

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

CONFORMIS, INC.,

Plaintiff,

v.

SMITH & NEPHEW, INC.,

Defendant.

CIVIL ACTION NO.

**COMPLAINT FOR PATENT  
INFRINGEMENT**

**DEMAND FOR JURY TRIAL**

Plaintiff, ConforMIS, Inc. (“ConforMIS”), files this Complaint for Patent Infringement against Defendant, Smith & Nephew, Inc. (“Smith & Nephew”). 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’ Industry-Leading Intellectual Property*

1. ConforMIS is the world’s leading designer, developer, and manufacturer of patient-specific knee implants as well as the patient-specific 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 and tools fit the patient rather than forcing the patient to fit the implant and tools.

2. For decades before ConforMIS’ 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 and tools, the implant and tools should be designed and developed specifically for the patient. This not only produces a better-seated 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<sup>®</sup> 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' iJig<sup>®</sup> 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 is tailored to the patient, preserves more of the patient's joint, and 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' patient-specific knee implants and customized tools

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

8. ConforMIS' novel idea to fit the implant to the patient has received consistent industry acclaim. ConforMIS' iTotal<sup>®</sup> 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' iUni<sup>®</sup> and iDuo<sup>®</sup> knee-resurfacing implants won the gold medal among implant and tissue-replacement products. In 2012, ConforMIS' iTotal CR Knee Replacement System won the silver medal in the same category.

9. Patent authorities worldwide have recognized that ConforMIS' iFit technology, its patient-specific implants, and its iJig patient-specific instruments are worthy of patent protection, and have granted ConforMIS over 195 patents on its technologies. These patents, and ConforMIS' many additional pending 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.

*Smith & Nephew's Willful Infringement of ConforMIS' Intellectual Property*

10. Smith & Nephew has developed products that utilize ConforMIS' innovations in the form of patient-specific cutting guides—Visionaire Cutting Guides—that are used with standard, off-the-shelf implants. Smith & Nephew has mispromoted, and upon information and belief has induced others to mispromote, total-knee arthroplasty procedures using its Visionaire Cutting Guides as being "custom fit" total-knee arthroplasty procedures, even though the end result uses a standard, off-the-shelf implant not customized for the patient. Upon information and belief, this mispromotion has harmed ConforMIS by, on information and belief, diminishing its potential sales base and market share, and also diluting the strength of its patient-specific

offering in the minds of the consuming public.

11. Smith & Nephew's Visionaire Cutting Guides are patient-specific instruments for use with certain of their standard, off-the-shelf implants, including at least the Journey II, Legion, and Genesis II. Smith & Nephew describes its Visionaire Cutting Guides as "patient-matched technology" that "uses the patient's own MRI and full leg X-Ray to design cutting blocks specific to that patient." Visionaire Cutting Guides, <http://www.smith-nephew.com/professional/products/all-products/visionaire-technology/visionaire/>, last visited Feb. 25, 2016. Through an eight-step process, Smith & Nephew contends that use of Visionaire Cutting Guides eliminates 22 surgical steps. *Id.* Moreover, because "[t]he inner shape of the [Visionaire] cutting guide matches the outer shape of [the] patient's distal femur and proximal tibia," the resulting "hand-in-glove fit allows surgeons to make the precise bone cuts needed to position the knee implant in the optimal alignment." *Id.*

12. Defendant's Visionaire Cutting Guides infringe fundamental aspects of ConforMIS' patent portfolio, including claims directed to:

- patient-specific resection-guide instruments and implant systems;
- patient-specific pin-first instruments and implant systems;
- patient-specific instrument systems that register to bone, cartilage, or both;
- patient-specific instruments with predetermined rotation, alignment, and/or orientation;
- patient-specific instruments derived from multiple image modalities; and
- patient-specific technology that registers to osteophytes for improved fit.

13. As explained further below, through multiple meetings and correspondence with ConforMIS, Smith & Nephew has willfully infringed and continues willfully to infringe the ConforMIS Patents (as defined below).

## **II. THE PARTIES**

14. 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 Wilmington, Massachusetts and employs hundreds of people in Massachusetts.

15. Defendant, Smith & Nephew, Inc., is incorporated in Delaware with its principal place of business at 1450 Brooks Road, Memphis, Tennessee 38116. Smith & Nephew has offices in Mansfield and Andover, Massachusetts (collectively “Massachusetts Offices”). On information and belief, work performed in the Massachusetts Offices is related to the sale, offer for sale, use, manufacture, design, development, or marketing of Visionaire Cutting Guides, Journey II, Legion, and/or Genesis II.

### **III. NATURE OF THE ACTION**

16. 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.

17. On July 19, 2011, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 7,981,158 (“the ’158 Patent”), entitled “Patient Selectable Joint Arthroplasty Devices and Surgical Tools,” to Philipp Lang, Wolfgang Fitz, Raymond A. Bojarski, and Daniel Steines. ConforMIS is the owner by assignment of the ’158 Patent. A copy of the ’158 Patent is attached hereto as Exhibit B.

18. 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 C.

19. On February 19, 2013, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 8,377,129 (“the ’129 Patent”), entitled “Joint Arthroplasty Devices and

Surgical Tools,” to Philipp Lang, Wolfgang Fitz, Daniel Steines, Konstantinos Tsougarakis, and Rene Vargas-Voracek. ConforMIS is the owner by assignment of the ’129 Patent. A copy of the ’129 Patent is attached hereto as Exhibit D.

20. On October 8, 2013, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 8,551,169 (“the ’169 Patent”), entitled “Joint Arthroplasty Devices and Surgical Tools,” to Philipp Lang, Wolfgang Fitz, and Daniel Steines. ConforMIS is the owner by assignment of the ’169 Patent. A copy of the ’169 Patent is attached hereto as Exhibit E.

21. On February 25, 2014, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 8,657,827 (“the ’827 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 ’827 Patent. A copy of the ’827 Patent is attached hereto as Exhibit F.

22. On June 16, 2015, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 9,055,953 (“the ’953 Patent”), entitled “Methods and Compositions for Articular Repair,” to Philipp Lang and Daniel Steines. ConforMIS is the owner by assignment of the ’953 Patent. A copy of the ’953 Patent is attached hereto as Exhibit G.

23. On December 22, 2015, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 9,216,025 (“the ’025 Patent”), entitled “Joint Arthroplasty Devices and Surgical Tools,” to Philipp Lang, Wolfgang Fitz, Daniel Steines, Konstantinos Tsougarakis, and Rene Vargas-Voracek. ConforMIS is the owner by assignment of the ’025 Patent. A copy of the ’025 Patent is attached hereto as Exhibit H.

24. ConforMIS is the owner of all rights, title, and interest in and to the ’263 Patent, the ’158 Patent, the ’302 Patent, the ’129 Patent, the ’169 Patent, the ’827 Patent, the ’953 Patent, and the ’025 Patent (collectively “ConforMIS Patents”). ConforMIS possesses all rights to sue and recover for past and future infringement of the ConforMIS Patents.

25. Smith & Nephew has directly infringed, and continues to infringe directly, the claimed apparatuses and methods of the ConforMIS Patents through at least the manufacture,

use, import, export, sale, and/or offer for sale of Visionaire Cutting Guides in conjunction with its off-the-shelf implants, including Journey II, Legion, and/or Genesis II.

26. Each of the ConforMIS Patents is valid and enforceable. ConforMIS has, at all relevant times, complied with 35 U.S.C. § 287(a), including by marking embodying products or packaging as appropriate.

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

28. Smith & Nephew has actual knowledge of ConforMIS' ground-breaking intellectual property and is therefore, on information and belief, willfully infringing the ConforMIS Patents. In and throughout 2011, ConforMIS communicated with Smith & Nephew and presented specific information about ConforMIS' patent portfolio and the need for Smith & Nephew to license ConforMIS' patents. Smith & Nephew did not take a license and communications ceased. In September 2013, ConforMIS sued two other competitors for infringing its patents. That litigation concluded in April 2015 with both competitors entering into license agreements with ConforMIS. Thereafter, in 2015, ConforMIS and Smith & Nephew again discussed a potential license to ConforMIS' patents. Smith & Nephew, however, has not communicated with ConforMIS about a license for an extended period, forcing ConforMIS to file this action.

29. In the face of these repeated overtures by ConforMIS, Smith & Nephew's continued manufacture, use, sale, offer for sale, importation, and/or export of Visionaire Cutting Guides in conjunction with its off-the-shelf implants, including Journey II, Legion, and/or Genesis II, despite an objectively high likelihood of infringement of the ConforMIS Patents, was objectively unreasonable. Smith & Nephew also knew or should have known that it was infringing the ConforMIS Patents.

#### **IV. JURISDICTION AND VENUE**

30. This Court has subject-matter jurisdiction over ConforMIS' 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.*

31. This Court has personal jurisdiction over Smith & Nephew, which has conducted and does conduct business within the State of Massachusetts. Smith & Nephew, directly or through intermediaries (including distributors, retailers, and others), ships, distributes, offers for sale, sells, and advertises products, including the Visionaire Cutting Guides and the Journey II, Legion, and Genesis II implants, that infringe the ConforMIS Patents. Smith & Nephew has purposefully and voluntarily placed one or more of these infringing products into the stream of commerce with the expectation that they would be purchased by customers in the District of Massachusetts. On information and belief, Smith & Nephew has continuous and systematic contacts with the State of Massachusetts, and its Massachusetts Offices constitute a regular and established place of business in this District.

32. 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)**

33. ConforMIS incorporates by reference Paragraphs 1 through 32, inclusive, as though fully set forth in this Paragraph.

34. Smith & Nephew has been and is now directly infringing the '263 Patent by making, using, selling, offering for sale, importing into the United States, and/or exporting at least the Visionaire Cutting Guides and Journey II, Legion, and Genesis II implants that practice or embody one or more claims of the '263 Patent, including without limitation claims 1-2, 6-9, 11-12, 15-16, 18, 20, 22-26, 28, 31-34, 36-39, 44 and 49. Defendant's actions violate one or more provisions of 35 U.S.C. § 271 (a), (f), and (g).



35. On information and belief, as detailed above, Smith & Nephew's infringement of the '263 Patent is willful.

36. Smith & Nephew's 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, Smith & Nephew will continue to infringe the '263 Patent.

**SECOND CLAIM FOR RELIEF**

**(Infringement of the '158 Patent)**

37. ConforMIS incorporates by reference Paragraphs 1 through 32, inclusive, as though fully set forth in this Paragraph.

38. Smith & Nephew has been and is now directly infringing the '158 Patent by making, using, selling, offering for sale, importing into the United States, and/or exporting at least the Visionaire Cutting Guides and Journey II, Legion, and Genesis II implants that practice or embody one or more claims of the '158 Patent, including without limitation claims 1-6, 8-24, 26-28, 30, 31, 33, 34, 38-56, 58, 59, 61, 62, 66-72, and 81. Defendant's actions violate one or more provisions of 35 U.S.C. § 271 (a), (f), and (g).

39. On information and belief, as detailed above, Smith & Nephew's infringement of the '158 Patent is willful.

40. Smith & Nephew's 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, Smith & Nephew will continue to infringe the '158 Patent.

**THIRD CLAIM FOR RELIEF**

**(Infringement of the '302 Patent)**

41. ConforMIS incorporates by reference Paragraphs 1 through 32, inclusive, as though fully set forth in this Paragraph.

42. Smith & Nephew has been and is now directly infringing the '302 Patent by

making, using, selling, offering for sale, importing into the United States, and/or exporting at least the Visionaire Cutting Guides and Journey II, Legion, and Genesis II implants that practice or embody one or more claims of the '302 Patent, including without limitation claims 1, 3, 5-8, 11-19, 28-32, 34-38, 47, 95-96, 98, 100, 102-103, 105-107, 110-111, 114, 116, 117, 119, 121, 123, and 125. Defendant's actions violate one or more provisions of 35 U.S.C. § 271 (a), (f), and (g).

43. On information and belief, as detailed above, Smith & Nephew's infringement of the '302 Patent is willful.

44. Smith & Nephew's 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, Smith & Nephew will continue to infringe the '302 Patent.

#### **FOURTH CLAIM FOR RELIEF**

##### **(Infringement of the '129 Patent)**

45. ConforMIS incorporates by reference Paragraphs 1 through 32, inclusive, as though fully set forth in this Paragraph.

46. Smith & Nephew has been and is now directly infringing the '129 Patent by making, using, selling, offering for sale, importing into the United States, and/or exporting at least the Visionaire Cutting Guides and Journey II, Legion, and Genesis II implants that practice or embody one or more claims of the '129 Patent, including without limitation claims 1-2, 4-24, 26-45, 47-63, and 65-83. Defendant's actions violate one or more provisions of 35 U.S.C. § 271 (a), (f), and (g).

47. On information and belief, as detailed above, Smith & Nephew's infringement of the '129 Patent is willful.

48. Smith & Nephew's 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, Smith & Nephew will continue to infringe the

'129 Patent.

**FIFTH CLAIM FOR RELIEF**

**(Infringement of the '169 Patent)**

49. ConforMIS incorporates by reference Paragraphs 1 through 32, inclusive, as though fully set forth in this Paragraph.

50. Smith & Nephew has been and is now directly infringing the '169 Patent by making, using, selling, offering for sale, importing into the United States, and/or exporting at least the Visionaire Cutting Guides and Journey II, Legion, and Genesis II implants that practice or embody one or more claims of the '169 Patent, including without limitation claims 29 and 30. Defendant's actions violate one or more provisions of 35 U.S.C. § 271 (a), (f), and (g).

51. On information and belief, as detailed above, Smith & Nephew's infringement of the '169 Patent is willful.

52. Smith & Nephew's 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, Smith & Nephew will continue to infringe the '169 Patent.

**SIXTH CLAIM FOR RELIEF**

**(Infringement of the '827 Patent)**

53. ConforMIS incorporates by reference Paragraphs 1 through 32, inclusive, as though fully set forth in this Paragraph.

54. Smith & Nephew has been and is now directly infringing the '827 Patent by making, using, selling, offering for sale, importing into the United States, and/or exporting at least the Visionaire Cutting Guides and Journey II, Legion, and Genesis II implants that practice or embody one or more claims of the '827 Patent, including without limitation claims 1-7, 11-22, 32, 33, 38, 39, 41-43, and 50-64. Defendant's actions violate one or more provisions of 35 U.S.C. § 271 (a), (f), and (g).

55. On information and belief, as detailed above, Smith & Nephew's infringement of

the '827 Patent is willful.

56. Smith & Nephew's 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, Smith & Nephew will continue to infringe the '827 Patent.

**SEVENTH CLAIM FOR RELIEF**

**(Infringement of the '953 Patent)**

57. ConforMIS incorporates by reference Paragraphs 1 through 32, inclusive, as though fully set forth in this Paragraph.

58. Smith & Nephew has been and is now directly infringing the '953 Patent by making, using, selling, offering for sale, importing into the United States, and/or exporting at least the Visionaire Cutting Guides and Journey II, Legion, and Genesis II implants that practice or embody one or more claims of the '953 Patent, including without limitation claims 1-8, 10-16, 19, 21-28, 30-38, and 40-60. Defendant's actions violate one or more provisions of 35 U.S.C. § 271 (a), (f), and (g).

59. On information and belief, as detailed above, Smith & Nephew's infringement of the '953 Patent is willful.

60. Smith & Nephew's 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, Smith & Nephew will continue to infringe the '953 Patent.

**EIGHTH CLAIM FOR RELIEF**

**(Infringement of the '025 Patent)**

61. ConforMIS incorporates by reference Paragraphs 1 through 32, inclusive, as though fully set forth in this Paragraph.

62. Smith & Nephew has been and is now directly infringing the '025 Patent by making, using, selling, offering for sale, importing into the United States, and/or exporting at

least the Visionaire Cutting Guides and Journey II, Legion, and Genesis II implants that practice or embody one or more claims of the '025 Patent, including without limitation claims 1, 2, 5-6, 8-13, 15, 16, 19, and 20. Defendant's actions violate one or more provisions of 35 U.S.C. § 271 (a), (f), and (g).

63. On information and belief, as detailed above, Smith & Nephew's infringement of the '025 Patent is willful.

64. Smith & Nephew's 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, Smith & Nephew will continue to infringe the '025 Patent.

## **VI. PRAYER FOR RELIEF**

WHEREFORE, ConforMIS requests entry of judgment in its favor and against Smith & Nephew as follows:

1. Entry of judgment holding Smith & Nephew liable for infringement of the ConforMIS Patents;
2. An order permanently enjoining Smith & Nephew, 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;
3. An order awarding ConforMIS statutory damages and damages according to proof resulting from Smith & Nephew's infringement of the ConforMIS Patents, together with pre-judgment and post-judgment interest;
4. Trebling of damages and pre-judgment interest under 35 U.S.C. § 284 in view of the willful and deliberate nature of Smith & Nephew's infringement of the ConforMIS Patents;
5. An order awarding ConforMIS its costs and attorneys' fees under 35 U.S.C. § 285; and
6. Any and all other legal and/or equitable relief as may be available under law and

which the Court deems proper.

## VII. JURY DEMAND

ConforMIS demands a jury trial for all issues so triable.

Dated: February 29, 2016

Respectfully submitted,

**ConforMIS, Inc.,**  
*By its attorneys*

By: /s/ Steven M. Bauer

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