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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

WARSAW ORTHOPEDIC, INC.,
Plaintiff,
v.
NUVASIVE, INC.,
Defendant.

Case No.: 12-CV-2738-CAB-MDD

**ORDER GRANTING MOTION FOR
SUMMARY JUDGMENT**

[Doc. Nos. 207, 214, 218]

Before the Court is defendant NuVasive’s motion for summary judgment of non-infringement of U.S. Patent No. 5,676,146 (“the ‘146 patent”). [Doc. Nos. 218, 247-1.]¹ Plaintiffs (collectively “Warsaw”) opposed. [Doc. No. 236.] NuVasive submitted a reply [Doc. No. 250-1], and the Court held oral argument. Having considered the submissions of the parties and the arguments of counsel, the motion is **GRANTED**.²

¹ All page references to docket entries correspond to the CM/ECF assigned page numbers for the docketed material.

² In light of the Court’s finding of non-infringement of the asserted claims, the Court declines to reach the defendant’s alternative arguments regarding improper claim broadening and invalidity, as well as its motion on damages. [Doc. No. 214.] These motions are deemed moot. In addition, the pending motions seeking to exclude the opinions of experts [Doc. Nos. 207, 214] are denied.

I. The Patented Invention and the Accused Product

1 The invention of the ‘146 patent is directed to a surgical implant containing a
2 resorbable radiopaque marker and a method of locating the implant within a body. [Doc.
3 No. 1-2.] The implant, which can be used to repair skeletal defects and irregularities,
4 incorporates radiopaque material, e.g., nondemineralized or partially demineralized bone
5 particles, which is resorbable in its entirety and may contribute to the healing of bone
6 through natural processes. [Id., at Col. 1:30-40.] This radiopaque material is distributed in
7 radiolucent resorbable or non-resorbable material, during the manufacture of the implant
8 such that the radiopaque material serves as a marker, which can be visualized by x-ray or
9 other radiographic technique, facilitating the determination of the location and/or position
10 of the implant within a body. [Id., at Col. 1:44-48; Col. 3:4-10.]

12 NuVasive makes and sells a product called Osteocel Plus, an allograft bone matrix.
13 [Doc. No. 247-2.] Osteocel Plus is used for the repair, replacement or reconstruction of
14 musculoskeletal defects in a variety of surgical and implant applications. Warsaw accuses
15 this product of direct infringement, and also alleges that NuVasive’s sale and instruction
16 regarding the use of this product as a surgical implant constitutes indirect infringement.

17 The components of Osteocel Plus include cancellous bone chips, demineralized
18 bone, and mesenchymal stem cells and osteoprogenitor cells. NuVasive promotes this
19 product as a complete “cocktail” for various musculoskeletal applications to support fusion
20 due to its inclusion of these three components necessary for bone healing; cells (the
21 mesenchymal stem cells and osteoprogenitor cells), signals (the demineralized bone) and
22 scaffold (the cancellous bone chips). [Id., at 3.] Osteocel Plus is packaged by placing the
23 cancellous bone particles which include the cells in a jar, adding the demineralized bone to
24 the jar and then mixing them with a cryopreservation solution for frozen storage. [Doc.
25 No. 247-6.]

26 NuVasive contends that the evidence Warsaw relies upon to support its allegations
27 of infringement does not demonstrate that Osteocel Plus meets the limitations of the
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1 asserted claims. NuVasive therefore moves for a judgment of non-infringement as a matter
2 of law.

3 **II. Legal Standard**

4 Under Federal Rule of Civil Procedure 56(a), “the court shall grant summary
5 judgment if the movant shows that there is no genuine dispute as to any material fact and
6 the movant is entitled to judgment as a matter of law.” The moving party has the burden
7 of establishing the absence of a genuine dispute of material fact. The court must view the
8 evidence in the light most favorable to the non-movant and draw all reasonable inferences
9 in the non-movant’s favor. *Matsushita Elec. Inds. Co. Ltd., v. Zenith Radio Corp.*, 475
10 U.S. 574, 587 (1986). Where the record taken as a whole could not lead a rational trier of
11 fact to find for the nonmoving party, there is no genuine issue for trial. *Id.*

12 After an adequate time for discovery, a motion for summary judgment is appropriate
13 against a party who fails to make a showing sufficient to establish the existence of an
14 element essential to that party’s case, and on which that party will bear the burden of proof
15 at trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986) (holding that the moving
16 party is entitled to a judgment as a matter of law if the nonmoving party fails to make a
17 sufficient showing on an essential element of its case with respect to which it has the burden
18 of proof).

19 Determining whether a patent claim is infringed requires a two-step inquiry: first,
20 the claim must be properly construed to determine its scope and meaning; second, the claim
21 as properly construed must be compared to the accused device or method. *See Wolverine*
22 *World Wide, Inc., v. Nike, Inc.*, 38 F.3d 1192, 1196 (Fed. Cir. 1994). The party alleging
23 infringement bears the burden of proving by a preponderance of evidence that every
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1 limitation set forth in the asserted claim is found in accused product or process, either
2 literally or by substantial equivalent. *Id.*³

3 **III. The Asserted Claims**

4 Warsaw alleges NuVasive's Osteocel Plus product infringes the following claims of
5 the '146 patent [Doc. No. 1-2.].

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

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

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

16 15. The method of claim 13 wherein the radiographic technique is x-ray
17 imaging.

18 21. An osteogenic surgical implant for surgical implantation in the body, the
19 implant comprising particles of a radiolucent material including
20 demineralized allograft bone particles in substantially uniform admixture with
21 a radiopaque material including particles of nondemineralized or partially
22 demineralized allograft bone, wherein the radiopaque material is provided in
23 sufficient quantity for use as a marker.

24 25. An osteogenic surgical implant for surgical implantation in the body
25 comprising nondemineralized or partially demineralized allograft bone
26 particles and demineralized allograft bone particles uniformly distributed in
27 an inert carrier, the nondemineralized or partially demineralized allograft
28 bone particles being provided in sufficient quantities for use as a marker, the
surgical implant being stored in a package for subsequent implantation.

³ In its opposition to NuVasive's motion, Warsaw withdrew its allegations of infringement by the doctrine of equivalence [Doc. No. 236, at 13], so the analysis herein is limited to sufficiency of Warsaw's evidence of literal infringement of the claims at issue.

1 26. An osteogenic surgical implant for surgical implantation in the body, the
2 implant comprising particles of a radiolucent material in substantially uniform
3 admixture with particles of nondemineralized or partially demineralized bone,
4 wherein the particles of nondemineralized or partially demineralized bone are
5 provided in sufficient quantities for use as a radiopaque marker, the surgical
6 implant being stored in a package for subsequent implantation.

7 Each of the asserted independent claims is directed at a surgical implant that includes
8 in its composition radiopaque material (nondemineralized or partially nondemineralized
9 allograft bone) which is uniformly distributed throughout or in a substantially uniform
10 admixture with radiolucent material, in sufficient quantity for the radiopaque material to
11 act as a marker for the determination of the location and/or orientation of the implant after
12 surgical implantation in the body.

13 **IV. Claim Construction and Reexamination Proceedings**

14 The parties submitted certain terms and phrases for claim construction, including the
15 phrase *uniformly distributed within*. However, they withdrew their request for construction
16 of *uniformly distributed*, sought only the construction of the word *within*. Although the
17 plain meaning of *within* would ordinarily be “inside,” in the context of the patent disclosure
18 the Court found such a construction to be nonsensical. It is clear from the specification
19 that the radiopaque material is uniformly distributed throughout the radiolucent material
20 comprising the implant. The patent does not teach putting the radiopaque material inside
21 the radiolucent material; such a construction would be illogical. Consequently, to the
22 extent the word *within* results in any ambiguity the Court construed it to mean in this
23 context, throughout. [Doc. No. 143.]

24 The invention of this patent is directed at fabricating an otherwise radiolucent
25 surgical implant with sufficient radiopaque material distributed throughout it, such that the
26 implant can be readily visualized by x-ray or other radiographic technique following
27 implantation in the body. The Court also found that individuals of skill in the art will
28 understand that the limitation that the particles of nondemineralized or partially
demineralized bone be *provided in sufficient quantity for use as a marker* means the

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