

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

CONFORMIS, INC.,)	
)	
Plaintiff,)	
)	Civil Action No. 21-640-RGA
v.)	
)	
DEPUY SYNTHES, INC., DEPUY SYNTHES)	JURY TRIAL DEMANDED
PRODUCTS, INC., and DEPUY SYNTHES)	
SALES, INC.)	
)	
Defendants.)	

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Conformis, Inc. (“Conformis”), for its Complaint and demand for a jury trial seeking relief for patent infringement against Defendants DePuy Synthes, Inc., DePuy Synthes Products, Inc., and DePuy Synthes Sales, Inc. (collectively, “DePuy” or “Defendants”), states and alleges as follows:

I. THE PARTIES

1. Plaintiff Conformis, Inc. is incorporated in Delaware with its worldwide headquarters at 600 Technology Park Drive, Billerica, Massachusetts, 01730.

2. Defendant DePuy Synthes, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 700 Orthopedic Drive, Warsaw, Indiana 46581.

3. Defendant DePuy Synthes Products, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 325 Paramount Drive, Raynham, Massachusetts 02767.

4. DePuy Synthes Sales, Inc. is a corporation organized and existing under the laws of Massachusetts with its principal place of business at 325 Paramount Drive, Raynham, Massachusetts, 02767.

5. On information and belief, Defendants DePuy Synthes Products, Inc. and DePuy Synthes Sales, Inc. are wholly-owned subsidiaries of DePuy Synthes, Inc., and each of the Defendants are wholly-owned indirect subsidiaries of Johnson & Johnson.

6. On information and belief, each of the Defendants work together as the DePuy Synthes group of companies to each provide patient-specific surgical solutions in the United States and perform the computer-aided design of custom medical devices, such as custom instruments, as part of those services. *See, e.g.*, “Discover Scientific Evidence Behind Our Innovations,” <https://www.jnjmedicaldevices.com/en-US/companies/depuy-synthes> (last visited Apr. 29, 2021) (“This site is published by the DePuy Synthes Companies, which are solely responsible for its content.”)

II. JURISDICTION AND VENUE

7. This Court has subject-matter jurisdiction over Conformis’s claims under 28 U.S.C. §§ 1331 and 1338(a) because these claims arise under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*

8. Defendants are subject to this Court’s general and specific personal jurisdiction at least because: Defendants DePuy Synthes Products, Inc. and DePuy Synthes, Inc. are at home in the State of Delaware where they are incorporated; Defendants have registered agents for service of process in Delaware, regularly conduct business in the State of Delaware, and therefore have substantial and continuous contacts within this judicial district; Defendants have purposefully

availed themselves of the privileges of conducting business in this judicial district; and Defendants have committed acts of patent infringement in this judicial district.

9. Venue in this Court is proper under the provisions of 28 U.S.C. §§ 1391(b)–(c) and 1400.

III. THE ASSERTED PATENTS

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

11. Patent authorities worldwide have recognized that Conformis’s patient-specific instrument systems are worthy of patent protection and have granted Conformis over 200 patents on its technologies. The United States Patent and Trademark Office (“USPTO”) awarded a robust patent portfolio that protects Conformis’s inventions relating to its iFit technology, its patient-specific implants, and its iJig® patient-specific instruments, including:

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

13. On March 29, 2016, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 9,295,482 (“the ’482 Patent”), entitled “Patient Selectable Joint Arthroplasty Devices and Surgical Tools,” to Wolfgang Fitz, Philipp Lang, Raymond Bojarski, and Daniel Steines. Conformis is the owner by assignment of the ’482 Patent. A copy of the ’482 Patent is attached hereto as Exhibit B.

14. On January 7, 2014, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 8,623,026 (“the ’026 Patent”), entitled “Patient Selectable Joint Arthroplasty Devices and Surgical Tools Incorporating Surgical Relief,” to Terrence Wong, Raymond Bojarski, Daniel Steines, and Philipp Lang. Conformis is the owner by assignment of the ’026 Patent. A copy of the ’026 Patent is attached hereto as Exhibit C.

15. On May 3, 2016, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 9,326,780 (“the ’780 Patent”), entitled “Patient Selectable Joint Arthroplasty Devices and Surgical Tools Incorporating Anatomical Relief,” to Terrence Wong, Raymond Bojarski, Daniel Steines, and Philipp Lang. Conformis is the owner by assignment of the ’780 Patent. A copy of the ’780 Patent is attached hereto as Exhibit D.

16. On November 17, 2015, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 9,186,161 (“the ’161 Patent”), entitled “Surgical Tools for Arthroplasty,” to Philipp Lang, Wolfgang Fitz, Ray Bojarski, Daniel Steines, Albert G. Burdulis, Jr., and Rene Vargas-Voracek. Conformis is the owner by assignment of the ’161 Patent. A copy of the ’161 Patent is attached hereto as Exhibit E.

17. 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 Wolfgang Fitz, Philipp Lang, 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 F.

18. On December 27, 2011, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 8,083,745 (“the '745 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 '745 Patent. A copy of the '745 Patent is attached hereto as Exhibit G.

19. Collectively, the '304, '482, '026, '780, '161, '129, and '745 Patents are the “Asserted Patents.”

20. This is an action for infringement of the “Asserted Patents.”

IV. FACTUAL BACKGROUND

Conformis's Revolutionary Technology

21. Conformis is the world's leading designer, developer, and manufacturer of patient-specific knee and hip implants and the surgical tools to fit those implants into a specific patient's body. Founded by doctors affiliated with Stanford and Harvard Medical Schools, Conformis began with a revolutionary idea: make the implant fit the patient rather than forcing the patient to fit the implant.

22. For decades before Conformis's innovation—and continuing today—implant manufacturers offered surgeons a standard set of implant sizes, akin to the small-medium-large sizing in off-the-rack department stores. This approach forces the surgeon to pick an implant size that appears closest in fit to the patient's anatomy but is not designed for and does not truly fit each individual patient. The surgeon must therefore make size, shape, and other compromises to fit the implant as best as possible.

23. These blunt efforts are further hampered by using standard tools to implant standard implants, none of which are designed using an individual patient's anatomy. Because of this imprecise approach, patients often suffer loss of movement and function, instability, and lingering pain after surgery.

24. Conformis recognized that the conventional joint-repair process was backwards: rather than fitting the patient to the implant, the implant should be designed and developed specifically for the patient. This produces a better-fitting implant with a 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.

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

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

27. Conformis’s patient-specific knee and hip implant systems are recognized around the world. The U.S. Food and Drug Administration has approved knee and hip implant systems by Conformis for use in the United States. The European Union has approved the knee-implant systems by Conformis for use in Europe. And Conformis currently sells a full line of patient-specific knee- and hip-implant systems in many countries worldwide. To date, Conformis’s patient-specific knee and hip implants and customized tools have helped improve the lives of thousands of Americans.

28. Conformis has complied at all times with the requirements of 35 U.S.C. § 287, at least by marking its patented products through its website, <https://www.conformis.com/patents/>, and otherwise, which included the ’026 Patent, the ’780 Patent, the ’129 Patent, and the ’745 Patent.

DePuy’s Infringing Activities

29. DePuy offers a line of patient-specific surgical systems and proprietary software that also allows surgeons to customize shoulder-implant and knee-implant surgery according to a patient’s unique anatomy (the “Accused Systems”) that includes patient-specific instruments (“PSI”) for use with its shoulder and knee implants. *See generally* Exs. P–W.

30. DePuy markets the Accused Systems relating to its Knee Replacement Solutions (the “Accused Knee Systems”) as its TRUMATCH® Personalized Solutions System and TRUMATCH® Patient Specific Instruments; and associated knee implants, such as, e.g., the SIGMA® Total Knee Implants and ATTUNE® Total Knee Implants. *See* Ex. T. The Accused Knee Systems include femoral and tibial resection guides and femoral and tibial pin guides.

31. DePuy markets the Accused Systems relating to its Shoulder System (the “Accused Shoulder Systems”) as its TRUMATCH® Personalized Solutions Shoulder System

and TRUMATCH Shoulder Guide; and associated shoulder implants, such as, e.g., the GLOBAL™ APG Shoulder System, the GLOBAL™ STEPTECH® APG Shoulder System, and the DELTA XTEND™ Reverse Shoulder System. *See* Ex. R. The Accused Shoulder Systems include shoulder guides.

32. On information and belief, DePuy is infringing the Asserted Patents by making, using, providing, offering to sell, importing, and selling (directly or through intermediaries) the Accused Systems in this District and elsewhere in the United States, and by contributing to the infringement of, or inducing others to infringe the Asserted Patents.

FIRST CLAIM FOR RELIEF

(Infringement of the '304 Patent)

33. Conformis realleges paragraphs 1–31 above as if fully set forth herein.

34. The '304 Patent is a valid, enforceable patent that was duly issued by the USPTO on June 11, 2013. Ex. A.

35. Conformis is the assignee of the '304 Patent with ownership of all substantial rights in the '304 Patent, including the right to exclude others and to enforce, sue, and recover damages for past and future infringements.

36. DePuy has directly infringed, and continues to directly infringe, at least claim 1 of the '304 Patent in violation of 35 U.S.C. § 271(a) by, for example and without limitation, making, using, offering to sell, selling, and/or importing in and into the United States the Accused Systems.

37. Claim 1 of the '304 Patent claims a:

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.

38. DePuy's Accused Systems meet each of the above limitations.

39. A more detailed analysis of DePuy's infringement of the '304 Patent can be found in Exhibit H, which is incorporated in its entirety as if set forth herein.

40. DePuy has actively induced others to infringe at least claim 1 of the '304 Patent in violation of 35 U.S.C. § 271(b) by instructing others to make, use, sell, offer to sell, and import into the United States the Accused Systems.

41. DePuy has also contributed, and continues to contribute, to its customers' and end users' direct infringement of the '304 Patent in violation of 35 U.S.C. § 271(c) by offering for sale and providing the Accused Systems to end-users. The Accused Systems are specially made using joint information derived from image data of an individual patient's joint. Such individualized surgical instruments are not staple articles of commerce and are not suitable for any substantial non-infringing use. This use infringes at least claim 1 of the '304 Patent.

42. Conformis has suffered economic harm because of DePuy's infringing activities in an amount to be proven at trial, but in no case less than a reasonable royalty.

43. DePuy has 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, DePuy will continue to infringe the '304 Patent.

SECOND CLAIM FOR RELIEF

(Infringement of the '482 Patent)

44. Conformis realleges paragraphs 1–42 above as if fully set forth herein.

45. The '482 Patent is a valid, enforceable patent that was duly issued by the USPTO on March 29, 2016. Ex. B.

46. Conformis is the assignee of the '482 Patent with ownership of all substantial rights in the '482 Patent, including the right to exclude others and to enforce, sue, and recover damages for past and future infringements.

47. DePuy has directly infringed, and continues to directly infringe, at least claim 13 of the '482 Patent in violation of 35 U.S.C. § 271(a) by, for example and without limitation, making, using, offering to sell, selling, and/or importing in and into the United States the Accused Systems.

48. Claim 13 of the '482 Patent claims:

A joint arthroplasty system for use in surgically repairing a diseased or damaged joint of a patient, comprising:

an implant; and

a block having a patient-specific surface and a guide:

the patient-specific surface having a first portion configured to have a shape that is substantially a negative of a subchondral bone surface of the diseased or damaged joint and a second portion configured to have a shape that is substantially a negative of a cortical bone surface of the diseased or damaged joint,

wherein the patient-specific surface is configured to reference an osteophyte of the diseased or damaged joint; and

the guide being sized and shaped to accommodate a surgical tool and have a position and orientation relative to the patient-specific surface to provide a predetermined path for the surgical tool that is aligned through a portion of the diseased or damaged joint.

49. DePuy's Accused Systems meet each of the above limitations.

50. A more detailed analysis of DePuy's infringement of the '482 Patent can be found in Exhibit I, which is incorporated in its entirety as if set forth herein.

51. DePuy has actively induced others to infringe at least claim 13 of the '482 Patent in violation of 35 U.S.C. § 271(b) by instructing others to make, use, sell, offer to sell, and import into the United States the Accused Systems.

52. DePuy has also contributed, and continues to contribute, to its customers' and end users' direct infringement of the '482 Patent in violation of 35 U.S.C. § 271(c) by offering for sale and providing the Accused Systems to end-users. The Accused Systems are specially made using joint information derived from image data of an individual patient's joint. Such individualized surgical instruments are not staple articles of commerce and are not suitable for any substantial non-infringing use. This use infringes at least claim 13 of the '482 Patent.

53. Conformis has suffered economic harm because of DePuy's infringing activities in an amount to be proven at trial, but in no case less than a reasonable royalty.

54. DePuy has 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, DePuy will continue to infringe the '482 Patent.

THIRD CLAIM FOR RELIEF

(Infringement of the '026 Patent)

55. Conformis realleges paragraphs 1–53 above as if fully set forth herein.

56. The '026 Patent is a valid, enforceable patent that was duly issued by the USPTO on January 7, 2014. Ex. C.

57. Conformis is the assignee of the '026 Patent with ownership of all substantial rights in the '026 Patent, including the right to exclude others and to enforce, sue, and recover damages for past and future infringements.

58. DePuy has directly infringed, and continues to directly infringe, at least claim 15 of the '026 Patent in violation of 35 U.S.C. § 271(a) by, for example and without limitation, making, using, offering to sell, selling, and/or importing in and into the United States the Accused Systems.

59. Claim 15 of the '026 Patent claims:

A system for joint arthroplasty, the system comprising:

a first template, the first template including:

at least one surface for engaging a first articular surface of a joint, the at least one surface being substantially a negative of portions or all of the first articular surface;

at least a portion of the at least one surface further including an anatomical relief; and

at least one guide for directing movement of a surgical instrument; and

wherein said at least one guide has a predetermined orientation relative to an anatomical or a biomechanical axis associated with the joint.

60. DePuy's Accused Systems meet each of the above limitations.

61. A more detailed analysis of DePuy's infringement of the '026 Patent can be found in Exhibit J, which is incorporated in its entirety as if set forth herein.

62. DePuy has actively induced others to infringe at least claim 15 of the '026 Patent in violation of 35 U.S.C. § 271(b) by instructing others to make, use, sell, offer to sell, and import into the United States the Accused Systems.

63. DePuy has also contributed, and continues to contribute, to its customers' and end users' direct infringement of the '026 Patent in violation of 35 U.S.C. § 271(c) by offering for sale and providing the Accused Systems to end-users. The Accused Systems are specially made using joint information derived from image data of an individual patient's joint. Such

individualized surgical instruments are not staple articles of commerce and are not suitable for any substantial non-infringing use. This use infringes at least claim 15 of the '026 Patent.

64. Conformis has complied with the requirements of 35 U.S.C. § 287(a) at least by virtually marking the Conformis products with the '026 Patent, and otherwise, and by giving actual notice to DePuy by at least May 4, 2021 via the filing of the original Complaint.

65. Conformis has suffered economic harm because of DePuy's infringing activities in an amount to be proven at trial, but in no case less than a reasonable royalty.

66. DePuy has 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, DePuy will continue to infringe the '026 Patent.

FOURTH CLAIM FOR RELIEF

(Infringement of the '780 Patent)

67. Conformis realleges paragraphs 1–64 above as if fully set forth herein.

68. The '780 Patent is a valid, enforceable patent that was duly issued by the USPTO on May 3, 2016. Ex. D.

69. Conformis is the assignee of the '780 Patent with ownership of all substantial rights in the '780 Patent, including the right to exclude others and to enforce, sue, and recover damages for past and future infringements.

70. DePuy has directly infringed, and continues to directly infringe, at least claim 1 of the '780 Patent in violation of 35 U.S.C. § 271(a) by, for example and without limitation, making, using, offering to sell, selling, and/or importing in and into the United States the Accused Systems.

71. Claim 1 of the '780 Patent claims:

A system for joint arthroplasty for repairing a joint of a patient, the system comprising:

a first template, the first template including:

a contact surface for engaging a first articular surface of the joint of the patient, the contact surface including shape information derived from electronic image data of at least a portion of the first articular surface;

at least a relieved portion of the contact surface further including an anatomical relief configured such that when the contact surface engages the first articular surface, the relieved portion does not engage an anatomical structure of the first articular surface; and

at least one guide for directing movement of a surgical instrument; and

wherein the guide has a predetermined orientation relative to one of an anatomical and a biomechanical axis associated with the joint of the patient.

72. DePuy's Accused Systems meet each of the above limitations.

73. A more detailed analysis of DePuy's infringement of the '780 Patent can be found in Exhibit K, which is incorporated in its entirety as if set forth herein.

74. DePuy has actively induced others to infringe at least claim 1 of the '780 Patent in violation of 35 U.S.C. § 271(b) by instructing others to make, use, sell, offer to sell, and import into the United States the Accused Systems.

75. DePuy has also contributed, and continues to contribute, to its customers' and end users' direct infringement of the '780 Patent in violation of 35 U.S.C. § 271(c) by offering for sale and providing the Accused Systems to end-users. The Accused Systems are specially made using joint information derived from image data of an individual patient's joint. Such individualized surgical instruments are not staple articles of commerce and are not suitable for any substantial non-infringing use. This use infringes at least claim 1 of the '780 Patent.

76. Conformis has complied with the requirements of 35 U.S.C. § 287(a) at least by virtually marking the Conformis products with the '780 Patent, and otherwise, and by giving actual notice to DePuy by at least May 4, 2021 via the filing of the original Complaint.

77. Conformis has suffered economic harm because of DePuy's infringing activities in an amount to be proven at trial, but in no case less than a reasonable royalty.

78. DePuy has 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, DePuy will continue to infringe the '780 Patent.

FIFTH CLAIM FOR RELIEF

(Infringement of the '161 Patent)

79. Conformis realleges paragraphs 1-75 above as if fully set forth herein.

80. The '161 Patent is a valid, enforceable patent that was duly issued by the USPTO on November 17, 2015. Ex. E.

81. Conformis is the assignee of the '161 Patent with ownership of all substantial rights in the '161 Patent, including the right to exclude others and to enforce, sue, and recover damages for past and future infringements.

82. DePuy has directly infringed, and continues to directly infringe, at least claim 1 of the '161 Patent in violation of 35 U.S.C. § 271(a) by, for example and without limitation, making, using, offering to sell, selling, and/or importing in and into the United States the Accused Systems.

83. Claim 1 of the '161 Patent claims:

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.

84. DePuy's Accused Systems meet each of the above limitations.

85. A more detailed analysis of DePuy's infringement of the '161 Patent can be found in Exhibit L, which is incorporated in its entirety as if set forth herein.

86. DePuy has actively induced others to infringe at least claim 1 of the '161 Patent in violation of 35 U.S.C. § 271(b) by instructing others to make, use, sell, offer to sell, and import into the United States the Accused Systems.

87. DePuy has also contributed, and continues to contribute, to its customers' and end users' direct infringement of the '161 Patent in violation of 35 U.S.C. § 271(c) by offering for sale and providing the Accused Systems to end-users. The Accused Systems are specially made using joint information derived from image data of an individual patient's joint. Such individualized surgical instruments are not staple articles of commerce and are not suitable for any substantial non-infringing use. This use infringes at least claim 1 of the '161 Patent.

88. Conformis has suffered economic harm because of DePuy's infringing activities in an amount to be proven at trial, but in no case less than a reasonable royalty.

89. DePuy has 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, DePuy will continue to infringe the '161 Patent.

SIXTH CLAIM FOR RELIEF

(Infringement of the '129 Patent)

90. Conformis realleges paragraphs 1–86 above as if fully set forth herein.

91. The '129 Patent is a valid, enforceable patent that was duly issued by the USPTO on February 19, 2013. Ex. F.

92. Conformis is the assignee of the '129 Patent with ownership of all substantial rights in the '129 Patent, including the right to exclude others and to enforce, sue, and recover damages for past and future infringements.

93. DePuy has directly infringed, and continues to directly infringe, at least claim 1 of the '129 Patent in violation of 35 U.S.C. § 271(a) by, for example and without limitation, making, using, offering to sell, selling, and/or importing in and into the United States the Accused Knee Systems.

94. Claim 1 of the '129 Patent claims:

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.

95. DePuy's Accused Systems meet each of the above limitations.

96. A more detailed analysis of DePuy's infringement of the '129 Patent can be found in Exhibit M, which is incorporated in its entirety as if set forth herein.

97. DePuy has actively induced others to infringe at least claim 1 of the '129 Patent in violation of 35 U.S.C. § 271(b) by instructing others to make, use, sell, offer to sell, and import into the United States the Accused Systems.

98. DePuy has also contributed, and continues to contribute, to its customers' and end users' direct infringement of the '129 Patent in violation of 35 U.S.C. § 271(c) by offering for sale and providing the Accused Systems to end-users. The Accused Systems are specially made using joint information derived from image data of an individual patient's joint. Such individualized surgical instruments are not staple articles of commerce and are not suitable for any substantial non-infringing use. This use infringes at least claim 1 of the '129 Patent.

99. Conformis has complied with the requirements of 35 U.S.C. § 287(a) at least by virtually marking the Conformis products with the '129 Patent, and otherwise, and by giving actual notice to DePuy by at least May 4, 2021 via the filing of the original Complaint.

100. Conformis has suffered economic harm because of DePuy's infringing activities in an amount to be proven at trial, but in no case less than a reasonable royalty.

101. DePuy has 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, DePuy will continue to infringe the '129 Patent

SEVENTH CLAIM FOR RELIEF

(Infringement of the '745 Patent)

102. Conformis realleges paragraphs 1–97 above as if fully set forth herein.

103. The '745 Patent is a valid, enforceable patent that was duly issued by the USPTO on December 27, 2011. Ex. G.

104. Conformis is the assignee of the '745 Patent with ownership of all substantial rights in the '745 Patent, including the right to exclude others and to enforce, sue, and recover damages for past and future infringements.

105. DePuy has directly infringed, and continues to directly infringe, at least claim 1 of the '745 Patent in violation of 35 U.S.C. § 271(a) by, for example and without limitation,

making, using, offering to sell, selling, and/or importing in and into the United States the Accused Systems.

106. Claim 1 of the '745 Patent claims:

A surgical instrument for use in surgically repairing a diseased or damaged joint of a patient, comprising:

a cutting block having a patient-specific surface and a guide configured to accommodate a surgical tool for cutting or drilling tissue;

at least a portion of the patient-specific surface having a shape that is substantially a negative of a corresponding cartilage surface of the diseased or damaged joint; and

the guide having a position and orientation relative to the patient-specific surface to define a predetermined cutting path for the surgical tool that is aligned through a portion of tissue associated with the diseased or damaged joint when the patient specific surface is placed against and aligned with the corresponding cartilage surface; and

wherein the cutting block containing the patient-specific surface and the guide is a single component.

107. DePuy's Accused Systems meet each of the above limitations.

108. A more detailed analysis of DePuy's infringement of the '745 Patent can be found in Exhibit N, which is incorporated in its entirety as if set forth herein.

109. DePuy has actively induced others to infringe at least claim 1 of the '745 Patent in violation of 35 U.S.C. § 271(b) by instructing others to make, use, sell, offer to sell, and import into the United States the Accused Systems.

110. DePuy has also contributed, and continues to contribute, to its customers' and end users' direct infringement of the '745 Patent in violation of 35 U.S.C. § 271(c) by offering for sale and providing the Accused Systems to end-users. The Accused Systems are specially made using joint information derived from image data of an individual patient's joint. Such

individualized surgical instruments are not staple articles of commerce and are not suitable for any substantial non-infringing use. This use infringes at least claim 1 of the '745 Patent.

111. Conformis has complied with the requirements of 35 U.S.C. § 287(a) at least by virtually marking the Conformis products with the '745 Patent, and otherwise, and by giving actual notice to DePuy by at least May 4, 2021 via the filing of the original Complaint.

112. Conformis has suffered economic harm because of DePuy's infringing activities in an amount to be proven at trial, but in no case less than a reasonable royalty.

113. DePuy has 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, DePuy will continue to infringe the '745 Patent.

V. PRAYER FOR RELIEF

WHEREFORE, Conformis requests entry of judgment in its favor and against DePuy as follows:

1. Entry of judgment holding DePuy liable for infringement of the Asserted Patents;
2. An order permanently enjoining each Defendant, its officers, agents, servants, employees, attorneys and affiliated companies, its assigns and successors in interest, and those persons in active concert or participation with it, from continued acts of infringement of the Asserted Patents;
3. An order awarding Conformis statutory damages and damages according to proof resulting from DePuy's past, current, and future infringement of the '026 Patent, '780 Patent, '129 Patent, and '745 Patent; current and future infringement of the '304 Patent, '482 Patent, and '161 Patent; together with prejudgment and post-judgment interest;

4. A declaration that this case is exceptional under 35 U.S.C. § 285, and an award of Conformis's reasonable attorneys' fees;

5. Any and all other legal or equitable relief as may be available under law and which the Court may deem proper.

VI. JURY DEMAND

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

Dated: November 15, 2021

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