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**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA**

WARSAW ORTHOPEDIC, INC.,
MEDTRONIC SOFAMOR DANEK
USA, INC., MEDTRONIC PUERTO
RICO OPERATIONS COMPANY,
and OSTEOTECH, INC.,

Plaintiffs,

vs.

NUVASIVE, INC.,

Defendant.

CASE NO. 12-cv-2738-CAB (MDD)
CLAIM CONSTRUCTION ORDER
AS TO THE '146 PATENT

I. Introduction

On November 7, 2013, the Court held a hearing to construe certain claims of United States Patent No. 5,676,146. The parties filed briefs and claim construction charts in accordance with the local rules of this District. [Doc. Nos. 109, 121, 123, 124 and related exhibits.] Luke Dauchot, Esq., Alexander MacKinnon, Esq., Nimalka Wickeramasekera, Esq., and Sharre Lotfollahi, Esq., appeared for Warsaw Orthopedic, Inc., Medtronic Sofamor Danek U.S.A., Inc., Medtronic Puerto Rico Operations Co., and Osteotech, Inc. (hereinafter collectively "Warsaw"). Frank Scherkenbach, Esq., Michael Kane, Esq., and John Lamberson, Esq., appeared for NuVasive, Inc. Having considered the submissions of the parties and the arguments of counsel, the Court

1 construes the disputed terms addressed at argument¹ as follows.

2 II. Legal Standard

3 The Court construes the claim language when the parties dispute what a person
4 of skill in the art would understand the term to mean. Claims are not read in a vacuum
5 but in the context of the entire patent including the specification. *See Phillips v. AWH*
6 *Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005)(en banc). The claims, the specification
7 and the prosecution history are the most significant source of the legally operative
8 meaning of disputed claims language. *See SmithKline Beecham Corp. v. Apotex Corp.*,
9 403 F.3d 1331, 1338 (Fed Cir. 2005). The words of a claim are generally given the
10 ordinary and customary meaning that a person of ordinary skill would have applied at
11 the time of the invention. *Phillips*, 415 F.3d at 1313.

12 III. U.S. Patent No. 5,676,146

13 Warsaw asserts that NuVasive infringes U.S. Patent No. 5,676,146 (“the ‘146
14 patent”). The invention of the ‘146 patent is directed to a surgical implant containing
15 a resorbable radiopaque marker and a method of locating the implant within a body.
16 [Doc. No. 102-1.] The implant, which can be used to repair skeletal defects and
17 irregularities, incorporates radiopaque material, e.g., nondemineralized or partially
18 demineralized bone particles, which is resorbable in its entirety and may contribute to
19 the healing of bone through natural processes. [*Id.*, at Col. 1:30-40.] This radiopaque
20 material is distributed in radiolucent resorbable or non-resorbable material during the
21 manufacture of the implant such that the radiopaque material serves as a marker, which
22 can be visualized by x-ray or other radiographic technique, facilitating the
23 determination of the location and/or position of the implant within a body. [*Id.*, at Col.
24 1:44-48; Col. 3:4-10.]

25 The terms and phrases of the following claim of the ‘146 patent, set forth in
26

27 ¹ At the hearing counsel represented that the parties had reached agreement as to the
28 construction of certain of the terms of the ‘146 patent previously submitted as disputed. Any terms
not addressed in this order are therefore deemed withdrawn from the Court’s consideration without
prejudice to a request for construction upon a showing of good cause.

1 italics, are presented by the parties for construction. These terms are common to all the
2 independent claims asserted in the litigation (Claims 13, 21, 25 and 26), and the
3 construction applies to each of them.

4 13. A method of determining the location and/or orientation of *an*
5 *osteogenic surgical implant* within a body which comprises:

6 a) surgically implanting within a body *an osteogenic implant* fabricated
7 from a radiolucent material comprising allograft bone particles and a
8 radiopaque material comprising particles of nondemineralized or partially
9 nondemineralized allograft bone, the radiopaque material being *uniformly*
10 *distributed within* the radiolucent material, wherein the radiopaque
11 material is *provided in sufficient quantity for use as a marker*; and

12 b) post-surgically determining the location and/or orientation of the
13 implant by a radiographic technique.

14 A. *An Osteogenic Surgical Implant*

15 The term *osteogenic* to describe the implant of the invention was added to certain
16 claims of the patent during reexamination. None of the original claims of the patent
17 included this term. Warsaw proposes that osteogenic has a plain and ordinary meaning
18 to one of ordinary skill in the art and does not need to be construed. The inventor of the
19 ‘146 patent, Nelson Scarborough, however, testified that the definition of osteogenic
20 is not unambiguous in the art. “I think a lot of people would probably have their own
21 definitions of these terms [osteogenic], and I’m not sure – everybody doesn’t agree
22 totally.” [Doc. No. 121-1, Ex. 7, at 124:18-125:16.] Consequently, the Court looks to
23 the patent specification and the file history to determine the meaning of osteogenic in
24 this invention.

25 Warsaw contends that if construction is needed the term should be limited to “a
26 surgical implant that includes live cells,” and therefore promotes bone growth by a
27 biological mechanism known as osteogenesis. NuVasive opposes the limited
28 construction advanced by Warsaw and argues for a broader construction of osteogenic
as a “surgical implant that participates in the process of new bone growth,” and
therefore promotes bone growth by any of three biological mechanisms – osteogenesis,
osteoconduction and osteoinduction.

1 The word “osteogenic” only appears once in the ‘146 patent’s specification in an
2 illustrative example of the claimed implant:

3 EXAMPLE 1

4 A sheet fabricated from demineralized elongated bone particles is
5 manufactured according to the method described in U.S. Pat. No.
6 5,507,813. While the sheet is being wet-laid nondemineralized bone
7 particles that have been classified to a predetermined range are added
8 thereto. The mineralized particles are uniformly distributed within the wet
9 sheet which is then subjected to the remaining manufacturing operations
10 described in the aforesaid patent. The resultant flexible sheets are then cut
11 into implant-sized pieces.

12 . . .

13 EXAMPLE 4

14 The nondemineralized particles of Example 1 can be distributed in
15 a flowable *osteogenic* composition which is comprised of demineralized
16 bone particles and an inert carrier such as glycerol.

17 [Doc. No. 102-1, Col. 3:34-43; Col. 4:4-8 (emphasis added).]

18 A flowable osteogenic composition comprised of demineralized bone particles
19 and glycerol is disclosed in U.S. Patent No. 5,507,813 (“the ‘813 patent”) [Doc. No. 98-
20 10], the content of which is incorporated by reference in the specification of the ‘146
21 patent. [Doc. No. 102-1, Col. 1:49-52.] The ‘813 patent defines “osteogenic” as the
22 ability of the material fabricated by the method disclosed in that patent to “participate
23 in the process of new bone growth regardless of the mechanism(s) involved,” e.g.
24 osteogenesis, osteoconduction and/or osteoinduction. [Doc. No. 98-10, Col. 2:1-13.]
25 The ‘146 patent adopts this definition of osteogenic through its incorporation of the
26 ‘813 patent; nothing in the specification or file history suggests the inventor of the ‘146
27 patent rejected or narrowed the ‘813 patent’s definition of osteogenic. This is further
28 evidenced by the ‘146 patent’s teaching that the implant of the ‘146 patent invention
when fabricated from demineralized bone leads to new bone growth by one or more
biological mechanisms such as osteogenesis, osteoconduction and/or osteoinduction.
[Doc. No. 102-1, Col. 2:62–3:1.] The patent specification does not limit its disclosed
implant to promoting bone growth by osteogenesis and provides no language that
modifies or limits the construction of an osteogenic implant to only an implant with live

1 cells. The term is used to describe materials that promote bone growth by all three of
2 the biological mechanisms.

3 During the reexamination, the term osteogenic was applied broadly by both the
4 examiner and the patentee to describe materials disclosed in prior art that were not
5 limited to promoting bone growth by osteogenesis. The Prewett reference (“U.S.
6 Patent No. 5,510,396”) discloses a process for producing a flowable osteogenic
7 composition using demineralized bone particles and glycerol to promote bone growth
8 by one or more mechanisms such as osteogenesis, osteoconduction and/or
9 osteoinduction. [Doc. No. 102-13, Col. 2:21-26.] The Frenkel reference² is described
10 as disclosing the use of osteogenic materials to enhance bone fusion. [Doc. No. 98-11,
11 at 13 of 66.] The text of that reference discloses a demineralized bone matrix gel acting
12 as an osteoconductive/osteoinductive material to enhance bone fusion. The Dowd
13 reference (the ‘813 patent), discussed above, teaches that osteogenic materials are those
14 that perform any of the three biological mechanisms to promote bone growth.
15 Throughout the reexamination the examiner and the patentee refer to osteogenic
16 compositions in the broad sense of the term as descriptive of a material that performs
17 any of the three biological mechanisms to promote bone growth.

18 The file history shows that the patentee introduced the word osteogenic to certain
19 claims during the final amendments filed in the reexamination proceeding. Claim 13
20 was amended adding the term osteogenic to describe the surgical implant of the
21 invention to distinguish it from the Kensey reference (U.S. Patent No. 5,441,517),
22 which is directed toward a device for vascular closure. The Kensey reference, the
23 patentee argued, has no discussion or application to the use of bone particles and is
24 directed to substantially different subject matter. [Doc. No. 98-11, at 64-66.] The
25 addition of osteogenic to traverse Kensey does not support an inference that the
26 patentee intended by this amendment to narrow the scope of osteogenic to cover only
27

28 ²Frenkel et al., *Use of Demineralized Bone Matrix Gel to Enhance Spine Fusion*. 19th Annual Meeting of the Society of Biomaterials, April 28-May 2, 1993, Birmingham, AL. p. 162.

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