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7 Attorneys for Plaintiffs/Counterclaim Defendants,
WARSAW ORTHOPEDIC, INC.; MEDTRONIC
8 SOFAMOR DANEK U.S.A., INC.; MEDTRONIC
PUERTO RICO OPERATIONS CO.; OSTEOTECH,
9 INC.; MEDTRONIC, INC.; and MEDTRONIC
10 SOFAMOR DANEK DEGGENDORF, GMBH

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

13 WARSAW ORTHOPEDIC, INC.;
14 MEDTRONIC SOFAMOR DANEK
U.S.A., INC.; MEDTRONIC PUERTO
15 RICO OPERATIONS CO.; and
OSTEOTECH, INC.,

16 Plaintiffs,
17 vs.

18 NUVASIVE, INC.,
19 Defendant.

20 AND RELATED COUNTERCLAIMS.

) CASE NO. 3:12-cv-02738-CAB (MDD)

) **SECOND AMENDED AND
SUPPLEMENTAL COMPLAINT FOR
PATENT INFRINGEMENT**

) **JURY TRIAL DEMANDED**

1 Plaintiffs Warsaw Orthopedic, Inc. (“Warsaw”), Medtronic Sofamor Danek
2 U.S.A., Inc. (“Sofamor Danek USA”), Medtronic Puerto Rico Operations Co.
3 (“MPROC”), and Osteotech, Inc. (“Osteotech”) (collectively “Plaintiffs”) bring this
4 First Amended Complaint for Patent Infringement and Jury Demand against
5 Defendant NuVasive, Inc. (“NuVasive”), alleging as follows:

6 **PARTIES, JURISDICTION, AND VENUE**

7 1. Plaintiff Warsaw is an Indiana corporation, with its principal place of
8 business in Warsaw, Indiana.

9 2. Plaintiff Sofamor Danek USA is a Tennessee corporation, with its
10 principal place of business in Memphis, Tennessee. Sofamor Danek USA researches,
11 develops, and distributes medical devices and instruments for use in connection with
12 spine surgery.

13 3. Plaintiff MPROC is a Cayman Islands corporation, with its principal
14 place of business in Humacao, Puerto Rico. MPROC manufactures and sells medical
15 devices and instruments for use in connection with spine surgery.

16 4. Plaintiff Osteotech is a Delaware corporation, with its principal place of
17 business in Eatontown, New Jersey. Osteotech makes and sells biologic and
18 regenerative therapy products for use in the repair of the musculoskeletal system.

19 5. Defendant NuVasive is a Delaware corporation, with its principal place
20 of business in San Diego, California. NuVasive manufactures and sells various
21 medical devices and instruments for use in the spine, including spinal implants and
22 bone graft products.

23 6. This action arises under the patent laws of the United States, 35 U.S.C. §
24 1 et seq., and seeks damages and injunctive relief pursuant to 35 U.S.C. §§ 271, 281,
25 283–285.

26 7. This Court has subject matter jurisdiction over the action pursuant to 28
27 U.S.C. §§ 1331 and 1338(a) because this action arises under the Acts of Congress
28 relating to patents.

1 8. Upon information and belief, NuVasive transacts business in this judicial
2 District by manufacturing, selling, or offering to sell products that infringe, by
3 contributing to the infringement of the patents at issue in this action, or by conducting
4 other business within this judicial District.

5 9. Venue is proper in this judicial District pursuant to 28 U.S.C. §§ 1391(b),
6 1391(c), 1391(d) and/or 1400(b).

7 **COUNT I**

8 10. Paragraphs 1–9 are incorporated into this count by reference.

9 11. United States Patent No. 8,021,430 (the “’430 patent,” a copy of which is
10 attached hereto as Exhibit A), entitled “Anatomic Spinal Implant Having Anatomic
11 Bearing Surfaces,” issued on September 20, 2011. Plaintiff Warsaw is the owner of
12 the ’430 patent by written assignment. Warsaw has granted to Plaintiff MPROC, via
13 written agreements, the exclusive license under the ’430 patent to use, make, have
14 made, import, offer for sale, and sell. MPROC has granted to Plaintiff Sofamor
15 Danek USA, via written agreements, the exclusive sub-license under the ’430 patent
16 to import, offer for sale, and sell. As a result of these agreements and Warsaw’s
17 ownership of the ’430 patent, Plaintiffs Warsaw, MPROC, and Sofamor Danek USA
18 have standing to bring suit for infringement of the ’430 patent.

19 12. NuVasive is infringing and has infringed the ’430 patent by making,
20 using, offering for sale, and selling infringing products, including but not limited to its
21 CoRoent XL family of spinal implants (e.g., CoRoent XL Thoracic, CoRoent XL
22 Standard, CoRoent XL Lordotic, CoRoent XL Wide Lordotic, CoRoent XL Wide
23 Standard, CoRoent XL Coronal Tapered Lordotic, CoRoent XL Coronal Tapered
24 Standard, and CoRoent Keeled) for use in its eXtreme Lateral Interbody Fusion
25 (“XLIF”) surgical procedure, as well as its CoRoent Large family of spinal implants
26 (e.g., CoRoent Large Wide and Narrow) for use in transforaminal or posterior surgical
27 approaches, within the United States.

28 13. NuVasive’s infringement of the ’430 patent has been without permission,

1 consent, authorization, or license of Plaintiffs.

2 14. NuVasive's infringement of the '430 patent has caused and will continue
3 to cause Plaintiffs substantial damages, and has caused and will continue to cause
4 Plaintiffs irreparable harm for which there is no adequate remedy at law.

5 **COUNT II**

6 15. Paragraphs 1–9 are incorporated into this count by reference.

7 16. United States Patent No. 5,676,146 C2 (the "'146 patent," a copy of
8 which is attached hereto as Exhibit B), entitled "Surgical Implant Containing A
9 Resorbable Radiopaque Marker And Method Of Locating Such Within A Body,"
10 issued on December 25, 2007. The original application issued as a patent on October
11 14, 1997, and reexamination certificates for the '146 patent issued on April 18, 2000
12 and December 25, 2007.

13 17. Plaintiff Osteotech was the owner of the '146 patent from original
14 issuance until April 15, 2011. Osteotech obtained its ownership by written
15 assignment. As owner of the '146 patent during this time period, Osteotech has
16 standing to sue for infringement of the '146 patent that occurred between original
17 issuance of the patent and April 15, 2011.

18 18. Plaintiff Warsaw is the current owner of the '146 patent by written
19 assignment from Osteotech. As a result of this assignment, Warsaw has been the
20 owner of the '146 patent since April 15, 2011. The April 15, 2011 assignment from
21 Osteotech to Warsaw did not transfer to Warsaw the right to sue for damages for
22 infringement that took place before the assignment.

23 19. Warsaw has granted to Plaintiff Sofamor Danek USA, via written
24 agreements, an exclusive license under the '146 patent to import, offer for sale, and
25 sell. As a result of these agreements and Warsaw's ownership of the '146 patent,
26 Plaintiffs Warsaw and Sofamor Danek USA have standing to bring suit for
27 infringement of the '146 patent that occurred from April 15, 2011 to the present, and
28 going forward.

1 20. NuVasive is infringing and has infringed the '146 patent from 2008 to the
2 present by making, using, offering for sale, and selling infringing products, including
3 but not limited to its Osteocel Plus bone graft product, within the United States.

4 21. NuVasive is inducing and has induced direct infringement of the '146
5 patent by surgeons in violation of 35 U.S.C. § 271(b) by actively taking steps to
6 facilitate purchase of Osteocel Plus and instructing surgeons to use Osteocel Plus in
7 spine surgery with knowledge that such use infringes one or more claims of the '146
8 patent, and with the specific intent to induce that infringement.

9 22. NuVasive is instructing and has instructed surgeons to use Osteocel Plus
10 in spine surgery, including in, but not limited to, its anterior cervical discectomy and
11 fusion ("ACDF"), XLIF, anterior lumbar interbody fusion ("ALIF"), posterior cervical
12 fusion ("PCF"), posterior laminoplasty, transforaminal lumbar interbody fusion
13 ("TLIF"), Interlaminar Lumbar Instrumented Fusion ("ILIF"), posterior lumbar
14 interbody fusion ("PLIF"), and posterior fixation surgical techniques.

15 23. Following NuVasive's instructions, surgeons have implanted, and
16 continue to implant, Osteocel Plus into patients' bodies during spine surgery, an act
17 that constitutes direct infringement of at least one claim of the '146 patent.

18 24. Upon information and belief, NuVasive has had knowledge of the '146
19 patent at least as early as 2008 given that the Grafton and Grafton Plus products that
20 compete with Osteocel Plus are marked with the '146 patent. Upon information and
21 belief, NuVasive's products have been used in spine surgery in conjunction with
22 Grafton products with NuVasive sales representatives present during the surgery.
23 NuVasive also has had knowledge of the '146 patent at least as early as August 21,
24 2012, when it was served with Plaintiffs' original Complaint for Patent Infringement
25 and Jury Demand.

26 25. NuVasive has acted with the specific intent to induce direct infringement
27 of the '146 patent by, among other things, actively continuing to sell Osteocel Plus
28 and actively continuing to instruct surgeons to use Osteocel Plus in spine surgery as

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