United States District Court,
W.D. Washington, at Seattle.

SIMULAB CORPORATION, a Washington corporation,
Plaintiff.
v.
SYNBONE AG, a Swiss corporation,
Defendant.

No. C07-1416Z

Sept. 8, 2008.

Paul Douglas Swanson, Randall Paul Beighle, Lane Powell PC, Seattle, WA, for Plaintiff.

Randolph E Digges, III, Rankin Hill Porter & Clark LLP, Cleveland, OH, Lawrence D. Graham, Black Lowe & Graham, Seattle, WA, for Defendant.

ORDER

THOMAS S. ZILLY**, District Judge.**

THIS MATTER comes before the Court pursuant to Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed.Cir.1995), to construe various terms in U.S. Patent No. 6,780,016 ("the '016 Patent"). The parties having agreed that claim construction in this matter does not require a hearing or oral argument, and the Court, having reviewed the opening and response briefs of both parties, docket nos. 18, 19, 20, and 21, now enters the following order.

Background

The '016 Patent discloses a "surgical trainer having a simulated human tissue structure." Abstract in Exh. 1 to Prehearing Statement (docket no. 16-3). Plaintiff Simulab Corporation, which owns the '016 Patent, manufactures and sells a surgical trainer under the registered trademark "TraumaMan." Complaint at para.para. 1 & 7 (docket no. 1). Defendant Synbone AG is a Swiss corporation that recently began selling in the United States a surgical trainer called "PRO624 SYNMAN." *Id.* at para.para. 3 & 8. Plaintiff alleges that defendant is infringing claims 1, 2, 3, 4, 37, and 43 of the '016 Patent." *See* Corrected Prehearing Statement at 1 (docket no. 17). Claims 1, 37, and 43 are independent. Claims 2, 3, and 4 depend from Claim 1.

With respect to all three independent claims, namely Claims 1, 37, and 43, the parties ask the Court to construe the following terms: "simulated membranous layer" and "simulated sub-membranous layer." The parties also dispute the proper interpretation of the term "structure simulating an internal anatomical structure of a human body," which appears in Claim 37. As to both Claims 37 and 43, the following terms are at issue: "relatively easier to dissect than" and "can readily be dissected using a blunt object" or "being

readily dissected using a blunt object." Finally, the parties have proposed different constructions of the terms "integral fluid channels," which is in Claim 1, "composite layer," which is in Claim 37, and "elastomeric layer," which is in Claims 1, 3, and 37.

Discussion

A. *Claim Construction Standards*

The Court has both the authority and the obligation to construe as a matter of law the meaning of language used in a patent claim. Markman, 52 F.3d at 979. In doing so, the Court must consider the intrinsic evidence in the record, meaning the claims, the specification, and the prosecution history. *Id*. The words of a claim are generally assigned their "ordinary and customary meaning." Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed.Cir.2005). The ordinary and customary meaning of a claim term is the definition ascribed to it by "a person of ordinary skill in the art in question at the time of the invention." Id. at 1313. The context in which a claim term is used may also be instructive. Id. at 1314. For example, if a claim refers to "steel baffles," the language implies that baffles are not necessarily made of steel. *Id*. The other claims of a patent may also illuminate the meaning of a term, through *inter alia* consistent usage of the same term, or inclusion in a dependent claim of an additional term not present in the related independent claim. *Id*. at 1314-15.

Claims must also be read in light of the specification. Markman, 52 F.3d at 979. The specification is "the single best guide to the meaning of a disputed term." Phillips, 415 F.3d at 1315. If the specification reveals a definition given to a claim term that differs from the meaning it would otherwise possess, the inventor's lexicography trumps the ordinary and customary, or dictionary, construction. Id. at 1316. In considering the specification, however, the Court must take care not to import limitations from the specification into the claims. Id. at 1323. The Federal Circuit has "repeatedly warned" against confining the claims of a patent to the specific embodiments described in the specification. *Id*.

Similar to the specification, the prosecution history evidences how the inventor understood the terms used in the patent. *Id*. at 1317. Because the prosecution history, however, represents the "ongoing negotiation" between the United States Patent and Trademark Office ("PTO") and the applicant, it may suffer from a lack of clarity and is often less useful for claim construction purposes than the specification. *Id*. In addition, although the prosecution history "can and should be used to understand the language used in the claims," it may not itself "enlarge, diminish, or vary" the limitations in the claims. Markman, 52 F.3d at 980.

The Court may, in its discretion, consider extrinsic evidence as an aid in deriving the "true meaning" of the language employed in the patent. *Id*. (quoting Seymour v. Osborne, 11 Wall. 516, 78 U.S. 516, 546, 20 L.Ed. 33 (1871)). Extrinsic evidence may include expert or inventor testimony, dictionaries, and learned treatises. *Id*. Extrinsic evidence is generally less reliable than intrinsic evidence in construing the claim terms, and the Court must assess such evidence accordingly, bearing in mind the flaws inherent in each type of extrinsic evidence. Phillips, 415 F.3d at 1318-19. Moreover, extrinsic evidence should never be used to vary or contradict the terms of the claims in the patent. Markman, 52 F.3d at 981.

B. *Claim Language*

Claims 1 and 37 both disclose a "surgical trainer," while Claim 43 discloses an "incisable simulated human tissue structure." Of the eight terms in dispute, all but one appear in Claim 37, which reads:

A surgical trainer, comprising:

at least one *structure simulating an internal anatomical structure of a human body;*

an exterior cover encompassing a substantial portion of the surgical trainer, the exterior cover having a least one opening defining an operative site for a structure, so that each opening is disposed adjacent to a different structure, to facilitate access to said structure; and

an incisable simulated human tissue structure disposed to cover each opening, an exterior surface of each simulated human tissue structure being substantially flush with respect to an outer surface of the exterior cover, each simulated human tissue structure being removable from the surgical trainer to be replaced after use, wherein at least one such incisable simulated human tissue comprises a plurality of *simulated membranous layers* and a plurality of *simulated sub-membranous layers,* each *simulated membranous layer* being relatively denser than any *simulated sub-membranous layer,* each *simulated sub-membranous layer* being relatively thicker than any *simulated membranous layer,* and each *simulated sub-membranous layer* being *relatively easier to dissect* than any *simulated membranous layer,* the at least one such simulated human tissue structure including:

a first *composite layer* corresponding to a *simulated membranous layer,* said first *composite layer* comprising at least one *elastomeric layer* reinforced by at least one fibrous layer;

a first *simulated sub-membranous layer* disposed below said first *composite layer,* said first *simulated sub-membranous layer* comprising at least one *elastomeric layer,* wherein each *elastomeric layer* of the first *simulated sub-membranous layer* has a lower density than any *elastomeric layer* of the first *composite layer,* such that said first *simulated sub-membranous layer can readily be dissected using a blunt object;*

at least one additional *composite layer* corresponding to a *simulated membranous layer* disposed below said first *simulated sub-membranous layer* and comprising at least one *elastomeric layer,* reinforced by at least one fibrous layer, wherein each *elastomeric layer* of the at least one additional *composite layer* has a higher density than any *elastomeric layer* of the first *composite layer,* such that each additional *composite layer* corresponding to a *simulated membranous layer* is relatively harder to dissect than the first *simulated membranous layer;* and

at least one additional *simulated sub-membranous layer* disposed below said first *simulated sub-membranous layer* and comprising at least one *elastomeric layer,* wherein each *elastomeric layer* of the at least one additional *simulated sub-membranous layer* has a lower density than any *elastomeric layer* of the first *composite layer*.

Exh. 1 to Prehearing Statement (docket no. 16-3) (emphasis added to highlight disputed claim terms). The only one of the eight disputed terms not appearing in Claim 37, namely "integral fluid channels," is in Claim 1, which states:

A surgical trainer, comprising:

a simulated human tissue structure, comprising:

at least one *simulated membranous layer* comprising at least one *elastomeric layer* reinforced by at least one fibrous layer; and

at least one *simulated sub-membranous layer* comprising at least one *elastomeric layer* underlying a first membranous layer, wherein at least one of said at least one *simulated membranous layer* and said at least one *simulated sub-membranous layer* has a plurality of *integral fluid channels,* a material comprising said at least one of said at least one *simulated membranous layer* and said at least one *simulated sub-membranous layer* defining walls of the plurality of *integral fluid channels*.

Exh. 1 to Prehearing Statement (docket no. 16-3) (emphasis added to highlight disputed claim terms). Claim 43 contains four of the eight disputed terms and describes:

An incisable simulated human tissue structure, comprising a plurality of *simulated membranous layers* and a plurality of *simulated sub-membranous layers,* each *simulated membranous layer* being relatively denser than any *simulated sub-membranous layer,* each *simulated sub-membranous layer* being relatively thicker than any *simulated membranous layer,* and each *simulated sub-membranous layer* being *relatively easier to dissect than* any *simulated membranous layer,* at least one *sub-membranous layer being readily dissected using a blunt object,* a membranous layer disposed at a top of said incisable simulated human tissue structure being less dense and *relatively easier to dissect than* each other membranous layer, the plurality of *simulated membranous layers* and *simulated sub-membranous layers* being disposed such that at least one *simulated membranous layer* is adjacent to at least one *simulated sub-membranous layer*.

Exh. 1 to Prehearing Statement (docket no. 16-3) (emphasis added to highlight disputed claim terms).

C. *Disputed Claim Terms*

1. "*Composite Layer*" *and* "*Elastomeric Layer*"

The Court begins in a different place than the parties, namely with an analysis of the terms "composite layer" and "elastomeric layer." With regard to "composite layer," the parties agree that such term refers to a layer formed of distinct parts, but dispute whether the various parts must be bonded to one another. As to "elastomeric layer," the parties disagree concerning the level of detail conveyed by such term, with plaintiff proffering a fairly circular meaning, "a layer made up of any elastomeric composition or material," and defendant proposing an extremely technical definition, requiring that the material in such layer be capable of being stretched at room temperature under low stress to at least twice its original length and of returning with force to its approximate original length immediately upon release of the stress.

In construing both terms, the Court starts with the ordinary and customary meanings ascribed by a person of ordinary skill in the art. The common definition of "composite" is "something that is made up of diverse elements." Webster's Third New Int'l Dictionary 466 (1981) [hereinafter "Webster's"]. The more technical meaning of "composite" is a material "that results when two or more materials, each having its own, usually different characteristics, are combined, giving useful properties for specific applications." McGraw-Hill Dictionary of Scientific & Technical Terms 448 (6th ed.2003) [hereinafter "McGraw-Hill"]. The source for this technical explanation does not define the words "combine" or "combined," and the Court therefore resorts to an everyday meaning, namely "to bring into close relationship." Webster's at 452. Thus, neither the common nor the technical meaning of "composite" require the bonding together of the various elements at issue.

Defendant contends that the specification of the '016 Patent indicates a different lexicon. Defendant, however, incompletely quotes from the specification, omitting the crucial language. In at least four places in

the specification, the patentee stated that layers could be bonded or not bonded together. *See* Col. 5 at 10-13, Col. 5 at 38-41, Col. 6 at 18-22, Col. 7 at 44-47, Exh. 1 to Prehearing Statement (docket no. 16-3). In particular, the text defendant has partially quoted reads in full as follows:

The silicone coated fibrous layer **204** is preferably pre-formed and cured, and is then applied below or atop an uncured silicone formulation while in the mold; as the silicone formulation cures, the pre-formed fibrous layer is bonded thereto. *However, other alternates can have the silicone coated fibrous layer non-bonded to the silicone blend layer*.

Col. 5 at 35-41, Exh. 1 to Prehearing Statement (docket no. 16-3) (emphasis added to highlight the portion omitted by defendant); *compare* Defendant's Opening Brief at 22 (docket no. 18). Because the specification clearly repudiates any requirement that elements be bonded together, which is consistent with the common and technical definitions of "composite," the Court construes the term "composite layer" to mean "a layer formed of two or more distinct parts that may or may not be bonded together."

With regard to "elastomeric," the Court again initially resorts to dictionaries as aids in understanding the ordinary and customary meaning of the term. The common definition of "elastomer" is "an elastic rubberlike substance (as a synthetic rubber or a plastic having some of the physical properties of natural rubber)." Webster's at 730. "Elastic" has several meanings, but the first definition with respect to a solid (as opposed to a liquid or a gas) is "capable of recovering size and shape after deformation." *Id* . "Rubber" is explained as "a substance that is obtained from the latex of many tropical plants ... [and usually] characterized by its elasticity though its properties vary widely depending upon its source and preparation." Webster's at 1983. Thus, although the common meaning of elastomer incorporates the characteristics of easily expanding and retracting, no particular time or dimensional requirements are included.

In contrast, the technical definition cited by defendant interposes rigid thresholds, stating that an elastomer is a "polymeric material, such as a synthetic rubber or plastic, which at room temperature can be stretched under low stress to at least twice its original length and, upon immediate release of the stress, will return with force to its approximate original length." *See* McGraw-Hill at 687. In the specification, plaintiff identifies as examples of suitable materials both latex and silicone. *See* Col. 5 at 33-35, Exh. 1 to Prehearing Statement (docket no. 16-3). Latex and silicone are considered elastomers. *See* McGraw-Hill at 1179 & 1932.

Despite having suggested specific elastomers as preferred materials, plaintiff seeks to escape the limitations of the technical definition by pointing to the inventor's use of the adjective form "elastomeric" rather than the noun "elastomer." Plaintiff contends that the suffix "ic" is expansive, resulting in a meaning of "like elastomers." Although the suffix "ic" does transform a noun into an adjective with a general meaning of "having the character or form of" or "being," as in "panoram *ic*" or "rhomb *ic*," *see* Webster's at 1119, plaintiff's argument is essentially circular. Plaintiff's interpretation merely informs that the material must be similar to an elastomer; it does not define the properties necessary for a material to be considered elastomeric.

As lexicographer, the patentee had the unfettered ability to choose among a variety of terms to express the invention and, in this case, the inventor could have used alternative adjectives like "polymeric" or "thermoplastic," which appear in other portions of the specification. *See* Col. 9 at 46-47, Col. 10 at 21-22, Col. 10 at 55-56, Exh. 1 to Prehearing Statement (docket no. 16-3). "Polymeric" has a fairly generic definition, namely "made of repeating subunits," while the related word "polymer" means a substance

"made of giant molecules formed by the union of simple molecules." McGraw-Hill at 1635. A "thermoplastic" is a "polymeric material with a linear macromolecular structure that will repeatedly soften when heated and harden when cooled; for example, styrene, acrylics, polyethylenes, vinyls, nylons, and fluorocarbons." McGraw-Hill at 2137. Defendant apparently seeks a construction of the term "elastomer" or "elastomeric" that would exclude the thermoplastic materials known as polyethylene foam and polyvinyl chloride. *See* Defendant's Opening at 20 (docket no. 18); *see also* McGraw-Hill at 747 (defining "ethylene resin," also known as "polyethylene") & 1638 (defining "polyvinyl chloride" as a "polymer of vinyl chloride," which is "insoluble in most organic solvents" and is "used in soft flexible films for food packaging").

In contrast, plaintiff argues that the elastic property of the material is not relevant because the elastomeric layer is combined with a fibrous layer to form a composite layer, which is not required to stretch. Plaintiff's contention lacks merit. As indicated in the prosecution history, a necessary feature of the surgical trainer invention is mimicking the resistance to cutting exhibited by actual human tissue. *See* Amendment & Request for Reconsideration at 15 (docket no. 16-5). Thus, the Court must ascribe significant importance to the patentee's selection of the term "elastomeric" as describing a class of materials uniquely suited to the task of providing a realistic response to incision or dissection. Because plaintiff has offered no evidence to the contrary, the Court assumes that this realistic response is due in substantial part to the material's capacity to expand linearly and retract to its original size. Whether the realistic response can be achieved, however, with a substance that stretches less or rebounds slower than a material meeting the specialized definition of an elastomer remains unclear. The Court therefore declines at this time to impose the technical requirements proposed by defendant, and instead interprets the term "elastomeric layer" to mean "a layer formed of a material that is capable of recovering size and shape after deformation." *See* Webster's at 730.

2. "*Dissect*"

The word "dissect" appears in two disputed claim terms, the second of which has two different phrasings: (i) "relatively easier to dissect than," and (ii) "can readily be dissected using a blunt object" or "being readily dissected using a blunt object." *See* Cols. 16 & 20, Exh. 1 to Prehearing Statement (docket no. 16-3). The dispute between the parties in construing these terms boils down to the meaning and import of the word "dissect." Like the parties, the Court starts with the dictionary definitions of "dissect," namely "to divide or separate into parts," Webster's at 656, or "to cut apart or separate the tissues of the body for study," Stedman's Medical Dictionary at 571 (28th ed.2006) [hereinafter "Stedman's"]. In contrast, the term "incise" means "to cut with a knife." Stedman's at 960. Both the claims and the specification use the terms "dissect" and "incise," but not interchangeably. In fact, in describing one of the procedures for which the invention offers training opportunities, the patentee used the phrase "dissecting with a scalpel," *see* Col. 12 at 1, Exh. 1 to Prehearing Statement (docket no. 16-3), implying that dissection may be accomplished with other than a scalpel or a knife. *See* Phillips, 415 F.3d at 1314 (the meaning of a term may be construed from the context of its use). By way of comparison, in discussing another medical procedure, the inventor employed the terminology "transverse incision," *see* Col. 13 at 2, Exh. 1 to Prehearing Statement (docket no. 16-3), which did not reference an instrument because the verb "incise" inherently conveys the use of a knife. Thus, the Court concludes that the patentee carefully delineated between dissection and incision, with the former term indicating a cutting apart or separating of tissues, either with or without a particular device, and the latter term implying the use of a knife, scalpel, or similar tool.

One of the disputed claim terms that uses "dissect" also includes words of comparison. A simulated sub-membranous layer is described as "relatively easier to dissect" than a simulated membranous layer. The

specification explains that, for purposes of the '016 Patent, human tissue is categorized as either supportive tissue, which is described as membranous, or bulky tissue, which is described as sub-membranous. *See* Col. 3 at 28-36, Exh. 1 to Prehearing Statement (docket no. 16-3). Membranous tissue is generally thinner, denser, and tougher than sub-membranous tissue. *Id*. Examples of membranous tissue are skin, the fasciae that bind the various muscles, the parietal pleura, which forms a sac around the chest cavity and encloses the lungs, and the peritoneum, which lines the cavity of the abdomen. *See* Col. 3 at 37-47, Col. 7 at 36-39, Col. 9 at 39-41, Exh. 1 to Prehearing Statement (docket no. 16-3); *see also* Stedman's at 701, 1465, & 1512. Examples of sub-membranous tissue are fat, muscle, or extra-peritoneal tissue, which occupy more space than, and are "generally easier to dissect" than, membranous tissue. *See* Col. 3 at 47-49, Exh. 1 to Prehearing Statement (docket no. 16-3).

The prosecution history offers an additional explanation concerning the difference between membranous and sub-membranous tissue:

When a surgeon performs an incision, it is normal to use a scalpel to form an incision in the skin of a patient (i.e., through a membranous layer). Once the initial incision is made, the surgeon will use his/her fingers or the blunt end of a scalpel to move through the fat layer until a lower membranous layer (such as the anterior rectus sheath) is exposed. Then, a scalpel will once again be employed to create an incision [in] the membranous layer beneath the layer of fat.

Declaration of Mika Sinanan, M.D., Ph.D. at para. 5 (docket no. 16-5 at 31). The prosecution history also contains the following argument as to why the invention was not obvious in light of prior art, namely U.S. Patent No. 5,775,916 ("Cooper"):

While the sub-membranous layer is thicker than the membranous layer, as recited by applicant's claims, Cooper teaches that the sub-membranous layer 2 is *denser* than membranous layer 3, which is the exact opposite of applicant's claimed invention.... While the Examiner correctly points out that Cooper discloses layers that are lightly bonded together, so as to be separable by a blunt instrument or object, FN1 applicant instead claims *a layer* that itself can readily be *dissected* (i.e., cut or separated) using a blunt instrument or object. A layer that can be separated from a second layer by a blunt instrument or object is not the same as a layer which itself can be separated into smaller portions using a blunt instrument or object.

FN1. Cooper's invention provided *inter alia* a means for students and physicians to practice the removal of cysts, haematomas, melanomas, and the like, by separating the simulated complaint from the surrounding simulated healthy tissue.

Amendment & Request for Reconsideration at 27 (docket no. 16-6) (emphasis in original).

The claim language, the specification, and the prosecution history all lead to the same conclusion, namely that the term "relatively easier to dissect than" describes a property of one or more sub-membranous layers. Both Claim 37 and Claim 43 incorporate the phrase "each simulated sub-membranous layer being relatively easier to dissect than any simulated membranous layer." The import of such phrase is that a sub-membranous layer will be easier to cut or separate than a membranous layer, and if more than one of each type of layer is present, all of the sub-membranous layers will be easier to cut or separate than any of the membranous layers. In contrast, the term "can readily be dissected using a blunt object" or "being readily dissected using a blunt object" must be treated as characterizing a particular layer, namely in Claim 37 the

"first simulated sub-membranous layer" and in Claim 43 "at least one sub-membranous layer." Thus, the specified layer must itself be easily cut or separated without the aid of a sharp instrument, as opposed to being separable from another layer. FN2 The specification, by defining sub-membranous tissue as "generally easier to dissect" than membranous tissue, and the prosecution history, by offering a surgeon's view of the procedure the invention is intended to simulate, and by differentiating the invention from prior art disclosing layers that are separable from one another, confirms the appropriateness of these constructions.

FN2. Although defendant anticipates an argument construing the claim as disclosing a simulated sub-membranous layer (A) that is easier to separate from another layer (B) and therefore easier to dissect than another simulated sub-membranous layer (C), *see* Defendant's Opening at 17 (docket no. 18), the Court does not view plaintiff as making such contention. To the extent plaintiff proffers such interpretation, namely that A is easier to dissect than C because A can be more readily separated from B, the Court holds that such construction runs contrary to the rules of English grammar and would render the claim language nonsensical.

Thus, the Court concludes that the phrase "each simulated sub-membranous layer being relatively easier to dissect than any simulated membranous layer" means that a sub-membranous layer will be easier to cut or separate than a membranous layer, and if more than one of each type of layer is present, all of the sub-membranous layers will be easier to cut or separate than any of the membranous layers. In contrast, the term "can readily be dissected using a blunt object" or "being readily dissected using a blunt object" applies to a particular layer, namely in Claim 37 the "first simulated sub-membranous layer" and in Claim 43 "at least one sub-membranous layer," and means that the specific layer must itself be easily cut or separated with the use of a blunt object.

3. *Membranous/Sub-Membranous Layers and Structure Simulating an Internal Anatomical Structure*

As to the terms "simulated membranous layer," "simulated sub-membranous layer," and "structure simulating an internal anatomical structure of a human body," the parties' approaches again differ with respect to the level of detail to associate with each phrase. Plaintiff proposes a minimal description, while defendant suggests an exhaustive list of examples, cataloging "membranous" tissue as including the skin, the peritoneum, the pericardium, the parietal pleura, the anterior and posterior rectus sheaths, ligaments, and tendons, describing "sub-membranous" tissue as fat, muscle, and extraperitoneal tissue, excluding from the definition of each term the items belonging to the other class of tissue, as well as bone, cartilage, and internal anatomical structures, and specifying that internal anatomical structures are the abdominal organs, lungs, sternum, ribs, heart, and cricothyroid cartilage.

Defendant's primary support for incorporating such limitations into the three disputed terms is the structure of two claims that are not at issue in this case, namely Claims 13 and 26, which read:

13. The surgical trainer of claim 5, further comprising:

a simulated abdominal cavity including a simulated internal organ, *underlying* the simulated human tissue structure.

26. The surgical trainer of claim 5, further comprising:

a simulated heart including at least one elastomeric layer *underlying* the simulated human tissue structure.

Exh. 1 to Prehearing Statement (docket no. 16-3) (emphasis added). Defendant contends that the word "underlying" indicates that the simulated internal organ referenced in Claim 13, of which the simulated heart described in Claim 26 is an example, is not part of the simulated human tissue structure, which is comprised of "at least one simulated membranous layer" and "at least one simulated sub-membranous layer," as stated in Claim 1. Defendant also cites to portions of the specification, which likewise delineate between simulated human tissue and particular simulated internal anatomical structures. *See* Figs. 5 & 7, Col. 3 at 14-15 & 18-20, Col. 8 at 34-67, & Col. 10 at 4-6, Exh. 1 to Prehearing Statement (docket no. 16-3).

The Court agrees with defendant that simulated human tissue structure as claimed in the '016 Patent does not include simulated internal organs. In reaching this conclusion, the Court distinguishes between internal anatomical structures and internal organs because the patentee explicitly disclaimed methods for making simulated internal organs. *See* Col. 8 at 54-56, Exh. 1 to Prehearing Statement (docket no. 16-3) ("Methods for making simulated organs have been described in U.S. Pat. No. 5,951,301 to Younker, which is herein incorporated by reference."). Methods for making simulated internal anatomical organs are therefore outside the scope of the '016 Patent. *See* Phillips, 415 F.3d at 1316 ("[T]he specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor.... [and] the [scope of the] inventor's intention, as expressed in the specification, is regarded as dispositive.").

The other limitations defendant requests, however, are not supported by the claim language or the specification. Although the specification provides illustrative examples of membranous and sub-membranous tissues, as well as internal anatomical structures, defendant offers no basis for confining the claims to the embodiments described therein. In light of the Federal Circuit's consistent warnings against using specific embodiments to narrow the claims of a patent, the Court adopts in substantial part the constructions proposed by plaintiff. The term "simulated membranous layer" is interpreted as "a layer in a simulated human tissue structure that simulates a category of tissue whose function is to bind, line, support, or surround other tissue." The term "simulated sub-membranous layer" is construed as "a layer in a simulated human tissue structure that simulates a category of tissue whose presence in a human body fills or lends significant bulk to the body." The term "structure simulating an internal anatomical structure of a human body" is held to mean "a structure in a surgical trainer that simulates an internal anatomical structure of a human body, including but not limited to an internal organ." Finally, the terms "simulated membranous layer" and "simulated sub-membranous layer" are interpreted to exclude "simulated internal organs."

4. ***Integral Fluid Channels***

The final term in dispute, "integral fluid channels," relates to the simulation of arteries and veins so that, [w]hen an incision is made in the [simulated] tissue, and a simulated vein is cut, simulated blood will flood the operative site, as in real life." Col. 2 at 46-48, Exh. 1 to Prehearing Statement (docket no. 16-3). Plaintiff construes the term to mean "a pathway of any size that simulates the method of movement of bodily fluids throughout the human body." In contrast, defendant proposes a narrower interpretation, namely "fluid-containing tubular conduits provided in a membranous layer or a sub-membranous layer of a simulated human tissue structure that simulate veins or arteries, wherein the fluid-contacting walls of the conduits are formed of the same material as the membranous layer or sub-membranous layer in which the conduits are provided."

In support of its construction, defendant cites to claims not at issue in this case, namely Claims 10, 15, and 28, which disclose:

10. The surgical trainer of claim 5, wherein the plurality of integral fluid channels convey a simulated bodily fluid.

15. The surgical trainer of claim 13, wherein the abdominal cavity contains simulated bodily fluid.

28. The surgical trainer of claim 26, wherein the heart contains simulated bodily fluids.

Exh. 1 to Prehearing Statement (docket no. 16-3). Although not entirely clear, defendant seems to assert that the term "integral fluid channels" must mean a fluid-containing conduit within a simulated membranous or sub-membranous layer because any abdominal cavity or heart containing simulated bodily fluid would lie below any membranous layer. Defendant's argument is flawed because it seeks to incorporate within the term "integral fluid channels" limitations that are otherwise specified in claim language. Claim 1 contains no mention of simulated bodily fluid, but Claim 10 envisions that the "integral fluid channels" will convey simulated bodily fluid. Thus, "integral fluid channels" may, but need not, contain simulated bodily fluid, and defendant's proposed description "fluid-containing" is overly restrictive. In addition, Claim 1 indicates that both a membranous layer and a sub-membranous layer will include a plurality of "integral fluid channels," the walls of which are defined by the respective layers. Thus, to define an "integral fluid channel" as contained within or "provided in" a simulated membranous layer or simulated sub-membranous layer is unnecessarily duplicative.

Defendant also cites to the specification, which explains one way in which integral fluid channels made be formed within simulated human tissue. String, fishing line, or other material is placed inside a mold either before or after an elastomeric compound is poured into the mold. Col. 7 at 61-Col. 8 at 1, Exh. 1 to Prehearing Statement (docket no. 16-3). After the elastomeric compound cures, the string, line, or other material is pulled out, leaving a channel within the elastomeric layer that is roughly the size and shape of the exterior of the string, line, or other material at issue. Col. 7 at 63-65, Col. 8 at 2-3, Exh. 1 to Prehearing Statement (docket no. 16-3). From this description, defendant infers that the "integral fluid channels" cannot be present in any simulated internal anatomical structures and that they must be tubular. Defendant's contention lacks merit. Again, "internal anatomical structures" must be distinguished from "simulated internal organs," the latter being explicitly disclaimed. Neither the claim language nor the specification rule out the manufacture of an internal anatomical structure comprised of simulated membranous or sub-membranous layers containing "integral fluid channels." To the extent, however, the internal anatomical structure is a simulated internal organ, the patent provides no basis for claiming infringement. In addition, although string and fishing line might fairly be characterized as tubular, the specification leaves open the possibility of using other, non-cylindrical materials to form the "integral fluid channels." *See* Wester's at 2459 & 2460 (defining "tubular" as "having the form of a tube," and "tube" as "a hollow elongated usu. cylindrical body").

Finally, defendant cites to the prosecution history, which contains the following argument as to why the invention was not obvious in light of prior art, namely U.S. Patent No. 5,775,916 ("Cooper"):

While Cooper discloses fluid channels in his invention, Cooper teaches that such channels are formed separately as tubes of a latex material that are incorporated into a layer .... Thus, according to Cooper the material comprising the walls of the channel is not the material comprising the layer.... Applicant has

determined that integral channels filled with fluid provide a much more realistic tactile experience when an incision is made into a simulated tissue layer containing such integral fluid channels ....

Amendment and Request for Reconsideration at 6 (docket no. 16-4). The prosecution history supports defendant's contention that "integral fluid channels" must be interpreted as being formed of the surrounding material, as opposed to separate tubes or conduits imbedded within the layer at issue. This construction comports with the definition of "integral," which means "formed as a unit with another part." Webster's at 1173. The Court therefore construes the term "integral fluid channels" to mean "pathways capable of containing fluid that are formed of the surrounding material."

In light of the timing of this Order, the Court will issue an amended scheduling order.

IT IS SO ORDERED.

W.D.Wash.,2008.
Simulab Corp. v. Synbone AG

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