

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEPUY SYNTHES PRODUCTS, INC.,
Petitioner,

v.

MEDIDEA, L.L.C.,
Patent Owner.

Case IPR2018-00315
Patent 6,558,426 B1

Before FRANCES L. IPPOLITO, MICHAEL L. WOODS, and
RICHARD H. MARSCHALL, *Administrative Patent Judges*.

WOODS, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

DePuy Synthes Products, Inc. (“Petitioner”) filed a Petition (Paper 1, “Pet.”) requesting *inter partes* review of claims 9 and 10 of U.S. Patent No. 6,558,426 B1 (“the ’426 patent”). Pet. 1. MedIdea, L.L.C. (“Patent Owner”) filed a Preliminary Response (Paper 6, “Prelim. Resp.”) to the Petition.

To institute an *inter partes* review, we must determine if the information presented in the Petition shows “a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). Upon consideration of the Petition and for the reasons set forth below, we conclude that the information presented in the Petition establishes a reasonable likelihood that Petitioner would prevail in challenging claims 9 and 10 of the ’426 patent. Accordingly, pursuant to 35 U.S.C. § 314, we hereby authorize an *inter partes* review to be instituted as to claims 9 and 10.

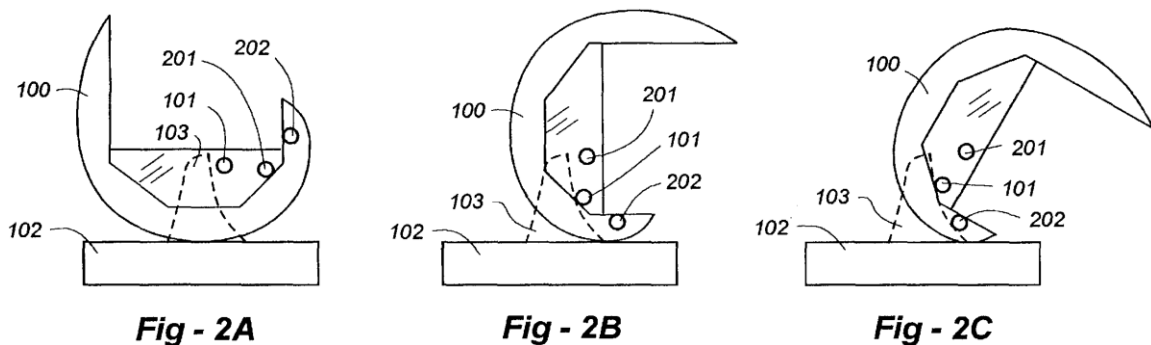
Our factual findings and conclusions at this stage of the proceeding are based on the record developed thus far. This is not a final decision as to patentability of claims for which *inter partes* review is instituted. Our final decision will be based on the full record developed during trial.

A. *Related Proceedings*

Petitioner represents that the ’426 patent has been asserted against it in *MedIdea, L.L.C. v. DePuy Orthopaedics, Inc., et al.*, Civil Action No. 1:17-cv-11172 (D. Mass.). Pet. 35.

B. The '426 patent (Ex. 1001)

The '426 patent is entitled “MULTIPLE-CAM, POSTERIOR-STABILIZED KNEE PROSTHESIS” and discloses a “distal femoral prosthesis having multiple distinct cams *contacting a post on its posterior surface* to a [sic] provide more normal range of motion for cruciate substituting knee replacement.” Ex. 1001, [54], 2:15–19 (emphasis added). During prosecution of the '426 patent, the applicant elected the species of Figures 2A–2C and stated that “at all times one of the [cam] members cooperates with the posterior aspect of the tibial post through a range of motion from extension to flexion.” Ex. 1002, 56. We reproduce copies of Figures 2A–2C, below:



According to the '426 patent, Figures 2A–2C illustrate a preferred embodiment of the invention in *extension*, *90° flexion*, and *120° flexion*, respectively. *Id.* at 3:6–11. In particular, these figures illustrate cams 101, 201, and 202 engaging tibial post 103 at from 0° flexion/extension (Fig. 2A), through 90° flexion (Fig. 2B), and through 120° flexion (Fig. 2C). *See id.* at 3:3:28–46; *see also id.* at 2:4–5 (identifying 102 as a tibial insert with post 103 (in relation to its discussion of Figure 1A)).

C. Illustrative Claims

Claims 9 and 10 are the challenged claims and are reproduced below, with emphasis added to a limitation discussed in this Decision:

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.*

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.

Ex. 1001, 5:6–19.

D. Alleged Ground of Unpatentability

Petitioner contends that claims 9 and 10 of the '426 patent are anticipated by PCT International Publication Number WO 99/27872, published June 10, 1999 (“Dennis”). Pet. 22. Petitioner also relies on the declaration testimony of Dr. Darryl D’Lima (Ex. 1003) in support of its Petition. *Id.* at 21.

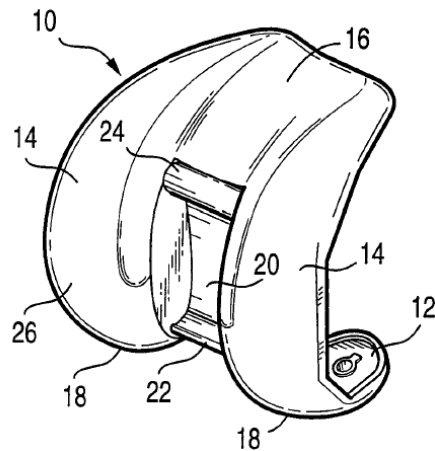
II. ANALYSIS

A. Claim Construction

Although Patent Owner and Petitioner proffer different interpretations of the claimed term, “physically separate and discontinuous points of cam action . . .,” we determine that neither this term nor any other term requires express construction for the purposes of this Decision. *Compare* Pet. 16–20, with Prelim. Resp. 28–46; *see Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) (“[C]laim terms need only be construed ‘to the extent necessary to resolve the controversy.’”) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

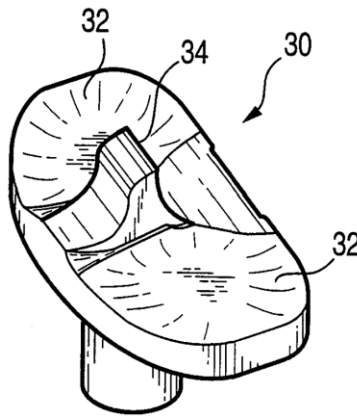
B. Dennis

Dennis discloses a knee prosthesis. Ex. 1006, 1:11–12. In particular, Dennis describes a femoral component with two cams and a tibial component for engaging the cams throughout knee flexion and extension. *See id.* at [57]. To illustrate Dennis’s femoral component, we reproduce Dennis’s Figure 1, below:

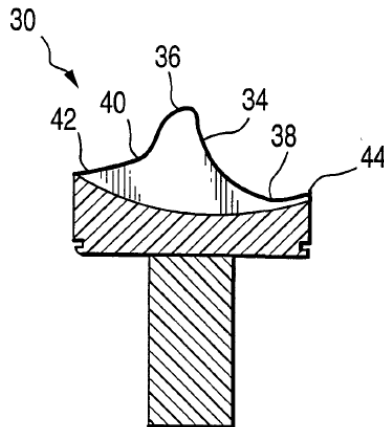


Dennis describes Figure 1 as depicting its femoral component 10. Ex. 1006, 5:10–12. Femoral component 10 includes slot 20 that runs down the middle of component 10. *Id.* at 5:25–26. Two cams (22, 24) are located across slot 20 and between condylar sections 14 of femoral component 10. *Id.* at 5:28–29. First cam 22 is located at the extreme posterior end and second cam 24 is located near the midpoint of femoral component 10 and towards the anterior end of the condylar sections. *See id.* at 5:29–3.

We also reproduce Figure 4 of Dennis, below:



Dennis describes Figure 4 as depicting tibial component 30 with spine/cam 34 rising between recessed surfaces 32. *See id.* at 6:8–17. Recess surfaces 32 are designed to receive protruding condylar sections 14 of femoral component 10. *Id.* at 6:13–14. To illustrate the lateral side of spine/cam 34, we reproduce Dennis's Figure 5, below:



Dennis describes Figure 5 as depicting lateral side of cam 34 (as taken along line 5-5 of Figure 3). *Id.* at 6:17. In particular, Figure 5 depicts spine/cam 34 as including lateral upper cam surface 36 dividing an anterior trough (misabeled as 38, rather than 40) from a posterior trough (misabeled as 40, rather than 38). *Id.* at 6:17–19; *compare id.* at Fig. 5, with *id.* at Figs. 6A–6D (depicting the correct reference numerals of Dennis’s anterior trough and posterior trough); *see also* Ex. 1003 ¶ 54, n.4 (testifying that the reference numerals in Figure 5 are erroneously swapped).

To illustrate the engagement between femoral component 10 and tibial component 30, we reproduce Dennis’s Figures 6A, 6B, 6C, and 6D, below:

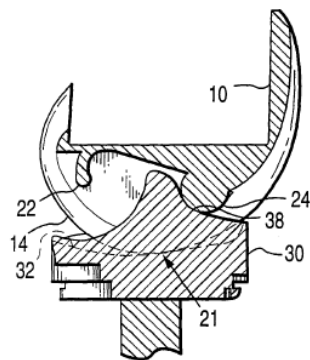


FIG. 6A

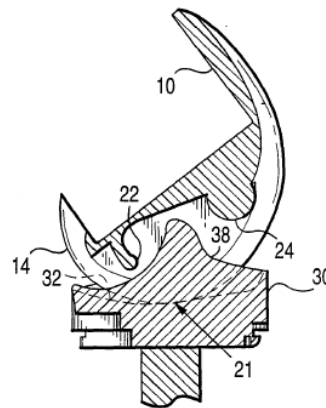


FIG. 6B

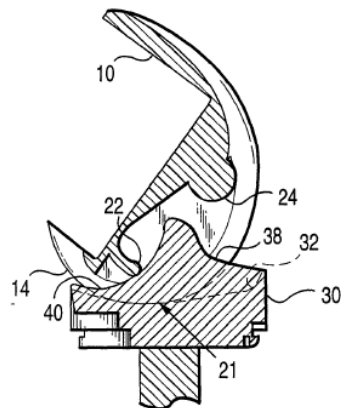


FIG. 6C

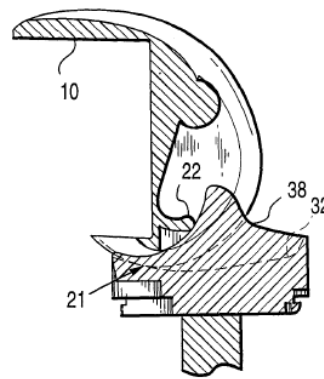


FIG. 6D

According to Dennis, Figures 6A, 6B, 6C, and 6D illustrate the interaction between femoral component 10 and tibial component 30 from full extension (0° flexion, Figure A), 30° flexion (Figure 6B), 60° flexion (Figure 6C), and full flexion (90° flexion, Figure 6D). *See* Pet. 6:21–29. Spine 34 of tibial component 30 engages posterior cam 22 and anterior cam 24 of femoral component 10 in a manner that produces sliding of femoral component 10 relative to tibial component 30 to emulate natural movement of a knee joint. *Id.* at 7:23–28. Figure 6A (0° flexion) depicts anterior cam 24 fully engaged with anterior trough 38 of tibial component 30. *Id.* at 6:2–29. Figure 6B

(30° flexion) depicts cams 24, 22 as not engaged with spine 34. *Id.* at 7:3–6. Figure 6C (60° flexion) depicts cam 22 as “impinged” upon tibial posterior trough 40. *Id.* at 7:9–11. Figure 6D (90° flexion) depicts cam 22 as fully engaged with tibial posterior trough 40. *Id.* at 7:16–20.

C. Claims 9 and 10 Anticipated by Dennis

Petitioner submits that claims 9 and 10 are unpatentable as anticipated by Dennis. Pet. 22. As claim 10 depends from independent claim 9, our analysis begins with claim 9. Ex. 1001, 5:6–19.

a. Independent Claim 9

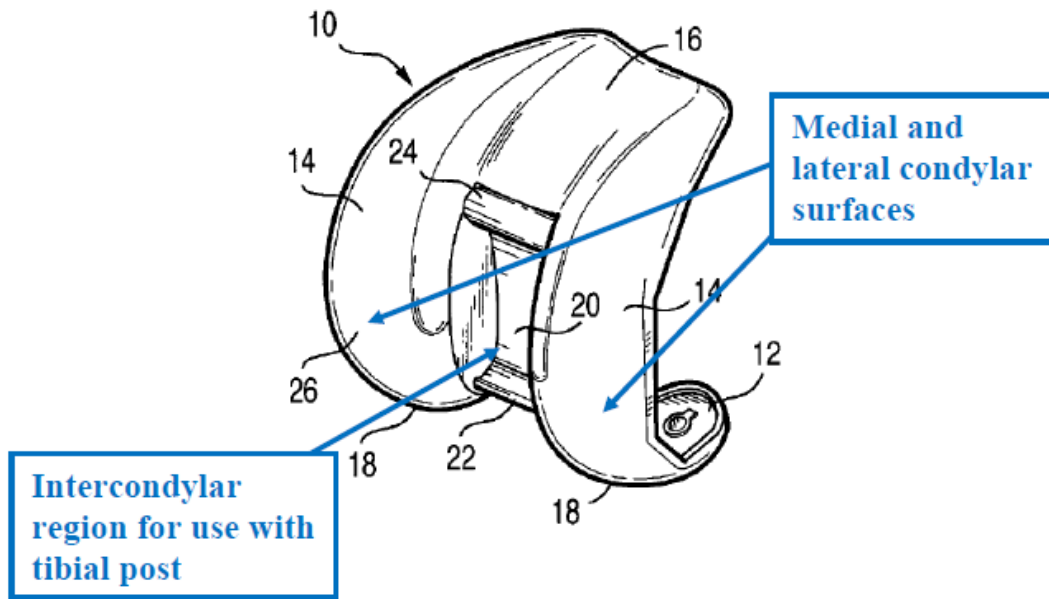
9. A distal femoral knee-replacement component configured for use with a tibial component having a bearing surface and superior tibial post with a posterior aspect, the distal femoral component comprising:

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

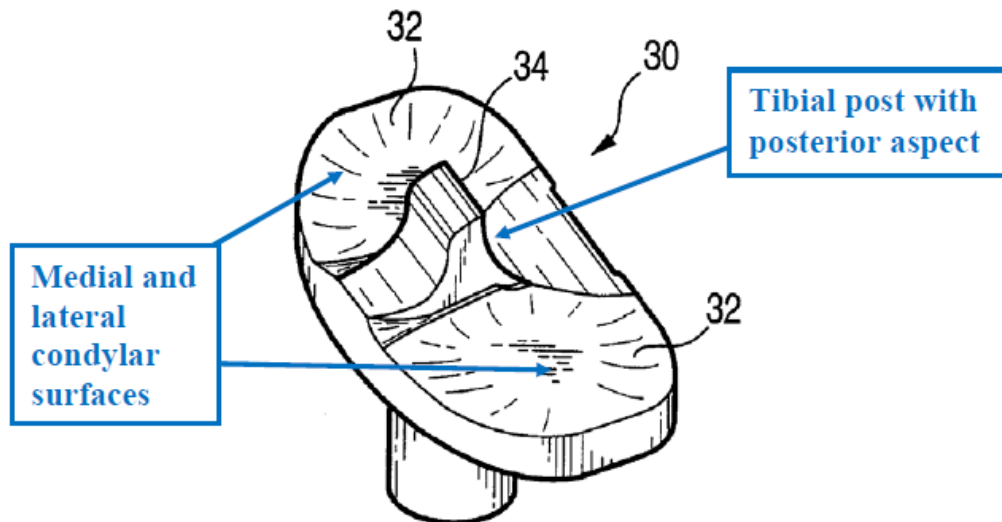
a structure providing more than one physically separate and discontinuous points of cam action as the knee moves from extension to flexion.

Ex. 1001, 5:6–15.

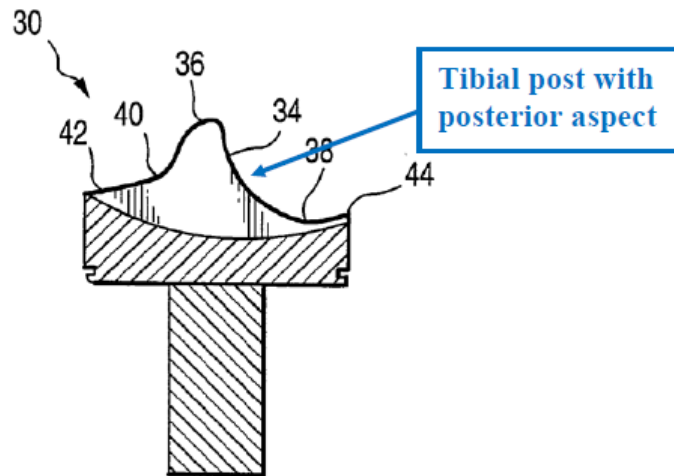
In addressing the claimed “distal femoral knee-replacement component configured for use with a tibial component,” as recited in the preamble, Petitioner submits an annotated version of Dennis’s Figure 1 (Pet. 23), which we reproduce, below:



According to Petitioner, and as shown above in the annotated Figure 1, Dennis's femoral component 10 has medial and lateral condylar bearing surfaces and an intercondylar region configured to receive Dennis's tibial post 30. Pet. 23–24 (citing Ex. 1003 ¶ 53). Petitioner also submits an annotated version of Dennis's Figure 4 to illustrate the tibial post (Pet. 24), which we also reproduce, below:



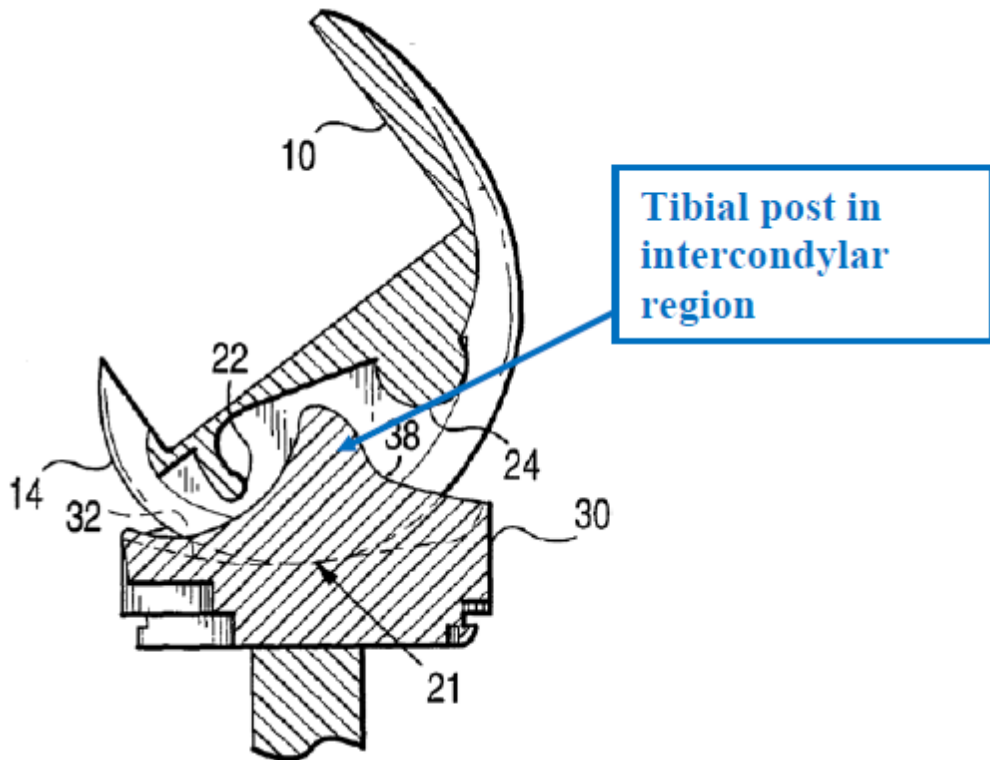
According to Petitioner, and as shown above in the annotated Figure 4, Dennis discloses tibial post 30 with recessed surfaces 32 designed to receive the protruding condylar sections 14 of femoral component 10. *See id.* at 23–24 (citing Ex. 1006, 4:18–19, 6:14–15). To further illustrate the posterior aspect of Dennis’s tibial post 30, Petitioner submits an annotated version of Dennis’s Figure 5 (Pet. 25), which we reproduce, below:



According to Petitioner, and as shown above in annotated Figure 5, tibial post includes anterior trough (misabeled as 40, should be 38) and posterior trough (misabeled as 38, should be 40), which is the posterior aspect of Dennis’s tibial post. *See* Pet. 24–25 (citing Ex. 1006, 6:15–19; Ex. 1003 ¶ 54); *see also id.* at 25, n.5 (“In Figure 5 of Dennis, reference numbers 40 and 42 are erroneously swapped with corresponding reference numbers 38 and 44”).

To address the claimed “body having a pair of medial and lateral condylar protrusions and an intercondylar region therebetween dimensioned to receive the tibial post,” Petitioner refers to the annotated version of Dennis’s Figure 1 (reproduced *supra* p. 10) as illustrating the claimed

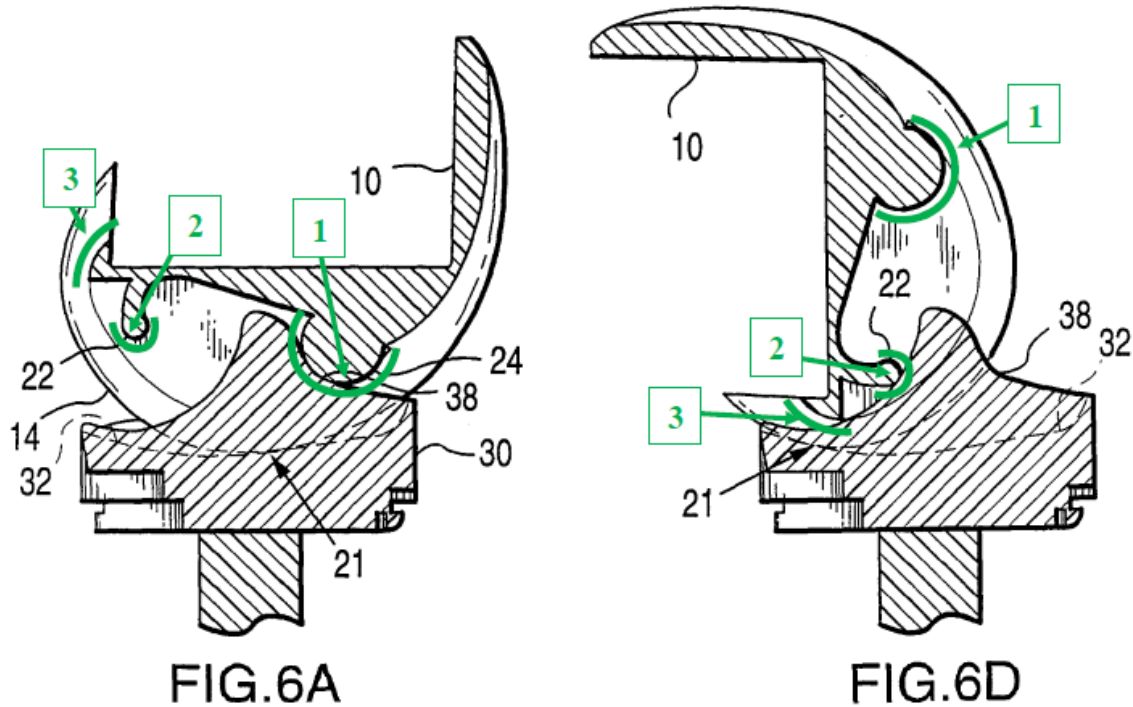
“medial and lateral condylar protrusions” and “intercondylar region dimensioned to receive a tibial post” (Pet. 27), and further submits an annotated version of Dennis’s Figure 6B (Pet. 28), which we reproduce below:



According to Petitioner, the above annotated Figure 6B depicts tibial post 30 positioned within the “intercondylar region” space between cams 22, 24, or slot. Pet. 28 (citing Ex. 1003 ¶ 58). Petitioner explains that cams 22, 24 are located across slot 20 (shown in Dennis’s Fig. 1) and between the condylar sections 14 of femoral component 10. *See id.* (citing Ex. 1006, 5:25–29).

To address the claimed “structure providing more than one physically separate and discontinuous points of cam action as the knee moves from

extension to flexion,” Petitioner submits annotated versions of Dennis’s Figures 6A and 6B (Pet. 30), which we reproduce, below:



According to Petitioner, the above annotated Figures 6A and 6B depict *three points of cam action*, which together satisfy the “more than one . . . points of cam action.” Pet. 29–30 (citing Ex. 1003 ¶¶ 61–65). In particular, and as identified by the annotated numbers “1,” “2,” and “3,” each of these three contacts are points of cam action, and “[o]ne 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 29 (citing Ex. 1003 ¶¶ 61–65) (emphasis added). In support of this assertion, Dr. D’Lima testifies that anterior cam 24, or cam “1,” contacts anterior trough 38, and each of cam “2” and cam “3” contacts posterior trough 40. Ex. 1003 ¶¶ 62, 63. Dr. D’Lima acknowledges that “Dennis does not expressly refer to the structure highlighted as No. 3 as a “cam,” but, nevertheless, testifies that “a

POSITA would have understood that the structure highlighted as No. 3 is, in fact, a cam.” *Id.* at ¶ 64.

Based in part on the foregoing findings, Petitioner argues that Dennis anticipates claim 9.

b. Dependent Claim 10

Claim 10 depends directly from claim 9 and further recites, “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.” Ex. 1001, 5:16–19.

To satisfy this claimed limitation, Petitioner relies on Dennis’s disclosure that anterior cam 24 remains in contact with tibial post 30 from 0° flexion to approximately 20° flexion and that “anterior cam 24 and posterior cam 22 act as steps to **limit the extent of anterior-posterior movement.**” Pet. 34 (citing Ex. 1006, 6:27–29, 7:5–7, 2–26, Fig. 6A; Ex. 1003 ¶ 69). Dr. D’Lima testifies in support of this finding. Ex. 1003 ¶ 69.

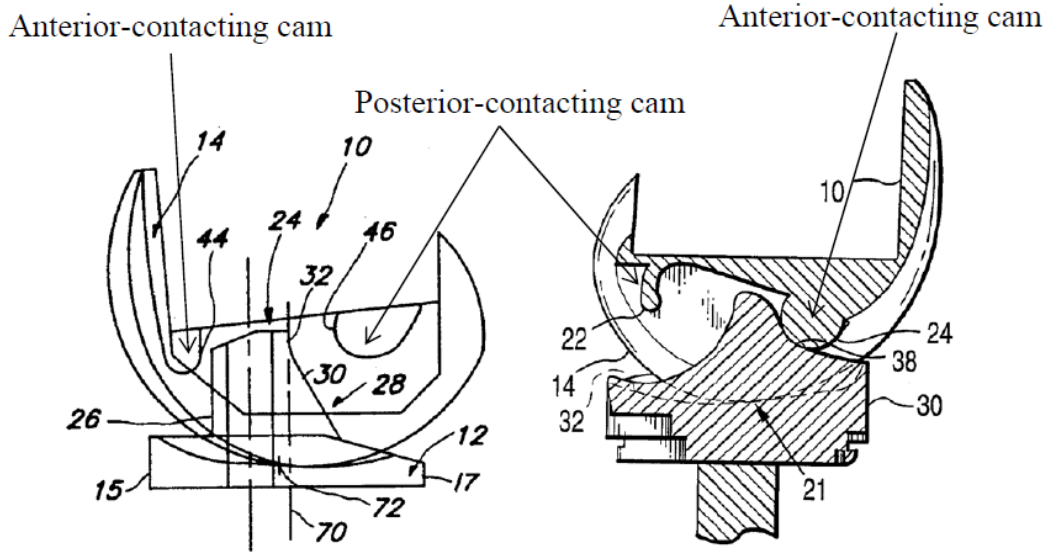
c. Analysis

Notwithstanding Patent Owner’s arguments, discussed below, we are persuaded at this stage of the proceeding that Petitioner is reasonably likely to show that Dennis’s femoral knee-replacement component anticipates claims 9 and 10.

i. 35 U.S.C. § 325 (d)

Patent Owner first argues that we should exercise our discretion under 35 U.S.C. § 325(d) to deny institution because the Petitioner relies on substantially the same prior art considered during prosecution. Prelim. Resp. 9; *see also* 35 U.S.C. § 314(a).

In particular, Patent Owner argues that the Examiner considered U.S. Patent No. 5,147,405 (“Van Zile,” Ex. 2001), which Patent Owner alleges is substantially similar to Dennis. *See id.* at 14–16. Patent Owner points out that Van Zile is identified in the *Background of the Invention* of the ’426 patent (Ex. 1001, 1:56–65) and that Van Zile discloses substantially the same cam structure disclosed in Dennis. *See* Prelim. Resp. 14–16. In support of its argument that Van Zile and Dennis are substantially similar, Patent Owner submits a side-by-side comparison of Van Zile’s Figure 6A and Dennis’s Figure 6A, both of which Patent Owner annotates (*id.* at 16), and both of which we reproduce, below:



Annotated Van Zile Fig. 6A

Annotated Dennis Fig. 6A

Van Zile – anterior surface cam 44 and posterior surface cam 46

Dennis – anterior surface cam 24 and posterior surface cam 22

According to Patent Owner, the above annotated Figures 6A of Dennis and Van Zile illustrate how both Van Zile and Dennis each discloses *one* anterior surface cam and *one* posterior surface cam. *See* Prelim. Resp. 15.

In addition to Van Zile, Patent Owner also submits annotated copies of figures from three other U.S. Patents (*id.* at 16 (referring to U.S. Patents to “Forte,” “Draganich,” and “Herrington”)) that likewise disclose knee prostheses structures with an anterior surface cam and a posterior surface cam. *See id.* at 16–18 (citations omitted).

Patent Owner argues that we should exercise our discretion and deny institution because—like Dennis—Van Zile, Forte, Draganich, and Herrington each discloses a single anterior cam and a single posterior cam. *See id.* at 19 (“[T]he structures of Van Zile, Forte, Draganich, and

Herrington are substantially the same as Dennis, as the structure of each of these references contain a single cam action surface[] that contacts the posterior surface of the tibial post and a single cam action surface that contacts the anterior surface of the tibial post.”); *see also id.* at 20–28.

Upon reviewing the record, we decline to exercise our discretion under 35 U.S.C. § 325(d). We are not persuaded that the same or substantially the same prior art or arguments were previously presented during prosecution.

First, during prosecution of the ’426 patent, the Examiner did not reject any of the pending claims based on any prior art, let alone Dennis, Van Zile, Forte, Draganich, or Herrington. *See, generally*, Ex. 1002. Second, Petitioner’s challenge relies on Dennis for disclosing *three* points of cam action, two of which contact the posterior surface of the tibial post. *See* Pet. 30. *Even if* the Examiner rejected the claims based on Van Zile, Forte, Draganich, or Herrington—which the Examiner did not—not one of these references discloses structure similar to that of Dennis, specifically, structure having three cams, with two cams that contact the posterior surface of a tibial post. *See* Prelim. Resp. 16–17 (identifying Van Zile, Forte, Draganich, and Herrington as only having two cams: one posterior surface cam and one anterior surface cam).

For the foregoing reasons, we decline to exercise our discretion to deny institution.

ii. *Claim Construction*

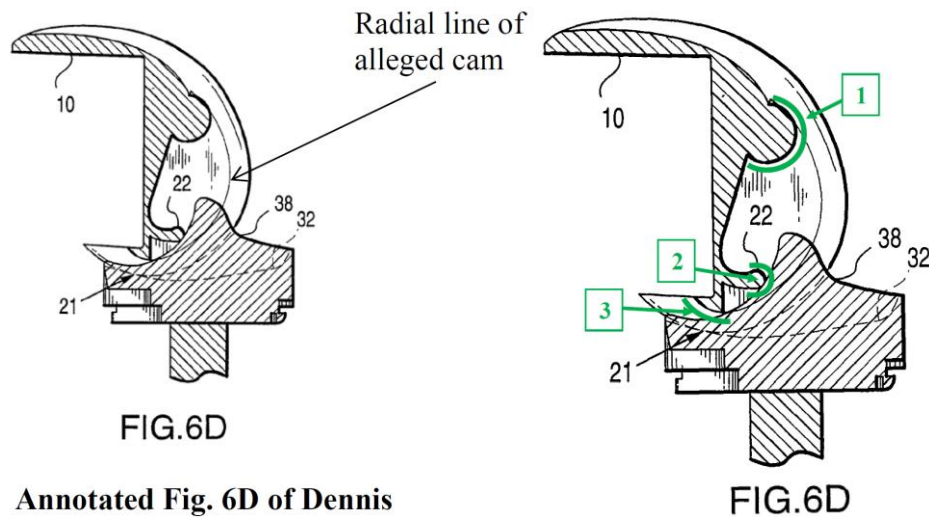
Second, Patent Owner argues that the Petition fails to properly construe the claims, which proper construction “requires two points, i.e., more than one, of cam action engaging the posterior surface of the tibial post as the knee moves from extension to flexion.” Prelim. Resp. 28. Patent Owner points out that in “concurrent litigation involving the ’426 patent,” Petitioner agreed with this particular construction. *See id.* (citing Ex. 2006, 3).

As discussed above (*see supra* Part II.A), at this stage of the proceeding, we determine that the disputed term does not require express construction for the purposes of this Decision. *See Wellman*, 642 F.3d at 1361. At this stage of the proceeding, we find that Dennis anticipates the claims *regardless* of whether Patent Owner’s or Petitioner’s interpretation is correct, as Petitioner has persuaded us that Dennis discloses three points of cam action, with two points of cam action that contact the posterior surface of its tibial post. *See infra* Part II.C.c.iii.; *see also* Pet. 29 (“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 . . . construction*”) (emphasis added); *see also* Ex. 1003 at ¶ 60, n.5 (“even using Patent Owner’s erroneous construction requiring two posterior cams, Dennis discloses this limitation based on the two posterior cams labeled 2 and 3 [in Dennis’s annotated Figures 6A, 6D, reproduced above]”). Our determination of this and other issues is not final, and the Patent Owner is free to brief this issue further in its Patent Owner Response.

iii. *Dennis does not disclose “more than one . . . points of cam action”*

In presenting its third argument, Patent Owner asserts that Dennis only discloses two points of cam action; a single posterior cam 22 that engages the tibial posterior surface, and a single anterior cam 24 that engages the tibial anterior surface. *See* Prelim. Resp. 46 (citing Ex. 1006, Figs. 6A–6D). In particular, Patent Owner disagrees with Petitioner’s assertion that Dennis discloses two cam action points that contact the posterior surface of the tibial post. *See id.* at 48 (“Dennis fails to disclose more than one cam action points that contact the posterior surface of the tibial post.”); *see also id.* at 54 (“Dennis discloses only two points of cam action, only one of which contacts the posterior surface.”).

In support of its argument, Patent Owner submits an annotated version of Dennis’s Figure 6D (Prelim. Resp. 51), which we reproduce below-left, alongside Petitioner’s annotated version below-right (Pet. 30), of the same figure:



According to Patent Owner, and “as evidenced by the accompanying radial line” in the above-left Figure 6D, the alleged third cam (denoted by Petitioner as cam “3” in the above-right figure) “is nothing more than a cross section of a portion of the condylar that straddles the post, and never engages the post.” *See* Prelim. Resp. 51. Patent Owner argues that “it does not make sense that a cam intended to contact the tibial post would have a sharp edge that would dig into the post” as a “sharp-edged ‘cam’ would not slide or, if it did, it would damage the post.” *Id.* (citing Ex. 1006, 7:20–22).

At this stage of the proceeding, we note that Dr. D’Lima’s uncontroverted testimony indicates that Dennis discloses three cams, with two cams that contact the posterior surface of its tibial post. Ex. 1003 ¶¶ 60–65. In particular, we find persuasive, on the current record, Dr. D’Lima’s testimony that “the cam highlighted as No. 3 . . . first contacts the tibial post at approximately 90 degrees of flexion, as illustrated in Figure 6D of Dennis” and that the “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.* at ¶ 63. Dr. D’Lima acknowledged that “Dennis does not expressly refer to the structure highlighted as No. 3 as a ‘cam,’” but nonetheless explained that “a POSITA would have understood that the structure highlighted as No. 3 is in fact, a cam.” *Id.* at ¶ 64.

Patent Owner cites to Dennis’s disclosure that at 90° flexion “posterior cam 22 is still fully engaged with the tibial posterior trough 40” and argues that “[f]rom this disclosure, one of ordinary skill in the art would understand that the structure . . . would not be expected to move past the point of full engagement of cam 22, i.e., 90° flexion.” Prelim. Resp. 49–50

(citing Ex. 1006, 7:19–20). However, Patent Owner’s argument is not supported by testimonial evidence from one of ordinary skill in the art. *See id.* Further, the cited portion of Dennis simply states that posterior cam 22 is fully engaged with posterior trough 40 at 90°, and we are not persuaded that this disclosure describes a limit to Dennis’s knee prosthesis flexion to be 90°, as Patent Owner argues. *See id.*; *see also* Ex. 1006, 7:19–20 (“At [90°] of flexion, the femoral component posterior cam 22 is still fully engaged with the tibial posterior trough 40.”). Rather, at this stage, we find this particular disclosure as stating that posterior cam 22 is fully engaged at 90°, not that it has reached an upper limit of flexion. *See* Ex. 1006, 7:19–20. Moreover, at this juncture, we are persuaded that Dr. D’Lima’s testimony that Dennis’s third cam continues to be engaged with the tibial post through the remainder of flexion at about 120° of flexion is supported by the current record. *See* Ex. 1003 ¶ 63.

For the foregoing reasons, at this stage of the proceeding, Patent Owner’s argument that Dennis only discloses one point of cam action that contacts the posterior surface of the tibial post is unavailing. *See* Prelim. Resp. 54.

III. CONCLUSION

Upon review of Petitioner’s analysis and supporting evidence, we conclude that Petitioner has demonstrated a reasonable likelihood that it will prevail with regards to its challenge of claims 9 and 10 as anticipated by Dennis. At this stage of the proceeding, although we exercise our discretion

and institute review, we remind the parties that we have not yet made a final determination as to the patentability of any challenged claims.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 9 and 10 of the '426 patent is instituted with respect to all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), *inter partes* review of the '426 patent shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

IPR2018-00315
Patent 6,558,426 B1

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