

**IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA**

WARSAW ORTHOPEDIC, INC.;)	
MEDTRONIC SOFAMOR DANEK U.S.A.,)	
INC.; MEDTRONIC PUERTO RICO)	
OPERATIONS CO.; and OSTEOTECH, INC.)	
)	
Plaintiffs,)	Case No. 3:12-cv-00438-JD-CAN
)	
v.)	
)	
NUVASIVE, INC.,)	
)	
Defendant.)	
)	

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

AND JURY DEMAND

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. Warsaw owns intellectual property and manufactures and sells medical devices and instruments in this judicial District for use in connection with spine surgery.

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. NuVasive has had, and continues to have, regular and systematic contacts with the State of Indiana and with this judicial District by selling or offering to sell products that infringe the patents at issue in this case, 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, consent, authorization, or license of Plaintiffs.

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 alleged with knowledge of the '146 patent.

26. NuVasive is also contributing and has contributed to the infringement of the '146 patent in violation of 35 U.S.C. § 271(c) by offering for sale, selling, promoting, teaching, and encouraging the use of Osteocel Plus in spine surgery. NuVasive markets Osteocel Plus as especially made or especially adapted for implantation within patients' bodies during surgery. Osteocel Plus is not a staple article of commerce suitable for substantial non-infringing use because it is especially designed for surgical implantation and its location and/or orientation is necessarily apparent using x-ray or other radiographic techniques. The use of Osteocel Plus in surgery necessarily and directly infringes at least one claim of the '146 patent.

27. NuVasive's infringement of the '146 patent has been without permission, consent, authorization, or license of Plaintiffs.

28. NuVasive's infringement of the '146 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 III

29. Paragraphs 1–12 are incorporated into this count by reference.

30. United States Patent No. 8,251,997 (the "997 patent," a copy of which is attached hereto as Exhibit C), entitled "A Method For Inserting An Artificial Implant Between Two Adjacent Vertebrae Along A Coronal Plane," issued on August 28, 2012 from U.S. Application No. 13/306,583 ("the '583 application"). The '997 patent relates generally to novel methods for performing surgical procedures in the human spine. Plaintiff Warsaw is the owner of the '997 patent by written assignment. Warsaw has granted to Plaintiff Sofamor Danek USA, via written agreements, the exclusive license under the '997 patent to use, make, have made, import, offer for sale, and sell. As a result of these agreements and Warsaw's ownership of the '997 patent,

Plaintiffs Warsaw and Sofamor Danek USA have standing to bring suit for infringement of the '997 patent.

31. NuVasive is inducing and has induced direct infringement of the '997 patent by surgeons in violation of 35 U.S.C. § 271(b) by actively taking steps to facilitate purchase of its CoRoent XL family of implants and at least its MaXcess 4 Retractor and instructing and training surgeons to use the CoRoent XL family of implants and at least the MaXcess 4 Retractor in NuVasive's minimally invasive spinal surgical procedure, XLIF, that is performed through the side of patients' bodies with knowledge that such use infringes one or more claims of the '997 patent, and with the specific intent to induce that infringement.

32. NuVasive is instructing and training and has instructed and trained surgeons to use its CoRoent XL family of implants and at least its MaXcess 4 Retractor in its XLIF surgical technique. NuVasive includes such instruction in, for example, published surgical techniques and CoRoent XL and MaXcess 4 Retractor marketing literature, and on its website, available at <http://www.nuvasive.com/patient-solutions/indications/lumbar-degenerative-disc-disease>. NuVasive also provides such instruction during training courses.

33. Following NuVasive's instructions, surgeons have implanted, and continue to implant, the CoRoent XL family of implants into patients' bodies using at least the MaXcess 4 Retractor while performing NuVasive's XLIF surgical technique, an act that constitutes direct infringement of at least one claim of the '997 patent.

34. NuVasive has had knowledge of the claims of the '997 patent at least as early as August 3, 2012, when notice was provided to NuVasive of a filing with the United States Patent & Trademark Office of an Opposition and Petition Under 37 C.F.R. § 1.183 in the *inter partes*

reexamination of U.S. Patent 7,207,949 (Control No. 95/001,202), which noted that the claims of the '583 application were allowed and the patent would issue shortly.

35. Upon information and belief, NuVasive has been monitoring patents in the '997 patent family at least as early as 2008.

36. NuVasive has acted with the specific intent to induce direct infringement of the '997 patent by, among other things, actively marketing, selling, supporting, and warranting the CoRoent XL family of implants and at least the MaXcess 4 Retractor and actively continuing to instruct surgeons to use the CoRoent XL family of implants and at least the MaXcess 4 Retractor while performing NuVasive's XLIF surgical technique as alleged with knowledge of the '997 patent.

37. NuVasive is also contributing and has contributed to the infringement of the '997 patent in violation of 35 U.S.C. § 271(c) by offering for sale, selling, promoting, teaching, and encouraging the use of its CoRoent XL family of implants and at least its MaXcess 4 Retractor in its XLIF surgical technique. NuVasive markets its CoRoent XL family of implants and MaXcess 4 Retractor as especially made or especially adapted for use in its XLIF surgical technique.

38. The CoRoent XL family of implants is not a staple article of commerce suitable for substantial non-infringing use. The CoRoent XL family of implants is especially designed for use in NuVasive's XLIF surgical technique, a procedure performed from the lateral aspect of the spine. For example, NuVasive markets "the CoRoent[®] XL family of implants [as] [d]esigned specifically for the eXtreme Lateral Interbody Fusion (XLIF[®]) procedure." The structural configurations of the CoRoent XL family of implants render them unsuitable for insertion from the anterior or posterior aspect of the spine. These structural configurations include at least the

dimensions, surface configurations, and insertion mechanisms. The use of the CoRoent XL family of implants in NuVasive's XLIF surgical technique necessarily and directly infringes at least one claim of the '997 patent.

39. The MaXcess 4 Retractor is not a staple article of commerce suitable for substantial non-infringing use. The MaXcess 4 retractor is especially designed for use in NuVasive's XLIF surgical technique, a procedure performed from the lateral aspect of the spine. For example, NuVasive markets its MaXcess 4 Retractor as the "fourth generation XLIF access system" "designed to deliver reproducible XLIF outcomes." The structural configurations of the MaXcess 4 Retractor render it unsuitable for use in surgery performed from the anterior or posterior aspect of the spine. These structural configurations include at least the blade length that is especially adapted for use in lateral spine surgery. The use of the MaXcess 4 Retractor in NuVasive's XLIF surgical technique necessarily and directly infringes at least one claim of the '997 patent.

40. NuVasive's infringement of the '997 patent has been without permission, consent, authorization, or license of Plaintiffs.

41. NuVasive's infringement of the '997 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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request that the Court:

1. Adjudge that NuVasive has infringed and is infringing the '430 patent;

2. Adjudge that NuVasive has directly infringed and is directly infringing and has induced and contributed to and is inducing and contributing to the infringement of the '146 patent;

3. Adjudge that NuVasive has induced and contributed to and is inducing and contributing to the infringement of the '997 patent;

4. Preliminarily and permanently enjoin NuVasive and its affiliates, subsidiaries, officers, directors, employees, agents, representatives, licensees, successors, and assigns, and all of those acting for it and on its behalf, or acting in concert with it, from further infringement of the '430, '146, and '997 patents;

5. Award compensatory damages to Plaintiffs, together with interest;

6. Order an accounting to the extent necessary to provide complete monetary relief to Plaintiffs;

7. Award Plaintiffs their costs and, where appropriate, reasonable attorney fees under 35 U.S.C. § 285; and

8. Award Plaintiffs any other such relief as the Court deems just and proper.

DATED: August 28, 2012

Respectfully submitted,

By: */s/ Timothy M. Curran*

John D. LaDue
jladue@lck-law.com
Timothy M. Curran
tcurran@lck-law.com
LADUE CURRAN & KUEHN LLC
200 First Bank Bldg
205 W. Jefferson Blvd.
South Bend, Indiana 46601
Telephone: (574) 968-0760
Facsimile: (574) 968-0761

Luke L. Dauchot (admitted *pro hac vice*)
luke.dauchot@kirkland.com
Alexander F. MacKinnon (admitted *pro hac vice*)
alexander.mackinnon@kirkland.com
Nimalka Wickramasekera (admitted *pro hac vice*)
nimalka.wickramasekera@kirkland.com
KIRKLAND & ELLIS LLP
333 South Hope Street
Los Angeles, California 90071
Telephone: (213) 680-8400
Facsimile: (213) 680-8500

Attorneys for Plaintiffs

JURY TRIAL DEMAND

PLAINTIFFS DEMAND A TRIAL BY JURY ON ALL ISSUES SO TRIABLE.

DATED: August 28, 2012

Respectfully submitted,

By: /s/ Timothy M. Curran

John D. LaDue
jladue@lck-law.com
Timothy M. Curran
tcurran@lck-law.com
LADUE CURRAN & KUEHN LLC
200 First Bank Bldg
205 W. Jefferson Blvd.
South Bend, Indiana 46601
Telephone: (574) 968-0760
Facsimile: (574) 968-0761

Luke L. Dauchot (admitted *pro hac vice*)
luke.dauchot@kirkland.com
Alexander F. MacKinnon (admitted *pro hac vice*)
alexander.mackinnon@kirkland.com
Nimalka Wickramasekera (admitted *pro hac vice*)
nimalka.wickramasekera@kirkland.com
KIRKLAND & ELLIS LLP
333 South Hope Street
Los Angeles, California 90071
Telephone: (213) 680-8400
Facsimile: (213) 680-8500

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on August 28, 2012 I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which sent notification of such filing to the following:

BECKMAN LAWSON, LLP
Matthew J. Elliott, #21242-02
melliott@beckmanlawson.com
201 W. Wayne Street
Fort Wayne, IN 46802
Phone: 260-422-0800
Fax: 260-420-1013

I also hereby certify that I have mailed by United States Postal Service the document to the following non CM/ECF participants:

FISH & RICHARDSON P.C.
Frank E. Scherkenbach (*Pro hac vice* pending)
scherkenbach@fr.com
Fish & Richardson P.C.
One Marina Park Drive
Boston, MA 02210-1878
Phone: 617-542-5070
Fax: 617-542-8906

FISH & RICHARDSON P.C.
Todd Miller (*Pro hac vice* pending)
miller@fr.com
Michael A. Amon (*Pro hac vice* pending)
amon@fr.com
Fish & Richardson P.C.
123 90 El Camino Real
San Diego, CA 92130
Phone: 858-678-5070
Fax: 858-678-5099

/s/ Timothy M. Curran

Timothy M. Curran