UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 12-11667-RGS

BONUTTI SKELETAL INNOVATIONS

v.

DEPUY MITEK LLC, et al.

MEMORANDUM AND ORDER ON CLAIM CONSTRUCTION

May 02, 2014

STEARNS, D.J.

In this intellectual property dispute, plaintiff Bonutti Skeletal Innovations (BSI) accuses defendants DePuy Mitek LLC, DePuy Institute LLC, DePuy Inc., and DePuy Orthopaedics, Inc. (collectively DePuy) of infringing U.S. Patents Nos. 5,527,343 (the '343 patent), 5,718,717 (the '717 patent), 5,980,559 (the '559 patent), 7,087,073 (the '073 patent), 6,702,821 (the '821 patent), 7,806,896 (the '896 patent), and 8,133,229 (the '229 patent). DePuy counterclaims for declarative judgment of invalidity and non-infringement of the seven asserted patents. Before the court are the parties' briefs on claim construction. The court heard argument, pursuant to *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996), on May 1, 2014.

BACKGROUND

The seven asserted patents name Dr. Peter Bonutti, an orthopedic surgeon, as

their inventor, and fall into two categories. The ’821,’896, and ’229 patents disclose methods relating to knee-replacement (arthroplasty) surgery, and the ’343, ’717, ’559, and ’073 patents disclose suture anchors and suturing methods. BSI avers that it is the owner, by assignment, of the asserted patents.

*The Knee-Replacement Surgery Patents*[1]

The ’896 and ’229 patents are both entitled “Knee Arthroplasty Method,” and were respectively issued on October 5, 2010, and March 13, 2012. The two patents share largely the same specification, and disclose improved methods for less invasive knee-replacement surgery.

> With known techniques, the patella is commonly everted from its normal position. When the patella is everted, the inner side of the patella is exposed and faces outward away from end portions of the femur and tibia. The outer side of the everted patella faces inward toward the end portions of the femur and the tibia. Moving the everted patella to one side of end portions of the femur and tibia tends to increase the size of the incision which must be made in the knee portion of the patient’s leg.

’229 patent, col. 2, ll. 19-27. The ’229 patent claims methods for performing knee-replacement surgery that offsets, rather than everts, the patella, and therefore may decrease the size of the incision necessary in the patient’s leg. Claim 18 is representative:

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[1] The ’821 patent is entitled “Instrumentation for Minimally Invasive Joint Replacement and Methods for Using Same,” and was issued on March 9, 2004. The parties do not dispute the construction of any claim terms in the ’821 patent.

18. A method of performing a joint arthroplasty surgery on a leg of a patient through an incision in a knee portion of the leg, comprising:

displacing a patella in the knee portion of the leg from a normal position to an offset position with an articulating surface of the patella facing the femur;

positioning a guide assembly proximally to the patella, the guide assembly including a pair of substantially parallel arms and a slot having a guide surface configured for receiving a patella cutting tool;

cutting the inner side of the patella, using the guide assembly, in the knee portion of the leg, prior to resecting the femur or the tibia, while the articulating surface of the patella faces towards a posterior portion of the knee portion of the leg, and includes removing at least a portion of the articulating surface of the patella; and

connecting at least one patella implant to the cut articulating surface of the patella,

wherein the cut articulating surface of the patella faces towards a posterior portion of the knee portion of the leg when the at least one patella implant is connected.

(emphases added to highlight disputed claim term).

The '896 patent claims methods for using guides to direct bone cutting. Claim 13 is representative:

13. A method of replacing at least a portion of a joint in a patient, the method comprising the steps of:

obtaining a customized cutting guide fabricated for the patient based on preoperative information, the cutting guide

positionable in a pre-determined position on a bone of the joint using references derived independently from an intramedullary device;

making an incision adjacent to the joint in the patient;

positioning the cutting guide in the pre-determined position by passing the cutting guide through the incision and on a surface of an end portion of an unresected bone of the joint;

moving a cutting tool through the incision into engagement with a guide surface on the positioned cutting guide;

cutting the unresected bone of the joint for the first time, by moving the cutting tool along the guide surface;

attaching a replacement portion of the knee to the cut surface, the replacement portion having a transverse dimension that is larger than a transverse dimension of the guide surface; and

disposing of the cutting guide, as it is no longer safely usable the bone for which it was custom fabricated having been cut and therefore changed.

(emphasis added).

*The Suture Anchor Patents*[2]

The '559 patent is entitled "Suture Anchor" and was issued on November 9, 1999. The '559 patent discloses a suture anchor that is at least partly formed from a material that absorbs body liquid and expands while in the body, thereby helping to

[2] The '343 and '717 patents are both entitled "Suture Anchor," and were respectively issued on June 18, 1996, and February 17, 1998. The parties do not dispute the construction of any claim terms in these two patents.

retain the suture anchor within the patient's body. Claims 24 and 34 are representative.

> 24. An apparatus which is at least partially received in body tissue, said apparatus comprising suture means for transmitting tension forces, and suture anchor means connected with said suture means for retaining at least a portion of said suture means against movement relative to body tissue under the influence of tension in said suture means, said suture anchor means being at least partially formed of a material which absorbs body liquid and expands while said suture anchor means is disposed in body tissue, said suture anchor means includes a side portion which extends between opposite end portions of said suture anchor means, said suture anchor means includes means for defining a passage having first and second openings in said side portion of said suture anchor means, said suture means being partially disposed in said passage between said first an [sic] second openings.
>
> 34. An apparatus which is at least partially received in body tissue, said apparatus comprising suture means for transmitting tension forces, and suture anchor means connected with said suture means for retaining at least a portion of said suture means against movement relative to body tissue under the influence of tension in said suture means, said suture anchor means being at least partially formed of a material which absorbs body liquid and expands while said suture anchor means is disposed in body tissue, said suture anchor means includes surface means for piercing an imperforate surface area on body tissue.

(emphases added).

The '073 patent is entitled "Method of Securing Body Tissue," and was issued on August 8, 2006. The '073 patent discloses methods for securing two body tissues by placing suture anchors within one body tissue, tensioning and connecting the sutures, and transmitting the tension through the suture to another body tissue. Claim 35 is representative:

> 35. A method of securing first body tissue with second body tissue, said method comprising the steps of moving a first anchor along a first path into the second body tissue with a first suture portion extending from the first anchor, moving a second anchor along the second path into the second body tissue with a second suture portion extending from the second anchor, tensioning the first and second suture portions, determining when a predetermined tension is present in the first and second suture portions during performance of said step of tensioning the first and second suture portions, interconnecting the first and second suture portions after determining that the predetermined tension is present in the first and second suture portions, and transmitting force through the suture to the first body tissue.

(emphases added).

## DISCUSSION

Claim construction is a question of law for the determination of the court. *See Markman*, 517 U.S. at 388-389. Claim terms are generally given their ordinary and customary meaning to a person of ordinary skill in the art in question at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-1313 (Fed. Cir. 2005) (en banc) (citations omitted). "The person of ordinary skill in the art is deemed to read the claim term . . . in the context of the entire patent, including the specification." *Id.* at 1313.

The patent 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." *Id.* at 1315, quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d

1576, 1582 (Fed. Cir. 1996). Because the purpose of the specification is to "teach and enable those of skill in the art to make and use the invention and to provide the best mode for doing so," *Phillips*, 415 F.3d at 1323, it is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." *Id.* at 1317.

In addition to the patent's specification, the prosecution history "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.* Although not as reliable as the patent and its prosecution history, the court may also consider extrinsic evidence "if the court deems it helpful in determining the true meaning of language used in the patent claims." *Id.* at 1318. Ultimately, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention [in the specification] will be, in the end, the correct construction." *Id.* at 1316.

1. '229 patent – "articulating surface of the patella"

BSI proposes that "articulating surface of the patella" should be given its ordinary meaning because that is how the phrase is used in the patent. DePuy contends that the "articulating surface of the patella" must be in its "native uncut state" because

where the claims of '229 patent refer to the surface after it has been cut, the term is qualified by "cut." *See*, *e.g.*, '229 patent, claim 18. BSI objects to the insertion of an extraneous limitation into this claim term, and the court agrees. The claims refer to the "cut articulating surface of the patella" only after specifying a cutting step. *See id*. Nothing in the patent or the prosecution history would mandate that the "articulating surface of the patella" must be in a "native uncut state" (or any particular state) prior to the specified cutting step. Indeed, as BSI points out, inserting the "native uncut" requirement would exclude surgical procedures on previously operated-upon patellas, an exclusion nowhere supported by the intrinsic evidence.

Defendants have, since their opening brief, withdrawn their proposal that the "articulating surface of the patella" be construed as the "inner surface of the patella." As the term is not one of common parlance, defendants' original instinct that it would be helpful to the jury to have the "articulating surface of the patella" defined, however, is sound. The court largely agrees with defendants' original position – the "articulating surface of the patella" is the "inner side of the patella."

In describing the procedures for everting and not everting the patella during knee-replacement surgery, the '229 patent uses the terms "inner side" and "outer side" to describe the two sides of the patella:

> [a]fter the incision 114 has been elastically expanded, a patella 120 and

> tissue on the lateral side of the incision may be everted in a manner illustrated in FIG. 7. Thus, the patella 120 is moved from the normal orientation of FIG. 6 to the everted or flipped orientation of FIG. 7, preferably while the leg 70 of the patient is in the extended orientation of FIG. 7. At this time, the *inner side 122* of the patella 120 is facing outward away from other bones in the knee portion 76. The outer side of the everted patella 120 is facing inward toward other bones in the knee portion 76. This enables the *inner side 122* of the patella 120 to be examined.
>
> . . .
>
> If desired, the foregoing step of inverting the patella 120 may be omitted. The patella 120 may be left in orientations in which the *inner side 122* of the patella faces inward throughout the operation. If this is done, the *inner side 122* of the patella 120 may be inspected by tilting the patella from its normal orientation and/or using viewing devices, such as an endoscope. Regardless of how the *inner side 122* of the patella 120 is inspected, moving the patella to the offset position of FIG. 8, with the *inner side 122* facing inward, facilitates utilization of an incision 114 having a limited length.

'229 patent, col. 15, l. 60 - col. 16, l. 27 (emphases added). Later, in describing the eversion procedure and referring to the same numbered element in the figures, the patent uses the terms "inner side" and "articular surface" interchangeably: "[t]he *inner side or articular surface 122* of the patella 120 faces outward and is exposed." *Id*. col. 29, ll. 55-57 (emphasis added).

BSI contends that because claim 18 of the '229 patent recites both the "articulating surface of the patella" and the "inner side of the patella", the two terms must be distinct. Although ordinarily it is true that the use of two different terms in the same claim refers to two different elements, *see Ethicon Endo-Surgery, Inc. v. U.S.*

*Surgical Corp.*, 93 F.3d 1572, 1579 (Fed. Cir. 1996), claim 18 is only logically sound if the two terms are one and the same, as reflected in the specification. The claim recites "displacing a patella . . . with an articulating surface of the patella facing the femur," then specifies "cutting the inner side of the patella," and later refers to "the cut articulating surface of the patella." Without understanding the "inner side of the patella" to refer to the "articulating surface of the patella," the "cut articulating surface of the patella" would have no rational antecedent. *See Philips*, 415 F.3d at 1327 ("[C]laims should be construed, if possible, as to sustain their validity.").

BSI also relies on the declaration of its expert witness for the arthroplasty patents, Dr. Scott Schoifet, for the proposition that the "articulating surface of the patella" is not the "inner side of the patella." However, where the intrinsic record is clear, as it is here, it is unnecessary for the court to turn to extrinsic evidence. *See Victronics*, 90 F.3d at 1584 ("Only if there were still some genuine ambiguity in the claims, after consideration of all available intrinsic evidence, should the trial court have resorted to extrinsic evidence, such as expert testimony, in order to construe claim 1. Moreover, even if the judge permissibly decided to hear all the possible evidence before construing the claim, the expert testimony, which was inconsistent with the specification and file history, should have been accorded no weight."). Finally, Dr. Schoifet's opinion is contradicted by the established medical dictionary definition.

Consistent with the use in the '229 patent, the "articular surface of the patella" is defined as "the posterior surface of the patella." *Stedman's Medical Dictionary* (27th ed. 2000). Thus, the court construes the "articulating surface of the patella" as referring to the "inner side of the patella."[3]

2. '896 patent – "customized cutting guide fabricated for the patient"

BSI also proposes that "customized cutting guide fabricated for the patient" be given its ordinary meaning because the phrase is given its common meaning in the patent. DePuy contends, based on the dictionary definition of "customize," that a "customized cutting guide fabricated for the patient" is "a cutting guide made or altered in any way for a specific patient." BSI objects because the phrase "altered in any way" suggests that any minor adjustment made to a cutting guide would suffice, which contradicts the meaning of the word "fabricate" in the claim term. BSI also points out that during prosecution, the patentee argued to the PTO that "'custom fabricated' is clearly distinct from 'adjusted,'"[4] Pl. Ex. 3, Response to Final Office Action, November 25, 2003, at 11, thereby excluding the mere adjustment to a cutting guide

[3] The court will accept, as the parties proposed during oral argument, an agreed-upon definition of the term "articulating" as used in the context of the '229 patent.

[4] The court does not consult the prosecution history to establish prosecution history disclaimer, that is, to "limit the meaning of a claim term that would otherwise be read broadly," but to confirm the ordinary meaning of the claim term. *See 800 Adept, Inc. v. Murex Sec., Ltd.*, 539 F.3d 1354, 1364 (Fed. Cir. 2008).

from the scope of this claim term.

The court agrees with BSI that DePuy's proposed "altered in any way" construction unjustifiably broadens the common understanding of the word "fabricate." Nothing in the patent suggests that "fabricate" is used in any but its ordinary sense. Without "an express intent to impart a novel meaning," the words of this claim term, being unspecialized and non-technical, should be given their ordinary meaning in the English language. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002). Thus, the court construes "customized cutting guide fabricated for the patient" as having its ordinary meaning – "a cutting guide constructed or manufactured for a specific patient."

3. '559 patent – "suture anchor means"

DePuy contends, and BSI disagrees, that "suture anchor means" is a means-plus-function claim term subject to analysis under 35 U.S.C. § 112(f). Subsection (f) provides that

> [a]n element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The application of subsection (f) "operates to restrict claim limitations drafted in such functional language to those structures, materials, or acts disclosed in the specification

(and their equivalents) that perform the claimed function." *Personalized Media Commc'ns, LLC v. Int'l Trade Comm'n*, 161 F.3d 696, 703 (Fed. Cir. 1998).

As DePuy points out, "[a] claim limitation that actually uses the word 'means' will invoke a rebuttable presumption that § 112[(f)] applies." *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1369 (Fed. Cir. 2002). However, the means-plus-function presumption may be overcome if the claim "goes on to elaborate sufficient structure, material, or acts within the claim itself to perform entirely the recited function." *Personalized Media*, 161 F.3d at 704, *citing Sage Prods. v. Devon Indus., Inc.*, 126 F.3d 1420, 1427-1428 (Fed. Cir. 1997). To determine whether subsection (f) is invoked "involves an analysis of the patent and the prosecution history, and consulting a dictionary definition of [the disputed claim term] to understand if one of skill in the art would understand this term to connote structure." *Personalized Media*, 161 F.3d at 704. Ultimately, "[i]n deciding whether either presumption has been rebutted, the focus remains on whether the claim as properly construed recites sufficiently definite structure to avoid the ambit of [subsection (f)]." *Id.*

BSI argues, and the court agrees, that the recitation of "suture anchor" provides sufficient structure to overcome the means-plus-function presumption. The '559 patent is entitled "Suture Anchor" and its specification discusses the material and structures of various suture anchors already known in the art. *See, e.g.*, '559 patent, col. 2, ll. 39-

48 ("Suture anchors have previously been utilized to retain sutures in either hard or soft tissue in a human patient's body. *The suture anchors have previously been formed of metal, biodegradable materials, and other materials.* These known suture anchors have been retained in the patient's body by changing the orientation of the anchor relative to the patient's body once it has been inserted into the patient's body. Alternatively, *known anchors have been retained in the patient's body by a mechanical interlock formed with the material of the patient's body by barbs or other projections*.") (emphasis added).

The claims of the '559 patent disclose additional structural elements to "suture anchor means." For example, claim 24 describes the "suture anchor means" as "connected with said suture means . . . being at least partially formed of a material which absorbs body liquid and expands while said suture anchor means is disposed in body tissue, said suture anchor means includes a side portion which extends between opposite end portions of said suture anchor means . . . [and] includes means for defining a passage . . . ." The parties agree that if "suture anchor means" were to be a means-plus-function claim term, its function would be "retaining at least a portion of a suture against movement relative to body tissue under the influence of tension in the suture." It is clear that "material which absorbs body liquid and expands while said suture anchor means is disposed in body tissue" performs this function. *See*

*Personalized Media*, 161 F.3d at 704.

Professor Stephen Belkoff, BSI's expert witness for the suture anchor patents, opines that "one of ordinary skill in the art would have understood [] that 'suture anchor' is a commonly used term that refers to any number of different structures." Pl. Ex. 9 ¶ 21. The opinion is supported by the use of "suture anchor" independent of "means," without challenge from DePuy, in the claims of the asserted '073 patent, another patent implicating the same art. Because "suture anchor means" recites sufficient structure – "suture anchor" – as would be understood by a person of ordinary skill in the art, it is not subject to 35 U.S.C. § 112(f). The court construes "suture anchor means" as "suture anchor."[5]

4. '559 patent – "means for defining a passage having first and second opening in said side portion of said suture anchor means"

The parties agree that "means for defining a passage having first and second opening in said side portion of said suture anchor means" is a means-plus-function element subject to analysis under 35 U.S.C. § 112(f). The parties further agree that the function of the claim term is "defining a passage." BSI contends that the structure of

[5] Like some of her colleagues, the drafter of the '559 patent was evidently "enamored of the word 'means.'" *Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 531 (Fed. Cir. 1996).

this claim term is "all suture anchor structures disclosed in the specification that have first and second opening in a side portion of the suture anchor and structural equivalents." DePuy contends that the structure is "tunnel in suture anchor, in the shapes disclosed in figure 9 and col. 11:7-10, and structural equivalents of the foregoing." In essence, the parties agree that the structure 30d disclosed in figure 9 of the '559 patent is within the ambit of this claim term, but dispute whether structure 30e of figure 10 is. Both figures are reproduced below:

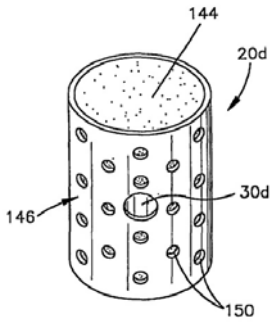

Fig.9

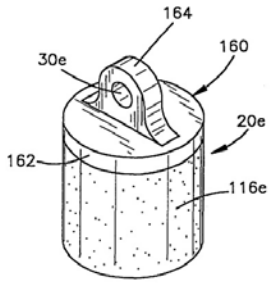

Fig.10

DePuy is right that structure 30e does not correspond with a "means for defining a passage having first and second opening in said side portion of said suture anchor means." The "side portion" of the "suture anchor means" "extends between opposite end portions of said suture anchor means," and "the means for defining a passage [has] first and second openings in said side portion of said suture anchor means." '559 patent, claim 24. The openings of passage 30e are not in a side portion of the suture

anchor that "extends between opposite end portions," rather "passage 30e is formed in a projection 164 which extends axially outward from the end wall 162." *Id.*, col. 12, ll. 10-12.

BSI argues that passage 30e should be included in the construction of "means for defining a passage . . ." because it is a structural equivalent of passage 30d. Under 35 U.S.C. § 112(f), "the claim shall be construed to cover the corresponding structure, material, or acts described in the specification and *equivalents thereof*." (emphasis added). While BSI may be right that passage 30e is structurally equivalent[6] to passage 30d, this is not an inquiry for the court during claim construction. The determination of equivalence for analysis of infringement is a task for the jury (or the court at the summary judgment stage if there are no genuine disputes of material facts). *See Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 38 (1997). Thus, the court will not expand its role at claim construction and identify potential equivalents of structure 30d. The court construes "means for defining a passage having first and second opening in said side portion of said suture anchor means" as "a passage having first and second opening in a side portion of the suture anchor, in the shapes disclosed

[6] The statutory equivalence analysis under §112(f) is narrower than the general doctrine of equivalence in that it requires functional identity before engaging in an analysis of whether there are insubstantial differences in the "way" and the "result." *Odetics, Inc. v. Storage Tech. Corp.*, 185 F.3d 1259, 1267 (Fed. Cir. 1999).

in figure 9, and col. 11:7-10, and structural equivalents thereof."

5. '559 patent – "surface means for piercing an imperforate surface area on body tissue"

The parties also dispute whether "surface means for piercing an imperforate surface area on body tissue" is subject to analysis under 35 U.S.C. § 112(f). As with "suture anchor means," DePuy argues that the use of "means" in this term triggers the means-plus-function presumption, which cannot be overcome because the claim term does not primarily recite structure. BSI contends, and the court agrees, that the recitation of "surface" provides sufficient structure to this claim term.

In *Cole*, the Court of Appeals for the Federal Circuit agreed that "perforation means" was not a means-plus-function claim element because "perforation" is commonly understood as a structural element, namely "a hole, or one of a number of holes, bored or punched through something, as those between individual postage stamps of a sheet to facilitate separation." *Cole*, 102 F.3d at 531, quoting *Webster's Encyclopedic Unabridged Dictionary* (1989). As in *Cole*, the parties here do not contend that "surface" is used in any way other than its ordinary meaning. The dictionary defines "surface" as "the outer face, outside, or exterior boundary of a thing; outermost or uppermost layer or area." *Random House Unabridged Dictionary* (2d ed. 1993). "Surface" clearly "connote[s] structure," *Personalized Media*, 161 F.3d at

704, and read in the context of the claims, "surface means" refers to the surface of the suture anchor.[7] The court construes "surface means for piercing an imperforate surface area on body tissue" as "surface for piercing an imperforate surface area on body tissue."

6. '073 patent – "predetermined tension"

BSI proposes that "predetermined tension" should be given its ordinary meaning because the phrase is used in its common sense in the patent. DePuy contends that a "predetermined tension" is "a specific tension measurement that is determined prior to tensioning the suture portions." For support, DePuy first points to the claim language, which requires "tensioning the first and second suture portions" and then "determining when a predetermined tension is present . . . during performance of said step of tensioning . . . ." '073 patent, claim 35. Logically, DePuy argues, a practitioner of the method must have a specific tension measurement in mind before tensioning. DePuy also relies on passages in the specification that describe how to measure the "predetermined tension force" using a load cell or other transducer. *See*, *e.g.*, *id*. col. 8, ll. 45-47; col. 29, ll. 42-44. The '073 patent also discloses a force application assembly wherein the tension measurement device is associated with the suture

[7] DePuy does not challenge that the other use of surface in the same claim term – "an imperforate surface area on body tissue" – connotes structure.

insertion device, so that the tension may be measured as the suture is inserted into the patient. *Id.* col. 36, ll. 48-54; col. 37, ll. 5-12.

BSI objects, and the court agrees, that the '073 patent does not require that the "predetermined tension" be a specific measurement. Although DePuy is correct that the claim language specifying "determining when a predetermined tension is present" requires that the "predetermined tension" be known in advance, it does not imply that the tension is necessarily a specific measurement. BSI suggests that a range is also conceivable – and nothing in the patent rules out that possibility. It is similarly true that the specification of the '073 describes several embodiments where the tension is measured, or where a predetermined amount of tension is applied to the suture portions by a force application assembly. However, "it is improper to read limitations from a preferred embodiment described in the specification – even if it is the only embodiment – into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 913 (Fed. Cir. 2004).

BSI also argues that "a specific tension measurement" is too narrow a construction because the '073 patent describes that tensioning may be accomplished manually, and DePuy has no proposal for how to achieve a specific tension measurement manually. "The two leg portions of the suture would be tensioned after

the anchors 18e and 20e had moved into the body tissue 14e. *This could be accomplished manually* or by the use of a force application assembly. . . ." '073 patent, col. 41, ll. 12-14 (emphasis added). Based on this passage, BSI contends that a predetermined tension may be achieved manually based on a surgeon's experience, such as a person may use tactile feedback to tie her shoelaces.

The court disagrees. DePuy correctly points out that the '073 patent claims both tensioning sutures generally (e.g., claim 6) and also tensioning sutures to a "predetermined tension," and that the former is a broader limitation than the latter. In describing the former, the patent describes tensioning the sutures when "the surgeon pulls on the free end of the legs portions 50 and 52 and moves the retainer 54 toward the body tissue 12." *Id.* col. 27, ll. 49-51. However, only specialized equipment is described when obtaining a "predetermined tension." In the passage that follows the reference to manual tensioning, "predetermined tension" is established using a force application assembly and not manually:

> [t]he two leg portions of the suture would be tensioned after the anchors 18e and 20e had moved into the body tissue 14e. This could be accomplished manually or by the use of a force application assembly, corresponding to the force application assembly 60 of FIG. 10. In this situation, a force application member, corresponding to the force application member 66 of FIG. 10 may be utilized to press the retainer against the body tissue. *While the suture 24e is being tensioned with a predetermined force and while the retainer is being pressed against the body tissue with a predetermined force, force application members,*

> *corresponding to force application members 76 and 78 of FIG. 10, would be utilized to effect deformation of the retainer.*

*Id.* col. 41, ll. 12-24, (emphasis added).

Although tensioning may certainly be performed manually, there is no support in the patent for tensioning to a "predetermined tension" based on tactile feedback while tensioning. In the court's experience, a person will know when a shoe is comfortably laced to the right tension when she gets there, but will not know in advance what that tension is until she gets there. The critical understanding then, is that the "predetermined tension" must be known in advance. Thus, the court construes "predetermined tension" as having its ordinary meaning – "a tension that is determined in advance of (and not during) tensioning the suture portions."

## CONCLUSION

The claim terms at issue will be construed for the jury and any other purpose in this litigation in a manner consistent with the above rulings of the court.

SO ORDERED.

/s/ Richard G. Stearns

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UNITED STATES DISTRICT JUDGE