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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

Puget BioVentures, LLC,

Plaintiff,

v.

Stryker Corporation and
Howmedica Osteonics Corp. (d/b/a Stryker
Orthopaedics),

Defendants.

CIVIL CASE NO.: 2:17-cv-04703

Civil Action

COMPLAINT AND JURY DEMAND

Plaintiff Puget BioVentures, LLC (“PugetBV”) files this Complaint for willful patent infringement of U.S. Patent No. 7,967,822 (“the ’822 patent”) against Stryker Corporation and Howmedica Osteonics Corp. (collectively “Stryker” or “Defendants”), and alleges:

THE PARTIES

1. PugetBV is a Washington limited liability corporation with its place of business in Saratoga Springs, New York.

2. Stryker Corporation is a Michigan corporation with its place of business in Kalamazoo, Michigan.

3. Stryker Corporation segregates its operations into three reportable business segments, one of which is an orthopaedics business segment.

4. Howmedica Osteonics Corp. (“Stryker Orthopaedics”), which does business as Stryker Orthopaedics, is a wholly owned subsidiary of Stryker Corporation. Howmedica is a New Jersey Corporation with its place of business in Mahwah, New Jersey. Howmedica is part of Stryker Corporation’s orthopaedics business segment.

JURISDICTION AND VENUE

5. This is an action for patent infringement under the United States patent laws, Title 35 of the United States Code.

6. The Court has original jurisdiction over the subject matter of this action under 28 U.S.C. § 1338(a).

7. This Court has general and specific personal jurisdiction over Stryker Corporation because it conducts business in New Jersey and has had continuous and systematic contacts with New Jersey, and has availed itself of this jurisdiction in the past. Stryker Corporation represents that it owns a manufacturing and distribution facility in Mahwah, New Jersey where it manufactures and distributes orthopaedic products. Between 2006 to the present, Stryker Corporation, by and through its agents, has occupied at least 4 roles as directors and/or corporate officers for Stryker Orthopaedics. Stryker Corporation has established minimum contacts within the forum such that the exercise of jurisdiction over Stryker Corporation would not offend traditional notions of fair play and substantial justice.

8. This Court has general and specific personal jurisdiction over Stryker Orthopaedics because it resides in this district.

9. Venue in this district is proper as to Stryker under 28 U.S.C. § 1400(b) at least because this is a district in which Stryker (a) has committed acts of patent infringement; and (b) has a regular and established place of business.

The '822 Patent and the '541 Patent

10. PugetBV owns all right, title, and interest in U.S. Patent No. 7,967,822 (“the ’822 patent”), entitled “Methods and Apparatus for Orthopedic Implants.” (A true and accurate copy of the ’822 patent is attached as **Exhibit A**.) PugetBV obtained this right, title, and interest in the ’822 patent from Hudson Surgical Design, Inc. (“Hudson Surgical”).

11. The ’822 patent was duly and legally issued by the United States Patent and Trademark Office (“Patent Office”) on June 28, 2011 to Hudson Surgical, listing Timothy G. Haines and David B. Goldstein as inventors. Hudson Surgical transferred its right, title, and interest in the ’822 patent to PugetBV.

12. The ’822 patent claims priority to application No. 08/479,363, filed on June 7, 1995. (See **Exhibit A**, “Related U.S. Application Data.”)

13. The Patent Office issued U.S. Pat. No. 7,344,541 (“the ’541 patent”) on March 18, 2008, to Hudson Surgical, listing Timothy G. Haines and David B. Goldstein as inventors. Hudson Surgical transferred its right, title, and interest in the ’541 patent to PugetBV. The ’541 patent also claims priority to application No. 08/479,363, filed on June 7, 1995.

14. The ’822 patent and ’541 patent are related patents that are part of PugetBV’s patent portfolio.

Stryker Has Long Known of PugetBV’s Patent Rights in the Field of Minimally Invasive Total Knee Arthroplasty

15. Both the ’822 patent and the ’541 patent relate to minimally invasive total knee arthroplasty (“MIS TKA”).

16. Stryker has been aware of PugetBV’s patent rights since at least 2011.

17. On July 13, 2011, counsel for Hudson Surgical, PugetBV's predecessor-in-interest, wrote to Curtis Hall, then General Counsel of Stryker Corporation. (A true and accurate copy of correspondence between counsel for Hudson Surgical and Stryker is attached as **Exhibit B.**)

18. Stryker was informed of PugetBV's patent portfolio in the field of total knee replacement, and was explicitly informed that the '822 patent should be of interest to Stryker because the '822 patent claims cover cutting guides for minimally-invasive total knee replacement products that were made, marketed and provided by most of the major orthopedic companies.

19. Stryker did not and has not obtained a license to practice the claimed inventions of the '822 patent.

Puget has Enforced its Rights in the '541 Patent and Other Patents Against Stryker's Competitors

20. Stryker has a limited number of competitors in the orthopedic industry. Its competitors include: DePuy Orthopaedics, Zimmer Biomet, and Smith & Nephew.

21. PugetBV, including its predecessor-in-interest Hudson Surgical, has litigated patent infringement cases against DePuy, Biomet, Zimmer, and Smith & Nephew.

22. On March 18, 2008, Hudson filed a Complaint against Zimmer in the Northern District of Illinois for infringement of the '541 patent. (Complaint, *Hudson Surgical Design, Inc. v. Zimmer Holdings, Inc.*, 1:08-cv-01566 (N.D. Ill. Mar. 18, 2008), D.I. 1).

23. On September 21, 2011, Hudson filed a Complaint against Smith & Nephew, Inc. in the Western District of Washington for infringement of the '822 patent. (Complaint, *Hudson Surgical Design, Inc. v. Smith & Nephew, Inc.*, 2:11-cv-01371 (W.D. Wash. Sept. 21, 2011), D.I. 1).

24. On April 5, 2010, Hudson filed a Complaint against DePuy in the Northern District of Illinois for infringement of the '541 patent. (Complaint, *Hudson Surgical Design, Inc. v. DePuy Orthopaedics, Inc.*, 1:10-cv-02103 (N.D. Ill. Apr. 5, 2010), D.I. 1).

25. On November 3, 2010, the '541 action against DePuy was transferred to the Northern District of Indiana. (Notice of Transfer, *Hudson Surgical Design, Inc. v. DePuy Orthopaedics, Inc.*, 1:10-cv-02103 (N.D. Ill. Nov. 3, 2010), D.I. 48) (hereinafter, “the DePuy '541 case”).

26. PugetBV, as the current owner of the '541 patent, has been substituted as the named plaintiff in *Hudson Surgical Design, Inc. v. DePuy Orthopaedics, Inc.*, 3:10-cv-00463 (N.D. Ind. Fed. 1, 2017) (D.I. 104).

27. On July 19, 2010, Hudson filed a Complaint against Biomet in the Northern District of Illinois for infringement of the '541 patent. (Complaint, *Hudson Surgical Design, Inc. v. Biomet Orthopedics, LLC and Biomet Manufacturing Corporation*, 1:10-cv-04459 (N.D. Ill. July 19, 2010), D.I. 1).

28. On November 4, 2010, the '541 action against Biomet was transferred to the Northern District of Indiana. (Notice of Transfer, *Hudson Surgical Design, Inc. v. Biomet Orthopedics, LLC and Biomet Manufacturing Corporation*, 1:10-cv-04459 (N.D. Ind. Nov. 4, 2010), D.I. 30) (hereinafter, “the Biomet '541 case”).

29. PugetBV, as the current owner of the '541 patent, has been substituted as the named plaintiff in *Hudson Surgical Design, Inc. v. Biomet Orthopedics, LLC and Biomet Manufacturing Corporation*, 1:10-cv-04459 (N.D. Ind. Feb. 9, 2017) (D.I. 94).

30. The DePuy '541 case and the Biomet '541 case have been stayed since December of 2010 pending *inter partes* reexamination of the '541 patent that Biomet initiated and has pursued, without success.

31. As part of the reexamination of the '541 patent, the United States Court of Appeals for the Federal Circuit affirmed a claim construction that required “using a single cutting guide placed on one side of a bone to cut all the way across the bone without requiring a second cut from the other side (although some free-hand grinding or polishing to smooth any rough spots may be permissible).”

32. On March 3, 2017, during the reexamination and on remand from the Federal Circuit, the Examiner confirmed the patentability of original claims 31, 33, 39, 40, 45, and 47 of the '541 patent.

33. DePuy has been similarly unsuccessful in attempting to invalidate the claims of the '822 patent.

34. On September 7, 2012, DePuy requested an *inter partes* reexamination of the '822 patent with the Patent Office.

35. On October 29, 2012, the Patent Office ordered reexamination of the '822 patent.

36. Since then, the '822 patent's reexamination has been pending for over four-and-a-half years.

37. On December 16, 2016, the Patent Trial and Appeal Board ("PTAB") confirmed the validity of originally issued claims 1, 2, 5, 6 and 14-27 of the '822 patent.

38. As the PTAB recognized, the '822 patent claims new and novel methods for knee arthroplasty that involve "positioning a cutting guide only on one side of the bone and cutting through the guide on both the medial and lateral sides of the bone to create a resected surface."

COUNT I
Stryker's Infringement of the '822 Patent

39. PugetBV repeats and realleges all allegations set forth above in paragraphs 1-38 as if they were stated in full and incorporated herein

40. Stryker does not have, and has not had, authority or permission to make, use, offer to sell, or sell the subject matter claimed in the '822 patent in the United States.

41. In violation of 35 U.S.C. § 271, Stryker manufactured, offered to sell, sold, or otherwise made available in the District of New Jersey and elsewhere in the United States knee arthroplasty products (and instrumentation for use with the same), including but not limited to the Triathlon Total Knee System and the Triathlon Titanium Knee, the Triathlon Surgical Technique

Instruments, the MIS Surgical Technique Instruments, the Triathlon Titanium Surgical Protocol Instruments, the Scorpio Knee System and Scorpio Instruments, Precision Knee Navigation Instruments, and ShapeMatch Instruments. The use of the products and instrumentation directly infringed, either literally or under the Doctrine of Equivalents, one or more claims of the '822 patent. Stryker's manufacture, sale, and offer to sell these products and instrumentation indirectly infringes, either literally or under the Doctrine of Equivalents, one or more claims of the '822 patent, specifically, claims 2, 6, 15 and/or claims that depend therefrom for reasons set forth herein.

42. Stryker had knowledge of the '822 patent at least since July 13, 2011.

43. In conjunction with the sale of infringing products and instrumentation, and in violation of 35 U.S.C. § 271(b), Stryker acted with specific intent to actively induce physicians, specifically orthopedic surgeons, to infringe, either literally or under the Doctrine of Equivalents, one or more of claims 1, 5, 14, and of the '822 patent and/or claims that depend therefrom. Stryker directly infringed one or more claims of the '822 patent by providing instrumentation, implants, and information for a total knee arthroplasty procedure.

44. For example, Stryker intentionally and actively induced orthopedic surgeons who performed knee arthroplasty procedures using Stryker's Triathlon® Knee System and MIS Surgical Technique Instruments to directly infringe one or more claims of the '822 patent. Stryker provided manuals, surgical guides, written instructions, or other printed (or videotaped) training or instructive material in the United States regarding the use of the Triathlon® Knee System and MIS Surgical Technique Instruments in a manner that infringes at least one claim of the '822 patent.

45. Stryker has made its Triathlon® Knee System and MIS Triathlon Knee System Instruments available since 2004. (See **Exhibit C**, Stryker, *Stryker Receives FDA 510(K)*)

Clearance for Shapematch® Cutting Guides, Stryker.com (May 24, 2011), <http://phx.corporate-ir.net/phoenix.zhtml?c=118965&p=irol-newsArticle&ID=1567066>).

46. As recited in claim 5 of the '822 patent, Stryker's Triathlon® Knee System and MIS Surgical Technique Instruments have been used by orthopedic surgeons, according to Stryker's instructions, to perform a total knee arthroplasty procedure on a knee joint in a patient's body. (See **Exhibit D**, Stryker, Triathlon® Knee System MIS Surgical Protocol 2, 63 (2015), <http://www.bizwan.com/mydoc/stryker/Knee/008%20Triathlon%20MIS%20Surgical%20Technique.pdf>).

► Minimally Invasive Orthonomic Design of the Triathlon Knee System
Instrumentation is designed to become the standard in the industry. A

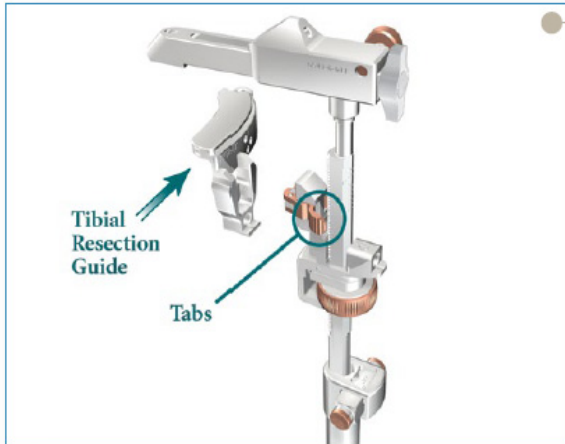
Indications

General Total Knee Arthroplasty (TKR) Indications include:

- Painful, disabling joint disease of the knee resulting from: non-inflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or rheumatoid arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful knee replacement or other procedure.
- Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture management techniques.

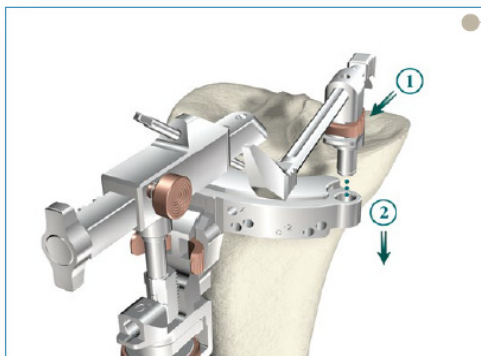
47. As recited in claim 5 of the '822 patent, Stryker's Triathlon® Knee System and MIS Surgical Technique Instruments have been used by orthopedic surgeons, according to Stryker's instructions, to position a cutting guide having at least one guide surface adapted to guide an

oscillating saw blade proximate an end portion of one long bone of the knee joint. (See **Exhibit D**, Stryker, Triathlon® Knee System MIS Surgical Protocol 5, 21 (2015)).



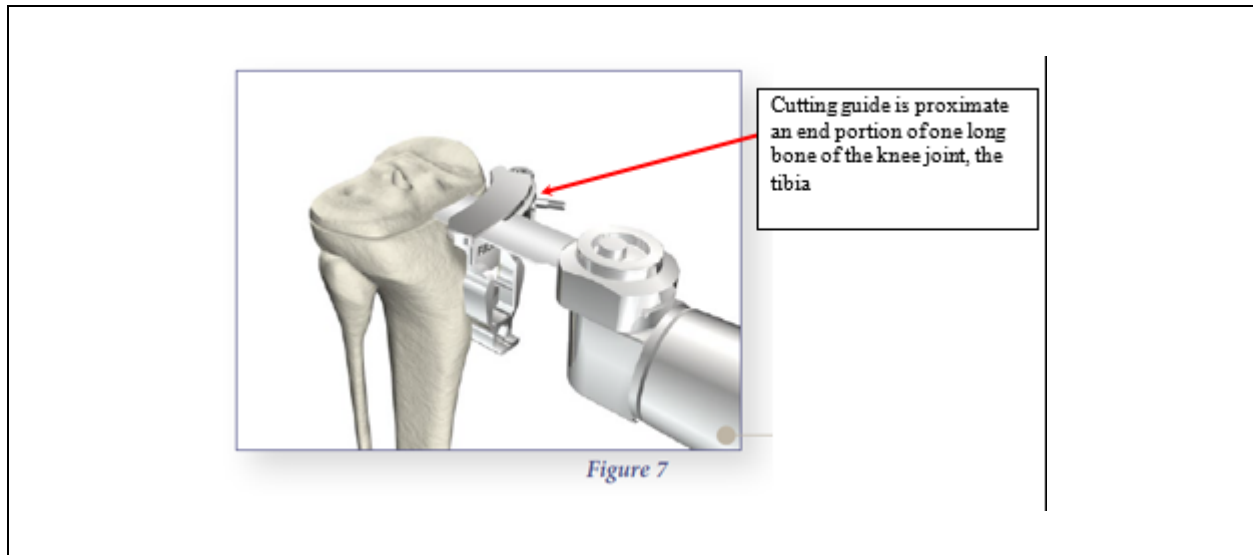
Assembly 1D

- ▶ Squeeze the bronze tabs on the Tibial Adjustment Housing and assemble the MIS Captured, MIS Uncaptured, or Standard Uncaptured Tibial Resection Guide with the resection surface facing up.
- ▶ Release the bronze tabs and ensure that the Tibial Resection Guide is locked in place.



Assembly 1F

- ▶ Squeeze the bronze swing trigger ① on the Tibial Stylus and insert the post into the medial hole ② located on the resection plane of the Tibial Resection Guide.
- ▶ Release the bronze swing trigger ① to lock the Tibial Stylus in place.



48. Stryker provides instructions regarding how an orthopedic surgeon should position, and use, Stryker's tibial resection guide, which has at least one guide surface adapted to guide an oscillating saw blade proximate an end portion of one long bone of the knee joint (i.e. the tibia). (See **Exhibit D**, Stryker, Triathlon® Knee System MIS Surgical Protocol 18-21 (2015)).

49. As recited in claim 5 of the '822 patent, Stryker's tibial resection guide comprises a cutting guide having opposite medial and lateral ends which are spaced apart by a first distance. (See **Exhibit D**, Stryker, Triathlon® Knee System MIS Surgical Protocol 21 (2015)).

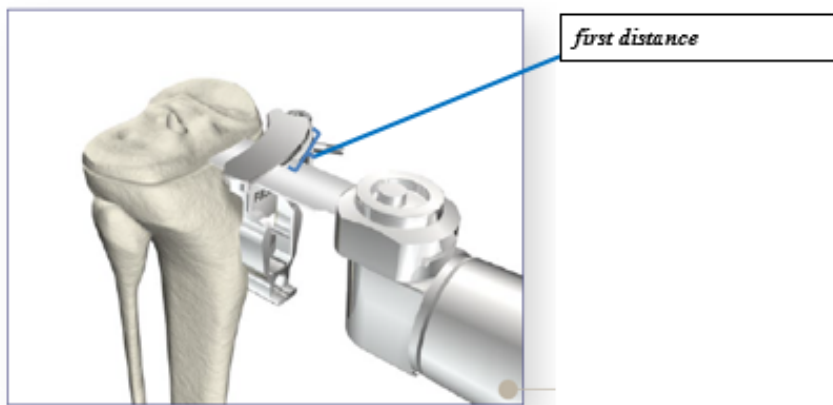


Figure 7

- ▶ Once all alignment instruments are removed leaving the tibial resection guide in place, the proximal tibia is osteotomized using either the right or left captured or uncaptured tibial resection guide.

50. As recited in claim 5 of the '822 patent, Stryker's Triathlon® Knee System and MIS Surgical Technique Instruments were instructed by Stryker to be used, and have been used, by orthopedic surgeons to move an oscillating saw blade into engagement with the one long bone at the knee joint (i.e. the tibia). (See **Exhibit D**, Stryker, Triathlon® Knee System MIS Surgical Protocol 21 (2015)).

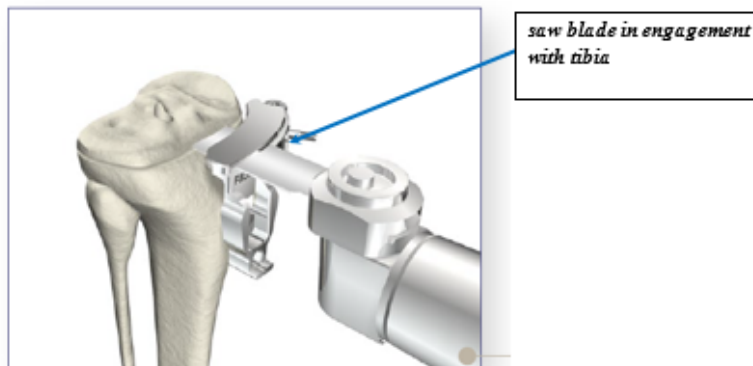
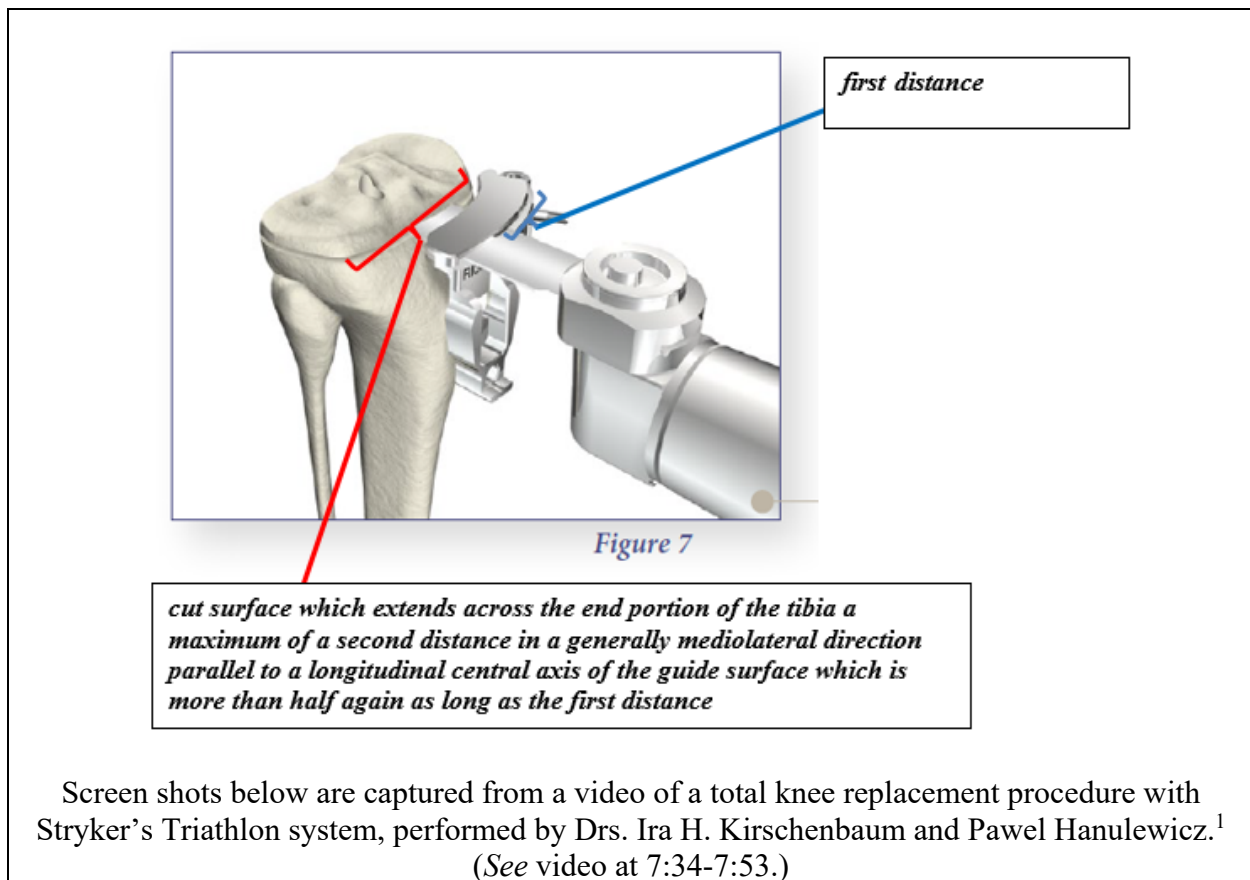




Figure 7

- ▶ Once all alignment instruments are removed leaving the tibial resection guide in place, the proximal tibia is osteotomized using either the right or left captured or uncaptured tibial resection guide.

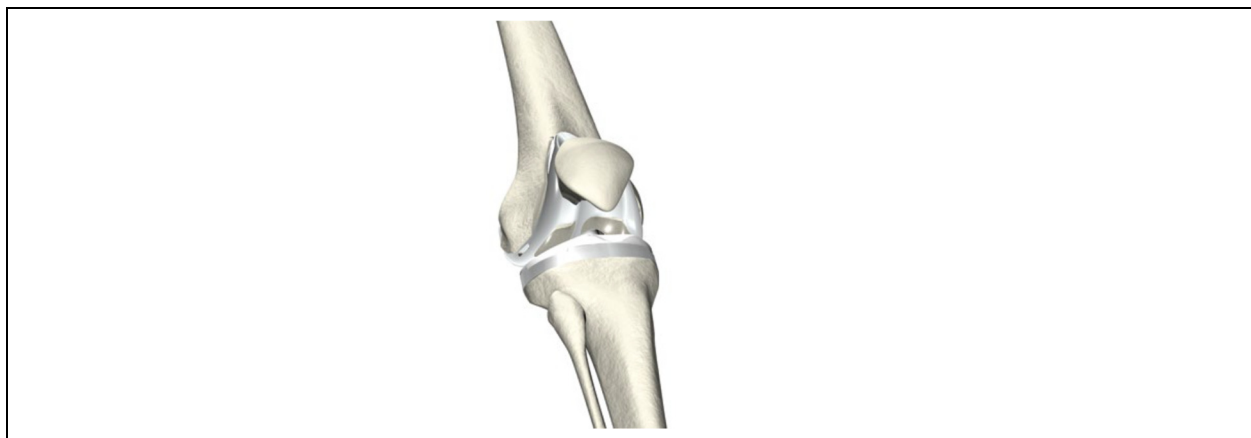
51. As recited in claim 5 of the '822 patent, Stryker's Triathlon® Knee System and MIS Surgical Technique Instruments were instructed by Stryker to be used, and have been used, by orthopedic surgeons to cut the one long bone at the knee joint (i.e. the tibia) with an oscillating saw blade by moving the oscillating saw blade along the guide surface on the cutting guide and cutting bone to form a cut surface which extends across the end portion of the one long bone a maximum of a second distance in a generally mediolateral direction parallel to a longitudinal central axis of the guide surface which is more than half again as long as the first distance of the cutting guide between the opposite medial and lateral ends. (See **Exhibit D**, Stryker, Triathlon® Knee System MIS Surgical Protocol 21 (2015)).





¹ See Pawel Hanulewicz, *Total Knee Replacement Short Instructional Video*, YOUTUBE (Dec. 20, 2013), <https://www.youtube.com/watch?v=mfqObHXeJpw> (last accessed June 16, 2017).

	
<p>(7:35) (resecting the lateral tibia with the blade positioned medially)</p>	<p>(7:47) (resecting the medial tibia with the blade positioned medially)</p>

52. As recited in claim 5 of the '822 patent, Stryker's Triathlon® Knee System and MIS Surgical Technique Instruments were instructed by Stryker to be used, and have been used, by orthopedic surgeons to position a total knee arthroplasty implant into engagement with the cut surface. (See **Exhibit D**, Stryker, Triathlon® Knee System MIS Surgical Protocol 46-49 (2015)).



Screen shots below are captured from a video of a total knee replacement procedure with Stryker's Triathlon system, performed by Drs. Ira H. Kirschenbaum and Pawel Hanulewicz.

	
<p>(26:09) (depicting femoral implant in situ)</p>	<p>(29:06) (depicting femoral and tibial implant in situ)</p>

53. In conjunction with the sale of infringing products and instrumentation, and in violation of 35 U.S.C. § 271(c), Stryker contributorily infringed one or more claims of the '822 patent, as set forth above in paragraphs 39-52

54. Stryker has made, offered to sell, and sold within the United States at least one component of the invention of the '822 patent—the tibial resection guide shown in paragraphs 47-51 above. This tibial resection guide is used by orthopedic surgeons to directly infringe at least claim 5 of the '822 patent.

55. Stryker has made, offered to sell, and sold the tibial resection guide with knowledge of the '822 patent, and with knowledge that it was a material part of the invention especially made or adapted for use in infringing the '822 patent.

56. The tibial resection guide that Stryker has offered to sell and sold is not a staple article or commodity of commerce suitable for substantial noninfringing use. As set forth above, Stryker intends orthopedic surgeons to use the tibial resection guide to resect the tibia in a medial to lateral direction, according to the steps in claim 5 of the '822 patent.

57. Stryker's direct and indirect infringement of the '822 patent has been willful.

58. PugetBV notified Stryker of the '822 patent in July 2011.

59. Despite this notice, Stryker did not acquire or obtain a license to any rights in the '822 patent.

60. Nor did Stryker stop manufacturing and selling its products and instrumentation that are used to infringe the methods of the asserted claims of the '822 patent.

61. Stryker subjectively knew, or in the alternative should have known, that it infringed the asserted claims of the '822 patent before the filing of this Complaint.

PRAYER FOR RELIEF

WHEREFORE, PugetBV prays for judgment against Stryker as follows:

1. That Stryker infringes, either literally or under the Doctrine of Equivalents, one or more claims of the '822 patent;
2. That Stryker's infringement of the '822 patent was willful;
3. That Stryker accounts for and pays to PugetBV damages adequate to compensate it for Stryker's infringement in an amount to be proven at trial, together with interest and costs as fixed by the Court;
4. That this case is exceptional and awarding PugetBV its costs and attorneys' fees in accordance with 35 U.S.C. § 285;
5. An award of enhanced damages for Stryker's willful infringement; and
6. That PugetBV be awarded such other and further relief as the Court may deem just and equitable.

Dated: June 26, 2017

Respectfully submitted,

By: s/ Rayna E. Kessler

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Attorneys for Puget BioVentures, LLC

JURY DEMAND

Plaintiff hereby demands a trial by jury on all issues so triable.

Dated: June 26, 2017

By: s/ Rayna E. Kessler

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Attorneys for Puget BioVentures, LLC

CERTIFICATION OF OTHER ACTIONS

The undersigned hereby certifies that the matter in controversy is not the subject of any other action pending in any court, arbitration, or administrative proceeding, other than the matters below:

1. *Puget BioVentures, LLC v. DePuy Orthopaedics, Inc.*, 3:17-cv-00503 (N.D. Ind. June 26, 2017).
2. *Puget BioVentures, LLC v. Biomet Orthopedics, LLC and Biomet Manufacturing, LLC*, 3:17-cv-00502 (N.D. Ind. June 26, 2017).

Dated: June 26, 2017

By: s/ Rayna E. Kessler

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