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

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

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

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

NuVasive contends that the evidence Warsaw relies upon to support its allegations of infringement does not demonstrate that Osteocel Plus meets the limitations of the

asserted claims. NuVasive therefore moves for a judgment of non-infringement as a matter of law.

II. Legal Standard

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

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

Determining whether a patent claim is infringed requires a two-step inquiry: first, the claim must be properly construed to determine its scope and meaning; second, the claim as properly construed must be compared to the accused device or method. *See Wolverine World Wide, Inc., v. Nike, Inc.*, 38 F.3d 1192, 1196 (Fed. Cir. 1994). The party alleging infringement bears the burden of proving by a preponderance of evidence that every

limitation set forth in the asserted claim is found in accused product or process, either literally or by substantial equivalent. *Id.*[3]

III. The Asserted Claims

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

> 13. A method of determining the location and/or orientation of an osteogenic surgical implant within a body which comprises:
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> a) surgically implanting within a body an osteogenic implant fabricated from a radiolucent material comprising allograft bone particles and an radiopaque material comprising particles of nondemineralized or partially nondemineralized allograft bone, the radiopaque material being uniformly distributed within the radiolucent material, wherein the radiopaque material is provided in sufficient quantity for use as a marker; and
>
> b) post-surgically determining the location and/or orientation of the implant by a radiographic technique.
>
> 15. The method of claim 13 wherein the radiographic technique is x-ray imaging.
>
> 21. An osteogenic surgical implant for surgical implantation in the body, the implant comprising particles of a radiolucent material including demineralized allograft bone particles in substantially uniform admixture with a radiopaque material including particles of nondemineralized or partially demineralized allograft bone, wherein the radiopaque material is provided in sufficient quantity for use as a marker.
>
> 25. An osteogenic surgical implant for surgical implantation in the body comprising nondemineralized or partially demineralized allograft bone particles and demineralized allograft bone particles uniformly distributed in an inert carrier, the nondemineralized or partially demineralized allograft bone particles being provided in sufficient quantities for use as a marker, the surgical implant being stored in a package for subsequent implantation.

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[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.

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

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

IV. Claim Construction and Reexamination Proceedings

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

The invention of this patent is directed at fabricating an otherwise radiolucent surgical implant with sufficient radiopaque material distributed throughout it, such that the implant can be readily visualized by x-ray or other radiographic technique following implantation in the body. The Court also found that individuals of skill in the art will 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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