

**UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION**

CONFORMIS, INC.,

Plaintiff,

v.

EXACTECH, INC.

Defendant.

Civil Action No.:

**COMPLAINT FOR PATENT INFRINGEMENT, PERMANENT
INJUNCTIVE RELIEF REQUESTED,
AND DEMAND FOR A JURY TRIAL**

Plaintiff Conformis, Inc. (“Conformis”), for its Complaint and demand for a jury trial seeking relief for patent infringement against Defendant Exactech, Inc. (“Exactech” or “Defendant”), 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. On information and belief, Defendant Exactech, Inc. is a corporation organized under the laws of the State of Florida, and maintains a place of business at 1189 Tallevast Road, Sarasota, Florida 34243.

II. JURISDICTION AND VENUE

3. 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.*

4. Exactech is subject to this Court's general and specific personal jurisdiction at least because: Exactech is at home in the State of Florida where it is incorporated; Exactech has registered agents for service of process in Florida, regularly conducts business in the State of Florida and within this judicial district, and has substantial and continuous contacts within this judicial district; Exactech has purposefully availed itself of the privileges of conducting business in this judicial district and has a regular and established place of business in this judicial district; and Exactech has committed acts of patent infringement in this judicial district by selling and offering to sell products and services throughout the United States, including in this judicial district, and introducing infringing products and services into the stream of commerce knowing that they would be sold in this judicial district and elsewhere in the United States.

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

III. THE ASSERTED PATENTS

6. 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 System, and related surgical techniques. The technology covered by this patent portfolio is applicable to major joint systems, including knee, hip, shoulder, and ankle joints.

7. 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:

8. 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.

9. 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.

10. 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.

11. 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.

12. 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.

13. Collectively, the '304, '482, '026, '780, and '161 Patents are the "Asserted Patents."

14. This is an action for infringement of the Asserted Patents.

IV. FACTUAL BACKGROUND

Conformis's Revolutionary Technology

15. 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.

16. 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.

17. 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.

18. 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.

19. 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.

20. 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.

21. Conformis's patient-specific 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 Conformis's knee-implant systems 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 implants and customized tools have helped improve the lives of thousands of Americans.

Exactech's Infringing Activities

22. Exactech offers a line of patient-specific surgical systems and proprietary software that allows surgeons to customize ankle-implant surgery according to a patient's unique anatomy that includes patient-specific instruments ("PSI") for use with its ankle implants (the "Accused System"). *See generally* Exs. K-T.

23. On March 10, 2016, the Food and Drug Administration (FDA) provided 510(k) clearance for the Vantage® Total Ankle System under the Device

Classification Name: “Prosthesis, Ankle, Semi-Constrained, Cemented, Metal/Polymer.” Ex. T at 1. On November 09, 2020, the FDA provided 510(k) clearance for the Vantage® Ankle PSI under the Device Classification Name: “Ankle Arthroplasty Implantation System.” Ex. K at 1.

24. Exactech markets the Accused System relating to its Ankle Replacement Solutions as its Vantage® Total Ankle System and Vantage® Ankle PSI, part of its Active Intelligence® initiative. *See e.g.* Exs. L, Q.

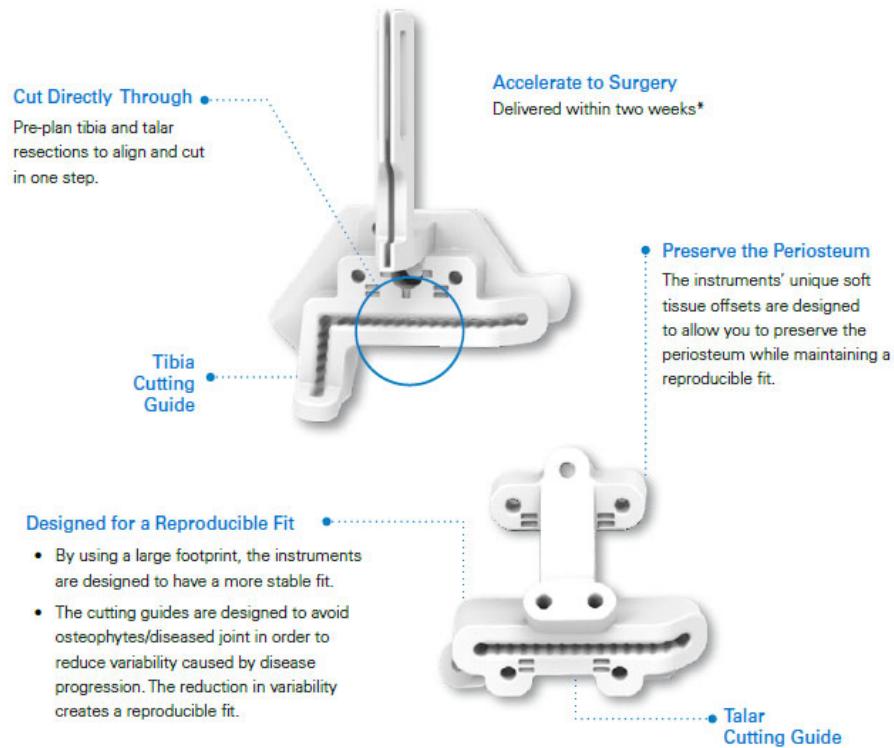


Final X-ray of the total ankle procedure that used the Vantage Ankle PSI.

Ex. M at 3. The Accused System includes 3D-printed tibia and talar cutting guides and the associated ankle implants. Ex. M at 3-4.

25. Exactech markets its Vantage® Ankle PSI 3D-printed tibia and talar cutting guides as “designed for patients’ unique anatomies” and stating that they

“allow surgeons to pre-plan, are part of Exactech’s Active Intelligence® initiative and are used exclusively with the Vantage Total Ankle System.” Ex. L at 2.



Id. The “cutting guides are created from patients’ CT scans and delivered in approximately two weeks. The cutting slots on the instrumentation feature a rippled surface to allow water to flow through to keep the bone cool during surgery. In addition, the instrumentation features soft tissue offsets, which are designed to allow the surgeon to remove less soft tissue.” Ex. M at 3-4.

26. On information and belief, Exactech is infringing the Asserted Patents by making, using, providing, offering to sell, importing, and selling (directly or through intermediaries) the Accused System 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)

27. Conformis realleges paragraphs 1–26 above as if fully set forth herein.
28. The '304 Patent is a valid, enforceable patent that was duly issued by the USPTO on June 11, 2013. Ex. A.
29. 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.
30. Exactech 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 System.

31. Claim 1 of the '304 Patent claims:

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.

32. Exactech's Accused System meets each of the above limitations.

33. A more detailed analysis of Exactech's infringement of the '304

Patent can be found in Exhibit F, which is incorporated in its entirety as if set forth herein.

34. Exactech 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 System.

35. Exactech 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 System to end-users. The Accused System is 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. Exactech's use infringes at least claim 1 of the '304 Patent.

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

37. Exactech 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, Exactech will continue to infringe the '304 Patent.

SECOND CLAIM FOR RELIEF

(Infringement of the '482 Patent)

38. Conformis realleges paragraphs 1–37 above as if fully set forth herein.

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

40. 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.

41. Exactech has directly infringed, and continues to directly infringe, at least claim 1 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 System.

42. Claim 1 of the '482 Patent claims:

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.

43. Exactech's Accused System meets each of the above limitations.

44. A more detailed analysis of Exactech's infringement of the '482

Patent can be found in Exhibit G, which is incorporated in its entirety as if set forth herein.

45. Exactech has actively induced others to infringe at least claim 1 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 System.

46. Exactech 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 System to end-users. The Accused System 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. Exactech's use infringes at least claim 1 of the '482 Patent.

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

48. Exactech 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, Exactech will continue to infringe the '482 Patent.

THIRD CLAIM FOR RELIEF

(Infringement of the '026 Patent)

49. Conformis realleges paragraphs 1–48 above as if fully set forth herein.

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

51. 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.

52. Exactech has directly infringed, and continues to directly infringe, at least claim 24 of the '026 Patent in violation of 35 U.S.C. § 271(a) and/or (g) by, for example and without limitation, making, using, offering to sell, selling, and/or importing in and into the United States the Accused System.

53. Claim 24 of the '026 Patent claims:

A method of making a surgical tool, the method comprising:

- obtaining image data associated with at least a portion of a joint;
- deriving joint surface information from the image data;
- determining at least a portion of the joint surface to be engaged by a contact surface;
- determining an anatomical structure to be disengaged from a corresponding anatomical relief surface, and
- providing a surgical tool that includes a guide, the contact surface and the anatomical relief surface, the contact surface for engaging at least a portion of the joint surface, the anatomical relief surface being substantially disengaged from the anatomical structure when the contact surface is engaged with the at least a portion of the joint surface, the guide being configured to direct movement of a surgical instrument.

54. Exactech's Accused System meets each of the above limitations and/or are made by processes that meet each of the above limitations.

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

56. Exactech has actively induced others to infringe at least claim 24 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 System.

57. Exactech 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 System to end-users. The Accused System 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. Exactech's use infringes at least claim 24 of the '026 Patent.

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

59. Exactech 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, Exactech will continue to infringe the '026 Patent.

FOURTH CLAIM FOR RELIEF

(Infringement of the '780 Patent)

60. Conformis realleges paragraphs 1–59 above as if fully set forth herein.
61. The '780 Patent is a valid, enforceable patent that was duly issued by the USPTO on May 3, 2016. Ex. D.
62. 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.
63. Exactech 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 System.

64. 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.

65. Exactech's Accused System meets each of the above limitations.

66. A more detailed analysis of Exactech's infringement of the '780

Patent can be found in Exhibit I, which is incorporated in its entirety as if set forth herein.

67. Exactech 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 System.

68. Exactech 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 System to end-users. The Accused System 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. Exactech's use infringes at least claim 1 of the '780 Patent.

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

70. Exactech 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, Exactech will continue to infringe the '780 Patent.

FIFTH CLAIM FOR RELIEF

(Infringement of the '161 Patent)

71. Conformis realleges paragraphs 1–70 above as if fully set forth herein.

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

73. 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.

74. Exactech 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 System.

75. 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.

76. Exactech's Accused System meets each of the above limitations.

77. A more detailed analysis of Exactech's infringement of the '161

Patent can be found in Exhibit J, which is incorporated in its entirety as if set forth herein.

78. Exactech 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 System.

79. Exactech 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 System to end-users. The Accused System 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. Exactech's use infringes at least claim 1 of the '161 Patent.

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

81. Exactech 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, Exactech will continue to infringe the '161 Patent.

V. PRAYER FOR RELIEF

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

1. Entry of judgment holding Exactech liable for infringement of the Asserted Patents;
2. An order permanently enjoining Exactech, 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 Exactech's past, current, and future infringement

of the Asserted Patents, 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: June 3, 2021.

Respectfully submitted,

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