

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDIVATORS INC.,

Petitioner,

v.

ARC MEDICAL DESIGN LIMITED,

Patent Owner.

IPR2021-00707

Patent 9,808,142 B2

Before JOHN G. NEW, ZHENYU YANG, and
CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

NEW, *Administrative Patent Judge*.

DECISION

Denying Institution of *Inter Partes* Review

35 U.S.C. § 314(a), 37 C.F.R. § 42.4

I. INTRODUCTION

Petitioner Medivator Inc. (“Petitioner”) has filed a Petition (Paper 1, “Pet.”) seeking *inter partes* review of claims 1–5, 8, and 9 of US Patent 9,808,142 B2¹ (Ex. 1002, the “’142 patent”). Patent Owner Arc Medical Design Limited (“Patent Owner”) timely filed a Preliminary Response. Paper 6 (“Prelim. Resp.”). Petitioner subsequently filed a Reply to Patent Owner’s Preliminary Response (Paper 12), and Patent Owner filed a Sur-Reply. (Paper 13).

Under 35 U.S.C. § 314, the Board “may not authorize an *inter partes* review to be instituted unless ... the information presented in the petition ... and any response ... shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” Upon consideration of the Petition and Preliminary Response, Petitioner’s Reply (Paper 13), Patent Owner’s Sur-Reply (Paper 14), and the evidence of record, we determine that the evidence presented fails to demonstrate a reasonable likelihood that Petitioner would prevail in establishing the unpatentability of at least one challenged claim of the ’142 patent.

¹ US 10,722,103 B2 (the “’103 patent”) is a continuation of the “’142 patent.” Petitioner has also filed a Petition to institute *inter partes* review of the ’103 patent. See IPR2021-00706, Paper 1.

II. BACKGROUND

A. *Related Matters*

The '142 patent has been asserted in pending civil action *Arc Medical Design Ltd. and Keymed (Medical and Industrial Equipment) Ltd. v. Medivators Inc. and Cantel Medical Corp.*, 4:21-CV-929 (S.D. Tex.). Pet. 1; Paper 4 at 1. The complaint was filed March 22, 2021. *Id.*

B. *The Asserted Grounds of Unpatentability*

Petitioner contends that claims 1–5, 8, and 9 of the '142 patent are unpatentable, based upon the following grounds:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–5, 8, 9	103	Hitoshi ²
1–5, 8, 9	103	Hitoshi, Reydel ³

Petitioner also relies upon the Declaration of Dr. James East (the “East Declaration,” Ex. 1001).

C. *The '142 Patent*

The '142 patent is directed to a covering or sheath having external projections for use with a medical device, and in particular for use with

² Hitoshi (JP2003-339631A, December 2, 2003) (“Hitoshi”) (Ex. 1004). Hitoshi was originally published in Japanese and is provided with a certified English translation. See Ex. 1004, 19. All page numbers cited from Hitoshi are from the provided certified English translation.

³ Reydel (WO 99/29362 A1, June 17, 1999) (“Reydel”) (Ex. 1006).

flexible medical scoping devices such as endoscopes or enteroscopes. Ex. 1002, col. 1, ll. 16–19. Specifically, the '142 patent discloses:

[A] cover comprising an elongate tubular member and being arranged for application over the medical scoping device shaft with the cover extending along at least a part of the length of a distal end of the shaft, the tubular member comprising an inner surface at least a part of which grips the shaft and acts to hold the cover in place and an outer surface comprising a plurality of spaced projecting elements having a tip and a base that are moveable between a resting position to a position wherein the tip of the projecting element is substantially parallel to a longitudinal axis of the medical scoping device and to a position that is at an angle that is approximately perpendicular to the longitudinal axis of the medical scoping device shaft so that the said projecting elements are fanned out to contact with and provide support for and to dilate a lumen wall of a body passage into which the medical scoping device has been inserted.

Id. at col. 3, ll. 33–48. Figure 1 of the '142 patent depicts an embodiment of the device.

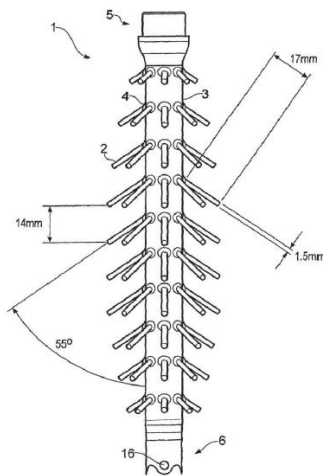


FIG. 1

Figure 1 of the '142 patent depicts a view of an embodiment of the claimed cover

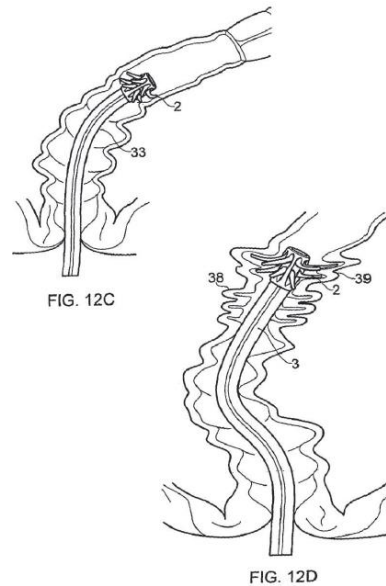
The '142 patent explains that:

[W]hen advancing the medical scoping device into the patient's bowel or small intestine and the distal end encounters a bend or loop in the patient's bowel or small intestine, the medical scoping device is withdrawn towards its proximal end causing the projecting elements to splay or fan out and to dilate the lumen of the bowel or small intestine whilst holding the medical scoping device in position ... so said projecting elements engage with and grip the body passage wall, the medical scoping device is then further withdrawn towards the proximal end causing it to straighten and the body passage wall to concertina along the shaft of the scope proximal to the bend or loop whilst the lumen ahead of the distal end opens up, the medical scoping device is then advanced towards its distal end and the bend or loop is navigated.

Id. at col. 4, ll. 22–39. Furthermore, the invention of the '142 patent provides:

[A] method of improving endoscopic visualisation ... wherein the projecting elements open a lumen and evert[,] thereby flattening colonic folds for inspection during withdrawal whereby visualisation is further enhanced as colonic folds revert to their normal anatomical position permitting light from the medical scoping device to play across the mucosa, thus enabling careful visualisation of the surface of the mucosa that was hitherto hidden or difficult to view.

Id. at col. 4, ll. 41–50. Figures 12C and 12D depict the claimed invention deployed in the colon as described in this passage:



Figures 12C and 12D depict schematic anatomical through sections of a medical scoping device with a cover of the present invention in the course of a medical scoping procedure. Figure 12C shows controlled withdrawal, flattening of the colonic wall and improved visualisation and; Figure 12D shows air suction causing the colon wall to collapse or wrap around the device and to grip the cover and device

D. Illustrative Claims

Independent claims 1 and 8 of the '142 patent are representative of the claims at issue. Claim 1 recites:

1. [1.1] A method of endoscopic visualization of a bowel and/or small intestine, the method comprising:

[1.2] inserting a medical scoping device shaft having an air suction conduit for removing air from a body passage into the bowel or small intestine of a patient under investigation, [1.3] the medical scoping device farther comprising a cover releasably attached to the medical scoping device shaft and covering at least a part of the shaft at its distal end, wherein the cover includes a member having an inner surface for gripping the shaft and an outer

surface from which a plurality of projecting elements project radially outwardly;

[1.4] advancing the medical scoping device in the direction of its distal end within the patient's bowel or small intestine, wherein the projecting elements deflect to a first radially inward position to facilitate advancing the medical scoping device;

[1.5] partially withdrawing the medical scoping device toward its proximal end, such withdrawal causing the projecting elements to deflect to a second radially outward position in which at least some tips of the projecting elements extend distally further than a distal end of the cover [1.6] and the distal end of the medical scoping device in response to contact with a lumen wall to dilate a lumen of the bowel or small intestine while holding the medical scoping device in position for visualization of the lumen and to evert and engage colonic folds that are more distal than the distal end of the cover and the medical scoping device whereby visualization is allowed as the colonic folds revert to their normal anatomical position permitting a light from the medical scoping device to emit across a mucosa of the bowel or small intestine providing visualization of at least a portion of a surface of the mucosa; and

[1.7] withdrawing the medical scoping device wherein the projecting elements deflect so that the tips of the projecting elements extend distally further than the distal end of the cover and the distal end of the medical scoping device to facilitate withdrawal of the medical scoping device.

Ex. 1002, cols. 16–17, ll. 31–3. Claim 8 recites:

8. [8.1] A method of endoscopic visualization of a bowel and/or small intestine, the method comprising:

- [8.2] inserting a medical scoping device shaft having air suction for removing air from a body passage into the bowel or small intestine of a patient under investigation, [8.3] the medical scoping device further comprising a cover releasably attached to the medical scoping device shaft and covering at least a part of the shaft at its distal end, wherein the cover grips the shaft and comprises a plurality of projecting elements that project radially outwardly;
- [8.4] advancing the medical scoping device in the direction of its distal end within a lumen of the patient's bowel or small intestine or bowel and small intestine, wherein the projecting elements deflect to a first radially inward position to facilitate advancing the medical scoping device;
- [8.5] partially withdrawing the medical scoping device toward its proximal end, such withdrawal causing the projecting elements to deflect to a second radially outward position at which at least some tips of the projecting elements extend distally further than a distal end of the cover [8.6] and the distal end of the medical scoping device in response to contact with a lumen wall to dilate the lumen while holding the medical scoping device in position for visualization of the lumen and to evert and engage colonic folds that are more distal than the distal end of the cover and the medical scoping device whereby visualization is allowed as the colonic folds revert to their normal anatomical position permitting a light from the medical scoping device to emit across a mucosa of the lumen providing visualization of at least a portion of a surface of the mucosa; and
- [8.7] withdrawing the medical scoping device wherein the projecting elements deflect so that at least some of the tips of the projecting elements extend distally further than the distal end of the cover and the distal end of the medical

scoping device to facilitate withdrawal of the medical
scoping device.

Ex. 1002, cols. 17–18, ll. 28–30.

E. Prosecution History of the '142 Patent

The '142 patent was filed as U.S. Application No. 13/699,172 A1 (the “'172 application”) on November 20, 2012 and claims priority to PCT/GB2011/050981, filed May 24, 2011. Ex. 1002, Codes (21), (22), (86). The claims were allowed on June 20, 2017. *Id.* at 15 (citing Ex. 1030, 1).

III. ANALYSIS

A. Claim Construction

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). *See* 37 C.F.R. § 100(b) (2020). 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 (quoting *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004)).

Neither Petitioner nor Patent Owner proposes, at this stage of the proceeding, any claim construction, agreeing that the claim terms should be given the ordinary and customary meaning that they would have to a person of ordinary skill in the art at the time of the invention. Pet. 16; Prelim. Resp. 14.

B. A Person of Ordinary Skill in the Art

Petitioner contends that a person of ordinary skill in the field of the ‘142 patent would be “a physician specializing in gastroenterology or a GI surgeon having an interest in colonoscopy or bowel cancer prevention. The POSA may be such a person working with members of a development team for devices to be used with colonoscopes.” Pet. 16 (citing Ex. 1001 ¶ 17). Patent Owner does not contest this definition in its Preliminary Response, and we consequently adopt Petitioner’s definition for the purposes of this Decision.

C. Ground I: Alleged Obviousness of Claims 1–5, 8, and 9 over Hitoshi

1. Overview of Hitoshi

Hitoshi was published in December, 1993 and on this record is prior art to the ‘142 patent. Ex. 1004, 1. Hitoshi is directed to an “endoscope insertion assistance tool,” designed to enable an endoscope insertion portion to be easily advanced, without requiring any special actions by the operator, when performing a pressing-in operation and to hold the position of the endoscope insertion portion by increasing the resistance when a pulling

operation is performed, thereby improving ease of insertion of the endoscope insertion portion. *Id.* at Abstr.

Specifically, Hitoshi claims:

An endoscope insertion assistance tool comprising:

- a fixed portion integral with or releasably fixed to an endoscope insertion portion; and one or more flexible thin fin-shaped projections connected with said fixed portion in a condition in which they project distally or in inclined fashion distally with respect to the direction of insertion into a body cavity;

- wherein the position of said endoscope insertion portion in a body cavity passage is held by contact of said fin-shaped projections with the body cavity passage wall, when a pulling operation is performed on this endoscope insertion portion within the body cavity passage, in a condition in which said fixed portion is fixed to said endoscope insertion portion;

- characterised in that at least part of the circumferential portion of said fin-shaped projections is softer than part of the portion where said fin-shaped projections are connected with said fixed portion.

Ex. 1004, 1 (claim 1). Figure 2 of Hitoshi depicts a detail of an embodiment of the invention:

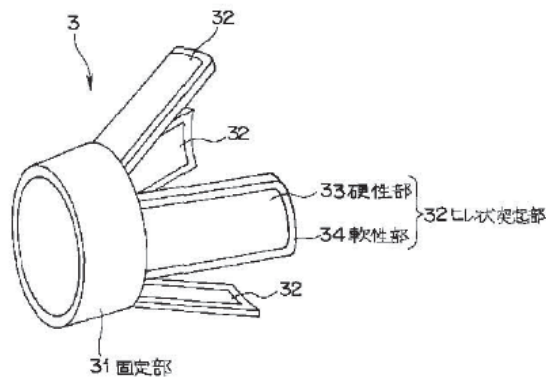


Figure 2 of Hitoshi is a perspective view of the claimed endoscope insertion assistance tool

Hitoshi's Figure 2 comprises a fixed portion 31 and four fin-shaped projections 32. Ex. 1004 ¶ 21. The fixed portion 31 is formed in cylindrical shape and is mounted on the endoscope insertion portion. The four fin-shaped projections 32 are of a soft and flat thin shape and project from the outside surface of the aforementioned fixed portion 31 with a prescribed distally inclined angle with respect to the direction of insertion into the body cavity passage. *Id.* at ¶ 22. Furthermore, Hitoshi teaches that the fin-shaped projection can be deformed so as to contact the endoscope insertion portion, in a condition with the aforementioned endoscope insertion assistance tool attached to the endoscope insertion portion. *Id.* at ¶ 59, Fig. 15.

Figure 8 of Hitoshi depicts the claimed invention fitted to the distal end of an endoscope 21 deployed in a colon:

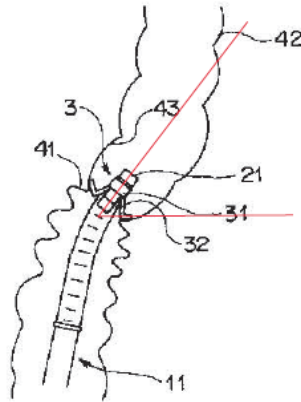


Figure 8 of Hitoshi illustrates straightening of a bend in the colon via the operator performing a further pulling operation and a bending operation

With respect to Figure 8, Axon teaches that the s-shaped colon 41 and the descending colon 42 can be made to assume a substantially linear condition by the operator performing a further pulling operation and a bending operation. Ex. 1004 ¶ 41.

2. Obviousness of claims 1–5, 8, and 9 over Hitoshi

a. Independent claim 1

Petitioner identifies how the teachings of Hitoshi, in combination with Axon, teaches each of the limitations of independent claim 1. Pet. 23–37. Because we find limitations [1.5] and [1.7] to be dispositive of our decision to deny institution with respect to claim 1 on Ground 1, we focus our analysis on those limitations.

- i. **[1.5] “partially withdrawing the medical scoping device toward its proximal end, such withdrawal causing the projecting elements to deflect to a second radially outward position in which at least some tips of the projecting**

elements extend distally further than a distal end of the cover”

Petitioner points to Figure 7 of Hitoshi, which depicts withdrawal of the endoscope within the colon, causing the projecting fins of the cover to engage with the colon walls. Pet. 37. Figures 7 and 8 of Hitoshi are reproduced below:

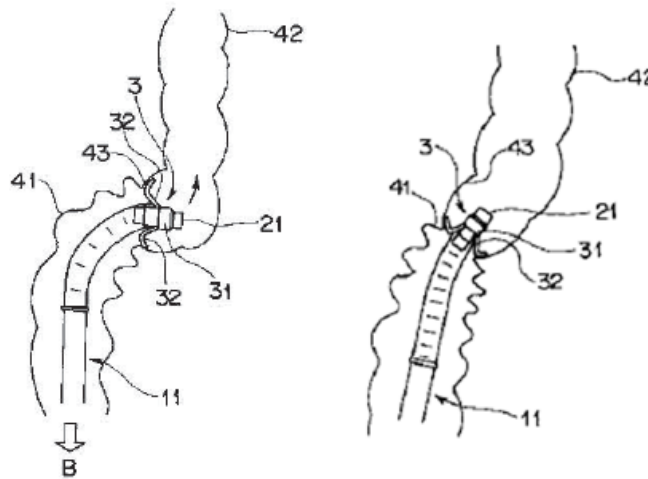


Figure 7

Figure 8

Figures 7 and 8 of Hitoshi illustrate how the endoscope insertion portion 11 is inserted from the S-shaped colon of the large intestine 41 into the descending colon 42

Petitioner contends that Figures 7 and 8 of Hitoshi demonstrate that engagement of the fins with the colon wall causes the walls behind the distal end of the scope to concertina around the colon itself to straighten. Pet. 37–38. Petitioner asserts that Hitoshi thus teaches that when the endoscope insertion portion 11 is pulled, the fin-shaped projection 32 is in contact with the wall of the colon at the peripheral portion of the fin-like projection 32,

end of an endoscope cover, or alternatively the proximal end or middle of the fixed portion of the endoscope cover. *Id.* (citing Ex. 1004 ¶ 87; Ex. 1001 ¶ 115).

Petitioner contends that a person of ordinary skill in the art, upon viewing Figures 7 and 8, would have understood that given the disclosed length and flexibility of the projecting elements 32 of the hood, as well as the teaching of positioning the projecting elements in any position along the endoscope cover, the device of Hitoshi could readily be adapted such that at least some of the projecting elements 32 of the distal ring extend further distally than the end of hood 31. Pet. 40–41 (citing Ex. 1001 ¶ 115).

- ii. **[1.7] “withdrawing the medical scoping device wherein the projecting elements deflect so that the tips of the projecting elements extend distally further than the distal end of the cover and the distal end of the medical scoping device to facilitate withdrawal of the medical scoping device.”**

Petitioner argues that Hitoshi teaches that the projecting fins readily deform to lie against the scope, which means the resistance on intubation with the cover is scarcely increased compared to intubation with an endoscope without a cover. Pet. 47 (citing Ex. 1004 ¶ 35; Ex. 1001 ¶ 123). Petitioner notes that the projecting fins are described as being flexible, with a soft portion 34 that can easily be deformed, and which gently contacts the intestinal wall 43. *Id.* (citing Ex. 1004 ¶ 43; Ex. 1001 ¶ 123). Petitioner asserts that a person of ordinary skill in the art would understand that the distally-located projecting fins of Hitoshi would be capable of deflecting in such a manner that their tips extend distally further than the distal end of the cover and endoscope as shown in Hitoshi’s Figure 21. *Id.* at 47–48 (*see* Ex.

1004, Fig. 21 *supra*; Ex. 1001 ¶ 123). Furthermore, argues Petitioner, the fins can be mounted at any point along the longitudinal axis of the cuff, and can be of varying length. *Id.* at 48. Therefore, Petitioner reasons, if a long protrusion was mounted on the cuff near the endoscope tip, a skilled artisan would have understood that the tip of such a protrusion would fall into the visual field when “turned over” on withdrawal. *Id.* (citing Ex. 1004 ¶ 87; Ex. 1001 ¶ 123).

Petitioner also argues that, for the reasons explained with respect to limitation [1.5] *supra*, a skilled artisan, upon viewing Figure 7 of Hitoshi, would understand that, given the disclosed length and flexibility of the projecting elements 32 of the hood, the use of such a device in a colon having a relatively narrow diameter would result in at least some of the projecting elements 32 extending further distally than the end of hood 31. *Id.* (citing Ex. 1001 ¶ 124).

b. Patent Owner’s preliminary response

Patent Owner notes that independent claim 1 recites that, during partial withdrawal, “at least some tips of the projecting elements extend distally further than a distal end of the cover and the distal end of the medical scoping device.” Prelim. Resp. 16 (citing Ex. 1002, claim 1) (emphasis omitted). Specifically, Patent Owner points out, the projecting elements must extend distally further than both “a distal end of the cover” and “the distal end of the medical scoping device.” *Id.* Patent Owner asserts that the significance of this feature cannot be understated, because this feature was the last feature that was amended into the independent claims before allowance during prosecution. *Id.* Patent Owner notes that the

Examiner expressly identified this feature as being one of the reasons for allowance, and that Hitoshi was specifically evaluated against this feature during prosecution. *Id.* (citing, e.g., Exs. 1028–1030).

Patent Owner asserts that Petitioner does not address whether Hitoshi purportedly renders obvious that projecting elements extend distally further than “the distal end of the medical scoping device.” Specifically, argues Patent Owner, Petitioner partitions the feature of claim 1 that recites that “at least some tips of the projecting elements extend distally further than a distal end of the cover and the distal end of the medical scoping device.” *Id.* at 17 (citing Pet. Sections VII.E.5 and VII.E.6.6).

Patent Owner argues that Petitioner alleges that Hitoshi renders obvious that “at least some tips of the projecting elements extend distally further than a distal end of the cover,” as recited in claim 1. Prelim. Resp. 17 (citing Pet. Section VII.E.5). Patent Owner contends that Petitioner fails to address whether Hitoshi purportedly renders obvious that “at least some tips of the projecting elements extend distally further than . . . the distal end of the medical scoping device,” as also recited in claim 1. *Id.* at 17–18. According to Patent Owner, Hitoshi teaches that element 21, as depicted in the figures of Hitoshi that Petitioner cites, is the “leading end portion 21” of the “endoscope insertion portion 11” that is also shown in the figures of Hitoshi that Petitioner cites. *Id.* at 18 (citing Ex. 1004 ¶ 15).

Patent Owner therefore asserts that “leading end portion 21” of Hitoshi can be interpreted to be the “distal end of the medical scoping device” of claim 1. Prelim Resp. 18. Patent Owner contends that, despite Hitoshi’s mention of “leading end portion 21,” Petitioner never addresses whether the projecting elements of Hitoshi extend distally further than

“leading end portion 21” (the equivalent of the “distal end of the medical scoping device” recited in claim 1), or allege that such a relationship would be obvious. *Id.*

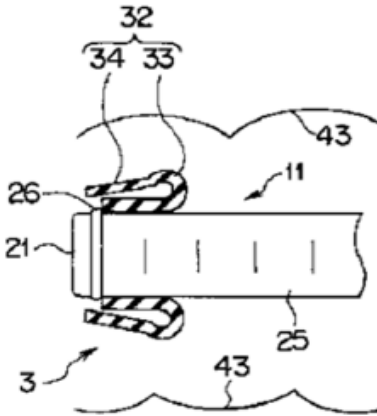
Similarly, Patent Owner argues, Petitioner fails to address whether the projecting elements of Hitoshi extend distally further than “leading end portion 21” of Hitoshi, which Patent Owner contends is the equivalent of the claim term “distal end of the medical scoping device” recited in claim 1, such a relationship would be obvious. Prelim. Resp. 18–19.

Patent Owner further points to Petitioner’s statement that “[a] POSA would immediately envisage that the hood of Hitoshi is adapted for one or more of the tips of the projecting elements to be sized and configured to extend distally further than the distal end of the cover and endoscope given the Figures and disclosure.” Prelim Resp. 19 (quoting Pet. 40). However, Patent Owner argues, that single sentence merely states “endoscope” generally, and plausibly could refer to the entire endoscope-operating portion 12, the endoscope insertion portion 11, the part of the endoscope before the proximal end of the endoscope insertion assistance tool 3, or various other parts of the endoscope 2. *Id.* at 19–20. Patent Owner asserts that Hitoshi neither discloses nor suggest that the projecting elements extend beyond leading end portion 21. *Id.* at 20.

c. Analysis

We conclude that Petitioner has not established a reasonable likelihood of prevailing at trial because Hitoshi neither teaches nor suggests the limitations [1.5] and [1.7] of independent claim 1 reciting “wherein the projecting elements deflect so that the tips of the projecting elements extend

distally further than the distal end of the cover and the distal end of the medical scoping device to facilitate withdrawal of the medical scoping device.” Ex. 1002, claim 1. Petitioner relies upon Figure 21 of Hitoshi, which we again reproduce below, as teaching this limitation:



Scrutiny of Figure 21 does not show that “the one or more of the tips [34] of the projecting element are sized and configured to extend distally further than the distal end of the cover and the distal end of the medical scoping device shaft [21].” We note here that Hitoshi teaches that “[i]n the construction of the aforementioned endoscope insertion portion 11, from the leading end side, a leading end portion 21, a bendable portion 22 and a soft portion 23 are sequentially linked.” Ex. 1004 ¶ 15. We thus find that the “leading end portion” of Hitoshi’s endoscope insertion portion would be understood by a person of ordinary skill in the art to correlate to “the distal end of the medical scoping device shaft,” as recited in claim 1.

However, and more importantly, the text of Hiroshi supporting Figure 21 reveals that the situation depicted in the Figure is not a desirable or intended feature of the device, but in fact represents an *undesirable* situation,

that should be avoided, and which can be ameliorated by certain structural refinements. Specifically, Hitoshi teaches that:

As described above, the aforementioned fin-shaped projections 32 are formed of thin flexible resilient members and are deformed by being pressed against the intestinal wall 43 accompanying a pulling operation of the aforementioned endoscope insertion portion 11: as shown in Fig. 20, the intestinal wall 43 is thereby folded up (in the direction of the arrow C) on the distal side of the aforementioned endoscope insertion assistance tool 3, and the intestinal tract is thereby compressed.

...

However, if the external force $G^{[4]}$ is excessively large or if for example the external force G is applied to the vicinity of the root portion of the aforementioned fin-shaped projections 32 (i.e., [the vicinity of the portion connected with the fixed portion 31]), the deformed portion may extend beyond the aforementioned fin-shaped projections 32 so that rolling-back takes place from the aforementioned fixed portion 31, with the result that, *as shown in Fig. 21, the fin-shaped projections 32 remain in a condition in which they are folded up towards the leading-end portion 21 of the insertion portion. In the condition shown in Fig. 21, there was a risk that during a pulling operation the effect of the aforementioned endoscope insertion assistance tool 3 in pressing*

⁴ Although this and the succeeding quoted paragraphs recite “external force G ,” we find that this is either a typographical error on the part of the author or a translational error by the translator. As defined in the preceding paragraph “Force C” is a “pulling operation,” i.e., a backward- or proximally-directed force, that causes the fin-shaped projections 32 to grasp and retract the intestinal wall. See Hitoshi Fig. 20. “Force G ,” on the other hand, is a pushing or forward force, i.e., in the distal direction. See Hitoshi Figs. 19, 20. Only a pulling (i.e., proximally directed) force, i.e., “Force C,” could cause the over-deflection of the fin-shaped projections 32 such that they point forward towards the distal end of the endoscope device 21. Consequently, we conclude that, as used in this passage, “Force G ” can logically only be interpreted as meaning “Force C.”

on the intestinal wall would be lost and, furthermore, even in the case of insertion by a pressing-in operation, ease of insertion would deteriorate, due to increase in diameter of the insertion portion.

...

To deal with this, in the third embodiment shown in Fig. 17 and Fig. 18, when a pulling operation in the body cavity passage is performed on the aforementioned endoscope insertion portion 11 with the aforementioned endoscope insertion assistance tool 203 attached, even if an external force G as shown in Fig. 19 is applied to the aforementioned fin-shaped projections 32, the aforementioned endoscope insertion assistance tool 203 is so constructed that the aforementioned fixed portion 231 is not easily deformed, by making the connection portion of the aforementioned fixed portion 231 with the aforementioned fin-shaped projections 32 of increased thickness: *consequently, folding back of the aforementioned fixed portion 231 cannot occur.*

...

Also, in the third embodiment shown in Fig. 17 and Fig. 18, thickening is applied solely in the vicinity of the connection portion of the aforementioned fin-shaped projections 32 and the aforementioned fixed portion 31, so the increase in the external diameter of the portion that is inserted into the body cavity is suppressed to the minimum: ease of insertion cannot therefore be much impaired by increase in external diameter.

Hitoshi ¶¶ 77–80 (emphases added). As explained, Figure 19 of Hitoshi depicts the increased thickness at the connection portion of the fin-shaped projections and the fixed position, which Hitoshi teaches is specifically designed to avoid or ameliorate the situation depicted in Figure 21:

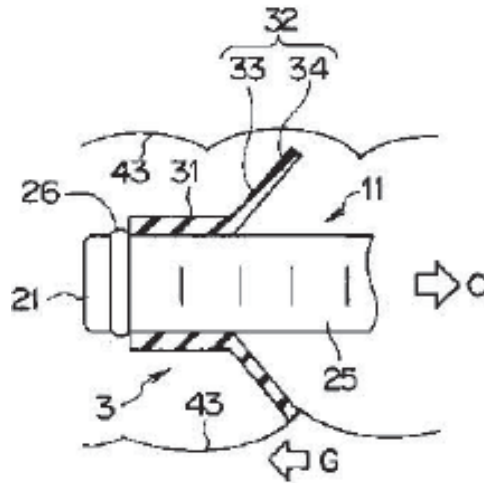


Figure 21 depicts how thickening at the point where the fin-shaped projection is joined to the fixed position [31] is designed to resist the type of deformation depicted in Figure 21

Figure 22 depicts another embodiment of the same concept:

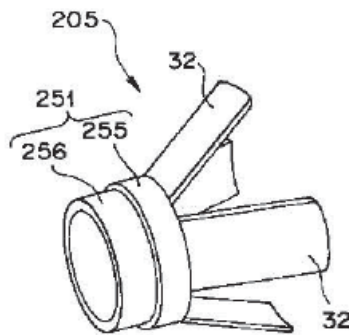


Figure 22 of Hitoshi depicts another embodiment of the concept described in Figure 19, with a thickening at the base of the fin-shaped projections [255] to prevent deformation of the projections [32] in a distal direction

In sum, Hitoshi teaches that the situation depicted in Figure 21, in which the fin-shaped projections are deflected so as to “point towards a distal end of the cover,” as recited in claim 1, is one to be avoided because “during a pulling operation the effect of the aforementioned endoscope

insertion assistance tool 3 in pressing on the intestinal wall would be lost and, furthermore, even in the case of insertion by a pressing-in operation, ease of insertion would deteriorate, due to increase in diameter of the insertion portion.” Hitoshi ¶ 78.

We conclude that a person of ordinary skill in the art would consequently be “discouraged from following the path set out in the reference.” *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). As such, we conclude that Hitoshi teaches away from the third position in which:

[O]ne or more of the tips of the projecting elements of the distal ring point towards a distal end of the cover, and wherein, when coupled to the medical device shaft and in the third position, the one or more of the tips of the projecting element are sized and configured to extend distally further than the distal end of the cover and the distal end of the medical scoping device shaft,

as recited in claim 1.

The testimony of Petitioner’s Declarant, Dr. East, fails to squarely address this teaching away by Hitoshi. Dr. East attests merely that “Hitoshi discloses an embodiment where the tips of the projecting elements extend distally further than the distal end of the endoscope cover in Figure 21, extending past projection 26” and that:

A POSA would immediately envisage that the hood of Hitoshi is adapted for one or more of the tips of the projecting elements to be sized and configured to extend distally further than the distal end of the cover and endoscope given the Figures and disclosure.... A POSA viewing Figures 7 and 8 would understand that given the disclosed length and flexibility of the projecting elements 32 of the hood, as well as the teaching of positioning the projecting elements in any position along the endoscope cover, the device of Hitoshi could readily be adapted such that at least some of the projecting elements 32 of the distal

ring extend further distally than the end of hood 31 and the distal end of the medical scoping device 21.

East Decl. ¶¶ 182–183. Dr. East does not mention that Hitoshi teaches that the situation depicted in Figure 21, in which the fin-like projections are deflected to point distally, is a situation that Hitoshi expressly warns is to be avoided, and to which Hitoshi teaches preventative structural elements. *See* Hitoshi ¶ 80. Nor does Petitioner, or Dr. East, point to any teaching in Axon that would negate this teaching away in Hitoshi.

Consequently, because Hitoshi teaches away from this limitation, we conclude that Petitioner does not have a reasonable likelihood of prevailing at trial with respect to claim 1 upon this ground.

d. Independent claim 8

With respect to claim 8, Petitioner incorporates and repeats the arguments presented *supra* with respect to the limitations of claim 1. Pet. 53–55.

As we have explained with respect to limitations [1.5] and [1.7] of claim 1 *supra*, Hitoshi expressly teaches that deflection of the fin-shaped projections toward the distal end of the endoscope is as undesirable situation, and one to be avoided, and, further, teaches structural elements to prevent such an occurrence from happening.

The teachings of Hitoshi would thus discourage a person of ordinary skill in the art from arriving at the limitation of claim 8 in which “the projecting elements deflect so that at least some of the tips of the projecting elements extend distally further than the distal end of the cover and the distal end of the medical scoping device.” Because Hitoshi expressly teaches

away from this limitation, we conclude that Petitioner has not established a reasonable likelihood of prevailing at trial.

e. Dependent claims 2–5, and 9

Claims 2–5 depend from claim 1 of the ‘142 patent and claim 9 depends from claim 8. Petitioner’s arguments with respect to these claims consequently suffer from the same defects as claims 1 and 8, viz., Hitoshi’s teaching away from the limitation reciting “the projecting elements deflect so that the tips of the projecting elements extend distally further than the distal end of the cover and the distal end of the medical scoping device.” The same applies with respect to the claims that depend from those claims.

Consequently, and for these same reasons, we conclude that Petitioner has not succeeded in establishing a reasonable likelihood of prevailing at trial upon Ground I of the Petition.

D. Ground II: Alleged Obviousness of Claims 1–5, 8, and 9 over Hitoshi and Reydel

1. Overview of Reydel

Reydel was published on June 19, 1999, and is prior art to the ‘142 patent. Reydel is directed to “[a] medical device for intrusion of body cavities and canals, such as the gastrointestinal, urinal, vaginal and vascular tracts, ... with unconventional surface structure, namely one having a bidirectional coefficient of friction upon ingress and egress into a body cavity, such surface replacing conventional slippery low friction surfaces.” Ex. 1006, Abstr. Specifically, Reydel teaches that:

If a flexible endoscope is advanced along this pathway provided with the different bidirectional surface characteristics of this invention, the human tissue along the intestinal wall will tend to grab and hold on upon egress, while the ingress orientation is favorably comparable with prior art lubricated instrumentation along the desired ingress route....Thus, an endoscope-catheter distal end can be jiggled or inch-wormed back and forth during the ingress to create pleating or accordioneing of the walls of the intestine tract onto the scope. In this “pleating” procedure when feeding the device and/or instrument into the intestine, the zig-zag incremental feeding using the interface surface texture with the intestine walls moves a pleat outwardly and straightens out the canal walls inwardly into a relatively straight increment for ingress of the instrumentation, such as the endoscope.

Ex. 1006, 7.

Pertinently, Reydel teaches that:

[S]mooth device surfaces that will contact human tissue in the insertion and removal process can be surface texturized, for example, to produce angled crests of a multi-peaked or fibrous surface texture with the crests forming barb-like tips slanting at an angle toward the proximal end of a catheter, thereby to encourage the ingress of the device into the work site, and impede withdrawal.... Thus, the instruments have the characteristic of grabbing or clinging to the tissue of the canal walls. In general, the textured surface can occur along the catheter length.

Ex. 1006, 4. Reydel’s Figure 15 provides an example:

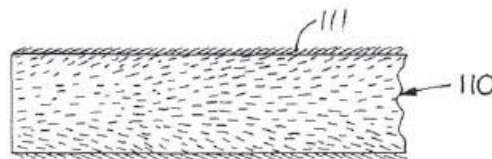
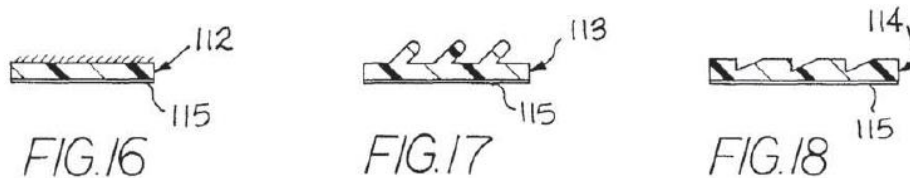


FIG. 15

Figure 15 of Reydel is a side view sketch of a removable plastic sleeve embodiment of the invention

Reydel teaches, with respect to Figure 15, that “the sheath 110 employs a different bidirectional surface texture 111, which can be obtained, for example, by brushing or milling the surface of a polymer such as polyiden to give the generally macroscopic bidirectional characteristic.” Ex. 1006, 20. Figures 16–18 depict additional embodiments of the surface structures providing the bidirectional frictional properties:



Figures 16–18 of Reydel are different section view fragments of adhesive plastic film embodiments of the invention having different surface geometry patterns

2. Obviousness of claims 1–5, 8, and 9 over Hitoshi and Reydel

a. Independent claim 1

Petitioner identifies how the teachings of Hitoshi, in combination with Reydel, teaches each of the limitations of independent claim 1. Pet. 23–37. Because we find limitations [1.5] and [1.7] to be dispositive of our decision to deny institution with respect to claim 1 on Ground 1, we focus our analysis on those limitations.

- i. **[1.5] “partially withdrawing the medical scoping device toward its proximal end, such withdrawal causing the projecting elements to deflect to a second radially outward position in which at least some tips of the projecting elements extend distally further than a distal end of the cover”**

Petitioner argues that Reydel teaches that the projecting elements (textured surface 75) impede egress (i.e., withdrawal) because of friction with the wall tissue of the colon 70 wherein the “barbs” contact the walls during egress as shown by arrow 76 in Figure 10B of Reydel. Pet. 62–63 (citing Ex. 1006, 19, Fig. 10B; Ex. 1001 ¶ 145). Figure 10B of Reydel is reproduced below:

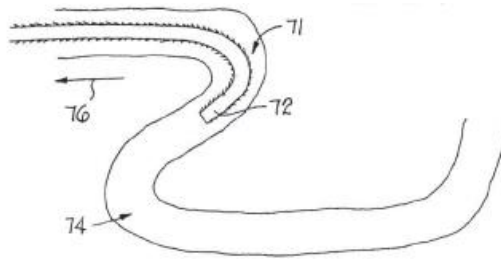


Fig 10B of Reydel depicts a portion of a colon during ingress of an endoscope illustrating the improved “inchworm” incremental back and forth method of pushing an endoscope into the small intestine

Petitioner contends that Reydel teaches that the surface films of the invention containing the projecting elements may be made of a thin semi-stretchable plastic. Pet. 63 (citing Ex. 1006, 21; Ex. 1001 ¶ 146). According to Petitioner, a person of ordinary skill in the art would have understood that a semi-stretchable plastic would bend outwardly when it meets the colon wall during a pulling motion, or “egress,” where the endoscope is being moved in a proximal direction. *Id.* (citing Ex. 1001 ¶ 146).

Petitioner argues further that a skilled artisan would also envisage that the projecting elements could extend distally further than a distal end of the cover. Pet. 63. Petitioner refers to Figure 10B as demonstrating that the projecting elements of Reydel can protrude from the most distal end of the

scoping device cover. *Id.* (citing Ex. 1001 ¶ 147). Petitioner notes that Reydel teaches that:

Either microscopic or macroscopic surface size can be provided, depending upon the work missions required and the characteristics of the tissue or canals to be invaded. The surface texture pattern and the geographical distribution can be custom designed for particular medical procedures. Thus, the instruments have the characteristic of grabbing or clinging to the tissue of the canal walls.

Id. at 63–64 (quoting Ex. 1006, 4; Ex. 1001 ¶ 147) (bracketed alteration and internal quotation marks omitted).

Petitioner therefore contends that a person of ordinary skill in the art would understand that Reydel contemplates that the projecting elements of the invention could be sized for a given medical application such that they cling to the tissues of the canal walls. Pet. 64 (citing Ex. 1001 ¶ 147). Petitioner asserts that the skilled artisan would therefore understand that the stretchable protrusions located at the distal end of the scoping device cover could be provided with such a length that they would bend outwardly such that some of the protrusions would extend past the distal end of the cover on egress. (Ex. 1001 ¶ 147).

- ii. **[1.7] “withdrawing the medical scoping device wherein the projecting elements deflect so that the tips of the projecting elements extend distally further than the distal end of the cover and the distal end of the medical scoping device to facilitate withdrawal of the medical scoping device.”**

Petitioner repeats the argument presented with respect to limitation [1.5] *supra*, that the textured surface projections of Reydel are flexible, and a

skilled artisan would understand that the tips of at least some of the projections of Reydel could extend distally further than the distal end of the cover and scoping device upon egress for the reasons explained above. Pet. 68 (citing Ex. 1001 ¶ 153).

Additionally, argues Petitioner, Reydel recites “a catheter of a length reaching from outside a body into a work site adapted for entry into, movement along and withdrawal from a body canal for supporting medical surveillance and therapy at a work site inside the body.” Pet. 68–69 (quoting Ex. 1006, claim 31; Ex. 1001 ¶ 153). Therefore, Petitioner argues, an express purpose of the surface structure device of Reydel is to aid in withdrawal from a body canal and supporting medical surveillance. *Id.* at 69 (citing Ex. 1001 ¶ 153). Petitioner notes that Reydel teaches that the different bidirectional coefficient of friction, which impedes the spontaneous withdrawal of the device and/or instrument, is not extreme enough to traumatize the canal walls, and therefore egress is not significantly more uncomfortable than with conventionally surfaced devices and/or instruments. *Id.* (citing Ex. 1006, 8; Ex. 1001 ¶ 153).

Petitioner argues that this limitation is obvious in light of Hitoshi. Pet. 69. Petitioner reasons that a person of ordinary skill in the art would have understood that the projections on the hood of Hitoshi would facilitate withdrawal of the endoscope while enabling the necessary function of visualizing colonic folds during withdrawal. *Id.* at 69–70 (citing Ex. 1001 ¶ 154). According to Petitioner, the projecting fins are described as being flexible, with a soft portion 34 that can easily be deformed and which gently contacts the intestinal wall 43, and a skilled artisan would understand that projecting fins of Hitoshi would be capable of deflecting such that their tips

extend distally further than the distal end of the cover and endoscope. *Id.* at 70 (citing Ex. 1004 ¶ 43; Ex. 1001 ¶ 155).

b. Patent Owner's preliminary response

Patent Owner points out that claim 1 recites “at least some tips of the projecting elements extend distally further than a distal end of the cover and the distal end of the medical scoping device.” Prelim. Resp. 21 (emphasis in original). Patent Owner contends that the projecting elements must thus extend distally further than both “a distal end of the cover” and “the distal end of the medical scoping device,” and not just one or the other. *Id.* at 21–22. However, Patent Owner argues, Petitioner arbitrarily partitions the limitation of claim 1 that recites that “at least some tips of the projecting elements extend distally further than a distal end of the cover and the distal end of the medical scoping device” in a manner that causes the feature to span two different sections of the Petition. *Id.* (citing Pet. 62–64, 68–70).

According to Patent Owner, Petitioner alleges that Reydel renders obvious that “at least some tips of the projecting elements extend distally further than a distal end of the cover,” as recited in claim 1. Prelim. Resp. 23 (citing Pet. 63). However, Patent Owner argues, nowhere does Petitioner argue that the projecting elements of Reydel extend distally further than the “distal end of the medical scoping device,” recited in claim 1. *Id.*

Furthermore, Patent Owner argues, Petitioner proffers an interpretation of Reydel that is not supported by the evidence cited by the Petitioner, rather, Patent Owner contends, Petitioner impermissibly relies upon hindsight analysis. Prelim. Resp. 44.

c. Analysis

As an initial matter, we have already explained why we find unpersuasive Petitioner’s argument that Hitoshi teaches or suggests the limitation of claim 1 reciting “the projecting elements deflect so that the tips of the projecting elements extend distally further than the distal end of the cover and the distal end of the medical scoping device to facilitate withdrawal of the medical scoping device.” Indeed, we have explained why we find that Hitoshi, in fact, teaches away from this limitation. We incorporate that reasoning here with respect to Ground II.

With respect to the teachings of Reydel as supporting this limitation, we find Petitioner’s argument to be almost entirely devoid of any factual basis in the evidentiary record. Nowhere does Reydel expressly teach that the apparently hair-like protrusions of its surface film are capable of extending distally further than the distal end of the cover and the distal end of the medical scoping device to facilitate withdrawal of the medical scoping device. Indeed, Figures 15–18 appear to demonstrate that the textured coating is such that the projections imparting the directionally-dependent frictional properties are not long enough to project distally past the end of either the cover or the medical scoping device, but serve only to create a bidirectional coefficient for the device. Moreover, Patent Owner’s argument that that Reydel’s teaching that “the different bidirectional coefficient of friction which impedes the spontaneous withdrawal of the device and/or instrument is not extreme enough to traumatize the canal walls, and therefore egress is not significantly more uncomfortable than with conventionally surfaced devices and/or instruments” (*see* Pet. 69), somehow teaches that the projections of the bidirectional coating are capable of

extending distally beyond the end of the cover or the scoping device, is similarly without factual basis. To the contrary, Reydel teaches that:

The patient's comfort is also an objective of this invention, which is enhanced by simpler and less traumatic ingress methods. The different bidirectional coefficient of friction which impedes the spontaneous withdrawal of the device and/or instrument is not extreme enough to traumatize the canal walls, and therefore egress is not significantly more uncomfortable than with conventionally surfaced devices and/or instruments.

Ex. 1006, 8. The plain language of this passage states merely that, due to the properties of the instrument cover, there are different coefficients of friction for distal and proximal movement of the endoscope, but that the difference between the frictional coefficients is not so great as to damage or traumatize the walls of the colon. Petitioner's contention that this is caused by forward deflection of the projections of the cover in the distal direction, such that they extend beyond the end of the cover or of the scoping device, is mere conjecture and attorney argument to which we accord little probative weight. *See In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997).

In short, we conclude that Petitioner has failed to meet the burden of demonstrating a reasonable likelihood of prevailing at trial because neither Reydel nor Hitoshi teaches or suggests the limitations of claim 1 reciting "the projecting elements deflect so that the tips of the projecting elements extend distally further than the distal end of the cover and the distal end of the medical scoping device to facilitate withdrawal of the medical scoping device."

d. Independent claim 8

Regarding claim 8, Petitioner expressly relies upon the same arguments made with respect to claim 1. *See* Pet. 74–75. In addressing limitation [8.7] of claim 37, Petitioner expressly repeats the same arguments made with respect to limitation [1.7] in Ground II and, by incorporation, limitation [1.7] in Ground I. Pet. 75 (“This element is obvious over Reydel for the reasons set forth regarding Ground 2, element 1.7 above”). For the reasons we have explained, we do not find this argument persuasive and, for those reasons, we conclude that Petitioner has failed to establish a reasonable likelihood of prevailing at trial with respect to independent claim 8.

e. Dependent claims 2–5 and 9

Petitioner’s arguments with respect to claims 2–5 and 9 consequently suffer from the same defects as claims 1 and 8, *viz.*, neither Reydel nor Hitoshi teach or suggest the limitations of independent claims 1 and 8 reciting “the projecting elements deflect so that the tips of the projecting elements extend distally further than the distal end of the cover and the distal end of the medical scoping device.” The same applies with respect to the claims which depend from those claims.

Consequently, and for these same reasons, we conclude that Petitioner has not succeeded in establishing a reasonable likelihood of prevailing at trial upon Ground II of the Petition.

IV. CONCLUSION

For the reasons we have explained, we conclude that Petitioner has

failed to establish a sufficiently persuasive showing that the cited prior art references disclose, teach, or suggest the elements of at least one of claims 1–5, 8 or 9 of the '142 patent. Furthermore, because we so conclude, we need not reach Patent Owner's additional arguments. Petitioner has thus failed to establish a reasonable likelihood of prevailing at trial with respect to at least one of claims 1–5, 8, or 9 of the '142 patent over the cited prior art set forth in the asserted Grounds I and II. 35 U.S.C. § 314. Furthermore, and for the reasons set forth, we need not reach a decision whether to exercise our discretion under 35 U.S.C. § 325(d) to deny institution of *inter partes* review.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED, pursuant to 35 U.S.C. § 314(a), that the Petition for *inter partes* review of claims 1–5, 8, or 9 of US 9,808,142 B2 is DENIED with respect to all grounds in the Petition; and

FURTHER ORDERED that no *inter partes* review is instituted.

IPR2021-00707
Patent 9,808,142 B2

For PETITIONER:

Erik Swenson
Matthew Goggin
CARLSON, CASPERS, VANDENBURGH & LINDQUIST, P.A. Capella
eswenson@carlsoncaspers.com
mgoggin@carlsoncaspers.com

For PATENT OWNER:

Katherine Vidal
Michael R. Rueckheim
WINSTON & STRAWN LLP
kvidal@winston.com
mrueckheim@winston.com
Winston-IPR-ArcMedical@winston.com