

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
EASTERN DIVISION**

CONFORMIS, INC.,

Plaintiff,

v.

WRIGHT MEDICAL TECHNOLOGY, INC.;
WRIGHT MEDICAL GROUP, INC.; and
MICROPORT ORTHOPEDICS INC.,

Defendants.

CIVIL ACTION NO. 1:13-cv-12312

**FIRST AMENDED COMPLAINT FOR
PATENT INFRINGEMENT**

DEMAND FOR JURY TRIAL

Plaintiff ConforMIS, Inc. (“ConforMIS”) files this First Amended Complaint for Patent Infringement against Defendants Wright Medical Technology, Inc., Wright Medical Group, Inc., and MicroPort Orthopedics Inc. (collectively “Defendants”). ConforMIS hereby alleges on personal knowledge as to its own activities, and on information and belief as to the activities of others, as follows:

I. FACTUAL BACKGROUND

ConforMIS’s Ground-Breaking Intellectual Property

1. ConforMIS is the world’s leading designer, developer, and manufacturer of patient-specific knee implants as well as the surgical tools required to best fit those implants into a specific patient’s body. Founded by doctors affiliated with Stanford and Harvard Medical Schools, ConforMIS began with a revolutionary idea: make the implant fit the patient rather than forcing the patient to fit the implant.

2. For decades before ConforMIS’s innovation and continuing today, implant manufacturers have been offering a standard set of implant sizes, akin to the small-medium-large sizing in off-the-rack department stores, from which a surgeon could select. This approach forces the surgeon to pick an implant size that, in the surgeon’s judgment, appears closest in fit to the patient’s anatomy, but that is not designed for and that does not truly fit the individual

patient's articular geometry. The surgeon, therefore, is forced to make a number of size, shape and other compromises in an effort to get the implant to fit as well as possible.

3. These blunt efforts are further hampered by the use of standard tools to implant standard implants, none of which is designed with reference to the anatomy of the individual patient. As a result of this imprecise approach, after surgery, patients commonly suffer loss of movement and function, instability, and lingering pain.

4. ConforMIS recognized that the conventional process of joint repair was backwards: rather than fitting the patient to the implant, the implant should be designed and developed specifically for the patient. This not only produces a better-fitting implant but also an implant shape that feels more natural to the patient because patients vary physiologically in the size, dimensions, shape, position, orientation, and range of motion of their joints.

5. ConforMIS therefore set out to develop its proprietary iFit[®] technology to create both patient-specific implants and instruments. ConforMIS implants are individually sized and shaped to fit each patient's unique anatomy, providing a precise anatomic fit and preserving healthy tissue while leading to better function and a more natural feel. ConforMIS patient-specific instrument systems, which use ConforMIS's iJig[®] technology, precisely place the patient-specific implant, reduce surgical time and trauma, and create a reproducible surgical technique. ConforMIS iJigs eliminate many of the traditional instruments associated with conventional surgery while concurrently simplifying and improving the surgical technique.

6. By combining personalized implants with patient-specific instrumentation, a surgeon is able to provide treatment that: a) is tailored to the patient; b) preserves more of the patient's joint; and c) minimizes surgical trauma. These patient-specific implant systems fit and work with the individual patient's anatomy.

7. The U.S. Food and Drug Administration has approved ConforMIS knee-implant systems for use in the United States. The European Union has likewise done so for use in Europe. ConforMIS currently sells a full line of patient-specific knee-implant systems in many countries worldwide. To date, ConforMIS's patient-specific knee implants and customized tools

have helped improve the lives of thousands of Americans, many of whom live in Massachusetts.

8. ConforMIS's novel idea to fit the implant to the patient has received consistent industry acclaim. ConforMIS's iTotal[®] knee-replacement system won the 2011 American Technology Award, the only national "Best Of" award that recognizes products and services across the technology industry. ConforMIS has twice won Medical Design Excellence Awards, the premier awards program for the medical technology community. In 2009, ConforMIS's iUni[®] and iDuo[®] knee-resurfacing implants won the gold medal among implant and tissue-replacement products. In 2012, ConforMIS's iTotal CR Knee Replacement System won the silver medal in the same category.

9. ConforMIS has developed significant intellectual property associated with its iFit technology, its patient-specific implants, and its iJig patient-specific instruments, including a large portfolio of patents and pending patent applications. These patents and patent applications span a range of related technologies including imaging software, image processing, patient-specific orthopedic implants, patient-specific orthopedic instrumentation, methods of design and manufacture of patient-specific systems, and related surgical techniques. The technology and patent portfolio are applicable to all major joint systems, including knee, hip, shoulder, and ankle joints.

Defendants' Infringement of ConforMIS's Intellectual Property

10. Defendants offer a line of patient-specific instruments for use with their standard, off-the-shelf implants. Defendants market these patient-specific instruments as their PROPHECY Pre-Operative Navigation Guides and PROPHECY INBONE Pre-Operative Navigation System.

11. Defendants' patient-specific PROPHECY guides infringe fundamental aspects of ConforMIS's intellectual-property portfolio, including pin-first instruments and systems, resection-guide instruments and systems, patient-specific instrument systems that register to cartilage, patient-specific instruments that register to bone, MRI-based patient-specific technology, CT-based patient-specific technology, knee-joint systems, ankle-joint systems, and

systems for other joints.

PROPHECY Pin-First Guides and Resection Guides

12. PROPHECY patient-specific guides are manufactured both as pin-alignment guides and as alignment-and-resection guides.

13. PROPHECY pin-alignment guides are “pin-first” devices that align surgical pins to secure a standard, off-the-shelf resection guide, which is used to resect a joint during surgery. PROPHECY pin alignment guides infringe various ConforMIS patent claims, including patent claims related to pin-first devices.

14. PROPHECY alignment-and-resection guides are “cut guide” devices that incorporate a resection guide into the device for resecting the joint during surgery. PROPHECY alignment-and-resection guides infringe various ConforMIS patent claims, including patent claims related to cut-guide devices.

CT-Based Guides and MRI-Based Guides

15. PROPHECY patient-specific guides can be designed using imaging modalities that image bone (such as Computed Tomography or CT) or can alternatively be designed using imaging modalities that primarily image bone, cartilage, and other soft tissues (such as Magnetic Resonance Imaging or MRI).

16. PROPHECY guides manufactured using CT scans infringe various ConforMIS patent claims, including patent claims related to patient-specific bone surfaces. PROPHECY guides manufactured using MRI scans infringe various ConforMIS patent claims, including patent claims related to patient-specific cartilage surfaces.

Patient-specific Instruments for Knee Joints and Other Joints

17. PROPHECY patient-specific guides can be used for the treatment of both knee joints (such as the PROPHECY Pre-Operative Navigation Guides) and ankle joints (PROPHECY INBONE Pre-Operative Navigation System).

18. PROPHECY Pre-Operative Navigation Guides, manufactured for the treatment of knee joints, infringe various ConforMIS patent claims, including patent claims directly related to

knee devices. PROPHECY INBONE Pre-Operative Navigation Systems, manufactured for the treatment of ankle joints, infringe various ConforMIS patent claims, including patent claims related to ankle and other joints.

II. THE PARTIES

19. Plaintiff ConforMIS, Inc. is incorporated in Delaware with its worldwide headquarters at 28 Crosby Drive, Bedford, MA 01730. ConforMIS principally manufactures its patient-specific implant systems in Burlington, Massachusetts and employs scores of people in Massachusetts.

20. Defendant Wright Medical Technology, Inc. is incorporated in Delaware with its principal place of business at 1023 Cherry Road, Memphis, TN 38117.

21. Defendant Wright Medical Group, Inc. is incorporated in Delaware with its principal place of business at 1023 Cherry Road, Memphis, TN 38117.

22. Wright Medical Technology, Inc. is, on information and belief, a wholly-owned subsidiary of Wright Medical Group, Inc.

23. Defendant MicroPort Orthopedics Inc. is incorporated in Delaware with its principal place of business at 5677 Airline Road, Arlington, TN 38002.

III. NATURE OF THE ACTION

24. On May 19, 2009, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 7,534,263 (“the ’263 Patent”), entitled “Surgical Tools Facilitating Increased Accuracy, Speed and Simplicity in Performing Joint Arthroplasty,” to Albert G. Burdulis, Jr., Wolfgang Fitz, Rene Vargas-Voracek, Philipp Lang, Daniel Steines, and Konstantinos Tsougarakis. ConforMIS is the owner by assignment of the ’263 Patent. A copy of the ’263 Patent is attached hereto as Exhibit A.

25. On November 22, 2011, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 8,062,302 (“the ’302 Patent”), entitled “Surgical Tools for Arthroplasty,” to Philipp Lang, Wolfgang Fitz, Ray Bojarski, Daniel Steines, Albert G. Burdulis, and Rene Vargas-Voracek. ConforMIS is the owner by assignment of the ’302 Patent. A copy of the ’302

Patent is attached hereto as Exhibit B.

26. On November 29, 2011, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 8,066,708 (“the ’708 Patent”), entitled “Patient Selectable Joint Arthroplasty Devices and Surgical Tools,” to Philipp Lang, Wolfgang Fitz, Raymond A. Bojarski, Daniel Steines, Albert G. Burdulis, Jr., and Rene Vargas-Voracek. ConforMIS is the owner by assignment of the ’708 Patent. A copy of the ’708 Patent is attached hereto as Exhibit C.

27. On June 11, 2013, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 8,460,304 (“the ’304 Patent”), entitled “Joint Arthroplasty Devices and Surgical Tools,” to Wolfgang Fitz, Philipp Lang, Daniel Steines, Konstantinos Tsougarakis, and Rene Vargas-Voracek. ConforMIS is the owner by assignment of the ’304 Patent. A copy of the ’304 Patent is attached hereto as Exhibit D.

28. On October 8, 2013, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 8,551,099 (“the ’099 Patent”), entitled “Surgical Tools for Arthroplasty,” to Philipp Lang, Wolfgang Fritz, Raymond A. Bojarski, Daniel Steines, Albert G. Burdulis, Jr., and Rene Vargas-Voracek. ConforMIS is the owner by assignment of the ’099 Patent. A copy of the ’099 Patent is attached hereto as Exhibit E.

29. ConforMIS is the owner of all rights, title, and interest in and to the ’263 Patent, the ’302 Patent, the ’708 Patent, the ’304 Patent, and the ’099 Patent (collectively “ConforMIS Patents”). ConforMIS possesses all rights to sue and recover for past and future infringement of the ConforMIS Patents.

30. Defendants have infringed, and continue to infringe, directly, contributorily, and/or through the inducement of others, the claimed apparatuses and methods of the ConforMIS Patents through at least the PROPHECY Pre-Operative Navigation Guides or the PROPHECY INBONE Pre-Operative Navigation System that Defendants make, use, import, export, sell, and/or offer for sale. Given the ConforMIS Patents’ groundbreaking nature and Defendants’ infringement of these patents, on information and belief, Defendants are aware of the ConforMIS

Patents, have knowledge of the infringing nature of its activities, but have nevertheless continued their infringing activities, and that infringing activity has been and continues to be willful.

31. Each of the ConforMIS Patents is valid and enforceable.

32. ConforMIS has been damaged as a result of Defendants' infringing conduct and Defendants are liable to ConforMIS in an amount that adequately compensates ConforMIS for their infringement, together with interest and costs as fixed by this Court. Defendants' acts have also caused, and unless restrained and enjoined, will continue to cause, irreparable injury and damage to ConforMIS.

IV. JURISDICTION AND VENUE

33. This Court has subject-matter jurisdiction over ConforMIS's claims asserted herein pursuant to 28 U.S.C. §§ 1331 and 1338(a) because those claims arise under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*

34. This Court has personal jurisdiction over Defendants, who have conducted and do conduct business within the State of Massachusetts. Defendants, directly or through intermediaries (including distributors, retailers, and others), ship, distribute, offer for sale, sell, and advertise products, including the PROPHECY line of pre-operative navigation guides, such as PROPHECY Pre-Operative Navigation Guides for knee and PROPHECY INBONE Pre-Operative Navigation System for ankle, that infringe the patent claims involved in this action in the United States and the District of Massachusetts. Defendants have purposefully and voluntarily placed one or more of their PROPHECY pre-operative navigation guides or systems into the stream of commerce with the expectation that they would be purchased by customers in the District of Massachusetts. On information and belief, Defendants have continuous and systematic contacts with the State of Massachusetts.

35. Defendants sell and offer for sale their PROPHECY line of pre-operative navigation guides and systems in the District of Massachusetts, and have a significant commercial presence in the District of Massachusetts.

36. Venue is proper in the District of Massachusetts pursuant to 28 U.S.C. § 1391 and

28 U.S.C. § 1400(b).

V. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

(Infringement of the '263 Patent)

37. ConforMIS incorporates by reference Paragraphs 1 through 36, inclusive, as though fully set forth in this Paragraph.

38. Defendants have been and are now directly infringing the '263 Patent by making, using, selling, offering for sale, importing into the United States, and/or exporting at least the PROPHECY line of products that practice or embody one or more claims of the '263 Patent, including without limitation claim 1. Defendants also have been and are now contributing to and/or inducing others, such as doctors in the District of Massachusetts, to directly infringe one or more claims of the '263 Patent. Defendants' actions violate one or more provisions of 35 U.S.C. § 271 (a), (b), (c), (f), and (g).

39. Defendants' infringement of the '263 Patent is willful. Defendants were aware of the '263 Patent and their infringement of that patent no later than October 8, 2013.

40. Defendants' acts have caused, and unless restrained and enjoined, will continue to cause, irreparable injury and damage to ConforMIS for which there is no adequate remedy at law. Unless enjoined by this Court, Defendants will continue to infringe the '263 Patent.

SECOND CLAIM FOR RELIEF

(Infringement of the '302 Patent)

41. ConforMIS incorporates by reference Paragraphs 1 through 36, inclusive, as though fully set forth in this Paragraph.

42. Defendants have been and are now directly infringing the '302 Patent by making, using, selling, offering for sale, importing into the United States, and/or exporting at least the PROPHECY line of products that practice or embody one or more claims of the '302 Patent, including without limitation claim 1. Defendants also have been and are now contributing to and/or inducing others, such as doctors in the District of Massachusetts, to directly infringe one

or more claims of the '302 Patent. Defendants' actions violate one or more provisions of 35 U.S.C. § 271 (a), (b), (c), (f), and (g).

43. Defendants' infringement of the '302 Patent is willful. Defendants were aware of the '302 Patent and their infringement of that patent no later than October 8, 2013.

44. Defendants' acts have caused, and unless restrained and enjoined, will continue to cause, irreparable injury and damage to ConforMIS for which there is no adequate remedy at law. Unless enjoined by this Court, Defendants will continue to infringe the '302 Patent.

THIRD CLAIM FOR RELIEF

(Infringement of the '708 Patent)

45. ConforMIS incorporates by reference Paragraphs 1 through 36, inclusive, as though fully set forth in this Paragraph.

46. Defendants have been and are now directly infringing the '708 Patent by making, using, selling, offering for sale, importing into the United States, and/or exporting at least the PROPHECY line of products that practice or embody one or more claims of the '708 Patent, including without limitation claim 23. Defendants also have been and are now contributing to and/or inducing others, such as doctors in the District of Massachusetts, to directly infringe one or more claims of the '708 Patent. Defendants' actions violate one or more provisions of 35 U.S.C. § 271 (a), (b), (c), (f), and (g).

47. Defendants' infringement of the '708 Patent is willful. Defendants were aware of the '708 Patent and their infringement of that patent no later than October 8, 2013.

48. Defendants' acts have caused, and unless restrained and enjoined, will continue to cause, irreparable injury and damage to ConforMIS for which there is no adequate remedy at law. Unless enjoined by this Court, Defendants will continue to infringe the '708 Patent.

FOURTH CLAIM FOR RELIEF

(Infringement of the '304 Patent)

49. ConforMIS incorporates by reference Paragraphs 1 through 36, inclusive, as though fully set forth in this Paragraph.

50. Defendants have been and are now directly infringing the '304 Patent by making, using, selling, offering for sale, importing into the United States, and/or exporting at least the PROPHECY line of products that practice or embody one or more claims of the '304 Patent, including without limitation claim 1. Defendants also have been and are now contributing to and/or inducing others, such as doctors in the District of Massachusetts, to directly infringe one or more claims of the '304 Patent. Defendants' actions violate one or more provisions of 35 U.S.C. § 271 (a), (b), (c), (f), and (g).

51. Defendants' infringement of the '304 Patent is willful. Defendants were aware of the '479 Patent and their infringement of that patent no later than October 8, 2013.

52. Defendants' acts have caused, and unless restrained and enjoined, will continue to cause, irreparable injury and damage to ConforMIS for which there is no adequate remedy at law. Unless enjoined by this Court, Defendants will continue to infringe the '304 Patent.

FIFTH CLAIM FOR RELIEF

(Infringement of the '099 Patent)

53. ConforMIS incorporates by reference Paragraphs 1 through 36, inclusive, as though fully set forth in this Paragraph.

54. Surgeons, nurses, and other medical providers who perform procedures using the Prophecy Pre-Operation Navigation Guides infringe one or more claims of the '099 patent, including without limitation claim 1. Defendants have had knowledge of the '099 patent and ConforMIS's contention that use of the Prophecy Pre-Operation Navigation Guides infringes since no later than November 6, 2013. Despite that knowledge, Defendants have, on information and belief, specifically intended that surgeons, nurses, and other medical providers who perform procedures using the Prophecy Pre-Operation Navigation Guides infringe. Defendants thus have been and are now contributing to and/or inducing others, including those in the District of Massachusetts, to infringe directly one or more claims of the '099 Patent. Defendants' actions violate one or more provisions of 35 U.S.C. § 271 (a), (b), (c), (f), and (g).

55. Defendants' infringement of the '099 Patent is willful. Defendants were aware of

the '099 Patent and their infringement of that patent no later than November 6, 2013.

56. Defendants' acts have caused, and unless restrained and enjoined, will continue to cause, irreparable injury and damage to ConforMIS for which there is no adequate remedy at law. Unless enjoined by this Court, Defendants will continue to infringe the '099 Patent.

VI. PRAYER FOR RELIEF

WHEREFORE, ConforMIS requests entry of judgment in its favor and against Defendants as follows:

57. Entry of judgment holding Defendants liable for infringement of the ConforMIS Patents;

58. An order permanently enjoining each Defendant, its officers, agents, servants, employees, attorneys and affiliated companies, its assigns and successors in interest, and those persons in active concert or participation with it, from continued acts of infringement of the ConforMIS Patents;

59. An order awarding ConforMIS statutory damages and damages according to proof resulting from Defendants' infringement of the ConforMIS Patents, together with prejudgment and post-judgment interest;

60. Trebling of damages and pre-judgment interest under 35 U.S.C. § 284 in view of the willful and deliberate nature of Defendants' infringement of the ConforMIS Patents;

61. An order awarding ConforMIS its costs and attorneys' fees under 35 U.S.C. § 285; and

62. Any and all other legal and/or equitable relief as may be available under law and which the court may deem proper.

VII. JURY DEMAND

ConforMIS demands a jury trial for all issues so triable.

Dated: February 19, 2014

Respectfully submitted,

ConforMIS, Inc.,
By its attorneys

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CERTIFICATE OF SERVICE

I, Abhishek Bajoria, hereby certify that on February 19, 2014, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system through which all participating parties are deemed served.

/s/ Abhishek Bajoria
Abhishek Bajoria