

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOARD OF REGENTS, THE)	
UNIVERSITY OF TEXAS SYSTEM AND)	
TISSUEGEN, INC.,)	
)	
Plaintiffs,)	
)	C.A. No. 18-cv-392 (MN)
v.)	
)	
BOSTON SCIENTIFIC CORPORATION,)	
)	
Defendant.)	
)	

MEMORANDUM ORDER

At Wilmington this 15th day of April 2021:

IT IS HEREBY ORDERED that the claim terms of U.S. Patent No. 6,596,296 (“the ’296 Patent”) with agreed-upon constructions are construed as follows (*see* D.I. 85)¹:

1. “first phase” means “the polymer portion of the fiber” (’296 Patent, claims 1, 11, 12, 16, 17, & 26);
2. “second phase” means “the discrete drug-containing regions dispersed throughout the fiber” (’296 Patent, claims 1, 11, 12, 16, 17, & 26); and
3. “immiscible” means “incapable of dissolving into one another” (’296 Patent, claims 1, 11, 12, 16, 17, & 26).

Further, as announced at the hearing on March 19, 2021, IT IS HEREBY ORDERED that the disputed claim terms of the ’296 Patent are construed as follows:

1. “fiber” shall have its plain and ordinary meaning (’296 Patent, claims 1, 11, 12, 16, 17, & 26);

¹ The parties filed two Joint Claim Construction Charts. D.I. 71; D.I. 85. The Court refers to and considers the final chart, D.I. 85, Parties’ Amended Joint Claim Construction Chart dated March 15, 2021.

2. “the first and second phases being immiscible” is not indefinite and shall have its plain and ordinary meaning (’296 Patent, claims 1, 11, 12, 16, 17, & 26); and
3. “radioactive agent” means “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”² (’296 Patent, claim 12).

The parties briefed the issues (*see* D.I. 80) and submitted an appendix containing both intrinsic and extrinsic evidence, including expert declarations (*see* D.I. 81). Both sides also provided tutorials describing the relevant technology. The Court carefully reviewed all submissions in connection with the parties’ contentions regarding the disputed claim terms, heard oral argument (*see* D.I. 89), and applied the following legal standards in reaching its decision.

I. LEGAL STANDARD

“[T]he ultimate question of the proper construction of the patent [is] a question of law,” although subsidiary fact-finding is sometimes necessary. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837–38 (2015). “[T]he words of a claim are generally given their ordinary and customary meaning [which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc) (internal citations and quotation marks omitted). Although “the claims themselves provide substantial guidance as to the meaning of particular claim terms,” the context of the surrounding words of the claim also must be considered. *Id.* at 1314. “[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent.” *Id.* at 1321 (internal quotation marks omitted).

² At the hearing, the parties agreed upon the construction of this term. The Court adopts this agreed-upon construction.

The patent specification “is always highly relevant to the claim construction analysis . . . [as] it is the single best guide to the meaning of a disputed term.” *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). It is also possible that “the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor’s lexicography governs.” *Phillips*, 415 F.3d at 1316. “Even when the specification describes only a single embodiment, [however,] the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction.” *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (internal quotation marks omitted) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)).

In addition to the specification, a 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) (en banc), *aff’d*, 517 U.S. 370 (1996). The prosecution history, which is “intrinsic evidence, . . . consists of the complete record of the proceedings before the PTO [(Patent and Trademark Office)] and includes the prior art cited during the examination of the patent.” *Phillips*, 415 F.3d at 1317. “[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Id.*

In some cases, courts “will 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*, 135 S. Ct. at 841. 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. Expert testimony can be useful “to ensure that the court’s understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field.” *Phillips*, 415 F.3d at 1318. Nonetheless, courts must not lose sight of the fact that “expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence.” *Id.* Overall, although extrinsic evidence “may be useful to the court,” it is “less reliable” than intrinsic evidence, and its consideration “is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence.” *Id.* at 1318–19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

II. THE COURT’S RULING

The Court’s rulings regarding the disputed claim terms of the ’296 Patent were announced from the bench at the conclusion of the hearing. The Court’s rulings are as follows:

At issue are the disputed claim terms of U.S. Patent No. 6,596,296. We started with three disputed terms and reached agreement on one of them during the hearing.

I am prepared to rule on the remaining two disputes. I will not be issuing a written opinion, but I will issue an order stating my rulings. I want to emphasize before I announce my decisions that although I am not issuing a written opinion, we have followed a full and thorough process before making the decisions I am about to state. I have reviewed the patent in dispute and all of the evidence submitted by the parties. There was full briefing on each of the disputed terms and each party submitted a technology tutorial. There has been argument here today. All of that has been carefully considered.

Now as to my rulings. As an initial matter I am not going to read into the record my understanding of claim construction law

generally. I have a legal standard section that I have included in earlier opinions including recently in *Purewick Corporation v. Sage Products, LLC*, Civil Action No. 19-1508. I incorporate that law and adopt it into my rulings and will also set it out in the order that I issue.

As to a person of ordinary skill in the art, the parties through their experts have offered some different definitions. The parties, however, have not asserted that the differences are relevant to the issues before me today. Now the disputed terms.

The first term is “fiber” in claims 1, 11, 12, 16, 17, and 26 of the ’296 Patent. Plaintiffs propose that no construction is necessary or alternatively “a unit of matter having a high length-to-width ratio, e.g., 100 to 1, and a small cross-section.” Defendant proposes the construction “a slender threadlike structure – e.g., a filament,” and asserts that the term should not be construed to encompass coating, layers or films.

Here I agree with Plaintiffs 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.^[3] They may be, but need not be, woven into support structures^[4] and may be used as drug delivery reservoirs with metal stents,^[5] or they may be attached directly to vessel walls or tacked down in the eye^[6]. These fibers may be made by various solvent exchange methods.^[7]

Defendant does not disagree with any of that. Instead, Defendant 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 Defendant’s proposed construction, but rather whether the term “fiber” can encompass what Defendant 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

³ (See, e.g., ’296 Patent at 6:63–7:14, 7:24–32; *id.* at FIGS. 1, 2, 3A, 3B, 6, 7).

⁴ (See, e.g., *id.* at 8:41–45).

⁵ (See, e.g., *id.* at 22:40–51 (Example 7)).

⁶ (See, e.g., *id.* at 23:31–54 (Example 10)).

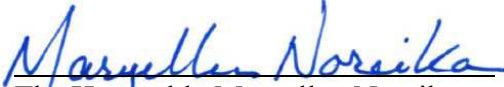
⁷ (See, e.g., *id.* at 17:36–19:36 (Example 1), 19:37–20:5 (Example 2), 20:6–36 (Example 3), 25:13–31 (Example 15), 25:32–49 (Example 16)).

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 that really is a claim construction dispute, Defendant can raise the issue again in connection with summary judgment briefing to the extent appropriate.

The second term is "the first and second phases being immiscible," also in claims 1, 11, 12, 16, 17 and 26 of the '296 Patent. The parties agree that the word "immiscible" means "incapable of being dissolved into one another." But Defendant asserts that the entire phrase should be found to be indefinite. Plaintiffs disagree.

Defendant bears the burden of proving indefiniteness by clear and convincing evidence. Here I do have some concerns about this term. There is nothing in the specification about immiscibility. And Defendant has offered arguments that a POSA would not understand when or how immiscibility is to be determined, and that as Plaintiffs would construe the term immiscibility is meaningless. But I am not convinced at this time that Defendant has met its burden of proving indefiniteness on the record before me, so as no one has offered a construction, I will give this term its plain and ordinary meaning. But again, after the fact and expert discovery, Defendant may raise the issue if necessary.

The third term is "radioactive agent."^[8] During the hearing the parties agreed to the construction "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." I will adopt that construction.


The Honorable Maryellen Noreika
United States District Judge

⁸ This term is in claim 12 of the '296 Patent.