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

PARTIES, JURISDICTION, AND VENUE

- 1. Plaintiff Warsaw is an Indiana corporation, with its principal place of business in Warsaw, Indiana.
- 2. Plaintiff Sofamor Danek USA is a Tennessee corporation, with its principal place of business in Memphis, Tennessee. Sofamor Danek USA researches, develops, and distributes medical devices and instruments for use in connection with spine surgery.
- 3. Plaintiff MPROC is a Cayman Islands corporation, with its principal place of business in Humacao, Puerto Rico. MPROC manufactures and sells medical devices and instruments for use in connection with spine surgery.
- 4. Plaintiff Osteotech is a Delaware corporation, with its principal place of business in Eatontown, New Jersey. Osteotech makes and sells biologic and regenerative therapy products for use in the repair of the musculoskeletal system.
- 5. Defendant NuVasive is a Delaware corporation, with its principal place of business in San Diego, California. NuVasive manufactures and sells various medical devices and instruments for use in the spine, including spinal implants and bone graft products.
- 6. This action arises under the patent laws of the United States, 35 U.S.C. § 1 et seq., and seeks damages and injunctive relief pursuant to 35 U.S.C. §§ 271, 281, 283–285.
- 7. This Court has subject matter jurisdiction over the action pursuant to 28 U.S.C. §§ 1331 and 1338(a) because this action arises under the Acts of Congress relating to patents.



- 8. Upon information and belief, NuVasive transacts business in this judicial District by manufacturing, selling, or offering to sell products that infringe, by contributing to the infringement of the patents at issue in this action, or by conducting other business within this judicial District.
- 9. Venue is proper in this judicial District pursuant to 28 U.S.C. §§ 1391(b), 1391(c), 1391(d) and/or 1400(b).

COUNT I

- 10. Paragraphs 1–9 are incorporated into this count by reference.
- 11. United States Patent No. 8,021,430 (the "'430 patent," a copy of which is attached hereto as Exhibit A), entitled "Anatomic Spinal Implant Having Anatomic Bearing Surfaces," issued on September 20, 2011. Plaintiff Warsaw is the owner of the '430 patent by written assignment. Warsaw has granted to Plaintiff MPROC, via written agreements, the exclusive license under the '430 patent to use, make, have made, import, offer for sale, and sell. MPROC has granted to Plaintiff Sofamor Danek USA, via written agreements, the exclusive sub-license under the '430 patent to import, offer for sale, and sell. As a result of these agreements and Warsaw's ownership of the '430 patent, Plaintiffs Warsaw, MPROC, and Sofamor Danek USA have standing to bring suit for infringement of the '430 patent.
- 12. NuVasive is infringing and has infringed the '430 patent by making, using, offering for sale, and selling infringing products, including but not limited to its CoRoent XL family of spinal implants (e.g., CoRoent XL Thoracic, CoRoent XL Standard, CoRoent XL Lordotic, CoRoent XL Wide Lordotic, CoRoent XL Wide Standard, CoRoent XL Coronal Tapered Lordotic, CoRoent XL Coronal Tapered Standard, and CoRoent Keeled) for use in its eXtreme Lateral Interbody Fusion ("XLIF") surgical procedure, as well as its CoRoent Large family of spinal implants (e.g., CoRoent Large Wide and Narrow) for use in transforaminal or posterior surgical approaches, within the United States.
 - 13. NuVasive's infringement of the '430 patent has been without permission,



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

COUNT II

- 15. Paragraphs 1–9 are incorporated into this count by reference.
- 16. United States Patent No. 5,676,146 C2 (the "'146 patent," a copy of which is attached hereto as Exhibit B), entitled "Surgical Implant Containing A Resorbable Radiopaque Marker And Method Of Locating Such Within A Body," issued on December 25, 2007. The original application issued as a patent on October 14, 1997, and reexamination certificates for the '146 patent issued on April 18, 2000 and December 25, 2007.
- 17. Plaintiff Osteotech was the owner of the '146 patent from original issuance until April 15, 2011. Osteotech obtained its ownership by written assignment. As owner of the '146 patent during this time period, Osteotech has standing to sue for infringement of the '146 patent that occurred between original issuance of the patent and April 15, 2011.
- 18. Plaintiff Warsaw is the current owner of the '146 patent by written assignment from Osteotech. As a result of this assignment, Warsaw has been the owner of the '146 patent since April 15, 2011. The April 15, 2011 assignment from Osteotech to Warsaw did not transfer to Warsaw the right to sue for damages for infringement that took place before the assignment.
- 19. Warsaw has granted to Plaintiff Sofamor Danek USA, via written agreements, an exclusive license under the '146 patent to import, offer for sale, and sell. As a result of these agreements and Warsaw's ownership of the '146 patent, Plaintiffs Warsaw and Sofamor Danek USA have standing to bring suit for infringement of the '146 patent that occurred from April 15, 2011 to the present, and going forward.



- 20. NuVasive is infringing and has infringed the '146 patent from 2008 to the present by making, using, offering for sale, and selling infringing products, including but not limited to its Osteocel Plus bone graft product, within the United States.
- 21. NuVasive is inducing and has induced direct infringement of the '146 patent by surgeons in violation of 35 U.S.C. § 271(b) by actively taking steps to facilitate purchase of Osteocel Plus and instructing surgeons to use Osteocel Plus in spine surgery with knowledge that such use infringes one or more claims of the '146 patent, and with the specific intent to induce that infringement.
- 22. NuVasive is instructing and has instructed surgeons to use Osteocel Plus in spine surgery, including in, but not limited to, its anterior cervical discectomy and fusion ("ACDF"), XLIF, anterior lumbar interbody fusion ("ALIF"), posterior cervical fusion ("PCF"), posterior laminoplasty, transforaminal lumbar interbody fusion ("TLIF"), Interlaminar Lumbar Instrumented Fusion ("ILIF"), posterior lumbar interbody fusion ("PLIF"), and posterior fixation surgical techniques.
- 23. Following NuVasive's instructions, surgeons have implanted, and continue to implant, Osteocel Plus into patients' bodies during spine surgery, an act that constitutes direct infringement of at least one claim of the '146 patent.
- 24. Upon information and belief, NuVasive has had knowledge of the '146 patent at least as early as 2008 given that the Grafton and Grafton Plus products that compete with Osteocel Plus are marked with the '146 patent. Upon information and belief, NuVasive's products have been used in spine surgery in conjunction with Grafton products with NuVasive sales representatives present during the surgery. NuVasive also has had knowledge of the '146 patent at least as early as August 21, 2012, when it was served with Plaintiffs' original Complaint for Patent Infringement and Jury Demand.
- 25. NuVasive has acted with the specific intent to induce direct infringement of the '146 patent by, among other things, actively continuing to sell Osteocel Plus and actively continuing to instruct surgeons to use Osteocel Plus in spine surgery as



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