

**UNITED STATES DISTRICT COURT
DISTRICT OF MAINE**

COPAN ITALIA S.P.A., et al.,)	
)	
Plaintiffs,)	
)	
v.)	1:18-cv-00218-JDL
)	
PURITAN MEDICAL PRODUCTS COMPANY LLC, et al.,)	
)	
Defendants.)	

CLAIM CONSTRUCTION ORDER

Copan Italia S.p.A. and Copan Diagnostics, Inc. (collectively, “Copan”) bring this patent infringement suit against Puritan Medical Products Company LLC, Puritan Diagnostics LLC, Hardwood Products Company LP, and Hardwood Products Company LLC (collectively, “Puritan”). Because the parties request construction of the preambles and thirteen claim terms in the patents-in-suit, *see* ECF No. 129 at Page ID 3348–49, the Court held a *Markman* claim construction hearing on June 26, 2019. *See generally Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996).

I. FACTUAL BACKGROUND

The five patents-in-suit—Patent No. 8,114,027 (“the ‘027 Patent”), Patent No. 8,317,728 (“the ‘728 Patent”), Patent No. 8,979,784 (“the ‘784 Patent”), Patent No. 9,011,358 (“the ‘358 Patent”), and Patent No. 9,173,779 (“the ‘779 Patent”)—relate to a flocked swab device and a method for using flocked swabs to collect, transport, and

release biological specimen samples for analysis. All five patents are related, as they all descend from the same patent application and share a common specification.¹

The industry predecessor of Copan’s flocked swab was a fiber swab similar in construction to a Q-tip: a small rod with a wad of fibers wrapped around the tip. Copan asserts that it identified several problems with using fiber swabs to collect biological specimens, including that “on average only about 40% of the liquid specimen collected” could be recovered from the fiber swab for analysis. ‘027 Patent, ECF No. 72-1 at Page ID 768. In response to these problems, Copan developed its flocked swab. Instead of wrapping a wad of fibers around the tip of a rod, Copan used a process known as electrostatic flocking to cover the tip of the rod with fibers. *Id.* Electrostatic flocking consists of placing a rod with adhesive on the tip in an electrostatic field and charging both the rod and the fibers, causing the fibers to fly towards the rod and adhere to the tip. Copan claims that a flocked swab “is capable of releasing about 90% of the absorbed specimen” for analysis, in contrast to the fiber swab’s 40% average release rate. *Id.* at Page ID 769.

II. LEGAL ANALYSIS

A. Claim Construction 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). The construction of patent claims is a question of law which is “exclusively within the province of the court.” *Markman*, 517 U.S. at 372, 384. “In determining the proper

¹ A specification is a written description of the invention claimed by a patent. See 35 U.S.C.A. § 112 (West 2019); 37 C.F.R. §§ 1.71, 1.77 (2018).

construction of a claim,” a court “look[s] first to the intrinsic evidence of record, *i.e.*, the patent itself, including the claims, the specification and, if in evidence, the prosecution history.” *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Courts may also consult extrinsic evidence, “which consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Phillips*, 415 F.3d at 1317 (quotation marks omitted). But “such evidence is generally of less significance than the intrinsic record.” *Endo Pharm. Inc. v. Actavis LLC*, 922 F.3d 1365, 1371 (Fed. Cir. 2019) (quoting *Wi-LAN, Inc. v. Apple Inc.*, 811 F.3d 455, 462 (Fed. Cir. 2016)).

“[C]laim construction must begin with the words of the claims themselves.” *Id.* at 1370 (quoting *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1301 (Fed. Cir. 2006)). The terms within 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*, 415 F.3d at 1313. “[T]he person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.” *Id.* Additionally, where, as here, “multiple patents derive from the same parent application and share many common terms, [a court] must interpret the claims consistently across all asserted patents.” *Samsung Elecs. Co. v. Elm 3DS Innovations, LLC*, 925 F.3d 1373, 1378 (Fed. Cir. 2019) (quotation marks omitted).

Though the general rule is that claim terms are given their ordinary meaning, courts may construe a claim term more narrowly than its ordinary meaning in two circumstances: “1) when a patentee sets out a definition and acts as [its] own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution.” *Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1324, 1330 (Fed. Cir. 2012). A patentee acts as its own lexicographer if it “clearly set[s] forth a definition of the disputed claim term’ other than [the term’s] plain and ordinary meaning.” *Thorner v. Sony Comput. Entm’t Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (quoting *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)). A patentee disavows the full scope of a claim term if the specification or prosecution history “makes clear that the invention does not include a particular feature,” even if the language of the claims otherwise “might be considered broad enough to encompass the feature in question.” *Id.* at 1366 (quoting *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001)).

B. Analysis

1. Defining a Person of Ordinary Skill in the Art

As discussed above, the “ordinary and customary meaning” of a claim term 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.” *Phillips*, 415 F.3d at 1313. The parties dispute how a “person of ordinary skill in the art” should be defined in the context of the five patents-in-suit. Copan argues that the patents-in-suit involve two pertinent arts: clinical microbiology, and flocked fiber and textiles arts. Copan asserts that a person

of ordinary skill in clinical microbiology has at least a bachelor's degree in biology or comparable science, as well as two years of practical experience in biological specimen collection and analysis. Copan further asserts that a person of ordinary skill in the flocked fiber and textiles arts has either four years of experience in fiber science or a bachelor's degree in chemistry or physics and two years of experience related to fiber science.

Puritan proposes a broader, simpler definition, asserting that the pertinent art is any field that would give an artisan general knowledge of flocking techniques and capillarity. Puritan contends that a person of ordinary skill in such a field has either a graduate degree in electrical, mechanical, or material engineering, or an undergraduate degree in the same and experience in electrostatic flocking.

Although claim construction depends upon the understanding of a person of ordinary skill in the art, the scope of the pertinent art and the exact level of skill that such a person should possess are factual questions. *See Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966) (citing 35 U.S.C. § 103). I decline to resolve the parties' dispute regarding the meaning of the term "a person of ordinary skill in the art" at this juncture, absent a more fulsome evidentiary record. Moreover, I conclude that under either Copan's or Puritan's proposed definition of the term, a person of ordinary skill in the art would understand the disputed terms of the patents-in-suit in the same way. Thus, I do not decide that issue at this stage of the proceeding.

2. The Preambles

"A claim typically contains three parts: the preamble, the transition, and the body." *Acceleration Bay, LLC v. Activision Blizzard Inc.*, 908 F.3d 765, 770 (Fed. Cir.

2018) (quoting 3 Chisum on Patents § 8.06 (2018)). Depending on “the facts of each case in light of the claim as a whole and the invention described in the patent,” a preamble term may or may not be construed as limiting the scope of the claim. *Am. Med. Sys., Inc. v. Biolitec, Inc.*, 618 F.3d 1354, 1358 (Fed. Cir. 2010) (quoting *Storage Tech. Corp. v. Cisco Sys., Inc.*, 329 F.3d 823, 831 (Fed. Cir. 2003)). For example, a preamble may limit the invention “if it recites essential structure or steps,” or if the patent applicant clearly relies on it during prosecution in order to distinguish the claimed invention from prior art. *Acceleration Bay*, 908 F.3d at 770 (quotation marks omitted); *Marrin v. Griffin*, 599 F.3d 1290, 1294 (Fed. Cir. 2010). By contrast, a preamble “is not limiting where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention.” *Acceleration Bay*, 908 F.3d at 770 (quotation marks omitted). “Generally, the preamble does not limit the claims.” *Allen Eng’g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1346 (Fed. Cir. 2002).

Here, Copan argues that the preambles for the patents-in-suit are limiting because the patent applicant, Daniele Triva, relied on them during prosecution to distinguish Copan’s flocked swab from prior art. To support this argument, Copan points out that Triva explained to the patent examiner that collecting biological samples was part of the intended invention and further notes that the preambles contain language to that effect. *E.g.*, ‘027 Patent, ECF No. 72-1 at Page ID 769 (introducing the invention as a “method for collecting biological specimen to be analyzed”); ‘784 Patent, ECF No. 72-3 at Page ID 788 (introducing the invention as a “biological specimen collection swab”). Puritan counters that the preambles merely

recite an intended use and do not limit the scope of the claims, likewise turning to the prosecution history for support.

I conclude that the preambles are not limiting for two reasons. First, although Triva did argue during prosecution that the preamble distinguished the invention from prior art, *see* ECF No. 72-8 at Page ID 908–09, the patent examiner disagreed because the prior art that Triva sought to overcome could also be used for collecting biological specimens. *See* ECF No. 79-7 at Page ID 2550; *see also Catalina Mktg. Int’l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 810 (Fed. Cir. 2002) (affirming the district court’s holding that preamble language did not limit a claim where the patent examiner considered the preamble “insignificant for patentability”).

Second, the bodies of the claims in each patent describe a complete invention, and I agree with the patent examiner’s finding that the preambles do not structurally limit the invention but merely state its intended use. *See* ECF No. 79-7 at Page ID 2550. For example, claim 1 of the ‘027 Patent states, in relevant part:

A method for collecting biological specimen to be analyzed, with a swab comprising a rod terminating in a tip, a layer of fibers of uniform thickness, covering the tip and disposed in an ordered arrangement and perpendicular to the surface of the tip by flocking, . . . the method comprising the steps of:

collecting a liquid specimen to be analyzed by absorbing a quantity between 40 μ l and 100 μ l of liquid specimen in said layer of fibers by capillarity effect;
storing and transporting said quantity of specimen in said layer of fibers; and
releasing a quantity of said specimen to be analyzed from said layer of fibers.

‘027 Patent, ECF No. 72-1 at Page ID 769–70. The preamble “collecting biological specimen to be analyzed” does not add an essential step to the method—a person of

ordinary skill in the art would understand how to use the swab solely from the language of the claim. Arguably, the claim's description of the method as "collecting a liquid specimen to be analyzed" is more specific than the preamble language. *Id.* at 770.

The apparatus claims similarly describe a structurally complete invention. For example, claim 1 of the '784 Patent states:

A biological specimen collection swab comprising:
a plastic rod terminating in a tip; and
a layer of fibers disposed on a surface of said tip by flocking, with a flocking technique in which the fibers were deposited, in an electrostatic field, in an ordered manner perpendicularly to the surface of the tip of the swab rod, the layer of fibers having a thickness from 0.6 to 3 mm and a fiber count of 1.7 to 3.3 Dtex, in which said layer of fibers is configured to be capable of absorbing a quantity of 40 μ l to 100 μ l of specimen in said layer of fibers on the tip of the rod.

'784 Patent, ECF No. 72-3 at Page ID 788. The preamble's "biological specimen collection swab" does not recite an essential structure. The word "swab," which is the only part of the preamble that describes the physical structure of the invention, also appears in the body of the claim. The body of the claim also includes detailed structural parameters for the invention. Thus, a person of ordinary skill in the art would understand the structure of the invention without the use of the phrase "biological specimen collection swab."

For the foregoing reasons, I conclude that the preambles merely recite an intended use and do not limit the scope of the asserted claims.

3. Agreed-Upon Claim Terms

a. “tip”

The parties agree that this term should be given its plain and ordinary meaning, which is: “The flocked end of a swab.”

b. “swab”

The parties agree that this term should be given its plain and ordinary meaning, which is: “A stick or wire with a small piece of absorbent material attached to the end.”

4. Claim Terms that Puritan Asserts are Indefinite

Puritan argues that the patents-in-suit do not provide sufficient guidance as to the meaning of seven claim terms, and thus that the claims in which those terms appear are invalid because they are indefinite. “The Patent Act requires that a patent specification ‘conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as [the] invention.’” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014) (emphasis omitted) (quoting 35 U.S.C. § 112, ¶ 2 (2006 ed.)).² This ensures that the patent affords clear notice of what is claimed, thereby apprising the public of what is still open to them and avoiding the “zone of uncertainty.” *Markman*, 517 U.S. at 373, 390 (quotation marks omitted). A patent claim does not satisfy this statutory requirement, and thus is indefinite, if its language, when read in light of the

² When the America Invents Act, Pub. L. No. 112-29, took effect on September 16, 2012, section 112 was divided into subsections and paragraph 2 became subsection (b). The applications resulting in the patents at issue in this case were filed before the AIA took effect, but the substantive content of section 112 as it pertains to the indefiniteness analysis in this case did not change. *Compare* 35 U.S.C.A. § 112, ¶ 2 (West through Sept. 15, 2012), *with* 35 U.S.C.A. § 112 (West 2019).

specification and prosecution history, “fail[s] to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus*, 572 U.S. at 901. “[T]he dispositive question . . . is whether the claims, not particular claim terms” are indefinite. *Cox Commc’ns, Inc. v. Sprint Commc’n Co.*, 838 F.3d 1224, 1231 (Fed. Cir. 2016).

Patents are presumptively valid, so the burden of establishing that a patent claim is invalid for indefiniteness rests on the party asserting such invalidity. *See Microsoft Corp. v. i4i Ltd. P’ship*, 564 U.S. 91, 97, 102 (2011). “Any fact critical to a holding on indefiniteness must be proven by the challenger by clear and convincing evidence.” *Cox Commc’ns, Inc.*, 838 F.3d at 1228 (quotation marks and alteration omitted).

a. “ordered arrangement” / “ordered manner”

The term “ordered arrangement” appears in the sole independent claim of the ‘027 Patent and in a dependent claim of the ‘728 Patent.³ *See* ‘027 Patent, Claim 1, ECF No. 72-1 at Page ID 769; ‘728 Patent, Claim 13, ECF No. 72-2 at Page ID 779. Copan also used the phrase “ordered arrangement” during prosecution in an attempt to distinguish its flocking method from prior art. *See* ECF No. 73-8 at Page ID 1383–86. “Ordered manner” appears in independent claims in the ‘784 Patent, the ‘358 Patent, and the ‘779 Patent. *See* ‘784 Patent, Claim 1, ECF No. 72-3 at Page ID 788; ‘358 Patent, Claims 1, 14, 23, and 24, ECF No. 72-4 at Page ID 798; ‘779 Patent,

³ An independent claim stands alone, whereas a dependent claim refers to “a claim previously set forth and then specif[ies] a further limitation on the subject matter claimed.” 35 U.S.C.A. § 112(d) (West 2019). The construction of an independent claim is incorporated by reference into all of its dependent claims. *Id.* By contrast, dependent claims include additional limitations that are usually not incorporated into the construction of the independent claim from which they flow. *GE Lighting Sols., LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1310 (Fed. Cir. 2014).

Claims 1, 13, ECF No. 72-5 at Page ID 808. A representative example of the term as it appears in an independent claim is: “a flocking technique in which the fibers were deposited, in an electrostatic field, in an ordered manner perpendicularly to the surface of the tip of the rod” ‘779 Patent, Claim 1, ECF No. 72-5 at Page ID 808. “Ordered manner” also appears in the specification: “The flocking technique is preferably of the type conducted in an electrostatic field which deposits the fibres in an ordered manner, perpendicular to the surface of the tip of the swab rod” ‘728 Patent, ECF No. 72-2 at Page ID 778.

Puritan argues that “ordered arrangement” and “ordered manner” are indefinite because they are vague and subjective descriptors that do not clearly indicate the scope of the claims in which they appear, and that neither the prosecution history nor the specification provide any guidance as to the meaning of the terms. However, the terms “ordered,” “arrangement,” and “manner” are all common words that are readily understood, not only by a person of ordinary skill in the art but also by a layperson. The adjective “ordered” indicates that the noun it modifies “is dictated by some logic, rule, or governing principle.” *Netflix, Inc. v. Blockbuster, Inc.*, 477 F. Supp. 2d 1063, 1071 (N.D. Cal. 2007).

The intrinsic evidence supports this construction. Viewed in the context of the patents-in-suit, “ordered arrangement” and “ordered manner” are used to instruct how to deposit the fibers onto the surface of the swab. The independent claims that include “ordered manner” all instruct that the flocking technique involves depositing the fibers “in an ordered manner perpendicularly to the surface of the tip of the rod.” *E.g.*, ‘779 Patent, Claim 1, ECF No. 72-5 at Page ID 808. The dependent claim where

“ordered arrangement” appears similarly instructs that the layer of fibers is “disposed on said tip in an ordered arrangement by flocking.” ‘728 Patent, Claim 13, ECF No. 72-2 at Page ID 779. Additionally, Triva argued during prosecution that Copan’s flocked swab was distinct from prior art because prior art “advocates avoiding the adjustment of the flock direction. Thus, flocking as such cannot provide an ordered arrangement of the fibers normal to the target substrate unless the fibers are intentionally oriented to such purpose. Such ordered arrangement of normal fibers does not flow naturally from the flocking process.” ECF No. 73-8 at Page ID 1386. In the context of the patents, it is clear that “normal” is synonymous with “perpendicular.” *See also Streamfeeder, LLC v. Sure-Feed Sys., Inc.*, 175 F.3d 974, 980 (Fed. Cir. 1999) (treating “normal” as synonymous with “perpendicular to a surface”). Based on the patents and the prosecution history, a person of ordinary skill in the art would understand “ordered arrangement” and “ordered manner” to mean that the fibers need to be intentionally arranged so that they are perpendicular to the rod’s tip when they are flying toward it during the flocking process.

Puritan contends that this construction violates the doctrine of claim differentiation, which presumes that “each claim in a patent has a different scope,” *Versa Corp. v. Ag-Bag Int’l Ltd.*, 392 F.3d 1325, 1330 (Fed. Cir. 2004), because it makes “ordered arrangement” and “ordered manner” redundant with other descriptors in the patents, such as “in an electrostatic field,” “perpendicular,” and “substantially parallel.” ECF No. 77 at Page ID 2187. But the plain and ordinary meaning of each of these descriptors is distinct from the plain and ordinary meaning of “ordered.” Viewed in the context of the patent as a whole, these descriptors modify

the term “ordered,” providing additional guidance as to how the fibers should be arranged during the flocking process. As such, the doctrine of claim differentiation does not preclude construing “ordered” according to its plain and ordinary meaning.

Thus, Puritan has not met its burden of establishing that the claims containing the terms “ordered arrangement” and “ordered manner” are indefinite, and I conclude that those terms should be given their plain and ordinary meaning.

b. “a thickness between 0.6 and 3 mm” & variants

Puritan argues that this term is indefinite because “there are at least four different ways to measure the thickness of a layer of fibers,” the intrinsic record does not provide guidance as to which method to use, and the different methods result in “materially different measurements.” ECF No. 77 at Page ID 2194. However, during prosecution, Copan clarified that “thickness” refers to the layer of fibers and not the thickness of the individual fibers. ECF No. 78 at Page ID 2283. The specification further indicates that the length of the fibers determines the thickness of the layer, such that both the length of the fibers and the thickness of the layer are to measure between 0.6 and 3 millimeters. *See, e.g.*, ‘027 Patent, ECF No. 72-1 at Page ID 769 (explaining that “the fiber lengths can be from 0.6 mm to 3 mm, which is the thickness of the layer”). Neither party suggests that there is more than one way to measure the length of a fiber. Thus, the specification and the prosecution history provide enough guidance about how to measure thickness to resolve the ambiguity that Puritan has identified. This is not a situation where “[c]ompetitors trying to practice the invention or to design around it would be unable to discern the bounds of the invention.” *Honeywell Int’l, Inc. v. Int’l Trade Comm’n*, 341 F.3d 1332, 1341 (Fed.

Cir. 2003) (finding a patent claim indefinite where the patentee failed to specify a method because a person of ordinary skill in the art would not be able to discern the bounds of the invention). Accordingly, I conclude that the claims containing this term are not indefinite and accord the term its plain and ordinary meaning.

c. “fibers define capillaries in said layer of fibers, conferring hydrophilic properties by capillarity to the layer of fibers” & variants

Puritan contends that the phrase “hydrophilic . . . by capillarity” is indefinite. Puritan concedes that both “hydrophilic” and “capillarity” have well-understood technical meanings. ECF No. 77 at Page ID 2198. “Hydrophilic” means “[h]aving an affinity for, attracting, adsorbing, or absorbing water.” *Id.* “Capillarity” or “capillary action” means “[t]he action by which the surface of a liquid where it contacts a solid is elevated or depressed because of the relative attraction of the molecules of the liquid for each other and for those of the solid.” *Id.*

“Properly viewed, the ‘ordinary meaning’ of a claim term is its meaning to the ordinary artisan after reading the entire patent.” *Phillips*, 415 F.3d at 1321. Here, the ordinary meaning of the words comprising this claim term are not in dispute. I conclude that a person of ordinary skill in the art, after reading the whole patent, would accordingly understand the phrase “hydrophilic by capillarity” to mean that the space between the fibers creates an additional hydrophilic effect by drawing liquid into the layer of fibers by capillary action.

Puritan asserts that the phrase “hydrophilic . . . by capillarity” is indefinite because that phrase has no established meaning and did not exist in the art at the time of the invention. ECF No. 77 at Page ID 2200. But to accept Puritan’s argument

would ignore the purpose of patent protection. If patents were limited to inventions containing only previously known components or effects, the goal of promoting new and useful inventions through the patent system would be impaired. Thus, Puritan has not demonstrated that a person of ordinary skill in the art, after reviewing the intrinsic record, would not understand the scope of the claims containing the disputed “hydrophilic by capillarity” term. I therefore conclude that the claims where this term appears are not indefinite and construe the term according to its plain and ordinary meaning.

d. “about 90%”

Copan argues that the term “about 90%” has a clear meaning because “about” is generally understood to mean “approximately” or “reasonably close to” and that the term should be construed accordingly. ECF No. 78 at Page ID 2289. Puritan responds that the term is indefinite, emphasizing that the United States Patent and Trademark Office informed Copan that “about 90%” was indefinite in two separate patent applications. However, a district court construing terms in patents that have already issued applies a different standard than the Patent and Trademark Office applies during patent examination. “During examination, claims are to be given their broadest reasonable interpretation consistent with the specification” *In re Montgomery*, 677 F.3d 1375, 1379 (Fed. Cir. 2012) (internal alterations and quotation marks omitted). Thus, the Patent and Trademark Office’s statements imply that it found the broadest reasonable interpretation of “about 90%” indefinite. By contrast, courts construe claims in issued patents according to “the plain meaning of the claim terms themselves in light of the intrinsic record,” not according to the broadest

reasonable interpretation of the claim terms. *In re CSB-Sys. Int'l, Inc.*, 832 F.3d 1335, 1340 (Fed. Cir. 2016). Thus, the Patent and Trademark Office's statements during prosecution are not determinative here.

“[A] patentee need not define his invention with mathematical precision in order to comply with the definiteness requirement.” *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1384 (Fed. Cir. 2005). “Claim language employing terms of degree has long been found definite where it provide[s] enough certainty to one of skill in the art when read in the context of the invention.” *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1370 (Fed. Cir. 2014). By contrast, a claim is indefinite when the meaning of a term is “purely subjective.” *Id.* Here, the patent employs the term of degree “about 90%” to indicate how much of the collected specimen can be recovered from the fibers for analysis. The word “about” in this context is not a purely subjective term but rather modifies “90%” and, therefore, provides an objective boundary by establishing that a swab that releases “approximately 90%” of the specimen absorbed would be infringing. *See Merck & Co., Inc. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1369–72 (Fed. Cir. 2005) (according the word “about” its plain and ordinary meaning of “approximately”).

I conclude that Puritan has not demonstrated by clear and convincing evidence that “about 90%” is indefinite, and I construe “about 90%” to have its plain and ordinary meaning of “approximately 90%.”

**e. “rod is suitable for human clinical collection” and its variant,
“a clinical swab, configured for human clinical collection”**

The phrase “suitable for human clinical collection” appears only in dependent claims in the ‘784 Patent and the ‘358 Patent, where the phrase modifies the word “rod,” and the ‘779 Patent, where the phrase modifies the word “swab.”⁴ ‘784 Patent, Claim 4, ECF No. 72-3 at Page ID 788; ‘358 Patent, Claim 6, ECF No. 72-4 at Page ID 798; ‘779 Patent, Claim 9, ECF No. 72-5 at Page ID 808. Puritan argues that this term is indefinite because the intrinsic record provides no guidance as to the scope of these terms and, consequently, there are no objective boundaries that would allow a person of ordinary skill in the art to determine whether a swab or method infringes the patents-in-suit.

However, viewed as a whole, the patents provide ample guidance as to what makes a swab suitable for human clinical collection. For example, the specification of the ‘779 Patent states that a rod with a truncated, unprotected end would make specimen collection difficult for clinicians and uncomfortable for patients. The specification goes on to explain the drawbacks of the flocked swab’s industry predecessor, including that a swab with “maximum protective effect” for the patient would have a thick wad of fiber on the end, which would cause liquid to become trapped instead of releasing easily. ECF No. 72-5 at Page ID 806. By comparison, one of the asserted advantages of the flocked swab is that “the required rounded shape of the swab, i.e. free of edges, no longer has to depend on the mass of fibre itself

⁴ The parties have agreed to drop claim 24 of the ‘779 Patent, which includes the phrase “during a human clinical collection procedure.” ECF No. 72-5 at Page ID 808. Therefore, only claim 9 of the ‘779 Patent is in dispute here.

but on the tip of the rod, which can therefore be preferably shaped into a round form” *Id.* at Page ID 807. The specification also provides more detailed examples of characteristics that may be required for specific kinds of human clinical collection—like ocular or urethral collection, where “swabs of the greatest possible thinness are required”—but notes that the shape of the swab will vary according to the specific kind of collection it is intended for. *Id.*

Because the intrinsic record provides sufficient guidance to make the scope of the claims reasonably certain to a person of ordinary skill in the art, Puritan has not established by clear and convincing evidence that the claims including the phrase “rod is suitable for human clinical collection” and its variants are indefinite. I therefore accord the term its plain and ordinary meaning.

f. “rigid”

The term “rigid” appears in the ‘784 Patent, the ‘358 Patent, and the ‘779 Patent, each of which states: “said rod tip is rigid.” ECF No. 72-3 at Page ID 788; ECF No. 72-4 at Page ID 798; ECF No. 72-5 at Page ID 808. Puritan argues that this term is indefinite because the intrinsic record provides no guidance as to the scope of the term. Copan argues that the term should be accorded its plain and ordinary meaning, which is clear even to a lay person.

The term “rigid” also appears in the specification, which states: “The tip of the cylindrical rod, [is] generally manufactured from essentially rigid material such as plastic. . . .” ECF No. 72-3 at Page ID 786. Puritan argues that this offers no objective guidance to a person of ordinary skill in the art because plastic comes in many forms. But plastic is simply an example of a material that may provide rigidity.

A person of ordinary skill reading the term in the context of the patents-in-suit would understand that the swab needs to be rigid enough to perform the claimed method of collecting liquid samples. Sometimes claim construction requires “little more than the application of the widely accepted meaning of commonly understood words.” *Phillips*, 415 F.3d at 1314. That is the case here. To the extent a definition is required, I define “rigid” to be synonymous with “stiff.”

Puritan has not met its burden of proving indefiniteness. Thus, I find that a person of ordinary skill in the art would be able to determine the scope of the claims that include this term with reasonable certainty.

g. “an amount of fiber deposited”

The phrase “an amount of fiber deposited” appears in two independent claims in the ‘358 Patent. Puritan argues that the term is indefinite because the intrinsic record offers no guidance as to what the “amount” is or how to measure it. Though Puritan identifies several parts of the specification that provide examples or instruction regarding calculation of the amount of fiber that is required, it argues that they provide no guidance.

But no further guidance is needed. In Claims 1 and 14 of the ‘358 Patent, the term appears as follows: “an amount of fiber deposited forming the flocked layer being configured to enable 40 μ l of specimen to be absorbed in said layer of fibers on the tip of the rod.” ECF No. 72-4 at Page ID 798. In this context, even a layperson would understand that “an amount of fiber deposited” means the amount necessary for the layer of fibers to absorb 40 microliters of specimen. Example 1 of the specification confirms this understanding, stating: “The polyamide flock of 0.7 mm length and 1.7

Dtex allows 0.5 μl per mm to be absorbed, therefore by flocking the 10 mm long tip of said rod the absorbing capacity obtained is 40 μl .” ‘358 Patent, ECF No. 72-4 at Page ID 797. This informs a person of skill in the art that the amount of fiber must be calculated based on the type of fiber being used, and it provides an example of a fiber length and density that would allow for the collection of 40 microliters of specimen. Thus, the context of the claims and the specification would inform a person of ordinary skill in the art of the invention’s scope with reasonable certainty. “Reasonable certainty does not require absolute or mathematical precision.” *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1365 (Fed. Cir. 2017) (quotation marks omitted). Additionally, the standard “does not exclude claim language that identifies a product by what it does. Nothing inherent in the standard of ‘reasonable certainty’ precludes a relevant skilled artisan from understanding with reasonable certainty what compositions perform a particular function.” *Id.* at 1366.

Puritan contends that, under the doctrine of claim differentiation, the specification cannot serve as guidance for defining the term “an amount of fiber deposited” because the specification does not use that term while discussing the absorption capacity of the swab. Puritan asserts that without such guidance, the term is indefinite. But claim differentiation ordinarily applies only to prohibit incorporating dependent claim limitations into the construction of independent claim terms. *See GE Lighting Sols., LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1310 (Fed. Cir. 2014). It does not preclude construing a claim term in light of the specification, including portions of the specification that do not explicitly reference the claim term. Thus, the cited portions of the specification can properly inform the construction of

“an amount of fiber deposited.” Because the patent as a whole would provide reasonably certainty as to the meaning of this term to a person of ordinary skill in the art, as discussed above, the term is not indefinite and is accorded its plain and ordinary meaning.

5. Other Claim Terms

a. “uniform thickness”

The term “uniform thickness” appears in all five of the patents-in-suit, once in an independent claim and five times in dependent claims. Copan and Puritan both argue that this term should be given its plain and ordinary meaning, but Puritan offers the following construction, with which Copan disagrees: “the fibers have the same height over the entire layer of fibers without interruptions.” ECF No. 77 at Page ID 2182; *see also* ECF No. 78 at Page ID 2263. Puritan draws its definition from portions of the prosecution history.

I begin, as I must, with the language of the claims. *Endo Pharm.*, 922 F.3d at 1370. In context, “thickness” describes the “layer of fibers” on the tip of the flocked swab. For example, Claim 1 of the ‘027 Patent describes the claimed invention as “a swab comprising a rod terminating in a tip [and] a layer of fibers of uniform thickness,” and the specification explains that the fibers should be “disposed as a layer of uniform thickness.” ‘027 Patent, ECF No. 72-1 at Page ID 769, 770. As discussed above in the context of the term “a thickness between 0.6 and 3 mm,” the thickness of the layer depends upon the fiber length. Additionally, “uniform” is a commonly understood word synonymous with “constant.” *Talarico v. Marathon Shoe Co.*, 182 F. Supp. 2d 102, 109–110 (D. Me. 2002); *see also Ductmate Indus., Inc. v.*

Famous Supply Corp., 55 F. Supp. 2d 777 (N.D. Ohio 1999) (construing “uniform thickness” to mean “the same thickness throughout”). There is nothing in the record to suggest that the inventor intended a more specific definition. Thus, a person of ordinary skill in the art would understand the term “uniform thickness” to mean that the layer of fibers on the tip of the swab must have a constant thickness. Because the meaning of “uniform thickness” is plain, I conclude that no further construction is required and decline to adopt Puritan’s proposed definition.

b. “covering the tip” / “cover the tip”

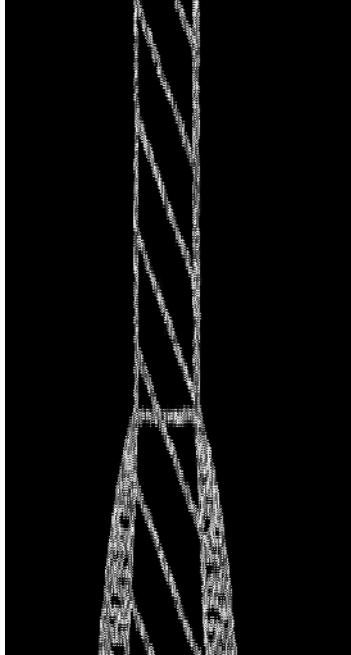
The terms “covering the tip” and “cover the tip” appear in independent claims in the ‘027 Patent and the ‘728 Patent, both of which claim a method for using a flocked swab to collect a liquid⁵ specimen for analysis. Copan argues that the terms should be given their plain and ordinary meaning. Puritan argues that Copan acted as its own lexicographer and urges the adoption of the following definition: “Flocking is completed to saturation, when no more fibers can be anchored to the surface, with a very high packing density of the deposited fibers, close to an ideal hexagonal close packing of fibers.” ECF No. 77 at Page ID 2184.

Acting as one’s own lexicographer is one of two exceptions to the general rule that terms should be given their plain and ordinary meaning. *Aventis Pharma*, 675 F.3d at 1330. A patentee acts as its own lexicographer if it “clearly set[s] forth a definition of the disputed claim term’ other than [the term’s] plain and ordinary

⁵ The word “liquid” appears only in Claim 1 of the ‘027 Patent, not Claim 1 of the ‘728 Patent, but both claims recite a method for collecting 40 to 100 microliters of specimen. *Compare* ‘027 Patent, ECF No. 72-1 at Page ID 770, *with* ‘728 Patent, ECF No. 72-2 at Page ID 779. Therefore, even where the word “liquid” is not present, a person of ordinary skill in the art would likely infer from the use of a volume measurement that the specimen to be absorbed is liquid.

meaning.” *Thorner*, 669 F.3d at 1365 (quoting *CCS Fitness*, 288 F.3d at 1366). Here, Puritan argues that Copan acted as its own lexicographer when it defined “covering the tip” during the prosecution of one of its European patents. But this prosecution communication fails to establish that Triva, the applicant, “clearly set forth a definition” of “covering the tip” other than the plain and ordinary meaning of that term for two reasons. First, the communication is part of the prosecution history of Copan’s European patent, not a patent-in-suit. Second, it is part of the prosecution history and not the patent itself. While the prosecution history may aid a court in construing claim terms, it is often less relevant than the patent itself: “[B]ecause the prosecution history represents an ongoing negotiation between the [Patent and Trademark Office] and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes.” *Phillips*, 415 F.3d at 1317.

Because the prosecution history does not establish that Copan acted as its own lexicographer, the terms should be given their plain and ordinary meaning. In the context of the invention, the terms “covering the tip” and “cover the tip” have a plain meaning that is apparent even to a layperson: forming a layer over the tip of the swab. That construction is also consistent with Figure 2, which appears in each of the patents-in-suit and depicts the flocked swab:



ECF No. 72-1 at Page ID 767.

Puritan’s proposed definition is inconsistent with this plain meaning because it adds limitations that do not make sense in the context of the patents. Specifically, Puritan proposes that “covering the tip” requires fibers to be attached to the tip “with a very high packing density” until “no more fibers can be anchored to the surface.” ECF No. 77 at Page ID 2184. But the invention claimed in the ‘027 and ‘728 Patents is a method for collecting a certain number of microliters of liquid specimen for analysis, which would indicate to a person of ordinary skill in the art that there needs to be some space between the fibers so that the liquid can be absorbed into the flocked tip of the swab. *See* ECF No. 72-1 at Page ID 769–70; ECF No. 72-2 at Page ID 779. I therefore decline to adopt Puritan’s proposed definition and construe the terms “covering the tip” and “cover the tip” according to their plain and ordinary meaning, as described above.

c. “perpendicular” / “perpendicularly”

The term “perpendicular” or “perpendicularly” appears in all five of the patents-in-suit, in eight independent claims and one dependent claim. *See* ‘027 Patent, Claim 1, ECF No. 72-1 at Page ID 769; ‘728 Patent, Claim 6, ECF No. 72-2 at Page ID 779; ‘784 Patent, Claim 1, ECF No. 72-3 at Page ID 788; ‘358 Patent, Claims 1, 14, 23, 24, ECF No. 72-4 at Page ID 798; ‘779 Patent, Claims 1, 13, ECF No. 72-5 at Page ID 808. Copan argues that the term should be accorded its plain and ordinary meaning. Puritan argues that the plain and ordinary meaning does not govern claim construction because Copan disavowed the full scope of the term during prosecution.

Prosecution disavowal is one of two exceptions to the general rule that a claim term is construed according to its plain and ordinary meaning. *Uship Intellectual Props., LLC v. United States*, 714 F.3d 1311, 1313 (Fed. Cir. 2013). “Since it is the claims that define the metes and bounds of the patentee’s invention, the patentee is free to choose a broad term and expect to obtain the full scope of its plain and ordinary meaning unless the patentee explicitly disavows its full scope.” *Intellectual Ventures I LLC v. T-Mobile USA, Inc.*, 902 F.3d 1372, 1378 (Fed. Cir. 2018) (internal alterations and quotation marks omitted). Disavowal is an “exacting” standard. *Thorner*, 669 F.3d at 1366.

In support of its prosecution disavowal argument, Puritan points out that, during prosecution, the patent examiner objected to a claim that required the layer of fibers to be “disposed substantially perpendicular to a surface of the tip.” ECF No. 73-30 at Page ID 1761. Copan responded by amending the claim to remove the term “substantially,” after which the claim read: “said layer of fibers are [sic] directly

disposed on said tip in an ordered arrangement and perpendicular to a surface of the tip by flocking.” ECF No. 73-31 at Page ID 1785. Puritan asserts that Copan disavowed of the full scope of the term “perpendicular” by making this amendment and thus proposes the following definition: “the fibers must stand upright at precisely 90 degrees to the tangent of the surface of the tip of the swab.” ECF No. 77 at Page ID 2190–91. But Copan’s amendment, at most, disavowed the term “substantially perpendicular,” in favor of the term “perpendicular.” While this apparent disavowal would prevent Copan from attempting to reinsert the word “substantially” before “perpendicular,” it does not affect the plain and ordinary meaning of “perpendicular.” Thus, the prosecution disavowal exception does not apply, and the plain and ordinary meaning governs.

Within the context of the claims, the terms “perpendicular” and “perpendicularly” describe how the fibers are oriented with respect to the surface of the swab rod during the flocking process. The language of the patents themselves supports this construction: The independent claims where “perpendicular” and “perpendicularly” appear all use the terms in the context of describing “a flocking technique in which the fibers were deposited, in an electrostatic field, in an ordered manner perpendicularly to the surface of the tip of the swab rod” *E.g.*, ‘358 Patent, Claim 1, ECF No. 72-4 at Page ID 798. Therefore, as Copan argues, a person of ordinary skill in the art would understand that “during the flocking process an electrostatic field causes the fibers to ‘fly’ towards the surface such that they are perpendicular to the surface being flocked and parallel to each other, attaching to a previously applied adhesive.” ECF No. 72 at Page ID 750. A person of ordinary skill

in the art would also understand that the fibers would not remain perfectly perpendicular after they adhere to the swab, contrary to Puritan's proposed definition. Thus, I decline to adopt Puritan's proposed definition and construe the terms "perpendicular" and "perpendicularly" according to their plain and ordinary meaning.

d. "0.5 μ l of liquid specimen are absorbed per mm^2 of said layer of fibers"

The phrase "0.5 μ l of liquid specimen are absorbed per mm^2 of said layer of fibers" appears only once in the asserted patents, in a dependent claim of the '027 Patent. ECF No. 72-1 at Page ID 770. Copan argues that the term should be given its plain and ordinary meaning. Puritan argues that Copan disavowed the full scope of the term "0.5 μ l" because it removed the words "about or at least" immediately preceding "0.5 μ l" during prosecution. Puritan thus asserts that the word "0.5 μ l" should be construed as "exactly 0.5 μ l." ECF No. 77 at Page ID 2203. But here, as with the term "perpendicular," the plain meaning of the disputed term is not affected by the alleged disavowal. A person of ordinary skill in the art reading the numerical value in this contested term would understand it to mean just what it says—that each square millimeter of the layer of fibers absorbs 0.5 microliters of liquid specimen. Therefore, I conclude that this term needs no further construction.

e. "90%"

The term "90%" appears in a dependent claim of the '779 Patent, which reads: "The swab according to claim 1, wherein said layer of fibers is configured to be capable of releasing 90% of the quantity of specimen absorbed." ECF No. 72-5 at Page ID 808.

Copan argues that the term should be given its plain and ordinary meaning, while Puritan asserts that the proper construction is “precisely 90%” because Copan disavowed any broader scope during prosecution.

To support its prosecution disavowal argument, Puritan points out that Copan amended the claim to read “90%” instead of “about 90%” after the patent examiner objected that the word “about” rendered the claim indefinite because it was “unclear how close to being configured to release 90% of the quantity of specimen absorbed a device could be while being inside or outside of the scope of the claim” ECF No. 73-34 at Page ID 1873; ECF No. 77 at Page ID 2204–05. However, while Copan may have disavowed the full scope of the phrase “about 90%” by making that amendment, such a disavowal would only prevent Copan from now arguing that “90%” means “about 90%,” an argument which Copan has not pressed. Puritan has presented no evidence that Copan intended to define “90%” as “precisely 90%.” Accordingly, I conclude that Copan did not disavow the full scope of the term “90%” and construe the term according to its plain and ordinary meaning.

On its own, the ordinary meaning of “90%” is ambiguous. The key context within the claim comes from the phrase “configured to be capable of releasing.” ECF No. 72-5 at Page ID 808. A layer of fibers would fall within the scope of this claim if it were configured to be capable of releasing precisely 90% of the collected specimen, but it would also fall within the scope of the claim if it were configured to be capable of releasing, for example, 91% or 96% of the collected specimen. In other words, a swab that is capable of releasing greater than 90% of the collected specimen would necessarily fall within this claim because it would encompass the lesser value of 90%.

Accordingly, viewing the term “90%” in the context of the claim where it appears, I conclude that the addition of the word “precisely” is inconsistent with the ordinary meaning of “90%.” Therefore, I decline to adopt Puritan’s proposed definition and find that the term “90%” requires no further construction.

f. “from 90% to 100%”

The phrase “from 90% to 100%” appears in a dependent claim of the ‘728 Patent which reads: “The method according to claim 1 further comprising: releasing, from said layer of fibers, a quantity from 90% to 100% of said specimen absorbed.” ECF No. 72-2 at Page ID 779. Copan argues that the term should be given its plain and ordinary meaning, while Puritan proposes a precise definition and argues that Copan disavowed any broader scope during prosecution by amending the claim from its original language, “at least about 90%,” ECF No. 73-16 at Page ID 1516, to read “from 90% to 100%.” ECF No. 73-20 at Page ID 1583. Puritan’s proposed construction is: “a percentage within the closed range of 90% to 100% (including endpoints).” ECF No. 77 at Page ID 2205.

Again, prosecution disavowal does not apply because Copan does not argue that the term “from 90% to 100%” should be construed to mean “from about 90% to 100%.” The phrase “from 90% to 100%” has a plain and ordinary meaning that a person of ordinary skill in the art, and even a layperson, can easily discern. To the extent further construction of the term is required, the word “from” in this context means “between.” Therefore, I construe “from 90% to 100%” to mean “between 90% and 100%.”

III. CONCLUSION

For the foregoing reasons, it is **ORDERED** that the claim terms are construed as follows:

1. The preambles do not limit the claims, but rather provide a statement of intended use;
2. The parties agree that “tip” means “the flocked end of a swab”;
3. The parties agree that “swab” means “a stick or wire with a small piece of absorbent material attached to the end”;
4. The term “ordered arrangement” / “ordered manner” is not indefinite and is accorded its plain and ordinary meaning in the context of the patents;
5. The term “a thickness between 0.6 and 3 mm” and its variants are not indefinite and are accorded their plain and ordinary meaning in the context of the patents, where “thickness” refers to the layer of fibers and depends upon the length of the fibers;
6. The term “fibers define capillaries in said layer of fibers, conferring hydrophilic properties by capillarity to the layer of fibers” and its variants are not indefinite, and “hydrophilic . . . by capillarity” is construed according to its plain and ordinary meaning in the context of the patents, as referring to the additional hydrophilic effect created by the space between the fibers when it draws liquid into the layer of fibers by capillary action;
7. The term “about 90%” is not indefinite and is accorded its plain and ordinary meaning in the context of the patents, which is “approximately 90%”;
8. The terms “rod is suitable for human clinical collection” and its variant, “a clinical swab, configured for human clinical collection” are not indefinite and are accorded their plain and ordinary meaning in the context of the patents;
9. The term “rigid” is not indefinite and is accorded its plain and ordinary meaning in the context of the patents, which is “stiff”;
10. The term “an amount of fiber deposited” is not indefinite and is accorded its plain and ordinary meaning in the context of the patent;
11. The term “uniform thickness” is accorded its plain and ordinary meaning in the context of the patents;

12. The term “covering the tip” / “cover the tip” is accorded its plain and ordinary meaning in the context of the patents, which is “forming a layer over the tip of the swab”;
13. The term “perpendicular” / “perpendicularly” is accorded its plain and ordinary meaning in the context of the patents;
14. The term “0.5 μ l of liquid specimen are absorbed per mm^2 of said layer of fibers” requires no further construction beyond its plain meaning;
15. The term “90%” requires no further construction beyond its plain meaning;
and
16. The term “from 90% to 100%” is accorded its plain and ordinary meaning in the context of the patent, which is “between 90% and 100%.”

SO ORDERED.

Dated this 4th day of November, 2019.

/s/ JON D. LEVY
CHIEF U.S. DISTRICT JUDGE