## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

ZIMMER US, INC. and	)
BIOMET MANUFACTURING, LLC,	
	)
Plaintiffs,	)
	)
v.	) C.A. No
CONTORNES DIS	)
CONFORMIS, INC.,	) DEMAND FOR JURY TRIAL
	)
Defendant.	)

### **COMPLAINT**

Plaintiffs Zimmer US, Inc. and Biomet Manufacturing, LLC (together, "Zimmer"), for their Complaint against Defendant Conformis, Inc. ("Conformis"), hereby allege as follows:

## **THE PARTIES**

- Plaintiff Zimmer US, Inc. is a Delaware corporation having an office at
   345 East Main Street, Warsaw, Indiana 46580.
- 2. Plaintiff Biomet Manufacturing, LLC is a limited liability company organized under the laws of the State of Indiana having an office at 56 East Bell Drive, Warsaw, Indiana 46582.
- 3. Upon information and belief, Defendant Conformis is a Delaware corporation with a place of business at 600 Technology Park Drive, Billerica, Massachusetts 01821.

### **NATURE OF THE ACTION**

4. This is a civil action concerning the infringement of United States Patent Nos. 6,510,334 ("the '334 patent"), 8,486,150 ("the '150 patent"), 8,979,936 ("the '936 patent"),

9,173,661 ("the '661 patent"), and 9,795,399 ("the '399 patent") (collectively, "the Patents-in-Suit"). This action arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 et seq.

### **JURISDICTION AND VENUE**

- 5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).
- 6. This Court has personal jurisdiction over Conformis because it is a Delaware corporation and, *inter alia*, the fact that it has availed itself of the rights and benefits of the laws of Delaware by engaging in systematic and continuous contacts with Delaware and because it markets, sells, and/or distributes products that infringe the Patents-in-Suit to residents of this State.
- 7. This Court also has personal jurisdiction over Conformis by virtue of, *inter alia*, the fact that it has committed, aided, abetted, contributed to, and/or participated in the commission of the tortious act of patent infringement that has led to foreseeable harm and injury to Zimmer.
  - 8. Venue is proper in this Court pursuant to 28 U.S.C. § 1400(b).

#### THE PATENTS-IN-SUIT

- 9. On January 21, 2003, the '334 patent, titled "Method of Producing an Endoprosthesis as a Joint Substitute for a Knee Joint," was issued. A copy of the '334 patent is attached as Exhibit A.
- 10. On July 16, 2013, the '150 patent, titled "Patient-modified Implant" was issued. A copy of the '150 patent is attached as Exhibit B.
- 11. On March 17, 2015, the '936 patent, titled "Patient-modified Implant," was issued. A copy of the '936 patent is attached as Exhibit C.

- 12. On November 3, 2015, the '661 patent, titled "Patient Specific Alignment Guide with Cutting Surface and Laser Indicator," was issued. A copy of the '661 patent is attached as Exhibit D.
- 13. On October 24, 2017, the '399 patent, titled "Patient-specific Knee Alignment Guide and Associated Method," was issued. A copy of the '399 patent is attached as Exhibit E.
- 14. Biomet Manufacturing, LLC is the assignee and owner of each of the Patents-in-Suit. Zimmer US, Inc. has an exclusive license from Biomet Manufacturing, LLC to market, sell, and distribute orthopedic reconstructive products in the United States and the rest of the world.

## **ACTS GIVING RISE TO THIS ACTION**

- 15. For over 90 years, Zimmer has designed, manufactured, and marketed innovative solutions that allow orthopedic surgeons and clinicians to improve the quality of life for people around the world. Due to its musculoskeletal technologies and related products and services, Zimmer is a trusted partner to healthcare providers in over 100 countries.
- 16. Zimmer has created the most comprehensive inventory for joint reconstruction and bone and skeletal repair. Zimmer maintains its position as one the most respected companies in the world through its commitment to constant technological innovation. To that end, Zimmer owns or controls through licensing arrangements thousands of issued patents throughout the world that relate to technology incorporated into its products. Such patents include those directed to the use of joint imaging in the manufacture and use of patient-specific orthopedic implants and guide tools.
- 17. Conformis makes, uses, provides, offers to sell, and sells patient-specific instrument systems based on images of a patient's knee joint including the iUni G2 Patient-

Specific Unicompartmental Knee Resurfacing System ("iUni"), the iDuo G2 Patient-Specific Bicompartmental Knee Resurfacing System ("iDuo"), the iTotal G2 Patient-Specific Cruciate-Retaining Knee Replacement System ("G2CR"), and the iTotal PS Customized Posterior-Stabilized Knee Replacement System ("PS") (collectively "the Accused Products").

- 18. The Accused Products include patient-specific guides that assist the implantation of the prosthesis during joint replacement surgery. Conformis also provides surgeons with technique manuals that instruct the surgeon on how to use the Accused Products.
- 19. The Accused Products utilize iFit® image-to-implant technology ("iFit"), which uses software to design patient-specific implants and instrumentation by converting a CT scan of a patient's knee into a three-dimensional model by mapping the articular surface of the joint and defining the area of disease. The three-dimensional model is then used to design the patient-specific implant surface and surgical instrumentation.
- 20. Conformis's iView patient-specific planning images provide the surgeon with patient-specific tibial and femoral resection values, intraoperative iJig positioning information, and final implant positioning information as determined by the iFit software.
- 21. Conformis is directly infringing the '334 patent by making, using, providing, offering to sell, and selling, directly or indirectly through intermediaries, at least the Accused Products in this District and throughout the United States.
- 22. Conformis is directly infringing the '150 by making using, providing, offering to sell, and selling, directly or indirectly through intermediaries, at least the iDuo, G2CR, and PS products in this District and throughout the United States.

- 23. Conformis is directly infringing the '936 patent by making, using, providing, offering to sell, and selling, directly or indirectly through intermediaries, at least the Accused Products in this District and throughout the United States.
- 24. Conformis is actively inducing infringement of the '661 patent by causing, instructing, urging, encouraging, and/or aiding others to directly infringe one or more claims of the '661 patent by making, using, providing, offering to sell, and selling, directly or indirectly through intermediaries, at least the G2CR and PS products and their associated surgical technique manuals. Conformis is also contributing to others' direct infringement of the '661 patent by providing or selling, directly or indirectly through intermediaries, at least the G2CR and PS products in this District and throughout the United States.
- 25. Conformis is actively inducing infringement of the '399 by causing, instructing, urging, encouraging, and/or aiding others to directly infringe one or more claims of the '399 patent by making, using, providing, offering to sell, and selling, directly or indirectly through intermediaries, at least the G2CR and PS products and their associated surgical technique manuals. Conformis is also contributing to others' direct infringement of the '399 patent by providing or selling, directly or indirectly through intermediaries, at least the G2CR and PS products in this District and throughout the United States.

# FIRST COUNT INFRINGEMENT OF U.S. PATENT NO. 6,510,334

- 26. Zimmer re-alleges paragraphs 1-25 as if fully set forth herein.
- 27. Upon information and belief, Conformis is currently making, using, providing, offering for sale, and/or selling knee replacement systems manufactured by a method that meets every limitation in one or more claims of the '334 patent either literally or under the doctrine of equivalents.

- 28. For example, claim 1 of the '334 patent is directed to a "method of producing an endoprosthesis as a joint substitute for knee joints." Upon information and belief, Conformis makes the Accused Products, which include prosthetic knee joints manufactured using the iFit software. (*See, e.g.*, Exhibit F, Conformis Customized Knee Implant Pamphlet at 8.)
- 29. Claim 1 of the '334 patent requires "preparing a preoperative tomographic image of the damaged knee joint." Upon information and belief, the iFit software utilizes CT imaging to create a patient-specific implant by mapping the surface of the joint and defining the area of disease in three dimensions. (*See*, *e.g.*, Exhibit G, Image-to-Implant Process, CONFORMIS.COM, available at http://www.conformis.co.uk/patient-specific-knee-implants/image-to-implant-process/.)
- 30. Claim 1 of the '334 patent also requires "virtually altering the preoperative tomographic image for approximating the contours of at least the femoral bone and of the tibia of the damaged knee joint to those of a healthy knee joint." Upon information and belief, the iFit software uses a patient's CT scan to map the surface of the patient's knee joint in three dimensions, which includes recreating the patient's unique articulating surfaces by, *inter alia*, correcting the data for any underlying arthritic deformity such as bone spurs, cysts, or flattening of the joint. (*See, e.g., id.*)
- 31. Claim 1 of the '334 patent further requires "virtually severing the altered femoral and tibial components defining respective components of a healthy knee joint as respectively visual patterns for the endoprosthesis." Upon information and belief, the iFit software generates patient-specific tibial and femoral resection values, intraoperative iJig positioning information, and final implant positioning information, which is shown in the iView

planning images. (*See, e.g.*, Exhibit H, iView iTotal CR Patient-Specific Surgical Plan at 1-2.) Upon information and belief, the iFit software also corrects the J-curve for deformity as the basis for the femoral implant design. (*See, e.g.*, Exhibit G.)

- 32. Claim 1 of the '334 patent further requires "whereby this severing is carried out on marked severing areas which later serve as thusly predetermined severing areas for severing the associated components of the damaged knee joint from the joint bones during operation of the damaged knee joint." Upon information and belief, the iFit software generates images that provide resection values for the positioning of the Accused Products' iJigs that determine where intraoperative cuts will be made in the femur and the tibia, which is shown in the iView planning images. (See, e.g., Exhibit H at 1-2; see also Exhibit G.)
- 33. Claim 1 of the '334 patent further requires "virtually transferring the marked severing areas for virtually preparing tomographic images of a femoral and of a tibial template for the femoral and the tibial components of the damaged knee joint as respectively separate visual patterns of an implantation aid which fits snugly to the damaged knee joint." Upon information and belief, the Accused Products' iJigs are patient-specific and designed based on mapping of the knee in the iFit software. (*See, e.g.,* Exhibit G.) Upon information and belief, Conformis's tibial and femoral iJigs are also designed to sit flush against the bone. (*See, e.g.,* Exhibit I, iTotal CR Surgical Technique Guide, Patient-specific Cruciate-retaining Knee Replacement System, Measured Resection, at 7-8, 11.)
- 34. Claim 1 of the '334 patent further requires "whereby the severing areas when virtually transferred to the implantation aid are exemplified as virtual guiding slots of a guide aid for guiding an oscillating sawing blade during operation of the damaged knee joint when the damaged knee joint components are factually severed from the joint bones." Upon

information and belief, the iJigs in the Accused Products are designed to include slots that will accommodate a standard saw blade thickness. (*See, e.g., id.* at 5.) Upon information and belief, the iJig slot positions are determined by the iFit software and correspond to where bone cuts will be made intraoperatively as shown in the iView planning images. (*See, e.g.,* Exhibit H at 1-2.)

- 35. Claim 1 of the '334 patent further requires "preparing three-dimensional femoral and tibial components of the endoprosthesis and three-dimensional femoral and tibial components of the associated implantation aid on the basis of their respective visual patterns." Upon information and belief, Conformis's manufacturing process for the Accused Products' iJigs and prostheses uses iFit software, which allows for the design of patient-specific implants and instrumentation by converting a CT scan of the knee to a three-dimensional model through mapping of the articular surface of the joint. (*See, e.g.*, Exhibit G.) Upon information and belief, the iFit software generates patient-specific tibial and femoral resection values, intraoperative iJig positioning information, and final implant positioning information as shown in the iView planning images. (*See, e.g.*, Exhibit H at 1-2.)
- 36. As a result of Conformis's infringement of the '334 patent, Zimmer has suffered and will continue to suffer harm and injury, including monetary damages in an amount to be determined at trial.

## SECOND COUNT INFRINGEMENT OF U.S. PATENT NO. 8,486,150

- 37. Zimmer re-alleges paragraphs 1-36 as if fully set forth herein.
- 38. Upon information and belief, Conformis is currently making, using, providing, offering for sale, and/or selling knee replacement systems manufactured by a method that meets every limitation in one or more claims of the '150 patent either literally or under the doctrine of equivalents.

- 39. For example, claim 1 of the '150 patent is directed to "[a] method for manufacturing an orthopedic implant." Upon information and belief, Conformis makes the iDuo, G2CR, and PS products, which include orthopedic implants manufactured using the iFit software. (See, e.g., Exhibit F at 4, 8.)
- 40. Claim 1 of the '150 patent requires "constructing a three-dimensional digital image of a patient's joint using computer modeling." Upon information and belief, the iDuo, G2CR, and PS products are manufactured using iFit software, which utilizes CT images to create a three-dimensional model of the patient's joint. (See, e.g., id.)
- 41. Claim 1 of the '150 patent also requires "obtaining a digital image of a femoral implant having a non-custom inner bone-engaging surface including a plurality of planar surfaces configured for engagement with standard size femoral bone cuts prepared for a non-custom femoral implant." Upon information and belief, the iFit software used to manufacture the iDuo, G2CR, and PS products does not modify the digital image of the non-custom inner bone-engaging surface of the femoral implant. (*See, e.g.*, Exhibit H at 1-2.) Upon information and belief, the iDuo, G2CR, and PS products utilize implants that have a non-articulating inner bone-engaging surface with a standard multiple chamfer cut design that is not patient-specific. (*See, e.g.*, Exhibit J, iTotal G2 Patient-specific Cruciate-Retaining Knee Replacement System at 6; Exhibit K, "How Does a 3D Printed Knee Replacement Work?" CONFORMIS.COM BLOG, https://www.conformis.com/custom-made-knee-implants/patient-resources/blog/3d-printing-how-does-it-work/.) Upon information and belief, these products utilize iJigs that are designed to accommodate sawblades of standard lengths, widths, and thicknesses for making cuts in the femoral bone that mate with the implant's inner surface. (*See, e.g.*, Exhibit I at 5.)

- 42. Claim 1 of the '150 patent further requires "modifying the digital image of the femoral implant by configuring an anterior femoral flange of the femoral implant to have a patient-specific shape and size and to closely match a corresponding portion of a femur of a specific patient based on the three-dimensional image of the patient's joint." Upon information and belief, the iDuo, G2CR, and PS products include implants with a patient-specific anterior femoral flange, which is made based on the iFit software's three-dimensional modeling of the patient's joint, and provides a precise fit. (*See, e.g.*, Exhibit J at 6; *see also* Exhibit F at 6.)
- 43. Claim 1 of the '150 patent further requires "manufacturing the femoral implant based on the digital image." Upon information and belief, the iDuo, G2CR, and PS products are manufactured using iFit software that designs the implant to match the three-dimensional model of the patient's knee. (*See, e.g.*, Exhibit F at 4, 8.)
- 44. As a result of Conformis's infringement of the '150 patent, Zimmer has suffered and will continue to suffer harm and injury, including monetary damages in an amount to be determined at trial.

# THIRD COUNT INFRINGEMENT OF U.S. PATENT NO. 8,979,936

- 45. Zimmer re-alleges paragraphs 1-44 as if fully set forth herein.
- 46. Upon information and belief, Conformis is currently making, using, providing, offering for sale, and/or selling knee replacement systems that infringe one or more claims of the '936 patent either literally or under the doctrine of equivalents.
- 47. For example, claim 1 of the '936 patent is directed to "[a]n orthopedic implant." Upon information and belief, Conformis makes the Accused Products, which include prosthetic knee joints manufactured using the iFit software. (*See*, *e.g.*, Exhibit F at 4, 8.)

- 48. Claim 1 of the '936 patent requires "a tibial bearing including a non-custom portion." Upon information and belief, the Accused Products' prosthetic knee implants use poly inserts that include a non-custom bottom surface. (*See, e.g.*, Exhibit I at 17-18.)
- 49. Claim 1 of the '936 patent also requires "a tibial tray including a non-custom locking mechanism configured to be coupled with the non-custom portion of the tibial bearing." Upon information and belief, the Accused Products' prosthetic knee implants include a tibial tray having a non-custom mechanism for locking the poly insert into the tibial tray. (*See, e.g., id.*) Upon information and belief, the insert is locked into a non-custom portion of the tibial tray via a reusable poly impactor instrument. (*See, e.g., id.* at 4, 17-18.)
- 50. Claim 1 of the '936 patent further requires "wherein the tibial tray has a patient specific profile configured during a preoperative plan to closely match a corresponding profile of a tibia of a specific patient based on a three-dimensional digital image of a patient's joint using computer modeling." Upon information and belief, the Accused Products' prosthetic knee implants utilize a patient-specific tibial tray that provides patient-specific rotation and coverage. (See, e.g., Exhibit J at 6, 8.) Upon information and belief, the tibial tray is configured preoperatively to have a patient-specific profile using the three-dimensional patient-specific model generated by the iFit software. (See, e.g., id. at 5.)
- 51. Claim 1 of the '936 patent further requires "wherein the patient-specific profile of the tibial tray is obtained by modifying a digital image of a non-custom tibial implant without modifying the non-custom locking mechanism." Upon information and belief, the Accused Products' prosthetic knee implants are made using iFit software that matches the profile of a patient's tibial surface by modifying digital images of a standard tibial tray. (See, e.g., Exhibit H at 1; see also Exhibit G.) Upon information and belief, during the manufacturing

process, the iFit software does not modify the non-custom locking mechanism on the implants, which is secured using a reusable poly impactor instrument. (*See, e.g.*, Exhibit I at 4, 17-18.)

52. As a result of Conformis's infringement of the '936 patent, Zimmer has suffered and will continue to suffer harm and injury, including monetary damages in an amount to be determined at trial.

# FOURTH COUNT INFRINGEMENT OF U.S. PATENT NO. 9,173,661

- 53. Zimmer re-alleges paragraphs 1-52 as if fully set forth herein.
- 54. Upon information and belief, Conformis is actively inducing others to infringe one or more claims of the '661 patent either literally or under the doctrine of equivalents through its surgical technique guides and other means it uses to provide the surgeon with instructions for using its G2CR and PS products.
- 55. For example, claim 8 of the '661 patent is directed to "[a] method of guiding an instrument relative to an anatomical feature of a patient." Upon information and belief, the G2CR and PS surgical technique guides instruct the surgeon to guide a reciprocating saw blade through the F3c iJig to complete the distal femoral resection. (*See, e.g.*, Exhibit I at 8, Fig. 1.5.)
- 56. Claim 8 of the '661 patent requires "nesting a patient-specific guide on a distal femoral bone of the patient, such that a first inner surface of a first portion of the guide mates to an unresected anterior surface of the femoral bone and simultaneously a second inner surface of a second portion of the guide mates to an unresected distal surface of the femoral bone." Upon information and belief, the G2CR and PS surgical technique guides instruct the surgeon to attach the F2 alignment iJig, which registers on the uncut distal surface of the femur, to the F3c distal resection iJig, which registers on the uncut anterior surface of the femur, and to

subsequently place the assembly onto the uncut femur. (*See*, *e.g.*, Exhibit I at 8, Fig. 1.4.) Upon information and belief, the G2CR and PS surgical technique guides further describe the F3c iJig as having a patient-specific surface and describe the F2 iJig as fitting the shape of the uncut distal femur. (*See*, *e.g.*, *id.* at 8, Figs. 1.4-1.5.)

- 57. Claim 8 of the '661 patent also requires "wherein the first and second inner surfaces are patient-specific according to image scans of the femoral bone of the specific patient, such that the first and second inner surfaces conformingly contact and match three-dimensional surfaces of the femoral bone." Upon information and belief, the G2CR and PS products used by the surgeon are made using iFit software, which utilizes a patient-specific three-dimensional model to determine patient-specific tibial and femoral iJig placement. (See, e.g., id. at 2, 6.) Upon information and belief, the G2CR and PS products utilize an F3c iJig that has a patient-specific surface that fits on the anterior surface of the femur and an F2 iJig that fits the shape of the distal surface of the femur. (See, e.g., id. at 8, Figs. 1.4-1.5.)
- 58. Claim 8 of the '661 patent further requires "wherein the first portion has a first mateable surface and the second portion has a second mateable surface and the first portion is directly coupled to and removeably separable from the second portion via the corresponding first and second mateable surfaces." Upon information and belief, the F3c and F2 iJigs in the G2CR and PS products used by the surgeon are designed to attach to each other to form one iJig assembly. (See, e.g., id. at 8, Fig. 1.4.) Upon information and belief, the F3c and F2 iJigs can be removed from each other via release tabs on the F2 iJig. (See, e.g., id.)
- 59. Claim 8 of the '661 patent further requires "securing the guide having the first portion and the second portion to the femoral bone by securing only the first portion to the femoral bone with a primary pin." Upon information and belief, the G2CR and PS surgical

technique guides instruct the surgeon to drill and pin two anterior holes in the Fc3 iJig when it is placed on the femur as part of the iJig assembly. (See, e.g., id.)

- 60. Claim 8 of the '661 patent further requires "removing the second portion from the guide without removing the primary pin." Upon information and belief, the G2CR and PS surgical technique guides instruct the surgeon to remove the F2 iJig after drilling and pinning the iJig assembly, leaving the F3c iJig and the pins secured to the femur. (*See, e.g., id.*)
- 61. Claim 8 of the '661 patent further requires "leaving the first portion secured to femoral bone." Upon information and belief, the G2CR and PS surgical technique guides instruct the surgeon to remove the F2 iJig after drilling and pinning the iJig assembly, leaving the F3c iJig secured to the femur. (See, e.g., id. at 8, Figs. 1.4-1.5.)
- 62. Claim 8 of the '661 patent further requires "guiding a cutting instrument through a guide surface of an elongated opening of the first portion." Upon information and belief, the G2CR and PS surgical technique guides instruct the surgeon to insert an oscillating saw blade through the opening in the G2CR and PS products' F3c iJigs. (See, e.g., id. at 8, Fig. 1.5.)
- 63. Claim 8 of the '661 patent further requires "resecting the femoral bone along a cutting plane passing through the elongated opening." Upon information and belief, the G2CR and PS surgical technique guides instruct the surgeon to complete the distal femoral resection through the opening in the F3c iJig. (See, e.g., id.)
- 64. Conformis has been aware of the existence of the '661 patent since at least the filing of this complaint, and is aware that surgeons directly infringe the '661 patent by following the instructions set forth in Conformis's surgical technique guides for using its G2CR

and PS products. Accordingly, Conformis is actively inducing others to infringe the '661 patent, and its acts constitute indirect infringement of the '661 patent under 35 U.S.C. § 271(b).

- 65. Conformis has also contributed and continues to contribute to its customers' direct infringement of the '661 patent under 35 U.S.C. § 271(c) by selling, offering to sell, or importing into the United States mateable, patient-specific iJigs especially adapted for guiding the surgeon's saw blade during resection of the distal femur in accordance with the methods claimed in the '661 patent. These iJigs are specifically designed for use by a surgeon in resecting the distal femur and are not suitable for any other use.
- 66. As a result of Conformis's indirect infringement of the '661 patent, Zimmer has suffered and will continue to suffer harm and injury, including monetary damages in an amount to be determined at trial.

## COUNT FIVE INFRINGEMENT OF U.S. PATENT NO. 9,795,399

- 67. Zimmer re-alleges paragraphs 1-66 as if fully set forth herein.
- 68. Upon information and belief, Conformis is currently inducing others to infringe one or more claims of the '399 patent either literally or under the doctrine of equivalents through its surgical technique guides and other means it uses to provide the surgeon with instructions for using its G2CR and PS products.
- 69. For example, claim 1 of the '399 patent is directed to "[a] method for accessing a portion of a bone of a patient relative to a soft tissue on a surface of the bone." Upon information and belief, the G2CR and PS surgical technique guides instruct the surgeon to use the iJigs for the purpose of resecting the proximal tibia bone where osteoarthritis has occurred in order to access underlying layers of the bone for implantation. (See, e.g., id. at 2, 11.)

- 70. Claim 1 of the '399 patent requires "mating a patient-specific three-dimensional curved inner surface of a first guide onto a corresponding three-dimensional surface of the bone." Upon information and belief, the G2CR and PS surgical technique guides instruct the surgeon to place the T1 iJig, which has a curved inner surface and is set to the patient's native slope, onto the tibia so that it sits flush with the bone. (*See, e.g., id.* at 11, Fig. 2.1-2.2.) Upon information and belief, the T1 iJigs used by the surgeon are manufactured based on the iFit software's patient-specific three-dimensional model, which includes CT scan data of the proximal tibia. (*See, e.g., id.* at 6.)
- 71. Claim 1 of the '399 patent also requires that "the patient-specific three-dimensional curved inner surface [is] preoperatively configured from three dimensional images of the bone." Upon information and belief, the G2CR and PS products used by the surgeon utilize iFit software that converts a CT scan of the knee to a three-dimensional model that is used to design the implant and the surgical instrumentation. (*See, e.g., id.* at 2, 6.) Upon information and belief, included in this process are iView patient-specific planning images based on the iFit software, which provide the surgeon with, *inter alia*, patient-specific tibial T1 iJig intraoperative positioning information. (*See, e.g., id.* at 6.)
- 72. Claim 1 of the '399 patent further requires "where the first guide is based on converted scan data to three dimensional images of the bone of the patient's anatomy including a knee joint anatomy including images of the knee joint surfaces of at least one of a distal femur bone or a proximal tibial bone with or without associated soft tissue on the distal femur bone or the proximal tibial bone." Upon information and belief, the G2CR and PS products used by the surgeon are made using iFit software, which converts a patient's CT scan of

the knee to a three-dimensional model that is used to design the implant and the surgical instrumentation, including the tibial T1 iJigs. (See, e.g., id. at 2, 6, 11, Fig. 2.2.)

- 73. Claim 1 of the '399 patent further requires "drilling a first hole into the bone surface through a first guiding aperture of the first guide." Upon information and belief, the G2CR and PS surgical technique guides instruct the surgeon to drill into the bone through the holes on the tibial T1 iJigs. (See, e.g., id. at 11, Fig. 2.3.)
- 74. Claim 1 of the '399 patent further requires "placing a member in the first hole into the bone near the knee joint surface." Upon information and belief, the G2CR and PS surgical technique guides instruct the surgeon to pin the tibial T1 iJig into place through the previously drilled holes near the tibial plateau. (See, e.g., id.)
- 75. Claim 1 of the '399 patent further requires "wherein drilling the first hole into the bone surface through the first guiding aperture of the first guide includes drilling the first hole through the first guide aperture that is at least one of positioned on an anterior-medial side of the bone or an anterior-lateral side of the bone." Upon information and belief, the G2CR and PS surgical technique guides instruct the surgeon to drill through the tibial T1 iJig's guide aperture, which is located on the anterior-medial side of the tibia when the surgeon properly seats the tibial T1 iJig on the bone. (See, e.g., id. at 11, Figs. 2.2-2.3.)
- 76. Conformis has been aware of the existence of the '399 patent since at least the filing of this complaint, and is aware that surgeons directly infringe the '399 patent by following the instructions set forth Conformis's surgical technique guides for using its G2CR and PS products. Accordingly, Conformis is actively inducing others to infringe the '399 patent, and its acts constitute indirect infringement of the '399 patent under 35 U.S.C. § 271(b).

- 77. Conformis has also contributed and continues to contribute to its customers' direct infringement of the '399 patent under 35 U.S.C. § 271(c) by selling, offering to sell, or importing into the United States patient-specific iJigs especially adapted for positioning on the anterior-medial side of the tibia and having guides through which the surgeon drills a hole in accordance with the methods claimed in the '399 patent. These iJigs are specifically designed for use in guiding a surgeon's drill when positioned on the anterior-medial side of the patient's tibia and are not suitable for any other use.
- 78. As a result of Conformis's indirect infringement of the '399 patent, Zimmer has suffered and will continue to suffer harm and injury, including monetary damages in an amount to be determined at trial.

### PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

- A. Conformis has infringed and is continuing to infringe one or more claims of the '334 patent, the '150 patent, the '936 patent, the '661 patent, and the '399 patent;
- B. That Conformis be ordered to pay Zimmer all damages that Zimmer has sustained as a consequence of the acts stated herein in an amount to be determined at trial, including any increased, exemplary, and punitive damages allowed by law;
- C. That a judgment be entered awarding damages pursuant to 35 U.S.C. § 284 compensating Zimmer for Conformis's infringement of the '334 patent, the '150 patent, the '936 patent, the '661 patent, and the '399 patent;
- D. Declaring that this is an exceptional case and that Zimmer be awarded its attorney fees under 35 U.S.C. § 285;
- E. That Zimmer be awarded costs and expenses that it incurs in prosecuting this action; and

F. That Zimmer be awarded such other and further relief as this Court deems just and proper, including injunctive relief.

### **JURY DEMAND**

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/Jack B. Blumenfeld

OF COUNSEL:

Naveen Modi Chetan R. Bansal PAUL HASTINGS LLP 875 15th Street, N.W. Washington, D.C. 20005 (202) 551-1700

Young J. Park Michael F. Werno PAUL HASTINGS LLP 200 Park Avenue New York, N Y 10166 (212) 318-6000

November 5, 2019

Jack B. Blumenfeld (#1014)
Brian P. Egan (#6227)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
began@mnat.com

Attorneys for Plaintiffs Zimmer US, Inc. and Biomet Manufacturing, LLC