IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the *Inter Partes* Review of U.S. Patent No. 6,558,426

Trial No.: Not Yet Assigned

Issued: May 6, 2003

Filed: November 28, 2000

Inventors: Michael A. Masini

Assignee: MedIdea, L.L.C.

Title: MULTIPLE-CAM POSTERIOR-STABILIZED KNEE PROSTHESIS

MAIL STOP PATENT BOARD
Patent Trial and Appeal Board
United States Patent & Trademark Office
P.O. Box 1450
Alexandria, Virginia 22313-1450

PETITION FOR INTER PARTES REVIEW UNDER 37 C.F.R. § 42.100

On behalf of DePuy Synthes Products, Inc. ("Petitioner" or "DePuy") and in accordance with 35 U.S.C. § 311 and 37 C.F.R. § 42.100, *inter partes* review is respectfully requested for claims 9 and 10 of U.S. Patent No. 6,558,426 ("the '426 patent," attached hereto as Exhibit 1001), which is assigned to MedIdea, L.L.C. ("Patent Owner").

The undersigned representative of Petitioner authorizes the Patent Office to charge the $23,000 Petition Fee, as well as any additional fees, to Deposit Account No. 50-3013, ref: 362327-600012.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

CASES

STATUTES

OTHER AUTHORITIES

LIST OF EXHIBITS

Exhibit No.	Document
1001	U.S. Patent No. 6,558,426 ("the '426 patent").
1002	Excerpts from the Prosecution History of the '426 patent.
1003	D'Lima declaration.
1004	Color Atlas of Anatomy, 3rd Ed. (1993).
1005	U.S. Patent No. 5,824,100 ("Kester").
1006	PCT Publication No. WO99/27872 ("Dennis")
1007	Intentionally Left Blank
1008	Great Grandchild Patent U.S. 9,492,280.
1009	Child Patent U.S. 8,273,132.
1010	Grandchild Patent U.S. 8,721,730.
1011-1015	Intentionally Left Blank
1016	Excerpts from file history of '280 patent.
1017	Excerpts from file history of '132 patent.
1018	Excerpts from file history of '730 patent.
1019	Waiver of Service Filed December 16, 2016.

Exhibit No.	Document
1020	MedIdea, L.L.C.'s First Supplemental Responses to Defendant's First Set of Interrogatories for *MedIdea, L.L.C. v. DePuy Orthopaedics, Inc., et al.*, Civil Action No. 1:16-cv-10638.
1021	Declaration of Anthony T. Jacono

I. INTRODUCTION

The Office allowed independent claim 9 and dependent claim 10 of U.S. Patent No. 6,558,426 (the "'426 patent") after a single interview without any prior-art rejections of the claims. (*See*, Ex. 1002, '426 Patent File History.) It should not have. Although present in claim 1, neither of the reasons for allowance resulting from the interview (*i.e.*, "the plurality of cam members…, which [1] engage with the posterior aspect of the tibial post [2] throughout the range of motion") appear in claims 9 or 10. (Ex. 1002 at 65.) Thus, a substantial amount of prior art falls within the scope of claims 9 and 10, including PCT Publication No. WO99/27872 ("Dennis") addressed in this Petition.

Patent Owner admits that Dennis discloses every limitation in claim 9 except one: "a structure providing more than one physically separate and discontinuous points of cam action as the knee moves from extension to flexion." (Ex. 1020 at 6.) As evidenced herein, Dennis discloses that limitation and, in fact, depicts *three* physically separate and discontinuous points of cam action as highlighted in green below in Figure 6A from Dennis:

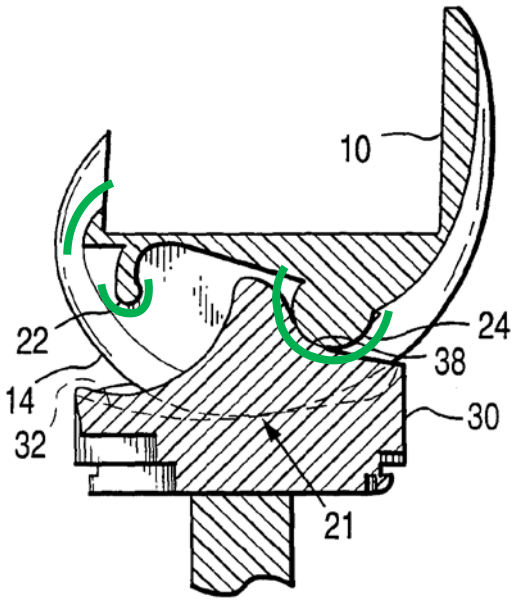


Figure 6A from Dennis

(Ex. 1006 at Figure 6A.) Dennis also discloses the additional requirement in claim 10 that "the cam member of cam action is operative to minimize translation of the condylar protrusions relative to the bearing surface of the tibial component at the initiation of flexion." Indeed, Dennis explains that "anterior cam 24 and posterior cam 22 act as steps to limit the extent of anterior-posterior movement[.]" (*Id*. at 7:25-26.)

Accordingly, the Board should institute a trial to examine claims 9 and 10 of the '426 patent, and should cancel them.

II. GROUNDS FOR STANDING UNDER 37 C.F.R. § 42.204(a)

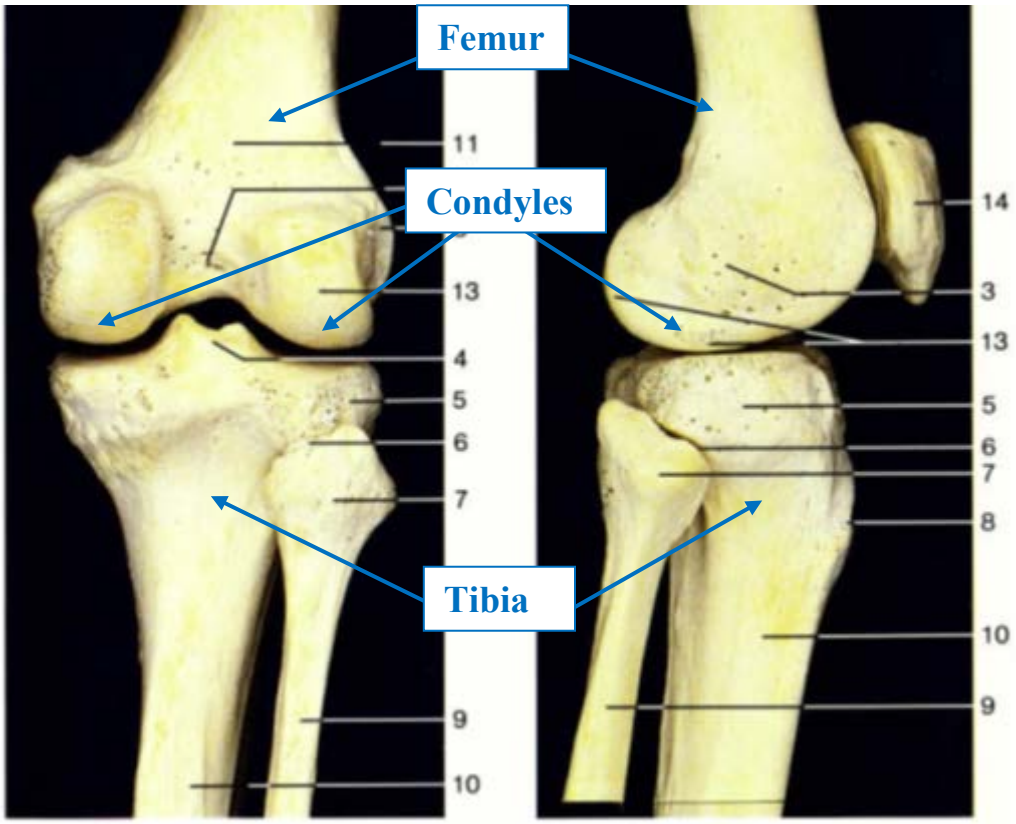
Petitioner certifies that the '426 patent is eligible for IPR, and Petitioner is not barred or estopped from requesting an IPR on the grounds identified herein. Patent

Owner filed a Complaint for patent infringement of the '426 patent on November 16, 2016. *MedIdea, L.L.C. v. DePuy Orthopaedics, Inc., et al.*, Civil Action No. 1:16-cv-10638, docket entry 1. Patent Owner requested that Petitioner waive service of the Complaint, and Petitioner agreed. Patent Owner filed the executed waiver of service with the district court on December 16, 2016. (Ex. 1019.) Petitioner is deemed to have been served on the date Patent Owner filed the executed waiver of service with the district court, December 16, 2016. *See* FED. R. CIV. P. 4(d)(4) ("When the plaintiff files a waiver, proof of service is not required and these rules apply as if a summons and complaint had been served at the time of filing the waiver."); *accord Brinkmann Corp. v. A&J Manuf.,* IPR2015-00056, Paper 10, 6–7 (PTAB Mar. 23, 2015); *Macauto U.S.A. v. Bos GmbH & KG*, IPR2012-00004, Paper 18, 16 (PTAB Jan. 24, 2013); *Motorola Mobility LLC v. Arnouse*, IPR2013-00010, Paper 20, 6 (PTAB Jan. 30, 2013); *The Scotts Co. LLC v. Encap, LLC*, IPR2013-00110, Paper 12, 3 (PTAB July 3, 2013).

III. BACKGROUND INFORMATION AND THE '426 PATENT

A. Posterior Stabilized Knee Replacements Generally

The '426 patent relates to replacement knees, also called knee prostheses. (Ex. 1003 at ¶ 21.) In a healthy leg, the femur and tibia come together to form the knee as depicted below:



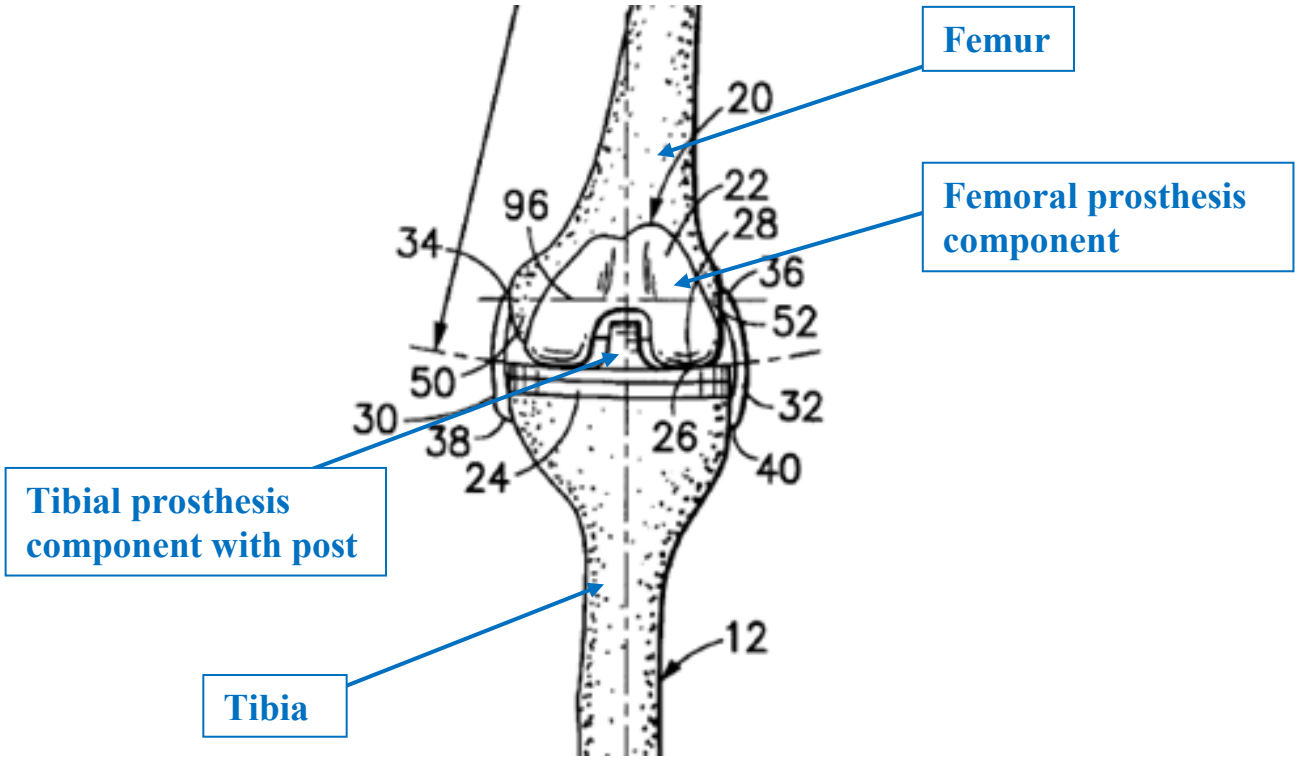
Bones of right knee joint (dorsal aspect).

Bones of right knee joint (lateral aspect).

(*Id.*)[1] At the end of the femur, there are two round protuberances, known as condyles, that engage the end of the tibia at the knee joint. (*Id.* at ¶ 22.)

A prosthesis typically replaces the knee joint with a femoral component (attached to the end of the femur) and a tibial component (attached to the end of the tibia), for example as depicted in the following picture:

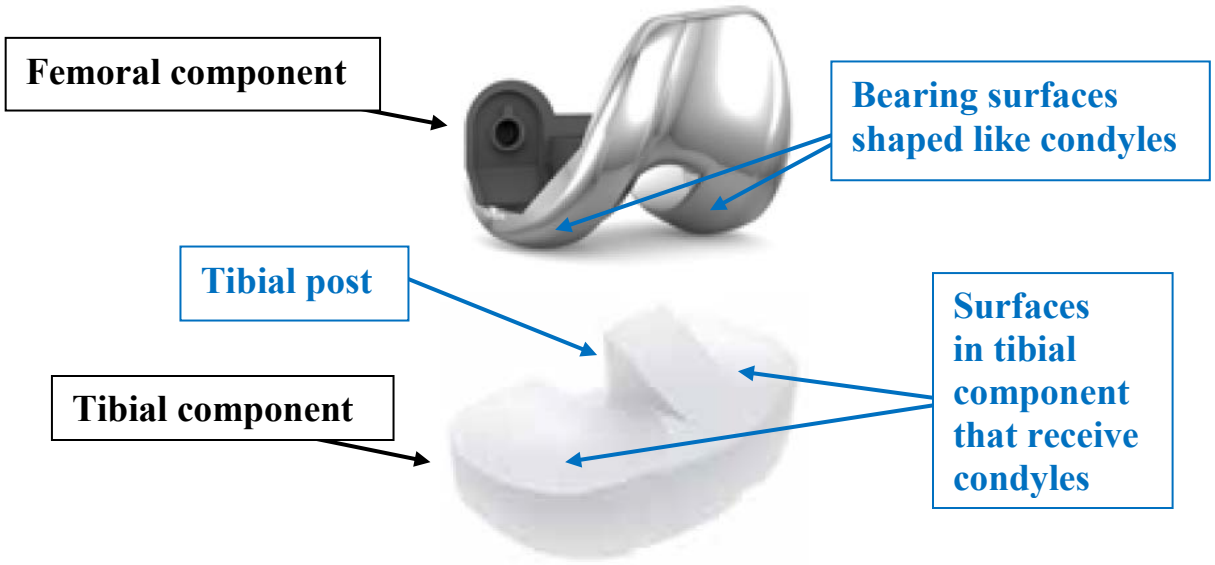
[1] Images are from Ex. 1004 - *Color Atlas of Anatomy*, 3rd Ed., at 415 (1993).



(Ex. 1005 ("Kester") at Figure 1 (Kester is discussed as background prior art in the '426 patent at 1:31-1:39); Ex. 1003 at ¶ 27.)

A knee prosthesis is often shaped similarly to the portions of the femur and tibia bones it replaces. (Ex. 1003 at ¶ 28.) Such a femoral component has bearing surfaces shaped like the condyles of the femur, and is designed to be received by, and articulate with, the tibial component. (*Id.*) An example of such a prosthesis is Petitioner's Sigma Knee System, as illustrated below:[2]

[2] The Sigma Knee System is described in multiple prior art publications Patent Owner submitted during prosecution of the '426 patent family. (*See* Ex. 1008, Great-grandchild Patent U.S. Patent No. 9,492,280, at page 6, identifying



(*Id.*)

"Procedure, References Guide for Use with P.F.C. Sigma Knee Systems, 1998" and "'PFC Sigma Knee System with Rotating Platform Technical Monograph', 1999.")

Once implanted, the tibial and femoral components articulate with one another to allow the reconstructed knee to bend, as illustrated in the following example:

(Ex. 1003 at ¶ 29.)

In a healthy knee, the femur and tibia are held together at the knee joint by four ligaments: the anterior cruciate ligament; the posterior cruciate ligament ("PCL"); and the medial and lateral cruciate ligaments. (*Id*. at ¶¶ 23-25.) In some patients receiving knee implants, the PCL may be damaged or deficient, or the surgeon may remove it during the surgical procedure to facilitate implanting the prosthesis. (*Id*. at ¶ 26.) The absence of a healthy PCL decreases the stability of the back of the knee and could lead to dislocation. (*Id*.) Those patients require a prosthesis that also provides the type of stabilization usually provided by the missing

or damaged PCL. (*Id*.) In such cases, a PCL-stabilized prosthesis – also known as a posterior-stabilized ("PS") prosthesis – may be used. (*Id*.)

A PS prosthesis mimics the functionality of the knee's ligaments. It restricts or limits the movement of the tibia relative to the femur by using a "post" on the tibial component and a "cam" on the femoral component. (Ex. 1003 at ¶ 30.) These cam and post structures are located between the two condyles in a space known as the intercondylar region, as illustrated above. (*Id*.) The post and cam come into contact as the leg moves back and forth from being straight or extended (*i.e.*, extension) to being bent (*i.e.*, flexion). (*Id*.) This cam-post contact minimizes translation (or sliding[3]) of the femoral component with respect to the tibial component, including preventing the femoral component from sliding completely off the tibial component resulting in a dislocation of the knee. (*Id*. at ¶ 31.)

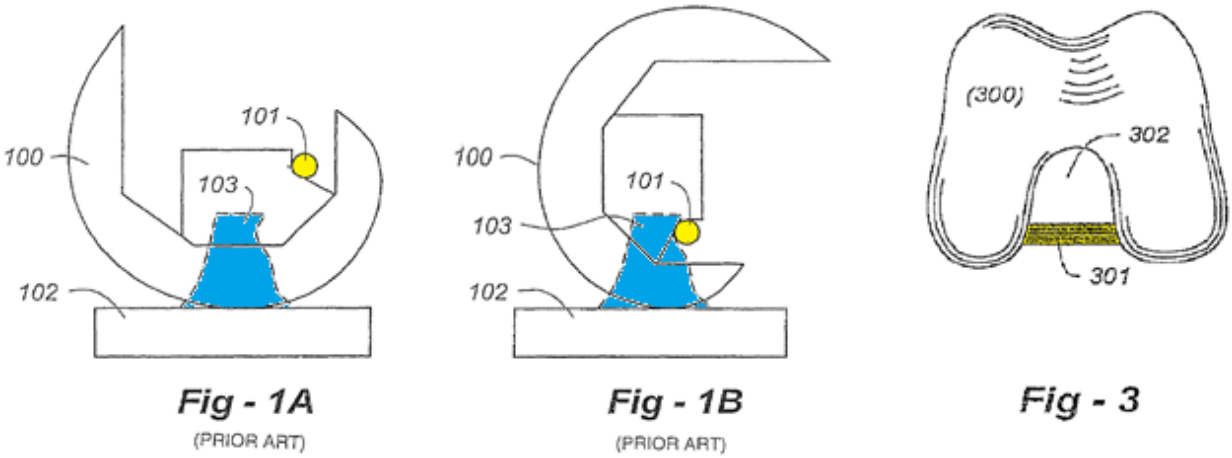
[3] The '426 patent uses the terms "translation" and "sliding" synonymously. (*Compare* Ex. 1001 at 2:11-14, "following a considerable amount of flexion, the cam 101 finally engages with the post 103. Until engagement occurs, however, the [femoral] component 100 may be permitted to ***slide*** relative to the tibial insert," *with id*. at 1:62-65, "there is a space between the cam and the post when the knee is in extension, necessitating anterior ***translation*** of the femur on the tibia prior to contacting the posterior cam;" *see also* Ex. 1003 at ¶ 31.)

B. The Specification of The '426 Patent

The '426 patent is directed to a total knee replacement prosthesis that is used when a patient's posterior cruciate ligament has been removed. (Ex. 1001 at 1:6-19; Ex. 1003 at ¶ 33.) As described above, patients who do not have a PCL need a knee prosthesis that can provide added stability and compensate for the missing PCL. (*Id*.) That is accomplished using a "cam-and-post configuration" in the prosthesis. (Ex. 1001 at 1:6-19; Ex. 1003 at ¶ 33.)

Cam-and-post prostheses are not new. (Ex. 1003 at ¶ 34.) Nor does the '426 patent characterize them as such. (*Id*.) In fact, it identifies numerous examples in the prior art. (Ex. 1001 at 1:20-2:18.) The patent illustrates a "typical prior-art cam-and-post mechanism" as follows, with the cam highlighted in yellow and the post in blue:[4]

[4] Color emphasis is added throughout to ease comparisons. Such colors do not appear in the original documents. Emphasis within quotes herein has been added unless indicated otherwise.



(*Id*. at 2:2-4, 3:15-16, Figures 1A, 1B, and 3; Ex. 1003 at ¶ 34.) These figures depict a cross-section of the prosthesis when the leg is straight (Figure 1A) and bent (Figure 1B), as well as from the front (Figure 3). (Ex. 1001 at 2:2-4, 3:2-5, 3:15-16; Ex. 1003 at ¶ 34.) When the cam contacts the post, as in Figure 1B, the cam provides added stability to the knee. (Ex. 1003 at ¶ 34.)

The ’426 patent characterizes – and then distinguishes – this “prior-art cam-and-post mechanism” as using only a single cam to interface with the posterior (*i.e.*, back) of a tibial post. (Ex. 1001 at 2:2-4, 2:12-14, 2:34-37, 3:66-4:3; Ex. 1003 at ¶ 35.) The alleged “invention” is described as using multiple cams. (Ex. 1001 at 3:17-18; *see also, id.* at 2:30-33; Ex. 1003 at ¶ 35.) Indeed, the title of the ’426 patent is “*Multiple-Cam* Posterior-Stabilized Knee Prosthesis.”

The ’426 patent illustrates this multiple-cam design in Figures 2C and 2D (among others). (Ex. 1003 at ¶ 36.) The cams (or “points of cam action”)[5] are highlighted in yellow below:

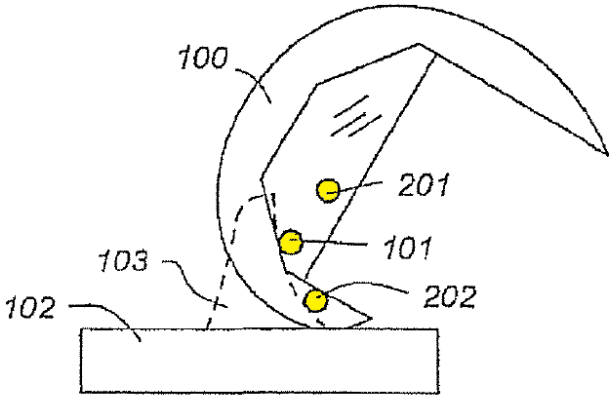


Fig - 2C

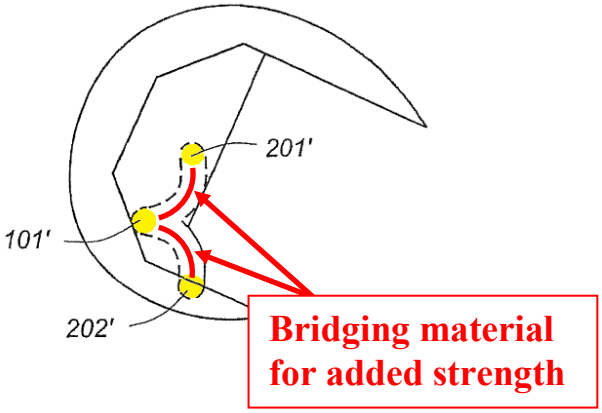


Fig – 2D

(*Id*.) The cams can be separate, but in Figure 2D, the convex cam-action surfaces are connected by concave bridging material. (*Id*.; Ex. 1001 at 3:46-48.)

C. Prosecution History of The ’426 Patent

The ’426 patent was issued without a substantive Office Action. The application was filed on November 28, 2000. (Ex. 1002 at 19-39.) The Examiner issued a Restriction Requirement on August 8, 2002, and Patent Owner filed a

[5] The ’426 patent uses the terms “cam” and “point of cam action” synonymously. (*See*, *e.g.*, Ex. 1001 at 2:45-47, “In the preferred embodiment, the component includes three distinct points of cam action. The first is preferably located substantially where existing cams are found . . . .”; Ex. 1003 at ¶ 36 n.3.)

corresponding Response on November 8, 2002. An interview was held on December 10, 2002, during which the Patent Owner and the Examiner appear to have discussed certain clarity objections the Examiner had to the pending claims. (*Id.* at 58-61; Ex. 1003 at ¶ 37.)

In response to the interview, Patent Owner amended the claims, and the Examiner issued a Notice of Allowance on December 16, 2002. (Ex. 1002 at 61, 63-65.) In the Notice of Allowance, the Examiner stated: "The plurality of cam members bridging the intercondylar region, which engage with the posterior aspect of the tibial post throughout a range of motion is not well known in the art and therefore would not have been an obvious modification to one of ordinary skill in the art." (*Id.* at 65.)

But the claim limitation corresponding to the Examiner's reasons for allowance only appears in claim 1 of the '426 patent:

> a plurality of members cam at least partially bridging the intercondylar region, the placement of the members being such that ***at all times one of the members engages with the posterior aspect of the tibial post through a range of motion from extension to flexion***.

No such limitation appears in claims 9 or 10. (Ex. 1003 at ¶¶ 38-39.)

D. The Challenged Claims in The '426 Patent

Claim 9 of the '426 patent recites:

> 9. 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 therebetween 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.

Claim 10 of the '426 patent recites:

> 10. The distal femoral component of claim 9, whereby the cam member of cam action is operative to minimize translation of the condylar protrusions relative to the bearing surface of the tibial component at the initiation of flexion.

The '426 patent admits that the first limitation of claim 9 (*i.e.*, the pair of medial and lateral condylar protrusions and an intercondylar region therebetween dimensioned to receive the tibial post) is not new. (Ex. 1003 at ¶ 41.) Specifically, the specification states that "FIG. 3 shows an anterior view of a ***prior-art*** cruciate substituting knee component at 300 having an open-type box 302 including a single transverse member 301 for illustrative purposes." (Ex. 1001 at 3:67-4:3.)[6]

[6] Patent Owner has further admitted in the co-pending litigation that Dennis discloses the preamble and first limitation of claim 9. (Ex. 1020 at 6.)

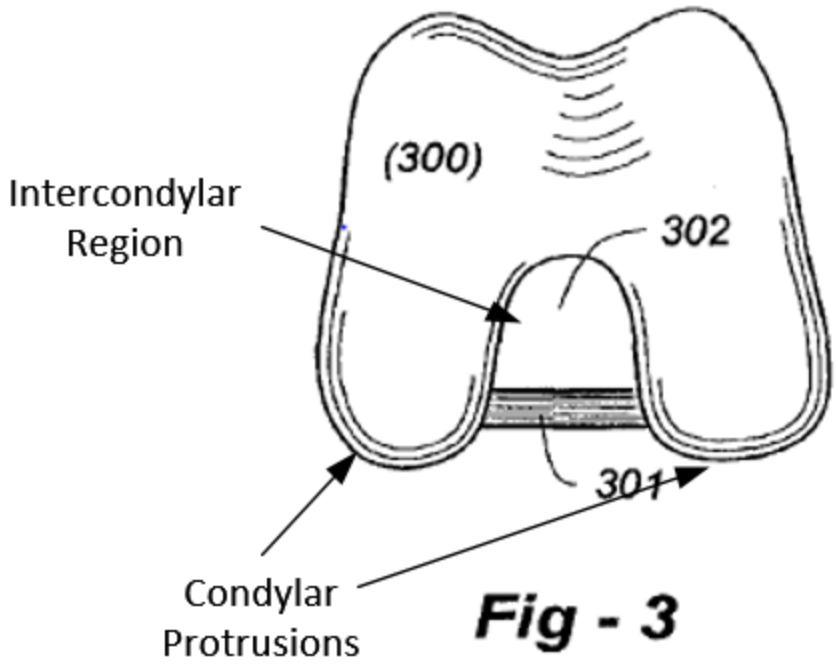


Fig - 3

(Ex. 1003 at ¶ 41.)

Thus, the only portion of claim 9 that could possibly impart patentability is the final limitation:

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

(Ex. 1003 at ¶ 42.) But that limitation is claimed so broadly that it reads on the prior art. (*Id*.) Neither claim 9, nor dependent claim 10, contains a limitation as to where cam contact is made during movement of the knee replacement – *i.e.*, the features that the Examiner found important to allowance of the '426 patent. (*Id*.) Under the Broadest Reasonable Interpretation (BRI) standard applied at the PTAB (37 C.F.R. 42.100(b)), neither of the limitations corresponding to the Examiner's reasons for allowance should be read into the claims from the specification/file history.

The Board should institute Inter Partes Review of claims 9 and 10.

IV. IDENTIFICATION OF CHALLENGES UNDER 37 C.F.R. 42.204(B)

A. 37 C.F.R. § 42.204(b)(1): Identification of Relief Requested

Petitioner requests the institution of an IPR for, and cancellation of, claims 9 and 10 of the '426 patent.

B. 37 C.F.R. § 42.204(b)(2): Identification of Prior Art and Specific Ground For Challenge of Claims

Petitioner requests an IPR trial and cancellation of claims 9 and 10 on the following ground: Anticipation of claims 9 and 10 based on Dennis, under 35 U.S.C. § 102.

Dennis is prior art to the '426 patent under 35 U.S.C. § 102(b) because it was published on June 10, 1999, which is more than one year prior to the '426 patent's earliest possible priority date of November 28, 2000. Dennis was not of record during prosecution of the '426 patent.

C. 37 C.F.R. § 42.204(b)(3): Claim Construction

Pursuant to 37 C.F.R. § 42.100(b), and solely for the purposes of this IPR, Petitioner submits that the claim terms should be given their broadest reasonable interpretation, as understood by one of ordinary skill in the art and consistent with the disclosure. Petitioner submits that only the following term requires construction in relation to the ground presented.

1. "Physically Separate and Discontinuous Points of Cam Action"

Petitioner submits that claim 9's recitation of "physically separate and discontinuous points of cam action" be construed as "physically separate and discontinuous points of cam engagement with the anterior or posterior aspect of the tibial post." Claim 9 does not recite where on the tibial post (*i.e.*, on the anterior or posterior side) the claimed "points of cam action" must engage. Nor does dependent claim 10. As such, claims 9 and 10 encompass prostheses where the "points of cam action" are on either the anterior or posterior aspect of the post, or both. (Ex. 1003 at ¶¶ 44.)

On November 22, 2017, in co-pending litigation, Patent Owner submitted Plaintiff's First Supplemental Responses And Objections to Defendants' First Set of Interrogatories To Plaintiff. (Ex. 1020.) In response to Interrogatory No. 9, which asked Patent Owner to "[p]rovide the factual and legal bases for MedIdea's contention that the Asserted Claims are valid and/or patentable in view of the prior art," Patent Owner stated that "[a]ll of the claims of the Asserted Patents [including claims 9 and 10 of the '426 patent] recite at least two distinct cam action surface areas that engage ***only the posterior surface*** of the tibial post." (*Id*., at 2.)

But, as detailed below, there is no basis for claims 9 or 10 of the '426 patent to be narrowly limited to require multiple cams that engage only the posterior surface

of the post, especially under the broadest reasonable interpretation standard. 37 C.F.R. § 42.100(b).

The Claim Language

Claim 9 recites more than one "physically separate and discontinuous points of cam action" as the knee moves from extension to flexion. This language does not limit where on the tibial post the points of cam action engage. (Ex. 1003 at ¶ 45.) Claim 10 is similarly silent as to where cam/post engagement occurs. (*Id*.) Where a claim is silent as to a limitation, "the claim, broadly, but reasonably" is construed "without restriction." *MotivePower*, *Inc. v. Cutsforth, Inc.*, IPR2013-00270, Paper 36 at 10 (PTAB, Oct. 30, 2014); *Owens Corning v. Fast Felt Corp.*, 873 F.3d 896, 901 (Fed. Cir. 2017) (reversing narrow construction, and explaining that even though the preferred embodiments focused on certain roofing materials, that was not enough to narrow the claim scope in an IPR because the claims were not "limited to 'roofing materials'").

Claims 9 and 10 are in stark contrast to claim 1 of the '426 patent. Claim 1 expressly requires that "at all times one of the members engages with the ***posterior aspect*** of the tibial post." (Ex. 1003 at ¶ 45.) Thus, the Patent Owner knew how to draft a claim in which multiple cam action occurs only with the posterior aspect of the tibial post.

Because claims 9 and 10, unlike claim 1, do not recite a limitation requiring multiple cam action with only the posterior aspect of the tibial post, the Board should reject Patent Owner's attempt to read such a limitation into those claims. 37 C.F.R. § 42.100(b).

The Specification

The '426 patent is directed to a "distal femoral knee-replacement component [that] provides additional points of cam action to facilitate a more normal rollback." (Ex. 1001 at Abstract.) The '426 patent describes preferred embodiments, one of which includes three distinct points of cam action that interact with the posterior of the tibial post (*e.g.*, the disclosure of FIGS. 2A-2C described at 3:29-46).

But the '426 patent is not limited to this "preferred embodiment." (Ex. 1001 at 2:45-46.) In fact, the '426 patent's disclosure is explicitly broader. The '426 patent states that more or fewer than three cams may be utilized, and that those cams may be positioned at a variety of different locations:

> as opposed to distinct structures themselves. It should also be noted that the cam structures may be located at different locations from the posterior to the anterior aspect of the knee design, as well as from the distal or proximal, depending upon implant size, patient physiology, desired range of motion, and other requirements. It should further be noted that as opposed to using three separate cams, one could use two cams intended to contact the posterior aspect of the post or for that matter, use more than three if desired.

(Ex. 1001 at 4:16-24; Ex. 1003 at ¶ 46.) Therefore, the broadest reasonable construction of the claims must likewise allow for "cam structures [that] may be located at different locations from the posterior to the anterior aspect of the knee design." *Corning*, 873 F.3d at 901 (narrow construction based on preferred embodiment was error because the claims were not so limited).

The File History

As noted above, the '426 patent was issued without a substantive Office Action. The Examiner held an interview on December 10, 2002, where the Patent Owner and the Examiner appear to have discussed certain clarity objections that the Examiner had with the pending claims. (Ex. 1002 at 61.) The Patent Owner accepted the Examiner's suggestions regarding the clarity objections, and the Examiner issued a Notice of Allowance on December 16, 2002. (*Id.* at 61, 63-65.) In the Notice of Allowance, the Examiner stated: "The plurality of cam members bridging the intercondylar region, which engage with the posterior aspect of the tibial post throughout a range of motion is not well known in the art and therefore would not have been an obvious modification to one of ordinary skill in the art." (*Id.* at 65.) This statement is a near verbatim recitation of the final limitation of claim 1:

> a plurality of members cam at least partially bridging the intercondylar region, the placement of the members being such that ***at all times one of the members engages with the posterior aspect of the tibial post through a range of motion from extension to flexion***.

No such limitation appears in claims 9 or 10. (Ex. 1003 at ¶ 47.)

The Examiner's recitation of the final limitation of claim 1 as the reason for allowance indicates that this claim language was critical to allowance. (*Id*.) The file history contains no arguments by the Patent Owner or statements by the Examiner that would indicate an understanding that those claim limitations, explicitly recited in claim 1, were somehow inherently, implicitly, or otherwise present in claims 9 or 10 of the '426 patent.[7] (*Id*.) Accordingly, the file history provides no basis for reading a "posterior aspect" limitation into the claims. (*Id*.)

The Proper Construction

In sum, based on the claim language, the specification, and the file history, the broadest reasonable construction of the claim term, "physically separate and discontinuous points of cam action," is "physically separate and discontinuous points of cam engagement with the anterior or posterior aspect of the tibial post." Ex. 1003 at ¶ 48.)

[7] The Examiner's reason for allowance, which is directed to the explicitly recited feature in claim 1, cannot be used to read the limitation into claims 9 and 10, where that limitation does not appear. *Salazar v. Procter & Gamble Co.*, 414 F.3d 1342, 1347 (Fed. Cir. 2005) ("An examiner's statement cannot amend a claim.").

D. 37 C.F.R. § 42.204(b)(4): How Claims 9 and 10 Are Unpatentable

Section VI below sets forth an explanation of how claims 9 and 10 of the '426 patent are unpatentable, including identification of where each claim limitation is found in the prior art.

E. 37 C.F.R. § 42.204(b)(5): Identification of Supporting Evidence

Per 37 C.F.R. § 42.6(d), copies of the references supporting the grounds for this Petition are filed herewith. Also filed herewith is the declaration of Dr. Darryl D'Lima under 37 C.F.R. § 1.68, in which he explains as of the earliest possible priority date, November 28, 2000, what the prior art, specification, and other intrinsic evidence for the '426 patent would have conveyed to a person of ordinary skill in the art ("POSITA"), and why claims 9 and 10 are anticipated.

V. STATE OF THE ART AND LEVEL OF SKILL IN THE ART AT THE TIME OF THE EARLIEST POSSIBLE PRIORITY DATE OF THE '426 PATENT

A POSITA with respect to the art of PS prostheses would have had knowledge of femoral and tibial bone implants, including tibial posts and cam mechanisms. (Ex. 1003 at ¶ 20.) Furthermore, a POSITA would typically have (1) had a Bachelor's Degree in Mechanical Engineering, Bioengineering, or another related field of science, as well as 3 to 7 years of related experience in the field of artificial knee implants; (2) had an advanced degree in Mechanical Engineering, Bioengineering, or another related field of science, as well as 2 to 5 years of related experience in the field of artificial knee implants; or (3) been a practicing orthopedic surgeon with at

least five years of experience, as well as some number of years of experience in the design of artificial knee implants. (*Id*.)

VI. THERE IS A REASONABLE LIKELIHOOD THAT AT LEAST ONE CLAIM OF THE '426 PATENT IS UNPATENTABLE

Patent Owner has admitted in interrogatory responses that Dennis discloses all the limitations of claim 9, except for the final limitation. (Ex. 1020 at 6.) As further described below, Dennis anticipates claims 9 and 10 of the '426 patent.

A. Dennis Anticipates Independent Claim 9 Of The '426 Patent

1. Independent Claim 9 – "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"

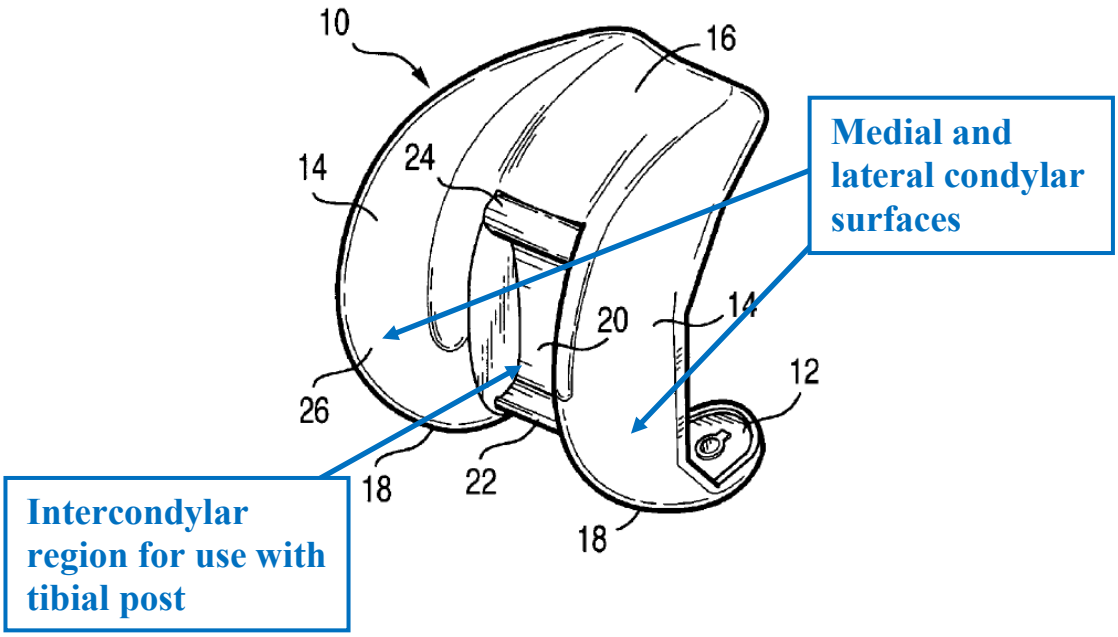
With respect to the preamble of claim 9, to the extent that it is construed as a limitation, Dennis discloses a distal femoral knee-replacement component configured for use with a tibial component having a bearing surface and superior tibial post with a posterior aspect. (Ex. 1006 at Abstract and 1:11-12; Ex. 1003 at ¶ 50.)

Patent Owner has admitted in interrogatory responses that Dennis discloses the preamble:

Claim 9 Elements		WO 99/27872 (Dennis)
9.1	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:	**Element 9.1 is disclosed by Dennis to the extent the preamble is a limitation.**

(Ex. 1020 at 6; Ex. 1003 at ¶ 51.)

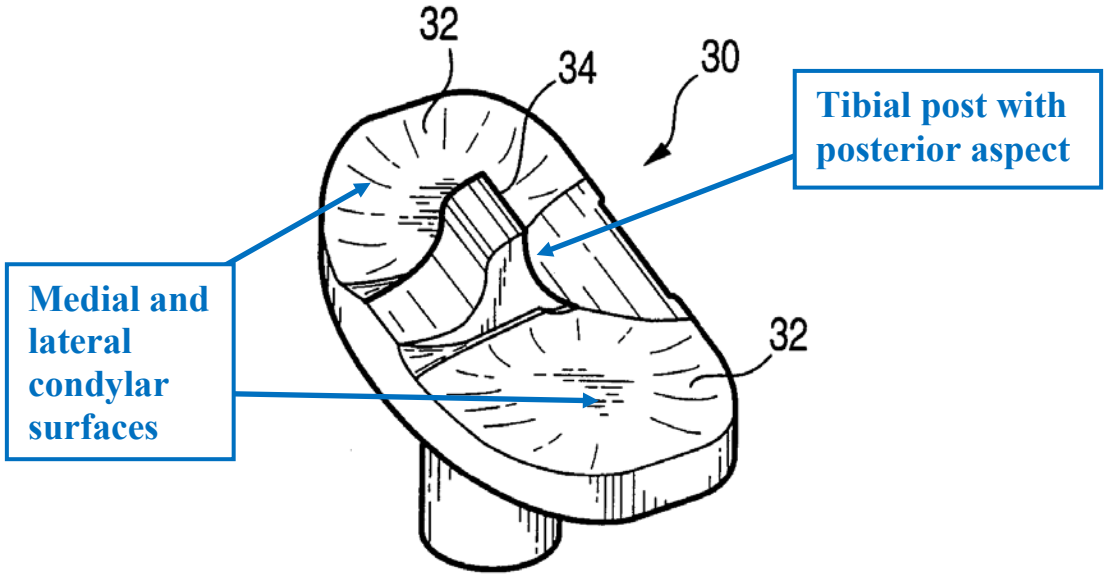
Specifically, Dennis discloses a distal femoral component having medial and lateral condylar bearing surfaces and an intercondylar region configured to receive a tibial post:



(Ex. 1006 at Fig. 1; Ex. 1003 at ¶ 53.)

"The tibial component of the prosthesis includes a bearing surface to receive the bearing surfaces of the condyles of the mating femoral component." (Ex. 1006 at 4:18-19.) Specifically, the "tibial component 30 [as shown in Figure 4] includes

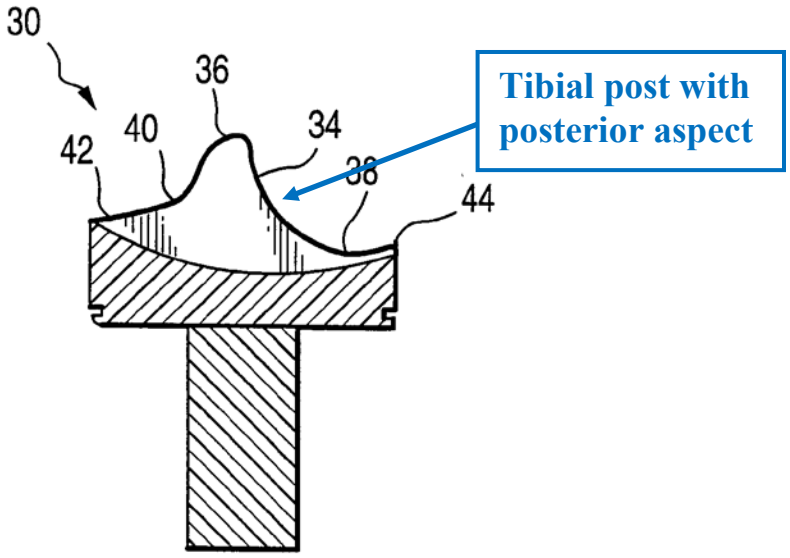
recessed surfaces 32 designed to receive the protruding condylar sections 14 of the femoral component." (*Id.* at 6:14-15; Ex. 1003 at ¶ 53.)



(Ex. 1006 at Fig. 4; Ex. 1003 at ¶ 53.)

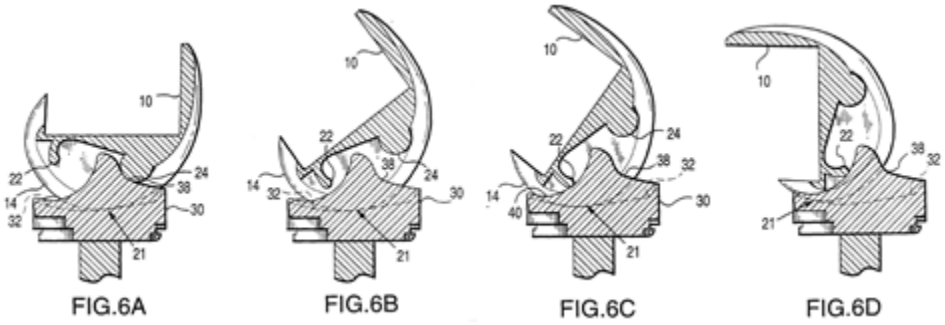
Dennis illustrates a superior (*i.e.*, toward the head) tibial post with a posterior aspect via spine 34. (Ex. 1003 at ¶ 54.) "[S]pine 34 rises from the tibial component 30 between recessed surfaces 32, and extends generally in the anterior-posterior direction as best shown in the sectional views of FIG. 5 taken along line 5-5 of FIG. 3 to show the lateral side of cam 34. Cam 34 includes lateral upper cam surface 36 dividing anterior trough [40] from posterior trough [38]. Posterior trough [38] is

defined at the posterior end by posterior bump [44]."[8] (Ex. 1006 at 6:15-19; Ex. 1003 at ¶ 54.)



Dennis discloses that the condylar surfaces articulate with the bearing surfaces of the tibial component over a range of motion from extension through flexion:

[8] In Figure 5 of Dennis, reference numbers 40 and 42 are erroneously swapped with corresponding reference numbers 38 and 44. (Ex. 1003 at ¶ 54 n.4.) (Figures 6A-6D properly show reference number 38 on the anterior side of the post.) The bracketed reference numbers in this paragraph correspond to the erroneous labeling in annotated Figure 5 below. (*Id.*)



(Ex. 1003 at ¶ 55.) Dennis states that "FIGS. 6A-6D are side cut-away views of the femoral and tibial components of the present invention articulating in approximately 0, 30, 60 and 90° of flexion, respectively." (Ex. 1006 at 5:5-7.)

Thus, Dennis discloses the preamble of claim 9. (Ex. 1003 at ¶ 55.)

2. Independent Claim 9 – "a body having a pair of medial and lateral condylar protrusions and an intercondylar region therebetween dimensioned to receive the tibial post"

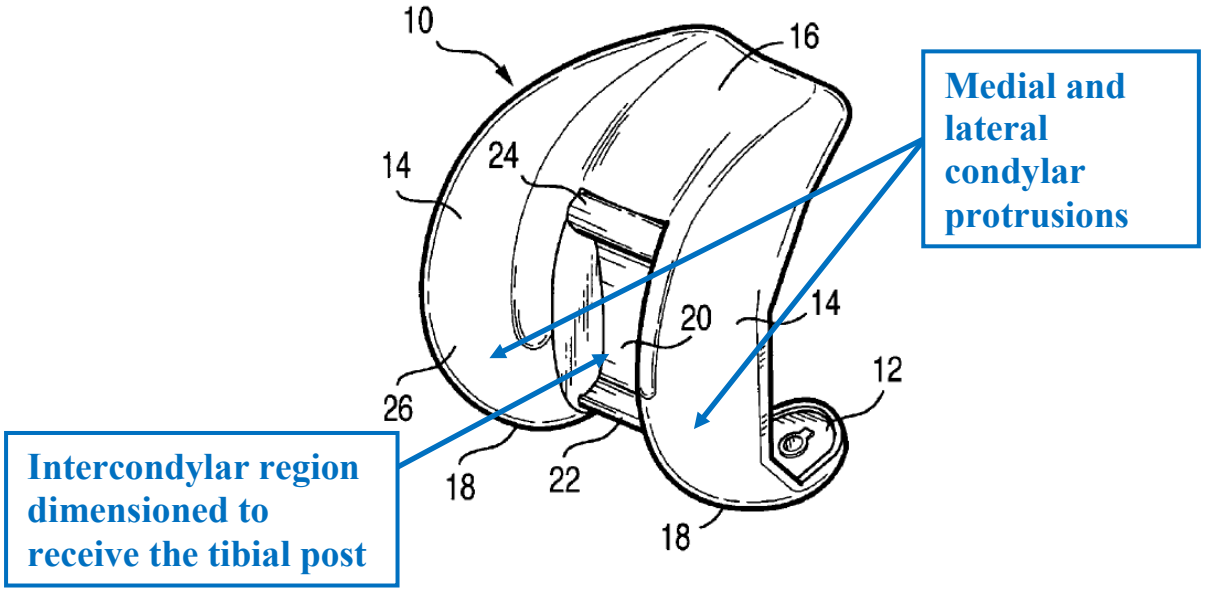
Dennis discloses a body having a pair of medial and lateral condylar protrusions and an intercondylar region therebetween dimensioned to receive the tibial post. (Ex. 1003 at ¶ 56.)

Patent Owner has admitted in interrogatory responses that Dennis discloses this limitation:

9.2	a body having a pair of medial and lateral condylar protrusions and an intercondylar region therebetween dimensioned to receive the tibial post; and	**Element 9.2 is disclosed by Dennis.**

(Ex. 1020 at 6.)

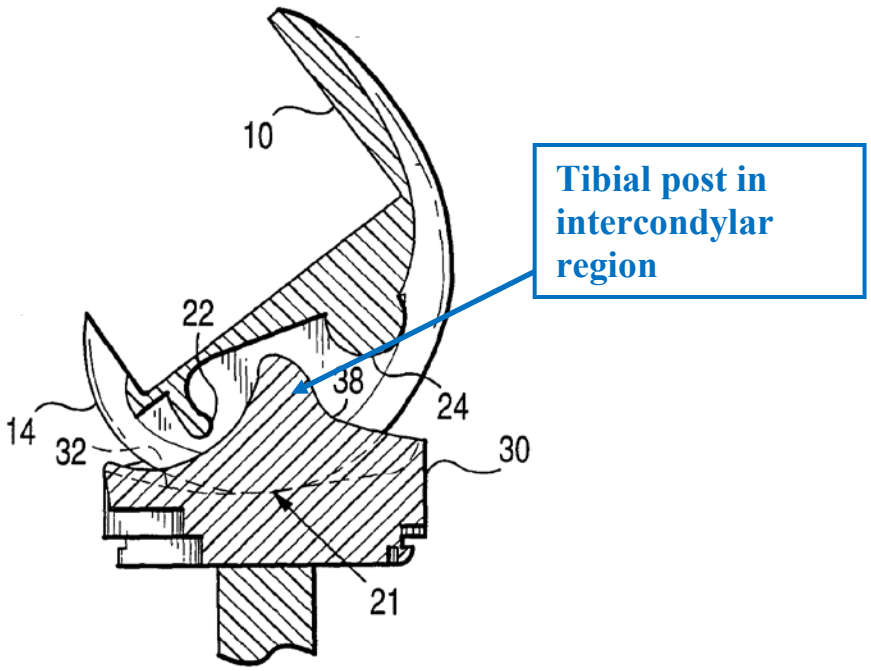
Specifically, Dennis discloses a distal femoral component having medial and lateral condylar bearing surfaces 14 and an intercondylar region 20 configured to receive a tibial post:



(Ex. 1006 at Fig. 1; Ex. 1003 at ¶ 56.) "The femoral component 10 includes two condylar protrusions 14 which run the length of each side of the component 10. The condylar sections 14 flatten and merge at one end of the femoral component 10 to create a patellar surface groove 16. The condylar sections 14 protrude more distinctly towards the other end of the femoral component 10, curving sharply at the end 18 to replicate the condyles normally found in the lower femur." (Ex. 1006 at 5:17-22.)

Dennis discloses an "intercondylar region" in the form of slot 20: "The femoral component 10 includes a slot 20 running down the middle of the component 10. The slot 20 forms out of the patellar surface 16 of the component 10 and deepens as it runs to the posterior end where the condylar sections 14 are most pronounced. Two cams [22, 24] are located across the slot 20 and between the condylar sections 14 of the femoral component 10." (*Id*. at 5:25-29.)

Dennis depicts the tibial post positioned within slot 20 between the two cams 22, 24 in FIGS. 6A-6D (Figure 6B shown as an example below):



(Ex. 1003 at ¶ 58.)

Thus, Dennis discloses the first limitation of claim 9. (*Id*.)

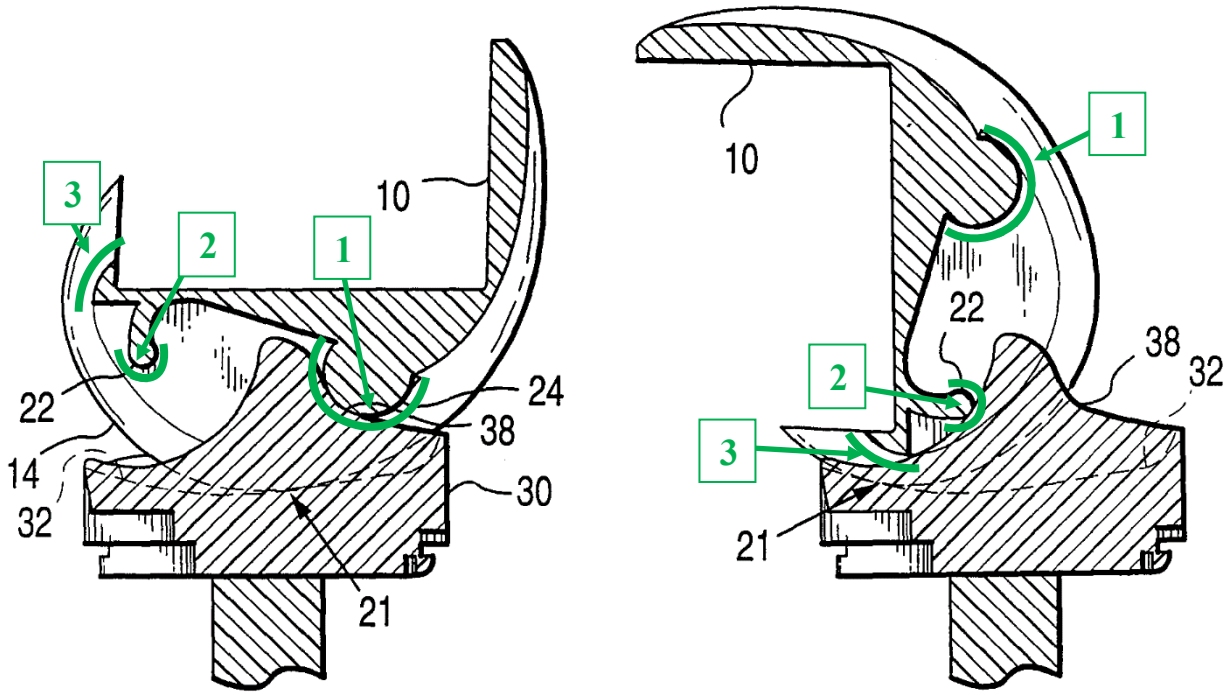
3. Independent Claim 9 – "a structure providing more than one physically separate and discontinuous points of cam action as the knee moves from extension to flexion"

Dennis discloses a structure providing more than one physically separate and discontinuous points of cam action as the knee moves from extension to flexion under Petitioner's proposed construction or under Patent Owner's expected (erroneous) construction. (Ex. 1003 at ¶ 60 n.5.)

Patent Owner argues in litigation that this claim element "is limited to a femoral cam structure that provides more than one physically separate and discontinuous points of cam action which are configured to only contact the posterior surface of the tibial post." (Ex. 1020 at 6.) But as discussed above, the broadest reasonable interpretation of claim 9 should not be limited to a cam that has multiple points of cam engagement only on the "posterior surface of the tibial post." Unlike claim 1, which states that "at all times one of the members engages with the posterior aspect of the tibial post," claim 9 omits that language.

Dennis discloses three points of cam action, which meet claim 9's "more than one physically separate and discontinuous points of cam action." (Ex. 1003 at ¶ 60.) One of those points of cam action is with the anterior surface of the tibial post, and two points of cam action are with the posterior surface. (*Id*. at ¶¶ 61-64.) Thus, Dennis discloses this claim limitation under the proper construction or Patent Owner's expected (erroneous) construction. (*Id*. at ¶ 65.) Those three cams that

separately and discontinuously interact with the tibial post are highlighted in annotated Figures 6A and 6D below.



(*Id*. at ¶ 60.) Figure 6A illustrates anterior cam 24 (labeled 1) contacting the anterior surface 38 of the tibial post at full extension of the knee. (*Id*.) Figure 6D illustrates posterior cam 22 (labeled 2) and a third cam (labeled 3) contacting the posterior surface 40 of the tibial post at 90º of flexion. (*Id*.)

Anterior cam 24 (labeled 1) contacts the anterior surface of the tibial post from 0º to about 20º of flexion such that cam 24 provides cam action "as the knee moves from extension to flexion." Dennis states: "At 0° flexion, that is, full extension (FIG. 6A), it can be seen that the femoral component 10 anterior cam 24 is fully engaged with the anterior trough 38 of the tibial component 30." (Ex. 1006, 6:27-29.) Dennis

specifically states that anterior cam 24 remains in contact with the tibial post from extension to "approximately 20º flexion." (Ex. 1006 at 7:5-7.) Anterior cam 24 is a point of cam action as recited in claim 9. (Ex. 1003 at ¶ 61.)

Regarding posterior cam 22 (labeled 2), Dennis states: "At 90° flexion (FIG. 6D), it can be seen that the point of contact between the femoral condyles 14 and the tibial recessed bearing surfaces 32 is approximately 8 mm posterior from a centerline of the tibial component 30. At that degree of flexion, the femoral component posterior cam 22 is still fully engaged with the tibial posterior trough 40." (Ex. 1006 at 7:16-20; Ex. 1003 at ¶ 62.) Patent Owner admits that posterior cam 22 discloses one of the recited points of cam action.

> Dennis discloses only two cams, an "anterior cam 24" and a "posterior cam 22," and only cam 22 is disclosed to contact the posterior aspect of the tibial post.

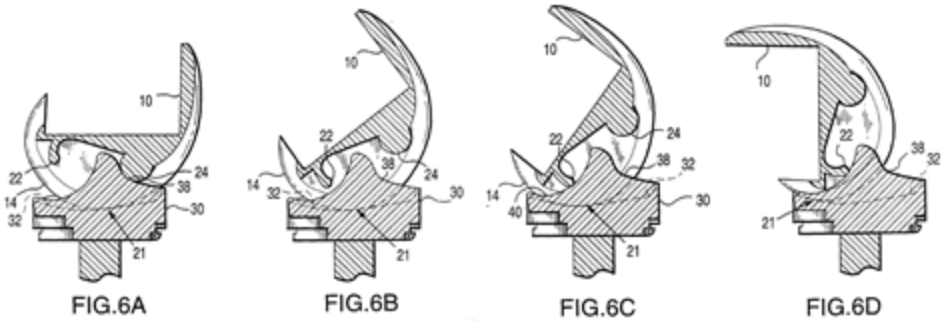
(Ex. 1020 at 6.)

The third cam (labeled 3) is shown contacting the tibial post at approximately 90 degrees of flexion, as illustrated in Figure 6D of Dennis.[9] (Ex. 1003 at ¶ 63.) The

[9] Dennis does not expressly refer to the structure labeled 3 as a "cam." However, given its location in the intercondylar region, the fact that it is disclosed as contacting the post at approximately 90 degrees of flexion, and the fact that

curved portion of this third cam continues to be engaged with the tibial post through the remainder of flexion (*e.g.*, through about 120 degrees of flexion). (*Id*.)

Dennis' Figure 6A-6D progression illustrates the claimed physically separate and discontinuous points of cam action.



Thus, Dennis discloses the second limitation of claim 9. (*Id*. at ¶ 65.)

B. Dennis Anticipates Dependent Claim 10 Of The '426 Patent

Claim 10 depends from claim 9, which is discussed above and which discussion is incorporated into the discussion of dependent claim 10 below.

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normal knee flexion will continue beyond 90 degrees to approximately 120 degrees, a POSITA would have understood that the structure labeled 3 is, in fact, a cam. (Ex. 1003 at ¶ 64.)

1. Dependent Claim 10 – "The distal femoral component of claim 9, whereby the cam member of cam action is operative to minimize translation of the condylar protrusions relative to the bearing surface of the tibial component at the initiation of flexion."

Dennis discloses that a cam member[10] of cam action is operative to minimize translation of the condylar protrusions relative to the bearing surface of the tibial component at the initiation of flexion. (Ex. 1006 at 6:27-29, 7:5-7, 7:25-26, Fig. 6A; Ex. 1003 at ¶ 66.)

Claim 10 does not require that translation be prevented, or quantify the amount of translation that is permitted by the cam in order to satisfy this limitation. (Ex. 1003 at ¶ 67.) Nor does the claim require that the translation be "minimized" in the anterior or posterior direction. (*Id*.) It simply requires a cam member that is operative to minimize *some* amount of translation at the initiation of flexion.[11] (*Id*.)

[10] Claim 10 recites this "cam member" limitation as "*the* cam member," even though there is no apparent antecedent basis for it. Nevertheless, to the extent there was proper antecedent basis support, Dennis discloses claim 10 for the reasons set forth herein.

[11] Patent Owner has not yet provided its contentions as to the validity of claim 10 because it asserted that claim against Petitioner for the first time just one week before the deadline for filing this Petition. Patent Owner has also not provided any

The purpose of a cam is to limit or restrict the amount of translation or sliding of the femoral component with respect to the tibial component. (*See supra* at Section III.A; Ex. 1003 at ¶¶ 31, 68.) Dennis discloses an anterior cam 24 that remains in contact with the tibial post from "0° flexion" to "approximately 20º flexion." (Ex. 1006, 6:27-29, 7:5-7, Fig. 6A.) And, Dennis discloses that the cam minimizes translation: "anterior cam 24 and posterior cam 22 act as steps to ***limit the extent of anterior-posterior movement***[.]" (*Id*. at 7:25-26; Ex. 1003 at ¶ 69.)

Thus, Dennis discloses the limitation in dependent claim 10. (Ex. 1003 at ¶ 69.)

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construction of the phrase "initiation of flexion." However, there is no need to construe this phrase because Dennis discloses it under any interpretation, based on its depiction and description of the anterior cam engaging the tibial post from "0° flexion" to "approximately 20º flexion." (Ex. 1006, 6:27-29, 7:5-7, Fig. 6A.)

VII. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8

A. 37 C.F.R. § 42.8(b)(1): Real-Party-In-Interest

DePuy Synthes Products, Inc. and DePuy Synthes Sales, Inc. are affiliates of Johnson & Johnson and are the Real Parties-In-Interest. Additionally, the Patent Owner asserts that DePuy Orthopaedics, Inc. is also a Real Party-In-Interest.

B. 37 C.F.R. § 42.8(b)(2): Related Matters

The '426 patent has been asserted against Petitioner in a litigation filed in the U.S. District Court for the Northern District of Illinois, styled as *MedIdea, L.L.C. v. DePuy Orthopaedics, Inc., et al.*, Civil Action No. 1:16-cv-10638, which was transferred to the U.S. District Court for the District of Massachusetts on June 8, 2017 and is now styled Civil Action No. 1:17-cv-11172. Petitioner is not aware of any other judicial or administrative proceeding or matter that would affect, or be affected by, a decision in this proceeding.

C. 37 C.F.R. § 42.8(b)(3): Lead and Back-Up Counsel, and 37 C.F.R. § 42.8(b)(4): Service Information

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Pursuant to 37 C.F.R. § 42.10(b), a Power of Attorney accompanies this Petition. Please direct all correspondence to lead counsel at the above address. Petitioner consents to email service at the addresses noted above.

VIII. CONCLUSION

Claims 9 and 10 of the '426 patent are unpatentable based on disclosure in Dennis. Petitioner has established a reasonable likelihood of prevailing on this ground, and prompt and favorable consideration of this Petition is respectfully requested.

RESPECTFULLY SUBMITTED,
Jones Day

Dated: December 15, 2017

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PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,558,426

CERTIFICATION OF SERVICE (37 C.F.R. §§ 42.6(e), 42.105(a))

The undersigned hereby certifies that the above-captioned "PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,558,426 UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.100 *et seq*.," including its supporting evidence (Exhibits 1001-1021), was served in its entirety on December 15, 2017, upon the following attorney of record via UPS overnight:

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TROY, MI 48084

Additionally, courtesy copies of the foregoing have been served via UPS overnight on the following:

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Dated: December 15, 2017

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PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,558,426

CERTIFICATE OF WORD COUNT UNDER 37 C.F.R. § 42.24(a)

I, the undersigned, do hereby certify that the attached Petition, including footnotes, contain 5787 words, as measured by the Word Count function of Word 2007. This is less than the limit of 14,000 words as specified by 37 C.F.R. § 42.24(a)(i).

Jones Day

Dated: December 15, 2017

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