UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION

PUGET BIOVENTURES, LLC, Plaintiff, v. BIOMET ORTHOPEDICS, LLC and BIOMET MANUFACTURING, LLC Defendants.	)	Cause No. 3:17-cv-502 **Jury Trial Demanded**

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 Biomet Orthopedics, LLC and Biomet Manufacturing, LLC ("Biomet" 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. Biomet Orthopedics, LLC is an Indiana limited liability company with its place of business in Warsaw, Indiana.

3. Biomet Manufacturing, LLC is an Indiana limited liability company with its place of business in Warsaw, Indiana.

Jurisdiction and Venue

4. 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).

5. This Court has general and specific personal jurisdiction over Biomet Orthopedics, LLC and Biomet Manufacturing, LLC because they conduct business,

maintain their places of business, and reside in this District. This Court has general and specific personal jurisdiction over Biomet Orthopedics, LLC and Biomet Manufacturing, LLC because they have established minimum contacts within this forum such that the exercise of jurisdiction over each Defendant would not offend traditional notions of fair play and substantial justice.

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

The '822 Patent and the '541 Patent

7. Puget 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").

8. 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.

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

10. 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.

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

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

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

13. Biomet has been aware of PugetBV's patent rights for the better part of a decade. At least by July 14, 2008, Hudson Surgical had contacted Biomet's Vice President of Intellectual Property, Dave Ahlersmeyer, regarding its patent portfolio, and to inform Biomet that it infringed the '541 patent.

14. Hudson Surgical contacted Biomet again, in early 2010, to reiterate its belief that Biomet continued to actively induce and contributorily infringe the '541 patent. Hudson Surgical also informed Biomet that the '541 patent was part of a patent family that—at that time—included eight related patent applications, all of which claimed priority to the '363 application.

15. 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), DE 1).

16. 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"). 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) (DE 94).

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

18. 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).”

19. 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.

20. Biomet has known about the ’822 patent at least since July 2011.

21. On July 1, 2011, Hudson Surgical identified the ’822 patent to Biomet. In that letter, Hudson Surgical stated that Biomet needed a license to the ’822 patent. (A true and accurate copy of an excerpt of a letter from counsel for Hudson Surgical to Biomet is attached as **Exhibit B**.)

22. For instance, during the reexamination of the ’541 patent, to which Biomet was a party, PugetBV submitted the Patent Office’s June 1, 2011 Notice of Allowance for the ’822 patent.

23. PugetBV’s appeal brief in the ’541 patent reexamination, submitted on September 13, 2012, also identified the ’822 reexamination proceeding instituted by DePuy.

24. PugetBV and Biomet’s joint report to this Court on December 18, 2012, in connection with the litigation on the ’541 patent, identifies the ’822 patent as well.

25. On its face, the ’822 patent claims priority to the same patent application to which the ’541 patent claims priority, application No. 08/300, 379. (**Exhibit A**.)

26. In its own patents on less invasive knee resection, Biomet Manufacturing, LLC (formerly Biomet Manufacturing Corporation) has cited to multiple patents— issued to the inventors of the ’541 and ’822 patents —that also claim priority to application No. 08/300, 379. These include at least

a. U.S. Pat. No. 7,837,690, entitled *Method and apparatus for less invasive knee resection*, citing to U.S. Pat. Nos. 5,643,272; 5,755,803; and 5,810,827;

b. U.S. Pat. No. 7,789,885, entitled *Instrumentation for knee resection*, citing to U.S. Pat. Nos. 5,643,272; 5,755,803; 5,810,827; and 5,879,354;

c. U.S. Pat. No. 7,695,520, entitled *Prosthesis and implementation system*, citing to U.S. Pat. Nos. 5,643,272; 5,755,803; 5,810,827; and 6,056,754; and

d. U.S. Pat. No. 7,887,542, entitled *Method and apparatus for less invasive knee resection*, citing to U.S. Pat. Nos. 5,643,272; 5,755,803; 5,810,827; 5,879,354; 6,056,754; and 6,197,064.

27. Biomet knew of, or was willfully blind to, its infringement of the ’822 patent since at least July of 2011.

28. Biomet did not and has not obtained a license to practice the claimed inventions of the ’822 patent, or of any related patents.

29. On September 7, 2012, DePuy Orthopaedics, Inc. attempted to invalidate the claims of the ’822 patent by requesting an *inter partes* reexamination of the ’822 patent with the Patent Office, which was ordered on October 29, 2012.

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

31. 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.

32. 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
Biomet’s Infringement of the ’822 Patent

33. PugetBV repeats and realleges all allegations set forth above in paragraphs 1-32 as if they were stated in full and incorporated herein.

34. Biomet 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.

35. In violation of 35 U.S.C. § 271, Biomet 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 Vanguard Knee System, Signature Personal Patient Care Knee System (Vanguard Complete Knee System), and Vanguard Revision Knee System, with Microplasty Instrumentation, Microplasty Elite Instrumentation, Premier Instrumentation, and/or Signature Instrumentation. The use of these knee systems and instrumentation directly infringed, either literally or under the Doctrine of Equivalents, one or more claims of the '822 patent. Biomet'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. Biomet directly infringed one or more claims of the '822 patent by providing instrumentation, implants, and information for a total knee arthroplasty procedure, specifically, claims 2, 6, 15 and/or claims that depend therefrom for the reasons set forth herein.

36. Biomet has known of the '822 patent at least since July of 2011.

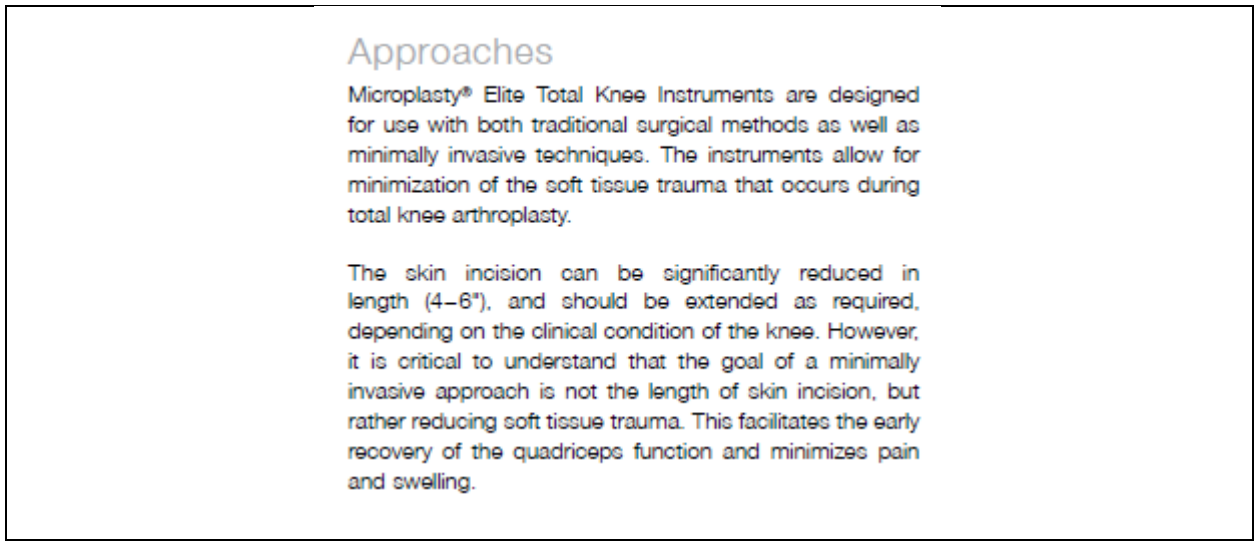
37. In conjunction with the sale of infringing products and instrumentation, and in violation of 35 U.S.C. § 271(b), Biomet acted with specific intent to actively induce physicians, specifically orthopedic surgeons, to infringe, either literally or under the

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

38. Biomet intentionally and actively induced orthopedic surgeons who, for example, performed knee arthroplasty procedures using Biomet's Vanguard® Complete Knee System with Microplasty® Total Knee Instrumentation, to directly infringe one or more claims of the '822 patent. With knowledge of the '822 patent, Biomet provided manuals, surgical guides, written instructions, or other printed (or videotaped) training or instructive material in the United States regarding the use of its Vanguard® Complete Knee System with Microplasty® Total Knee Instrumentation in a manner that infringes at least one claim of the '822 patent.

39. Biomet has made its Vanguard® Complete Knee System and its Microplasty® Total Knee Instrumentation available since at least March of 2005. (*See* **Exhibit C**, Biomet, *Knee: Total Knee Arthroplasty Featuring the new Vanguard TM Knee System From Biomet, Inc.* ®, BroadcastMed (Mar. 22, 2005), https://www.broadcastmed.com/orthopedics/4532/videos/total-knee-arthroplasty).

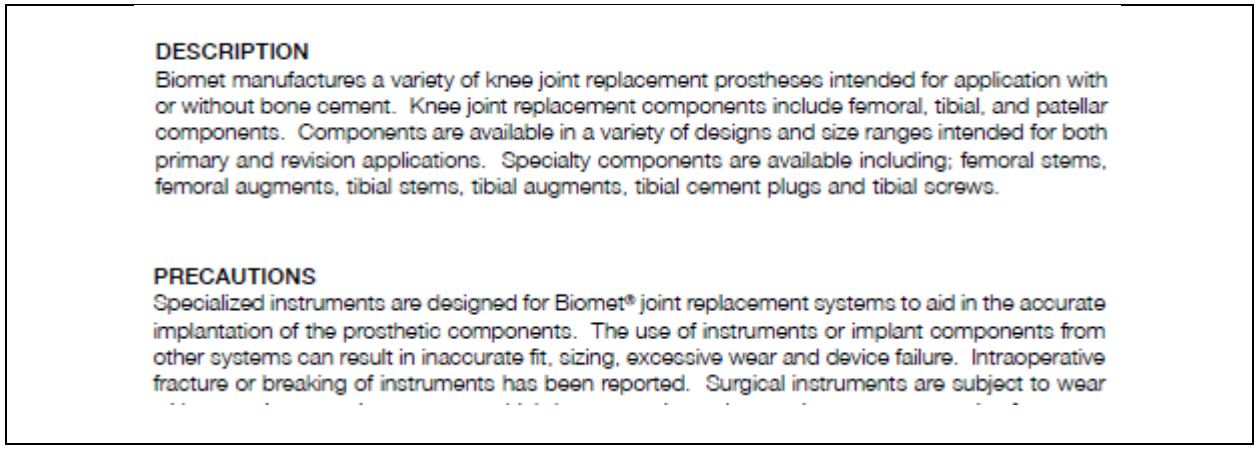
40. As recited in claim 5 of the '822 patent, Biomet's Vanguard® Complete Knee System with Microplasty® Total Knee Instrumentation have been used by orthopedic surgeons, according to Biomet's instructions, to perform a total knee arthroplasty procedure on a knee joint in a patient's body. (*See* Biomet, *Microplasty® Elite Total Knee Instrumentation, Surgical Technique Vanguard® Complete Knee System* 3, 64 (2011), http://www.biomet.com/wps/wcm/connect/internet/7b8245b5-8c99-4eab-8b26-1b5ac9ea0214/BOI0428.1.pdf?MOD=AJPERES&CACHEID=7b8245b5-8c99-4eab-8b26-1b5ac9ea0214) (a true and accurate copy of which is attached as **Exhibit D**).



Approaches

Microplasty® Elite Total Knee Instruments are designed for use with both traditional surgical methods as well as minimally invasive techniques. The instruments allow for minimization of the soft tissue trauma that occurs during total knee arthroplasty.

The skin incision can be significantly reduced in length (4–6"), and should be extended as required, depending on the clinical condition of the knee. However, it is critical to understand that the goal of a minimally invasive approach is not the length of skin incision, but rather reducing soft tissue trauma. This facilitates the early recovery of the quadriceps function and minimizes pain and swelling.



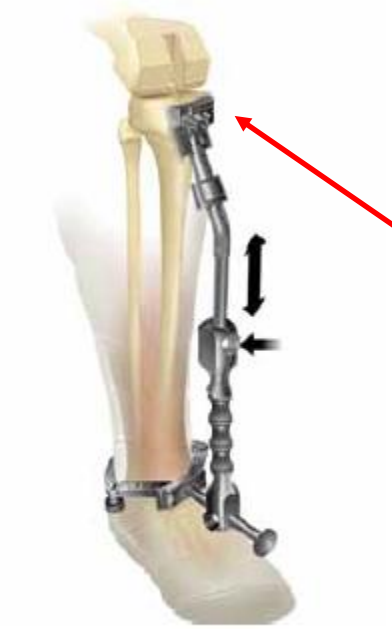
DESCRIPTION

Biomet manufactures a variety of knee joint replacement prostheses intended for application with or without bone cement. Knee joint replacement components include femoral, tibial, and patellar components. Components are available in a variety of designs and size ranges intended for both primary and revision applications. Specialty components are available including; femoral stems, femoral augments, tibial stems, tibial augments, tibial cement plugs and tibial screws.

PRECAUTIONS

Specialized instruments are designed for Biomet® joint replacement systems to aid in the accurate implantation of the prosthetic components. The use of instruments or implant components from other systems can result in inaccurate fit, sizing, excessive wear and device failure. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear

41. As recited in claim 5 of the '822 patent, Biomet's Vanguard® Complete Knee System with Microplasty® Total Knee Instrumentation have been used by orthopedic surgeons, according to Biomet'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**, Biomet, *Microplasty® Elite Total Knee Instrumentation, Surgical Technique Vanguard® Complete Knee System* 22 Fig. 32, 23 Fig. 33, 25 Fig. 37, 27 Fig. 42 (2011)).

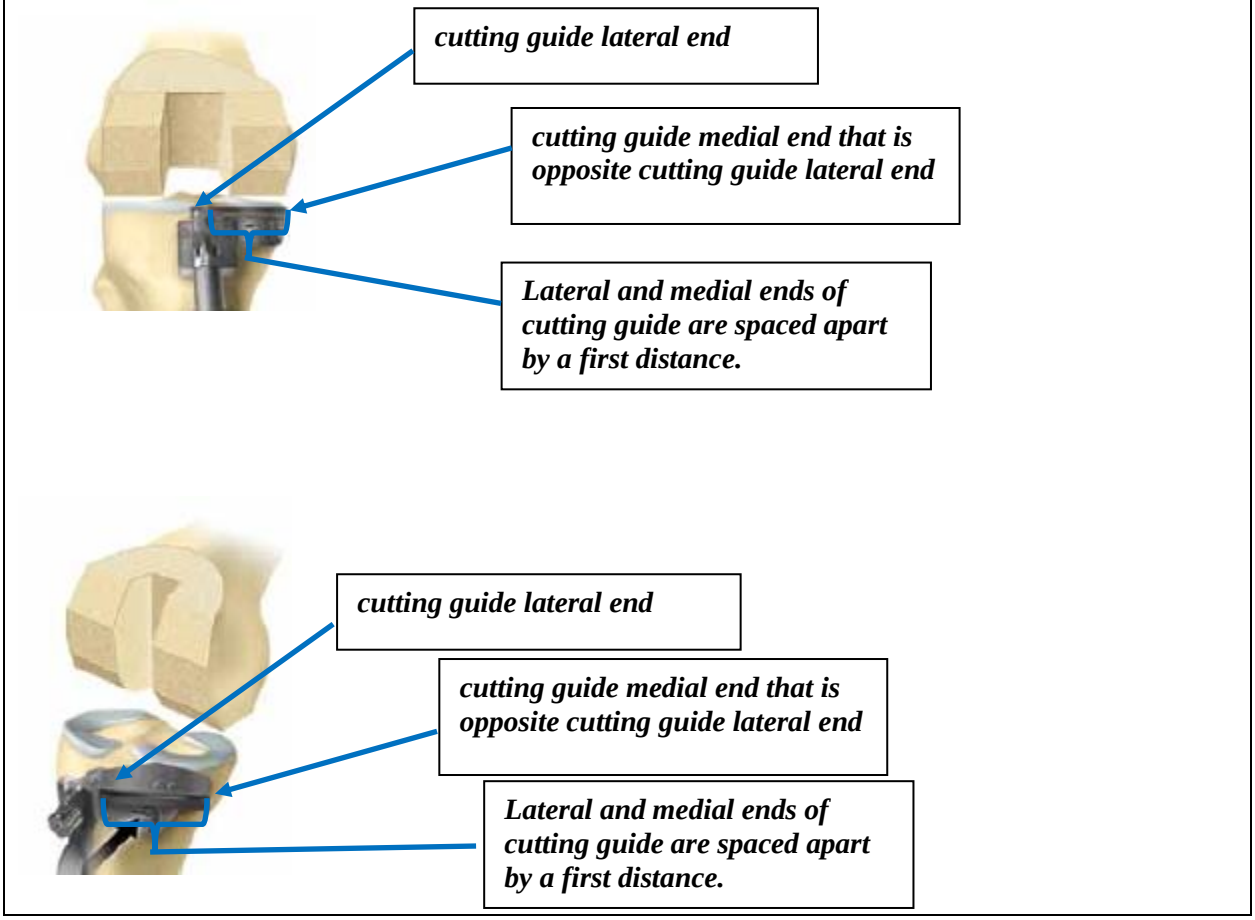


tibial resection block having at least one guide surface adapted to guide an oscillating saw blade proximate an end portion of one long bone of the knee joint

Figure 32

42. Biomet provides instructions regarding how an orthopedic surgeon should position, and use, Biomet's tibial resection 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**, Biomet, *Microplasty® Elite Total Knee Instrumentation, Surgical Technique Vanguard® Complete Knee System* 22-29 (2011)).

43. As recited in claim 5 of the '822 patent, Biomet's tibial resection block comprises a cutting guide having opposite medial and lateral ends which are spaced apart by a first distance. (*See* **Exhibit D**, Biomet, *Microplasty® Elite Total Knee Instrumentation, Surgical Technique Vanguard® Complete Knee System* 23 Fig. 33, 27 Fig. 43 (2011)).



44. As recited in claim 5 of the '822 patent, Biomet's Vanguard® Complete Knee System with Microplasty® Total Knee Instrumentation were instructed by Biomet 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**, Biomet, *Microplasty® Elite Total Knee Instrumentation, Surgical Technique Vanguard® Complete Knee System* 25, 29 (2011)).

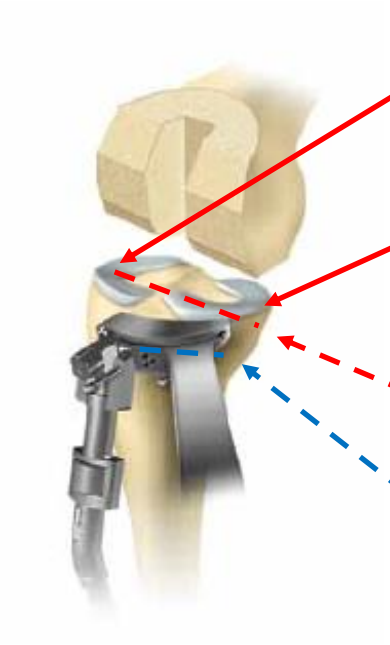
Figure 38

Remove the stylus from the resector. The EM Guide may be removed or left attached to the resector. Resect the tibial plateau through the slot in the resection head with a .054" saw blade (Figure 38).

Figure 46

Remove the stylus from the modular capture. The EM Guide may be removed or remain attached to the resector. Resect the tibial plateau through the slot in the modular capture with a .054" saw blade (Figure 46).

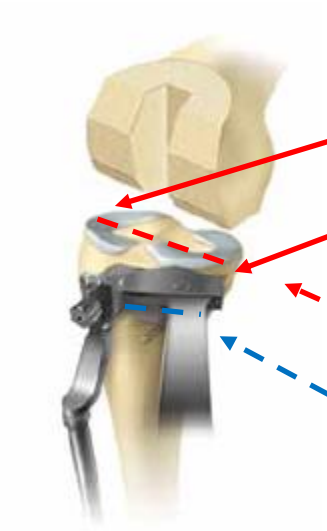
45. As recited in claim 5 of the '822 patent, Biomet's Vanguard® Complete Knee System with Microplasty® Total Knee Instrumentation were instructed by Biomet to be used, and have been used, by orthopedic surgeons to cut the one long bone at the knee joint (i.e. the tibia) with an oscillating saw blade 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**, Biomet, *Microplasty® Elite Total Knee Instrumentation, Surgical Technique Vanguard® Complete Knee System* 25, 29 (2011)).



Cut surface that extends across the tibia in a generally mediolateral direction parallel to the longitudinal central axis of the guide surface.

Cut surface extends across the tibia a second distance that is more than half again as long as the first distance of the cutting guide between the opposite medial and lateral ends

Figure 38



Cut surface that extends across the tibia in a generally mediolateral direction parallel to the longitudinal central axis of the guide surface.

Cut surface extends across the tibia a second distance that is more than half again as long as the first distance of the cutting guide between the opposite medial and lateral ends

Figure 46

46. As recited in claim 5 of the '822 patent, Biomet's Vanguard® Complete Knee System with Microplasty® Total Knee Instrumentation were instructed by Biomet 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**, Biomet, *Microplasty® Elite Total Knee Instrumentation, Surgical Technique Vanguard® Complete Knee System* 41, 42 (2011)).

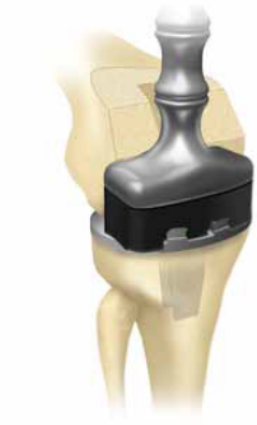


Figure 71

Tibial Implant Insertion

Assemble the modular tibial component, by choosing the appropriate stem (most primary cases will require a 40mm stem). The locking screw for the stem is included in the stem's packaging. Place the stem taper on the bottom of the appropriate modular tibial baseplate. Be sure that the alignment keys match between stem and plate. Impact the tip of the stem once with a mallet to seat the stem taper.

Note: The stem taper will hold the stem and plate together during insertion. The screw is tightened into the threads of the stem for added stem fixation. Plugs can be left in the screw holes of the baseplate if screw fixation is not used. Utilize the tibial impactor to firmly seat the component (Figure 71). Remove excess cement with a curette.

Optional screw fixation: Using the drill guide and ⅛" drill, prepare a hole for screw acceptance.

Note: The low-profile screws may be angled at 15 degrees in any direction to engage the best available cancellous and/or cortical bone. Frequent reference to the X-rays will guide the drilling and screw insertion sequence.

With the baseplate firmly fixed, the provisional bearing may be reinserted, and a trial reduction performed to confirm joint tension and stability.

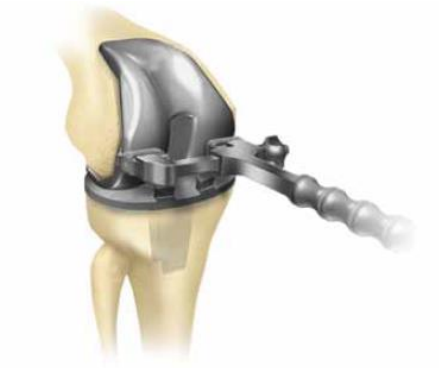


Figure 72

Figure 73

Femoral Implant Insertion

Note: If distal femoral pegs were selected to be added to the femoral component, use the peg wrench (Part No. 32-486122) to assemble the pegs to the femoral component. The peg wrench may also be used to remove pegs from the femoral component.

Place the appropriate femoral component on the end of the femur and insert it manually as far as possible (until about 1cm of space remains between the component and the distal femur). Fully seat the component using the control femoral impactor (Figure 72).

Remove the extruded cement with a curette. Running through a range-of-motion will help to pressurize the cement.

Patellar Implant Insertion

Place the appropriate patellar component into the patella and push it into position with finger pressure so the peg(s) engage(s) the prepared hole(s).

Position the patellar clamp onto the component and tighten the handle until the clamp head contacts the component. Clamp tightly to compress the implant (Figure 73). Remove extruded cement with a curette. The clamp should be left in position until the cement cures.

47. In conjunction with the sale of infringing products and instrumentation, and in violation of 35 U.S.C. § 271(c), Biomet contributorily infringed one or more claims of the '822 patent, as set forth above in paragraphs 33-46.

48. Biomet 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 block shown in paragraphs 41-45 above. This tibial resection block is used by orthopedic surgeons to directly infringe at least claim 5 of the ’822 patent.

49. Biomet has made, offered to sell, and sold the tibial resection 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.

50. The tibial resection block that Biomet has offered to sell and sold is not a staple article or commodity of commerce suitable for substantial noninfringing use. As set forth in paragraphs 33-49 above, Biomet intends orthopedic surgeons to use the tibial resection block to resect the tibia in a medial to lateral direction, according to the steps in claim 5 of the ’822 patent.

51. Biomet’s direct and indirect infringement of the ’822 patent has been willful.

52. By at least 2008, Biomet was aware of the ’541 patent.

53. By at least 2010, Biomet was aware of patents related to the ’541 patent.

54. By at least 2011, Biomet was aware of the ’822 patent.

55. On information and belief, despite Biomet’s research and investigation into PugetBV’s patent portfolio, Biomet chose not to acquire or obtain a license to any rights in any PugetBV patent, including the ’822 patent.

56. Nor did Biomet stop manufacturing and selling its products and instrumentation that are used to infringe the methods of the asserted claims of the ’822 patent.

57. Biomet subjectively knew, or 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 Biomet as follows:

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

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

3. That Biomet accounts for and pays to PugetBV damages adequate to compensate it for Biomet's infringement in an amount to be proven at trial, together with interest and costs as fixed by the Court;

4. Declaring 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 Biomet'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

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Index of Exhibits	
Exhibit A	U.S. Patent No. 7,967,822
Exhibit B	Letter from Hudson Surgical to Biomet
Exhibit C	Biomet, *Knee: Total Knee Arthroplasty Featuring the new Vanguard TM Knee System From Biomet, Inc.* ®, BroadcastMed (Mar. 22, 2005).
Exhibit D	Biomet, *Microplasty® Elite Total Knee Instrumentation, Surgical Technique Vanguard® Complete Knee System* 3, 64 (2011).