

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AURIS HEALTH, INC.,
Petitioner,

v.

INTUITIVE SURGICAL OPERATIONS, INC.,
Patent Owner.

IPR2019-01189
Patent 6,800,056 B2

Before ULRIKE W. JENKS, TINA E. HULSE, and JAMES A. WORTH,
Administrative Patent Judges.

HULSE, *Administrative Patent Judge.*

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314, 37 C.F.R. § 42.4

I. INTRODUCTION

Auris Health, Inc. (“Petitioner”) filed a Petition requesting an *inter partes* review of claims 1, 3–8, 11, 12, 14, 16, 17, 22–26, and 32 of U.S. Patent No. 6,800,056 B2 (Ex. 1001, “the ’056 patent”). Paper 1 (“Pet.”). Intuitive Surgical Operations, Inc. (“Patent Owner”) filed a Preliminary Response. Paper 6 (“Prelim. Resp.”).

We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted “unless . . . there is 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 considering the argument and evidence presented in the Petition, we determine that it is appropriate to exercise our discretion to deny institution under 35 U.S.C. § 325(d). Accordingly, we decline to institute an *inter partes* review of any challenged claim of the ’056 patent.

A. *Real Parties-in-Interest*

Petitioner identifies itself, Ethicon, Inc., and Johnson & Johnson as real parties-in-interest to this proceeding. Pet. 1. Patent Owner identifies itself and Intuitive Surgical, Inc. as real parties-in-interest. Paper 4, 1.

B. *Related Proceedings*

Petitioner identifies a list of issued patents and pending applications that are related to the ’056 patent. Pet. 1. The parties also state the ’056 patent has been asserted in the copending district court proceeding, *Intuitive Surgical, Inc. v. Auris Health, Inc.*, No. 18-cv-01359 (MN) (D. Del.). Pet. 2; Paper 4, 1.

C. The '056 Patent

The '056 patent, entitled “Endoscope with Guiding Apparatus,” relates to a method and apparatus to facilitate insertion of a flexible endoscope along a tortuous path, as in colonoscopy. Ex. 1001, 1:15–17. According to the '056 patent, because the path of the colon is tortuous, considerable manipulation is required to advance the colonoscope through the colon. *Id.* at 1:39–40. As the colonoscope is inserted further into the colon, it becomes more difficult to maintain the curve of the colonoscope because the colonoscope rubs against the mucosal surface of the colon along the outside of each turn. *Id.* at 1:45–49. Accordingly, the '056 patent describes “an improved endoscopic apparatus . . . for examination of a patient’s colon or other internal bodily cavities with minimal impingement upon bodily cavities or upon the walls of the organs.” *Id.* at 1:66–2:2.

D. Illustrative Claim

Petitioner challenges claims 1, 3–8, 11, 12, 14, 16, 17, 22–26, and 32 of the '056 patent. Claims 1 and 14, the only independent claims of the '056 patent, are illustrative and are reproduced below:

1. A method of advancing an instrument along an arbitrary path, comprising:

selectively steering a distal portion of the instrument to assume a selected shape along an arbitrary path;

advancing an elongate guide along the instrument such that a portion of the guide conforms to and assumes the selected shape; and

maintaining a position of the guide while advancing the instrument along the guide such that a proximal portion of the instrument assumes the selected shape defined by the guide, wherein the elongate guide is freely slidable along the length of the instrument such that advancing of the instrument along the guide is unconstrained.

14. An apparatus for insertion into a body cavity, comprising:

an elongate body having a proximal portion and a selectively steerable distal portion and defining a lumen therebetween, the steerable distal portion being configurable to assume a selected shape along an arbitrary path;

an elongate guide having a proximal section, a distal section, and a length therebetween, the guide being slidably disposed without constraint within the lumen along the length for selectively supporting the body, wherein the guide is configured to conform to and selectively maintain the selected shape assumed by the steerable distal portion; and

wherein the proximal portion of the elongate body when advanced distally is configured to conform to the selected curve maintained by the guide.

Ex. 1001, 17:29–41, 18:16–32.

E. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1, 3–8, 11, 12, 14, 16, 17, 22–26, and 32 of the '056 patent on the following grounds:

Claims Challenged	Basis	References
1, 5–8, 11, 12, 14, 16, 17, 22–26, 32	§ 103	Sturges, ¹ Zehel ²
3, 4	§ 103	Sturges, Sturges II ³

Petitioner also relies on the Declaration of Blake Hannaford.
Ex. 1003.

II. ANALYSIS

A. Person of Ordinary Skill in the Art

Petitioner asserts that a person of ordinary skill in the art at the time of the invention would have had an undergraduate education in electrical engineering, mechanical engineering, robotics, biomedical engineering, or a related field of study, and about two years of experience studying or developing robotics or medical devices such as surgical systems or endoscopes. Pet. 16 (citing Ex. 1003 ¶ 30). Patent Owner does not offer a proposed definition of the level of ordinary skill in the art in the Preliminary Response. *See generally* Prelim. Resp.

¹ R.H. Sturges, Jr. and S. Laowattana, *A Flexible Tendon-Controlled Device for Endoscopy*, 12 INT’L J. ROBOTICS RESEARCH 121–31 (1993) (“Sturges,” Ex. 1004).

² Zehel et al., US 5,251,611, issued Oct. 12, 1993 (“Zehel,” Ex. 1005).

³ R.H. Sturges, Jr. and S. Laowattana, *A Voice-Actuated Tendon-Controlled Device for Endoscopy*, COMPUTER-INTEGRATED SURGERY, TECHNOLOGY AND CLINICAL APPLICATIONS (“Sturges II,” Ex. 1006).

On this record, and absent opposition from Patent Owner, we adopt Petitioner’s definition of the level of ordinary skill in the art because it is consistent with the level of skill reflected in the asserted prior art references. Accordingly, the prior art itself is sufficient to demonstrate the level of skill in the art at the time of the invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required “where the prior art itself reflects an appropriate level and a need for testimony is not shown”) (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985)).

B. Claim Construction

Where, as here, a petition is filed after November 13, 2018, the Board applies the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b). 37 C.F.R. § 100(b) (2019); *see* Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340 (Oct. 11, 2018).

Under that standard, claim terms “are generally given their ordinary and customary meaning” as understood by a person of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). “In determining the meaning of the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence.” *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006) (citing *Phillips*, 415 F.3d at 1312–17). Extrinsic evidence is “less significant than the

intrinsic record in determining ‘the legally operative meaning of claim language.’” *Phillips*, 415 F.3d at 1317.

The Board will consider any prior claim construction determination in a civil action or proceeding before the International Trade Commission that is timely made of record in the *inter partes* review proceeding. 37 C.F.R. § 42.100(b). The Board will also consider statements regarding claim construction made by Patent Owner and Petitioner in other proceedings, if the statements are timely made of record. Trial Practice Guide July 2019 Update, 17.

Petitioner asserts the terms “freely slidable along the length of the instrument” in claim 1 (i.e., the “freely slidable” term) and “guide being slidably disposed without constraint within the lumen along the length” in independent claim 14 (i.e., the “slidably disposed” term) should be construed to mean that “the elongate guide is freely slidable and is capable of unconstrained movement along the entire length of the instrument.” Pet. 17–18. Patent Owner disagrees with Petitioner’s construction, stating it conflicts with the language of the claims and overlooks the differences between claim 1 and claim 14. Prelim. Resp. 7–8. Patent Owner, however, does not offer its own construction in this proceeding. *See id.*

On November 20, 2019, after the parties filed the Petition and Preliminary Response, the district court in the copending district court case, *Intuitive Surgical, Inc. v. Auris Health, Inc.*, No. 18-1359 (MN) (D. Del.), held a Markman Hearing and ruled on certain claim terms of the ’056 patent at the end of the hearing. With our authorization, Petitioner submitted the transcript as an exhibit in this proceeding. Ex. 1012. We also authorized the parties to file supplemental papers to explain the relevance of the district

court's construction in this proceeding. *See* Paper 11 (“Pet. Supp. Br.”); Paper 13 (“PO Supp. Br.”).

In the Markman Hearing, Petitioner asserted the same definition it asserts here for both claim terms—that is, that the “elongate guide is freely slidable and is capable of unconstrained movement along the entire length of the instrument.” Ex. 1012, 132:24–133:2. Patent Owner asserted that no construction is needed or, if construed, that the two terms should be construed differently. *Id.* at 132:14–17. Specifically, Patent Owner asserted that the “freely slidable” term should mean “the elongate guide is freely slidable along the length of the instrument, and the instrument can be advanced without constraint along the guide” and the “slidably disposed” term should mean “the guide can slide without constraint within the lumen along the length of the guide and can selectively support the body of the lumen.” *Id.* at 132:17–23.

The district court determined that no construction is necessary for either term. *Id.* at 133:3–4. According to the court, “[t]he claim language is clear and does not require more.” *Id.* at 133:4–5. Moreover, the court held that there was no prosecution history disclaimer, because the court did not find the allegedly limiting statements in the prosecution history to be clear and unambiguous. *Id.* at 133:5–8. For example, the court noted that the examiner used the phrase “entire length” in the reasons for allowance, but did not include the word “entire” in the amendment to the claims. *Id.* at 133:18–21. Accordingly, it rejected Petitioner's construction that the claims should be limited to require sliding along the “entire length” of the instrument.

Having considered the parties' respective arguments and the district court's construction, we determine that it is unnecessary to expressly

construe any claim terms for purposes of rendering this Decision. *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)).

C. Whether to Exercise our Discretion Under 35 U.S.C. § 325(d)

Institution of *inter partes* review is discretionary. *See Harmonic Inc. v. Avid Tech, Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) (explaining “the PTO is permitted, but never compelled, to institute an IPR proceeding”). For instance, § 325(d) states “[i]n determining whether to institute or order a proceeding under this chapter . . . [t]he Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.”

In evaluating whether the same or substantially the same prior art or arguments were previously presented to the Office under § 325(d), the Board has considered a number of non-exclusive factors, including, for example:

- (a) the similarities and material differences between the asserted art and the prior art involved during examination;
- (b) the cumulative nature of the asserted art and the prior art evaluated during examination;
- (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;
- (d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguished the prior art;

- (e) whether Petitioner has pointed out sufficiently how the Examiner erred in its consideration of the asserted prior art; and
- (f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the asserted prior art or arguments.

Becton, Dickinson & Co. v. B. Braun Melsungen AG, IPR2017-01586, Paper 8 at 17–18 (PTAB Dec. 15, 2017) (precedential as to § III.C.5, ¶ 1) (“the *Becton Dickinson* factors”).

Patent Owner argues that we should exercise our discretion to deny institution under § 325(d) because the same and substantially the same prior art was previously considered by the Office during prosecution of the ’056 patent application. Pet. 8–32. We, therefore, begin our analysis with a brief summary of the relevant prosecution history.

1. Brief Summary of Prosecution History

The ’056 patent application was filed on March 1, 2002. Ex. 1001, (22). During prosecution, the examiner issued a single office action in which she rejected claims 1, 5–12, 14, 16, 17, 22–26, 31, and 32 as anticipated by U.S. Patent No. 5,759,151 to Robert H. Sturges (“Sturges ’151,” Ex. 1007). Ex. 1002, 146–53. The examiner also identified and made of record certain prior art references that she considered “pertinent to applicant’s disclosure,” including Zehel. *Id.* at 151.

Sturges ’151 relates to a flexible, steerable device for conducting exploratory procedures. Ex. 1007, Abstract. Figure 1 of Sturges ’151 is reproduced below:

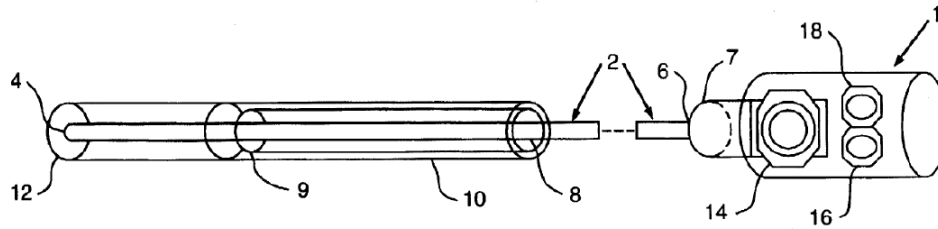


FIG. 1

Figure 1 depicts the device of the Sturges '151 invention. Device 1 includes spine 2 having distal end 4 and proximal end 6. *Id.* at 3:24–25. Spine 2 extends through and is generally coaxial with flexible sheath 8. *Id.* at 3:29–30. Sheath 8 and spine 2 are slidably movable with respect to one another. *Id.* at 3:34–35. Sheath 8 is secured to flexible instrument conduit 10, with steerable tip 12 mounted on the distal end of sheath 8. *Id.* at 3:37–38, 48–49. Distal end 4 of spine 2 has a “maximum limit of travel wherein the distal end 4 is inserted into the steerable tip 12,” and a “minimum limit of travel wherein the distal end 4 is retracted from the steerable tip 12 into the conduit 10.” *Id.* at 3:52–56.

According to Sturges '151, the operation of the device when used as an endoscope is as follows:

1. Spine 2 is retracted to its minimum limit and made rigid. The distal end of device 1 (sheath 8 and instrument conduit 10) is inserted into the gut up to the first substantial curve of the gut.
2. Distal tip 12 is flexed to observe and determine the next desired direction of forward travel. Spine 2 is relaxed and advanced to its maximum limit and stiffened. Distal tip 12, sheath 8 and instrument conduit 10 remain stationary with respect to the patient during the advancing of spine 2.
3. Distal tip 12, sheath 8 and instrument conduit 10 are inserted farther into the gut using rigid spine 2 as a guide. Spine 2 remains relatively stationary with respect to the patient as distal tip 12, sheath 8 and instrument conduit 10 are further inserted into the gut. The total forward movement of the

device should equal the travel limit of spine 2 within sheath
8.

4. Steps 2 and 3 are repeated cyclically until distal tip 12 reaches the target site in the gut.

Id. at 4:48–5:2.

In response to the office action, the applicant noted that Sturges ’151 describes a device in which “[t]he distal end 4 of the spine 2 has a **maximum limit of travel** wherein the distal end 4 is inserted into the steerable tip 12, as shown in FIG. 1. The distal end 4 of the spine 2 has a **minimum limit of travel** wherein the distal end 4 is retracted from the steerable tip 12 into the conduit 10.” Ex. 1002, 167. The applicant argued that, in contrast, independent claim 1 recites “wherein the elongate guide is freely slidable along the instrument such that advancing of the instrument along the guide is unconstrained.” *Id.* Similarly, independent claim 14 recites “the guide being slidably disposed without constraint within the lumen.” *Id.* Accordingly, the applicant argued Sturges ’151 did not anticipate the rejected claims because “Sturges [’151] fails to recite the feature of having a guide which is freely slidable through the device, as recited in the claims.” *Id.* at 167.

Following the office action response, the applicant had a telephonic interview with the examiner during which they agreed upon an amendment to claims 1 and 14 that would traverse the rejection over Sturges ’151. *Id.* at 171. The examiner then entered an examiner’s amendment adding that the guide is “freely slidable along the length of the instrument” in claim 1 and that the “guide being slidably disposed without constraint within the lumen along the length [of the elongate guide]” in claim 14. *Id.* at 174. In the reasons for allowance, the examiner stated the claims were amended “to

define the instant invention over [Sturges '151].” *Id.* at 175. The examiner explained:

[A]lthough the spine 2 of Sturges ['151] was confined to a particular area of the device, it appeared to be able to move freely within that area or, in other words, was unconstrained within that area. Accordingly, to further define the instant invention over Sturges ['151], the examiner suggested adding the limitation ‘along the length’ [of the instrument] to independent claims 1 and 14 to indicate that the guide of the instant invention was freely slidable and was capable of unconstrained movement along the entire length of the instrument, rather than in a particular area, as in the device of Sturges ['151]. Thus, as amended, independent claims 1 and 14 define the instant invention over the prior art of record.

Id. at 176.

2. *Application of Our Discretion Under 35 U.S.C. § 325(d)*

Patent Owner argues that each of the *Becton Dickinson* factors weighs in favor of exercising our discretion and denying the Petition. Prelim. Resp. 8–32. Having considered the parties’ respective arguments and evidence, we agree with Patent Owner.

a. *Becton Dickinson Factors (a)–(d)*

Becton Dickinson factors (a)–(d) relate to whether and to what extent the prior art asserted in the Petition was considered and relied upon by the examiner during prosecution. Here, the same and substantially the same prior art that Petitioner asserts in both grounds was substantively considered by the examiner during prosecution. Specifically, Sturges '151, which was the subject of an anticipation rejection, is substantially similar to Sturges and Sturges II,⁴ which Petitioner asserts in the Petition. Moreover, Zehel, which

⁴ As Petitioner notes, Sturges II “contains a near-verbatim recitation of the disclosures in [Sturges] but also includes a supplemental section directed to

the examiner identified as “pertinent” during prosecution, is the same Zehel reference asserted in the Petition. Ex. 1002, 151.

In the Preliminary Response, Patent Owner compares the Sturges Publications with Sturges ’151, identifying the similarities in the disclosures relied upon by Petitioner. *See* Prelim. Resp. 10–17, 18–22. We agree with Patent Owner that the relevant disclosures of all three Sturges references are substantively very similar, for the reasons stated in the Preliminary Response. *See id.*

Petitioner contends that the Sturges Publications “disclose variations on the instrument and procedure described in Sturges ’151.” Pet. 14. Petitioner also asserts that “[u]nlike the Sturges ’151 Patent identified during prosecution of the ’056, the Sturges [Publications] at issue here describe[] a spine that is freely slidable and capable of unconstrained movement along the entire length of the instrument.” Pet. 36. Thus, Petitioner essentially argues that there are material differences between the asserted Sturges Publications and Sturges ’151 involved during prosecution.

We are not persuaded by Petitioner’s argument. Specifically, we disagree with Petitioner’s characterization that the Sturges Publications asserted in the Petition are materially distinct from Sturges ’151 considered by the examiner. As explained above, the applicant distinguished Sturges ’151 from the claimed invention because the spine of Sturges ’151 has maximum and minimum travel limits, whereas the guide of the claimed invention was “freely slidable and capable of unconstrained movement along

integrating a voice control system for advancing and retracting the endoscope.” Pet. 57–58. Because the voice control system of Sturges II is not pertinent to our Decision, we consider and refer to Sturges and Sturges II together as the “Sturges Publications.”

the entire length of the instrument, rather than in a particular area, as in the device of Sturges [’151].” Ex. 1002, 176.

We find the Sturges Publications also teach travel limits. As Patent Owner notes, the Sturges Publications depict a device with bidirectional “spine axial travel limits,” as shown in Figure 2 of Sturges, reproduced below (with highlighting added by Patent Owner):

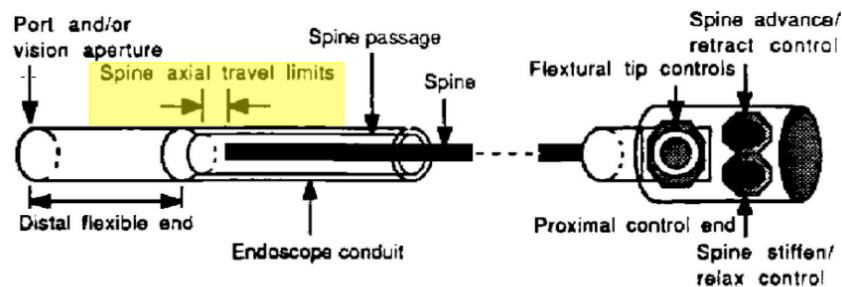


Fig. 2. Cross section of an endoscope with controllable stiffness spine.

Prelim. Resp. 28; Ex. 1004, 124 (Fig. 2); *see also* Ex. 1006, 606 (Fig. 48.3). Figure 2 illustrates a cross-section of the endoscope described by the Sturges Publications. The Sturges Publications teach that “[w]hile the spine is sufficiently stiff, the flexible conduit moves incrementally relative to the spine and *within the predetermined axial travel limits*, using the spine as a guide.” Ex. 1004, 124 (emphasis added); Ex. 1006, 606. The Sturges Publications further state that “[t]he total forward insertion distance of the endoscope is equal to the spine axial travel limits.” Ex. 1004, 124; Ex. 1006, 606. Thus, the Sturges Publications teach a cyclical advancement of the conduit and the spine at a distance no more than the spine axial travel limit with each cycle. Ex. 1004, 124; Ex. 1006, 606. In other words, when advancing the instrument into the body, the guide is not freely slidable along the length of the instrument, as required by claim 1, or slidably disposed without constraint, as required by claim 14. When advancing the endoscope

in the Sturges Publications, the guide is limited by the spine axial travel limit, much like the guide of Sturges '151 is limited by the maximum and minimum limit of travel.

Petitioner asserts that the Sturges Publications place no restriction on the “minimum limit of travel” of the spine and teach no restraint on the spine axial travel limits because the limits can “be adjusted to meet the specific requirements for the radius of curvature at each bend of the colon.” Pet. 35 (quoting Ex. 1004, 124). We disagree. Although the Sturges Publications do not explicitly refer to a “minimum limit of travel,” they do state that the endoscope can be removed from the colon “[b]y reversing the above procedure.” Ex. 1004, 124; Ex. 1006, 606. In other words, the Sturges Publications teach removing the endoscope incrementally and “within the predetermined axial travel limits.” Ex. 1004, 124; Ex. 1006, 606. Moreover, as Patent Owner notes, “a variable constraint is still a constraint.” Prelim. Resp. 29.

Petitioner also argues the Sturges Publications teach a spine for which the maximum limit motion “includes the distal tip,” and is therefore freely slidable along the length of the instrument. Pet. 34 (citing Ex. 1004, 124). But Petitioner’s argument is directly contradicted by the prosecution history for Sturges '151. Ex. 1013. As the applicant of Sturges '151 noted during prosecution, the device in the Sturges Publications is distinct from the device in Sturges '151 because “the spine disclosed in the Sturges [Publications] *never* enters the distal flexible end of the device. Instead, the spine travels within the endoscope conduit within axial travel limits as shown in Figure 2 of the publication.” *Id.* at 74 (emphasis added). Thus, despite Petitioner’s assertion that the Sturges Publications teach a maximum limit that includes

the distal tip, the inventor and author of the Sturges Publications stated otherwise during prosecution.

Notwithstanding its contrary argument in the Petition, Petitioner tries to distinguish the references by arguing the guide of Sturges '151 is “limited to the steerable distal tip whereas the Sturges [Publications] did not require any such restriction.” Pet. Supp. Br. 5 (citing Ex. 1013, 74, 90). But, as the Sturges applicant explained during prosecution, the guide of the Sturges Publications has travel limits restricting its movement, as well, albeit within the endoscope conduit. Ex. 1013, 74 (stating “the spine travels within the endoscope conduit *within axial travel limits*”) (emphasis added).

The problem with Petitioner’s argument is that the location of the travel limit—whether in the distal tip or in the conduit—is not pertinent to our analysis. The point is that both travel limits in Sturges '151 and the Sturges Publications fail to teach a guide that is freely slidable along the length of the instrument or slidably disposed without constraint, as required by the '056 patent claims. Thus, we are not persuaded that Petitioner’s alleged distinction between the guide of Sturges '151 and the guide of the Sturges Publications is a material difference for purposes of this Decision under § 325(d).

Petitioner also argues that the Sturges Publications do not teach a restraint because, like the '056 patent, the Sturges Publications teach that “the spine can be removed from the conduit entirely and be replaced by other therapeutic/diagnostic devices.” Pet. 35 (citing Ex. 1004, 124; Ex. 1003 ¶ 97). We are not persuaded by that argument, either. The claims require that the guide be freely slidable “such that advancing the instrument along the guide is unconstrained” (claim 1) or slidably disposed “without constraint . . . along the length for selectively supporting the body” (claim

14). That is, the guide of the '056 patent must be freely slidable while advancing the instrument (or while supporting the instrument). Whether the spine of the device of the Sturges Publications can be removed is inapposite to our analysis.

Accordingly, we find the Sturges Publications are substantially the same as—and not materially different than—Sturges '151, which was substantively evaluated during prosecution as a basis for an anticipation rejection. Moreover, Zehel, which the examiner identified as “pertinent to applicant’s disclosure” (Ex. 1002, 151), is the same Zehel reference asserted in the Petition. Although the examiner did not rely on Zehel to reject the claims during prosecution, the fact that the examiner identified the reference and considered it “pertinent to applicant’s disclosure” (Ex. 1002, 151) supports exercising our discretion. We, therefore, find *Becton Dickinson* factors (a) through (d) weigh heavily in favor of exercising our discretion to deny institution.

b. Becton Dickinson Factors (e) and (f)

Becton Dickinson factors (e) and (f) look to the Petition and whether Petitioner has made a case for reconsidering the asserted prior art. We find that Petitioner has not. As explained above, we find the Sturges Publications asserted in the Petition are substantially the same as, and not materially different than, Sturges '151 considered during prosecution. We also find the examiner considered Zehel as “pertinent” to the application. Ex. 1002, 151. Petitioner has not otherwise identified any reason why the examiner erred in her consideration of Sturges '151 or Zehel. Nor has Petitioner identified any additional facts and evidence that justify reconsidering the prior art or arguments set forth in the Petition. The district court’s claim construction

does not change our analysis.⁵ We, therefore, find *Becton Dickinson* factors (e) and (f) also weigh in favor of exercising our discretion.

Accordingly, under the facts and circumstances of this case, we find that each of the *Becton Dickinson* factors weigh in favor of exercising our discretion to deny institution. We, therefore, determine that denying institution under § 325(d) is appropriate because substantially the same prior art and arguments were previously presented to the Office.

III. CONCLUSION

For the foregoing reasons, we exercise our discretion under 35 U.S.C. § 325(d) and decline to institute an *inter partes* review of the challenged claims of the '056 patent.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is *denied* as to all challenged claims of the '056 patent and no trial is instituted.

⁵ To the extent Patent Owner argues the Board's analysis of the *Becton Dickinson* factors should *never* depend on claim scope (PO Supp. Br. 2), we disagree. Under the facts and circumstances of this case, however, the district court's claim construction does not impact the outcome of this Decision, because our analysis is primarily based on the substantial similarity of the prior art references.

PETITIONER:

Ching-Lee Fukuda
Thomas Broughan
SIDLEY AUSTIN LLP
clfukuda@sidley.com
tbroughan@sidley.com

PATENT OWNER:

Erika Arner
Daniel Tucker
Arpita Bhattacharyya
Benjamin Saidman
Alexander Boyer
Gracie Mills
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
erika.arnier@finnegan.com
daniel.tucker@finnegan.com
arpita.bhattacharyya@finnegan.com
benjamin.saidman@finnegan.com
alexander.boyer@finnegan.com
gracie.mills@finnegan.com