

**UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE**

MIGHTY OAK MEDICAL, INC.,

Plaintiff,

v.

MEDACTA INTERNATIONAL SA AND
MEDACTA USA, INC.,

Defendants.

Civil Action No. _____

JURY TRIAL DEMANDED

COMPLAINT FOR PATENT INFRINGEMENT

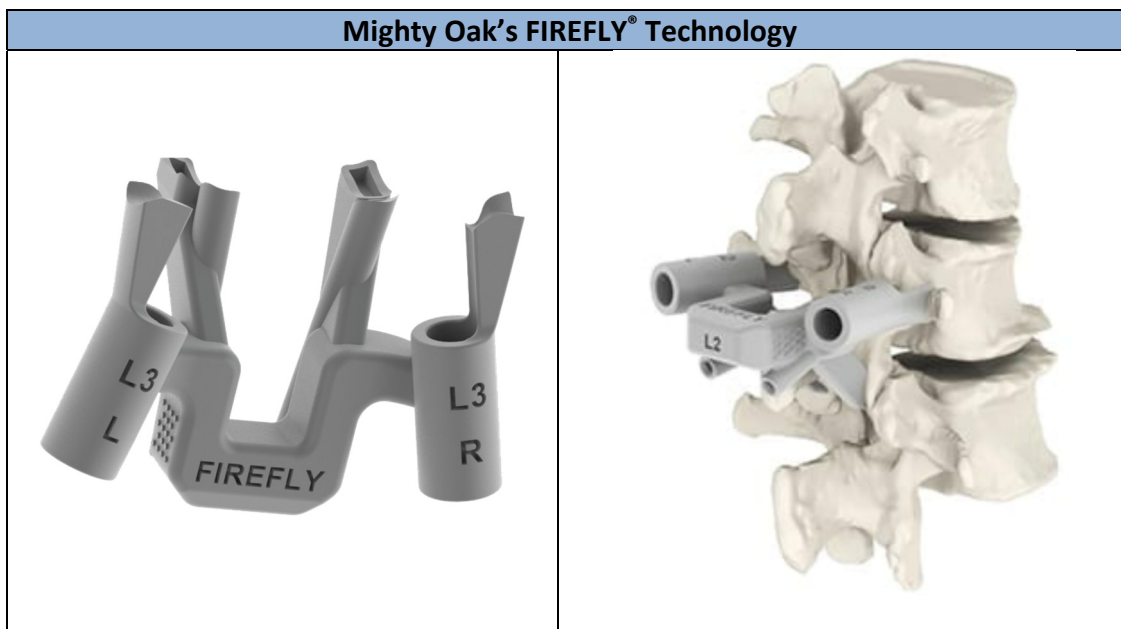
Plaintiff Mighty Oak Medical, Inc. (“Mighty Oak” or “Plaintiff”) files this Complaint and demand for a jury trial seeking relief for patent infringement by Defendants Medacta International SA (“Medacta International”) and Medacta USA, Inc. (“Medacta USA”) (collectively “Medacta” or “Defendants”). Plaintiff states and alleges the following:

THE PARTIES

1. Mighty Oak Medical, Inc. is a corporation organized and existing under the laws of the state of Colorado, with its principal place of business located at 750 West Hampden Avenue, Suite 120, Englewood, CO 80110. Mighty Oak is a medical device technology company created for the purpose of developing and commercializing patient-specific surgical solutions, and for the protection and licensing of any resulting inventions and intellectual property.

2. Mighty Oak was founded in 2011 under the direction of Dr. George Frey, a noted spinal surgeon and inventor of spinal fixation and surgical navigation-related technologies. Dr. Frey, Chief Medical Officer of Mighty Oak, is a named inventor on more than 35 issued patents in the United States directed to medical devices, surgical guides, instruments and methods.

Eighteen of those issued U.S. patents relate to Mighty Oak's FIREFLY® navigation guides for use in spinal surgeries (the "FIREFLY® technology"), such as shown in the exemplary images below:

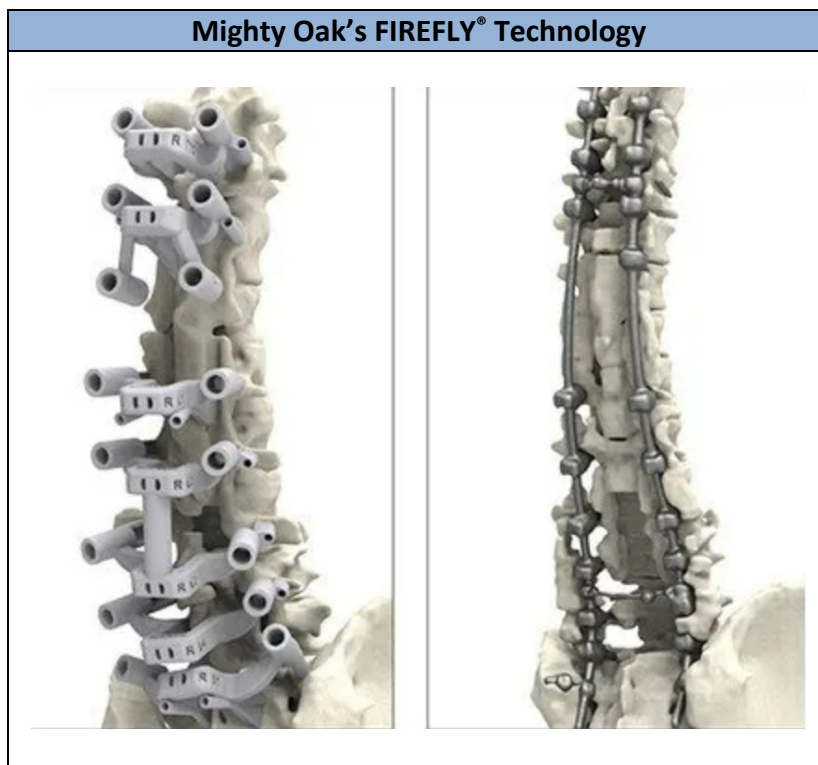


See, e.g., <https://www.mightyoakmedical.com>; https://www.orthoworld.com/wp-content/uploads/2020/08/Product_OrthoPediatrics_Firefly-Guide.jpg.

3. Mighty Oak's patent portfolio includes inventions directed to patient-specific surgical guides used to constrain surgical instrumentation along pre-operatively-planned trajectories. Building on this novel foundation, Mighty Oak's patent portfolio also includes inventive concepts directed to cortical, cervical, osteotomy, and pelvic guides, as well as guides for use in minimally-invasive surgery (MIS). Mighty Oak's asserted patents in this case, discussed in more detail below, include inventions for which Dr. Frey filed for patent protection no later than June 2010.

4. Mighty Oak's FIREFLY® technology allows surgeons to define parameters of a surgical guide or template, pre-operatively, for use in a patient-specific operation, thereby enabling optimal placement and alignment of a variety of surgical instruments, implants and devices used in conjunction with the FIREFLY® technology. The patented FIREFLY® guides can be used with

a wide range of medical devices, including pedicle screws, manufactured or sold by others, and accommodate surgical procedures for the spine ranging from the occipital, cervical, thoracic, lumbar, and/or sacroiliac regions.



See, e.g., <https://orthospinenews.com/2016/12/05/firefly-spinal-navigation-guides-receive-universal-clearance-from-fda/>.

5. Mighty Oak has marked and continues to mark its patented FIREFLY® technology, pursuant to 35 U.S.C. § 287(a). For example, Mighty Oak has included on the labeling for each of these products a statement that the product is patent protected, and the address of a freely-accessible public website that associates the patented product with the one or more patents covering that product. Mighty Oak has marked its FIREFLY® technology in this way since it began selling products covered by its patents.

6. In addition to being awarded patents covering the novel FIREFLY® technology, Mighty Oak has also received numerous awards and approvals for its FIREFLY® guides, including

the Spine Technology Award in 2012, 2016, and 2022, the Colorado Advanced Industries Grant in 2015, and multiple 510(k) approvals from the U.S. Food & Drug Administration in January and November 2016.

7. Mighty Oak has expended substantial resources in designing, developing, manufacturing, marketing, distributing and selling Mighty Oak's FIREFLY[®] navigation guides. Through its continued innovation and development of the FIREFLY[®] technology, Mighty Oak has become recognized as a leader in the area of patient-matched surgical guide technology.

8. On information and belief, Defendant Medacta International SA is a corporation organized and existing under the laws of Switzerland, having a principal place of business at Strada Regina, 6874 Castel San Pietro, Switzerland.

9. On information and belief, Defendant Medacta USA, Inc. is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at 6640 Carothers Parkway, Suite 420, Franklin, TN 37067.

10. On information and belief, Defendants operate in concert to make, use, sell, offer for sale, and/or import surgical guides throughout the United States, including the accused products identified herein.

JURISDICTION AND VENUE

11. This is a civil action for patent infringement under the patent laws of the United States, 35 U.S.C. § 271, *et seq.* This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338.

12. This Court has general personal jurisdiction over Medacta because it regularly conducts business in the State of Delaware and therefore has substantial and continuous contacts within this judicial District; because it has purposefully availed itself to the privileges of

conducting business in this judicial District; and/or because it has committed acts of infringement in this judicial District giving rise to this action.

13. Venue in this Court is proper under the provisions of 28 U.S.C. §§ 1391(b) and (c) and 28 U.S.C. § 1400. Medacta USA is incorporated in Delaware and thus resides in this State. In addition, Medacta International is subject to suit in this Court pursuant to 28 U.S.C. 1391(c)(3).

ASSERTED PATENTS

14. On June 24, 2014, United States Patent No. 8,758,357 (“the ’357 patent”) entitled “Patient Matching Surgical Guide and Method for Using the Same” was duly and legally issued by the United States Patent and Trademark Office. Mighty Oak owns the ’357 patent by assignment. A true and correct copy of the ’357 patent is attached as Exhibit 1.

15. On October 28, 2014, United States Patent No. 8,870,889 (“the ’889 patent”) entitled “Patient Matching Surgical Guide and Method for Using the Same” was duly and legally issued by the United States Patent and Trademark Office. Mighty Oak Medical, Inc. owns the ’889 patent by assignment. A true and correct copy of the ’889 patent is attached as Exhibit 2.

16. On December 1, 2015, United States Patent No. 9,198,678 (“the ’678 patent”) entitled “Patient-Matched Apparatus and Methods for Performing Surgical Procedures” was duly and legally issued by the United States Patent and Trademark Office. Mighty Oak owns the ’678 patent by assignment. A true and correct copy of the ’678 patent is attached as Exhibit 3.

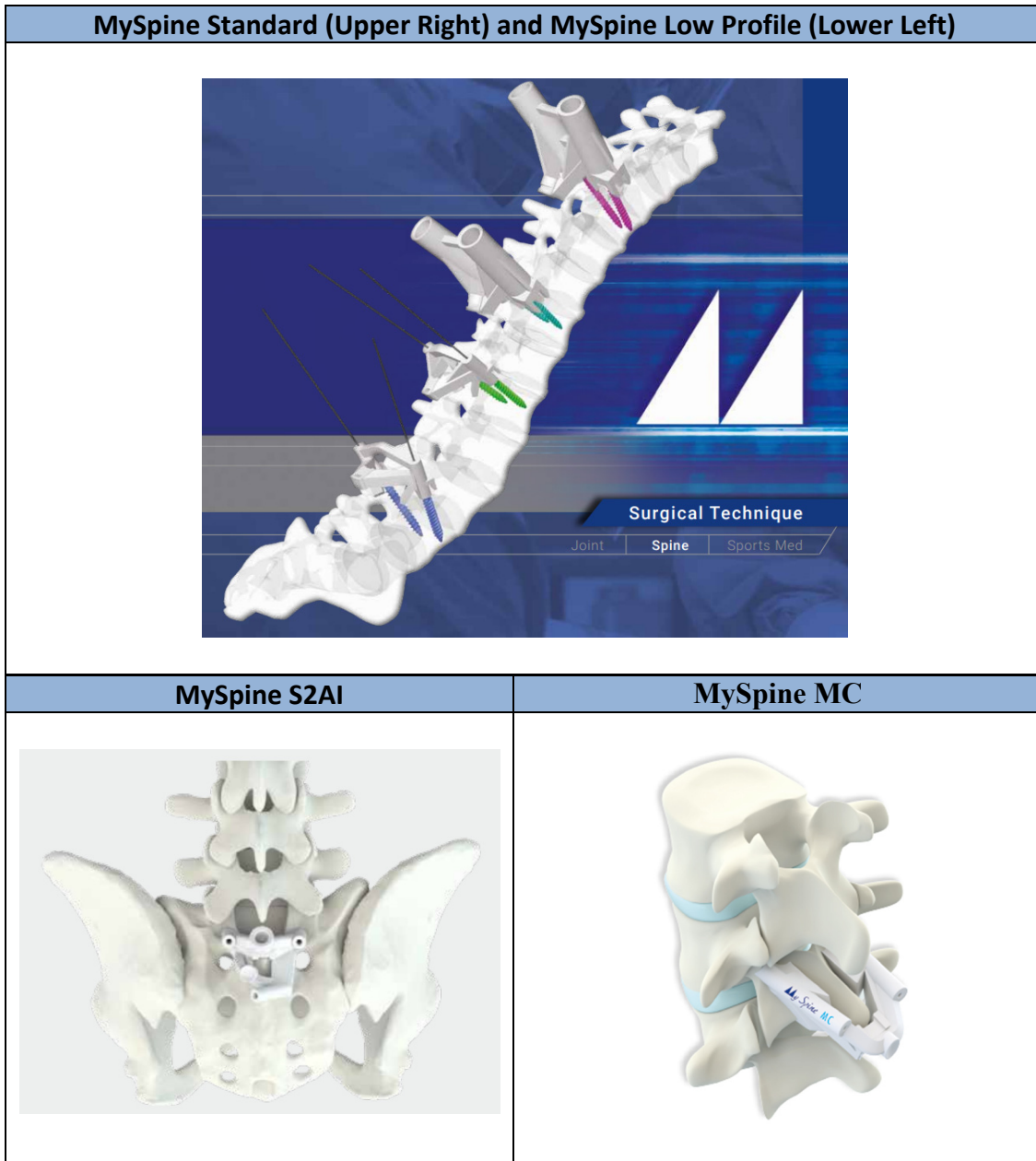
17. On May 9, 2017, United States Patent No. 9,642,633 (“the ’633 patent”) entitled “Patient-Matched Apparatus and Methods for Performing Surgical Procedures” was duly and legally issued by the United States Patent and Trademark Office. Mighty Oak owns the ’633 patent by assignment. A true and correct copy of the ’633 patent is attached as Exhibit 4.

18. On June 5, 2018, United States Patent No. 9,987,024 (“the ’024 patent”) entitled “Patient-Matched Apparatus and Methods for Performing Surgical Procedures” was duly and legally issued by the United States Patent and Trademark Office. Mighty Oak owns the ’024 patent by assignment. A true and correct copy of the ’024 patent is attached as Exhibit 5.

BACKGROUND

19. Medacta has been aware of the inventions described in Mighty Oak’s patent portfolio since at least 2012. For example, Defendant Medacta International identified Dr. Frey’s U.S. Patent Publication No. US 2011/0319745 (which later issued as the asserted ’357 patent, to which all of the other asserted patents claim priority) in the specifications of its own patent applications starting as early as December 2012. (*E.g.*, Ex. 6 (European Patent No. EP2749235B1, filed December 31, 2012).)

20. On information and belief, after becoming aware of Dr. Frey’s inventions, Medacta recognized the value of Dr. Frey’s work and included his inventive concepts in their products. Specifically, Medacta included Dr. Frey’s concepts in the accused MySpine products. The first of these products—the MySpine Standard device, discussed in more detail below—received FDA clearance in May 2014 and was used in surgeries in the United States by November 2014. *See, e.g.*, <https://www.businesswire.com/news/home/20141125005163/en/Medacta-Announces-Completion-of-First-Surgeries-with-MySpine-Patient-Matched-Technology-in-the-United-States>. Over several years following this clearance, multiple other Medacta products—including other accused MySpine products pictured here and discussed in more detail below—also received FDA clearance and were used in surgeries in the United States.



See, e.g., <https://www.medacta.com/EN/home-myspine>; <https://media.medacta.com/media/99my4612-07.pdf>; <https://media.medacta.com/media/99-my46s2ai-12-rev00.pdf>; <https://media.medacta.com/media/99my46s2ai11-00.pdf>; <https://media.medacta.com/media/brochure-myspinemc-ex-99-my46mcp-11-rev00.pdf>; <https://www.medacta.com/EN/myspine-mc>.

21. Medacta has been aware of at least the asserted '357 and '889 patents since at least 2014. In 2014, Heidi Frey, President of Mighty Oak, met with Meinrad Fiechter, R&D Director for Medacta International, near her office in Colorado. During that meeting, Mr. Fiechter informed Mrs. Frey that Medacta had received the 2014 Spine Technology Award for its MySpine products. Mrs. Frey recognized that the MySpine products were directed at the same inventive concepts as Mighty Oak's FIREFLY[®] guides, which received the same Spine Technology Award two years prior (in 2012). Later that same year, Mr. Fiechter and Eric Dremel, President of Defendant Medacta USA, sent emails to Dr. Frey, seeking a meeting to discuss a potential collaboration between Mighty Oak and Medacta. In a November 2014 email to Dr. Frey, Mr. Dremel stated that "Medacta is aware of your IP with the Firefly technology via Mighty Oak Medical," and that the purpose of a meeting would be to "discuss opportunities to collaborate in bringing this technology to market." (*E.g.*, Ex. 7 (November 6, 2014 Email fr. Dremel to Frey).) On November 10, 2014, Dr. Frey and Mrs. Frey met in Denver, Colorado with Mr. Fiechter and Jim Searle, Director of Sales & Marketing for the Spine Division of Medacta USA, to discuss Mighty Oak's FIREFLY[®] technology and the asserted '357 and '889 patents, as well as a potential collaboration with Medacta.

22. In January 2015, Dr. Frey and Mrs. Frey met in Denver with Mr. Dremel and Francesco Siccardi, Vice President of Defendant Medacta International, to follow up on the November 2014 discussions with Mr. Fiechter and to discuss what Mr. Dremel had described as "the Firefly IP situation and how an exclusive collaboration with Medacta in this area could be mutually beneficial." (*E.g.*, Ex. 8 (December 19, 2015 Email fr Dremel to Frey).) Following this meeting, Mr. Dremel sent several emails to Mrs. Frey, indicating that a written proposal for a collaboration would be forthcoming. Instead, in February 2015, Mr. Siccardi sent a letter to

Mrs. Frey to share “our evaluation of the Firefly patents,” attaching Medacta’s analysis of the ’357 patent and the ’889 patent, and identifying a reference that Medacta alleged to be “prior art” relevant to these patents. (*E.g.*, Ex. 9 (February 23, 2015 letter fr. Siccardi to Frey).) In the letter, Mr. Siccardi also declined to enter into a collaboration with Mighty Oak.

23. Following receipt of Mr. Siccardi’s February 2015 email, Mighty Oak repeatedly identified to the United States Patent and Trademark Office (“USPTO”) the same reference Mr. Siccardi had identified. Indeed, Mighty Oak identified this same reference to the USPTO during prosecution of each of its subsequent patent applications related to the ’357 and ’889 patents. Over the next several years, Mighty Oak obtained five more United States patents allowed over the reference Mr. Siccardi had identified in February 2015 (including the asserted ’678, ’633, and ’024 patents), totaling over one hundred issued claims.

24. After declining to enter into a collaboration with Mighty Oak, Medacta went on to expand its MySpine product offerings. For example, in 2016, Mighty Oak became aware that Medacta had launched low-profile versions of its MySpine devices. *See, e.g.*, <https://www.businesswire.com/news/home/20161026005181/en/Medacta-Announces-First-Surgeries-With-MySpine-Low-Profile-Guide-Following-FDA-Clearance>. Mighty Oak recognized that, like the MySpine Standard device, these low-profile MySpine devices were aimed at the inventive concepts described and claimed in Mighty Oak’s then-issued patents.

25. In May 2017, Medacta filed PCT Application Nos. PCT/IB2015/058399 and PCT/IB2015/058772 with the USPTO. These applications are directed at patient-specific navigational guides for spinal surgery, and ultimately issued as U.S. Patent Nos. 10,806,469 and 10,806,470. However, despite Medacta’s awareness of Mighty Oak’s patents at the time, Medacta

failed to identify any of Mighty Oak's then-issued patents to the USPTO when it filed either of these applications.

26. In October 2017, Mrs. Frey sent another letter to Mr. Siccardi and Mr. Dremel, informing them that Mighty Oak currently had “four issued U.S. utility patents and eight issued U.S. design patents for our FIREFLY® guides.” The letter also stated that Medacta’s “low-profile patient-specific guides clearly infringe many of [Mighty Oak’s] issued claims.” (Ex. 10 (October 19, 2017 Letter fr. Frey to Siccardi).) Later that month, at the meeting of the North American Spine Society in Orlando, Florida, Mrs. Frey met with Mr. Fiechter and showed him a draft complaint for patent infringement as well as multiple claim charts, mapping claims from Mighty Oak’s then-issued ’357, ’889, ’678, and ’633 patents onto Medacta’s accused MySpine Standard and MySpine Low Profile products.

27. Mighty Oak and Medacta continued their ongoing communications in early 2018 regarding Mighty Oak’s patent infringement claims. Counsel for both parties exchanged multiple letters and had several telephonic discussions regarding Mighty Oak’s infringement claims and Medacta’s interest in meeting with Mighty Oak to discuss the possibility of settlement and/or licensing of Mighty Oak’s patents. In June 2018, Mighty Oak’s counsel requested that Medacta provide an opening offer or term sheet for Mighty Oak’s consideration. However, no licensing or settlement offer was ever received, and these communications broke down in mid-2018. Mighty Oak never entered into a business relationship with any Medacta entity, and no Medacta entity ever obtained a license to any of Mighty Oak’s patents. Notably, up to that point, Medacta had never disclosed any of the “four issued U.S. utility patents and eight issued U.S. design patents for [Mighty Oak’s] FIREFLY® guides” to the USPTO in connection with its pending U.S. patent applications.

28. Instead of providing the “business solution” Medacta’s counsel had promised early in 2018, Medacta repeatedly and unsuccessfully attempted to evade Mighty Oak’s patents, both in the United States and in Europe, by unsuccessfully challenging certain of those patents in lengthy patent office proceedings. On December 22, 2018, Medacta filed a request for *Ex Parte* Reexamination of the asserted ’357 patent with the USPTO, citing references that included the same reference Mr. Siccardi had identified in his February 2015 letter. However, in August 2019, the USPTO confirmed the patentability of all claims of the ’357 patent. (Ex. 11 (August 26, 2019 Ex Parte Reexamination Certificate)). Immediately following this decision by the USPTO, Mighty Oak’s counsel wrote a letter to Medacta’s counsel to suggest a meeting to resume settlement discussions. Medacta’s counsel did not respond and no such meeting ever took place.

29. Less than one month after the USPTO confirmed the validity of the asserted ’357 patent, Medacta attempted to invalidate Mighty Oak’s European Patent No. EP2588009 (“the ’009 European patent”). This patent, like the asserted ’357, ’889, ’633, and ’024 patents, claims priority to U.S. Provisional Patent Application No. 61/393,695. In September 2019, Defendant Medacta International filed an opposition to the ’009 European patent with the European Patent Office. During these proceedings, Medacta’s cited references including the same reference Mr. Siccardi had identified in his February 2015 letter. However, during oral proceedings in February 2021, the European Patent Office rejected Medacta’s opposition and found all claims of the ’009 European patent allowable over the references Medacta had cited. Immediately following this decision by the European Patent Office, Mighty Oak’s European counsel wrote a letter to Medacta’s European counsel, requesting further discussion and/or negotiation between Mighty Oak and Medacta. No response was ever received.

30. After failing to invalidate Mighty Oak's U.S. and European patents, Medacta went on to identify patent publications from Mighty Oak's portfolio—including the asserted '357, '889, '024, '678, and '633 patents—during prosecution of its own patent applications. (*See, e.g.*, Ex. 12 (November 24, 2020 Information Disclosure Statement filed by Medacta during prosecution of U.S. Patent Application No. 16/333,057).)

31. On information and belief, Medacta has been aware of the '357, '889, '678, '633, and '024 patents at least since shortly after they issued in June 2014, October 2014, December 2015, May 2017, and June 2018, or was willfully blind to the existence of the patents.

32. On information and belief, since that time, Medacta has not taken any affirmative steps to avoid infringing the Mighty Oak patents, including the Asserted Patents in this case. Rather, the steps Medacta has taken include: (a) unsuccessfully challenging and tying up Mighty Oak's patents in post-grant proceedings, and (b) placating Mighty Oak's concerns by repeatedly promising settlement proposals, but never delivering.

COUNT I

(Patent Infringement of United States Patent No. 8,758,357)

33. Plaintiff restates and realleges the preceding paragraphs of this Complaint.

34. Medacta has directly infringed, and continues to directly infringe, literally and/or under the doctrine of equivalents, one or more claims of the '357 patent by making, using, testing, selling, offering for sale and/or importing into the United States Medacta's '357 Accused Products pursuant to 35 U.S.C. § 271(a). Medacta's '357 Accused Products include, but are not necessarily limited to, the MySpine Standard, MySpine Low Profile, MySpine MC, and MySpine S2AI devices, and any other Medacta products, either alone or in combination, that operate in a reasonably similar manner.

35. The claim chart attached hereto as Exhibit 13 describes how the elements of exemplary claim 1 of the '357 patent are practiced by Medacta's '357 Accused Products.

36. Medacta's '357 Accused Products practice all of the limitations of claim 1 of the '357 patent. For example, Medacta's '357 Accused Products are each a patient specific pedicle screw guide that anatomically mates with the spinous processes of a particular vertebral body, comprising the following as required by claim 1: a medial body comprising a longitudinal cavity located on a first lower surface of the medial body, such that the longitudinal cavity provides a first patient-contacting surface that mates with at least one contour of a first spinous process; a first elongated wing extending laterally from a first side of the medial body and terminating with a first cylindrical column, wherein the first cylindrical column comprises a second lower surface comprising a second patient-contacting surface that mates with at least one contour of a second spinous process; and a second elongated wing extending laterally from a second side of the medial body and terminating with a second cylindrical column, wherein the second cylindrical column comprises a third lower surface comprising a third patient-contacting surface that mates with at least one contour of a third spinous process. *See, e.g.*, <https://www.medacta.com/EN/home-myspine>; <https://media.medacta.com/media/99my4612-07.pdf>; <https://media.medacta.com/media/99-my46s2ai-12-rev00.pdf>; <https://media.medacta.com/media/99my46s2ai11-00.pdf>; <https://media.medacta.com/media/brochure-myspinemc-ex-99-my46mexp-11-rev00.pdf>; <https://www.medacta.com/EN/myspine-mc>.

37. Medacta also indirectly infringes the '357 patent by actively inducing the direct infringement by third parties such as doctors and other medical institutions under 35 U.S.C. § 271(b). Medacta has knowledge that these third-party activities concerning Medacta's '357

Accused Products infringe one or more claims of the '357 patent. On information and belief, Medacta will continue to encourage, aid, or otherwise cause these third parties to import, sell, offer for sale, and use the '357 Accused Products (which are acts of direct infringement of the '357 patent) and Medacta has and will continue to encourage those acts with the specific intent to infringe one or more claims of the '357 patent. Further, Medacta provides information and technical support to its customers (such as doctors and other medical institutions), including product manuals, brochures, videos, demonstrations, and website materials encouraging its customers to purchase and instructing them to use Medacta's '357 Accused Products with knowledge that usage in accordance with their instructions constitutes an act of direct infringement of the '357 patent, or with willful blindness to that fact. Alternatively, Medacta knows and/or will know that there is a high probability that the importation, sale, offer for sale, and use of the '357 Accused Products constitutes direct infringement of the '357 patent but took deliberate actions to avoid learning of these facts.

38. For example, Medacta has had knowledge of the '357 patent as set forth in detail above. On information and belief, Medacta has had knowledge that Medacta's '357 Accused Products infringe the '357 patent. Medacta obtained this knowledge prior to this suit, and no later than upon the filing and service of this Complaint as demonstrated by the attached claim chart. To the extent that Medacta did not have actual knowledge of its infringement prior to filing and service of the Complaint, Medacta's lack of actual knowledge is due to its deliberate decision to avoid learning of these facts. Medacta, therefore, had knowledge that its customers' use of Medacta's '357 Accused Products infringe the '357 patent, or Medacta was otherwise willfully blind to that fact.

39. Medacta, for example, encourages doctors and other medical institutions to purchase Medacta's '357 Accused Products and to use them to perform spinal surgeries. The use of the '357 Accused Products in the United States constitutes an act of direct infringement under 35 U.S.C. § 271(a). On its website, Medacta encourages doctors to implement its '357 Accused Products—upon information and belief, doctors in the United States perform surgeries using the accused Medacta products and thus are direct infringers of the '357 Patent. *See, e.g.,* <https://www.medacta.com/EN/home-myspine>.

40. Medacta provides information and technical support to its customers (such as doctors and other medical institutions), including product manuals, brochures, videos, demonstrations, and website materials encouraging its customers to purchase and instructing them to use Medacta's '357 Accused Products. This information and support is found, for example, on Medacta's website. *See, e.g.,* <https://www.medacta.com/EN/home-myspine>; <https://media.medacta.com/media/99my4612-07.pdf>; <https://media.medacta.com/media/99-my46s2ai-12-rev00.pdf>; <https://media.medacta.com/media/99my46s2ai11-00.pdf>; <https://media.medacta.com/media/brochure-myspinemc-ex-99-my46mcp-11-rev00.pdf>; <https://www.medacta.com/EN/myspine-mc>.

41. Medacta's individual product pages provide direction on the use of Medacta products, including photographs and videos. *See, e.g.,* <https://www.medacta.com/EN/home-myspine>.

42. Medacta products are described in catalogs and manuals directed towards healthcare professionals. *See, e.g.,* <https://media.medacta.com/media/99my4612-07.pdf>; <https://media.medacta.com/media/99-my46s2ai-12-rev00.pdf>. On information and belief, Medacta products are also described in journals directed toward spine professionals, including

without limitation, The Spine Journal, The European Spine Journal, and The Journal of Spinal Disorders and Techniques.

43. On information and belief, Medacta's actions demonstrate an intent not only to have caused the above acts that form the basis of direct infringement by third parties, but also that they caused these acts with the specific intent to infringe the '357 patent. At a minimum, Medacta's conduct demonstrates that Medacta either knew or should have known that the acts of such third parties directly infringed/infringe the '357 patent.

44. On information and belief, Medacta's infringement of the '357 patent has been willful and merits increased damages.

45. On information and belief, Medacta has known that its activities concerning the '357 Accused Products infringed one or more claims of the '357 patent since at least shortly after the patent issued in June 2014. As set forth above, Medacta cited a patent publication that ultimately issued as the '357 patent during prosecution of Medacta's own patent applications, more than a year before the '357 patent issued. Also, after the '357 patent issued, Mighty Oak and its representatives engaged in extensive communications with Medacta, in which Mighty Oak disclosed Dr. Frey's inventions, including those described and claimed in the '357 patent. On information and belief, Medacta learned all it could from Mighty Oak's patent portfolio to design, develop, and sell Medacta's '357 Accused Products without compensating Mighty Oak for its infringement of the '357 patent. Moreover, Mighty Oak informed Medacta that its activities infringed the '357 patent as detailed previously. For example, Mighty Oak informed Medacta of its infringement of the '357 patent in 2017, when it showed Medacta a draft complaint and claim charts detailing Medacta's infringement.

46. On information and belief, Medacta has made no attempt to design around the claims of the '357 patent.

47. On information and belief, Medacta did not have a reasonable basis for believing that the claims of the '357 patent were invalid. Indeed, Medacta tried and failed to have the claims of the '357 patent invalidated by the USPTO when it filed its request for *Ex Parte* Reexamination of the '357 patent.

48. On information and belief, Medacta's '357 Accused Products are available to businesses and individuals throughout the United States including in this District.

49. Mighty Oak has been damaged as the result of Medacta's willful infringement. Upon information and belief, Medacta will continue to infringe one or more claims of the '357 patent unless and until they are enjoined by this Court.

50. Medacta has caused and will continue to cause Mighty Oak irreparable injury and damage by infringing one or more claims of the '357 patent. Mighty Oak will suffer further irreparable injury, for which it has no adequate remedy at law, unless and until Medacta is enjoined from infringing the claims of the '357 patent.

COUNT II

(Patent Infringement of U.S. Patent No. 8,870,889)

51. Plaintiff restates and realleges the preceding paragraphs of this Complaint.

52. Medacta has directly infringed, and continues to directly infringe, literally and/or under the doctrine of equivalents, one or more claims of the '889 patent by making, using, testing, selling, offering for sale and/or importing into the United States Medacta's '889 Accused Products pursuant to 35 U.S.C. § 271(a). Medacta's '889 Accused Products include, but are not necessarily limited to, the MySpine Standard, MySpine Low Profile, MySpine MC, and MySpine S2AI

devices, and any other Medacta products, either alone or in combination, that operate in a reasonably similar manner.

53. The claim chart attached hereto as Exhibit 14 describes how the elements of exemplary claim 1 of the '889 patent are practiced by Medacta's '889 Accused Products.

54. Medacta's '889 Accused Products practice all of the limitations of claim 1 of the '889 patent. For example, Medacta's '889 Accused Products are each a patient-specific pedicle screw guide that mates with the anatomical features of a particular vertebra, comprising the following as required by claim 1: a medial body configured to be positioned adjacent a vertebra; a first elongated wing extending from a first side of the medial body and terminating with a first column, wherein the first column comprises a first lower surfaces that anatomically mates with at least one first contour of the particular vertebra; and a second elongated wing extending from a second side of the medial body opposite the first side and terminating with a second column, wherein the second column comprises a second lower surface that anatomically mates with at least one second contour of the particular vertebra; and wherein the first and second lower surfaces are determined from and complementary to the patient's anatomy. *See, e.g.,* <https://www.medacta.com/EN/home-myspine>; <https://media.medacta.com/media/99my4612-07.pdf>; <https://media.medacta.com/media/99-my46s2ai-12-rev00.pdf>; <https://media.medacta.com/media/99my46s2ai11-00.pdf>; <https://media.medacta.com/media/brochure-myspinemc-ex-99-my46mexp-11-rev00.pdf>; <https://www.medacta.com/EN/myspine-mc>.

55. Medacta also indirectly infringes the '889 patent by actively inducing the direct infringement by third parties such as doctors and other medical institutions under 35 U.S.C. § 271(b). Medacta has knowledge that these third-party activities concerning Medacta's '889

Accused Products infringe one or more claims of the '889 patent. On information and belief, Medacta will continue to encourage, aid, or otherwise cause these third parties to import, sell, offer for sale, and use the '889 Accused Products (which are acts of direct infringement of the '889 patent) and Medacta has and will continue to encourage those acts with the specific intent to infringe one or more claims of the '889 patent. Further, Medacta provides information and technical support to its customers (such as doctors and other medical institutions), including product manuals, brochures, videos, demonstrations, and website materials encouraging its customers to purchase and instructing them to use Medacta's '889 Accused Products with knowledge that usage in accordance with their instructions constitutes an act of direct infringement of the '889 patent, or with willful blindness to that fact. Alternatively, Medacta knows and/or will know that there is a high probability that the importation, sale, offer for sale, and use of the '889 Accused Products constitutes direct infringement of the '889 patent but took deliberate actions to avoid learning of these facts.

56. For example, Medacta has had knowledge of the '889 patent as set forth in detail above. On information and belief, Medacta has had knowledge that Medacta's '889 Accused Products infringe the '889 patent. Medacta obtained this knowledge prior to this suit, and no later than upon the filing and service of this Complaint as demonstrated by the attached claim chart. To the extent that Medacta did not have actual knowledge of its infringement prior to filing and service of the Complaint, Medacta's lack of actual knowledge is due to its deliberate decision to avoid learning of these facts. Medacta, therefore, had knowledge that its customers' use of Medacta's '889 Accused Products infringe the '889 patent or Medacta was otherwise willfully blind to that fact.

57. Medacta, for example, encourages doctors and other medical institutions to purchase Medacta's '889 Accused Products and to use them to perform spinal surgeries. The use of the '889 Accused Products in the United States constitutes an act of direct infringement under 35 U.S.C. § 271(a). On its website, Medacta encourages doctors to implement its '889 Accused Products—upon information and belief, doctors in the United States perform surgeries using the accused Medacta products and thus are direct infringers of the '889 patent. *See, e.g.*, <https://www.medacta.com/EN/home-myspine>.

58. Medacta provides information and technical support to its customers (such as doctors and other medical institutions), including product manuals, brochures, videos, demonstrations, and website materials encouraging its customers to purchase and instructing them to use Medacta's '889 Accused Products. This information and support is found, for example, on Medacta's website. *See, e.g.*, <https://www.medacta.com/EN/home-myspine>; <https://media.medacta.com/media/99my4612-07.pdf>; <https://media.medacta.com/media/99-my46s2ai-12-rev00.pdf>; <https://media.medacta.com/media/99my46s2ai11-00.pdf>; <https://media.medacta.com/media/brochure-myspinemc-ex-99-my46mcp-11-rev00.pdf>; <https://www.medacta.com/EN/myspine-mc>.

59. Medacta's individual product pages provide direction on the use of Medacta products, including photographs and video. *See, e.g.*, <https://www.medacta.com/EN/home-myspine>.

60. Medacta products are described in catalogs and manuals directed towards healthcare professionals. *See, e.g.*, <https://media.medacta.com/media/99my4612-07.pdf>; <https://media.medacta.com/media/99-my46s2ai-12-rev00.pdf>. On information and belief, Medacta products are also described in journals directed toward spine professionals, including

without limitation, The Spine Journal, The European Spine Journal, and The Journal of Spinal Disorders and Techniques.

61. On information and belief, Medacta's actions demonstrate an intent not only to have caused the above acts that form the basis of direct infringement by third parties, but also that they caused these acts with the specific intent to infringe the '889 patent. At a minimum, Medacta's conduct demonstrates that Medacta either knew or should have known that the acts of such third parties directly infringed/infringe the '889 patent.

62. On information and belief, Medacta's infringement of the '889 patent has been willful and merits increased damages.

63. On information and belief, Medacta has known that its activities concerning the '889 Accused Products infringed one or more claims of the '889 patent since at least shortly after the patent issued in October 2014. As set forth above, Medacta cited a patent publication that ultimately issued as the '357 patent—to which the '889 patent claims priority—during prosecution of Medacta's own patent applications, nearly two years before the '889 patent issued. Also, after the '889 patent issued, Mighty Oak and its representatives engaged in extensive communications with Medacta, in which Mighty Oak disclosed Dr. Frey's inventions, including those described and claimed in the '889 patent. On information and belief, Medacta learned all it could from Mighty Oak's patent portfolio to design, develop, and sell Medacta's '889 Accused Products without compensating Mighty Oak for its infringement of the '889 patent. Moreover, Mighty Oak informed Medacta that its activities infringed the '889 patent as detailed previously. For example, Mighty Oak informed Medacta of its infringement of the '889 patent in 2017, when it showed Medacta a draft complaint and claim charts detailing Medacta's infringement

64. On information and belief, Medacta has made no attempt to design around the claims of the '889 patent.

65. On information and belief, Medacta did not have a reasonable basis for believing that the claims of the '889 patent were invalid.

66. On information and belief, Medacta's '889 Accused Products are available to businesses and individuals throughout the United States including in this District.

67. Mighty Oak has been damaged as the result of Medacta's willful infringement. Upon information and belief, Medacta will continue to infringe one or more claims of the '889 patent unless and until they are enjoined by this Court.

68. Medacta has caused and will continue to cause Mighty Oak irreparable injury and damage by infringing one or more claims of the '889 patent. Mighty Oak will suffer further irreparable injury, for which it has no adequate remedy at law, unless and until Medacta is enjoined from infringing the claims of the '889 patent.

COUNT III

(Patent Infringement of United States Patent No. 9,198,678)

69. Plaintiff restates and realleges the preceding paragraphs of this Complaint.

70. Medacta has directly infringed, and continues to directly infringe, literally and/or under the doctrine of equivalents, one or more claims of the '678 patent by making, using, testing, selling, offering for sale and/or importing into the United States Medacta's '678 Accused Products pursuant to 35 U.S.C. § 271(a). Medacta's '678 Accused Products include, but are not necessarily limited to, the MySpine Standard, MySpine Low Profile, MySpine MC, and MySpine S2AI devices, and any other Medacta products, either alone or in combination, that operate in a reasonably similar manner.

71. The claim chart attached hereto as Exhibit 15 describes how the elements of exemplary claim 11 of the '678 patent are practiced by Medacta's '678 Accused Products.

72. Medacta's '678 Accused Products practice all of the limitations of claim 11 of the '678 patent. For example, Medacta's '678 Accused Products are each an orthopedic device for use in a minimally invasive surgical procedure, comprising the following as required by claim 11:

11. An orthopedic device for use in a minimally invasive surgical procedure, comprising: a first patient-specific element configured to at least one patient-specific surface determined from a patient's anatomy and which anatomically conforms to at least a first subcutaneous anatomic feature of a specific patient; a second patient-specific element configured to at least one second patient-specific surface determined from a patient's anatomy and which anatomically conforms to at least a second subcutaneous anatomic feature of a specific patient; and an arcuate bridge coupling the first and second patient-specific elements, the arcuate bridge configured to be selectively engaged with the first and second patient-specific elements at a location beyond the patient's anatomy. See, e.g., <https://www.medacta.com/EN/home-myspine>; <https://media.medacta.com/media/99my4612-07.pdf>; <https://media.medacta.com/media/99-my46s2ai-12-rev00.pdf>; <https://media.medacta.com/media/99my46s2ai11-00.pdf>; <https://media.medacta.com/media/brochure-myspinemc-ex-99-my46mcp-11-rev00.pdf>; <https://www.medacta.com/EN/myspine-mc>.

73. Medacta also indirectly infringes the '678 patent by actively inducing the direct infringement by third parties such as doctors and other medical institutions under 35 U.S.C. § 271(b). Medacta has knowledge that these third-party activities concerning Medacta's '678 Accused Products infringe one or more claims of the '678 patent. On information and belief, Medacta will continue to encourage, aid, or otherwise cause these third parties to import, sell, offer

for sale, and use the '678 Accused Products (which are acts of direct infringement of the '678 patent) and Medacta has and will continue to encourage those acts with the specific intent to infringe one or more claims of the '678 patent. Further, Medacta provides information and technical support to its customers (such as doctors and other medical institutions), including product manuals, brochures, videos, demonstrations, and website materials encouraging its customers to purchase and instructing them to use Medacta's '678 Accused Products with knowledge that usage in accordance with their instructions constitutes an act of direct infringement of the '678 patent, or with willful blindness to that fact. Alternatively, Medacta knows and/or will know that there is a high probability that the importation, sale, offer for sale, and use of the '678 Accused Products constitutes direct infringement of the '678 patent but took deliberate actions to avoid learning of these facts.

74. For example, Medacta has had knowledge of the '678 patent as set forth in detail above. On information and belief, Medacta has had knowledge that Medacta's '678 Accused Products infringe the '678 patent. Medacta obtained this knowledge prior to this suit, and no later than upon the filing and service of this Complaint as demonstrated by the attached claim chart. To the extent that Medacta did not have actual knowledge of its infringement prior to filing and service of the Complaint, Medacta's lack of actual knowledge is due to its deliberate decision to avoid learning of these facts. Medacta, therefore, had knowledge that its customers' use of Medacta's '678 Accused Products infringe the '678 patent, or Medacta was otherwise willfully blind to that fact.

75. Medacta, for example, encourages doctors and other medical institutions to purchase Medacta's '678 Accused Products and to use them to perform spinal surgeries. The use of the '678 Accused Products in the United States constitutes an act of direct infringement under

35 U.S.C. § 271(a). On its website, Medacta encourages doctors to implement its '678 Accused Products—upon information and belief, doctors in the United States perform surgeries using the accused Medacta products and thus are direct infringers of the '678 patent. *See, e.g.,* <https://www.medacta.com/EN/home-myspine>.

76. Medacta provides information and technical support to its customers (such as doctors and other medical institutions), including product manuals, brochures, videos, demonstrations, and website materials encouraging its customers to purchase and instructing them to use Medacta's '678 Accused Products. This information and support is found, for example, on Medacta's website. *See, e.g.,* <https://www.medacta.com/EN/home-myspine>; <https://media.medacta.com/media/99my4612-07.pdf>; <https://media.medacta.com/media/99-my46s2ai-12-rev00.pdf>; <https://media.medacta.com/media/99my46s2ai11-00.pdf>; <https://media.medacta.com/media/brochure-myspinemc-ex-99-my46mcp-11-rev00.pdf>; <https://www.medacta.com/EN/myspine-mc>.

77. Medacta's individual product pages provide direction on the use of Medacta products, including photographs and video. *See, e.g.,* <https://www.medacta.com/EN/home-myspine>.

78. Medacta products are described in catalogs and manuals directed towards healthcare professionals. *See, e.g.,* <https://media.medacta.com/media/99my4612-07.pdf>; <https://media.medacta.com/media/99-my46s2ai-12-rev00.pdf>. On information and belief, Medacta products are also described in journals directed toward spine professionals, including without limitation, The Spine Journal, The European Spine Journal, and The Journal of Spinal Disorders and Techniques.

79. On information and belief, Medacta's actions demonstrate an intent not only to have caused the above acts that form the basis of direct infringement by third parties, but also that they caused these acts with the specific intent to infringe the '678 patent. At a minimum, Medacta's conduct demonstrates that Medacta either knew or should have known that the acts of such third parties directly infringed/infringe the '678 patent.

80. On information and belief, Medacta's infringement of the '678 patent has been willful and merits increased damages.

81. On information and belief, Medacta has known that its activities concerning the '678 Accused Products infringed one or more claims of the '678 patent since at least shortly after the '678 patent issued in December 2015. As set forth above, Medacta cited a patent publication that ultimately issued as the '357 patent—to which the '678 patent claims priority—during prosecution of Medacta's own patent applications, approximately three years before the '678 patent issued. Also, Mighty Oak and its representatives engaged in extensive communications with Medacta, in which Mighty Oak disclosed Dr. Frey's inventions, including those described and claimed in patents related to the '678 patent. On information and belief, Medacta learned all it could from Mighty Oak's patent portfolio to design, develop, and sell Medacta's '678 Accused Products without compensating Mighty Oak for its infringement of the '678 patent. Moreover, Mighty Oak informed Medacta that its activities infringed the '678 patent as detailed previously. For example, Mighty Oak informed Medacta of its infringement of the '678 patent in 2017, when it showed Medacta a draft complaint and claim charts detailing Medacta's infringement.

82. On information and belief, Medacta has made no attempt to design around the claims of the '678 patent.

83. On information and belief, Medacta did not have a reasonable basis for believing that the claims of the '678 patent were invalid.

84. On information and belief, Medacta's '678 Accused Products are available to businesses and individuals throughout the United States including in this District.

85. Mighty Oak has been damaged as the result of Medacta's willful infringement. Upon information and belief, Medacta will continue to infringe one or more claims of the '678 patent unless and until they are enjoined by this Court.

86. Medacta has caused and will continue to cause Mighty Oak irreparable injury and damage by infringing one or more claims of the '678 patent. Mighty Oak will suffer further irreparable injury, for which it has no adequate remedy at law, unless and until Medacta is enjoined from infringing the claims of the '678 patent.

COUNT IV

(Patent Infringement of United States Patent No. 9,642,633)

87. Plaintiff restates and realleges the preceding paragraphs of this Complaint.

88. Medacta has directly infringed, and continues to directly infringe, literally and/or under the doctrine of equivalents, one or more claims of the '633 patent by making, using, testing, selling, offering for sale and/or importing into the United States Medacta's '633 Accused Products pursuant to 35 U.S.C. § 271(a). Medacta's '633 Accused Products include, but are not necessarily limited to, the MySpine Standard, MySpine Low Profile, MySpine MC, and MySpine S2AI devices, and any other Medacta products, either alone or in combination, that operate in a reasonably similar manner.

89. The claim chart attached hereto as Exhibit 16 describes how the elements of exemplary claim 10 of the '633 patent are practiced by Medacta's '633 Accused Products.

90. Medacta's '633 Accused Products practice all of the limitations of claim 10 of the '633 patent. For example, Medacta's '633 Accused Products are each a patient-specific guide for use in a surgical procedure the guide adapted to contact a predetermined portion of a vertebra of a patient, comprising the following as required by claim 10: a body with a proximal portion and a distal portion, the body having at least one of a bore and a track oriented in a predetermined trajectory determined from anatomical features of the patient, the bore or track adapted to guide an instrument or a fixation device in one of a cortical bone trajectory, a pedicle screw trajectory, a cortical trajectory, a sacral pedicle trajectory, a sacral alar trajectory and an S2-alar-iliac trajectory; and at least two legs extending from the body, a portion of each leg comprising patient-specific contours determined from the patient's anatomy and configured to contact and substantially conform to at least a first subcutaneous anatomic feature of the vertebra of the patient. *See, e.g.*, <https://www.medacta.com/EN/home-myspine>; <https://media.medacta.com/media/99my4612-07.pdf>; <https://media.medacta.com/media/99-my46s2ai-12-rev00.pdf>; <https://media.medacta.com/media/99my46s2ai11-00.pdf>; <https://media.medacta.com/media/brochure-myspinemc-ex-99-my46mcp-11-rev00.pdf>; <https://www.medacta.com/EN/myspine-mc>.

91. Medacta also indirectly infringes the '633 patent by actively inducing the direct infringement by third parties such as doctors and other medical institutions under 35 U.S.C. § 271(b). Medacta has knowledge that these third-party activities concerning Medacta's '633 Accused Products infringe one or more claims of the '633 patent. On information and belief, Medacta will continue to encourage, aid, or otherwise cause these third parties to import, sell, offer for sale, and use the '633 Accused Products (which are acts of direct infringement of the '633 patent) and Medacta has and will continue to encourage those acts with the specific intent to

infringe one or more claims of the '633 patent. Further, Medacta provides information and technical support to its customers (such as doctors and other medical institutions), including product manuals, brochures, videos, demonstrations, and website materials encouraging its customers to purchase and instructing them to use Medacta's '633 Accused Products with knowledge that usage in accordance with their instructions constitutes an act of direct infringement of the '633 patent, or with willful blindness to that fact. Alternatively, Medacta knows and/or will know that there is a high probability that the importation, sale, offer for sale, and use of the '633 Accused Products constitutes direct infringement of the '633 patent but took deliberate actions to avoid learning of these facts.

92. For example, Medacta has had knowledge of the '633 patent as set forth in detail above. On information and belief, Medacta has had knowledge that Medacta's '633 Accused Products infringe the '633 patent. Medacta obtained this knowledge prior to this suit, and no later than upon the filing and service of this Complaint as demonstrated by the attached claim chart. To the extent that Medacta did not have actual knowledge of its infringement prior to filing and service of the Complaint, Medacta's lack of actual knowledge is due to its deliberate decision to avoid learning of these facts. Medacta, therefore, had knowledge that its customers' use of Medacta's '633 Accused Products infringe the '633 patent or Medacta was otherwise willfully blind to that fact.

93. Medacta, for example, encourages doctors and other medical institutions to purchase Medacta's '633 Accused Products and to use them to perform spinal surgeries. The use of the '633 Accused Products in the United States constitutes an act of direct infringement under 35 U.S.C. § 271(a). On its website, Medacta encourages doctors to implement its '633 Accused Products—upon information and belief, doctors in the United States perform surgeries using the

accused Medacta products and thus are direct infringers of the '633 patent. *See, e.g.*, <https://www.medacta.com/EN/home-myspine>.

94. Medacta provides information and technical support to its customers (such as doctors and other medical institutions), including product manuals, brochures, videos, demonstrations, and website materials encouraging its customers to purchase and instructing them to use Medacta's '633 Accused Products. This information and support is found, for example, on Medacta's website. *See, e.g.*, <https://www.medacta.com/EN/home-myspine>; <https://media.medacta.com/media/99my4612-07.pdf>; <https://media.medacta.com/media/99-my46s2ai-12-rev00.pdf>; <https://media.medacta.com/media/99my46s2ai11-00.pdf>; <https://media.medacta.com/media/brochure-myspinemc-ex-99-my46mcp-11-rev00.pdf>; <https://www.medacta.com/EN/myspine-mc>.

95. Medacta's individual product pages provide direction on the use of Medacta products, including photographs and video. *See, e.g.*, <https://www.medacta.com/EN/home-myspine>.

96. Medacta products are described in catalogs and manuals directed towards healthcare professionals. *See, e.g.*, <https://media.medacta.com/media/99my4612-07.pdf>; <https://media.medacta.com/media/99-my46s2ai-12-rev00.pdf>. On information and belief, Medacta products are also described in journals directed toward spine professionals, including without limitation, The Spine Journal, The European Spine Journal, and The Journal of Spinal Disorders and Techniques.

97. On information and belief, Medacta's actions demonstrate an intent not only to have caused the above acts that form the basis of direct infringement by third parties, but also that they caused these acts with the specific intent to infringe the '633 patent. At a minimum, Medacta's

conduct demonstrates that Medacta either knew or should have known that the acts of such third parties directly infringed/infringe the '633 patent.

98. On information and belief, Medacta's infringement of the '633 patent has been willful and merits increased damages.

99. On information and belief, Medacta has known that its activities concerning the '633 Accused Products infringed one or more claims of the '633 patent since at least shortly after the '633 patent issued in May 2017. As set forth above, Medacta cited a patent publication that ultimately issued as the '357 patent—to which the '633 patent claims priority—during prosecution of Medacta's own patent applications, more than four years before the '633 patent issued. Also, Mighty Oak and its representatives engaged in extensive communications with Medacta, in which Mighty Oak disclosed Dr. Frey's inventions, including those described and claimed in patents related to the '633 patent. On information and belief, Medacta learned all it could from Mighty Oak's patent portfolio to design, develop, and sell Medacta's '633 Accused Products without compensating Mighty Oak for its infringement of the '633 patent. Moreover, Mighty Oak informed Medacta that its activities infringed the '633 patent as detailed previously. For example, Mighty Oak informed Medacta of its infringement of the '633 patent in 2017, when it showed Medacta a draft complaint and claim charts detailing Medacta's infringement.

100. On information and belief, Medacta has made no attempt to design around the claims of the '633 patent.

101. On information and belief, Medacta did not have a reasonable basis for believing that the claims of the '633 patent were invalid.

102. On information and belief, Medacta's '633 Accused Products are available to businesses and individuals throughout the United States including in this District.

103. Mighty Oak has been damaged as the result of Medacta's willful infringement. Upon information and belief, Medacta will continue to infringe one or more claims of the '633 patent unless and until they are enjoined by this Court.

104. Medacta has caused and will continue to cause Mighty Oak irreparable injury and damage by infringing one or more claims of the '633 patent. Mighty Oak will suffer further irreparable injury, for which it has no adequate remedy at law, unless and until Medacta is enjoined from infringing the claims of the '633 patent.

COUNT V

(Patent Infringement of United States Patent No. 9,987,024)

105. Plaintiff restates and realleges the preceding paragraphs of this Complaint.

106. Medacta has directly infringed, and continues to directly infringe, literally and/or under the doctrine of equivalents, one or more claims of the '024 patent by making, using, testing, selling, offering for sale and/or importing into the United States Medacta's '024 Accused Products pursuant to 35 U.S.C. § 271(a). Medacta's '024 Accused Products include, but are not necessarily limited to, the MySpine Standard, MySpine Low Profile, MySpine MC, and MySpine S2AI devices, and any other Medacta products, either alone or in combination, that operate in a reasonably similar manner.

107. The claim chart attached hereto as Exhibit 18 describes how the elements of exemplary claim 12 of the '024 patent are practiced by Medacta's '024 Accused Products.

108. Medacta's '024 Accused Products practice all of the limitations of claim 12 of the '024 patent. For example, Medacta's '024 Accused Products are each a surgical device formed by using anatomical data for a specific patient, comprising the following as required by claim 12: a body configured to be positioned near an anatomical feature of the patient; a first contact surface

that is matched to a specific patient and configured to be positioned on a first portion of the anatomical feature within a first incision; and a first internal cannulae with a first bore having a first trajectory that intersects a portion of the anatomical feature, wherein, when the first contact surface is positioned on the first portion, the first internal cannulae is positioned within the first incision and the first bore is aligned to guide an instrument advanced along the first trajectory through a second incision; wherein the first trajectory is oriented along one of: (1) a cortical bone trajectory; (2) a pedicle screw trajectory; (3) a cortical trajectory; (4) a midline trajectory; (5) a sacral pedicle trajectory; (6) a sacral alar trajectory; (7) a sacral alar iliac trajectory; (8) an S2-alar-iliac trajectory; and (9) an iliac trajectory. *See, e.g.*, <https://www.medacta.com/EN/home-myspine>; <https://media.medacta.com/media/99my4612-07.pdf>; <https://media.medacta.com/media/99-my46s2ai-12-rev00.pdf>; <https://media.medacta.com/media/99my46s2ai11-00.pdf>; <https://media.medacta.com/media/brochure-myspinemc-ex-99-my46mexp-11-rev00.pdf>; <https://www.medacta.com/EN/myspine-mc>.

109. Medacta also indirectly infringes the '024 patent by actively inducing the direct infringement by third parties such as doctors and other medical institutions under 35 U.S.C. § 271(b). Medacta has knowledge that these third-party activities concerning Medacta's '024 Accused Products infringe one or more claims of the '024 patent. On information and belief, Medacta will continue to encourage, aid, or otherwise cause these third parties to import, sell, offer for sale, and use the '024 Accused Products (which are acts of direct infringement of the '024 patent) and Medacta has and will continue to encourage those acts with the specific intent to infringe one or more claims of the '024 patent. Further, Medacta provides information and technical support to its customers (such as doctors and other medical institutions), including product manuals, brochures, videos, demonstrations, and website materials encouraging its

customers to purchase and instructing them to use Medacta's '024 Accused Products with knowledge that usage in accordance with their instructions constitutes an act of direct infringement of the '024 patent, or with willful blindness to that fact. Alternatively, Medacta knows and/or will know that there is a high probability that the importation, sale, offer for sale, and use of the '024 Accused Products constitutes direct infringement of the '024 patent but took deliberate actions to avoid learning of these facts.

110. For example, Medacta has had knowledge of the '024 patent as set forth in detail above. On information and belief, Medacta has had knowledge that Medacta's '024 Accused Products infringe the '024 patent. Medacta obtained this knowledge prior to this suit, and no later than upon the filing and service of this Complaint as demonstrated by the attached claim chart. To the extent that Medacta did not have actual knowledge of its infringement prior to filing and service of the Complaint, Medacta's lack of actual knowledge is due to its deliberate decision to avoid learning of these facts. Medacta, therefore, had knowledge that its customers' use of Medacta's '024 Accused Products infringe the '024 patent or Medacta was otherwise willfully blind to that fact.

111. Medacta, for example, encourages doctors and other medical institutions to purchase Medacta's '024 Accused Products and to use them to perform spinal surgeries. The use of the '024 Accused Products in the United States constitutes an act of direct infringement under 35 U.S.C. § 271(a). On its website, Medacta encourages doctors to implement its '024 Accused Products—upon information and belief, doctors in the United States perform surgeries using the accused Medacta products and thus are direct infringers of the '024 patent. *See, e.g.*, <https://www.medacta.com/EN/home-myspine>.

112. Medacta provides information and technical support to its customers (such as doctors and other medical institutions), including product manuals, brochures, videos, demonstrations, and website materials encouraging its customers to purchase and instructing them to use Medacta's '024 Accused Products. This information and support is found, for example, on Medacta's website. *See, e.g.,* <https://www.medacta.com/EN/home-myspine>; <https://media.medacta.com/media/99my4612-07.pdf>; <https://media.medacta.com/media/99-my46s2ai-12-rev00.pdf>; <https://media.medacta.com/media/99my46s2ai11-00.pdf>; <https://media.medacta.com/media/brochure-myspinemc-ex-99-my46mcp-11-rev00.pdf>; <https://www.medacta.com/EN/myspine-mc>.

113. Medacta's individual product pages provide direction on the use of Medacta products, including photographs and video. *See, e.g.,* <https://www.medacta.com/EN/home-myspine>.

114. Medacta products are described in catalogs and manuals directed towards healthcare professionals. *See, e.g.,* <https://media.medacta.com/media/99my4612-07.pdf>; <https://media.medacta.com/media/99-my46s2ai-12-rev00.pdf>. On information and belief, Medacta products are also described in journals directed toward spine professionals, including without limitation, The Spine Journal, The European Spine Journal, and The Journal of Spinal Disorders and Techniques.

115. On information and belief, Medacta's actions demonstrate an intent not only to have caused the above acts that form the basis of direct infringement by third parties, but also that they caused these acts with the specific intent to infringe the '024 patent. At a minimum, Medacta's conduct demonstrates that Medacta either knew or should have known that the acts of such third parties directly infringed/infringe the '024 patent.

116. On information and belief, Medacta's infringement of the '024 patent has been willful and merits increased damages.

117. On information and belief, Medacta has known that its activities concerning the '024 Accused Products infringed one or more claims of the '024 patent since at least shortly after the '024 patent issued in June 2018. As set forth above, Medacta cited a patent publication that ultimately issued as the '357 patent—to which the '024 patent claims priority—during prosecution of Medacta's own patent applications, more than five years before the '024 patent issued. Moreover, Mighty Oak and its representatives engaged in extensive communications with Medacta, in which Mighty Oak disclosed Dr. Frey's inventions, including those described and claimed in patents related to the '024 patent. On information and belief, Medacta learned all it could from Mighty Oak's patent portfolio to design, develop, and sell Medacta's '024 Accused Products without compensating Mighty Oak for its infringement of the '024 patent. Moreover, Mighty Oak informed Medacta that its activities infringed the '024 patent as detailed previously.

118. On information and belief, Medacta has made no attempt to design around the claims of the '024 patent.

119. On information and belief, Medacta did not have a reasonable basis for believing that the claims of the '024 patent were invalid.

120. On information and belief, Medacta's '024 Accused Products are available to businesses and individuals throughout the United States including in this District.

121. Mighty Oak has been damaged as the result of Medacta's willful infringement. Upon information and belief, Medacta will continue to infringe one or more claims of the '024 patent unless and until they are enjoined by this Court.

122. Medacta has caused and will continue to cause Mighty Oak irreparable injury and damage by infringing one or more claims of the '024 patent. Mighty Oak will suffer further irreparable injury, for which it has no adequate remedy at law, unless and until Medacta is enjoined from infringing the claims of the '024 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Mighty Oak respectfully requests that this Court:

- 1) Enter judgment that Medacta has infringed one or more claims of the Asserted Patents;
- 2) Enter an order permanently enjoining Medacta and its officers, agents, employees, attorneys, and all persons in active concert or participation with any of the foregoing, from infringing the claims of the Asserted Patents;
- 3) Award Mighty Oak damages in an amount sufficient to compensate it for Medacta's infringement of one or more claims of the Asserted Patents, together with pre-judgment and post-judgment interest costs, and all other damages permitted under 35 U.S.C. § 284;
- 4) Perform an accounting of Medacta's infringing activities through trial and judgment;
- 5) Treble the damages awarded to Mighty Oak under 35 U.S.C. § 284 by reason of Medacta's willful infringement of the Asserted Patents;
- 6) Declare this case to be "exceptional" and find Mighty Oak to be the prevailing party for all claims and defenses in this action, and award Mighty Oak its attorneys' fees, expenses, and costs incurred in this action under 35 U.S.C. § 285; and
- 7) Award Mighty Oak such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff Mighty Oak demands a jury trial on all issues so triable.

Dated: December 22, 2022

Respectfully Submitted,

FISH & RICHARDSON P.C.

By: /s/ Martina Tyreus Hufnal

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