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Attorneys for Plaintiff
KFX MEDICAL, LLC

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF CALIFORNIA

KFX MEDICAL, LLC,

Plaintiff,

v.

STRYKER CORPORATION AND HOWMEDICA OSTEONICS CORP. d/b/a STRYKER ORTHOPAEDICS,

Defendants.

Case No. 3:18-cv-01799-DMS-WVG

FIRST SUPPLEMENTAL COMPLAINT FOR PATENT INFRINGEMENT

and

DEMAND FOR JURY TRIAL

Hon. Dana M. Sabraw

Plaintiff KFx Medical, LLC ("KFx") hereby complains of Defendants Stryker Corporation and Howmedica Osteonics Corp. d/b/a Stryker Orthopaedics (collectively "Stryker" or "Defendants") and alleges as follows:

JURISDICTION AND VENUE

1. This Complaint states causes of action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and, more particularly, 35 U.S.C. §§ 271 and 281. This Court has subject-matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

2. On information and belief: Defendants rent or own the property at 6696 Mesa Ridge Road, San Diego, CA 92121, and conduct regular and ongoing business from that location. Defendants' website (www.stryker.com) advertises jobs based at their San Diego office. Defendants have committed the acts of infringement detailed herein within this judicial district.

3. Venue is proper in this judicial district under 28 U.S.C. § 1400(b).

PARTIES

4. KFx Medical, LLC is a Delaware limited liability company having its principal place of business at 990 Highland Drive, Suite 212-I, Solana Beach, CA 92075.

5. On information and belief, Defendant Stryker Corporation is a Delaware corporation having its principal place of business at 2825 Airview Boulevard, Kalamazoo, MI 49002 USA.

6. On information and belief, Defendant Howmedica Osteonics Corp. d/b/a Stryker Orthopaedics is a subsidiary of Stryker Corporation and is a New Jersey corporation having its principal place of business at 325 Corporate Drive, Mahwah, NJ 07430.

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ALLEGATIONS FOR ALL CLAIMS

The KFx Patents

7. On September 8, 2009, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 7,585,311 ("the '311 patent"), titled "System and Method for Attaching Soft Tissue to Bone."

8. On February 10, 2015, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 8,951,287 ("the '287 patent"), titled "System and Method for Attaching Soft Tissue to Bone."

9. The '311 and '287 patents name Michael L. Green, Dr. Joseph C. Tauro, and Bart Bojanowski as inventors.

10. KFx is the owner by assignment of all right, title, and interest in the '311 and '287 patents. A true and correct copy of the '311 patent is attached hereto as Exhibit 1. A true and correct copy of the '287 patent is attached hereto as Exhibit 2.

KFx's Innovative Surgical Technology

11. Prior to advancements in arthroscopic surgeries, rotator cuff repairs were performed as "open" surgeries, requiring large, invasive incisions. Although arthroscopic procedures allowed surgeons to perform minimally invasive rotator cuff repairs, they were difficult to execute, took a long time to learn, and required the surgeon to have exceptional skill and dexterity to perform reproducibly or reliably. For example, because the arthroscopic procedures were performed through tubes or cannulas placed in tiny incisions in the shoulder, it was difficult to manipulate the sutures within the surgical site, making it hard to tie suture knots.

12. In addition, many arthroscopic repairs did not create downward pressure on the rotator cuff tendon over a wide enough area to sufficiently promote re-attachment and healing of the injury.

13. KFx set out to address these and other shortcomings. The KFx patents are directed to some of the inventive methods KFx developed that are

particularly useful in repairing torn rotator cuffs. The KFx methods made the surgical procedure easier to perform in a reproducible manner and also improved the strength of the repair.

14. In KFx's method, suture is connected between at least two anchors—a first anchor located underneath the soft tissue (the "medial" anchor) and a second anchor located beyond an edge of the soft tissue (the "lateral" anchor). The use of one or more medial anchors with one or more lateral anchors is often referred to as a "double row" repair.

15. KFx's patented methods generally include inserting a first anchor (the medial anchor) into a bone wherein it is located underneath the soft tissue and inserting a second anchor (the lateral anchor) beyond the edge of the soft tissue. A length of suture passes through and over the soft tissue to connect the first (medial) anchor to the second (lateral) anchor. After inserting the second anchor, the suture is tensioned to compress the tendon to the bone surface. The suture is fixedly secured to the second anchor without tying any knots to complete the repair.

16. By tensioning the suture after the second anchor has been inserted into bone, the surgeon can fine-tune the degree to which the soft tissue is compressed to the bone and determine exactly how the repair will look and feel in the final construct.

17. In 2004, the named inventors filed three provisional patent applications that led to the '311 patent. In January 2006, the United States Patent and Trademark Office published KFx Medical's patent application (Application No. 11/143,007), and on September 8, 2009 the '311 patent issued.

18. The '311 patent was later reexamined and the patentability of the reexamined claims (1-3, 5-25, and 28-30) was confirmed by the United States Patent and Trademark Office. No amendments were made to the '311 patent during this reexamination.

19. Claim 1 of the ’311 patent illustrates a method claimed by the ’311 patent. It recites:

> 1. A method of attaching soft tissue to bone, comprising:
>
> inserting a first anchor into bone, wherein the first anchor is positioned underneath the soft tissue such that no part of the anchor extends beyond an edge of the soft tissue;
>
> passing a first length of suture from said first anchor over the soft tissue;
>
> inserting a second anchor into bone, wherein the second anchor is positioned beyond the edge of the soft tissue such that it is not underneath the soft tissue;
>
> after inserting the second anchor, tensioning the first length of suture to compress an area of tissue to bone between the edge of the soft tissue and the first anchor; and
>
> fixedly securing the first length of suture to the second anchor without tying any knots.

20. KFx worked to commercialize its invention with a product and technique called the SutureCross® system. Although the product was well received by surgeons, KFx ultimately could not compete with larger companies, which had established sales organizations and were promoting techniques using KFx’s patented methods.

21. KFx has licensed its patents, including the ’311 and ’287 patents, to major medical device companies, including Stryker’s competitors in the sports medicine field.

Prior Litigation Involving the ’311 Patent

22. In 2011, KFx filed a lawsuit against Arthrex, Incorporated (“Arthrex”) in the Southern District of California, alleging that Arthrex infringed the ’311 patent and later added two related KFx patents to the lawsuit. Case No. 3:11-cv-

01698, U.S. District Court for the Southern District of California ("Arthrex Litigation").

23. A jury in the Arthrex Litigation found the '311 patent, and two related KFx patents, not invalid and found that Arthrex infringed these patents. The jury awarded KFx $29 million in damages. The Court also taxed costs, awarded additional damages, and awarded prejudgment and post-judgment interest for a total award of approximately $36 million.

24. On appeal, the Federal Circuit summarily affirmed the district court's judgment of patent validity, infringement, and damages. The Supreme Court later denied Arthrex's petition for certiorari.

Stryker's Knowledge of Its Need for a Patent License

25. Stryker has been aware of the '311 patent since at least 2012.

26. On information and belief, Stryker has been aware of the '287 patent since at least 2015 when the patent issued.

27. Stryker has been aware of the Arthrex Litigation on the '311 patent and related patents since at least 2013.

28. Stryker has also been aware that its competitors have taken licenses from KFx for the lawful right to practice the inventions of the '311 patent and related patents.

29. KFx informed Stryker that Stryker needed a license under the '311 patent estate on multiple occasions dating from at least 2012 to present.

30. Stryker has been aware that its products, namely the ReelX STT suture anchors, when used for double-row repairs as promoted and advertised by Stryker infringe the KFx patents.

Stryker's Infringing Activities

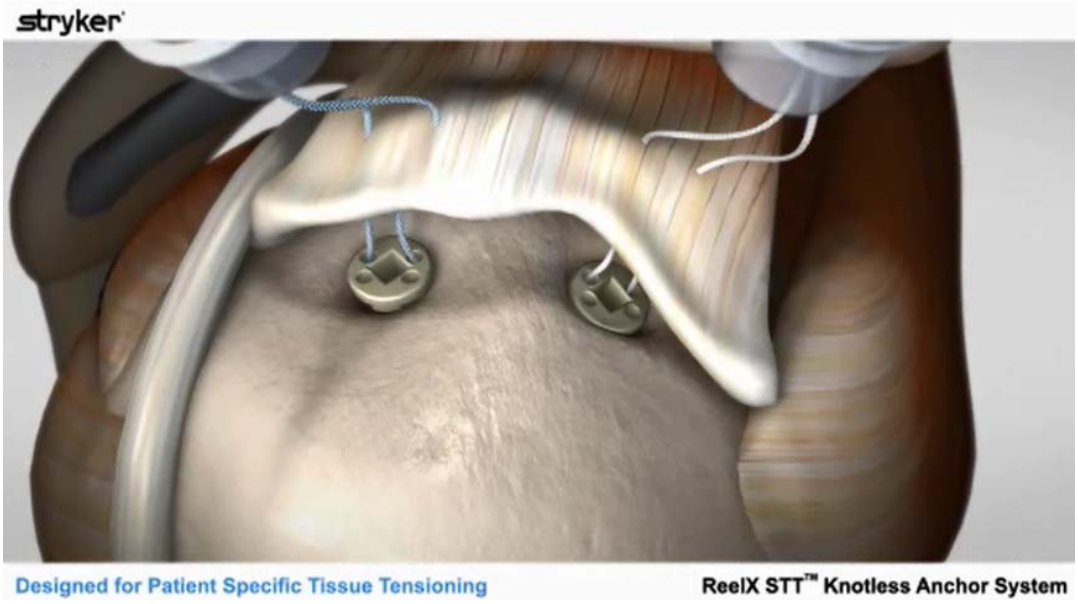
31. On information and belief, Defendants design, manufacture, and sell knotless suture anchors under the ReelX brand, including the 4.5mm ReelX STT Knotless Anchor System and the 5.5mm ReelX STT Knotless Anchor System.

32. The ReelX STT Knotless Anchor System, in both the 4.5mm and 5.5mm sizes, is used in double-row repair procedures. A true and correct copy of Stryker promotional guide, titled "ReelX STT Knotless Anchor System Quick Reference Guide" is attached hereto as Exhibit 3. The guide promotes the ReelX STT Knotless Anchor System for use in double-row repair procedures.

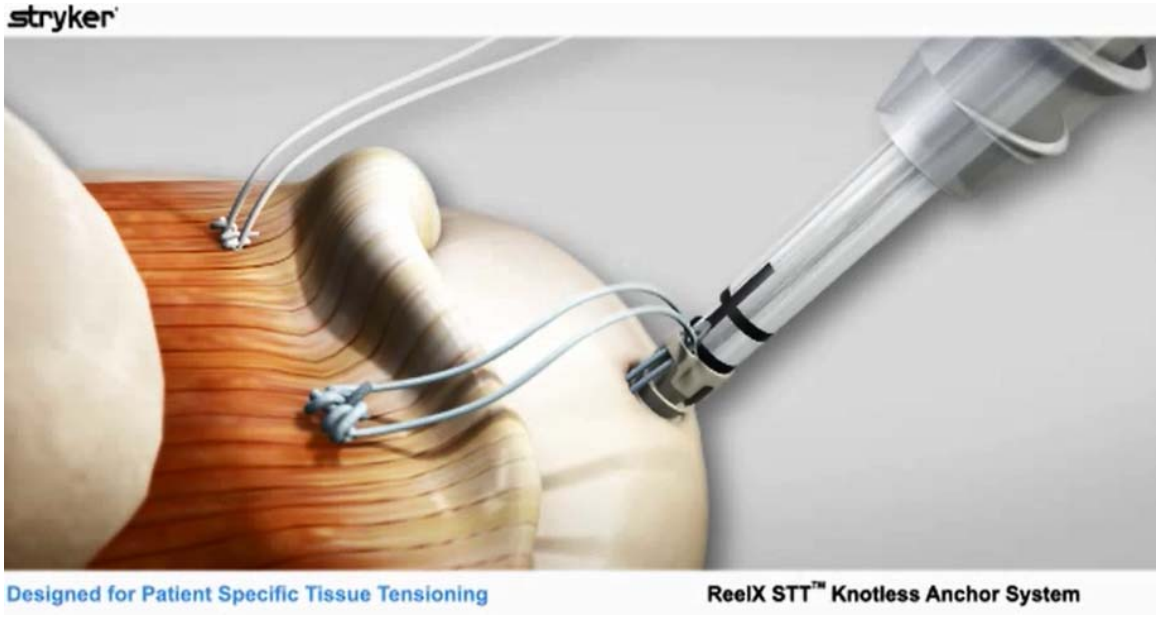
33. When used in a double-row repair procedure there is no substantial non-infringing use for Stryker's ReelX STT Knotless Anchor System.

34. Defendants have also created and used an instructional animation for demonstrating to surgeons how to use the ReelX STT Knotless Anchor System in a double-row rotator cuff repair ("Stryker Instructional Animation"). The Stryker Instructional Animation is and has been made available to surgeons on Stryker's website (http://www.stryker.com/en-us/products/Orthopaedics/SportsMedicine/UpperExtremity/Anchors/Peek/ReelX/index.htm).

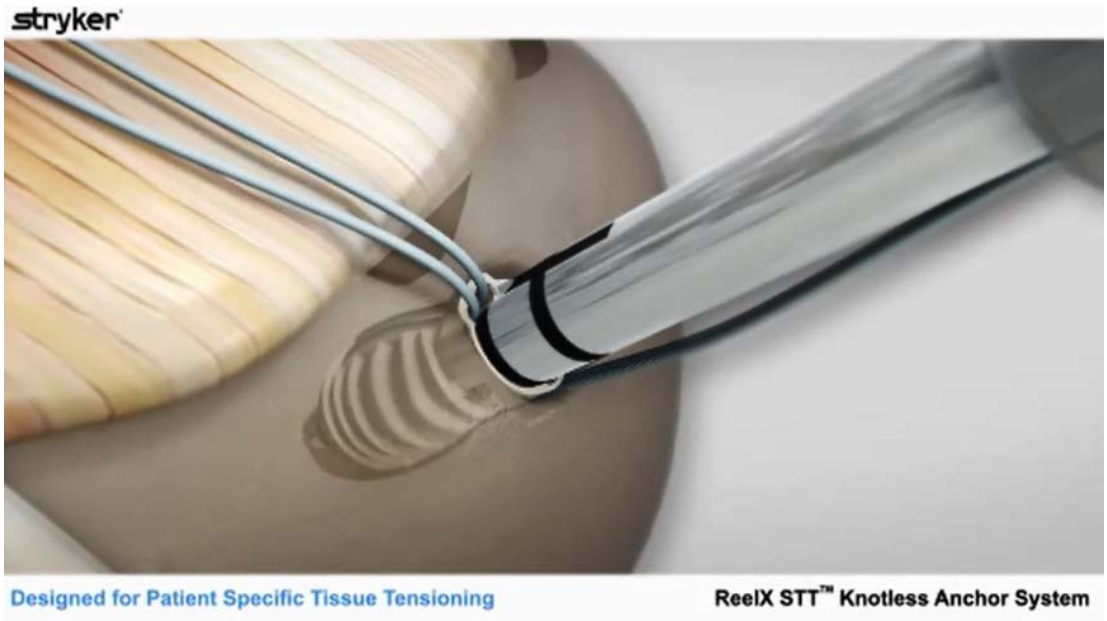
35. The Stryker Instructional Animation instructs the surgeon to place a first pair of anchors (the medial anchors) into the bone and positioned underneath the soft tissue (rotator cuff) and pass a length of suture from the first anchor over the soft tissue. These steps are depicted below:



36. The Stryker Instructional Animation further instructs the surgeon to insert a second pair of anchors (the lateral anchors) into bone beyond the edge of the soft tissue such that the anchors are not underneath the soft tissue. Insertion of one such lateral anchor is shown below:



37. The Stryker Instructional Animation further instructs the surgeon to tension the sutures to compress an area of tissue to bone between the edge of the soft tissue and the first anchor. This is shown below:



38. The Stryker Instructional Animation further instructs the surgeon to fixedly secure the suture to the second pair of anchors without tying any knots. The suture is secured to the second pair of anchors by compressing the suture between at least two surfaces on each of the second anchors. A completed repair is shown below:

39. Defendants also market the ReelX STT for repair of the Achilles tendon. A true and correct copy of a Stryker technique guide for using the ReelX STT in double-row Achilles tendon repair is attached as Exhibit 4 ("Stryker Achilles Tendon Technique Guide").

40. Step 7 of the Stryker Achilles Tendon Technique Guide (shown below) instructs the surgeon to insert a first pair of anchors (with sutures attached thereto) into bone wherein the first pair of anchors are positioned underneath the soft tissue to be repaired.

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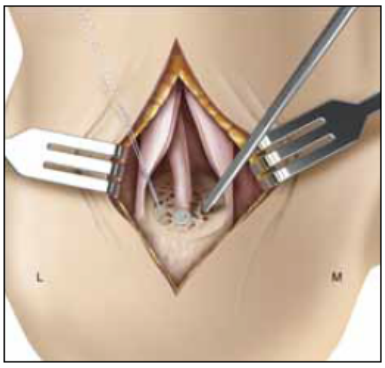
Step 7

Using a 5mm BioZip drill, create a pilot hole medial and lateral to the FHL tunnel. Both holes should be just anterior to the FHL tunnel. Insert a 5.5mm PEEK Zip anchor into each of the pilot holes. Remove one of the sutures from each anchor so the anchors are single-loaded.

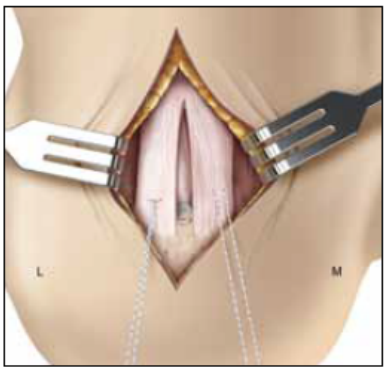


Step 7.

41. Step 8 of the Stryker Achilles Tendon Technique Guide (shown below) instructs the surgeon to pass the sutures through and over the Achilles tendon.

Step 8

Pass both limbs of the sutures through the corresponding half of the Achilles, approximately 1cm from the distal end of the tendon. Tie the sutures in a horizontal mattress or modified Mason Allen technique.



Step 8.

42. Step 10 of the Stryker Achilles Tendon Technique Guide (shown below) instructs the surgeon to insert the ReelX STT knotless suture anchor into the bone such that it is not underneath the soft tissue and "twist the top of the handle with 2 fingers clockwise until the sutures are pulled to the desired tension. Cut the excess high strength sutures as they exit the ReelX STT anchor."

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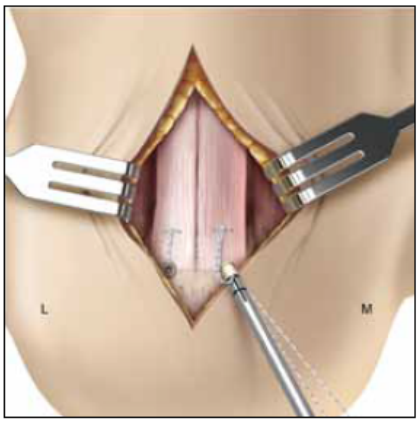
Step 10

Pass two of the limbs from the "proximal row" knots through a ReelX STT knotless suture anchor and insert the tip of the anchor into the lateral pilot hole. Make sure the vertical laser line on the inserter shaft faces the Achilles tendon and allow some slack in the suture. Impact the ReelX STT device until it is seated to the first laser line on the insertion shaft. *Remove the white suture from the top of the ReelX STT handle and twist the top of the handle with 2 fingers clockwise until the sutures are pulled to the desired tension. Cut the excess high strength sutures as they exit the ReelX STT anchor.* Repeat this process again with the remaining limbs from the "proximal row" knots through another ReelX STT anchor inserted on the medial aspect of the calcaneus.



Step 10.

43. The Stryker Achilles Tendon Technique Guide does not instruct the surgeon to tie any knots to fixedly secure the first length of suture to the second anchor. The suture is secured to the second pair of anchors by compressing the suture between at least to surfaces on each of the second anchors.

44. At least by sometime in or about 2019, Defendants began marketing Omega anchors for use in knotless double-row soft tissue repairs. Defendants have posted a written and illustrated technique guide ("Technique") for the Omega anchor on their website. A true and correct copy of Defendants' technique guide is attached hereto as Exhibit 5. Defendants have also posted an animated technique guide showing how the Omega anchor is used in double-row rotator cuff repair, which is available at https://www.stryker.com/us/en/sports-medicine/products/omega.html.

45. As depicted in the Technique, Defendants instruct surgeons to repair a rotator cuff, i.e. attach soft tissue to bone, using the Omega knotless anchor and other devices promoted by Defendants. Per the Technique, Defendants instruct the surgeon to place a first pair of anchors (the medial anchors) into the bone and positioned underneath the soft tissue (rotator cuff tendon). The medial anchors in the Technique are the ICONIX All Suture Anchors. A first medial anchor is depicted on pg. 3 of the Technique and the second medical anchor is depicted on pg. 4. As depicted on pg. 5, both of the medial anchors are positioned underneath

the soft tissue such that no part of the anchor extends beyond an edge of the soft tissue.

46. Per the Defendants' Technique, the surgeon passes suture from the medial anchors through and over the soft tissue using Defendants' Cobra reusable suture passer. See Technique at pp. 4 and 5. As shown on pg. 5 in the second drawing, the sutures from the medial anchors have been passed through and over the soft tissue and extend through the anterior (left) and posterior (right) portals.

47. Per the Defendants' Technique, the surgeon inserts a second anchor into the bone at a position beyond the edge of the soft tissue such that the anchor is not underneath the soft tissue. See Technique at p. 5 (beginning at last drawing). Per the Defendants' Technique, "The Omega Knotless Anchor features a self-punching all-PEEK eyelet." Technique at p. 5. In particular, the surgeon inserts the distal eyelet portion of the Omega knotless anchor.

48. Per the Defendants' Technique, after inserting the Omega anchor the surgeon tensions a first length of suture from a medial anchor to compress an area of tissue to bone between the edge of the soft tissue and first anchor. Specifically, the Defendants' Technique instructs, "While maintaining slight downward pressure on the screwdriver handle, pull desired tension on the suture limbs one at a time and place in the cleats if desired." Technique at p. 6. The tensioning is evident from the progression of figures on pg. 6 of the Technique.

49. Per the Defendants' Technique, the suture is fixedly secured to the lateral anchor without tying any knots by screwing in the proximal screw portion of the Omega anchor. The completed repair (without any knots to secure the suture to the lateral anchors) is shown on pg. 7 of the Technique.

50. Defendants do not have a license to any KFx patents to make, use, sell, offer for sale, or import into the United States the ReelX STT products, Omega products, or any other products.

FIRST CLAIM FOR RELIEF:

(Induced Patent Infringement of U.S. Patent No. 7,585,311)

(35 U.S.C. § 271(b))

51. KFx repeats and re-alleges the allegations of paragraphs 1-44 of this Complaint as if set forth fully herein.

52. Defendants' have induced infringement of the '311 patent, including at least Claim 1 of the '311 patent, under 35 U.S.C. § 271(b).

53. Defendants have actual knowledge of the '311 patent because, among other reasons, KFx has previously brought the patent to their attention.

54. Defendants have knowingly and actively induced infringement of the '311 patent by, *inter alia*, marketing and selling systems and devices used to attach soft tissue to bone, including for rotator cuff repairs, knowing and intending that such systems and devices, including the ReelX STT, be used by Defendants' customers and users in a manner that infringes at least Claim 1 of the '311 patent. To that end, Defendants provide instructions and teachings to their customers and users that the ReelX STT be used in the manner claimed in at least Claim 1 of the '311 patent.

55. As instructed by Defendants, surgeons have used the ReelX STT and related products marketed by Defendants in a manner that directly infringes the '311 patent, including at least Claim 1 of the '311 patent.

56. Defendants' acts of induced infringement of the '311 patent includes at least their marketing, sale, promotion, and instructions for use of the systems and devices that Defendants market as the ReelX STT Knotless Anchor System for use in at least double-row rotator cuff and Achilles tendon repair.

57. Defendants' acts of induced infringement were undertaken without permission or a license from KFx.

58. Defendants actions constitute willful infringement of the ’311 patent, entitling KFx to enhanced damages under 35 U.S.C. § 284 and attorneys’ fees and costs under 35 U.S.C. § 285.

59. On information and belief, Defendants have derived and received, and will continue to derive and receive, gains, profits, and advantages from the aforesaid acts of infringement in an amount that is not presently known to KFx. By reason of the aforesaid infringing acts, KFx has been damaged and is entitled to monetary relief in an amount to be determined.

60. If the aforesaid infringing acts were to continue unabated and without an adequate on-going royalty paid to KFx, KFx would suffer great and irreparable injury.

SECOND CLAIM FOR RELIEF:

(Induced Patent Infringement of U.S. Patent No. 8,951,287)

(35 U.S.C. § 271(b))

61. KFx repeats and re-alleges the allegations of paragraphs 1-54 of this Complaint as if set forth fully herein.

62. Defendants’ have induced infringement of the ‘287 patent, including at least Claim 1 of the ’287 patent, under 35 U.S.C. § 271(b).

63. On information and belief, Defendants have actual knowledge of the ’287 patent.

64. Defendants have knowingly and actively induced infringement of the ’287 patent by, *inter alia*, marketing and selling systems and devices used to attach soft tissue to bone, including for rotator cuff repairs, knowing and intending that such systems and devices, including the ReelX STT, be used by Defendants’ customers and users in a manner that infringes at least Claim 1 of the ’287 patent. To that end, Defendants provide instructions and teachings to their customers and users that the ReelX STT be used in the manner claimed in at least Claim 1 of the ’287 patent.

65. As instructed by Defendants, surgeons have used the ReelX STT and related products marketed by Defendants in a manner that directly infringes the '287 patent, including at least Claim 1 of the '287 patent.

66. Defendants' acts of induced infringement of the '287 patent includes at least their marketing, sale, promotion, and instructions for use of the systems and devices that Defendants market as the ReelX STT Knotless Anchor System for use in at least double-row rotator cuff and Achilles tendon repair.

67. Defendants' acts of induced infringement were undertaken without permission or a license from KFx.

68. Defendants actions constitute willful infringement of the '287 patent, entitling KFx to enhanced damages under 35 U.S.C. § 284 and attorneys' fees and costs under 35 U.S.C. § 285.

69. On information and belief, Defendants have derived and received, and will continue to derive and receive, gains, profits, and advantages from the aforesaid acts of infringement in an amount that is not presently known to KFx. By reason of the aforesaid infringing acts, KFx has been damaged and is entitled to monetary relief in an amount to be determined.

70. If the aforesaid infringing acts were to continue unabated and without an adequate on-going royalty paid to KFx, KFx would suffer great and irreparable injury.

THIRD CLAIM FOR RELIEF:

(Induced Patent Infringement of U.S. Patent No. 7,585,311 based on Defendants' recently introduced Omega anchors)

(35 U.S.C. § 271(b))

71. KFx repeats and re-alleges the allegations of paragraphs 1-64 of this Complaint as if set forth fully herein.

72. Defendants have further induced infringement of the '311 patent, including at least Claim 1 of the '311 patent, under 35 U.S.C. § 271(b) by

marketing and selling the Omega anchor, which recently has been introduced and promoted for use in double-row rotator cuff repair.

73. Defendants have actual knowledge of the ’311 patent.

74. Defendants have knowingly and actively induced infringement of the ’311 patent by, *inter alia*, marketing and selling systems and devices used to attach soft tissue to bone, including for rotator cuff repairs, knowing and intending that such systems and devices, including the Omega, be used by Defendants’ customers and users in a manner that infringes at least Claim 1 of the ’311 patent. To that end, Defendants provide instructions and teachings to their customers and users that the Omega be used in the manner claimed in at least Claim 1 of the ’311 patent.

75. As instructed by Defendants, one or more surgeons have used the Omega and related products marketed by Defendants in a manner that directly infringes the ‘311 patent, including at least Claim 1 of the ’311 patent.

76. Defendants’ acts of induced infringement of the ’311 patent includes at least their marketing, sale, promotion, and instructions for use of the systems and devices that Defendants market as the Omega Knotless Anchor System for use in at least double-row rotator cuff repair.

77. Defendants’ acts of induced infringement were undertaken without permission or a license from KFx.

78. Defendants actions constitute willful infringement of the ’311 patent, entitling KFx to enhanced damages under 35 U.S.C. § 284 and attorneys’ fees and costs under 35 U.S.C. § 285. Defendants willful infringement is particularly evident by their knowledge that the Omega anchor and its use in double-row rotator cuff repair is, in all respects relevant to the ‘311 patent, the same as the previous adjudicated infringing use of the Arthrex Swivelock SP in the SpeedBridge technique of Arthrex.

79. On information and belief, Defendants have derived and received, and/or will derive and receive, gains, profits, and advantages from the aforesaid acts of infringement in an amount that is not presently known to KFx. By reason of the aforesaid infringing acts, KFx has been damaged and is entitled to monetary relief in an amount to be determined, and in no event less than a reasonable royalty.

80. If the aforesaid infringing acts were to continue unabated and without an adequate on-going royalty paid to KFx, KFx would suffer great and irreparable injury.

PRAYER FOR RELIEF

KFx respectfully prays for the following relief:

A. an order adjudging Defendants to have induced infringement the ’311 and ’287 patents;

B. an award of damages adequate to compensate KFx for Defendants’ patent infringement;

C. an on-going royalty for any future infringement, or absent such royalty, a permanent injunction enjoining Defendants, as well as its officers, agents, servants, employees, and attorneys and those persons in active concert or participation with Defendants, from infringing the ’311 and ’287 patents;

D. an order adjudging Defendants to have willfully infringed the ’311 and ’287 patents and declaring this to be an exceptional case;

E. an order trebling damages and/or for exemplary damages because of Defendants’ intentional and willful conduct;

F. an award of prejudgment and postjudgment interest and costs of this action against Defendants;

G. an award to KFx of its attorneys’ fees incurred in connection with this action; and

H. such other and further relief as the Court deems just and proper.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: February 11, 2020

/s/ *Joseph F. Jennings*

Joseph F. Jennings
Brian C. Horne
Brandon G. Smith

Attorneys for Plaintiff
KFX MEDICAL, LLC

DEMAND FOR JURY TRIAL

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff KFx hereby demands a trial by jury on all issues so triable.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: February 11, 2020

/s/ *Joseph F. Jennings*
Joseph F. Jennings
Brian C. Horne
Brandon G. Smith

Attorneys for Plaintiff
KFX MEDICAL, LLC

28677151

TABLE OF EXHIBITS

Page No.

PROOF OF SERVICE

I hereby certify that on February 11, 2020, I caused the foregoing document to be electronically filed with the Clerk of the Court using the CM/ECF system which will send electronic notification of such filing to the following person(s):

John D. Vaughn Christopher W. Rowlett PEREZ VAUGHN & FEASBY Inc. 600 B Street, Suite 2100 San Diego, California 92101 Telephone: (619) 702-8044 Facsimile: (619) 460-0437 E-Mail: vaughn@pvflaw.com; rowlett@pvflaw.com	Gregory S. Gewirtz David G. Leach Orville R. Cockings LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK, LLP 600 South Avenue West Westfield, NJ 07090-1497 Telephone: (908) 654-5000 Facsimile: (908) 654-7866 E-Mail: ggewirtz@lernerdavid.com; dleach@lernerdavid.com; ocockings@lernerdavid.com

I certify and declare under penalty of perjury under the laws of the State of California that I am employed in the office of a member of the bar of this Court at whose direction the service was made, and that the forgoing is true and correct.

Executed on February 11, 2020, at Irvine, California.

Claire A. Stoneman

32195567