

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

MEDIDEA, L.L.C.

Plaintiff,

v.

DEPUY ORTHOPAEDICS, INC.,

Defendant.

Civil Action No. 1:16-cv-10638

TRIAL BY JURY DEMANDED

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, MEDIDEA, L.L.C., by its attorneys, hereby complains against Defendant DEPUY ORTHOPAEDICS, INC. as follows:

I. PARTIES AND BACKGROUND

1. Plaintiff, MEDIDEA, L.L.C. ("MEDIDEA") is a limited liability company organized and existing under the laws of the State of Michigan.

2. On November 15, 2016, United States Patent Number 9,492,280 ("the '280 Patent") entitled "Multiple-Cam, Posterior-Stabilized Knee Prosthesis" was duly and lawfully issued by the United States Patent and Trademark Office ("USPTO") to MEDIDEA. A true and correct copy of the '280 Patent is attached as **Exhibit 1**.

3. MEDIDEA is the assignee of the '280 Patent and holds the rights to sue and recover for past, present and future infringement thereof.

4. The '280 Patent claims priority to the application which matured into U.S. Patent Number 6,558,426 ("the '426 Patent") entitled "Multiple-Cam, Posterior-Stabilized Knee Prosthesis."

5. The '426 Patent was duly and lawfully issued by the USPTO to MEDIDEA on May 6, 2003. A true and correct copy of the '426 Patent is attached as **Exhibit 2**.

6. MEDIDEA is the assignee of the '426 Patent and holds the rights to sue and recover for past, present and future infringement thereof.

7. The inventions described in the written disclosure of the '280 and the '426 Patent are identical and the two patents only differ in their respective patent claims.

8. Michael A. Masini, MD, the sole named inventor on the '280 and '426 Patents, is a board certified orthopedic surgeon with a special interest and training in total joint replacement and complex joint revision surgery. Masini, a prolific inventor, is named on over fifty United States patents which have been widely licensed throughout the orthopedic device industry.

9. Defendant DEPUY ORTHOPAEDICS, INC. ("DEPUY") is a corporation organized and existing under the laws of the State of Indiana and a principal place of business located at 700 Orthopaedic Drive, Warsaw, Indiana 46582.

10. DEPUY makes, distributes, sells and/or offers for sale certain total knee replacement prostheses, such as, for example, the Attune® Knee System.

11. Total knee replacement using the Attune® Knee System 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.

12. DEPUY publicly distributes a detailed product brochure for the Attune® Knee System available for download at: www.depuysynthes.com/hcp/knee/products/qs/ATTUNE-Knee-System (last accessed on November 7, 2016), a true and correct copy of which is attached as **Exhibit 3**.

13. On or about February or March 2003, Masini met in person with Dan Auger, at the time the Director for Knees, Research and Development at DEPUY and presented the disclosure of what was to be issued as the '426 Patent and offered to license the '426 Patent upon issuance and all future divisionals and continuations therefrom to DEPUY.

14. On March 24, 2003, DEPUY, through Dan Auger, acknowledged that it had been "considering and evaluating" the disclosure of what was to be issued as the '426 Patent, but declined the offered opportunity to license the '426 Patent upon issuance and any future divisionals and continuations therefrom. A true and correct copy of DEPUY's letter to Masini dated March 24, 2003 is attached as **Exhibit 4**.

15. On June 30, 2008, about five years after Masini's disclosure to DEPUY, U.S. Patent Application No. 12/165,582 was filed by Joseph G. Wyss *et al.* and assigned to DePuy Products, Inc., an affiliate of DEPUY. On June 26, 2012, the application issued as U.S. Patent No. 8,206,451 (the "Wyss Patent") and directed at a "posterior stabilized knee orthopaedic prosthesis." A true and correct copy of the Wyss Patent is attached as **Exhibit 5**.

16. The Wyss Patent cites to the '426 Patent (Masini) as prior art and it was disclosed to the USPTO by the applicant/DEPUY as part of an Information Disclosure Statement filed on January 11, 2012 ("IDS"). A true and correct copy of the IDS attached as **Exhibit 6**.

17. On March 20, 2013, about ten years after Masini's disclosure to DEPUY, DEPUY issued a press release widely introducing its "latest innovation in total knee replacement—the ATTUNE™ Knee System—at the 2013 American Academy of Orthopedic Surgeons (AAOS) annual meeting in Chicago."¹ The system was "designed to provide better range of motion and address the unstable feeling some patients experience during everyday activities, such as stair descent and bending." According to DEPUY, its "proprietary technologies include: [...] SOFCAM™ Contact: An S-curve design that provides a smooth engagement for stability through flexion, while reducing stresses placed on the implant [...]." A true and correct copy of the press release is attached as **Exhibit 7**.

18. In a product brochure for the Attune® Knee System, DEPUY further promotes the System as benefitting from "the patented s-shape of the cam and spine." See Figure 1 below. On information and belief, DEPUY's claim of patent protection of its commercial product relies, at least in part, on the Wyss Patent.

¹ The same press release also acknowledged that sales of the Attune® Knee System began prior to that date: "To date, more than 3,500 patients have received an ATTUNE Knee as part of a limited launch ..."



SOFCAM Contact

The **SOFCAM** Contact of the ATTUNE PS Knee provides contact mechanics for stability throughout flexion. The ATTUNE GRADIUS Curve introduces the femoral component slowly into engagement with the tibial spine, providing a smooth transition from condylar control to cam/spine control.^{7,8} *This smooth engagement also provides gradual rollback of the femoral component and stable motion throughout flexion.*^{7,8}

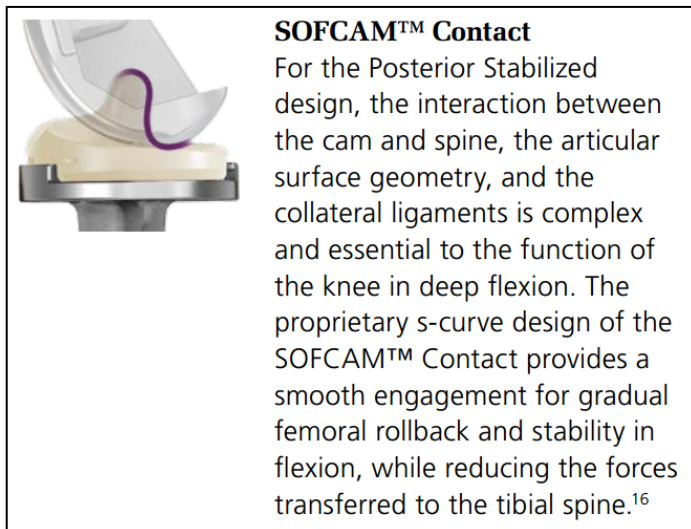
The patented s-shape of the cam and spine provides a large contact area as the cam initially engages the spine, with the cam/spine transitioning smoothly down the spine as the knee moves further into flexion. The low contact position in high flexion directs the forces through the thickest portion of the tibial insert.^{7,8}

Fig. 1 – Excerpt from Product Brochure (see Ex. 3 at p. 7).

19. DEPUY also promotes its product in its “Attune® Knee System – Value Analysis Brief” as shown in Figures 2a and 2b below. A true and correct copy of the Value Analysis Brief is attached as **Exh. 8**.

The ATTUNE Knee System delivers breakthrough discoveries that make the ATTUNE Knee an advancement for hospitals, patients, and surgeons. Each of these significant technologies was designed to provide function for surgeons in the operating room and for patients after surgery.

Fig. 2a



SOFCAM™ Contact

For the Posterior Stabilized design, the interaction between the cam and spine, the articular surface geometry, and the collateral ligaments is complex and essential to the function of the knee in deep flexion. The proprietary s-curve design of the SOFCAM™ Contact provides a smooth engagement for gradual femoral rollback and stability in flexion, while reducing the forces transferred to the tibial spine.¹⁶

Fig. 2b

Excerpts from Product Value Brief (see Ex. 8 at p. 3).

20. A press article, dated March 17, 2014, reported that since the Attune® Knee Systems was launched in March 2013, more than 31,000 of the devices have been implanted in just its first year. A true and correct copy of the press article is attached as **Exhibit 9**.

II. JURISDICTION AND VENUE

21. This Court has exclusive subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a) because this action arises under the patent laws of the United States, including 35 U.S.C. § 271 *et seq.* This Court has personal jurisdiction over DEPUY because it has committed acts giving rise to this action within Illinois and this judicial district and has established minimum contacts within the forum such that the exercise of jurisdiction over Defendants would not offend traditional notions of fair play and substantial justice.

22. Venue properly lies in the Northern District of Illinois pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b), because DEPUY has committed acts within this judicial district giving rise to this action, and DEPUY “resides” in this District as it is subject to personal jurisdiction in this District. Venue is also appropriate because DEPUY is doing business in this judicial district, including one or more of the infringing acts of offering for sale, selling, using infringing products, or providing service and support to DEPUY’s customers in this District and it does so through established distribution channels.

III. CLAIMS

COUNT I – INFRINGEMENT OF THE ‘426 PATENT

23. MEDIDEA realleges and incorporates by reference the allegations set forth in Paragraphs 1-22 above as if fully set forth herein.

24. Claim 9 of the ‘426 Patent requires:

A distal femoral knee-replacement component configured for use with a tibial component having a bearing surface and superior tibial post with a posterior aspect, the distal femoral component comprising:

a body having a pair of medial and lateral condylar protrusions and an intercondylar region there between dimensioned to receive the tibial post; and

a structure providing more than one physically separate and discontinuous points of cam action as the knee moves from extension to flexion.

See Exh. 2 – Independent claim 9 of the ‘426 Patent at column 5, lines 6-15.

25. In violation of 35 U.S.C. § 271, DEPUY is and has been directly infringing the ‘426 Patent by, among other activities, making, using, importing, offering for sale, selling, providing, maintaining and/or supporting, without license or authority, products falling within the scope of one or more claims of the ‘426 Patent. Such products include, without limitation, certain total knee prostheses, such as, for example, the Attune® Knee System.

26. Subject to additional information obtained during discovery, the court’s constructions of any patent terms about whose meaning the parties disagree, and the detailed initial and final infringement contentions MEDIDEA will make pursuant to this district’s Local Patent Rules (*see, e.g.* LRP 2.2, 3.1), the accused Attune® Knee System

(the “Accused Product”) infringes at least independent claim 9 of the ‘426 Patent as described in the following paragraphs.

27. The preamble of claim 9 of the ‘426 Patent requires “[a] distal femoral knee replacement component configured for use with a tibial component having a bearing surface and superior tibial post with a posterior aspect.” See Ex. 2 at col. 5, lines 6-9. The requirements of the preamble are present in the Accused Product as shown in Figures 3 and 4 below:

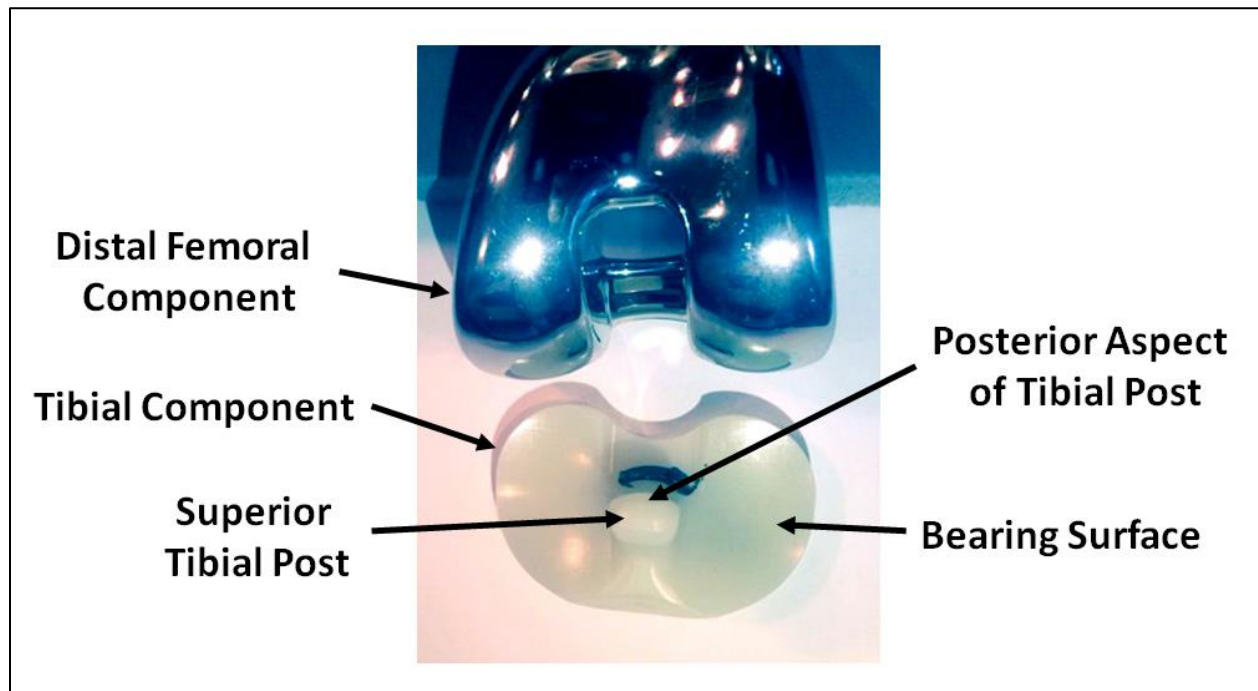


Fig. 3 - Annotated photograph of Accused Product.

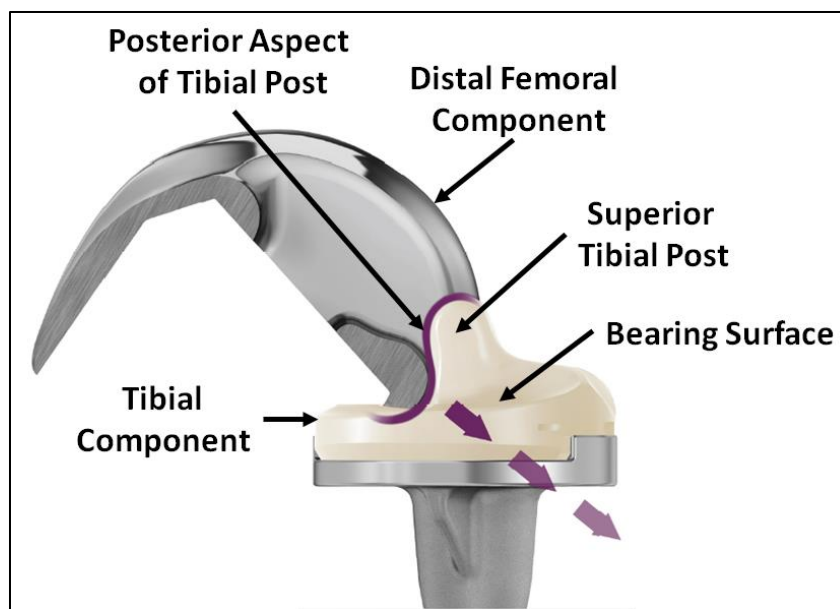


Fig. 4 - Annotated excerpt from DEPUY's product brochure (purple highlight in original) (see Ex. 3 at p. 7).

28. The first element of claim 9 of the '426 Patent requires that the distal femoral component comprises "a body having a pair of medial and lateral condylar protrusions and an intercondylar region there between dimensioned to receive the tibial post." See Ex. 2 - Claim 9 of the '426 Patent at column 5, lines 10-12. The first element is present in the Accused Product as shown in Figures 5 and 6 below:

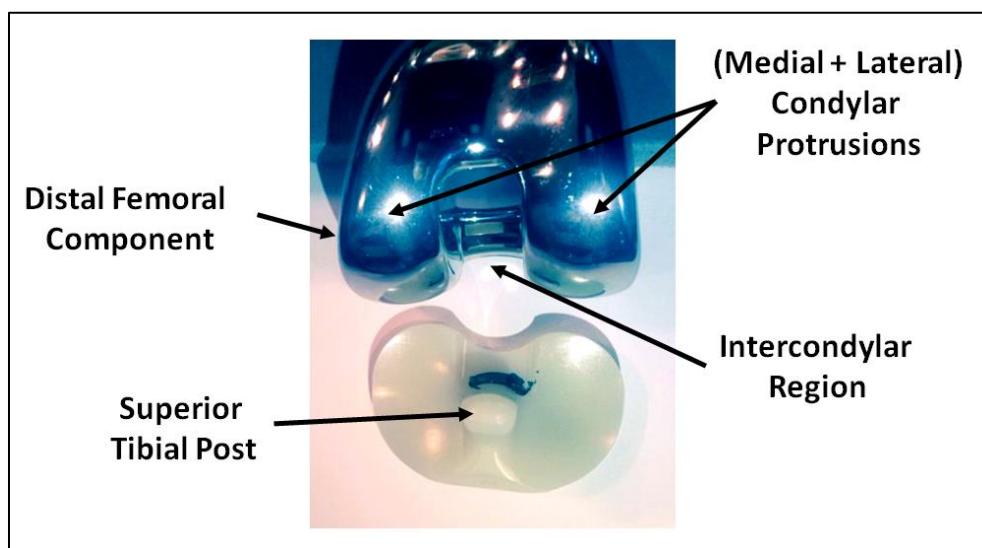


Fig. 5 - Annotated photograph of Accused Product.

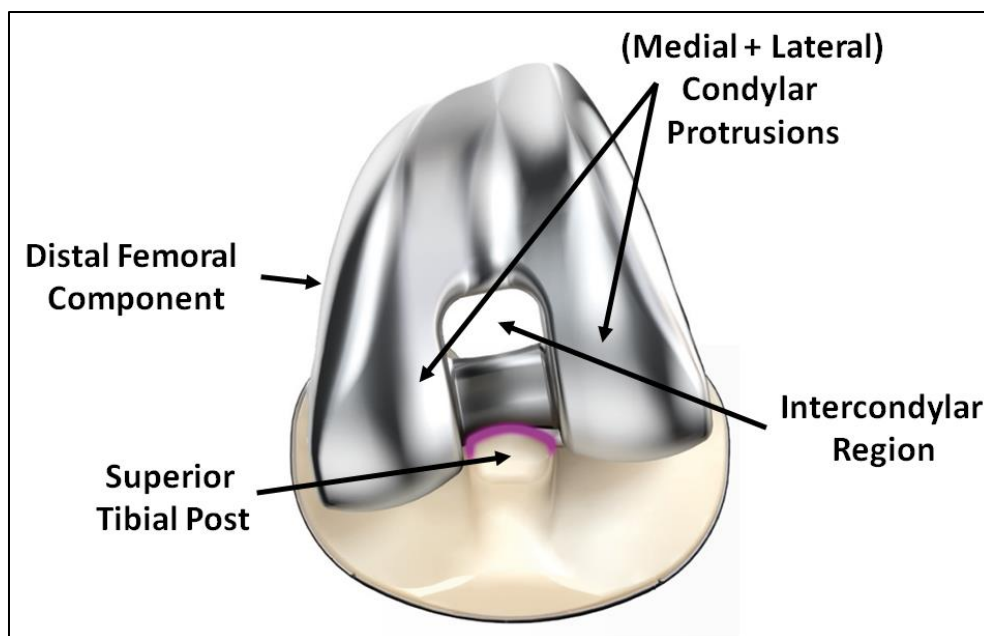


Fig. 6 - Annotated excerpt from DEPUY's product brochure (purple highlight in original) (see Ex. 3 at p.7).

29. The second element of claim 9 of the '426 Patent requires that the distal femoral component also comprises "a structure providing more than one physically separate and discontinuous points of cam action as the knee moves from extension to flexion." See Ex. 2 - Claim 9 of the '426 Patent at column 5, lines 13-15. The Accused Product has a structure, i.e., a cam surface that provides at least two separate and discontinuous points of cam action as shown in annotated Figure 7 below. In particular, the cam surface has at least a first point of cam action as part of a concave cam surface (annotated in RED [1]) and a second point of cam action as part of a convex cam surface (annotated in GREEN [2]). These at least two cam surfaces with distinct radii (concave and convex curvatures) are physically separate and discontinuous from each other because contact between a particular point of the cam surface and the corresponding

surface of the tibial post is not continuously maintained throughout the femoral component's movement from extension to flexion.

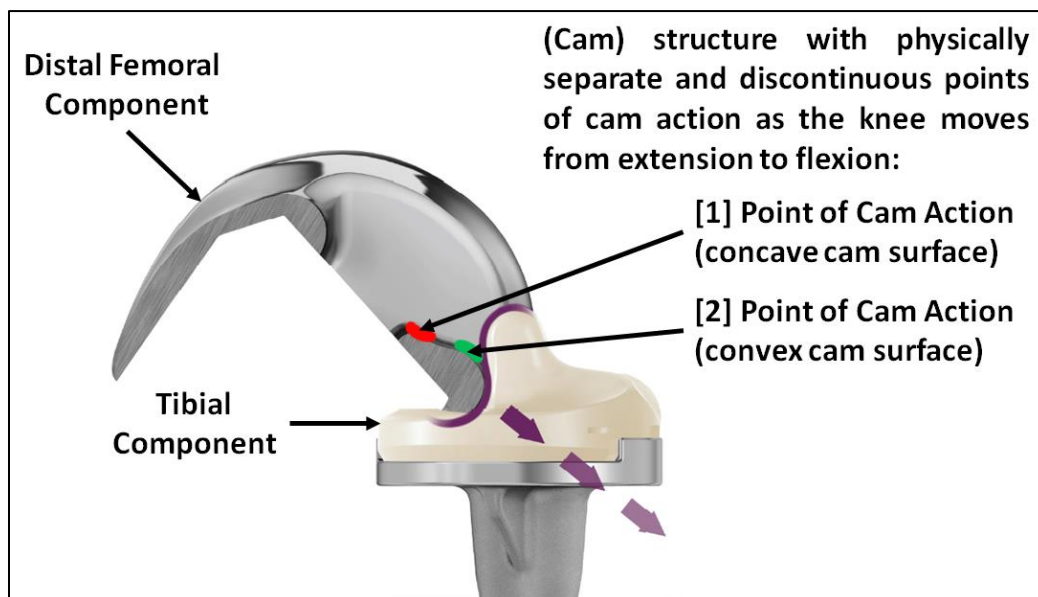


Fig. 7 - Annotated excerpt from DEPUY's product brochure (purple highlight in original) (see Ex. 3 at p.7).

30. As a result of DEPUY's unlawful infringement of the '426 Patent, MEDIDEA has suffered and will continue to suffer damage. Under 35 U.S.C. § 284, MEDIDEA is entitled to recover from DEPUY the damages suffered by MEDIDEA as a result of DEPUY's infringement of the '426 Patent.

31. Upon information and belief, DEPUY intends to continue its unlawful infringing activity, and DEPUY's infringement on MEDIDEA's exclusive rights under the '426 Patent will continue to damage MEDIDEA causing irreparable harm, for which there is no adequate remedy of law, unless enjoined by this Court under 35 U.S.C. § 283.

32. DEPUY has had knowledge of the '426 Patent since at least March 2003.

33. By continuing the infringement after the first sale of the Attune® Knee System, or at least after March 20, 2013, DEPUY has engaged and continues to engage in

willful and deliberate infringement of the '426 Patent. Despite knowing that MEDIDEA had offered DEPUY a license opportunity under the '426 Patent, which DEPUY had earlier declined, DEPUY never contact MEDIDEA to request a license or other authorization to directly or indirectly make, use, sell, offer for sale in the United States or import into the United States the accused Attune® Knee System. Instead, DEPUY elected to appropriate the inventions disclosed and claimed in the '426 Patent, and then at least use, offer to sell and sell the accused Attune® Knee System in the United States, deliberately infringing the '426 Patent. DEPUY's egregious conduct justifies an increase of three times the damages to be assessed pursuant to 35 U.S.C. § 284, and further qualifies this action as an exceptional case supporting an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT II – INFRINGEMENT OF THE '280 PATENT

34. MEDIDEA realleges and incorporates by reference the allegations set forth in Paragraphs 1-33 above as if fully set forth herein.

35. Claim 1 of the '280 Patent requires:

A total knee-replacement system, comprising:

a tibial component having a tibial post with a posterior surface;

a femoral component having medial and lateral condylar protrusions which form separated bearing surfaces configured to articulate with the tibial component, the femoral component further including an intercondylar femoral cam mechanism configured to articulate with the posterior surface of the tibial post;

wherein a majority of the posterior surface of the tibial post is concave in a sagittal plane, defined as a vertical plane extending from front to back;

wherein the cam mechanism of the femoral component has a superior convex portion, a concave central portion, and an inferior convex posterior portion;

wherein the inferior convex posterior portion contacts the posterior surface of the tibial post at or before 90 degrees of flexion;

wherein at least a portion of the posterior surface of the tibial post is convex in a transverse (horizontal) plane; and

wherein at least a portion of the cam mechanism of the femoral component is concave in the transverse (horizontal) plane.

See Exh. 1 – Independent claim 1 of the '280 Patent at col. 5, line 9 – col. 6, line 12.

36. In violation of 35 U.S.C. § 271, DEPUY is and has been directly infringing the '280 Patent by, among other activities, making, using, importing, offering for sale, selling, providing, maintaining and/or supporting, without license or authority, products falling within the scope of one or more claims of the '280 Patent. Such products include, without limitation, certain total knee prostheses, such as, for example, the Attune® Knee System (the "Accused Product").

37. Subject to additional information obtained during discovery, the court's constructions of any patent terms about whose meaning the parties disagree, and the detailed initial and final infringement contentions MEDIDEA will make pursuant to this district's Local Patent Rules (*see, e.g.* LRP 2.2, 3.1), the Accused Product infringes independent claim 1 and dependent claim 2 of the '280 Patent as described in the following paragraphs.

Independent Claim 1 of the '280 Patent

38. The Accused Product is a total knee-replacement ("TKR") system as required by the preamble of claim 1 of the '280 Patent.

39. The first element of claim 1 of the '280 Patent requires that the claimed TKR system comprises "a tibial component having a tibial post with a posterior surface." See Ex. 1 - Claim 1 of the '280 Patent at col. 5, lines 10-11. This element is present in the Accused Product as shown in Figures 8 and 9 below:

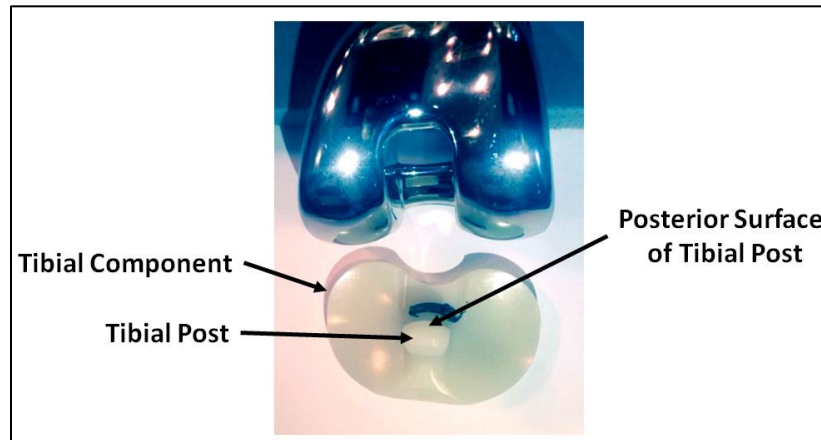


Fig. 8 - Annotated photograph of Accused Product.

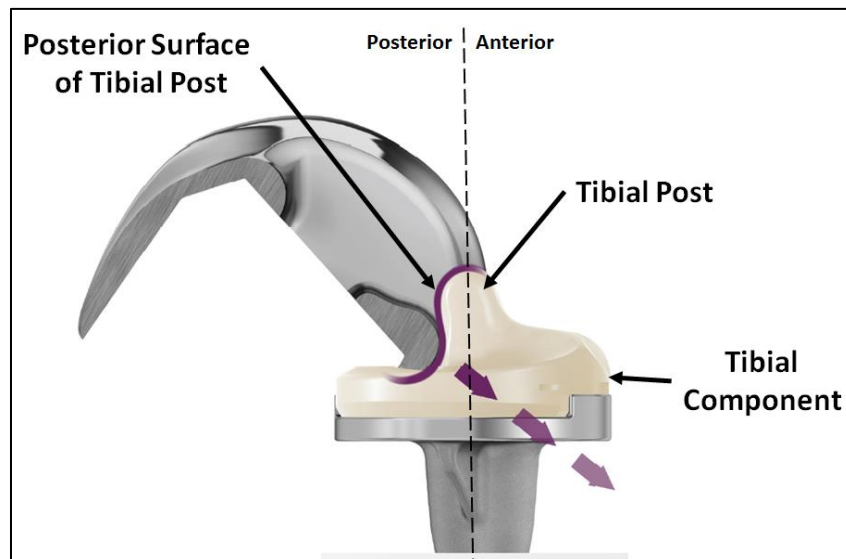


Fig. 9 - Annotated excerpt from DEPUY's product brochure (purple highlights in original) (see Ex. 3 at p. 7).

40. The second element of claim 1 of the '280 Patent requires that the claimed TKR system comprises "a femoral component having medial and lateral condylar protrusions which form separated bearing surfaces configured to articulate with the tibial component, the femoral component further including an intercondylar femoral cam mechanism configured to articulate with the posterior surface of the tibial post." See Ex. 1 at col. 5, lines 12-17. This element is present in the Accused Product as shown in Figures 10 and 11 below:

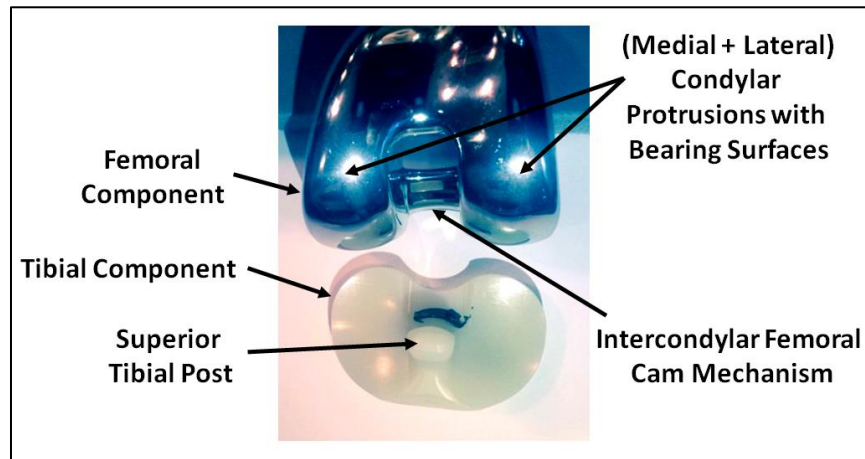


Fig. 10 - Annotated photograph of Accused Product.

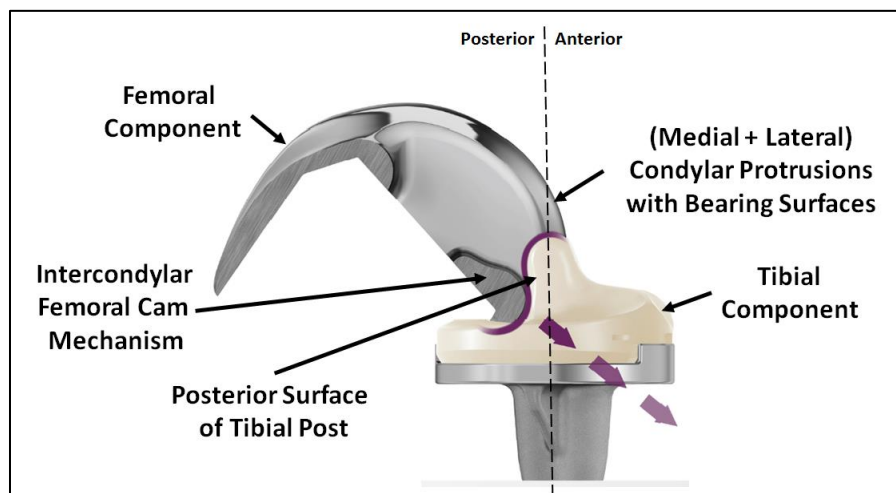


Fig. 11 - Annotated excerpt from DEPUY's product brochure (purple highlights in original) (see Ex. 3 at p. 7).

41. The third element of claim 1 of the '280 Patent requires that "a majority of the posterior surface of the tibial post is concave in a sagittal plane, defined as a vertical plane extending from front to back." See Ex. 1 at col. 5, lines 18-20. This element is present in the Accused Product as shown in Figure 12 below:

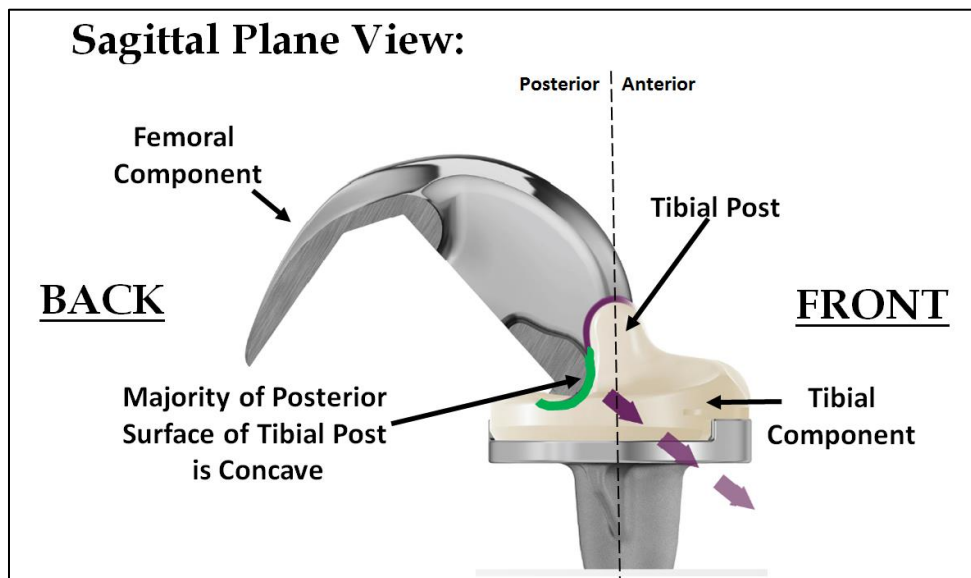


Fig. 12 - Annotated excerpt from DEPUY's product brochure (Green highlight added, purple highlights in original) (see Ex. 3 at p. 7).

42. The fourth element of claim 1 of the '280 Patent requires that "the cam mechanism of the femoral component has a [1] superior convex portion, a [2] concave central portion, and an [3] inferior convex posterior portion." See Ex. 1 at col. 6, lines 1-3. This element is present in the Accused Product as shown in Figure 13 below:

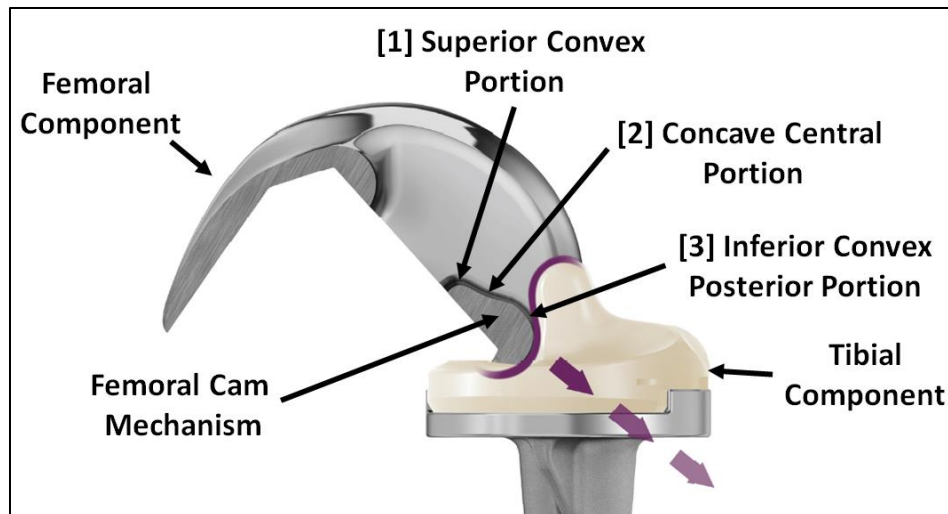


Fig. 13 - Annotated excerpt from DEPUY's product brochure (purple highlight in original) - see Ex. 3 at p. 7.

43. The fifth element of claim 1 of the '280 Patent requires that "the inferior convex posterior portion contacts the posterior surface of the tibial post at or before 90 degrees of flexion." See Exh. 1 at col. 6, lines 4-6. This element is present in the Accused Product and described and shown by the disclosure of the Wyss Patent (see Fig. 14 below), which, on information and belief, is embodied by the Accused Product:

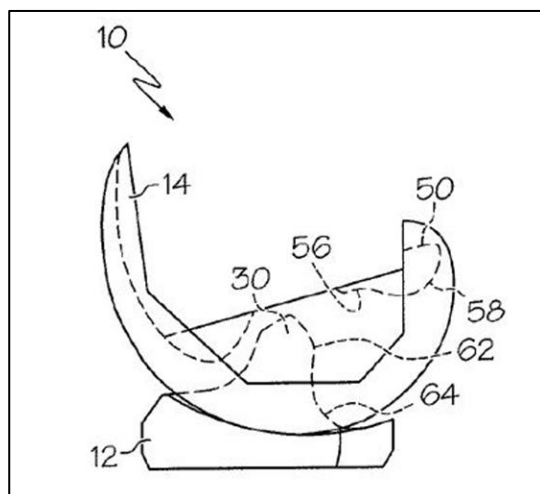


Fig. 14a

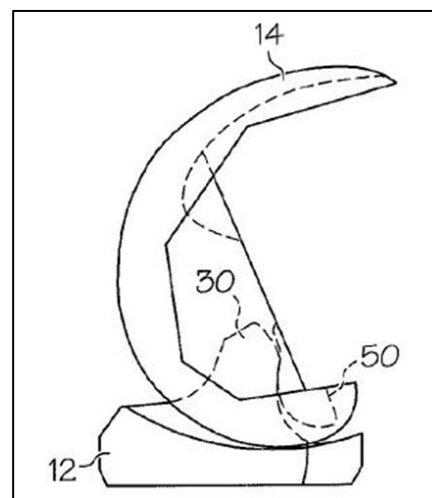


Fig. 14b

Excerpts from Wyss Patent for illustrative purpose (numerals in original).

For Fig. 14a see Ex. 5 at Fig. 6 - for Fig. 14b see Ex. 5 at Fig. 9.

44. Further with regard to the fifth element of claim 1 of the '280 Patent, on information and belief, the Accused Product embodies the operation disclosed in Figures 6 and 9 of the Wyss Patent (see Fig. 14 above) and with respect to the disclosed operation of the Wyss Patent states as follows: "As shown in FIG. 6 when the orthopaedic prosthesis **10** is in extension or is otherwise not in flexion (e.g., a flexion of about 0 degrees), the posterior cam **50** is not in contact with the spine **30**." See Ex. 5 at col. 7, lines 4-7. The Wyss Patent further discloses that "in one embodiment as illustrated in FIG. 9, the contact between the posterior cam **50** and the spine **30** begins transitioning to the cam surfaces **58, 64** at about 80 degrees. At this degree of flexion, initial contact between the convex cam surface 58 of the posterior 50 and the concave cam surface 64 of the spine 30 may be established." See Ex. 5 at col. 7, lines 31-37 (emphasis added).

45. The sixth element of claim 1 of the '280 Patent requires that "at least a portion of the posterior surface of the tibial post of the Accused Product is convex in a transverse (horizontal) plane." See Ex. 1 at col. 6, lines 7-9. This element is present in the Accused Product as shown in Figures 15 and 16 below:

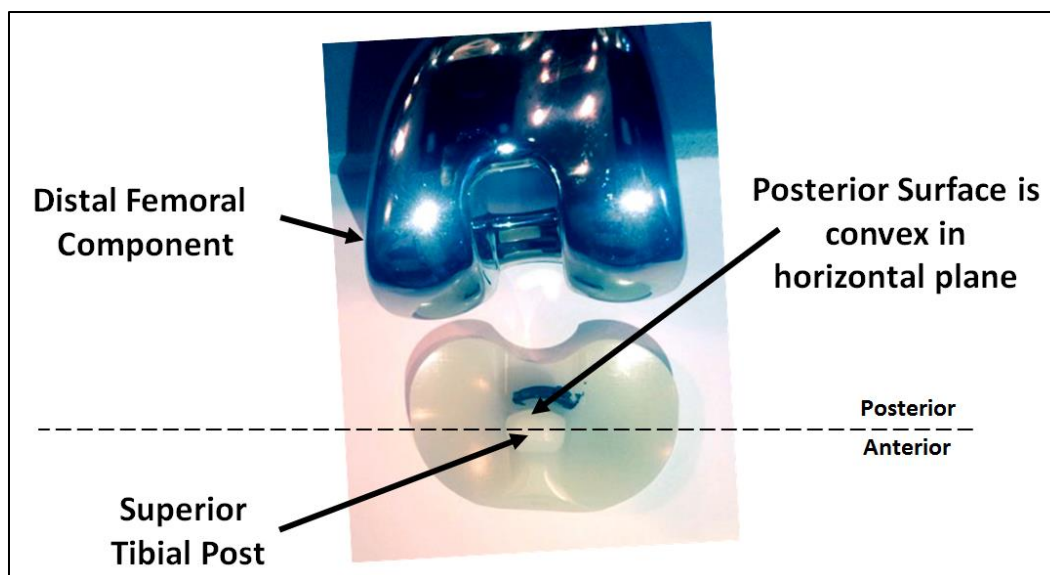


Fig. 15 - Annotated photograph of Accused Product.

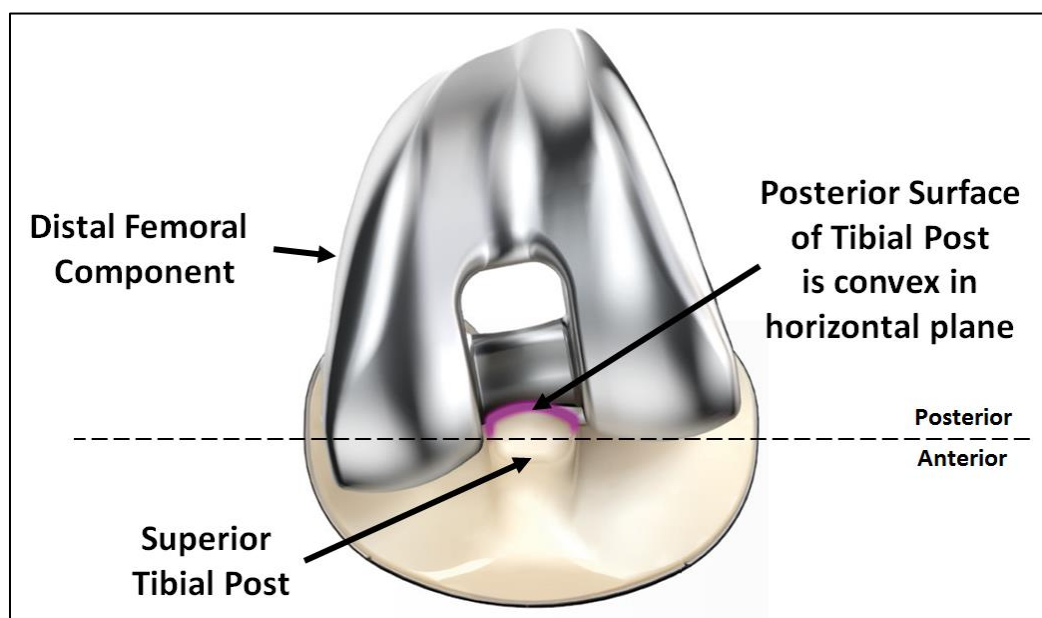


Fig. 16 - Annotated excerpt from DEPUY's product brochure (purple highlight in original) (see Ex. 3 at p. 7).

46. The seventh element of claim 1 of the '280 Patent requires that "at least a portion of the cam mechanism of Accused Product's femoral component is concave in the transverse (horizontal) plane." See Ex. 1 at col. 6, lines 10-13. This element is present in the Accused Product as shown in Figures 17 and 18 below:

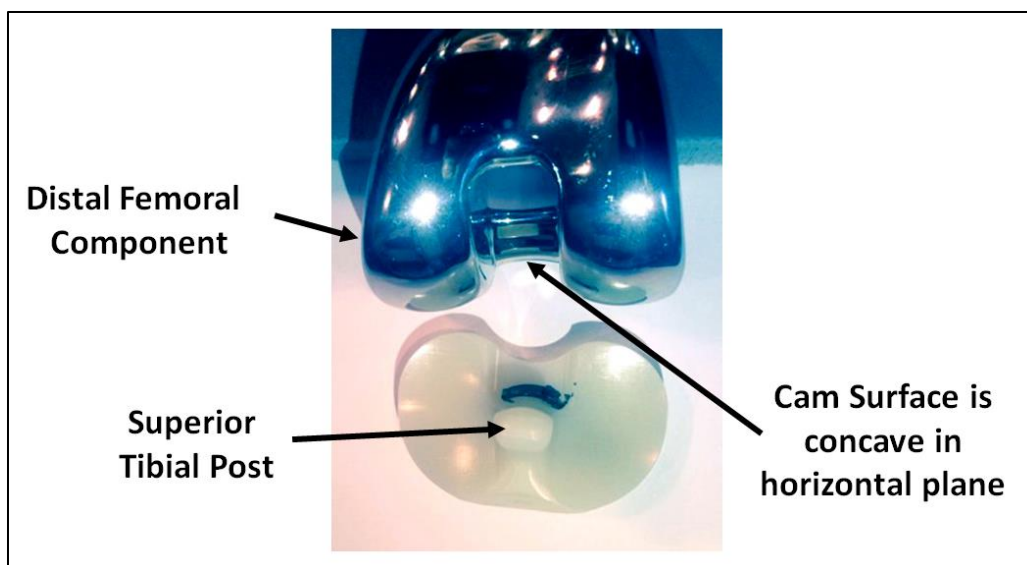


Fig. 17 - Annotated photograph of Accused Product.

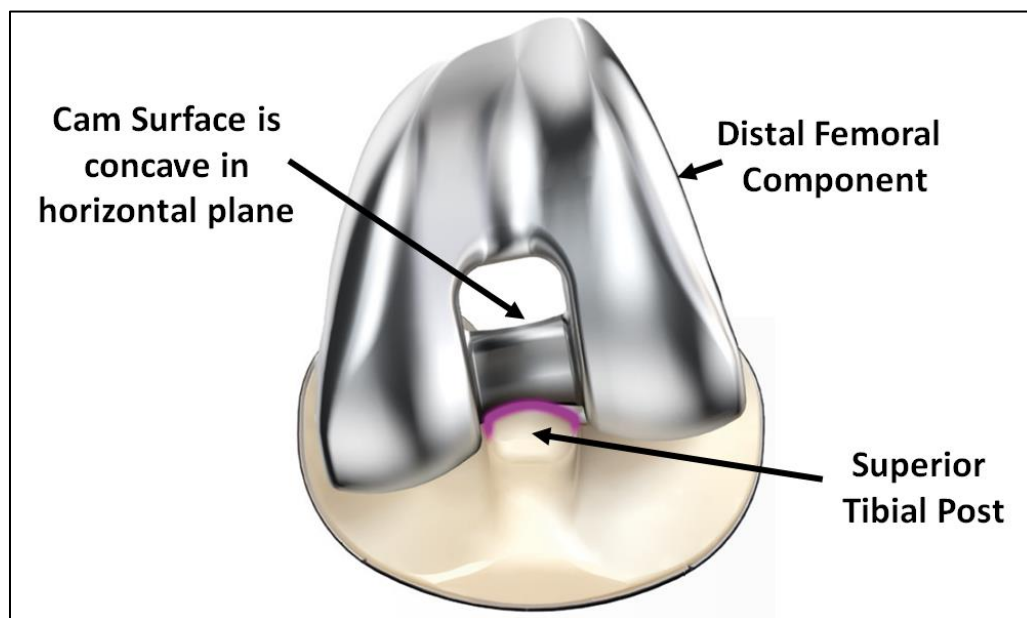


Fig. 18 - Annotated excerpt from DEPUY's product brochure - purple highlight in original (see Ex. 3 at p. 7).

Dependent Claim 2 of the '280 Patent

47. The first element of claim 2 of the '280 Patent requires that "a portion of the femoral cam mechanism forms an 's' shaped surface portion in the sagittal plane." See Ex. 1 at col. 6, lines 13-15. The Accused Product has an s-shaped cam as shown and

described in Figures 19 and 20 below. In particular, DEPUY highlights “the patented s-shape of the cam and spine:”

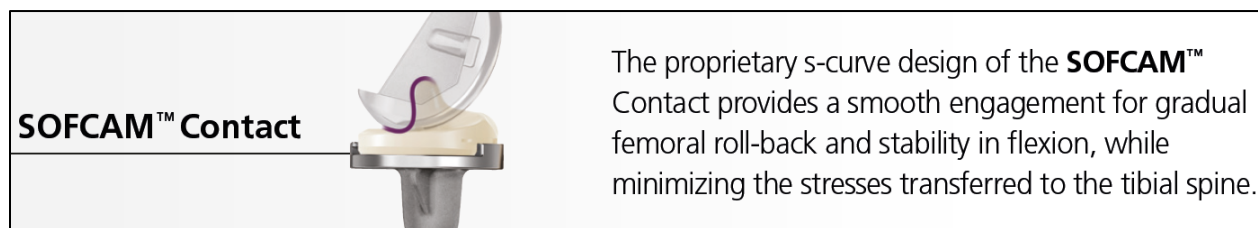


Fig. 19 - Excerpt from DEPUY's product brochure – purple highlight in original (see Ex. 3 at p. 5).

The patented s-shape of the cam and spine provides a large contact area as the cam initially engages the spine, with the cam/spine transitioning smoothly down the spine as the knee moves further into flexion. The low contact position in high flexion directs the forces through the thickest portion of the tibial insert.^{7,8}

Fig. 20 - Excerpt from DEPUY's product brochure – purple highlight in original (see Ex. 3 at p. 7).

48. The second element of claim 2 of the '280 Patent requires that “the ‘s’ shaped surface portion is formed from the superior aspect of the most superior surface of the femoral cam at its superior convex portion and terminates at the most inferior aspect of the concave surface.” See Ex. 1 at col. 6, lines 16-19. This element is present in the Accused Product as shown in Figure 21 below:

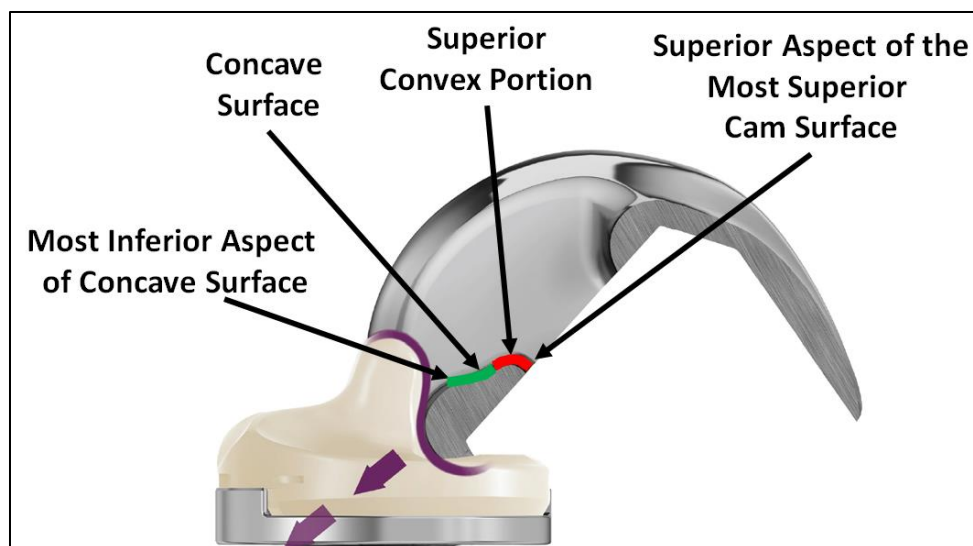


Fig. 21 - Annotated and mirrored (for illustration) excerpt from DEPUY's product brochure (purple highlights in original) (see Ex. 3 at p. 7).

49. As a result of DEPUY's unlawful infringement of the '280 Patent, MEDIDEA has suffered and will continue to suffer damage. Under 35 U.S.C. § 284, MEDIDEA is entitled to recover from DEPUY the damages suffered by MEDIDEA as a result of DEPUY's infringement of the '280 Patent.

50. Upon information and belief, DEPUY intends to continue its unlawful infringing activity, and DEPUY's infringement on MEDIDEA's exclusive rights under the '280 Patent will continue to damage MEDIDEA causing irreparable harm, for which there is no adequate remedy of law, unless enjoined by this Court under 35 U.S.C. § 283.

IV. PRAYER FOR RELIEF

WHEREFORE, MEDIDEA respectfully requests that this Court enter judgment against Defendant DEPUY as follows:

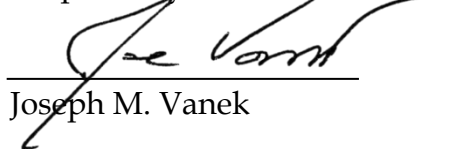
- (a) for declaration that the '280 and '426 Patents are good and valid in law;
- (b) for judgment that DEPUY has infringed and continues to infringe the '280 and '426 Patents;
- (c) for a permanent injunction under 35 U.S.C. § 283 against Defendant and its respective directors, officers, employees, agents, subsidiaries, parents, attorneys, and all persons acting in concert, on behalf of, in joint venture, or in partnership with DEPUY thereby enjoining any further acts of infringement;
- (d) for damages to be paid by DEPUY adequate to compensate MEDIDEA for its infringement, together with interest, costs and disbursements, and that damages be increased three times the amount found as justified under 35 U.S.C. 284;
- (e) for judgment finding this to be an exceptional case, and awarding MEDIDEA attorney fees under 35 U.S.C. 285; and
- (f) for such further relief at law and in equity as the Court may deem just and proper.

V. DEMAND FOR JURY TRIAL

Pursuant to Federal Rules of Civil Procedure Rule 38, Plaintiff MEDIDEA hereby demands a jury trial on all issues triable by jury.

Dated: November 16, 2016

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Joe Vanek", is written over a horizontal line.

Joseph M. Vanek

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MEDIDEA, L.L.C.*

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Jeffrey R. Moran, Esq.

Martin Amaro, Esq.

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