IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

Defendant.)
ZIMVIE INC.,) JURY TRIAL DEMANDED
V.) C.A. No
Plaintiff,)
ROGER P. JACKSON, M.D.,)

COMPLAINT

Roger P. Jackson, M.D. (hereinafter "Plaintiff" or "Dr. Jackson"), an individual, by and through his attorneys, for his Complaint against ZIMVIE Inc. a Delaware corporation (hereinafter and in the exhibits as "Defendant" or "Zimmer") hereby alleges as follows:

PARTIES, JURISDICTION AND VENUE

1. Plaintiff Roger P. Jackson, M.D. is an individual residing at 4706 W. 86th Street, Prairie Village, Kansas 66207.

2. Defendant ZIMVIE Inc. is a Delaware Corporation having its primary place of business at "Zimmer Biomet Spine, Inc., 10225 Westmoor Dr., Westminster, CO 80021," according to the ZIMVIE Inc. website. *See <u>https://www.zimvie.com/en/locations-global-</u> <i>contacts.html* (retrieved March 31, 2022).

3. According to a March 1, 2022, Press Release, ZIMVIE Inc. is the result of a spinoff of stock from Zimmer Biomet Holdings, Inc. "achieved through the distribution of 80.3% of the shares of ZimVie to holders of Zimmer Biomet common stock." *See https://investor.zimmerbiomet.com/news-and-events/news/2022/03-01-2022-120035502* (retrieved March 31, 2022). 4. Upon information and belief, ZIMVIE is the spun-off successor of Zimmer Biomet Spine, Inc.

5. Zimmer Biomet Spine, Inc. is a Delaware Corporation having its primary place of business at 10225 Westmoor Dr., Westminster, CO 80021. Zimmer Biomet Spine, Inc., or one of its predecessors-in-interest, is listed as the Applicant on the FDA's "510k Premarket Notification" associated with the spinal fixation systems accused of patent infringement herein.

6. Upon information and belief, Zimmer Biomet Spine, Inc. is a wholly owned subsidiary of Zimmer Biomet Holdings, Inc. Zimmer Biomet Holdings, Inc. is a Delaware Corporation having its principal place of business at 345 Main Street, Warsaw, Indiana 46580.

7. This action arises under the patent laws of the United States, Title 35 of the United States Code, 35 U.S.C. §§ 1 *et seq.* Consequently, this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a). Further, this Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1367 because the state law claims are so related to the patent infringement claims filed by Dr. Jackson over which this Court has original jurisdiction as to for part of the same case or controversy.

8. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(1) or (2). Venue is also proper in this Court pursuant to 28 U.S.C. § 1400(a) and (b).

9. Defendant Zimmer is subject to personal jurisdiction in this Court under 28 U.S.C.
 § 1391 as Zimmer is incorporated in the State where this District resides.

THE ASSERTED PATENTS

10. Plaintiff Dr. Jackson is a pioneering surgeon who focuses on maladies of the spine and is also a prolific inventor in the spinal implant industry. Dr. Jackson has been awarded over three hundred-fifty United States patents during a career spanning four decades. Among his many

innovations in the field of spinal surgery, Dr. Jackson has developed state-of-the-art patient positioning technologies and multiple spinal implant systems, involving rods and connectors that include separately inserted, pivotal bone screws incorporating one or more of his patented enabling technologies, as well as instruments and methodologies for using the same with the implant systems and their separately inserted related system components, such as hooks, screws, connectors, plates, rods, closures, etc. In particular, Dr. Jackson is a named inventor, sole owner and/or exclusive licensee (with substantially all of the rights therein to license, litigate and prosecute) certain patents, specifically: U.S. Patent Nos. 7,837,716; 8,911,479; 9,662,143; 9,808,292; 9,980,753; 9,999,452; 10,064,660; 10,524,840; 10,537,366; 10,548,641; 10,898,233; 10,952,777; 11,045,229; 11,129,646; and 11,134,993. Collectively, these patents will be referred to herein as the "Asserted Patents."

11. The Asserted Patents generally relate to spinal fixation systems composed of separately inserted implants used to fixate or align vertebrae of a patient by attachment thereto. Each of the Asserted Patents has been duly and legally issued, is valid and enforceable pursuant to 35 U.S.C. § 282. Plaintiff Dr. Jackson either solely owns all right, title and interest in each of the Asserted Patents or solely controls all substantive rights in each the Asserted Patents by way of an exclusive license agreement, as detailed below.

12. Plaintiff Dr. Jackson has satisfied the requirements of 35 U.S.C. § 287(a). As Dr. Jackson does not manufacture and sell products covered by the Asserted Patents, he himself does not have an obligation under § 287(a) to mark. However, Dr. Jackson has licensees — all of whom have a contractual obligation to mark the patents that they are licensed under.

Furthermore, Dr. Jackson provided actual notice of certain of the Asserted Patents
 to Defendant Zimmer prior to the filing of this Complaint, as detailed below.

U.S. Patent No. 7,837,716

14. Plaintiff owns all right, title and interest in U.S. Patent No. 7,837,716 (hereinafter the `716 patent), entitled "Threadform for Medical Implant Closure." The `716 patent duly and lawfully issued on November 23, 2010, with Roger Jackson as the sole named inventor. The `716 patent issued from Application No. 10/964,156, which was filed on October 13, 2004, and on its face ultimately claims priority to Application No. 09/644,777, filed on August 23, 2000. A true and correct copy of the `716 patent is attached hereto as **Exhibit 1.**

U.S. Patent No. 8,911,479

15. Plaintiff owns all right, title and interest in U.S. Patent No. 8,911,479 (hereinafter the '479 patent), entitled "Multi-Start Closures For Open Implants." The '479 patent duly and lawfully issued on December 16, 2014, with Roger Jackson and James Surber as the named inventors. The '479 patent issued from Application No. 13/694,849, which was filed on January 10, 2013, and on its face ultimately claims priority to Provisional Applications No. 61/631,746, filed on January 10, 2012, and 61/634,631, filed on February 28, 2012. A true and correct copy of the '479 patent is attached hereto as **Exhibit 2.**

U.S. Patent No. 9,662,143

16. Plaintiff owns all right, title and interest in U.S. Patent No. 9,662,143 (hereinafter the `143 patent), entitled "Dynamic Fixation Assemblies with Inner Core and Outer Coil-Like Member." The `143 patent duly and lawfully issued on May 30, 2017, with Roger Jackson as the sole named inventor. The `143 patent issued from Application 14/557,945, which was filed on December 2, 2014, and on its face ultimately claims priority to Application No. 11/522,503, filed on September 14, 2006, and to Provisional Application Nos.: 60/722,300, filed on September 30, 2005; 60/725,445, filed on October 11, 2005; 60/736,112, filed on November 10, 2005;

60/832,644, filed on July 21, 2005; 60/630,536, filed on November 23, 2004; and 60/655,239, filed on February 22, 2005. A true and correct copy of the `143 patent is attached hereto as **Exhibit 3**.

U.S. Patent No. 9,808,292

17. Plaintiff owns all right, title and interest in U.S. Patent No. 9,808,292 (hereinafter the `292 patent), entitled "Cannulated Polyaxial Screw." The `292 patent duly and lawfully issued on Nov. 7, 2017, with Roger Jackson as the sole named inventor. The `292 patent issued from Application No. 14/868,213, which was filed on September 28, 2015, and ultimately claims priority to Application No. 10/464,633, which was filed on June 18, 2003. A true and correct copy of the `292 patent is attached hereto as **Exhibit 4**.

U.S. Patent No. 9,980,753

18. Plaintiff owns all right, title and interest in U.S. Patent No. 9,980,753 (hereinafter the `753 patent), entitled "Pivotal Anchor with Snap-In-Place Insert Having Rotation Blocking Extensions." The `753 patent duly and lawfully issued on May 29, 2018, with Roger Jackson and James Surber as the named inventors. The `753 patent issued from Application No. 13/374,439, which was filed on December 29, 2011, and on its face ultimately claims priority to Provisional Application Nos.: 61/460,267, filed on December 29, 2010; 61/463,038, filed on February 11, 2011; 61/,456,649 filed on November 10, 2010; 61/460,234, filed on December 29, 2010; 61/278,240 filed on October 5, 2009; 61/336,911 filed on January 28, 2010; 61/343,737, filed on May 3, 2010; 61/395,564, filed on May 14, 2010; 61/395,752, filed on May 17, 2010; 61/396,390 filed on May 26, 2010; 61/398,807, filed on July 1, 2010; 61/400,504 filed on July 29, 2010; 61/402,959, filed on Sep. 8, 2010; 61/403,696, filed on September 20, 2010; 61/403,915, filed on September 23, 2010; 61/403,915, filed on September 23, 2010; 61/268,708, filed on June 15, 2009;

and 61/270,754, filed on July 13, 2009. A true and correct copy of the `753 patent is attached hereto as **Exhibit 5.**

U.S. Patent. No. 9,999,452

19. Plaintiff owns all right, title and interest in U.S. Patent No. 9,999,452 (hereinafter the '452 patent), entitled "Bone Anchor Receiver with Upper Tool Engaging Grooves and Planar Faces." The '452 patent duly and lawfully issued on June 19, 2018 with Roger Jackson as the sole named inventor. The '452 patent issued from Application No. 15/867,095, which was filed on January 10, 2018, and on its face ultimately claims priority to Application No. 10/996,349, filed on November 23, 2004 (now Patent No. 7,621,918). A true and correct copy of the '452 patent is attached hereto as **Exhibit 6.**

U.S. Patent No. 10,064,660

20. Plaintiff owns all right, title and interest in U.S. Patent No. 10,064,660 (hereinafter the '660 patent), entitled "Pivotal Bone Anchor Assembly with Interference Fit Insert." The '660 patent duly and lawfully issued on September 4, 2018 with Roger Jackson as the sole named inventor. The '660 patent issued from Application No. 15/702,442 and on its face ultimately claims priority to Application No. 11/140,343, filed on May 27, 2005 (now U.S. Patent No. 7,776,067). A true and correct copy of the '660 patent is attached hereto as **Exhibit 7**.

U.S. Patent No. 10,524,840

21. Plaintiff exclusively controls substantially all rights and interest in U.S. Patent No. 10,524,840 (hereinafter the `840 patent), entitled "Variable Angle Bone Anchor Assembly Having Biased Bushing Press Fitment." The `840 patent duly and lawfully issued on January 7, 2020, with Thomas Purcell, Don Hair and Tamas Frech as the named inventors. Plaintiff acquired substantially all rights and interest in the `840 patent, including the exclusive and unlimited right

to grant licenses to others, by way of an exclusive license with the title holder of the `840 patent, Alphatec Spine, Inc. A true and correct copy of this agreement is attached hereto as **Exhibit 8**.

22. The `840 patent issued from Application No. 16/372,240, which was filed on April 1, 2019, and on its face ultimately claims priority to Provisional Application Nos. 60/527,060, filed on December 4, 2003, and 60/472,578, filed on May 22, 2003. A true and correct copy of the `840 patent is attached hereto as **Exhibit 9**.

U.S. Patent No. 10,537,366

23. Plaintiff exclusively controls substantially all rights and interest in U.S. Patent No. 10,537,366 (hereinafter the `366 patent), entitled "Pivotal Bone Anchor Assembly with Snap-In-Place Bushing for Pre-Lock Friction Fit." The `366 patent duly and lawfully issued on January 21, 2020, with Thomas Purcell, Don Hair and Tamas Frech as the named inventors. Plaintiff acquired substantially all rights and interest in the `366 patent, including the exclusive and unlimited right to grant licenses to others, by way of an exclusive license with the title holder of the `366 patent, Alphatec Spine, Inc. A true and correct copy of this agreement is attached hereto as **Exhibit 8.**

24. The `366 patent duly and lawfully issued from Application No. 16/374,500, which was filed on April 3, 2019, and on its face ultimately claims priority to Provisional Application Nos. 60/527,060, filed on December 4, 2003, and 60/472,578, filed on May 22, 2003. A true and correct copy of the `366 patent is attached hereto as **Exhibit 10.**

U.S. Patent No. 10,548,641

25. Plaintiff owns all right, title and interest in U.S. Patent No. 10,548,641 (hereinafter the `641 patent), entitled "Medical Implant Receivers Having Dual Lead In Closure Mating Thread Forms." The `641 patent duly and lawfully issued on February 4, 2020, with Roger Jackson and

James Surber as the named inventors. The '641 patent issued from Application No. 15/964,502, which was filed on April 27, 2018, and on its face ultimately claims priority to Provisional Application Nos. 61/631,746, filed on January 10, 2012, and 61/634,361, filed on February 28, 2012. A true and correct copy of the '641 patent is attached as **Exhibit 11**.

U.S. Patent No. 10,898,233

26. Plaintiff owns all right, title and interest in U.S. Patent No. 10,898,233 (hereinafter the '233 patent), entitled "Medical Implant Receivers Having Dual Lead In Closure Mating Thread Forms and Curvate Extending Instrument Engaging Grooves." The '233 patent duly and lawfully issued on January 26, 2021, with Roger Jackson and James Surber as the named inventors. The '233 patent issued from Application No. 16/779,304, which was filed on January 31, 2020, and on its face ultimately claims priority to Provisional Application Nos. 61/631,746, filed on January 10, 2012, and 61/634,361, filed on February 28, 2012. A true and correct copy of the '233 patent is attached hereto as **Exhibit 12**.

U.S. Patent No. 10,952,777

27. Plaintiff owns all right, title and interest in U.S. Patent No. 10,952,777 (hereinafter the `777 patent), entitled "Pivotal Bone Screw Assembly with Receiver Having Threaded Open Channel and Lower Opening." The `777 patent duly and lawfully issued on Mar. 23, 2021, with Roger Jackson as the sole named inventor. The `777 patent issued from Application No. 12/462,623 which was filed on Aug. 6, 2009, and ultimately claims priority to Application No. 10/409,935 (now U.S. Patent No. 6,964,666), which was filed on Apr. 9, 2003. A true and correct coy of the `777 patent is attached hereto as **Exhibit 13.**

U.S. Patent No. 11,045,229

28. Plaintiff owns all right, title and interest in U.S. Patent No. 11,045,229 (hereinafter the '229 patent), entitled "Bone Anchor Receiver with Outer Tool Engaging Grooves Above an Internal Insert Constraining Recess." The '229 patent duly and lawfully issued on June 29, 2021, with Roger Jackson as the sole named inventor. The '229 patent issued from Application No. 16/671,527, which was filed on Nov. 1, 2019, and on its face ultimately claims priority to Provisional Application Nos.: 60/832,644, filed on July 21, 2006; 60/736,112, filed on November 10, 2005; 60/728,912, filed on Oct. 21, 2005; 60/725,445, filed on October 11, 2005; and 60/722,300 filed on September 30, 2005. A true and correct copy of the '229 patent is attached hereto as **Exhibit 14**.

U.S. Patent No. 11,129,646

29. Plaintiff owns all right, title and interest in U.S. Patent No. 11,129,646 (hereinafter the '646 patent), entitled "Medical Implant Threaded Plug Having a Start Structure with Symmetrically Shaped Concave and Convex Leading Surfaces." The '646 patent duly and lawfully issued on September 28, 2021, with Roger Jackson and James Surber as the named inventors. The '646 patent issued from Application No. 17/123,499, which was filed on December 16, 2020, and on its face ultimately claims priority to Provisional Application Nos. 61/634,361, filed on February 28, 2012, and 61/631,746, which was filed on January 10, 2012. A trued and correct copy of the '646 patent is attached hereto as **Exhibit 15**.

U.S. Patent No. 11,134,993

30. Plaintiff owns all right, title and interest in U.S. Patent No. 11,134,993 (hereinafter the `993 patent), entitled "Pivotal Bone Anchor Assembly with Snap-In-Place Insert." The `993 patent duly and lawfully issued on October 5, 2021, with Roger Jackson as the sole named

inventor. The `993 patent issued from Application No. 17/136,779, which was filed on December 29, 2020, and ultimately claims priority to Provisional Applications: No. 60/832,644, filed Jul. 21, 2006; No. 60/736,112, filed Nov. 10, 2005; No. 60/728,912, filed Oct. 21, 2005; No. 60/725,445, filed Oct. 11, 2005; and No. 60/722,300, filed Sep. 30, 2005. A true and correct copy of the `993 patent is attached hereto as **Exhibit 16.**

ZIMMER'S UNAUTHORIZED USE OF DR. JACKSON'S CONFIDENTIAL INFORMATION, BREACH OF CONFIDENTIALITY AGREEMENTS AND UNAUTHORIZED USE OF DR. JACKSON'S ASSERTED PATENTS

31. As alleged above, upon information and belief, Defendant is the successor of Zimmer Spine, Inc. and is a "spin off" of Zimmer Biomet Holdings, Inc. Defendant's former parent corporation Zimmer Biomet Holdings Inc., among other things, manufactures and sells a wide spectrum of medical devices, implants and other items through its various subsidiaries and business units. According to Zimmer Biomet Holdings Inc.'s 10k SEC filing for 2019, Zimmer Biomet Holdings Inc. generally divided its products into several categories, including Knees, Hips, S.E.T., Spine & CMF (Cranial Maxillo Facial), Dental and Others. *See* Exhibit 17, Zimmer Biomet Holdings Inc. 10k 2019 at p. 2. In 2019, the Spine & CMF division reported annual sales of approximately \$747 million dollars. *Id.*

32. Upon information and belief, what later became Zimmer Biomet Holdings Inc. was "spun off" from the Bristol-Myers Squibb company in 2001. After becoming independent, Zimmer Biomet Holdings Inc. built up its business through a series of acquisitions in the medical device industry. Among those acquisitions were Abbott Spine, Inc. in 2008 and Biomet, Inc. in 2015. Further, upon information and belief, at least portions of Biomet, Inc. (among potentially other business units) were combined and/or reorganized to form the Defendant in approximately 2015 or 2016.

33. Upon information and belief, Biomet, Inc. had also acquired several businesses in the medical device industry prior to being absorbed into Zimmer Biomet Holdings Inc. in 2015 or 2016. Among those acquisitions were Electronic-Biology Inc., which was acquired by Biomet, Inc. in 1988, and Interpore Cross International, Inc., which was acquired by Biomet, Inc. in 2004.

Predecessor Licenses:

34. Prior to their ultimate acquisition by Zimmer Biomet Holdings Inc., Abbott Spine, Inc., Interpore Cross International, Inc. and Electronic-Biology, Inc. entered into license agreements with Dr. Jackson. Abbott Spine Inc. first entered into a license agreement with Dr. Jackson on or about July 1, 2007. Interpore Cross International, Inc. first entered into a license agreement with Dr. Jackson on or about June 18, 2001. Electronic-Biology, Inc. first entered into a license agreement with Dr. Jackson on January 1, 2005. By virtue of the various acquisitions described above, the Defendant Zimmer Biomet Spine Inc. (now ZimVie) inherited certain rights from licenses granted by Dr. Jackson. Hereinafter, these license agreements, including any amendments and addendums thereto, are referred to as the "Predecessor Licenses."

35. The Predecessor Licenses included certain rights to patents and technologies invented and developed by Dr. Jackson. However, the Predecessor Licenses do not include rights to the specific products accused of infringement herein. In particular, with respect to the `716 patent (the sole Asserted Patent included within any of the Predecessor Licenses), Defendant obtained a narrow and limited license to certain "Non Break Off Closure Tops," which was defined by the Abbott Spine Agreement as:

non break off closure plugs and/or tops utilizing an internal print for driving and removal, and utilizing the Thread Forms or Helical Flanges ... that are used in open spinal implants. The Non Break Off Closure System is limited to those elements

identified in Schedule 1.10(b) and includes (i) open implants such as hooks, fixed and polyaxial screws and connectors, that can be closed with said Non Break Off Closure Tops, or (ii) Non Break Off Closure Tops that are used to close Polyaxial Screws identified in Section 1.10(d) below."

"Polyaxial Screws" were defined in the Predecessor License to Abbott as polyaxial screw products having an exclusive license from Dr. Jackson and a shank head "with at least one wedge or spline projection," among other requirements. The specific allegations of infringement contained herein for the `716 patent exclude those items falling within the Abbott license, as detailed below.

Zimmer Mutual Confidentiality and First Right of Refusal Agreement (as Amended and Extended):

36. Separate and apart from the discussions with those entities that entered the "Predecessor Licenses," under which Defendant later inherited rights, Defendant entered discussions with Plaintiff Dr. Jackson about the development of additional spinal implant products prior to and during 2010.

37. Further, upon information and belief, Zimmer Spine, Inc. through various acquisitions and reorganizations became Zimmer Biomet Spine, Inc., which later became the Defendant through a spin off. Accordingly, to avoid confusion "Zimmer Spine, Inc." will be referred to herein as Defendant.

38. As a result of these on-going discussions, on May 12, 2010, Plaintiff Dr. Jackson entered into a Mutual Confidential Information Disclosure Agreement "for the purpose of evaluating a potential relationship" between the parties relating to Dr. Jackson's inventive "pop-on polyaxial screw design ('the Subject')". <u>Exhibit 18</u>. On July 1, 2010, the Mutual Confidentiality Information Disclosure Agreement was amended to provide further detail regarding its "Subject." <u>Exhibit 18</u> (collectively, the Mutual Confidential Information Disclosure

Agreement and the amendments thereto, will hereinafter be referred to as the "Confidentiality Agreement"). Otherwise, per Section 2 of the Amendment, "[a]ll other terms and provisions ... remain unchanged and in full force and effect." *Id*. The original Confidentiality Agreement is subject to Minnesota law, and its confidentiality protections had no expiration date. *Id*. at Section 7.

39. Under the Confidentiality Agreement, Defendant agreed to protect Dr. Jackson's "Confidential Information," which included but was not limited to "any and all ... know-how, and data, technical or non-technical, that relates to the Subject." *Id.* at Section 1.

40. More specifically, Defendant agreed to protect Dr. Jackson's "Confidential Information with at least a level of care equal to that given by [Defendant] to its own confidential and proprietary information (but no less than reasonable care), and [agreed to] not disclose the Confidential Information to any third party." *Id.* at Section 2. Further, Defendant agreed to internally disclose Dr. Jackson's Confidential Information "only to those employees who have a need to know of it." *Id.* at Section 3.

41. Finally, Defendant agreed that it would "not use the Confidential Information for any purpose other than" to evaluate the potential relationship between the parties as set forth in the recitals. *Id.* at Section 4.

42. While the original Confidentiality Agreement states that it would be effective for a term of one year from the date of the agreement, "[t]ermination or expiration of this Agreement shall not, however, affect obligations set forth in this Agreement with respect to Confidential Information disclosed prior to termination or expiration." *Id.* at Section 11.

43. Importantly, the Confidentiality Agreement did not provide Defendant with a license to Dr. Jackson's Confidential Information as the Confidentiality Agreement provided that

"[n]othing in this Agreement will be construed as a license or other authorization for [Defendant] to use or practice the Confidential Information disclosed pursuant to this Agreement." *Id.* at Section 5.

44. Beginning on or about May 17, 2010, and continuing thereafter on multiple occasions, Dr. Jackson provided Confidential Information to Defendant pursuant to the Confidentiality Agreement. Specifically, Dr. Jackson provided Defendant with access to prototypes, photographs of prototypes, engineering drawings, design models and other disclosures as well as other supportive design documentation. Further, Dr. Jackson also met with employees of Defendant on November 28, 2011, and on December 12, 2011, and answered further questions regarding his pop-on polyaxial screw design and its associated technologies, including fasteners with dual lead thread forms and receivers with curvate extending instrument engaging grooves.

45. The Confidentiality Agreement acknowledges that disclosure of Dr. Jackson's Confidential Information could "occur orally, in writing, by observation or by other means." *Id.* at Section 1. The Confidentiality Agreement did not require any special legend or stamp be placed on any document, nor did it require any follow-up writing to provide notice to Defendant of what constituted "Confidential Information." All the information provided by Dr. Jackson to Defendant was understood to be Confidential Information.

46. After Dr. Jackson's first initial disclosures of Confidential Information to Zimmer pursuant to the Confidentiality Agreement, the parties also entered into a "First Right of Refusal Agreement," dated August 1, 2010, for certain of Dr. Jackson's new technologies (referred to in that Agreement as "Technologies"). <u>Exhibit 19.</u> As set forth in the recitals, "[Defendant] desire[d] to obtain a right of first refusal for a limited time to consider entering into a License Agreement with Dr. Jackson pertaining to such Technologies." *Id.*

47. Section 3 of the First Right of Refusal Agreement specified that the "Technologies" included a "platform pop-on polyaxial screw assembly characterized" by mandatory and optional features, including threaded closures with "a reverse angle threadform" and "top-drop inserts." *Id.* at Section 3(g). The distinction between mandatory and optional features was important only insofar as the mandatory features could result in an exclusive license to Defendant, whereas the optional features would be non-exclusively licensed. *Id.* Optional features were not subject to any lower duty of non-disclosure and non-use than the mandatory features.

48. Pursuant to the on-going First Right of Refusal Agreement (and extensions thereof), Dr. Jackson made additional disclosures of Confidential Information relating to the Technologies associated with his innovative pop-on polyaxial screw design. Again, in 2011, Dr. Jackson disclosed to Defendant his inventive dual lead threaded locking system (receiver and fastener) that incorporated diametrically opposite thread forms with improved start structures on the fasteners or set screws for a lower chance of any cross-threading. Dr. Jackson's proprietary start structures, combined with dual lead thread forms, allowed for a more balanced loading of the locking system that was faster and more efficient, requiring fewer revolutions for tightening and re-tightening.

49. During the period when Defendant's right of first refusal was active, through extensions, the First Right of Refusal Agreement provided Defendant with a research license, royalty-free: "Dr. Jackson hereby grants [Defendant] (and any of its affiliates who agree to be subject to the terms of this Agreement and the CDA reference in Section 10) a worldwide, royalty-free, research license ... to use the Technologies during the term of this Agreement *solely* to determine if Zimmer Spine desires to enter into a License Agreement for the Technologies." *Id.* at Section 6 (emphasis added).

50. Importantly, the First Right of Refusal Agreement specifically incorporated by reference and left intact the confidentiality and non-disclosure obligations of the Confidentiality Agreement: "The parties have entered into a Mutual Confidential Information Disclosure Agreement dated May 12, 2010 and a First Amendment thereto dated July, 1, 2010 (collectively the 'CDA') regarding Confidential Information to be exchanged by the parties pertaining to the Technologies, which is hereby incorporated by reference into this Agreement."

51. As set forth in Section 7 of the First Right of Refusal Agreement, "Dr. Jackson [was] preparing to file and/or ha[d] pending patent applications for the Technologies." *Id.* at Section 7. Indeed, Dr. Jackson was eventually awarded an array of patents arising out of the Technologies that were disclosed to Defendant pursuant to the Confidentiality Agreement and later First Right of Refusal Agreement, as amended, restated and extended, including several of the Asserted Patents, such as the `479, `641 and `646 patents.

52. The right of first refusal granted by the agreement is set forth in Section 4. *Id.* at Section 4. Dr. Jackson granted Defendant an exclusive right to evaluate and test the Technologies, which prevented Dr. Jackson from pursuing other opportunities to license his inventions or taking any step that "could reasonably be expected to, facilitate any license, assignment, sale or transfer of the Technologies to any third party." *Id.* Upon exercise of Defendant's rights through a written notice to Dr. Jackson, the parties were to negotiate in good faith an exclusive worldwide license for the Technologies. *Id.* at Section 4.

53. Pursuant to Section 1 of the First Right of Refusal Agreement, Defendant's option was to expire on February 28, 2011. *Id.* at Section 1. However, the parties agreed to extend by amendments the option period on four occasions: February 4, 2011; April 28, 2011; July 31, 2011;

and November 1, 2011. Defendant's option terminated once-and-for-all in 2012, when Defendant informed Dr. Jackson that it would not exercise its option to license any of the Technologies.

54. Notwithstanding Defendant's decision to decline the opportunity to negotiate a license for any of the disclosed Technologies, unbeknownst to Dr. Jackson, Defendant decided to make use of Dr. Jackson's Confidential Information and incorporate it into its new bone screw flagship product development, the "Vitality" screw and rod based spinal fixation system (launched in 2016 and discussed below), and also filed a patent application (U.S. Provisional Application No. 61/601,809) on February 22, 2012 entitled "Bone Screw Including a Dual Thread Closure Member," which showed and claimed at least some of Dr. Jackson's Technologies disclosed to Defendant under the CDA.

55. Specifically, upon information and belief, Defendant incorporated at least the dual lead locking system and proprietary start structures confidentially disclosed by Dr. Jackson to Defendant into at least the Vitality bone screw system and product line extensions (detailed below).

Further Failed Licensing Discussions with Defendant:

56. In at least as early as November of 2016, Dr. Jackson had engaged in discussions with Matt Doscotch, at Defendant, regarding licenses to the technology covered by certain Asserted Patents. Several of the Asserted Patents, including at least the `143, `716, `479 and `292 patents, were directly and specifically addressed in these discussions, which continued into 2017 and 2018 with Cindy Mitchell, at Defendant, in connection with the Zimmer "Vitality/Vital" bone screw and rod based spinal fixation systems and the Zimmer "Pathfinder NXT" screw and instrument systems, discussed below. Several others of the Asserted Patents were identified by the application from which they issue, including at least the `660 patent. Still others were identified indirectly as they are the descendants of patents or applications identified and discussed with

Defendant between November 2016 and February 2018, including the `840, `366, `641, and `452 patents.

57. Consequently, Defendant Zimmer had actual notice of at least the `143, `716, `479 and `292 patents at least as early as conclusion of these discussions, and correspondence with Cindy Mitchell on or about February 6, 2018, for purposes of 35 U.S.C. § 287(a) and 35 U.S.C. § 271(b), and wherein all of these patents had been issued.

58. Defendant had sufficient knowledge of these patents to satisfy the requirements of 35 U.S.C. § 271(b). Defendant Zimmer declined to acquire a license to at least the `143, `716, `479 and `292 patents out of the Asserted Patents on which Defendant's products infringe.

The Zimmer Vitality/Vital Spinal Implant Systems:

59. The Zimmer "Vitality Spinal Fixation System provides a comprehensive solution for rigid spinal fixation from the thoracic spine to the ilium." *See* Vitality Spinal Fixation System, Surgical Technique Guide (copyright 2018), hereinafter <u>Exhibit 20</u> at p. 3. The Vitality system includes closures, bone screws, hooks, connectors, and other spinal implant components, each inserted separately into or on the spine. The implants components include receiver parts with curvate extending instrument engaging grooves and planar outer surfaces.

60. With a narrower focus, the Zimmer "Vital Spinal Fixation System provides an optimized set configuration solution ... evolved from the advanced implant and instrument features of the comprehensive Vitality Spinal Fixation System." *See* Vital Spinal Fixation System Degenerative (copyright 2018), hereinafter <u>Exhibit 21</u> at p. 2. The Vital screws can be cannulated or not and share the same types of closures as the Vitality implants, having dual lead reverse angle thread forms.

61. Upon information and belief, the Zimmer Vital bone screws represent a subset of the Zimmer Vitality spinal implants with additional features, such as cannulation and, for purposes of the Asserted Patents, exhibit most of the same internal structures, structural parts, functions, and features, such as a pre-lock friction fit, as the assembled bone screws in the Vitality system. Consequently, hereinafter the Zimmer Vitality and Vital systems, including the closures, screws and other separately inserted implant components will be referenced together as the Zimmer "Vitality/Vital Products," unless specifically referenced otherwise.

62. The Zimmer Vitality/Vital systems are indicated for "degenerative disc disease ..., discogenic back pain with degeneration of the disc ..., spondylolisthesis, trauma (*i.e.*, fracture or dislocation), deformities or curvatures (*i.e.*, scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, pseudoarthrosis and/or failed previous fusion." *See* Vitality Spinal Fixation System, Surgical Technique Guide, hereinafter <u>Exhibit 20</u> at p. 54. The Vital screws can be used for minimally invasive surgeries (MIS) when cannulated.

63. The Zimmer Vitality/Vital systems include "multiple screw options; monoaxial, polyaxial, uniplanar, reduction and iliac. All screw types are available in multiple diameters and lengths designed to secure either to 5.5 or 6mm rods." *Id.* at p. 3. Further, the "Vitality System's dual lead bone threads require fewer revolutions to insert, improving surgeon efficiency by allowing them to insert screws twice as fast into the spine as comparable single lead screws without sacrificing pull-out strength." *Id.*

64. The Zimmer Vitality/Vital screws are comprised of an assembly of parts, including at least a threaded screw shank, a receiver with internal threads, a top-drop snap-in-place insert with alignment features. The assembled screws cooperate with other components of the system, such as rods and threaded closures. The receivers of the Vitality/Vital system include a Zimmer

so-called "Zim Rim" tool attachment feature configured as curvate extending instrument engaging grooves. As shown below, Zimmer sells the cooperating closure tops and the Vitality/Vital screws in various screw diameters and lengths that have various features (*e.g.*, polyaxial, uniplanar and monoaxial or fixed configurations), wherein the closure components (both non-breakoff and break-off which have a dual lead type of reverse angle thread) are sold separately from the monoaxial screws and the various pivotal bone screws, assembled with the shank and the insert parts in their respective receivers:



See <u>Exhibit 20</u> at p. 45. Notably, the Vitality spinal implant system includes a "shear off" closure top option as well as a closure top without a "shear off" portion.

65. The various components of the Zimmer Vitality spinal implant system can be sold separately or as an array of components within a surgical tray. Certain trays contain an assortment of screws, hooks, connectors, rods, closures and other cooperating system components as well as the various instruments for installing and manipulating the Vitality implant products in the patient's spine. The "Vitality Spinal Fixation System, Surgical Technique Guide" depicts several of these trays, shown below: 5.5 - 8.5 Polyaxial Screws 3



See <u>Exhibit 20</u> at p. 27 (polyaxial screws, upper image), p. 28 (transverse connector, reduction, fixation, lower image).

66. Similarly, the components of the Zimmer Vital spinal implant system are also sold separately or as part of trays, as depicted below:



See Exhibit 21 at p. 3. Again, the Vital bone screws can be sold cannulated and not.

The Zimmer Vital MIS System:

67. According to Zimmer's "Surgical Technique Guide" for the "Vital MIS Spinal

The Vital MIS Spinal Fixation System is a percutaneous screw delivery system that offers a broad range of cannulated implants and specialized instrumentation for a minimalized, percutaneous or mini-open approach. The system was designed to provide surgeons with the flexibility to utilize instrumentation based on their personal technique, preference and specific patient needs. Fixation System," the Vital MIS System is a percutaneous screw delivery system that utilizes a broad range of cannulated implants:

See VitalTM MIS Spinal Fixation System, Surgical Technique Guide (copyright 2021) at p. 2, hereinafter Exhibit 22.

68. According to this same guide, the Vital MIS spinal fixation system also utilizes dual-lead reverse angle thread closure tops:

Dual-lead Reverse Angle Thread Closure Top
Dual-lead reverse angle thread designed to improve engagement, advance quickly and help prevent head splay.
Closure top design supports loosening after final tightening

Id. at p. 4.

69. According to this same guide, upon information and belief, the Vital MIS spinal

fixation system also utilizes a type of top-drop snap-in-place insert as a part in the assembled screw:

T27 Hexalobe Drive Feature

• Screws and closure tops utilize a T27 drive feature (one of the largest in the industry): 30% stronger than a T25 (MDT), 90% greater strength than a T20 (D/S).

and re-tightening of closure top without performance loss.

Id. at p. 4.



70. The components of the Zimmer Vital MIS spinal fixation system are sold as trays or kits, examples of which are shown below:



Vital MIS Implant Kit 1 Kit Number: PCR800M1201

Id. at p. 23.

71. Vital MIS Implant Kit 1, Kit No. PCR800M1201 includes the following contents,

according to the Guide, with each component having its own part number or SKU:

Vital MIS Implant Kit 1 Kit Number: PCR800M1201

DESCRIPTION	QTY	PART NUMBER	DESCRIPTION	QTY	PART NUMBER
ø5.5 x 35 mm, MIS Polyaxial Screw	4	824M5535	ø5.5 x 60 mm, MIS Curved Ti Rod	4	815M1060
ø5.5 x 40 mm, MIS Polyaxial Screw	8	824M5540	ø5.5 x 65 mm, MIS Curved Ti Rod	4	815M1065
ø5.5 x 45 mm, MIS Polyaxial Screw	8	824M5545	ø5.5 x 70 mm, MIS Curved Ti Rod	4	815M1070
ø5.5 x 50 mm, MIS Polyaxial Screw	8	824M5550	ø5.5 x 75 mm, MIS Curved Ti Rod	4	815M1075
ø5.5 x 55 mm, MIS Polyaxial Screw	4	824M5555	ø5.5 x 80 mm, MIS Curved Ti Rod	4	815M1080
ø6.5 x 35 mm, MIS Polyaxial Screw	4	824M6535	ø5.5 x 90 mm, MIS Curved Ti Rod	4	815M1090
ø6.5 x 40 mm, MIS Polyaxial Screw	8	824M6540	ø5.5 x 100 mm, MIS Curved Ti Rod	4	815M1100
ø6.5 x 45 mm, MIS Polyaxial Screw	8	824M6545	ø5.5 x 110 mm, MIS Curved Ti Rod	4	815M1110
ø6.5 x 50 mm, MIS Polyaxial Screw	8	824M6550	ø5.5 x 120 mm, MIS Curved Ti Rod	4	815M1120
ø6.5 x 55 mm, MIS Polyaxial Screw	4	824M6555	ø5.5 x 130 mm, MIS Curved Ti Rod	4	815M1130
ø5.5 x 30 mm, MIS Curved Ti Rod	4	815M1030	ø5.5 x 140 mm, MIS Curved Ti Rod	4	815M1140
ø5.5 x 35 mm, MIS Curved Ti Rod	4	815M1035	ø5.5 x 150 mm, MIS Curved Ti Rod	4	815M1150
ø5.5 x 40 mm, MIS Curved Ti Rod	4	815M1040	ø5.5 x 200 mm, MIS Straight Ti Rod	4	815M3200
ø5.5 x 45 mm, MIS Curved Ti Rod	4	815M1045	ø5.5 x 450 mm, MIS Straight Ti Rod	4	815M5450
ø5.5 x 50 mm, MIS Curved Ti Rod	4	815M1050	Closure Tops	14	07.02010.001
ø5.5 x 55 mm, MIS Curved Ti Rod	4	815M1055			

Id. Each of the assembled individual screw components is labelled as a "MIS Polyaxial Screw."

72. Zimmer sells the necessary instruments for deploying the Vital MIS spinal fixation system in their own instrument trays or kits, such as the Vital MIS Instrument Kit 1, Kit No. PCR800M1600, shown below:



Vital MIS Instrument Kit 1 Kit Number: PCR800M1600

Id. at p. 25.

The Zimmer Pathfinder NXT System:

73. Upon information and belief, the Zimmer Pathfinder NXT bone screw product essentially replaced the earlier Zimmer Pathfinder bone screw product in the marketplace, and, for purposes of the Asserted Patents, the assembled Pathfinder NXT screw component has a receiver part that exhibits a certain type of tool attachment structure different from to the one included in the predicate Pathfinder. Therefore, and hereinafter, the Pathfinder and Pathfinder NXT systems, including their closure components, and the receivers with their assembled parts, will be referenced together as the Zimmer "Pathfinder NXT," unless specifically referenced otherwise.

74. According to Zimmer's "Surgical Technique Guide" for the Pathfinder NXT screw

product:

The PathFinder NXT System consists of polyaxial cannulated screws and rods and is intended to provide temporary stabilization following surgery to fuse the spine. A range of spinal rod lengths included with the PathFinder NXT System allows the surgeon to place polyaxial pedicle screws through an open or mini-open procedure.

The PathFinder NXT System is designed to aid in the surgical correction of several types of spinal conditions. This system is intended only to provide stabilization during the development of a solid fusion with autograft or allograft. These implants are intended to be removed after the development of a solid fusion mass.

See Pathfinder NXT, Surgical Technique Guide (copyright 2017), hereinafter Exhibit 23 at p. 43.

75. The Pathfinder NXT bone screw product is sold fully assembled and comprises three parts: a receiver; a retainer; and a threaded shank, which as described above can be cannulated. The receiver has an internal helical flange and an external so-called "Zim Rim" tool attachment feature configured as curvate extending instrument engaging grooves. The same Surgical Technique Guide provides an image of a Pathfinder NXT cannulated shank, after being bottom loaded into a receiver and articulated at an angle along with an articulating retainer part inside the receiver:



Polyaxial Screws	PART NUMBER	
4.5 mm-7.5 mm	3505-4530-3505-7560	

See Id. at p. 41.

76. The Pathfinder NXT receiver can accept one of several fixation rods, such as certain "Percutaneous Straight Rods," "Pre-bent Standard Rod[s]" and "Straight Standard Rods." *Id.*

77. Once accepted into the receiver, the rod is held in place by the non-breakoff type of "closure top" component, which as depicted below has a helically wound flange form (i.e., helical flange) having its own part or SKU number, as shown below:

Id. at p. 41.



Closure Top	PARTNUMBER
·	3301-1

Figure 33 Reduction with extender sleeves

78. As show below, a specific purpose Pathfinder NXT rod is in the process of being positioned within a series of three Pathfinder NXT screw products. The "Closure Top" shown above, has been positioned atop the rod and within the receiver as shown in the immediate foreground:

See Id. at p. 25.

79. The Pathfinder NXT bone screw products and closure tops can be sold separately or as an array of components within surgical trays, which Zimmer refers to as "Kits." These Kits

contain multiple fully assembled cannulated polyaxial screws of various sizes, an assortment of separately insertable or implantable specific rods and closure tops as well as the instruments that are designed and adapted to work with these implants. *See, e.g.,* **Exhibit 23** at pp. 38-40.

The Zimmer Virage System:

80. According to Zimmer's "Surgical Technique Guide" for the "Virage OCT Spinal

Fixation System":

The Virage System includes multiple polyaxial screw diameters and lengths. All Virage System polyaxial screws feature a unique 360° Omnidirectional extreme angle screw design. This design seeks to simplify rod alignment and minimize operating time.

All Virage System polyaxial screws have a friction fit head designed to hold the desired position and facilitate rod placement, maximizing efficiency and safety during the procedure.

The Virage System's dual lead screws require fewer revolutions to seat in the pedicle allowing surgeons to insert screws twice as fast compared to a single lead screw.

The Virage System offers adjustable head to head transverse connectors that can accommodate up to 20° of freedom in different planes to improve intraoperative surgical flow.

See Surgical Technique Guide for the Virage OCT Spinal Fixation System (copyright 2018),

hereinafter Exhibit 24 at p. 4.

81. Further, as shown in the Surgical Technique Guide, the Virage screw products are

polyaxial screws with a pre-lock friction fit:





82. In a brochure for the Virage screw product, Zimmer describes and depicts several of its important features:



See Virage OCT Spinal Fixation System (copyright 2016), hereinafter Exhibit 25 at p. 4.

83. According to the Guide, each Virage screw product is screwed into place "to the desired depth where polyaxial movement of the head is maintained." <u>Exhibit 24</u> at p. 10. Subsequently, the driver is removed by "rotating the knob counterclockwise until disengaged from the screw, then [the surgeon] pull[s] in the trajectory of the screw shank." *Id.*

84. Once all the implants are aligned (hooks and screws), the surgeon places the fixation rod and inserts the closure tops, as illustrated in Step 19 of the Guide:

Exhibit 24 at 16.



85. Finally, according to the Guide, "once all implants are securely in place and the rods are fully seated, final tightening is performed. Tighten closure tops using the final driver, torque-limiting handle, and inline counter torque." *Id.* at 19. The closure tops and hook and screw receivers have a type of reverse angle thread.

86. Final tightening is depicted in Figure 31 of the Guide:



Figure 31 Final tightening

Id.

87. As with the Zimmer Vitality/Vital and Pathfinder NXT implant systems, the Virage implant system is also sold as an array of components within surgical trays or "kits." For example, "Virage Standard Implants, Kit Number: 07.01973.411":



See Exhibit 24 at p. 41.

The Zimmer Ballista/Polaris System:

88. Upon information and belief, the assembled screws of the Ballista percutaneous screw placement system are a subset of the various components of the Polaris spinal system. Accordingly, the accused screws of the Zimmer Ballista will be referred to herein as the "Ballista/Polaris" screw product, unless specifically stated otherwise.

89. Based on the "Polaris 5.5 Spinal System Surgical Technique" Guide, the Polaris5.5 Spinal System:

The Polaris 5.5 Spinal System is a load sharing, top loading, low profile system. The seat enables secure interface with the instruments for maximum manipulation agility. The design goals were to aid the surgeon with intra-operative efficiency and effectiveness while maintaining integrity and ease.

The Polaris 5.5 Spinal System is designed to address degenerative pathologies. The trays are configured to include Multi-axial Screws, extended screws, pre-cut pre-contoured rods, Crossbar[™] Cross Connectors^{*}, lateral connectors, and ergonomic instrumentation for maximum tactile feedback. The Polaris System continues to advance the spinal fixation needs of the aging population by providing fixation, variability, and ease of use. See Polaris 5.5 Spinal System Surgical Technique (copyright 2015), hereinafter <u>Exhibit 26</u> at p.
3.

90. Further, as shown in <u>Exhibit 26</u> the screws of the Polaris system are "Multi-axial" screws:



Multi-axial Screws are available in 4.75, 5.5, 6.5, 7.5 and 8.5mm diameters in 30-55mm lengths.



Multi-axial Reduction Screws are available in 5.5, 6.5 and 7.5mm diameter in 30-55mm lengths.

See Id. at p. 5.

91. As **Exhibit 26** explains, the "Ballista Instruments are intended to be used with the Ballista/Polaris 5.5 Implants. Cannulated screws and percutaneous rods, may be used with the Ballista instruments to provide the surgeon with a percutaneous approach for posterior spinal surgery for the above indications." *Id.* at p. 18.

92. A "Biomet Spine" surgical technique guide specific to the Ballista screws indicated that the Ballista screw products were both cannulated and "multi-axial":



Cannulated Multi-axial Screws Available In 5.5mm, 6.5mm And 7.5mm Diameters In 30mm – 60mm Lengths

See Ballista[™] Percutaneous Screw Placement System, Surgical Technique guide, hereinafter Exhibit 27 (copyright 2014) at p. 3.

93. As with the Zimmer Vitality/Vital systems, the Ballista/Polaris system is also sold as part of an "Implant Case," with an array of screw and other components. For example, Zimmer's "Ballista" screw products are components within the surgical "Ballista Implant Case" and bear the SKU or catalog number #14-509624. *See Id.* at p. 24.

The Zimmer (Biomet) Cypher MIS System:

94. Based on the "Cypher[™] MIS Screw System, Surgical Technique Guide," the Cypher MIS percutaneous screw system includes the following features and benefits:

FEATURES	BENEFITS	
Translation Screw Technology	3 mm of medial-lateral translation relative to the screw shaft	
	Encourages optimal screw placement	
	Less rod manipulation, easier rod introduction	
Powerful Rod Reduction	Less rod manipulation, easier rod introduction	
Double-lead Thread	Immediate bone engagement	
Thread Profile	Fast and efficient screw placement	
	Thread form maximizes bone purchase and performance	
	Constant outer diameter	
Friction Fit Seat	Maintains position of screw seat	
Helical Flange Technology	Starts easily	
	Minimizes cross threading and seat splay	
	Forces are concentrated inward	
Multi-axial Screws	40° of conical angulation for optimum versatility	
5.5 mm Rod System	Low profile	
	Anatomical fit	
Color-coded Implants	Ease of screw identification	

See CypherTM MIS Screw System, Surgical Technique Guide (copyright 2018), hereinafter <u>**Exhibit 28**</u> at p. 5. The reference above to "40° of conical angulation for optimum versatility," indicates that the Cypher MIS screw system is polyaxial.

95. Further, as shown in <u>Exhibit 28</u>, the screws of the Cypher MIS screw system appear to be cannulated:



Id. at p. 5. This canulation is confirmed by the use of guidewires to position the Cypher MIS

screws:

Pedicle Preparation

- · Remove the first dilator from the patient.
- Select the appropriate size tap and assemble the tap to the tear drop handle.

Note: The Cypher System taps are line-to-line with the diameter of the corresponding pedicle screws and it is recommended to tap line-to-line.

- Place the tap over the guidewire and guide the tap until it is docked against the bony anatomy (Figure 6).
- Turn the handle clockwise to prepare the pedicle until the tap has reached the appropriate depth for the patient (Figure 7).

Note: Do not tap past the length of the guidewire.

Pedicle Screw Insertion (continued)

- Insert the pedicle screw over the guidewire and push down until the screw is docked against the bony anatomy (Figure 12a).
- Turn the handle clockwise until the pedicle screw has been implanted fully, verify position with lateral fluoroscopic imaging.
- · Remove the guidewire
- Remove the screw inserter by turning the central barrel counterclockwise until it has released from the screw head, and pull up out of the screw tower (Figure 12b).
- Verify final positioning with lateral fluoroscopic imaging (Figure 13).
- Repeat the above steps for the subsequent pedicles.

Exhibit 28 at p. 8 (left), 10 (right). Moreover, the Cypher MIS screws are described as cannulated

in the table of part numbers provided by **Exhibit 28**:

Cannulated Pedicle Screws	PART NUMBER	
5.5 mm x 30 mm	14-571330	
5.5 mm x 35 mm	14-571335	
5.5 mm x 40 mm	14-571340	
5.5 mm x 45 mm	14-571345	
5.5 mm x 50 mm	14-571350	
5.5 mm x 55 mm	14-571355	
5.5 mm x 60 mm	14-571360	
6.5 mm x 30 mm	14-571430	
6.5 mm x 35 mm	14-571435	
6.5 mm x 40 mm	14-571440	
6.5 mm x 45 mm	14-571445	
6.5 mm x 50 mm	14-571450	
6.5 mm x 55 mm	14-571455	
6.5 mm x 60 mm	14-571460	
7.5 mm x 30 mm	14-571530	
7.5 mm x 35 mm	14-571535	
7.5 mm x 40 mm	14-571540	
7.5 mm x 45 mm	14-571545	
7.5 mm x 50 mm	14-571550	
7.5 mm x 55 mm	14-571555	
7.5 mm x 60 mm	14-571560	

Exhibit 28 at p. 29.

96. As with the Zimmer Vitality/Vital and Ballista/Polaris systems, the Cypher MIS system is also sold as an array of screw and other components within a surgical tray or "Implant and Instrument Kit" and, for example, bears "Kit Number 14-571183":

Exhibit 28 at p. 28.



Implants and Instruments Kit Number: 14-571183

The Zimmer (Biomet) Telluride II Screw System:

97. Based on the "Telluride 2, MIS Spinal Fixation System, Surgical Technique" guide,

the Telluride II spinal fixation system is designed to provide stabilization of the thoracic, lumbar

and sacral regions of the spine:

TELLURIDE 2 MIS SPINAL FIXATION SYSTEM

The Telluride 2 MIS Spinal Fixation System is a simple, robust and versatile minimally invasive pedicle screw system consisting of implants and instruments to provide vertebral stabilization of spinal segments in the thoracic, lumbar and sacral regions.

The system features:

- Cannulated polyaxial pedicle screws
- Titanium rods
- Surgeon designed instrumentation
- Uses either a Percutaneous or Miniopen approach with a series of small, posterior incisions

The system provides:

- · Reduced muscle trauma & pain
 - Shorter hospital stays
- Faster return to normal activities



See Telluride 2, MIS Spinal Fixation System, Surgical Technique (copyright 2014), hereinafter

Exhibit 29 at p. 2. According to **Exhibit 29**, the Telluride II screws are cannulated polyaxial pedicle screws.

98. As with the Zimmer Vitality/Vital, Virage and Ballista/Polaris systems, the Zimmer (Biomet) Telluride II system is sold as an array of screw and other components within a surgical tray or "Case," as shown below for example, bearing the part number 7706-3501:

See Exhibit 29 at p. 25.

TELLURIDE IMPLANTS

Screw Diameter	Screw Length	Rod	Rod Length
5.5mm	30, 35, 40, 45 & 50mm	Pre-Bert	35, 40, 45, 50, 55, 80, 65, 70, 75, 80, 90, 100, 110 & 120mm
6.5mm	30, 35, 40, 45, 50 & 55mm	Streight	35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 90, 100, 110, 120,
7.5mm	30, 35, 40, 45, 50 & 55mm		130, 140, 150, 160, 170, 160, 190, 200, 300 & 400mm
8.5mm	30, 35, 40, 45, 50 & 55mm		

Case 1: 7706-3501 - Screws and Pedicle Prep Instruments

The Zimmer (Biomet) Vail Screw System:

99. According to the "Vail[™] Occipito-Cervico-Thoracic Spinal Fixation System, Surgical Technique Guide," Zimmer's Vail spinal fixation system is intended to "promote fusion
of the occipito-cervico-thoracic region of the spine." See VailTM Occipito-Cervico-Thoracic Spinal Fixation System, Surgical Technique Guide (copyrighted 2014), hereinafter <u>Exhibit 30</u> at p. 3.

100. As described by <u>Exhibit 30</u>, Zimmer's Vail spinal fixation system includes "occipital plates, rods, hooks, polyaxial screws, rod-to-rod connections, head-to-head crossbars and offset connectors." *Id.* at p. 4. Other features include the following:

See Id. at p. 4.

FEATURES:

- A complete posterior fixation system for Occipito-Cervico-Thoracic procedures
- Designed with unique implant features to improve implant performance
- Reverse buttress thread reduces the chance of cross threading the set screw or splaying the screw head
- Low-profile screw head allows for optimal screw and rod placement with 60° range of motion



101. As further described by <u>Exhibit 30</u>, Zimmer's Vail spinal fixation system includes a receiver having an open configuration that allows the receiver to accept a spinal rod, which is then seated and then fixated into place by the "reverse buttress thread[ed] ... set screw[s]" to "reduce the chance of ... splaying the screw head." *Id.* at p. 4.

102. Figure 13c of <u>Exhibit 30</u> provides a view of the open configuration receiver; Figure 25b provides a view of a polyaxial screw and receiver accepting a rod; and Figure 27 provides a view of the set screw, being screwed into place to fixate the rod:



See Exhibit 30 at p. 8, 15.

103. Collectively, the Zimmer Vitality/Vital, Vital MIS, Pathfinder NXT, Virage, Ballista/Polaris, Cypher MIS, Telluride II and Vail systems are referred to as the "Accused Products."

COUNT ONE

Infringement of the `716 Patent

104. Plaintiff repeats and realleges as if fully set forth herein, the allegations contained in all the preceding paragraphs ¶¶ 1 through 103.

105. As set forth below, Zimmer has infringed and continues to infringe one or more claims of the `716 patent under 35 U.S.C. § 271 by manufacturing, providing, selling, offering to sell, importing and/or distributing without authority the Vitality products utilizing break off ("shear off") closure tops:

106. Specifically, the Vitality products utilizing break off closure tops comprise a "bone screw apparatus" as set forth in claims 1 and 2 of the `716 patent. The claim chart attached hereto as **Exhibit 31** details how the Vitality screw products satisfies each and every limitation of *at least* claims 1 and 2 of the `716 patent either literally or under the doctrine of equivalents.

107. Further, when certain components of the Vitality products are implanted by a surgeon with break off closure tops in order to treat one of several spine conditions, those Vitality products also directly infringes *at least* claims 1 and 2 of the `716 patent.

108. Zimmer had or should have had actual knowledge of the `716 patent, to which Zimmer already had a limited license, and should have had actual knowledge of its unauthorized use beyond and outside of its license for the Accused Products as Dr. Jackson offered a license to Zimmer under the `716 patent in November 2016, and (upon information and belief) wherein Zimmer had been selling at least the Vitality system earlier than November 2016 and wherein the `716 patent had issued on November 23, 2010.

109. For the same reasons, upon information and belief, Zimmer has the specific intent to encourage surgeons to directly infringe *at least* claims 1 and 2 of the `716 patent by using and/or assembling components of the Vitality system by surgically implanting them in patients, as discussed above. Zimmer provides the components used in the fully assembled "bone screw apparatus" along with instructions and tools to accomplish their surgical implantation. Consequently, Zimmer induces the infringement of the `716 patent through at least its unauthorized sales of the Vitality system pursuant to 35 U.S.C. § 271(b).

110. Zimmer's Vitality system can be sold separately and as an array of components in surgical trays. These components, such as the "bone screw shank" (assembled with the "head") and the "closure," etc., as claimed, comprise "material components" of the "bone screw apparatus" of *at least* claims 1 and 2 of the `716 patent and are designed, configured and adapted to work with each other and have no substantial purpose other than as part of infringing devices and are, accordingly, not staple articles of commerce. Consequently, Zimmer contributes to the

infringement of the `716 patent through at least its unauthorized sales of the surgical trays incorporating the Vitality products pursuant to 35 U.S.C. § 271(c).

111. As outlined above, under the totality of the circumstances, Zimmer's infringement of the `716 patent was willful from at least as early as of the commencement of sales of the Vitality System.

COUNT TWO

Infringement of the `479 Patent

112. Plaintiff repeats and realleges as if fully set forth herein, the allegations contained in all the preceding paragraphs **¶** 1 through 111.

113. As set forth below, Zimmer has infringed and continues to infringe one or more claims of the `479 patent under 35 U.S.C. § 271 by manufacturing, providing, selling, offering to sell, importing and/or distributing without authority the Vitality/Vital system:

114. Specifically, the Vitality/Vital screw products comprise a "medical implant" as set forth in claims 1, 10 and 18 of the `479 patent as well as the "polyaxial bone anchor" of claim 21. The claim chart attached hereto as <u>Exhibit 32</u> details how the Vitality/Vital screw products satisfies each and every limitation of *at least* claims 1, 7, 8, 10, 16, 17, 18 and 21 of the `479 patent either literally or under the doctrine of equivalents.

115. Further, when certain components of the Vitality/Vital system are implanted by a surgeon in order to treat one of several spine conditions, the Vitality/Vital screw products also directly infringes *at least* claims 1, 7, 8, 10, 16, 17, 18 and 21 of the `479 patent.

116. Zimmer had or should have had actual knowledge of the `479 patent and Zimmer's unauthorized use thereof as Dr. Jackson offered a license to Zimmer under the `479 patent between November 2016 and February 2018 during the discussions between the parties.

117. For the same reasons, upon information and belief, Zimmer has the specific intent to encourage surgeons to directly infringe *at least* claims 1, 7, 8, 10, 16, 17, 18 and 21 of the `479 patent by using and/or assembling components of the Vitality/Vital screw products by surgically implanting them in patients, as discussed above. Zimmer provides the components used in the fully assembled bone anchor assembly for the Vitality/Vital screw products along with instructions and tools to accomplish their surgical implantation. Consequently, Zimmer induces the infringement of the `479 patent through at least its unauthorized sales of the Vitality/Vital system pursuant to 35 U.S.C. § 271(b).

118. Zimmer's Vitality/Vital screw products and their systems can be sold separately and as components within surgical trays. These components, such as the "closure member," etc., as claimed, comprise "material components" of the "medical implant" of *at least* claims 1, 7, 8, 10, 16, 17 and 18 and the "shank" and "receiver" of the "polyaxial bone anchor" of claim 21 of the '479 patent and are designed, configured and adapted to work with each other and have no substantial purpose other than as assembled components of infringing devices and are, accordingly, not staple articles of commerce. Consequently, Zimmer contributes to the infringement of the '479 patent through at least its unauthorized sales of the surgical trays incorporating the Vitality/Vital screw products pursuant to 35 U.S.C. § 271(c).

119. As outlined above, under the totality of the circumstances, Zimmer's infringement of the `479 patent was willful from at least as early as February 2018.

COUNT THREE

Infringement of the `143 Patent

120. Plaintiff repeats and realleges as if fully set forth herein, the allegations contained in all the preceding paragraphs ¶¶ 1 through 119.

121. As set forth below, Zimmer has infringed and continues to infringe one or more

claims of the `143 patent under 35 U.S.C. § 271 by manufacturing, providing, selling, offering to sell, importing and/or distributing without authority the Vitality/Vital system:

122. Specifically, the Vitality/Vital screw products comprise a "pivotal bone anchor assembly" as set forth in claim 1 of the `143 patent. The claim chart attached hereto as **Exhibit 33** details how the Vitality/Vital screw products satisfies each and every limitation of *at least* claims 11 and 15 of the `143 patent either literally or under the doctrine of equivalents.

123. Further, when certain components of the Vitality/Vital screw products are implanted by a surgeon in order to treat one of several spine conditions, the Vitality/Vital screw products also directly infringes *at least* claims 11 and 15 of the `143 patent.

124. Zimmer had or should have had actual knowledge of the `143 patent and Zimmer's unauthorized use thereof as Dr. Jackson offered a license to Zimmer under the `143 patent that had issued on May 30, 2017, during the on-going discussions in 2017 and early 2018.

125. For the same reasons, upon information and belief, Zimmer has the specific intent to encourage surgeons to directly infringe *at least* claims 11 and 15 of the `143 patent by using and/or assembling components of the Vitality/Vital screw products by surgically implanting them in patients, as discussed above. Zimmer provides the components used in the fully assembled bone anchor assembly for the Vitality/Vital screw products along with instructions and tools to accomplish their surgical implantation. Consequently, Zimmer induces the infringement of the `143 patent through at least its unauthorized sales of the Vitality/Vital screw products pursuant to 35 U.S.C. § 271(b).

126. Zimmer's Vitality/Vital screw products and their systems can be sold separately and as an array of components within surgical trays. These components, such as the "shank," (assembled with the "receiver" and "insert") etc., as claimed, comprise "material components" of

the "pivotal bone anchor assembly" of *at least* claims 11 and 15 of the `143 patent and are designed, configured and adapted to work with each other and have no substantial purpose other than as components of infringing devices and are, accordingly, not staple articles of commerce. Consequently, Zimmer contributes to the infringement of the `143 patent through at least its unauthorized sales of the surgical trays incorporating the Vitality/Vital screw products pursuant to 35 U.S.C. § 271(c).

127. As outlined above, under the totality of the circumstances, Zimmer's infringement of the `143 patent was willful from at least as early as February 2018.

COUNT FOUR

Infringement of the `292 Patent

128. Plaintiff repeats and realleges as if fully set forth herein, the allegations contained in all the preceding paragraphs **¶** 1 through 127.

129. As set forth below, Zimmer has infringed and continues to infringe one or more claims of the `292 patent under 35 U.S.C. § 271 by manufacturing, providing, selling, offering to sell, importing and/or distributing without authority the Cypher MIS, Telluride II, Ballista/Polaris and Vital MIS systems:

130. Specifically, the Cypher MIS, Telluride II, Ballista/Polaris and Vital MIS screw products each comprise a "cannulated polyaxial bone anchor assembly," as set forth in claim 1 of the `292 patent. The claim chart attached hereto as <u>Exhibit 34</u> details how the Cypher MIS screw product satisfies each and every limitation of *at least* claim 1 of the `292 patent either literally or under the doctrine of equivalents. The claim chart attached hereto as <u>Exhibit 35</u> details how the Telluride II screw product satisfies each and every limitation of *at least* claim 1 of *the* `292 patent either `292 patent either literally or under the doctrine of equivalents. The claim chart attached hereto as <u>Exhibit 35</u> details how the term of the `292 patent either literally or under the doctrine of equivalents. The claim chart attached hereto as <u>Exhibit 35</u> details how the '292 patent either literally or under the doctrine of equivalents. The claim chart attached hereto as <u>Exhibit 35</u> details how the '292 patent either literally or under the doctrine of equivalents. The claim chart attached hereto as <u>Exhibit 36</u> details how the '292 patent either literally or under the doctrine of equivalents. The claim chart attached hereto as <u>Exhibit 36</u> details how the Ballista/Polaris screw product satisfies each and every limitation of *at least* claim 1 of *the* '292 patent either literally or under the doctrine of equivalents. The claim chart attached hereto as <u>Exhibit 36</u> details how the Ballista/Polaris screw product satisfies each and every limitation of *at least* claim

1 of the `292 patent either literally or under the doctrine of equivalents. <u>Exhibit 37</u> details how the Vital MIS screw product satisfies each and every limitation of *at least* claim 1 of the `292 patent either literally or under the doctrine of equivalents.

131. Further, when certain components of the Cypher MIS, Telluride II, Ballista/Polaris and Vital MIS screw products are implanted by a surgeon in order to treat one of several spine conditions, the Cypher MIS, Telluride II, Ballista/Polaris and Vital MIS screw products also directly infringe *at least* claim 1 of the `292 patent.

132. Zimmer had or should have had actual knowledge of the `292 patent and Zimmer's unauthorized use thereof as Dr. Jackson offered a license to Zimmer under the `292 patent on or before February 2018.

133. For the same reasons, upon information and belief, Zimmer has the specific intent to encourage surgeons to directly infringe at least claim 1 of the `292 patent by using and/or assembling components of the Cypher MIS, Telluride II, Ballista/Polaris and Vital MIS screw products by surgically implanting them in patients, as discussed above. Zimmer provides the components used in the completed cannulated polyaxial bone anchor assembly for the Cypher MIS, Telluride II, Ballista/Polaris and Vital MIS screw products along with instructions and tools to accomplish their surgical implantation. Consequently, Zimmer induces the infringement of the `292 patent through at least its unauthorized sales of the Cypher MIS, Telluride II, Ballista/Polaris and Vital MIS screw products pursuant to 35 U.S.C. § 271(b).

134. Zimmer's Cypher MIS, Telluride II, Ballista/Polaris and Vital MIS screw products and their systems can be sold as an array of components within surgical trays. These components, such as the "anchor member" assembled with the "head," etc., as claimed, comprise "material components" of the "spinal screw assembly" of at least claim 1 of the `292 patent and are designed,

configured and adapted to work with each other and have no substantial purpose other than as components of infringing devices and are, accordingly, not staple articles of commerce. Consequently, Zimmer contributes to the infringement of the `292 patent through at least its unauthorized sales of the surgical trays incorporating the Cypher MIS, Telluride II, Ballista/Polaris and Vital MIS screw products pursuant to 35 U.S.C. § 271(c).

135. As outlined above, under the totality of the circumstances, Zimmer's infringement of the `292 patent is willful from at least as early as February 2018.

COUNT FIVE

Infringement of the `753 Patent

136. Plaintiff repeats and realleges as if fully set forth herein, the allegations contained in all the preceding paragraphs ¶¶ 1 through 135.

137. As set forth below, Zimmer has infringed and continues to infringe one or more claims of the `753 patent under 35 U.S.C. § 271 by manufacturing, providing, selling, offering to sell, importing and/or distributing without authority the Vitality/Vital systems:

138. Specifically, the Vitality/Vital screw products comprise a "bone anchor assembly" as set forth in claim 1 of the `753 patent. The claim chart attached hereto as <u>Exhibit 38</u> details how the Vitality/Vital screw products satisfies each and every limitation of *at least* claim 1 of the `753 patent either literally or under the doctrine of equivalents.

139. Further, when certain components of the Vitality/Vital screw products are implanted by a surgeon in order to treat one of several spine conditions, the Vitality/Vital screw products also directly infringes *at least* claim 1 of the `753 patent.

140. Zimmer had or should have had actual knowledge of the `753 patent and Zimmer's unauthorized use thereof as Dr. Jackson offered a license to Zimmer under the application that issued as the `753 patent as early as November 2016, but no later than May 218 when the patent

issued. Alternatively, this Complaint provides actual knowledge of the `753 patent and Zimmer's unauthorized use thereof.

141. For the same reasons, upon information and belief, Zimmer has the specific intent to encourage surgeons to directly infringe *at least* claim 1 of the `753 patent by using and/or assembling components of the Vitality/Vital screw products by surgically implanting them in patients, as discussed above. Zimmer provides the components used in the completed bone anchor assembly for the Vitality/Vital screw products along with instructions and tools to accomplish their surgical implantation. Consequently, Zimmer induces the infringement of the `753 patent through at least its unauthorized sales of the Vitality/Vital screw products pursuant to 35 U.S.C. § 271(b).

142. Zimmer's Vitality/Vital screw products and their systems can be sold separately and as an array of components within surgical trays. These components, such as the "receiver" assembled with the "bone attachment structure" and "insert," etc., as claimed, comprise "material components" of the "bone anchor assembly" of *at least* claim 1 of the `753 patent and are designed, configured and adapted to work with each other and have no substantial purpose other than as components of infringing devices and are, accordingly, not staple articles of commerce. Consequently, Zimmer contributes to the infringement of the `753 patent through at least its unauthorized sales of the surgical trays incorporating the Vitality/Vital screw products pursuant to 35 U.S.C. § 271(c).

143. As outlined above, under the totality of the circumstances, Zimmer's infringement of the `753 patent was willful from at least as early as November 2016.

COUNT SIX

Infringement of the `452 Patent

144. Plaintiff repeats and realleges as if fully set forth herein, the allegations contained in all the preceding paragraphs **¶** 1 through 143.

145. As set forth below, Zimmer has infringed and continues to infringe one or more claims of the `452 patent under 35 U.S.C. § 271 by manufacturing, providing, selling, offering to sell, importing and/or distributing without authority the Vitality/Vital system:

146. Specifically, the Vitality/Vital screw products comprise a "receiver of a bone anchor" as set forth in claim 1 of the `452 patent. The claim chart attached hereto as <u>Exhibit 39</u> details how the Vitality/Vital screw products satisfies each and every limitation of *at least* claim 1 of the `452 patent either literally or under the doctrine of equivalents.

147. Further, when certain components of the Vitality/Vital screw products are implanted by a surgeon in order to treat one of several spine conditions, the Vitality/Vital screw products also directly infringes *at least* claim 1 of the `452 patent.

148. Zimmer had or should have had actual knowledge of the `452 patent and Zimmer's unauthorized use thereof as of June 19, 2018, when the patent issued since Dr. Jackson had offered a license to Zimmer for this type of receiver for a bone anchor in February 2018 as the `452 patent is a descendant of at least one patent specifically identified during the discussions between the parties in 2017 and 208. Alternatively, this Complaint provides actual knowledge of the `452 patent and Zimmer's unauthorized use thereof.

149. For the same reasons, upon information and belief, Zimmer has the specific intent to encourage surgeons to directly infringe *at least* claim 1 of the `452 patent by using and/or assembling components of the Vitality/Vital screw products by surgically implanting them in patients, as discussed above. Zimmer provides the components used in the completed bone anchor assembly for the Vitality/Vital screw products along with instructions and tools to accomplish their surgical implantation. Consequently, Zimmer induces the infringement of the `452 patent through at least its unauthorized sales of the Vitality/Vital screw products pursuant to 35 U.S.C. § 271(b).

150. As outlined above, under the totality of the circumstances, Zimmer's infringement of the `452 patent is willful from at least as early as June 19, 2018.

COUNT SEVEN

Infringement of the `660 Patent

151. Plaintiff repeats and realleges as if fully set forth herein, the allegations contained in all the preceding paragraphs **¶¶** 1 through 150.

152. As set forth below, Zimmer has infringed and continues to infringe one or more claims of the `660 patent under 35 U.S.C. § 271 by manufacturing, providing, selling, offering to sell, importing and/or distributing without authority the Vitality/Vital system:

153. Specifically, the Vitality/Vital screw products comprise a "pivotal bone anchor assembly" as set forth in claim 28 of the `660 patent. The claim chart attached hereto as <u>Exhibit</u>
<u>40</u> details how the Vitality/Vital screw products satisfies each and every limitation of *at least* claim 28 of the `660 patent either literally or under the doctrine of equivalents.

154. Further, when certain components of the Vitality/Vital screw products are surgically implanted by a surgeon in order to treat one of several spine conditions, the Vitality/Vital screw products also directly infringes *at least* claim 28 of the `660 patent.

155. Zimmer had or should have had actual knowledge of the `660 patent and Zimmer's unauthorized use thereof as of September 4, 2018, when the patent issued as Dr. Jackson had offered a license to Zimmer for this type of insert technology during the discussions between the parties. Alternatively, this Complaint provides actual knowledge of the `660 patent and Zimmer's unauthorized use thereof.

156. For the same reasons, upon information and belief, Zimmer has the specific intent to encourage surgeons to directly infringe *at least* claim 28 of the `660 patent by using and/or

assembling components of the Vitality/Vital screw products by surgically implanting them in patients, as discussed above. Zimmer provides the components used in the completed bone anchor assembly for the Vitality/Vital screw products along with instructions and tools to accomplish their surgical implantation. Consequently, Zimmer induces the infringement of the `660 patent through at least its unauthorized sales of the Vitality/Vital screw products pursuant to 35 U.S.C. § 271(b).

157. Zimmer's Vitality/Vital screw products and their systems can be sold separately and as part of surgical trays. These components, such as the "closure," "receiver" assembled with the "shank" and "pressure insert," etc., as claimed, comprise "material components" of the "pivotal bone anchor assembly" of *at least* claim 28 of the `660 patent and are designed, configured and adapted to work with each other and have no substantial purpose other than as components of infringing devices and are, accordingly, not staple articles of commerce. Consequently, Zimmer contributes to the infringement of the `660 patent through at least its unauthorized sales of the surgical trays incorporating the Vitality/Vital screw products pursuant to 35 U.S.C. § 271(c).

158. As outlined above, under the totality of the circumstances, Zimmer's infringement of the `660 patent was willful from at least as early as September 4, 2018.

COUNT EIGHT

Infringement of the `840 Patent

159. Plaintiff repeats and realleges as if fully set forth herein, the allegations contained in all the preceding paragraphs ¶¶ 1 through 158.

160. As set forth below, Zimmer has infringed and continues to infringe one or more claims of the `840 patent under 35 U.S.C. § 271 by manufacturing, providing, selling, offering to sell, importing and/or distributing without authority the Vitality/Vital screw products:

161. Specifically, the Vitality/Vital screw products comprise a "bone screw assembly" as set forth in claim 17 of the `840 patent. The claim chart attached hereto as <u>Exhibit 41</u> details how the Vitality/Vital screw products satisfies each and every limitation of *at least* claim 17 of the `840 patent either literally or under the doctrine of equivalents.

162. Further, when certain components of the Vitality/Vital screw products are implanted by a surgeon in order to treat one of several spine conditions, the Vitality/Vital screw products also directly infringes *at least* claim 17 of the `840 patent.

163. Zimmer has been infringing the `840 patent since it issued on January 7, 2020. This Complaint provides actual knowledge of the `840 patent and Zimmer's unauthorized use thereof.

164. For the same reasons, upon information and belief, going forward, Zimmer will have the specific intent of encouraging surgeons to directly infringe *at least* claim 17 of the `840 patent by using and/or assembling components of the Vitality/Vital screw products by surgically implanting them in patients, as discussed above. Zimmer provides the components used in the completed bone anchor assembly for the Vitality/Vital screw products along with instructions and tools to accomplish this assembly. Consequently, Zimmer will induce the infringement of the `840 patent through at least its unauthorized sales of the Vitality/Vital screw products pursuant to 35 U.S.C. § 271(b).

165. Zimmer's Vitality/Vital screw products and their systems can be sold separately and as an array of components within surgical trays. These components, such as the "bone screw" assembled with the "body member" and the "compression bushing," etc., as claimed, comprise "material components" of the "bone screw assembly" of *at least* claim 17 of the `840 patent and are designed, configured and adapted to work with each other and have no substantial purpose other than as components of infringing devices and are, accordingly, not staple articles of

commerce. Consequently, Zimmer contributes to the infringement of the `840 patent through at least its ongoing unauthorized sales of the surgical trays incorporating the Vitality/Vital screw products pursuant to 35 U.S.C. § 271(c).

166. As outlined above, under the totality of the circumstances, Zimmer's infringement of the `840 patent was willful since January 7, 2020.

COUNT NINE

Infringement of the `366 Patent

167. Plaintiff repeats and realleges as if fully set forth herein, the allegations contained in all the preceding paragraphs **¶¶** 1 through 166.

168. As set forth below, Zimmer has infringed and continues to infringe one or more claims of the `366 patent under 35 U.S.C. § 271 by manufacturing, providing, selling, offering to sell, importing and/or distributing without authority the Vitality/Vital systems:

169. Specifically, the Vitality/Vital screw products comprise a "pivotal bone anchor assembly" as set forth in claim 22 of the `366 patent. The claim chart attached hereto as <u>Exhibit</u>
<u>42</u> details how the Vitality/Vital screw products satisfies each and every limitation of *at least* claim 22 of the `366 patent either literally or under the doctrine of equivalents.

170. Further, when certain components of the Vitality/Vital screw products are surgically implanted by a surgeon in order to treat one of several spine conditions, the Vitality/Vital screw products also directly infringes *at least* claim 22 of the `366 patent.

171. Zimmer had or should have had actual knowledge of the `366 patent and Zimmer's unauthorized use thereof as Dr. Jackson offered a license to Zimmer under the `366 patent in November 2016, as the `366 patent is a descendant of at least one patent specifically identified during the discussions between the parties. Alternatively, this Complaint provides actual

knowledge of the `366 patent and Zimmer's unauthorized use thereof since the `366 patent issued on January 21, 2020.

172. For the same reasons, upon information and belief, Zimmer has the specific intent to encourage surgeons to directly infringe *at least* claim 22 of the `366 patent by using and/or assembling components of the Vitality/Vital screw products by surgically implanting them in patients, as discussed above. Zimmer provides the components used in the completed bone anchor assembly for the Vitality/Vital screw products along with instructions and tools to accomplish their surgical implantation. Consequently, Zimmer induces the infringement of the `366 patent through at least its unauthorized sales of the Vitality/Vital screw products pursuant to 35 U.S.C. § 271(b).

173. Zimmer's Vitality/Vital screw products and their systems can be sold separately and as an array of components within surgical trays. These components, such as the "screw" assembled with the "body member" and the "bushing," etc., as claimed, comprise "material components" of the "pivotal bone anchor assembly" of *at least* claim 22 of the '366 patent and are designed, configured and adapted to work with each other and have no substantial purpose other than as components of infringing devices and are, accordingly, not staple articles of commerce. Consequently, Zimmer contributes to the infringement of the '366 patent through at least its unauthorized sales of the surgical trays incorporating the Vitality/Vital screw products pursuant to 35 U.S.C. § 271(c).

174. As outlined above, under the totality of the circumstances, Zimmer's infringement of the `366 patent was willful since January 21, 2020.

COUNT TEN

Infringement of the `641 Patent

175. Plaintiff repeats and realleges as if fully set forth herein, the allegations contained in all the preceding paragraphs ¶¶ 1 through 174.

176. As set forth below, Zimmer has infringed and continues to infringe one or more claims of the `641 patent under 35 U.S.C. § 271 by manufacturing, providing, selling, offering to sell, importing and/or distributing without authority the Vitality/Vital system:

177. Specifically, the Vitality/Vital screw products comprise a "medical implant" as set forth in claims 1 and 26 of the `641 patent. The claim chart attached hereto as <u>Exhibit 43</u> details how the Vitality/Vital screw products satisfies each and every limitation of *at least* claims 1, 4-5, 9, 12-14, and 26-28 of the `641 patent either literally or under the doctrine of equivalents.

178. Further, when certain components of the Vitality/Vital screw products are surgically implanted by a surgeon in order to treat one of several spine conditions, the Vitality/Vital screw products also directly infringes *at least* claims 1, 4-5, 9, 12-14, and 26-28 of the `641 patent.

179. Zimmer had or should have had actual knowledge of the `641 patent and Zimmer's unauthorized use thereof as Dr. Jackson offered a license to Zimmer under the `641 patent no later than February 2018, as the `641 patent is a descendant of at least one patent specifically identified during the discussions between the parties. Alternatively, this Complaint provides actual knowledge of the `641 patent and Zimmer's unauthorized use thereof since the patent issued on February 4, 2020.

180. For the same reasons, upon information and belief, Zimmer has the specific intent to encourage surgeons to directly infringe *at least* claims 1, 4-5, 9, 12-14, and 26-28 of the `641 patent by using and/or assembling components of the Vitality/Vital screw products as discussed above. Zimmer provides the components used in the completed bone anchor assembly for the Vitality/Vital screw products along with instructions and tools to accomplish their surgical implantation. Consequently, Zimmer induces the infringement of the `641 patent through at least its unauthorized sales of the Vitality/Vital screw products pursuant to 35 U.S.C. § 271(b).

181. Zimmer's Vitality/Vital screw products and their systems can be sold separately and as an array of components within surgical trays. These components, such as the "receiver," "closure," etc., as claimed, comprise "material components" of the "medical implant" of *at least* claims 1, 4-5, 9, 12-14, and 26-28 of the `641 patent and are designed, configured and adapted to work with each other and have no substantial purpose other than as components of infringing devices and are, accordingly, not staple articles of commerce. Consequently, Zimmer contributes to the infringement of the `641 patent through at least its unauthorized sales of the surgical trays incorporating the Vitality/Vital screw products pursuant to 35 U.S.C. § 271(c).

182. As outlined above, under the totality of the circumstances, Zimmer's infringement of the `641 patent was willful from at least as early as February 2018.

COUNT ELEVEN

Infringement of the `233 Patent

183. Plaintiff repeats and realleges as if fully set forth herein, the allegations contained in all the preceding paragraphs ¶¶ 1 through 182.

184. As set forth below, Zimmer has infringed and continues to infringe one or more claims of the `233 patent under 35 U.S.C. § 271 by manufacturing, providing, selling, offering to sell, importing and/or distributing without authority the Vitality/Vital screw products:

185. Specifically, the Vitality/Vital screw products comprise a "medical implant assembly" as set forth in claim 1 of the `233 patent. The claim chart attached hereto as <u>Exhibit</u> <u>44</u> details how the Vitality/Vital screw products satisfies each and every limitation of *at least* claim 1 of the `233 patent either literally or under the doctrine of equivalents.

186. Further, when certain components of the Vitality/Vital screw products are implanted by a surgeon in order to treat one of several spine conditions, the Vitality/Vital screw products also directly infringes *at least* claim 1 of the `233 patent.

187. Zimmer had or should have had actual knowledge of the `233 patent and Zimmer's unauthorized use thereof as Dr. Jackson offered a license to Zimmer for this type of receiver tool attachment structure in February 2018. Alternatively, this Complaint provides actual knowledge of the `233 patent and Zimmer's unauthorized use thereof since the patent issued on January 26, 2021.

188. For the same reasons, upon information and belief, Zimmer has the specific intent to encourage surgeons to directly infringe *at least* claim 1 of the '233 patent by using and/or assembling components of the Vitality/Vital screw products by surgically implanting them in patients, as discussed above. Zimmer provides the components used in the completed medical implant assembly for the Vitality/Vital screw products along with instructions and tools to accomplish their surgical implantation. Consequently, Zimmer induces the infringement of the '233 patent through at least its unauthorized sales of the Vitality/Vital screw products pursuant to 35 U.S.C. § 271(b).

189. Zimmer's Vitality/Vital screw products and their systems can be sold separately and as an array of components within surgical trays. These components, such as the "receiver," etc., as claimed, comprise "material components" of the "medical implant assembly" of *at least* claim 1 of the `233 patent and are designed, configured and adapted to work with each other and have no substantial purpose other than as components of infringing devices and are, accordingly, not staple articles of commerce. Consequently, Zimmer contributes to the infringement of the `233 patent through at least its unauthorized sales of the surgical trays incorporating the Vitality/Vital screw products pursuant to 35 U.S.C. § 271(c).

190. As outlined above, under the totality of the circumstances, Zimmer's infringement of the `233 patent was willful from at least as early as January 26, 2021.

COUNT TWELVE

Infringement of the `777 Patent

191. Plaintiff repeats and realleges as if fully set forth herein, the allegations contained in all the preceding paragraphs ¶¶ 1 through 190.

192. As set forth below, Zimmer has infringed and continues to infringe one or more claims of the `777 patent under 35 U.S.C. § 271 by manufacturing, providing, selling, offering to sell, importing and/or distributing without authority the Vitality/Vital screw products:

193. Specifically, the Vitality/Vital screw products comprise a "pivotal bone anchor assembly" as set forth in claim 1 of the `777 patent. The claim chart attached hereto as **Exhibit 45** details how the Vitality/Vital screw products satisfies each and every limitation of *at least* claims 1 and 10 of the `777 patent either literally or under the doctrine of equivalents.

194. Further, when certain components of the Vitality/Vital screw products are surgically implanted by a surgeon in order to treat one of several spine conditions, the Vitality/Vital screw products also directly infringes *at least* claims 1 and 10 of the `777 patent.

195. Zimmer had or should have had actual knowledge of the `777 patent and Zimmer's unauthorized use thereof as of March 23, 2021, when the patent issued. Alternatively, this Complaint provides actual knowledge of the `777 patent and Zimmer's unauthorized use thereof.

196. For the same reasons, upon information and belief, Zimmer has the specific intent to encourage surgeons to directly infringe *at least* claims 1 and 10 of the `777 patent by using and/or assembling components of the Vitality/Vital screw products by surgically implanting them in patients, as discussed above. Zimmer provides the components used in the completed bone anchor assembly for the Vitality/Vital screw products along with instructions and tools to accomplish their surgical implantation. Consequently, Zimmer induces the infringement of the

`777 patent through at least its unauthorized sales of the Vitality/Vital screw products pursuant to 35 U.S.C. § 271(b).

197. Zimmer's Vitality/Vital screw products and their systems can be sold separately and as an array of components within surgical trays. These components, such as the "shank" assembled with the "receiver" and "insert," *etc.*, as claimed, comprise "material components" of the "pivotal bone anchor assembly" of *at least* claims 1 and 10 of the `777 patent and are designed, configured and adapted to work with each other and have no substantial purpose other than as components of infringing devices and are, accordingly, not staple articles of commerce. Consequently, Zimmer contributes to the infringement of the `777 patent through at least its unauthorized sales of the surgical trays incorporating the Vitality/Vital screw products pursuant to 35 U.S.C. § 271(c).

198. As outlined above, under the totality of the circumstances, Zimmer's infringement of the `777 patent was willful from at least as early as March 23, 2021.

COUNT THIRTEEN

Infringement of the `229 Patent

199. Plaintiff repeats and realleges as if fully set forth herein, the allegations contained in all the preceding paragraphs ¶¶ 1 through 198.

200. As set forth below, Zimmer has infringed and continues to infringe one or more claims of the `229 patent under 35 U.S.C. § 271 by manufacturing, providing, selling, offering to sell, importing and/or distributing without authority the Vitality/Vital system:

201. Specifically, the Vitality/Vital screw products comprise a "receiver assembly" as set forth in claim 15 of the `229 patent. The claim chart attached hereto as **Exhibit 46** details how

the Vitality/Vital screw products satisfies each and every limitation of *at least* claim 15 of the `229 patent either literally or under the doctrine of equivalents.

202. Further, when certain components of the Vitality/Vital screw products are surgically implanted by a surgeon in order to treat one of several spine conditions, the Vitality/Vital screw products also directly infringes at least claim 15 of the `229 patent.

203. Zimmer had or should have had actual knowledge of the `229 patent and Zimmer's unauthorized use thereof as Dr. Jackson offered a license to Zimmer for this type of receiver tool attachment structure in February 2018 during the discussions between the parties. Alternatively, this Complaint provides actual knowledge of the `229 patent and Zimmer's unauthorized use thereof since the patent issued on June 29, 2021.

204. For the same reasons, upon information and belief, Zimmer has the specific intent to encourage surgeons to directly infringe at least claim 15 of the `229 patent by using and/or assembling components of the Vitality/Vital screw products by surgically implanting them in patients, as discussed above. Zimmer provides the components used in the completed receiver assembly for the Vitality/Vital screw products along with instructions and tools to accomplish their surgical implantation. Consequently, Zimmer induces the infringement of the `229 patent through at least its unauthorized sales of the Vitality/Vital screw products pursuant to 35 U.S.C. § 271(b).

205. Zimmer's Vitality/Vital screw products and their systems can be sold separately and as an array of components within surgical trays. These components, such as the "receiver" assembled with the "insert," etc., as claimed, comprise "material components" of the "receiver assembly" of *at least* claim 15 of the `229 patent and are designed, configured and adapted to work with each other and have no substantial purpose other than as part of infringing devices and are, accordingly, not staple articles of commerce. Consequently, Zimmer contributes to the

infringement of the `229 patent through at least its unauthorized sales of the surgical trays incorporating the Vitality/Vital material components pursuant to 35 U.S.C. § 271(c).

206. As outlined above, under the totality of the circumstances, Zimmer's infringement of the `229 patent was willful from at least as early as June 29, 2021.

COUNT FOURTEEN

Infringement of the `646 Patent

207. Plaintiff repeats and realleges as if fully set forth herein, the allegations contained in all the preceding paragraphs ¶¶ 1 through 206.

208. As set forth below, Zimmer has infringed and continues to infringe one or more claims of the `646 patent under 35 U.S.C. § 271 by manufacturing, providing, selling, offering to sell, importing and/or distributing without authority the Vitality/Vital system:

209. Specifically, the Vitality/Vital screw products comprise a "medical implant assembly" as set forth in claims 1 and 12 of the `646 patent. The claim chart attached hereto as **Exhibit 47** details how the Vitality/Vital screw products satisfies each and every limitation of *at least* claims 1 and 12 of the `646 patent either literally or under the doctrine of equivalents.

210. Further, when certain components of the Vitality/Vital screw products are implanted by a surgeon in order to treat one of several spine conditions, the Vitality/Vital screw products also directly infringes *at least* claims 1 and 12 of the `646 patent.

211. Zimmer had or should have had actual knowledge of the `646 patent and Zimmer's unauthorized use thereof as of September 28, 2021, when the patent issued. Alternatively, this Complaint provides actual knowledge of the `646 patent and Zimmer's unauthorized use thereof.

212. For the same reasons, upon information and belief, Zimmer has the specific intent to encourage surgeons to directly infringe *at least* claims 1 and 12 of the `646 patent by using and/or assembling components of the Vitality/Vital screw products by surgically implanting them

in patients, as discussed above. Zimmer provides the components used in the completed bone anchor assembly for the Vitality/Vital screw products along with instructions and tools to accomplish their surgical implantation. Consequently, Zimmer induces the infringement of the `646 patent through at least its unauthorized sales of the Vitality/Vital screw products pursuant to 35 U.S.C. § 271(b).

213. Zimmer's Vitality/Vital screw products and their systems can be sold separately and as an array of components within surgical trays. These components, such as the "receiver," "plug," etc., as claimed, comprise "material components" of the "pivotal bone anchor assembly" of *at least* claims 1 and 12 of the `646 patent and are designed, configured and adapted to work with each other and have no substantial purpose other than as components of infringing devices and are, accordingly, not staple articles of commerce. Consequently, Zimmer contributes to the infringement of the `646 patent through at least its unauthorized sales of the surgical trays incorporating the Vitality/Vital screw products pursuant to 35 U.S.C. § 271(c).

214. As outlined above, under the totality of the circumstances, Zimmer's infringement of the `646 patent is willful from at least as early as September 28, 2021.

COUNT FIFTEEN

Infringement of the `993 Patent

215. Plaintiff repeats and realleges as if fully set forth herein, the allegations contained in all the preceding paragraphs ¶¶ 1 through 214.

216. As set forth below, Zimmer has infringed and continues to infringe one or more claims of the `993 patent under 35 U.S.C. § 271 by manufacturing, providing, selling, offering to sell, importing and/or distributing without authority the Vitality/Vital system:

217. Specifically, the Vitality/Vital screw products comprise a "pivotal bone anchor assembly" as set forth in claim 1 of the `993 patent. The claim chart attached hereto as <u>Exhibit</u>
<u>48</u> details how the Vitality/Vital screw products satisfies each and every limitation of *at least* claim 1 of the `993 patent either literally or under the doctrine of equivalents.

218. Further, when certain components of the Vitality/Vital screw products are implanted by a surgeon in order to treat one of several spine conditions, the Vitality/Vital screw products also directly infringes *at least* claim 1 of the `993 patent.

219. Zimmer had or should have had actual knowledge of the `993 patent and Zimmer's unauthorized use thereof as of October 5, 2021, when the patent issued. Alternatively, this Complaint provides actual knowledge of the `993 patent and Zimmer's unauthorized use thereof.

220. For the same reasons, upon information and belief, Zimmer has the specific intent to encourage surgeons to directly infringe *at least* claim 1 of the `993 patent by using and/or assembling components of the Vitality/Vital screw products by surgically implanting them in patients, as discussed above. Zimmer provides the components used in the completed bone anchor assembly for the Vitality/Vital screw products along with instructions and tools to accomplish their surgical implantation. Consequently, Zimmer induces the infringement of the `993 patent through at least its unauthorized sales of the Vitality/Vital screw products pursuant to 35 U.S.C. § 271(b).

221. Zimmer's Vitality/Vital screw products and their systems can be sold separately and as an array of components within surgical trays. These components, such as the "shank" assembled with the "receiver" and "insert," *etc.*, as claimed, comprise "material components" of the "pivotal bone anchor assembly" of *at least* claim 1 of the `993 patent and are designed, configured and adapted to work with each other and have no substantial purpose other than as components of infringing devices and are, accordingly, not staple articles of commerce.

Consequently, Zimmer contributes to the infringement of the `993 patent through at least its unauthorized sales of the surgical trays incorporating the Vitality/Vital screw products pursuant to 35 U.S.C. § 271(c).

222. As outlined above, under the totality of the circumstances, Zimmer's infringement of the `993 patent was willful from at least as early as October 5, 2021.

<u>COUNT SIXTEEN</u>

Breach of Contract

223. Plaintiff repeats and realleges as if fully set forth herein, the allegations contained in all the preceding paragraphs ¶¶ 1 through 222.

224. Zimmer entered into the Confidentiality Agreement to obtain access to Dr. Jackson's innovative "pop-on polyaxial screw design," that incorporated several of Dr. Jackson's enabling device technologies. As stated in the Agreement, the purpose of the Confidentiality Agreement (as amended) was to allow Zimmer to "evaula[te] a potential relationship" with Dr. Jackson regarding a proprietary spinal implant design developed by Dr. Jackson. <u>Exhibit 18.</u>

225. In exchange for access to Dr. Jackson's proprietary designs and know-how, the Confidentiality Agreement forbid Zimmer from disclosing Dr. Jackson's Confidential Information to third parties and Zimmer personnel not having a "need to know" and forbid Zimmer from using Dr. Jackson's Confidential Information for any purpose other than evaluating a potential business relationship with Dr. Jackson. *Id.* at Section 3.

226. Further, Zimmer did not receive a license to the Confidential Information: "Nothing in this Agreement will be construed as a license or other authorization for [Zimmer] to use or practice the Confidential Information disclosed pursuant to this Agreement." *Id.* at Section 5.

227. While the Confidentiality Agreement states that it would be effective for a term of one year from the date of the agreement, "[t]ermination or expiration of this Agreement shall not, however, affect obligations set forth in this Agreement with respect to Confidential Information disclosed prior to termination or expiration." *Id.* at Section 11. In other words, Zimmer's obligation to keep Dr. Jackson's Confidential Information survived the termination or expiration of the agreement.

228. Beginning on or about May 17, 2010, and continuing thereafter, Dr. Jackson provided Confidential Information for his pedicle screw designs and enabling device technologies to Zimmer pursuant to the Confidentiality Agreement. Specifically, Dr. Jackson provided Zimmer with access to prototypes, photographs of prototypes, e-drawings and other specifications along with disclosure as well as know-how, including but not limited to proprietary receiver tool attachment structures, dual start threaded locking systems with and without reverse angle threads and closures configurable with diametrically opposite concave/convex start structures. Further, Dr. Jackson had multiple encounters with designees of Zimmer to disclose and discuss this information and answer questions regarding the developments, including meeting with Jeremy Lemoine and others in Austin, Texas on or about December 12, 2011.

229. Zimmer had previously negotiated and executed the First Right of Refusal Agreement on August 1, 2010. <u>Exhibit 19.</u> As set forth in the recitals, "Zimmer Spine desire[d] to obtain a right of first refusal for a limited time to consider entering into a License Agreement with Dr. Jackson pertaining to such Technologies." *Id.* at Preambles.

230. Pursuant to the First Right of Refusal Agreement, and extensions thereof, Dr. Jackson continued to make the above disclosures of Confidential Information so as to facilitate Zimmer's evaluation of his technologies. During the term of the First Right of Refusal Agreement,

Zimmer received a limited research license solely for the purpose of evaluating Dr. Jackson's developments: "Dr. Jackson hereby grants Zimmer Spine (and any of its affiliates who agree to be subject to the terms of this Agreement and the CDA reference in Section 10) a worldwide, royalty-free, research license ... to use the Technologies during the term of this Agreement *solely* to determine if Zimmer Spine desires to enter into a License Agreement for the Technologies." *Id.* at Section 6 (emphasis added).

231. Importantly, the First Right of Refusal Agreement specifically incorporated by reference and left intact the confidentiality and non-use obligations of the Confidentiality Agreement: "The parties have entered into a Mutual Confidential Information Disclosure Agreement dated May 12, 2010 and a First Amendment thereto dated July, 1, 2010 (collectively the 'CDA') regarding Confidential Information to be exchanged by the parties pertaining to the Technologies, which is hereby incorporated by reference into this Agreement." *Id.* at Section 10.

232. Dr. Jackson, as part of the First Right of Refusal Agreement, granted Zimmer an exclusive right to evaluate and test the Technologies. *Id.* at Section 4. This exclusive right prevented Dr. Jackson from pursuing other opportunities to license his inventions or taking any step that "could reasonably be expected to, facilitate any license, assignment, sale or transfer of the Technologies to any third party." *Id.*

233. Upon exercise of Zimmer's rights through a written notice to Dr. Jackson, the parties were to negotiate in good faith an exclusive worldwide license for the Technologies. *Id.* at Section 4.

234. Upon information and belief, Zimmer had no intention of negotiating in good faith with Dr. Jackson. Instead, upon information and belief, Zimmer decided to exploit the Confidentiality Agreement and First Right of Refusal Agreement and amendments and extensions

thereto to obtain as much of Dr. Jackson's Confidential Information as possible to jump start the development of its own product after breaking off contact with Dr. Jackson.

235. To that end, upon information and belief, Zimmer extended the term of the First Right of Refusal Agreement multiple times, only terminating the agreement in 2012.

236. Thereafter, Zimmer – relying on Dr. Jackson's Confidential Information – incorporated, for example, Dr. Jackson's dual lead locking system and start structure innovations into the new flagship Vitality product it developed going forward. Zimmer first applied for FDA premarket approval for Vitality product on April 2, 2015, and received the FDA's approval on August 31, 2015. Without Dr. Jackson's knowledge and upon information and belief, Zimmer's sales of Vitality began sometime thereafter.

237. Accordingly, Zimmer breached its duties of non-disclosure and non-use of Dr. Jackson's Confidential Information set forth in the First Right of Refusal Agreement by: (a) disclosing Dr. Jackson's Confidential Information to Zimmer personnel who lacked a need to know; (b) disclosing Dr. Jackson's Confidential Information to third parties; (c) exceeding the scope of the agreement, which limited Zimmer's use of Dr. Jackson's Confidential Information to evaluating Dr. Jackson's designs and a potential license agreement with Dr. Jackson; and, (d) exceeding the scope of the non-commercial license granted by Dr. Jackson, which did not permit Zimmer to develop a commercial product incorporating his Confidential Information.

238. Zimmer intentionally obscured and concealed its plan to incorporate Dr. Jackson's Confidential Information into the forthcoming Vitality product through the affirmative act of terminating its right of first refusal.

239. Accordingly, Zimmer's concealment that it had, in fact, abused and misused Dr. Jackson's Confidential Information to develop Vitality could not have been discovered by Dr.

Jackson's reasonable diligence until sometime after the product was being sold and presented to him, since Dr. Jackson never used the Vitality System products in his surgical practice.

240. Dr. Jackson was damaged by Zimmer's breach of the First Right of Refusal Agreement. Dr. Jackson was denied the royalties on the early sales of the Vitality Spinal Implants. Dr. Jackson was also not compensated for his services as a product development surgeon at his customary consulting rate. Finally, Dr. Jackson was damaged as he was prevented from taking even initial steps towards licensing his innovative and enabling device technologies to Zimmer competitors while the agreements were in effect.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Roger P. Jackson, M.D. respectfully requests that the Court:

- A. Hold that Defendant has infringed one or more claims of the Asserted Patents pursuant to 35 U.S.C. § 271.
- B. Preliminarily and permanently enjoin Defendant as well as its respective agents, servants, officers, directors, employees and all other persons or entities acting in concert with them, directly or indirectly, from infringing, inducing others to infringe, or contributing to the infringement of the Asserted Patents pursuant to 35 U.S.C. § 283.
- C. Order Defendant to account for and pay to Plaintiff damages as a consequence of Defendant's infringement of the Asserted Patents pursuant to 35 U.S.C. § 284.
- D. Find that Defendant's infringement is willful and accordingly award Plaintiff enhanced damages pursuant to 35 U.S.C. § 284.
- E. Declare this case exceptional pursuant to 35 U.S.C. § 285 and award Plaintiff reasonable attorneys' fees and costs in this action.

- F. Hold that Defendant breached its contractual obligations to Plaintiff set forth in the "First Right of Refusal Agreement."
- G. Order Defendant to account for and pay to Plaintiff damages as a consequence of Defendant's breaches of the First Right of Refusal Agreement.
- H. Award to Plaintiff its costs, expenses, disbursements, and attorneys' fees incurred herein.
- I. Award to Plaintiff pre-judgment and post-judgment interest on the foregoing amounts at the maximum rate recoverable by law.
- J. Award to Plaintiff such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff Roger P. Jackson, M.D. demand trial by jury of all issues triable by a jury.

POLSINELLI PC

/s/ Stephen J. Kraftschik

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