at 53 (“Support for [what is now Claim 1] can be found at pages 28 and 29 of the Specification”). UT does not appear to respond directly to this argument.

However, at this Court’s original *Markman* hearing, BSC explained that “[o]ur construction is not limited to any manufacturing method[.]” D.I. 89 at 11:25–12:1; *see also* D.I. 89 at 29:11–12, and BSC reiterated that before the Court, Tr. at 52:8–16 (“We’re not saying the method of manufacturing in and of itself is a limitation.”). As a result, the Court cannot assume that “standard extrusion processes” are the only means to create a fiber (or, more specifically, a fiber

of polymer). Thus, the Court finds that the intrinsic evidence does not require—but also does not disclaim—common molecular orientation of the fiber.

The intrinsic evidence does, however, show that a fiber may be any shape or length. For example, one embodiment teaches fibers “cut to pre-specified lengths,” D.I. 1-1 at 19:67, and Figures 1, 2, and 3a, shown above, display fibers of varying lengths, D.I. 1-1 at figs. 1, 2, 3a. As explained above, Example 3 describes “certain embodiments” in which fibers may be formed “with any desired cross-sectional shape.” D.I. 1-1 at 20:29–32. Thus, a construction that limits a fiber to a particular shape or length would be inconsistent with the written description of the ’296 patent. The intrinsic evidence also shows that fibers may, but need not be, woven into three-dimensional “scaffolding” to support cell and tissue growth. *See, e.g.*, D.I. 1-1 at 8:41–58. Fibers can be used “to deliver drugs at the placement site” of a metal stent without providing “any mechanical support[,]” D.I. 1-1 at 22:40–51, and can be attached to an existing structure, such as a blood vessel, D.I. 1-1 at 23:31–54. The patent promotes the variety of applications which fibers may support.

ii. Extrinsic Evidence

The Court finds as a factual matter that a POSA would have understood the plain and ordinary meaning of “fiber” to be “a thread-like structure of any length or shape.” The parties do not contest that Dr. Pitt and Dr. David Mooney, BSC’s expert, are both POSAs. D.I. 246-9, Attachment I, Ex. A ¶¶ 1–4 (explaining that Dr. Pitt has a Ph.D. in chemical engineering and experience with polymers and drug delivery); D.I. 246-18 ¶¶ 4–9 (explaining that Dr. Mooney has a Ph.D. in chemical engineering and experience with polymers and drug delivery); *see also* D.I. 246-18 ¶¶ 10–11 (describing minimum requirements for a POSA).

Dr. Mooney opines that “[a] ‘polymer fiber’ refers generally to a threadlike or filamentous structure made of polymer that has been drawn and/or pulled such that the polymer

chains generally have a common longitudinal orientation” D.I. 246-2, Ex. 1 ¶ 26. Dr. Mooney insists that “polymer fiber,” rather than “fiber,” is the proper term of art at issue, but Dr. Mooney explains that, in a polymer fiber, “the polymers have been stretched and/or pulled such that the polymers . . . have an independent, filament or thread-like structure.” D.I. 246-2, Ex. 1 ¶ 134. Thus, a “fiber” would also be “thread-like,” since the stretching and pulling of the polymers makes them into fibers. Dr. Mooney similarly said that a “fiber” being “threadlike” was “consistent with” his own opinion. D.I. 246-2, Ex. 1 ¶ 31.

BSC and UT disagree as to whether Dr. Pitt has similarly opined that a fiber is thread-like. See D.I. 245 at 11, 16. In *Board of Regents v. Ethicon*, C.A. No. 17-1084-LY, UT alleged that Defendant Ethicon “practice[d] claims of the ’296 patent[,]” the same patent that is at issue here. No. 17-1084, D.I. 93 ¶¶ 2, 5. In Dr. Pitt’s Rebuttal Expert Report, dated November 25, 2019, Dr. Pitt explained that Attachment B “set forth opinions concerning the knowledge of an ordinary artisan, including my opinion that an ordinary artisan would have known that . . . most [polymers] can be made into useful films . . . , but only a few can be made into useful fibers.” D.I. 246-7 at 5. In Attachment B, Dr. Pitt gave the following opinion:

An ordinary artisan would have known that of the many different types of polymers, most can be made into useful films or used to make molded articles, but only a few can be made into useful fibers. An ordinary artisan would have understood that *fibers* (at least before they are cut) ***are long, threadlike monofilament and multifilament structures*** that are spun by extrusion through a spinnerets or very fine holes, drawn, stretched (to provide molecular orientation), and possibly annealed (to enhance dimensional stability and/or biological performance) to obtain the mechanical properties desired. An ordinary artisan would also know that forming or spinning a fiber by extrusion may involve melt spinning, dry solution spinning, or wet solution spinning. An ordinary artisan would have known that a fiber can be woven, knitted, or braided alone or in combination with other fibers to form fabrics for various medical applications.

D.I. 246-7 at 6 (emphases added). Dr. Pitt argues that his opinions were taken out of context.

Dr. Pitt explains that “[t]he context” of his statement was “a discussion of the Choi ’709 patent in

which a polymer film is simply cast by pouring a polymer solution containing two solvents and one polymer into a mold and drying it.” D.I. 246-9, Attachment I ¶ 38. Dr. Mooney—who was also defendant’s expert in *Ethicon*—had opined that the ’296 patent was obvious because of the “Choi” patent, and Dr. Pitt responded that the “Choi” patent had not taught the “fiber forming process” described in the ’296 patent. *Id.* ¶¶ 38–39. Dr. Pitt argues that he was elucidating certain operations that could be performed on polymers to make them into “useful fibers” and that he never opined that “such additional operations were required for the fiber to remain a fiber that meets the other limitations of the claims.” *Id.* ¶¶ 39–40. “None of these words were used as requirements or limitations on ‘the plain and ordinary definition of fiber’” since they were pulled from embodiments. *Id.* ¶ 40.

The Court does not find Dr. Pitt’s distinction meaningful. First, Dr. Pitt argues that he was using terms from the ’296 patent, *Id.* ¶¶ 39–40 (“I used words from Examples in the ’296 patent . . .”), but Dr. Pitt describes “fibers” as “thread-like” even though “thread” never appears in the ’296 patent, *see* D.I. 1-1. Second, Dr. Pitt opined that an “ordinary artisan would have understood that *fibers* . . . are long, threadlike” even though he referred to “useful fibers” in the sentence prior. D.I. 246-7 at 6 (emphasis added). The use of “fibers” just after “useful fibers” suggests either that Dr. Pitt did not find important the distinction between “fibers” and “useful fibers” in the context of the ’296 patent or that Dr. Pitt intended a distinction and, thus, spoke of all fibers, not just useful fibers, when he explained that fibers “are long, threadlike monofilament and multifilament structures . . .” *Id.* Both interpretations undermine Dr. Pitt’s argument. Third, Dr. Pitt could still have provided a definition of “fiber” in the context of an anticipation opinion in *Ethicon*. Dr. Pitt attests before this Court that the “fiber forming process” of the ’296 patent rendered it non-obvious over the “Choi” reference in *Ethicon*. D.I. 246-9, Attachment I ¶¶

38–39. UT argued before the Court in *Ethicon* that “Choi does not disclose or teach an ordinary artisan a ‘fiber’ that includes the claimed second phase.” No. 17-1084, D.I. 131 at 6. Thus, the Court reads Dr. Pitt’s opinion as defining “fiber” as used in the context of the ’296 patent.

One reading of Dr. Pitt’s opinion is that it described only one (albeit preferred) process to make a “fiber” in the ’296 patent, rather than opining as to all fibers that the ’296 patent claims. As UT argued in *Ethicon*, Dr. Pitt opined that “fiber fabrication of the type described in UT’s ’296 patent” is difficult. No. 17-1084, D.I. 131 at 6–7. However, the Court finds it substantially more likely that Dr. Pitt sought to opine on the definition of “fiber” as used throughout the ’296 patent. Dr. Pitt argued that a major innovation of the ’296 patent was the creation of a fiber with discrete drug-containing regions (i.e., the “second phase”), and that argument supported the distinction between the ’296 patent’s drug-containing fiber and the “Choi” patent’s drug-containing film. *See* No. 17-1084, D.I. 131 at 6–7. Thus, the Court finds as a factual matter that Dr. Pitt defined “fiber” as used in the context of the ’296 patent in the *Ethicon* case.⁴

The Court finds as a factual matter that both Dr. Mooney and Dr. Pitt agree that a “fiber,” as understood by a POSA in the context of the ’296 patent, means a “thread-like structure.” The Court recognizes that Dr. Pitt in *Ethicon* also opined that “fibers . . . are stretched (to provide molecular orientation)” D.I. 246-7 at 6. Dr. Mooney’s opinion is similar. *See* D.I. 246-2, Ex. 1 ¶ 26. However, Dr. Pitt described stretching as part of a process of manufacturing such

⁴ The Court’s conclusion finds further support in UT’s references elsewhere in *Ethicon* to a “fiber” as “thread-like.” *See* No. 17-1084, D.I. 160-1 at 3 (describing in proposed *voir dire* questions “[a] major issue in this case” with reference to “a thread-like polymer fiber”); D.I. 160-3 at 2 (explaining in *voir dire* that “[t]he ’296 patent generally relates to implantable thread-like polymer fibers”); D.I. 160-12 (explaining in proposed jury instructions that “[t]he patent-in-suit generally relates to implantable thread-like polymer fibers”); *see also* No. 17-1084, D.I. 41 (describing the “benefits” of the fiber “format” to include “that fiber filaments or strands can be woven” (cleaned up)).

fibers (along with, e.g., extrusion), D.I. 246-7 at 6, and Dr. Mooney uses similar terminology, D.I. 246-2, Ex. 1 ¶ 65 (“[A] POSA would understand the ’296 Patent’s disclosure that the polymer has been ‘drawn’ or ‘extruded’ into a fiber as necessarily imparting the fiber with a common orientation of the polymer molecules.”). BSC has stated multiple times before this Court that it does not limit its construction to a method of manufacturing. *See* D.I. 89 at 11:25–12:1, 29:11–12; Tr. at 52:8–16. The experts otherwise disagree as to whether a “fiber” necessarily has a common molecular orientation. *Compare* D.I. 246-9 ¶ 27 (“[F]ibers produced by any of the above processes have no appreciable orientation in the polymer chains”), *with* D.I. 246-18 ¶ 25 (“[A] POSA would understand that a claimed fiber that has been ‘drawn and extruded’ would necessarily have common molecular orientation.” (citation omitted)). Therefore, the Court will not effectively import a manufacturing process into the definition of “fiber” based on extrinsic evidence alone by requiring that the fiber have a common orientation.

Two qualified POSAs agree that the ordinary meaning of “fiber” to a POSA, in the context of the ’296 patent, is a thread-like structure, and the intrinsic evidence clarifies that such a structure may be of any length or shape. Therefore, the Court construes “fiber” to take its plain and ordinary meaning to a POSA, which is “a thread-like structure of any length or shape.”

B. UT’s Request to Construe “Fiber” and “Biodegradable Polymer Fiber”

UT asks that the Court construe “biodegradable polymer fiber” to mean “[a] fiber capable of releasing drug slowly, in a controlled manner over time as the polymer breaks down chemically and mechanically in animal or human tissue[.]” D.I. 245 at 5.

The Court declines to construe “biodegradable polymer fiber” because UT’s request that the Court do so is untimely. The Court issued its claim construction Memorandum Order in this case on April 15, 2021. D.I. 90. Therein, the Court explained that, if the parties’ dispute as to the construction of the term “fiber” “really is a claim construction dispute, [BSC] can raise the

issue again in connection with summary judgment briefing to the extent appropriate.” D.I. 90 at 6. UT did not at that time move for reargument to ask that the Court now construe a new term. *See* Del. Loc. Civ. R. 7.1.5(a). Per the Court’s direction, BSC raised construction of “polymer fiber” (rather than of “fiber”) in its June 14, 2022 opening brief for summary judgment of noninfringement. *See* D.I. 200 at 13. UT did not request that the Court construe the term “biodegradable polymer fiber” in its responsive briefing. *See* D.I. 214 at 17 (“Assuming *arguendo*, the Court adopts [BSC]’s proposed construction of ‘polymer fiber,’ which it should not, summary judgment is still unwarranted.”). Instead, UT waited until October 26, 2022 to first request that the Court construe “biodegradable polymer fiber.” D.I. 245 at 5. Thus, the Court declines to construe the term because UT’s request for claim construction is untimely. Additionally, UT’s failure to even mention the term “biodegradable polymer fiber” in its Sur-Reply Brief suggests that UT has dropped its request for claim construction. D.I. 245 at 15–16 (referencing “the drug-releasing biodegradable polymer format”).

However, even if UT’s request was timely and had not been dropped, the intrinsic evidence does not support the limitations that UT asks the Court to read into the term “biodegradable polymer fiber.” UT points to column 2, lines 39–65, of the ’296 patent, D.I. 245 at 6, which explains that the invention provides “three-dimensional matrices for growing cells” that “comprise biodegradable polymer fibers capable of the controlled delivery of therapeutic agents” “over time[,]” D.I. 1-1 at 2:39–50. This language provides no support for UT’s contention that a “biodegradable polymer fiber” must be capable of releasing a drug “slowly.” UT also points to language in one of the invention’s embodiments, D.I. 245 at 6–7, which explains that “[t]he therapeutic agents are released from each individual fiber slowly, and in a controlled manner[,]” D.I. 1-1 at 8:36–40. However, the words “slow” and “slowly” are not used

in the written description or claims outside of illustrative embodiment A and Example 4, a “preferred embodiment[] of the invention.” D.I. 1-1 at 8:36–40, 17:26, 20:66. The Court should not limit a term’s construction “on the basis of a single exemplary embodiment, as [UT] urge[s]” here. *Supercell Oy v. GREE, Inc.*, 2021 WL 4452082, at *4 (Fed. Cir. Sept. 29, 2021); *see SIPCO, LLC v. Emerson Elec. Co.*, 980 F.3d 865, 872 (Fed. Cir. 2020) (“[T]he [Patent Trial and Appeal Board] did not err in declining to import exemplary embodiments . . . from the specification into the broader claim term . . .”). Lastly, the written description clarifies that “[t]he host [of the fiber-scaffold] will *typically* be an animal, preferably a mammal and more preferably a human.” D.I. 1-1 at 5:16–18 (emphasis added). Thus, the invention need not be used “in animal or human tissue.” The Court would reject UT’s proposed construction even if timely and not dropped.⁵

C. Permissible Scope of the Parties’ Arguments Before the Jury

“[I]t is improper to argue claim construction to the jury because the ‘risk of confusing the jury is high when experts opine on claim construction.’” *Cordis Corp. v. Bos. Sci. Corp.*, 561 F.3d 1319, 1337 (Fed. Cir. 2009) (citation omitted); *C R Bard, Inc. v. AngioDynamics Inc.*, 2018 WL 3130622, at *11 (D. Del. June 26, 2018) (similar). Thus, the parties should not revisit before the jury the Court’s decisions here. BSC may not argue that the fiber recited in Claim 1

⁵ Parts of the proposed definition find support in the ’296 patent. For example, UT argues that the Court should construe “biodegradable polymer fiber” to “break[] down chemically and mechanically” “over time” because the patent teaches that investigators in the field of tissue engineering implant cells on a “biodegradable” scaffolding, “meaning that over time it will break down both chemically and mechanically.” D.I. 245 at 5–6; D.I. 1-1 at 1:12–51. BSC does not appear to oppose this portion of UT’s request. D.I. 245 at 13; *see* D.I. 246-18 (mentioning “breaks down chemically and mechanically” only once). Thus, if the term had actually been in dispute, the Court would have construed “biodegradable” as “breaks down chemically and mechanically over time.” Additionally, the written description explains that the “biodegradable polymer fiber” is “capable of the controlled delivery of therapeutic agents,” *see* D.I. 245 at 5–6; D.I. 1-1 at 2:44–45.

must have a common molecular orientation. *See* Section III.A., *supra*. Similarly, UT may not argue that a “biodegradable polymer fiber” must be capable of releasing a drug slowly or that the invention must be used in animal or human tissue. *See* Section III.B., *supra*.

Rather, the parties may argue before the jury whether “the term ‘fiber’ can encompass what [BSC] says is a coating.” D.I. 90 at 5–6. UT has maintained that a construction of “thread-like” would not eliminate its infringement case. *See* D.I. 89 at 17:14–17 (“[I]f the construction was threadlike . . . , that still can include a coating.”); D.I. 214 at 17 (explaining that “summary judgment is still unwarranted” even if “the Court adopts [BSC]’s proposed construction of ‘polymer fiber’”). As UT explained at the prior *Markman* hearing, UT alleges that the biodegradable coating applied to each narrow ring included in the Accused Product is a fiber that meets the requirements of Claim 1 of the ’296 patent. D.I. 89 at 23:13–20. The Court does not understand its construction to resolve whether such a “coating” is one of the claimed “fibers,” since the Court’s construction does not, for example, require that the claimed “fiber” be solid rather than hollow or that the claimed fiber be free-standing. *See, e.g.*, D.I. 1-1 at 22:43–51 (explaining that a fiber may “be used in conjunction with commercially available stents” and “would not provide any mechanical support”). It is for a jury to decide whether the coating on the rings of BSC’s metal stent is, in fact, a “fiber”—a thread-like structure of any length or shape—as claimed in Claim 1.

IV. CONCLUSION

For the reasons explained above, the Court construes “fiber” as taking its plain and ordinary meaning, which is “a thread-like structure of any length or shape.” The Court declines as untimely the request to construe “biodegradable polymer fiber” and construes “fiber” rather than “polymer fiber.”

The Court will issue an Order consistent with this Memorandum Opinion.

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.

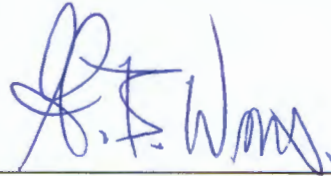
Defendant.

Civil Action No. 18-392-GBW

ORDER

At Wilmington this 17th day of November 2022:

For the reasons set forth in the Memorandum Opinion issued this day, IT IS HEREBY ORDERED that the Court construes the claim term “fiber” of United States Patent No. 6,596,296 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.”



GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE