UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF INDIANA SOUTH BEND DIVISION

PUGET BIOVENTURES, LLC,)
Plaintiff,))
V.) Cause No. 3:17-cv-503
DEPUY ORTHOPAEDICS, INC.,) Jury Trial Demanded
Defendant.)

COMPLAINT

Plaintiff Puget BioVentures, LLC ("PugetBV") files this Complaint for willful patent infringement of U.S. Patent No. 7,967,822 ("the '822 patent") against DePuy Orthopaedics, Inc. ("DePuy" or "Defendant"), and alleges:

The Parties

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

2. DePuy is an Indiana corporation with its place of business in Warsaw, Indiana.

Jurisdiction and Venue

3. This is an action for patent infringement under the United States patent laws, Title 35 of the United States Code. The Court has original jurisdiction over the subject matter of this action under 28 U.S.C. § 1338(a).

4. This Court has general and specific personal jurisdiction over DePuy because it conducts business, maintains its places of business, and resides in this District. DePuy has established minimum contacts within this forum such that the exercise of jurisdiction over DePuy would not offend traditional notions of fair play and substantial justice.

5. Venue in this district is proper under 28 U.S.C. §§ 1400(b) and 1391(b)(1).

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The '822 Patent and the '541 Patent

6. 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").

7. 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.

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

9. 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.

10. The '822 patent and '541 patent are related patents that are part of PugetBV's patent portfolio.

DePuy has Long Known of PugetBV's Patent Rights in the Field of Minimally Invasive Total Knee Arthroplasty

11. Both the '822 patent and the '541 patent relate to minimally invasive total knee arthroplasty ("MIS TKA").

12. DePuy has been aware of PugetBV's patent rights for over a decade.

13. DePuy was aware of Puget BV's patent rights no later than October of 2002.

14 At least by June of 2003, DePuy was aware of seven of the priority applications identified on the face of the '822 patent, including the applications that issued as U.S. Pat. No. 5,514,139; U.S. Pat. No. 5,643,272; U.S. Pat. No. 5,810,827; U.S. Pat. No. 5,755,803;

U.S. Pat. No. 5,879,354; U.S. Pat. No. 6,056,754; and U.S. Patent Application 09/799,325.

15. In 2003, DePuy investigated and reviewed PugetBV's portfolio of patents and applications. DePuy did not obtain any rights in any of Puget BV's patents.

16. To this day, DePuy did not and has not obtained a license to practice the claimed inventions of the '822 patent.

17. 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), DE 1). 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.*, 1:10cv-02103 (N.D. Ill. Nov. 3, 2010), DE 48) (hereinafter, "the DePuy '541 case"). 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) (DE 104).

18. On September 27, 2010, DePuy served its invalidity contentions for the '541 patent, which included a 68-page list of alleged prior art totaling more than 220 references, and a set of charts comprising 799 pages of DePuy's contentions regarding its assertion that the claims of the '541 patent were invalid.

19. PugetBV/Hudson Surgical Design, Inc. v. DePuy Orthopaedics, Inc., 3:10-cv-00463 (N.D. Ind. Dec. 9, 2010) (D.I. 63), along with the related case PugetBV/Hudson Surgical Design, Inc. v. Biomet Orthopedics, LLC and Biomet Manufacturing Corporation, 3:10-cv-00465 (N.D. Ind. Dec. 8, 2010) (DE 47), have been stayed since December of 2010 pending *inter partes* reexamination of the '541 patent that Biomet initiated and has pursued, without success.

20. 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

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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)."

21. 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, 47 of the '541 patent.

22. DePuy has known about the '822 patent at least since July 2011.

23. On July 1, 2011, Hudson Surgical identified the '822 patent to DePuy. (A true and accurate copy of an excerpt of a letter from counsel for Hudson Surgical to DePuy is attached as **Exhibit B**.)

24. In that letter, Hudson Surgical stated that DePuy needed a license to the '822 patent.

25. DePuy has been aware of, or in the alternative was willfully blind to, its infringement of the '822 patent since at least July of 2011.

26. On September 7, 2012, DePuy attempted to invalidate the claims of the '822 patent by requesting an *inter partes* reexamination of the '822 patent with the Patent Office.

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

28. Since then, the '822 patent's reexamination has been pending for over four-anda-half years.

29. 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.

30. 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 DePuy's Infringement of the '822 Patent

31. PugetBV repeats and realleges all allegations set forth above in paragraphs 1-30 as if they were stated in full and incorporated herein.

32. DePuy does not, 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.

33. In violation of 35 U.S.C. § 271, DePuy manufactured, offered to sell, sold, or otherwise made available in the Northern District of Indiana and elsewhere in the United States knee arthroplasty products (and instrumentation for use with the same), including but not limited to the Sigma and TruMatch knee systems with High Performance instrumentation; the ATTUNE knee system with Intuition instrumentation; and the LCS Knee System with LCS High Performance and Milestone Mini Instrumentation. 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. DePuy'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. DePuy directly infringed one or more claims of the '822 patent by providing instrumentation, implants, and information for a total knee arthroplasty procedure, including claims 2, 6, 15, and/or claims that depend therefrom, for the reasons set forth below.

34. DePuy had knowledge of the '822 patent at least since July 1, 2011.

35. In conjunction with the sale of infringing products and instrumentation, and in violation of 35 U.S.C .§ 271(b), DePuy acted with specific intent to actively induce physicians, specifically orthopedic surgeons, to infringe, either literally or under the

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Doctrine of Equivalents, one or more of claims 1, 5, 14 of the '822 patent, and claims that depend therefrom.

36. DePuy intentionally and actively induced orthopedic surgeons who, for example, performed knee arthroplasty procedures using Depuy's ATTUNE® Total Knee Arthroplasty System and its Intuition[™] Instrumentation, to directly infringe one or more claims of the '822 patent. DePuy provided manuals, surgical guides, written instructions, or other printed (or videotaped) training or instructive material in the United States regarding the use of the ATTUNE® Total Knee Arthroplasty System and its Intuition[™] Instrumentation in a manner that infringes at least one claim of the '822 patent.

37. DePuy has made the ATTUNE® Total Knee Arthroplasty System available since 2011. (*See* **Exhibit C**, David A. Fisher & David Parkin, Attune White Paper, Improving the Value of Primary Total Knee Arthroplasty: the ATTUNE® Knee System, DePuy Synthes Companies, 9 (March 2017),

http://synthes.vo.llnwd.net/o16/LLNWMB8/US%20Mobile/Synthes%20North%20Amer ica/Product%20Support%20Materials/White%20Papers/Attune%20White%20Paper%20Fi nal.pdf).

38. As recited in claim 5 of the '822 patent, DePuy's ATTUNE® Total Knee Arthroplasty System and its Intuition[™] Instrumentation have been used by orthopedic surgeons, according to DePuy's instructions, to perform a total knee arthroplasty procedure on a knee joint in a patient's body. (*See* Exhibit D, DePuy Synthes, ATTUNE Knee System® Intuition [™] Instruments Surgical Technique, PDF page 2, 5, 6, 71 (2013)).

This surgical technique provides guidelines for the implantation of the ATTUNE™ Knee System family of fixed bearing knees with the ATTUNE™ INTUITION™ Instrumentation.

The ATTUNE INTUITION Instrumentation is intended for use with the ATTUNE Knee System Implants only and should not be considered interchangeable with any other instrumentation unless specifically noted in the surgical technique.

<text>

ATTUNE™ KNEE SYSTEM FIXED BEARING KNEE

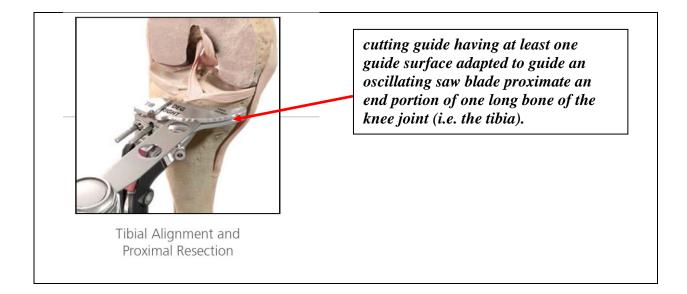


Final Component Implantation

INTENDED USE

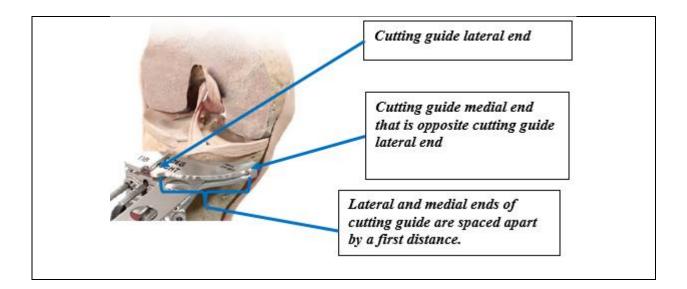
Total knee arthroplasty is intended to provide increased patient mobility and reduced pain by replacing the damaged knee joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total knee replacement may be considered for younger patients if, in the opinion of the surgeon, an unequivocal indication for total knee replacement outweighs the risks associated with the age of the patient, and if limited demands regarding activity and knee joint loading can be assured. This includes severely crippled patients with multiple joint involvement for whom a gain in knee mobility may lead to an expectation of significant improvement in the quality of their lives.

39. As recited in claim 5 of the '822 patent, DePuy's ATTUNE® Total Knee Arthroplasty System and its Intuition[™] Instrumentation have been used by orthopedic surgeons, according to DePuy'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, DePuy Synthes, ATTUNE Knee System ® Intuition [™] Instruments Surgical Technique 5 (2013)).



40. DePuy provides instructions regarding how an orthopedic surgeon should position, and use, DePuy's tibial cutting block, 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, DePuy Synthes, ATTUNE Knee System ® Intuition [™] Instruments Surgical Technique, 16-21 (2013)).

41. As recited in claim 5 of the '822 patent, DePuy's tibial cutting block comprises a cutting guide having opposite medial and lateral ends which are spaced apart by a first distance. (*See* **Exhibit D**, DePuy Synthes, ATTUNE Knee System ® Intuition [™] Instruments Surgical Technique 5 (2013)).

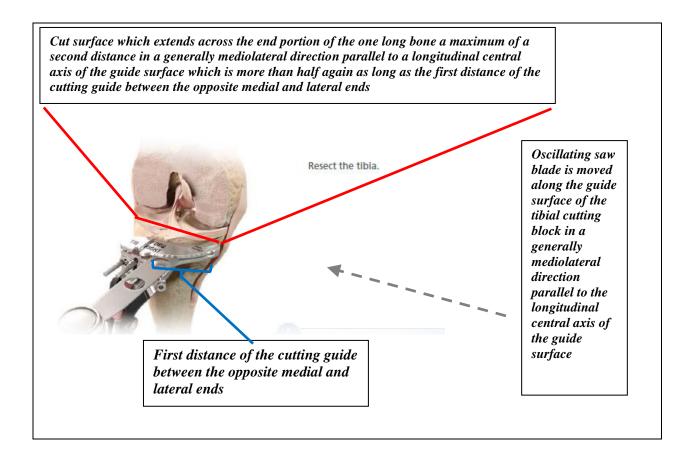


42. As recited in claim 5 of the '822 patent, DePuy's ATTUNE® Total Knee Arthroplasty System and its Intuition[™] Instrumentation were instructed by DePuy to be used, and have been used, by orthopedic surgeons to move an oscillating saw blade into engagement with the one long bone at the knee joint (i.e. the tibia). (*See* Exhibit D, DePuy Synthes, ATTUNE Knee System ® Intuition [™] Instruments Surgical Technique 21 (2013)).



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43. As recited in claim 5 of the '822 patent, DePuy's ATTUNE® Total Knee Arthroplasty System and its Intuition[™] Instrumentation were instructed by DePuy 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, DePuy Synthes, ATTUNE Knee System ® Intuition [™] Instruments Surgical Technique 5 (2013)).



44. As recited in claim 5 of the '822 patent, DePuy's ATTUNE® Total Knee Arthroplasty System and its Intuition[™] Instrumentation were instructed by DePuy 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, DePuy Synthes, ATTUNE Knee System ® Intuition [™] Instruments Surgical Technique 21, 71 (2013). *See e.g.*, Robert Gorab, *Attune*® *TKA Surgical Procedure – June 27th 2013 – Part 3*, YOUTUBE (Nov. 27, 2013), https://www.youtube.com/watch?v=OCfE7mXh1Dc (last accessed May 24, 2017)).

This surgical technique provides guidelines for the implantation of the ATTUNE™ Knee System family of fixed bearing knees with the ATTUNE™ INTUITION™ Instrumentation.

The ATTUNE INTUITION Instrumentation is intended for use with the ATTUNE Knee System Implants only and should not be considered interchangeable with any other instrumentation unless specifically noted in the surgical technique.

INTENDED USE

Total knee arthroplasty is intended to provide increased patient mobility and reduced pain by replacing the damaged knee joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total knee replacement may be considered for younger patients if, in the opinion of the surgeon, an unequivocal indication for total knee replacement outweighs the risks associated with the age of the patient, and if limited demands regarding activity and knee joint loading can be assured. This includes severely crippled patients with multiple joint involvement for whom a gain in knee mobility may lead to an expectation of significant improvement in the quality of their lives.





At minutes 3:34.

At minutes 4:50.

45. In conjunction with the sale of infringing products and instrumentation, and in violation of 35 U.S.C. § 271(c), DePuy contributorily infringed one or more claims of the '822 patent, as set forth above in paragraphs 31-44.

46. DePuy has made, offered to sell, and sold within the United States at least one component of the invention of the '822 patent—the tibial cutting block shown in paragraphs 39-43 above. This tibial cutting block is used by orthopedic surgeons to directly infringe at least claim 1 of the '822 patent.

47. DePuy has made, offered to sell, and sold the tibial cutting block 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.

48. The tibial cutting block that DePuy has made, offered to sell, and sold is not a staple article or commodity of commerce suitable for substantial noninfringing use. As set forth in paragraphs 31-47 above, DePuy intends orthopedic surgeons to use the tibial cutting block to resect the tibia in a medial to lateral direction, according to the steps in claim 5 of the '822 patent.

49. DePuy's direct and indirect infringement of the '822 patent has been willful.

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50. By at least 2003, DePuy had reviewed PugetBV's patent portfolio. At that time, DePuy had not released any products or instrumentation that are described in paragraphs 39-43.

51. Despite DePuy's research and investigation into PugetBV's patent portfolio, and the disclosures within, DePuy chose not to acquire or obtain a license to any rights in PugetBV's patent portfolio.

52. PugetBV notified DePuy of the '822 patent in July 2011.

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

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

55. Instead, DePuy attempted to invalidate the asserted claims of the '822 patent by filing an *inter partes* reexamination with the Patent Office. DePuy has not succeeded in invalidating any of the asserted claims in the '822 patent in reexamination.

56. DePuy 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.

JURY TRIAL DEMAND

PugetBV demands a trial by jury on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE PugetBV prays for judgment against DePuy as follows:

1. That DePuy infringes, either literally or under the Doctrine of Equivalents, one or more claims of the '822 patent;

2. That DePuy's infringement of the '822 patent was willful;

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3. That DePuy accounts for and pays to PugetBV damages adequate to compensate it for DePuy'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 DePuy's willful infringement;

6. That PugetBV be awarded such other and further relief as the Court may deem just and equitable.

Dated: June 26, 2017

Robins Kaplan LLP

By: <u>/s/ Patrick D. Murphy</u>

Ronald J. Schutz (MN #0130849) (pro hac application to be submitted) Patrick M. Arenz (MN #0386537) (pro hac application to be submitted) Sharon E. Roberg-Perez (MN #0348272) (pro hac application to be submitted) Mary Pheng (#0398500) (pro hac application to be submitted)

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Attorneys for Puget BioVentures, LLC

Index of Exhibits	
Exhibit A	U.S. Patent No. 7,967,822
Exhibit B	Letter from Hudson Surgical to DePuy
Exhibit C	David A. Fisher & David Parkin, Attune White Paper, Improving
	the Value of Primary Total Knee Arthroplasty: the ATTUNE®
	Knee System, DePuy Synthes Companies, 9 (March 2017)
Exhibit D	DePuy Synthes, ATTUNE Knee System [®] Intuition [™] Instruments
	Surgical Technique 21, 71 (2013).