IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

CONFORMIS, INC.,))
Plaintiff,	,))
v.) Civil Action No
ZIMMER BIOMET HOLDINGS, INC. and ZIMMER, INC.,))) JURY TRIAL DEMANDED
Defendants.))

COMPLAINT FOR PATENT INFRINGEMENT

For its Complaint against Zimmer Biomet Holdings, Inc. and Zimmer, Inc. (together, "Zimmer Biomet" or "Defendants"), Plaintiff Conformis, Inc. ("Conformis" or "Plaintiff"), by its attorneys, alleges as follows:

NATURE OF THE ACTION

- 1. This is a patent infringement action.
- 2. Conformis brings this action to seek damages and other relief arising from the infringement by Zimmer Biomet of (i) U.S. Patent No. 8,377,129 ("the '129 Patent," attached hereto as Exhibit A), entitled "Joint Arthroplasty Devices and Surgical Tools," (ii) U.S. Patent No. 8,460,304 ("the '304 Patent," attached hereto as Exhibit B), entitled "Joint Arthroplasty Devices and Surgical Tools," (iii) U.S. Patent No. 9,186,161 ("the '161 Patent," attached hereto as Exhibit C), entitled "Surgical Tools for Arthroplasty," and (iv) U.S. Patent No. 9,295,482 ("the '482 Patent," attached hereto as Exhibit D), entitled "Patient Selectable Joint Arthroplasty Devices and Surgical Tools" (collectively, "the Patents-In-Suit").

PARTIES

- 1. Plaintiff Conformis, Inc. is a Delaware corporation with its worldwide headquarters at 600 Technology Park Drive, Billerica, Massachusetts 01821.
 - 2. Conformis is the assignee and owner of the Patents-In-Suit.
- 3. Upon information and belief, Defendant Zimmer Biomet Holdings, Inc. is a Delaware corporation with its principal place of business at 345 East Main Street, Warsaw, Indiana 46580.
- 4. Upon information and belief, Defendant Zimmer, Inc. is a Delaware corporation with its principal place of business at 345 East Main Street, Warsaw, Indiana 46580.

JURISDICTION AND VENUE

- 5. Conformis' patent infringement claims arise under the Patent Laws of the United States, Title 35, of the United States Code. Accordingly, this Court has subject matter jurisdiction over such claims pursuant to 28 U.S.C. §§ 1331 (federal question) and 1338 (action arising under an Act of Congress relating to patents).
- 6. This Court has personal jurisdiction over Defendants, at least because Defendants are at home in the State of Delaware, where they are incorporated and have a registered agent for service of process. In addition, upon information and belief, Defendants regularly do or solicit business in the State of Delaware and have committed one or more acts of patent infringement complained of herein in the District of Delaware.
- 7. Venue in this Court is proper under the provisions of 28 U.S.C. §§ 1391(b) and (c) and 28 U.S.C. § 1400. Defendants are incorporated in Delaware and thus reside in this State.

FACTUAL BACKGROUND

A. <u>Background</u>

- 8. Conformis is the world's leading designer, developer, and manufacturer of patient-specific instrument systems required to best fit implants into a specific patient's body. Conformis also designs and manufactures patient-specific knee and hip replacement implant systems. 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.
- 9. For decades before Conformis' innovation, surgeons have been implanting medical devices using (and many are still using) standard instrument systems that have not been designed with reference to the anatomy of individual patients. As a result of this imprecise approach, after surgery, patients commonly suffer loss of movement and function, instability, and lingering pain.
- 10. Conformis recognized that the conventional process of joint repair was backwards: rather than fitting the patient to the tools, the tools should be designed and developed specifically for the patient, as this produces a better-seated implant.
- 11. Conformis therefore set out to develop patient-specific instrument systems, which precisely place an implant, reduce surgical time and trauma, and create a reproducible surgical technique. Conformis' patient-specific instrument systems eliminate many of the traditional instruments associated with conventional surgery while concurrently simplifying and improving surgical technique.

B. <u>Conformis' Patents</u>

12. Conformis has made significant investments in the research, development, and testing of patient-specific instrument systems for joint replacement surgery.

- 13. To protect those investments, Conformis applied for and obtained a number of patents, including the Patents-In-Suit.
- 14. Patent authorities worldwide have recognized that Conformis' patient-specific instrument systems are worthy of patent protection, and have granted Conformis over 200 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.
- 15. The '129 Patent was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on February 19, 2013, to Wolfgang Fitz, Philipp Lang, Daniel Steines, Konstantinos Tsougarakis and Rene Vargas-Voracek, after fair and full examination, for "Joint Arthroplasty Devices and Surgical Tools." The '129 Patent is assigned to Conformis.
- 16. The '304 Patent was duly and legally issued by the USPTO on June 11, 2013, to Wolfgang Fitz, Philipp Lang, Daniel Steines, Konstantinos Tsougarakis and Rene Vargas-Voracek, after full and fair examination, for "Joint Arthroplasty Devices and Surgical Tools."

 The '304 Patent is assigned to Conformis.
- 17. The '161 Patent was duly and legally issued by the USPTO on November 17, 2015, to Philipp Lang, Wolfgang Fitz, Ray Bojarski, Daniel Steines, Albert G. Burdulis, Jr., and Rene Vargas-Voracek, after fair and full examination, for "Surgical Tools for Arthroplasty." The '161 Patent is assigned to Conformis.

- 18. The '482 Patent was duly and legally issued by the USPTO on March 29, 2016, to Wolfgang Fitz, Philipp Lang, Raymond A. Bojarski and Daniel Steines, after fair and full examination, for "Patient Selectable Joint Arthroplasty Devices and Surgical Tools." The '482 Patent is assigned to Conformis.
- 19. Conformis is the owner of all rights, title, and interest in and to the Patents-In-Suit. Conformis possesses all rights to sue and recover for past and future infringement of the Patents-In-Suit.

C. Zimmer Biomet's Infringing Activities

- 20. Zimmer Biomet offers a line of patient-specific or personalized surgical instruments that are based on images of the patient's knee for knee replacement surgery, including at least Zimmer Biomet's SignatureTM Personalized Patient Care Vanguard[®] Complete Knee System ("Vanguard[®]"), Persona[®] The Personalized Knee System ("Persona[®]"), NexGen[®] Complete Knee Solution ("NexGen[®]") and Gender Solutions[®] Natural-Knee[®] Flex System ("Gender Solutions[®]").
- 21. Zimmer Biomet also offers a line of patient-specific or personalized surgical instruments that are based on images of the patient's shoulder for shoulder arthroplasty surgery, including at least Zimmer[®] PSI Shoulder for Trabecular MetalTM Reverse Glenoid and SignatureTM Personalized Patient Care for Comprehensive Total and Reverse Shoulder Systems.
- 22. Zimmer Biomet also offers patient-specific surgical instruments that are based on preoperative patient imaging scans for use during hip replacement surgery, including at least the Signature Personalized Patient Care System Acetabular Guide System.
- 23. Zimmer Biomet's patient-specific and personalized instruments compete with Conformis' innovative patient-specific products for joint surgery.

- 24. Zimmer Biomet is infringing all of the Patents-In-Suit by making, using, providing, offering to sell, and selling (directly or through intermediaries) at least the Vanguard[®], Persona[®], NexGen[®] and Gender Solutions[®] products, in this District and elsewhere in the United States abroad (collectively, the "Accused Knee Products").
- 25. Zimmer Biomet is infringing at least the '304 Patent and '161 Patent by making, using, providing, offering to sell, and selling (directly or through intermediaries) at least the Zimmer[®] PSI Shoulder for Trabecular MetalTM Reverse Glenoid and SignatureTM Personalized Patient Care for Comprehensive Total and Reverse Shoulder Systems (collectively, the "Accused Shoulder Products").
- 26. Zimmer Biomet is infringing at least the '304 Patent, '161 Patent and '482 Patent by making, using, providing, offering to sell, and selling (directly or through intermediaries) at least the Signature Personalized Patient Care System Acetabular Guide System (the "Accused Hip Product").

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 8,377,129

- 27. Conformis repeats and realleges each and every allegation set forth in the preceding paragraphs as if fully set forth herein.
- 28. Zimmer Biomet is presently making, using, offering for sale, and/or selling a patient-specific system for knee surgery that directly infringes one or more claims of the '129 Patent, literally or under the doctrine of equivalents.
- 29. The Accused Knee Products practice at least one claim of the '129 Patent. For example, claim 1 recites:

A patient-specific instrument system for surgery of a diseased or damaged knee joint of a patient, the instrument system comprising:

a patient-specific surface for engaging at least a portion of a substantially uncut joint surface of the diseased or damaged knee joint of the patient,

the patient-specific surface including cartilage information derived from image data of the diseased or damaged knee joint of the patient; and a guide for directing a surgical instrument,

wherein the guide has a predetermined position relative to the patient-specific surface and relative to from at least one of an anatomical axis and a biomechanical axis associated with said knee joint;

wherein the guide defines a drilling path through at least a portion of the knee joint,

the drilling path having a position based on a predetermined internal rotation angle or external rotation angle of an orthopedic implant.

30. As an exemplar product, Zimmer Biomet's Persona® system, is marketed as "THE PERSONALIZED KNEE SYSTEM" and is a product in Zimmer Biomet's line of "Patient Specific Instruments." Ex. E at Cover. Claim 1 of the '129 Patent recites "[a] patient-specific instrument system for surgery of a diseased or damaged knee joint of a patient," comprising "a patient-specific surface for engaging at least a portion of a substantially uncut joint surface of the" knee joint, which includes "cartilage information derived from image data" of the knee joint and also includes "a guide for directing a surgical instrument." Ex. A at Claim 1. The Persona® system

is indicated as an orthopedic instrument system to assist in the positioning of knee replacement components. It involves surgical planning software used pre-operatively to plan the surgical placement of the components on the basis of provided patient radiological images with identifiable placement anatomical landmarks, and surgical instrument components that include patient specific or customized guides fabricated on the basis of the surgical plan to precisely reference the placement of the implant components intra-operatively per the surgical plan.

Ex. F at INTRO.1. Additionally, the operator is instructed "not [to] remove any . . . cartilage from the femur" or tibia when using the instrument. *Id.* at 2, 9.

- 31. Claim 1 of the '129 Patent also recites that "the guide has a predetermined position relative to the patient-specific surface and relative to . . . an anatomical axis [or] a biomechanical axis associated" with the knee joint and "defines a drilling path through at least a portion of the knee joint . . . based on a predetermined internal rotation angle or external rotation angle of an orthopedic implant." Ex. A at Claim 1. The Persona® system consists of an "optional Tibial Rotational Guide . . . to set the axial rotation of the tibial component." Ex. F at INTRO.1. During the surgical procedure, the instrument guides are placed on the femur and tibia "and have pin holes to allow the surgeon to precisely insert reference pins . . . that set the position of the cut guides." *Id*.
 - 32. The other Accused Knee Products infringe the '129 Patent in a similar manner.
- Zimmer Biomet's infringing activities violate one or more subsections of 35U.S.C. § 271.
- 34. Zimmer Biomet has also actively induced, and continues to actively induce, others to infringe at least claim 1 of the '129 Patent in violation of 35 U.S.C. § 271(b) by causing, instructing, urging, encouraging and/or aiding others to directly infringe at least claim 1 of the '129 Patent by making, using, offering to sell, selling, and/or importing in and into the United States the Accused Knee Products, as detailed above. Zimmer Biomet's active inducement has included and/or will include, for example and without limitation, marketing, selling, and offering to sell the Accused Knee Products, providing instructions on how to use the Accused Knee Products, selling instrumentation or devices for use with the Accused Knee Products, and promoting the use of the Accused Knee Products. For example, Zimmer Biomet has encouraged and/or will encourage customers including scientists, researchers, and health care professionals to use the Accused Knee Products by means of marketing materials and videos.

Zimmer Biomet also has instructed and/or will instruct customers on how to use the Accused Knee Products by means of product manuals.

- 35. Zimmer Biomet has also contributed, and continues to contribute, to its customers' direct infringement of the '129 Patent in violation of 35 U.S.C. § 271(c) by providing products that are used in the infringing systems and that are not suitable for any substantial non-infringing use.
- 36. Upon information and belief, at least as early as the filing of the Complaint, Zimmer Biomet knows and/or is willfully blind to the fact that Zimmer Biomet's actions have infringed and/or will infringe and have induced and contributed and/or will induce and contribute to infringement of the '129 Patent with the knowledge and intent that one or more claims of the '129 Patent be infringed.
- 37. Zimmer Biomet has had notice of the '129 Patent at least as early as the filing of this Complaint. On information and belief, Zimmer Biomet's direct and indirect infringement of the '129 Patent has been willful.
- 38. Conformis has suffered economic harm as a result of Zimmer Biomet's infringing activities in an amount to be proven at trial, but in no case less than a reasonably royalty.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 8,460,304

- 39. Conformis repeats and realleges each and every allegation set forth in the preceding paragraphs as if fully set forth herein.
- 40. Zimmer Biomet is presently making, using, offering for sale, and/or selling patient-specific systems for knee surgery, hip surgery, and shoulder surgery that directly infringes one or more claims of the '304 Patent, literally or under the doctrine of equivalents.
- 41. Zimmer Biomet's systems practice at least one claim of the '304 Patent. For example, claim 1 recites:

A surgical instrument for use in surgically repairing a joint of a patient, the surgical instrument comprising:

a mold having an internal surface that includes joint information derived from image data of the joint of the patient; and

two or more guide holes, each configured to guide a surgical pin,

wherein at least one of the two or more guide holes has a position based on anatomical information of the joint of the patient to facilitate the placement of an articular repair system when the internal surface of the mold is aligned with the joint of the patient,

wherein the articular repair system has a predetermined rotation angle and

wherein the position is based on the predetermined rotation angle.

42. As an exemplar product, Zimmer Biomet's Persona® system, is marketed as "THE PERSONALIZED KNEE SYSTEM" and is a product in Zimmer Biomet's line of "Patient Specific Instruments." Ex. E at Cover. Claim 1 of the '304 Patent requires that the "surgical instrument for use in surgically repairing a joint of a patient . . . has an internal surface that includes joint information derived from image data of the joint of the patient." Ex. B at Claim 1. The Persona® system

is indicated as an orthopedic instrument system to assist in the positioning of knee replacement components. It involves surgical planning software used preoperatively to plan the surgical placement of the components on the basis of provided patient radiological images with identifiable placement anatomical landmarks, and surgical instrument components that include patient specific or customized guides fabricated on the basis of the surgical plan to precisely reference the placement of the implant components intra-operatively per the surgical plan.

Ex. F at INTRO.1.

43. Claim 1 of the '304 Patent also recites that the claimed instrument has "two or more guide holes, each configured to guide a surgical pin" and they have "a position based on anatomical information of the joint of the patient to facilitate the placement of an articular repair

system when the internal surface of the mold is aligned with the joint of the patient." Ex. B at Claim 1. During a surgical procedure using the Persona® system, the instrument guides are placed on the femur and tibia "and have pin holes to allow the surgeon to precisely insert reference pins . . . that set the position of the cut guides." Ex. F at INTRO.1.

- 44. Lastly, claim 1 of the '304 Patent recites that the "articular repair system has a predetermined rotation angle and . . . the position is based on the predetermined rotation angle." Ex. B at Claim 1. The Persona® system consists of an "optional Tibial Rotational Guide . . . to set the axial rotation of the tibial component." Ex. F at INTRO.1.
- 45. The other Accused Knee Products, the Accused Shoulder Products and the Accused Hip Product infringe the '304 Patent in a similar manner.
- 46. Zimmer Biomet's infringing activities violate one or more subsections of 35 U.S.C. § 271.
- 47. Zimmer Biomet has also actively induced, and continues to actively induce, others to infringe at least claim 1 of the '304 Patent in violation of 35 U.S.C. § 271(b) by causing, instructing, urging, encouraging and/or aiding others to directly infringe at least claim 1 of the '304 Patent by making, using, offering to sell, selling, and/or importing in and into the United States the infringing Accused Knee Products, Accused Shoulder Products and Accused Hip Product, as detailed above. Zimmer Biomet's active inducement has included and/or will include, for example and without limitation, marketing, selling, and offering to sell the Accused Knee Products, Accused Shoulder Products and Accused Hip Product, providing instructions on how to use the Accused Knee Products, Accused Shoulder Products and Accused Hip Product, selling instrumentation or devices for use with the Accused Knee Products, Accused Shoulder Products and Accused Knee Products, Accused Shoulder Products and Accused Knee Products, Accused Shoulder

Accused Shoulder Products and Accused Hip Product. For example, Zimmer Biomet has encouraged and/or will encourage customers including scientists, researchers, and health care professionals to use the Accused Knee Products, Accused Shoulder Products and Accused Hip Product by means of marketing materials and videos. Zimmer Biomet also has instructed and/or will instruct customers on how to use the Accused Knee Products, Accused Shoulder Products and Accused Hip Product by means of product manuals.

- 48. Zimmer Biomet has also contributed, and continues to contribute, to its customers' direct infringement of the '304 Patent in violation of 35 U.S.C. § 271(c) by providing products that are used in the infringing systems and that are not suitable for any substantial non-infringing use.
- 49. Upon information and belief, at least as early as the filing of the Complaint, Zimmer Biomet knows and/or is willfully blind to the fact that Zimmer Biomet's actions have infringed and/or will infringe and have induced and contributed and/or will induce and contribute to infringement of the '304 Patent with the knowledge and intent that one or more claims of the '304 Patent be infringed.
- 50. Zimmer Biomet has had notice of the '304 Patent at least as early as the filing of this Complaint. On information and belief, Zimmer Biomet's direct and indirect infringement of the '304 Patent has been willful.
- 51. Conformis has suffered economic harm as a result of Zimmer Biomet's infringing activities in an amount to be proven at trial, but in no case less than a reasonably royalty.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 9,186,161

52. Conformis repeats and realleges each and every allegation set forth in the preceding paragraphs as if fully set forth herein.

- 53. Zimmer Biomet is presently making, using, offering for sale, and/or selling patient-specific systems for knee surgery, hip surgery, and shoulder surgery that directly infringes one or more claims of the '161 Patent, literally or under the doctrine of equivalents.
- 54. Zimmer Biomet's systems practice at least one claim of the '161 Patent. For example, claim 1 recites:

A surgical system including an articular repair system and a surgical instrument for use in surgically repairing a joint of a patient, the surgical instrument comprising:

a mold having an internal surface that includes joint information derived from image data of the joint of the patient;

and two or more guide holes, each configured to guide a surgical pin,

wherein at least one of the two or more guide holes has a position and/or orientation based on anatomical information of the joint of the patient to facilitate the placement of the articular repair system when the internal surface of the mold is aligned with the joint of the patient,

wherein the articular repair system has a predetermined rotation angle and wherein the position and/or orientation is based on the predetermined rotation angle.

55. As an exemplar product, Zimmer Biomet's Persona® system, is marketed as "THE PERSONALIZED KNEE SYSTEM" and is a product in Zimmer Biomet's line of "Patient Specific Instruments." Ex. E at Cover. Claim 1 of the '161 Patent recites a "surgical system including an articular repair system and a surgical instrument for use in surgically repairing a joint of a patient" that comprises "a mold having an internal surface that includes joint information derived from image data of the joint of the patient." Ex. C at Claim 1. The Persona® system

is indicated as an orthopedic instrument system to assist in the positioning of knee replacement components. It involves surgical planning software used preoperatively to plan the surgical placement of the components on the basis of provided patient radiological images with identifiable placement anatomical landmarks, and surgical instrument components that include patient specific or customized guides fabricated on the basis of the surgical plan to precisely reference the placement of the implant components intra-operatively per the surgical plan.

Ex. F at INTRO.1.

- 56. Claim 1 of the '161 Patent also requires that the claimed invention have "two or more guide holes, each configured to guide a surgical pin" and "ha[ve] a position and/or orientation based on anatomical information of the" patient's joint "to facilitate the placement of the articular repair system when the internal surface of the mold is aligned with the" patient's joint. Ex. C at Claim 1. During the surgical procedure, the instrument guides are placed on the femur and tibia "and have pin holes to allow the surgeon to precisely insert reference pins . . . that set the position of the cut guides." Ex. F at INTRO.1.
- 57. Lastly, claim 1 of the '161 Patent requires that the "articular repair system" has "a predetermined rotation angle." Ex. C at Claim 1. The Persona® system consists of an "optional Tibial Rotational Guide . . . to set the axial rotation of the tibial component." Ex. F. at INTRO.1.
- 58. The other Accused Knee Products, the Accused Shoulder Products and the Accused Hip Product infringe the '161 Patent in a similar manner.
- 59. Zimmer Biomet's infringing activities violate one or more subsections of 35 U.S.C. § 271.
- 60. Zimmer Biomet has also actively induced, and continues to induce, others to infringe at least claim 1 of the '161 Patent in violation of 35 U.S.C. § 271(b) by causing, instructing, urging, encouraging and/or aiding others to directly infringe at least claim 1 of the '161 Patent by making, using, offering to sell, selling, and/or importing in and into the United States the infringing Accused Knee Products, Accused Shoulder Products and the Accused Hip Product, as detailed above. Zimmer Biomet's active inducement has included and/or will include, for example and without limitation, marketing, selling, and offering to sell the Accused

Knee Products, Accused Shoulder Products and the Accused Hip Product, providing instructions on how to use the Accused Knee Products, Accused Shoulder Products and the Accused Hip Product, selling instrumentation or devices for use with the Accused Knee Products, Accused Shoulder Products and the Accused Hip Product, and promoting the use of the Accused Knee Products, Accused Shoulder Products and the Accused Hip Product. For example, Zimmer Biomet has encouraged and/or will encourage customers including scientists, researchers, and health care professionals to use the Accused Knee Products, Accused Shoulder Products and the Accused Hip Product by means of marketing materials and videos. Zimmer Biomet also has instructed and/or will instruct customers on how to use the Accused Knee Products, Accused Shoulder Products and the Accused Hip Product by means of product manuals.

- 61. Zimmer Biomet has also contributed, and continues to contribute, to its customers' direct infringement of the '161 Patent in violation of 35 U.S.C. § 271(c) by providing products that are used in the infringing systems and that are not suitable for any substantial non-infringing use.
- 62. Upon information and belief, at least as early as the filing of the Complaint, Zimmer Biomet knows or is willfully blind to the fact that Zimmer Biomet's actions have infringed and/or will infringe and have induced and contributed and/or will induce and contribute to infringement of the '161 Patent with the knowledge and intent that one or more claims of the '161 Patent be infringed.
- 63. Zimmer Biomet has had notice of the '161 Patent at least as early as the filing of this Complaint. On information and belief, Zimmer Biomet's direct and indirect infringement of the '161 Patent has been willful.

64. Conformis has suffered economic harm as a result of Zimmer Biomet's infringing activities in an amount to be proven at trial, but in no case less than a reasonably royalty.

COUNT IV: INFRINGEMENT OF U.S. PATENT NO. 9,295,482

- 65. Conformis repeats and realleges each and every allegation set forth in the preceding paragraphs as if fully set forth herein.
- 66. Zimmer Biomet is presently making, using, offering for sale, and/or selling patient-specific systems for knee surgery and hip surgery that directly infringe one or more claims of the '482 Patent, literally or under the doctrine of equivalents.
- 67. Zimmer Biomet's systems practice at least one claim of the '482 Patent. For example, claim 1 recites:

A joint arthroplasty system for repairing a diseased or damaged joint of a patient comprising:

an implant; and

a patient-specific surgical instrument configured to facilitate the placement of the implant into the diseased or damaged joint, the instrument comprising:

a patient-specific surface for engaging a corresponding portion of the diseased or damaged joint,

the patient-specific surface including cartilage information derived from image data of the diseased or damaged joint,

wherein the corresponding portion of the diseased or damaged joint includes an osteophyte,

wherein the patient-specific surface references the osteophyte when the patient-specific surface is engaged and aligned with the corresponding portion of the diseased or damaged joint; and

a guide sized and shaped to accommodate a surgical tool, wherein the guide has a position and orientation relative to the patient-specific surface to provide a predetermined path for the surgical tool.

68. As an exemplar product, Zimmer Biomet's Persona® system, is marketed as "THE PERSONALIZED KNEE SYSTEM" and is a product in Zimmer Biomet's line of "Patient Specific Instruments." Ex. E at Cover. Claim 1 of the '482 Patent recites "[a] joint arthroplasty system for repairing a diseased or damaged joint" comprising "an implant," "a patient-specific surgical instrument . . . to facilitate the placement of the implant" and "engage a corresponding portion" of the joint. Ex. D at Claim 1. The Persona® system

is indicated as an orthopedic instrument system to assist in the positioning of knee replacement components. It involves surgical planning software used preoperatively to plan the surgical placement of the components on the basis of provided patient radiological images with identifiable placement anatomical landmarks, and surgical instrument components that include patient specific or customized guides fabricated on the basis of the surgical plan to precisely reference the placement of the implant components intra-operatively per the surgical plan.

Ex. F at INTRO.1.

- 69. In addition, claim 1 of the '482 Patent recites that the "patient-specific surface" includes "cartilage information derived from image data" and that the portion of the joint "includes [and references] an osteophyte." Ex. D at Claim 1. The operator of the Persona® system is instructed "not [to] remove osteophytes or cartilage from the femur" or tibia when using the instrument. Ex. F at 2, 9.
- 70. Lastly, claim 1 of the '482 Patent recites that the guide is "sized and shaped to accommodate a surgical tool, wherein the guide has a position and orientation relative to the patient-specific surface to provide a predetermined path for the surgical tool." Ex. D at Claim 1. The Persona® system consists of an "optional Tibial Rotational Guide . . . to set the axial rotation of the tibial component." Ex. F at INTRO.1. During the surgical procedure, the instrument guides are placed on the femur and tibia "and have pin holes to allow the surgeon to precisely insert reference pins . . . that set the position of the cut guides." *Id.* The technique guide

instructs the operator that a 3.2mm drill bit and pin/screw are used during the procedure. *Id.* at 4-5.

- 71. The other Accused Knee Products and the Accused Hip Product infringe the '482 Patent in a similar manner.
- 72. Zimmer Biomet's infringing activities violate one or more subsections of 35 U.S.C. § 271.
- 73. Zimmer Biomet has also actively induced, and continues to actively induce, others to infringe at least claim 1 of the '482 Patent in violation of 35 U.S.C. § 271(b) by causing, instructing, urging, encouraging and/or aiding others to directly infringe at least claim 1 of the '482 Patent by making, using, offering to sell, selling, and/or importing in and into the United States the infringing Accused Knee Products and Accused Hip Product, as detailed above. Zimmer Biomet's active inducement has included and/or will include, for example and without limitation, marketing, selling, and offering to sell the Accused Knee Products and Accused Hip Product, providing instructions on how to use the Accused Knee Products and Accused Hip Product, selling instrumentation or devices for use with the Accused Knee Products and Accused Hip Product, and promoting the use of the Accused Knee Products and Accused Hip Product. For example, Zimmer Biomet has encouraged and/or will encourage customers including scientists, researchers, and health care professionals to use the Accused Knee Products and Accused Hip Product by means of marketing materials and videos. Zimmer Biomet also has instructed and/or will instruct customers on how to use the Accused Knee Products and Accused Hip Product by means of product manuals.
- 74. Zimmer Biomet has also contributed, and continues to contribute, to its customers' direct infringement of the '482 Patent in violation of 35 U.S.C. § 271(c) by providing

products that are used in the infringing systems and that are not suitable for any substantial noninfringing use.

- 75. Upon information and belief, at least as early as the filing of the Complaint, Zimmer Biomet knows and/or is willfully blind to the fact that Zimmer Biomet's actions have infringed and/or will infringe and have induced and contributed and/or will induce and contribute to infringement of the '482 Patent with the knowledge and intent that one or more claims of the '482 Patent be infringed.
- 76. Zimmer Biomet has had notice of the '482 Patent at least as early as the filing of this Complaint. On information and belief, Zimmer Biomet's direct and indirect infringement of the '482 Patent has been willful.
- 77. Conformis has suffered economic harm as a result of Zimmer Biomet's infringing activities in an amount to be proven at trial, but in no case less than a reasonably royalty.

PRAYER FOR RELIEF

WHEREFORE, Conformis respectfully requests the following relief:

- A. The entry of a judgment in favor of Conformis, and against Zimmer Biomet, that Zimmer Biomet has directly infringed and induced and contributed to infringement of one or more claims of the '129 Patent, the '304 Patent, the '161 Patent, and the '482 Patent and declaring that Zimmer Biomet's importing, making, using, offering to sell, and/or selling at least Accused Knee Products, Accused Shoulder Products and the Accused Hip Product in the United States are and would be acts of infringement of one or more claims of the '129 Patent, the '304 Patent, the '161 Patent, and/or the '482 Patent.
- B. The entry of a judgment in favor of Conformis, and against Zimmer Biomet, that Zimmer Biomet has willfully infringed one or more claims of the '129 Patent, the '304 Patent, the '161 Patent, and the '482 Patent;

- C. The entry of a judgment awarding Conformis all damages resulting from Zimmer Biomet's infringement, including Conformis' lost profits and no less than a reasonable royalty, and that such amount be trebled based on Zimmer Biomet's willful infringement;
- D. The entry of a judgment declaring that this is an exceptional case and awarding Conformis its attorneys' fees in this matter pursuant to 35 U.S.C. § 285;
- E. The entry of a judgment in favor of Conformis, and against Zimmer Biomet, that interest, costs, and expenses be awarded in favor of Conformis; and
 - F. That this Court order such other relief as the Court may deem just and proper.

JURY DEMAND

Conformis hereby demands trial by jury in this action on all issues so triable.

Dated: August 15, 2019

OF COUNSEL:

Matthew M. Wolf Paul Margulies Michael Gershoni Victoria L. Reines*

ARNOLD & PORTER KAYE SCHOLER LLP

601 Massachusetts Ave., NW Washington, DC 20001 Telephone: (202) 942-5000 Matthew.Wolf@arnoldporter.com Paul.Margulies@arnoldporter.com Michael.Gershoni@arnoldporter.com Victoria.Reines@arnoldporter.com

* Admitted only in New York; practicing law in the District of Columbia during the pendency of her application for admission to the D.C. Bar and under the supervision of lawyers of the firm who are members in good standing of the D.C. Bar.

01:24990344.1

YOUNG CONAWAY STARGATT & TAYLOR LLP

/s/ Karen L. Pascale

Karen L. Pascale (#2903) [kpascale@ycst.com] Robert M. Vrana (#5666) [rvrana@ycst.com] Rodney Square 1000 North King Street Wilmington, DE 19801

Telephone: (302) 571-6600

Attorneys for Comformis, Inc.