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IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

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CLERK US DISTRICT COURT
WESTERN DISTRICT OF TEXAS

BY _____ **AD**
DEPUTY

BIOMEDICAL ENTERPRISES, INC., §
PLAINTIFF, §

V. §

CAUSE NO. 1:14-CV-095-LY

SOLANA SURGICAL, LLC, §
DEFENDANT. §

**MEMORANDUM OPINION AND ORDER REGARDING
CLAIMS CONSTRUCTION**

Before the court are the parties’ Joint Claim Construction Statement filed September 10, 2014 (Clerk’s Document No. 25); Plaintiff BioMedical Enterprises, Inc. (“BioMedical”) and Defendant Solana Surgical, LLC’s (“Solana”) Opening Claims Construction Briefs filed August 29, 2014 (Clerk’s Document Nos. 23 & 24); and BioMedical and Solana’s Responsive Claim Construction Briefs filed September 19, 2014 (Clerk’s Document Nos. 28 & 29).

The court held a claim-construction hearing on October 14, 2014. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (*en banc*), *aff’d*, 517 U.S. 370 (1996). After considering the patent and its prosecution history, the parties’ claim-construction briefs, the applicable law regarding claim construction, and argument of counsel, the court now renders its order with regard to claim construction.

I. Introduction

The court renders this memorandum opinion and order to construe claims in U.S. Patent No. 8,584,853 (the “‘853 Patent”). BioMedical, the holder of the ‘853 Patent, asserts claims against Solana for infringement of the ‘853 Patent, which generally relates to a disposable, sterile-packaged orthopedic-fixation system.

II. Legal Principles of Claim Construction

Determining infringement is a two-step process. *See Markman*, 52 F.3d at 976 (“[There are] two elements of a simple patent case, construing the patent and determining whether infringement occurred”). First, the meaning and scope of the relevant claims must be ascertained. *Id.* Second, the properly construed claims must be compared to the accused device. *Id.* Step one, claim construction, is the current issue before the court.

The court construes patent claims without the aid of a jury. *Id.* at 979. The “words of a claim ‘are generally given their ordinary and customary meaning.’” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (*en banc*) (quoting *Vitronics Corp. v. Conceptor, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). 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. *Id.* at 1313. The person of ordinary skill in the art is deemed to have read the claim term in the context of the entire patent. *Id.* Therefore, to ascertain the meaning of claims, courts must look to the claims, the specification, and the patent’s prosecution history. *Id.* at 1314–17; *Markman*, 52 F.3d at 979.

Claim language guides the court’s construction of claim terms. *Phillips*, 415 F.3d at 1314. “[T]he context in which a term is used in the asserted claim can be highly instructive.” *Id.* Other claims, asserted and unasserted, can provide additional instruction because “terms are normally used consistently throughout the patent.” *Id.* Differences among claims, such as additional limitations in dependent claims, can provide further guidance. *Id.*

Claims must also be read “in view of the specification, of which they are a part.” *Markman*, 52 F.3d at 979. The specification “is always highly relevant to the claim construction analysis.

Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.” *Teleflex, Inc. v. Ficoso N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002) (internal citations omitted). In the specification, a patentee may define a term to have a meaning that differs from the meaning that the term would otherwise possess. *Phillips*, 415 F.3d at 1316. In such cases, the patentee’s lexicography governs. *Id.* The specification may also reveal a patentee’s intent to disclaim or disavow claim scope. *Id.* Such intentions are dispositive for claim construction. *Id.* Although the specification may indicate that certain embodiments are preferred, particular embodiments appearing in the specification will not be read into the claims when the claim language is broader than the embodiment. *Electro Med. Sys., S.A. v. Cooper Life Scis., Inc.*, 34 F.3d 1048, 1054 (Fed. Cir. 1994).

The prosecution history is another tool to supply the proper context for claim construction because it demonstrates how the inventor understood the invention. *Phillips*, 415 F.3d at 1317. A patentee may serve as his own lexicographer and define a disputed term in prosecuting a patent. *Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1356 (Fed. Cir. 2004). Similarly, distinguishing the claimed invention over the prior art during prosecution indicates what the claims do not cover. *Spectrum Int’l v. Sterilite Corp.*, 164 F.3d 1372, 1378–79 (Fed. Cir. 1988). The doctrine of prosecution disclaimer precludes patentees from recapturing specific meanings that were previously disclaimed during prosecution. *Omega Eng’g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003). Disclaimers of claim scope must be clear and unambiguous. *Middleton, Inc. v. 3M Co.*, 311 F.3d 1384, 1388 (Fed. Cir. 2002).

Although “less significant than the intrinsic record in determining the legally operative meaning of claim language,” the court may rely on extrinsic evidence to “shed useful light on the relevant art.” *Phillips*, 415 F.3d at 1317 (quotation omitted). Technical dictionaries and treatises

may help the court understand the underlying technology and the manner in which one skilled in the art might use claim terms, but such sources may also provide overly broad definitions or may not be indicative of how terms are used in the patent. *Id.* at 1318. Similarly, expert testimony may aid the court in determining the particular meaning of a term in the pertinent field, but “conclusory, unsupported assertions by experts as to the definition of a claim term are not useful.” *Id.* Generally, extrinsic evidence is “less reliable than the patent and its prosecution history in determining how to read claim terms.” *Id.* Extrinsic evidence may be useful when considered in the context of the intrinsic evidence, *id.* at 1319, but it cannot “alter a claim construction dictated by a proper analysis of the intrinsic evidence.” *On-Line Techs., Inc. v. Bodenseewerk Perkin-Elmer GmbH*, 386 F.3d 1133, 1139 (Fed. Cir.2004).

III. Discussion

The parties submitted two agreed claim terms and five claim terms for construction by their Joint Claim Construction and Prehearing Statement.

A. Agreed Terms

Before the claims-construction hearing, the parties agreed to the construction of the following two claim terms:

<u>Claim Term/Phrase</u>	<u>Adopted Agreed Construction¹</u>
“stores a compressive force” (Claim 15)	stores a force that would cause the legs to converge
“releases the compressive force stored in the implant” (Claim 15)	releases the force that would cause the legs to converge

¹ Throughout, the **bolded** terms indicate the court’s adopted construction.

B. *Disputed Terms*

The parties dispute the construction of five claim terms. The following table summarizes the parties' proposed constructions of the disputed terms.

<u>Claim Term/Phrase</u>	<u>BioMedical's Proposed Constructions</u>	<u>Solana's Proposed Constructions</u>
<p>1. "Orthopedic fixation system" (Claims 15–21)</p>	<p>The preamble is a claim limitation meaning "a fixation system for bones"</p>	<p>(i) this preamble does not limit the scope of the claims and (ii) construction is unnecessary.</p> <p>However, if court finds preamble a limitation, then "components that work in conjunction to fixate bones together"</p>
<p>2. "Implant kit" (Claim 15)</p>	<p>"a collection of components, including an implant for fixating bones together"</p>	<p>"a collection of components, including an implant, that are packaged together and separately from instruments necessary to use the collection of components to fixate bones" <u>or alternatively,</u></p> <p>"a collection of components, that are packaged together, where the collection is limited to an implant and components that match the implant"</p>
<p>3. "the insertion device <i>maintains</i> the legs in their second substantially parallel position such that the implant stores the compressive force" (Claim 15)</p>	<p>"The insertion device <i>by itself keeps</i> the implant legs in the substantially parallel position so that a force that would cause the legs to converge is stored."</p>	<p>construction is unnecessary. However, if court determines construction helpful,</p> <p>"The insertion device <i>holds</i> the implant legs with its legs in their second substantially parallel position such that the implant stores a force that would cause the legs to converge"</p>

<p>4. “such that the insertion device <i>maintains</i> the legs in their second substantially parallel position”</p> <p>(Claim 15)</p>	<p>“The insertion device <i>by itself keeps</i> the legs in the substantially parallel position”</p>	<p>“The insertion device <i>holds</i> the implant with its legs in their second substantially parallel position”</p>
<p>5. “Multiple sizes of implant kits”</p> <p>(Claim 21)</p>	<p>“Implant kits that contain differently sized implants”</p>	<p>“Multiple implant kits that have different sizes”</p>

1. Preamble—“Orthopedic fixation system”

The parties dispute whether the court should conclude that “orthopedic fixation system,” which appears in the preamble to independent Claim 15 and dependent Claims 16 through 21, is a limitation on the scope of the claims. BioMedical argues that the court should construe the phrase as a limitation on the claims’ scope to only bones. Further, BioMedical argues that as reflected by the patent specification’s many references to bones, the preamble phrase is fundamental to the claimed invention.

Solana disagrees, contending that the phrase is not a limitation. Solana argues that the ‘853 Patent addresses the problem of packaging, delivering, and using implants and complementary instruments in a sterile format—a problem that is not unique to “orthopedic fixation.” Solana contends that the ‘853 Patent’s invention consists of a two-kit, sterile-packaged, delivery system, which consists of two separate packages: (1) the implant-kit package, with the sterilized implant in a ready-to-use configuration, together with (2) the instrument-kit package, with the complementary sterilized instruments needed to use “one or more . . . or any combination of implant kits.” Providing the two-kits together, satisfies all of the three objects that define the fundamental features of the “present invention.”

To support its respective position, each party relies on *Catalina Marketing International Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002). A preamble is construed as a limitation only “if it recites essential structure or steps, or if it is ‘necessary to give life, meaning, and vitality’ to the claim.” *Id.* (quoting *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1309 (Fed. Cir. 1999)). Conversely, 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. *Id.* (citing *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997)). Generally, unless the

patentee has relied on the preamble in the prosecution history to distinguish the claimed invention from prior art or the preamble is necessary to provide antecedent basis for the body of the claim, the preamble is not limiting. *Catalina*, 289 F.3d at 809. When deciding whether the preamble is limiting, a court must review the entire patent to gain an understanding of what the inventor actually invented and intended to encompass by the claim. *Id.* at 808; *see e.g., Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1572-73 (Fed. Cir. 1996) (holding “cold purge process” in preamble was limiting because it was essential to particularly point out invention defined by claims).

In reviewing the entirety of the ‘853 Patent, although the prosecution history includes some prior art that is not limited to orthopedics, references to “bones” and “orthopedics” appear throughout every section of the ‘853 Patent specification. Indeed, the following are a few representations in the ‘853 Patent: (1) the title of the ‘853 Patent—“Method and Apparatus For An Orthopedic Fixation System”—includes the term “orthopedic,” which, by its plain and ordinary meaning, relates to bones; (2) the section, “Background of the Invention” refers to “bone fusion and healing in orthopedics,” which often involve “implants being attached to bones in some way to fixate them together during the healing process”; (3) the figures include depictions of the invention solely with drawings of bones; and (4) the section, “Detailed Description of the Preferred Embodiments” refers repeatedly to bones. With regard to Claims 15 through 21, the only way these claims have any vitality or structure within the context of the patent is if the phrase “orthopedic fixation system” is a limitation of the scope of the patent to fixating bones. Interpreting the preamble phrase “orthopedic fixation system” in view of the specification’s focus on bones and orthopedics, rather than all “fixation systems,” is necessary to make sense of the claims. *See e.g., General Elec. Co. v. Nintendo Co.*, 179 F.3d 1350, 1361-62 (Fed. Cir.

1999) (limiting claim scope to “raster scanned display device” rather than all display systems in view of specification’s focus on prior art problem of displaying binary data on raster scan display devices); *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989) (limiting claim scope to “optical wavelengths” rather than all optical fibers in light of specification). The court finds that the preamble “orthopedic fixation system” limits Claims 15 through 21’s scope to fixating and healing bones, not all fixation systems. *See Catalina*, 289 F.3d at 808 (citing *Pitney Bowes*, 182 F.3d at 1306).

Having determined that “orthopedic fixation system” is a claim limitation, the court defines “orthopedic fixation system” as **a fixation system for bones**.

2. “Implant kit”

The essential difference between the parties’ constructions is that Solana’s construction adds a restriction to Claim 15—the implant kit’s components must be packaged separately from instruments that may be used by a surgeon during a bone-implant surgical procedure. Solana argues that this restriction is aligned with the invention described in the specification of the ‘853 Patent. BioMedical’s construction has no such restriction, which BioMedical argues is proper in light of the entire patent and the scope of the invention.

In reviewing the claims of the ‘853 Patent, only unasserted Claims 1 through 14 refer to a separate, sterile-packaged instrument kit that accompanies the implant kit. There is no reference to an instrument kit in the claims at issue—*independent* Claim 15 and *dependent* Claims 16 through 21. Claim 15 addresses the “sterile packaged implant kit, comprising”: (1) “at least one surgical implant,” (2) “an insertion device,” and (3) “an implant package.” Further, *dependent* Claim 19 provides that an “implant kit comprises a drill guide” that, according to the specification, allows a surgeon to drill

parallel holes into bone to match the implant. The term “comprising” means that the claim does not exclude additional, unrecited elements. *See e.g., Vivid Techs., Inc. v. American Science & Eng’r, Inc.*, 200 F.3d 795, 811 (Fed. Cir. 1999); *Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1178 (Fed. Cir. 1991). Nothing in Claim 15, nor in Claims 16 through 21 restricts or limits the implant kit from including additional components.

Additionally, the section of the ‘853 Patent “Summary of the Invention” includes, “[I]t should be understood that the scope of this invention is intended to be broad, and any combination of any subset of the features, elements, or steps described herein is part of the intended scope of the invention.” Further, the ‘853 Patent’s “Detailed Description of the Preferred Embodiments’s” closing paragraph instructs:

Although the present invention has been described in terms of the foregoing embodiments, such description has been for exemplary purposes only and, as will be apparent to those of ordinary skill in the art, many alternatives, equivalents, and variations of varying degrees will fall within the scope of the present invention. That scope, accordingly, is not to be limited in any respect by the foregoing detailed description; rather, it is defined only by the claims that follow.

By the existence of independent Claim 15 and dependent Claims 16 through 21, by the use of the term “comprising,” and the specification’s language, (1) that the scope of the invention is intended to be broad, with any combination of any subsets being within the scope of the invention, and (2) that the invention’s scope is not to be limited to the detailed description and is to be defined by the claims, the inventor contemplated the possibility that the implant kit could contain other items. To adopt Solana’s construction would require the court to read in a limitation to Claim 15 when lacking is any language in the patent that makes clear such limitation. *See Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371-72 (Fed. Cir. 2014). The court finds “no clear intention” by the patentee “to limit the

claim scope using words or expressions of manifest exclusion or restriction.” *Id.* Further, the court finds that to adopt Solana’s construction would require the court to find independent Claim 15 superfluous of Claim 1.

The court defines “implant kits” as “**a collection of components that includes an implant for fixating bones together.**”

3. “maintains”

BioMedical argues that the court should construe the word “maintains” as used twice in Claim 15: (1) “the insertion device *maintains* the legs in their second substantially parallel position such that the implant stores the compressive force,” and (2) “such that the insertion device *maintains* the legs in their second substantially parallel position”.² BioMedical proposes that in each instance, the claim language supports its construction that the insertion device “maintains” means the insertion device, *itself keeps*, or *by itself keeps*, the implant’s legs in their parallel position. BioMedical contends that if it is not the insertion device itself keeping the legs parallel, the shape-memory-material implant legs would converge, and the implant would be unuseable. Solana, initially posits that no construction of “maintains” is necessary. Nevertheless, if the court finds construction appropriate, Solana proposes a construction that the insertion device *holds* the implant. Contrary to BioMedical’s construction, Solana argues something else other than the insertion device is responsible for maintaining the implant legs in the parallel position.

BioMedical argues, that to use the word *holds*, improperly broadens the claim. BioMedical argues that based on the specification, the insertion device does not merely hold, passively, the shape-memory material implant. The difference here, Biomedical argues, is a contrast to prior art, which

² At argument, the parties agreed that the use of “second substantially” was of no import to the construction of “maintains.”

addressed a staple implant, not of shape-memory or superelastic material, that was simply held—there was no position other than a parallel position possible for the staple legs. With a staple implant, unlike an implant made of shape-memory or superelastic materials, no need exists to maintain the two staple implant legs parallel. BioMedical argues that the *by itself keeps* construction is consistent with other clauses in the patent and is consistent within the claim because after the term is used, there is reference to the storage of a compressive force in the implant, which is the result of the insertion device’s “maintaining” work. BioMedical argues that but for the insertion device, the implant legs would not be kept open, but instead would converge.

Solana argues that BioMedical is asking the court to rewrite the claim so that the insertion device itself keeps the legs parallel and, thus, is the sole mechanism that retains the legs of the implant parallel while the implant is mounted on the insertion device.

The Figures 2A and 2B and the corresponding detailed description of the preferred embodiments depict and describe an insertion device that “holds the implant such that implant legs are held mechanically in a parallel position for easier insertion into bone.” Based on the “such that” phrase, the specification provides that there is something more going on with the insertion device than only holding the shape-memory or superelastic implant; specifically, the implant is being “held mechanically in a parallel position.” And further, the description “shows the implant being inserted into two bones and [i]nsertion device can be twisted off implant, releasing the implant to squeeze [the] bones [together].”

The court finds no mention of “by itself keeps” anywhere in the patent. Additionally, to use Solana’s construction leaves out aspects of the insertion device working in conjunction with a shape-memory or superelastic implant.

The court finds no construction is necessary and the term “maintains” will be given its ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the context of the specification and prosecution history.

4. “multiple sizes of implant kits”

The parties’ dispute here centers on whether “multiple sizes of implant kits” requires that the actual, physical implant kits themselves be of different sizes, as Solana proposes, or, that the implants included within the implant kits are of different sizes, as BioMedical proposes.

The 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.” *Epos Techs. Ltd. v. Pegasus Techs. Ltd.*, 766 F.3d 1338, 1341 (Fed. Cir. 2014) (quoting *Phillips*, 415 F.3d at 1312-13).

Here, the specification resolves any ambiguity about the meaning of this phrase. It is stated explicitly in the specification, “implant kits are identical, except that the implants may be sized differently as required by the physician.” Thus, the implants within an implant kit can vary in size, while the implant kits are otherwise identical in size. “When there is more than one ordinary meaning for a claim term, the patent specification serves to point away from improper meanings and toward the proper meaning.” *See Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). Further, to accept Solana’s proposal would improperly read out the preferred embodiment from the scope of the claim. *See SanDisk Corp. v. Memorex Prods., Inc.*, 415 F.3d 1278, 1285 (Fed. Cir. 2005) (“A claim construction that excludes a preferred embodiment, moreover, is rarely, if ever correct.”).

The court defines “multiple sizes of implant kits” as **“implant kits that contain differently sized implants.”**

A. *Summary Table of Adopted Agreed and Disputed Terms*

<u>Claim Term/Phrase</u>	<u>Court's Construction</u>
stores a compressive force	stores a force that would cause the legs to converge
releases the compressive force stored in the implant	releases the force that would cause the legs to converge
Orthopedic fixation system (Claims 15–21)	a fixation system for bones
Implant kit (Claim 15)	a collection of components that includes an implant for fixating bones together
the insertion device maintains the legs in their second substantially parallel position such that the implant stores the compressive force (Claim 15)	no construction necessary—plain and ordinary meaning
such that the insertion device maintains the legs in their second substantially parallel position (Claim 15)	no construction necessary—plain and ordinary meaning
Multiple sizes of implant kits (Claim 21)	implant kits that contain differently sized implants

IV. Conclusion

For the above reasons, the court construes the above-listed claim terms as noted and so **ORDERS**. No further claim terms require construction.

IT IS FURTHER ORDERED that this case is set for a **Scheduling Conference on December 22, 2014, at 1:30 p.m.**, in Courtroom 7, Seventh Floor, United States Courthouse, 501 W. 5th Street, Austin, Texas 78701. The parties shall meet and confer in advance of that date in an attempt to settle this case. If the case is not settled, the parties shall confer in an attempt to reach agreement on a schedule to follow for the remainder of this case. The court will render a Scheduling Order as a result of the December 22, 2014 conference.

SIGNED this 4th day of November, 2014.



LEE YEAKEL
UNITED STATES DISTRICT JUDGE