IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ORTHOPHOENIX LLC, Plaintiff, v. DFINE INC., ET AL., Defendants.	:	C.A. No. 13-1003-LPS
ORTHOPHOENIX LLC, Plaintiff, v. WRIGHT MEDICAL TECHNOLOGY INC., ET AL., Defendants.	:	C.A. No. 13-1007-LPS
ORTHOPHOENIX LLC, Plaintiff, v. STRYKER CORPORATION, ET AL., Defendants.	:	C.A. No. 13-1628-LPS

MEMORANDUM ORDER

At Wilmington this **2nd** day of **February, 2016**, having reviewed the parties filings and heard oral argument on December 3, 2015 (D.I. 165) ("Tr."),[1]

IT IS HEREBY ORDERED that the disputed claim language of U.S. Patent Nos.

[1]For ease of reference, all docket citations ("D.I.") are to C.A. No. 13-1628-LPS.

6,440,138 ("the '138 patent"), 6,863,672 ("the '672 patent"), 6,663,647 ("the '647 patent"), 6,248,110 ("the '110 patent"), 6,981,981 ("the '981 patent"), and 7,044,954 ("the '954 patent") shall be construed, consistent with *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005), as follows:

1. **"Cavity forming structure"** ('138 patent claims 1, 11; '672 patent claims 1, 6, 11, 15, 19, 23): "A structure that is capable of forming a cavity."

The parties disagree about whether this term should be construed as a means-plus-function element pursuant to 35 U.S.C. § 112, ¶ 6. The presumption against means-plus-function treatment when "means" is not recited in the claim language can be overcome "if the challenger demonstrates that the claim term fails to recite sufficiently definite structure or else recites function without reciting sufficient structure for performing that function." *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1349 (Fed. Cir. 2015) (*en banc*) (internal quotation marks and citation omitted). Here, the claim language is sufficiently definite and provides sufficient structure for the basic function of "forming a cavity." (*E.g.*, '138 patent at 12:26-29 ("a cavity forming structure carried by the shaft comprising a surface which directly contacts and shears cancellous bone in response to rotating the shaft within and about the axis of the cannula"); '672 patent at 13:10-13 ("said distal end portion having a cavity forming structure comprising a surface which directly contacts cancellous bone in response to linear movement of the shaft along the axis of the cannula")) Defendants have not put forward any expert testimony or other evidence to support their contrary view. Accordingly, the Court does not construe this term pursuant to 35 U.S.C. § 112, ¶ 6.

2. **"Carried by the shaft"** ('138 patent claims 1, 11; '672 patent claims 6, 15, 23): Plain and ordinary meaning.

The parties disagree about whether a structure may be carried by another structure if the

two structures are integrated. Nothing in the intrinsic evidence suggests that the plain and ordinary meaning of "carried" necessarily requires strict structural separation. Defendants' construction seeks improperly to limit the term based on the specification's descriptions of preferred embodiments that use "carried" in the context of separate structures. The Court is not persuaded that the specification consistently and exclusively uses "carried" to refer to non-integrated structures. Moreover, as Defendants concede, there is no disclaimer here. (*See* Tr. at 71-72)

3. **"Shears cancellous bone in response to rotating the shaft within and about the axis of the cannula"** ('138 patent claims 1, 11): No construction necessary.

The specification explains that the cavity forming structure "slices or cut[s]" cancellous bone but does not explain the difference between the two. ('138 patent at 4:31-36) During prosecution, the patentee disclaimed forms of cutting that do not involve direct contact, such as ablation, by amending the claims to recite "directly contacts and shears" instead of "cuts" in order to overcome prior art that recited the use of tools involving electrical energy. (D.I. 133, Ex. C at ORTHO_001091-95) The Court does not interpret this as a disclaimer of all forms of cutting but, rather, views it as a disclaimer of forms of cutting that do not involve direct contact. This disclaimer is already captured elsewhere in claims 1 and 11 – which recite "a surface which ***directly contacts*** and shears cancellous bone in response to rotating the shaft within and about the axis of the cannula" ('138 patent at 12:27-29, 12:52-55) (emphasis added) – and, accordingly, need not also be reflected in the construction of this term.

4. **"Surface which directly contacts cancellous bone in response to [linear] movement of the shaft along the axis of the cannula"** ('672 patent claims 1, 6, 11, 15, 19, 23) / **"moving the shaft [linearly along [and not rotatingly about] the axis of the cannula] to cause the surface [to contact cancellous bone] to form a cavity"** ('672 patent claims 1, 6, 11, 15, 19, 23): Plain and ordinary meaning.

Stryker's proposed construction improperly reads limitations into the claim (direct causality between the movement of the shaft and the contacting of the surface) from preferred embodiments in the specification. According to Stryker, this is necessary to avoid a strained view of infringement, whereby this claim element is met by linear movement of the shaft ***at any point in time*** before causing the surface of the cavity forming structure to form a cavity, such as linear movement of the shaft on the operating table, long before insertion into the patient's body. (*See* Tr. at 83-85) The Court agrees with Defendants that the plain and ordinary meaning of these terms, particularly the requirements of "in response to" and "to cause," would not be met by a scenario in which the linear movement of the shaft was entirely removed in both time and space from the formation of the cavity. Having reached this conclusion (and thereby having resolved in Stryker's favor the concern it has raised with respect to this term), the Court perceives no need to rewrite the claim language.

5. **"Extending the cavity forming structure in situ radially from the shaft" / "cavity forming structure [. . .] adapted to [. . .] be extended in situ radially from the shaft"** ('672 patent claims 4, 9, 11, 15, 19, 23): "The cavity forming structure is advanced outwardly (or distally) from the shaft once it is placed in the body. When advanced from the shaft, the structure changes shape such that it extends in a radial direction from the shaft." / "The cavity forming structure is configured so that it can be advanced outwardly (or distally) from the shaft once it is placed in the body and, when advanced, the structure changes shape such that it extends in a radial direction from the shaft."

The parties' dispute focuses on whether the cavity forming structures must "change shape" when extended in situ. The Court agrees with Stryker that they must do so, at least to some extent.[2] During prosecution, the Examiner's Notice of Allowance was issued alongside the Examiner's own claim amendments which were proposed for the explicit purpose of overcoming

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[2]Orthophoenix concedes that for a particular embodiment that "doesn't change shape," the embodiment's radial extension nevertheless "changes the overall shape profile." (Tr. at 27-29)

prior art structures that did not change shape in situ, and the patentee accepted the Examiner's claim amendments without disagreeing with the Examiner's explanation. (C.A. 13-1007-LPS, D.I. 84, Ex. G at ¶¶ 65-69; D.I. 133, Ex. D at MEDT5993, MEDT6032, MEDT6040-42) However, the Court is not convinced that the change in shape requires radiating in all directions; instead, it appears that extending in at least one radial direction from the shaft suffices to meet the claim element. Accordingly, the Court partially adopts Stryker's proposed construction for this term, replacing "such that it radiates outwardly around and about the axis of the shaft" with "such that it extends in a radial direction from the shaft."

6. **"A cannula having [. . .] an axis establishing a percutaneous path leading into bone" / "deploying the cannula percutaneously to establish a path leading to inside bone"** ('138 patent claims 1, 11; '672 patent claims 1, 6, 11, 15, 19, 23): "A cannula, which includes tube-shaped structures, that can maintain a path through the skin to allow for access into bone."

The Court's construction reflects the parties' agreement that "cannula" includes "tube" – which previously was their only dispute with respect to these terms. (*See* D.I. 157 at 15-16; Tr. at 87)

7. **"Providing"** ('138 patent claim 11; '672 patent claims 1, 6, 11, 15, 19, 23): "Making available."

Nothing in the claim language requires the providing steps to involve two individuals, i.e., a provider and a recipient. Rather, "making available" is consistent with the plain and ordinary meaning of "providing." Contrary to Orthophoenix's assertion, it is not illogical for a physician to provide a tool for his own use. *See Meyer Intellectual Props. Ltd. v. Bodum, Inc.*, 690 F.3d 1354, 1368 (Fed. Cir. 2012); *Cephalon Inc. v. Mylan Pharm., Inc.*, 962 F. Supp. 2d 688, 699-700 (D. Del. 2013).

8. **"Resilient material"** ('138 patent claim 5): No construction necessary.

The parties' dispute with respect to this term is resolved by the Court's construction of the following term.

9. **"The cavity forming structure comprises resilient material"** ('138 patent claim 5): "The cavity forming structure is made from a material that allows the structure to return to its original form after being deformed."

"Comprising" is an open-ended term. *See Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l*, 246 F.3d 1336, 1348 (Fed. Cir. 2001). Nonetheless, Orthophoenix's proposed construction – which would allow this claim limitation to be satisfied by a cavity forming structure that includes an undetectable amount of resilient material entirely surrounded by non-resilient material (Tr. at 34) – goes too far. Plaintiff's approach would effectively read out of the claim the "comprises resilient material" limitation, which would be improper. *See, e.g., Kustom Signals, Inc. v. Applied Concepts, Inc.*, 264 F.3d 1326, 1332 (Fed. Cir. 2001) ("The open-ended transition 'comprising' does not free the claim from its own limitations."); *Spectrum Int'l, Inc. v. Sterilited Corp.*, 164 F.3d 1372, 1380 (Fed. Cir. 1998) ("'Comprising' is not a weasel word with which to abrogate claim limitations."). Accordingly, the Court's construction – without importing limitations from the specification (*e.g.*, '138 patent at 4:27-28) ("loop structure 20 springs open") as proposed by Stryker – clarifies that the cavity forming structure must derive some resilience from the resilient material.

10. **"Cavity forming structure is adapted to be deployed at an axis that transverses the axis of the shaft"** ('672 patent claims 3, 8, 13, 17, 21, 25): "Cavity forming structure is adapted to be deployed at an axis that lies across the axis of the shaft."

The parties' proposed constructions all reflect that the plain and ordinary meaning of "transverses" requires the cavity forming structure to lie across the axis of the shaft. Defendants' proposed construction improperly reads in an additional limitation from the

specification regarding the nature of the angle created when the cavity forming structure crosses the axis of the shaft. ('672 patent at 4:27-28, 5:60-61) Accordingly, the Court rejects Defendants' proposal to require a perpendicular angle be created by the axis and the shaft.

11. **"A tool according to [claim 1 or claim 5]"** ('138 patent claims 5, 6, 9): "A system according to [claim 1 or claim 5]."

It is apparent from the face of the patent that the dependent claims refer to the system in independent claims 1 and 5. The U.S. Patent and Trademark Office ("PTO") has issued a Certificate of Correction to this effect. (D.I. 155, Ex. F)

12. **"A system according to claim 11"** ('138 patent claim 12): "A method according to claim 11."

It is apparent from the face of the patent that the dependent claims refer to the method in independent claim 11. The PTO has issued a Certificate of Correction to this effect. (*Id.*)

13. **"Causing . . . expandable bodies to assume an expanded geometry" / "expandable bodies are caused to assume expanded geometries"** ('110 patent claims 3, 9): "Causing the expandable bodies, which are structures that are capable of expanding, to become larger."

The parties agree that the expanded geometries may assume any of an infinite number of shapes (including amorphous shapes) and sizes. They disagree about whether the expanded geometries must be (1) predefined, such that the final shape and size of an expanded geometry is known prior to insertion of an expandable body, and (2) constrained, such that the expandable body cannot expand beyond a certain point. (*See* Tr. at 139-40, 155-57) The specification consistently uses "geometry" to refer to particular shapes and sizes, many of which are predefined and constrained. (*E.g.*, '110 patent at 3:64-4:57, 11:31, 15:19-67, 22:10) (providing examples of different geometries) However, there is no lexicography or disclaimer requiring the Court to limit "expanded geometries" to predefined and constrained shapes and sizes.

Disclaimers made during the prosecution of related patents (D.I. 133, Ex. 5 at STRORT00174386, STRORT00174520-23, STROT00174534-35) do not constitute prosecution history disclaimer for the '110 patent. In addition to the absence of intrinsic evidence supporting Stryker's "predefined and constrained" limitation, the Court agrees with Orthophoenix that "expandable geometries" here is synonymous with "larger."

14. **"[First or second] body comprising an expandable wall"** ('110 patent claim 3): "The body includes an expandable wall, and if the body has generally elastic or semi-elastic properties, the body further includes or is used with some form of external or internal restraints."

The parties disagree about whether the expandable wall must comprise internal or external restraints if it has generally elastic or semi-elastic properties (which the parties agree it need not have). The specification explains that "expandable bodies 56 with generally elastic or generally semi-elastic properties will require some form of external or internal restraints to ensure proper deployment in bone." ('110 patent at 10:61-65) This is a clear disclaimer of the use of an expandable ***body*** with generally elastic or generally semi-elastic properties in the absence of external and internal restraints. However, contrary to Defendants' proposed construction, it is not a disclaimer of the use of an expandable ***wall*** with generally elastic or generally semi-elastic properties in the absence of external and internal restraints. Nor is it a disclaimer of the use of a ***body*** with generally elastic or generally semi-elastic properties that does not ***include*** any external or internal restraints, as the specification provides the example of a "movable o-ring" – which is clearly not included in the body – as a restraint. (*See id.* at 10:66-11:18, Fig. 6) Rather, the specification's use of "will require" language means only that a restraint must either be included or used with the expandable body should the expandable ***body*** have generally elastic or semi-elastic properties.

15. **"A device for insertion into a vertebral body to apply a force . . . . "** ('647 patent various claims): The preambles are limiting.

The preambles are limiting because they provide the antecedent basis for at least the "force capable of compacting cancellous bone and moving fractured cortical bone" referred to in the claim bodies' requirement of "the wall being further sized and configured to apply the force in response to expansion of the inflatable body within the vertebral body." (*E.g.*, *id.* at 15:20-22)

16. **"The wall including, when inflated, opposed side surfaces and opposed superior and inferior surfaces extending along an elongated longitudinal axis that is substantially aligned with the axis of the catheter"** ('647 patent claims 1, 18, 37, 56): "The wall, when inflated, includes opposed side surfaces and opposed top and bottom surfaces extending along an elongated length-wise axis that is substantially aligned with the axis of the catheter. 'Top' and 'bottom' are determined based on the intended orientation of the inflatable body in vivo, such that 'top' is above or near the head and 'bottom' is below or near the feet."

This term's reference to "superior and inferior surfaces" does not render the claims in which it appears indefinite, because the specification and claims themselves provide adequate orientation for a person of ordinary skill in the art to understand "superior" and "inferior" as "top" or "bottom," respectively, when the structure is placed in vivo according to the figures and descriptions. (*See id.* at 9:59-61, claims 1, 18, 37, 56) Stryker improperly seeks to import from the specification limitations of "substantially flat" and "parallel" based on preferred embodiments. The specification does not state that "substantially flat" or "parallel" surfaces are required in all instances, but rather explains that substantially flat surfaces are created by restraints (*id.* at 6:8-11), which are recited only in the dependent claims (*id.* at 15:45-48, 15:60-63), and will not be read into the independent claims.

17. **"The inflatable body, when inflated within the vertebral body, having . . . a height measured between the superior and inferior surfaces of approximately 0.5 cm to 3.5 cm[, an anterior to posterior dimension measured along the elongated axis of approximately 0.5 cm to 3.5 cm, and a side-to-side dimension measured between the opposed side surfaces of**

approximately 0.5 cm to 3.5 cm]" ('647 patent claims 1, 18): Plain and ordinary meaning.

Contrary to Stryker's view, measurement along the "anterior to posterior dimension" does not render the claim indefinite unless the catheter is inserted laterally (at exactly a 90 degree angle) to the anterior-posterior dimension, which the patent does not teach. (*See, e.g.*, *id.* at Figs. 2, 11) (showing catheter being inserted parallel to anterior-posterior direction and at less than 90 degree angle to anterior-posterior direction, respectively) Moreover, as with the previous term, Stryker's proposed construction – by requiring "measure[ment] at all points along their respective planes" – improperly imports a limitation from preferred embodiments, that the planes of the vertebral body must be flat. It also improperly excludes preferred embodiments with curved surfaces. Contrary to Stryker's view that flat surfaces are required for measurement, the specification shows distances being measured for non-flat structures. (*E.g.*, *id.* at 9:3-6)

18. **"A void creation device including an expandable structure"** ('981 patent claim 1, '954 patent claim 1): "A cavity creation device including an expandable structure."

Defining "void" as "empty space," as Stryker proposes, might be misunderstood as reading out of the claims preferred embodiments which have liquid or debris in the void. (*See* '981 patent at 11:46-47) "Void" is best understood as "cavity," as is indicated by the specifications of the '954 and '981 patents referring interchangeably to void creation and cavity creation. (*E.g.*, '954 patent at 1:54-62; '981 patent at Abstract, 4:29-30, 4:50-53)

19. **"The expandable structure having at least one dimension so that changing the expandable structure from the unexpanded configuration to the expanded configuration . . . compacts only a first region of the cancellous bone volume substantially without compacting a second region of the cancellous bone volume different form the first cancellous bone volume"** ('981 patent claim 1) / **"The expandable structure having at least one dimension so that the expandable structure will assume a predetermined shape and size when substantially expanded that compacts only a first**

volume of the cancellous bone volume to form a void, leaving a second volume of the cancellous bone volume substantially uncompacted by the expandable structure" ('954 patent claim 1): "The expandable structure having at least one particular, constrained dimension so that changing the expandable structure from the unexpanded configuration to the expanded configuration . . . compacts only a first region of the cancellous bone volume substantially without compacting a second region of the cancellous bone volume different form the first cancellous bone volume" / "The expandable structure having at least one particular, constrained dimension so that the expandable structure will assume a predetermined shape and size when substantially expanded that compacts only a first volume of the cancellous bone volume to form a void, leaving a second volume of the cancellous bone volume substantially uncompacted by the expandable structure."

The parties' disagreement centers on whether, as proposed by Stryker, the expanded configuration must maintain a predefined and constrained shape and size, in at least one direction with respect to the '981 patent and in all directions with respect to the '954 patent. Importantly, the claim language of the '981 patent – unlike that of the '954 patent – does not recite a predetermined shape and size. The Court agrees with Stryker that Orthophoenix's proposal that the Court not construe these terms would allow Orthophoenix improperly to read out of the claims the "at least one dimension" limitation. (*See* D.I. 154 at 24-25; Tr. at 221-22) The claim language "so that" makes clear that the at least one dimension ***allows*** for a second region of the cancellous bone to remain uncompacted, rather than merely existing as any one of the several dimensions in the expandable structure that may or may not compact cancellous bone. The prosecution history confirms the significance of this limitation, as the patentee overcame prior art by amending the claims to provide for at least one dimension ***responsible*** for the compaction of ***only*** a first region of cancellous bone. (*See* D.I. 133, Ex. 8 at STRORT179394; D.I. 133, Ex. 9 at STRORT179722) ("New claim 48 defines the act of providing a void creation device including an expandable body having at least one dimension ***for achieving the result*** (not taught or suggested by Scholten) of compacting only a first region of a

cancellous bone volume in a vertebral body (into which a filling material is placed) without substantially compacting a second region of the cancellous bone volume different from the first region.") (emphasis added) Logically, the portion of the expandable structure having at least one dimension allowing for a second region of cancellous bone to remain uncompacted must be distinguishable from at least another portion of the expandable structure which compacts a first region of cancellous bone, and the portion of the expandable structure having at least one dimension cannot have a role in preserving a second region of uncompacted cancellous bone if it lacks any form of constraint in its expansion. The Court's construction clarifies that the expandable structure must have "at least one particular, constrained dimension," as logically would be required for a second region of cancellous bone to remain uncompacted.

HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT JUDGE