Trials@uspto.gov
571.272.7822

Paper 9
Entered: November 29, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

D R BURTON HEALTHCARE LLC,
Petitioner,

v.

TRUDELL MEDICAL INTERNATIONAL,
Patent Owner.

Case IPR2018-01025
Patent 9,808,588 B1

Before JAMES A. TARTAL, TIMOTHY J. GOODSON, and CHRISTOPHER C. KENNEDY, *Administrative Patent Judges*.

KENNEDY, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Petitioner D R Burton Healthcare LLC filed a Petition challenging claims 1–26 of U.S. Patent No. 9,808,588 B1. Paper 2. Patent Owner Trudell Medical International filed a Preliminary Response.[1] Paper 6. With our permission, Petitioner filed a Reply to address certain arguments in the Preliminary Response. Paper 8.

Inter partes review may not be instituted unless the information presented in the petition 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." 35 U.S.C. § 314(a). For the reasons set forth below, we deny the Petition.

A. RELATED MATTERS

Petitioner identifies the following related matter: *Trudell Medical Int'l v. D R Burton Healthcare LLC*, No. 4:18-cv-00009 (E.D.N.C.). Pet. 2.

B. THE '588 PATENT

The '588 patent is titled "Oscillating Positive Respiratory Pressure Device." Ex. 1001, [54]. The subject matter of the challenged claims relates generally to oscillating positive expiratory pressure ("OPEP") devices, which can be used in the treatment of lung disease. *E.g.*, *id.* at 1:15–46. "It

[1] Patent Owner used an unconventional citation format in the Preliminary Response. *See* Prelim. Resp. 3 n.1 (explaining format), 36 n.2 (same). In the future, to avoid any appearance of attempting to reduce word count by use of an unconventional citation format, Patent Owner should use conventional citation formatting, e.g., "Ex. 2001 ¶ 3," "Pet. 5." *See* Trial Practice Guide Update (Aug. 2018) at 7 ("[D]eleting spacing between words . . . in order to circumvent the rules on word count, may lead to a party's brief not being considered.").

is believed that OPEP therapy, or the oscillation of exhalation pressure at the mouth during exhalation, effectively transmits an oscillating back pressure to the lungs, thereby splitting open obstructed airways and loosening the secretions contributing to bronchial obstructions." *Id.* at 1:35–40.

The '588 patent discloses apparatuses that are capable of generating such an oscillating back pressure. The apparatuses generally include an inlet that receives exhaled air, an outlet from which the exhaled air may exit the device, an opening between the inlet and the outlet, and a "blocking segment" that can move between an open and closed position relative to the opening. *E.g.*, *id.*, claims 1, 9, 18. "The respiratory pressure at the chamber inlet oscillates between a minimum when the . . . blocking segment is in the open position and a maximum when the . . . blocking segment is in the closed position." *Id.* at 2:5–8.

Figure 12, reproduced below, is a cross-sectional perspective view of one embodiment of an OPEP device.

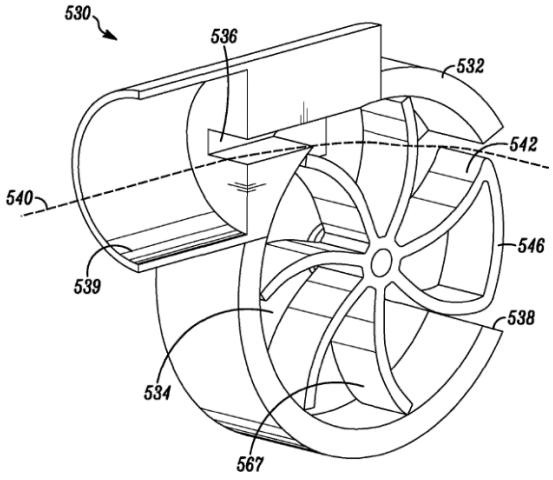


FIG. 12

Figure 12 depicts a mouthpiece 539 into which air is exhaled, inlet 536, outlet 538, blocking segment 546, and vanes 567 "adapted to rotate the

restrictor member 542 when a user exhales into the mouthpiece 539." *Id.* at 9:53–57. The '588 patent describes operation of the device as follows:

> [W]hen a user exhales into the mouthpiece 539, air is forced through the chamber inlet 536 and the restrictor member 542 begins to rotate. As the restrictor member rotates, and as the blocking segment 546 periodically passes by the chamber inlet 536, the exhalation pressure at the chamber inlet 536 oscillates between a minimum when the restrictor member 542 is in an open position and a maximum when the restrictor member 542 is in a closed position.

Id. at 9:58–65.

C. ILLUSTRATIVE CLAIM

Claim 1 is reproduced below. Additional claims are reproduced in our discussion below.

1. A respiratory treatment device comprising:

   an inlet configured to receive exhaled air into the device;

   an outlet configured to permit air to exit the device;

   an opening positioned in an exhalation flow path defined between the inlet and the outlet;

   a blocking segment configured to rotate relative to the opening between a closed position where the flow of air through the opening is restricted, and an open position where the flow of air through the opening is less restricted; and,

   a vane configured to rotate the blocking segment between the closed position and the open position in response to the flow of air through the opening;

   wherein a size of a blocking surface of the blocking segment is equal to or greater than a size of the opening.

D. PRIOR ART

Petitioner relies on the following prior art references, as well as the Declaration of its President and CEO, Dennis L. Cook (Ex. 1008):

Reference	Patent No.	Filing Date	Exhibit
Dunsmore	US 8,025,054 B2	Feb. 2, 2007	1005
Foran	US 6,581,598 B1	Nov. 24, 1999	1006
Blacker	US 7,905,228 B2	Oct. 3, 2006	1007
Fowler-Hawkins	US 6,702,769 B1	Oct. 21, 2002	1009

E. ASSERTED GROUNDS OF UNPATENTABILITY

Petitioner contends that the challenged claims are unpatentable based on the following grounds:

Reference(s)	Basis[2]	Claims Challenged
Dunsmore (Embodiment 1)[3]	§ 102	1, 2, 7–18, 20, 21, 25, and 26[4]

[2] The relevant sections of the Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112–29, took effect on March 16, 2013. Because the '588 patent claims priority to an application that was filed before that date, and Petitioner has not challenged the priority claim, we apply the pre-AIA statutory framework.

[3] Petitioner lists three different anticipation grounds based on different embodiments in Dunsmore. Consistent with the Petition and the Preliminary Response, we list the anticipation grounds based on Dunsmore as three separate proposed grounds of unpatentability.

[4] Petitioner's header for this ground lists claim 19. Pet. 19. Petitioner's analysis, however, does not include claim 19. *Id.* at 19–40. Accordingly, we do not consider claim 19 to be challenged as part of this proposed ground. *Cf.* Prelim. Resp. 42 n.3 (identifying error).

Reference(s)	Basis[2]	Claims Challenged
Dunsmore (Embodiment 2)	§ 102	1, 2, 4, 5, 7, 8, 18–22, 25, 26[5]
Dunsmore (Embodiment 3)	§ 102	1, 2, 4, 18, 20–22
Dunsmore	§ 103	3, 9–17, 23, 24[6]
Dunsmore and Blacker	§ 103	6
Dunsmore and Fowler-Hawkins	§ 103	11, 23, 24
Foran	§ 102	1–4, 6–8, 18, 20, 21, 25, 26

II. DISCUSSION

A. LEVEL OF ORDINARY SKILL IN THE ART

Petitioner asserts that a person of ordinary skill in the art "would have at least an Associate's degree from a Respiratory Therapy program, and/or a Bachelor of Science degree in Respiratory Therapy, engineering, or other comparable field." Pet. 17. Petitioner further asserts that "[t]he relevant person would also typically have at least five years of engineering or design experience, and/or five years of respiratory therapy device sales or clinical experience." *Id.*

[5] Petitioner's header for this ground lists claim 6 but does not list claim 22. Pet. 40. Petitioner's analysis does not include claim 6 but does include claim 22. *Id.* 40–51. Accordingly, we do not consider claim 6 to be challenged as part of this proposed ground, but we do consider claim 22 to be challenged as part of this proposed ground. *Cf.* Prelim. Resp. 57 n.4 (identifying error).

[6] Petitioner's header for this ground lists claim 5. Pet. 58. Petitioner's analysis, however, does not include claim 5. *Id.* at 58–69. Accordingly, we do not consider claim 5 to be challenged as part of this proposed ground. *Cf.* Prelim. Resp. 72 n.5 (identifying error).

Patent Owner does not acknowledge or dispute Petitioner's proposal but provides a slightly different description of the level of ordinary skill in the art: "[A] PHOSITA would have possessed the knowledge and skill known by an engineer or similar professional with at least an undergraduate degree in engineering, or a physician or respiratory therapist having experience with designing respiratory devices." Prelim. Resp. 35. Patent Owner further states that a person of ordinary skill in the art "also would have an understanding of engineering or medical device design principles." *Id.* Patent Owner provides no explanation as to whether or how there is any material difference between its proposal and Petitioner's proposal. *Id.*

Our findings and conclusions would be the same under either proposal. For clarity, we adopt Petitioner's proposal. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) ("[I]t is always preferable for the factfinder below to specify the level of skill it has found to apply to the invention at issue."). Additionally, we note that this level of ordinary skill in the art is supported by the prior art of record. *See id.*; *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995); *In re Oelrich*, 579 F.2d 86, 91 (CCPA 1978).

B. Claim Construction

Petitioner does not propose construction of any term and instead asserts that "the claim terms take on the customary and ordinary meaning that the terms would have to PHOSITA in view of the specification of the '588 Patent." Pet. 8.

Patent Owner proposes constructions for the following terms: (1) "a vane," (2) "to rotate," (3) "to translate relative to the opening," (4) "oblong cross-sectional shape," (5) "rectangular," (6) "a conduit having a length,"

and (7) "a side profile of the blocking segment [in the direction of the elongated second dimension] is shaped to mate with a side profile of the opening, when the blocking segment is in the closed position." Prelim. Resp. 36–42.

To the extent that claim construction is relevant to the issues presented in this case, we address it below in our discussion of the proposed grounds of unpatentability.

C. PRINCIPLES OF LAW

Anticipation under 35 U.S.C. § 102 requires "the presence in a single prior art disclosure of all elements of a claimed invention arranged as in the claim." *Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1325, 1332 (Fed. Cir. 2010) (internal quotation marks omitted); *see also Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008).

A claim is unpatentable under 35 U.S.C. § 103 if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). Obviousness is resolved based on underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness, i.e., secondary considerations. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

D. ANTICIPATION BY DUNSMORE (EMBODIMENT 1)

Petitioner asserts that embodiment 1 (Figs. 9–16) of Dunsmore anticipates claims 1, 2, 7–18, 20, 21, 25, and 26. Pet. 19–40.

1. Dunsmore (Embodiment 1)

Dunsmore, titled "Passive Respiratory Therapy Device," generally concerns respiratory therapy devices "including a housing and an interrupter valve assembly." Ex. 1005 at Abstract. The housing "defines a patient breathing passage . . . through which a patient inhales and exhales air." *Id.* The interrupter valve assembly includes a control port through which expiratory air passes and a valve body that "is sized to at least partially obstruct fluid flow through the control port." *Id.* The valve assembly also includes a drive mechanism that "moves the valve body relative to the control port in response to the expiratory airflow such that the valve body repeatedly transitions between a position of maximum obstruction and a position of minimum obstruction relative to the control port to create an oscillatory positive expiratory pressure effect." *Id.*

Figure 9 of Dunsmore is reproduced below.

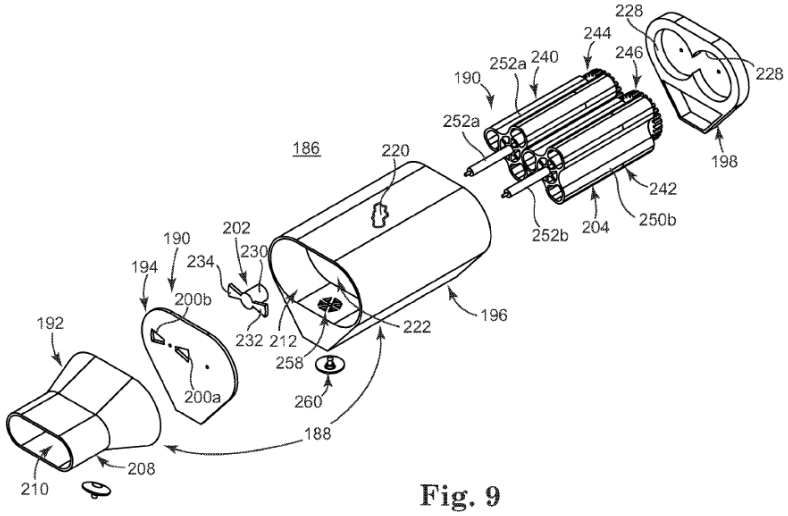


Fig. 9

Figure 9 is "an exploded, perspective view of" one embodiment of a respiratory therapy device disclosed by Dunsmore. *Id.* at 4:23–25. Of particular relevance to the issues before us, Figure 9 depicts (1) patient inlet 210, (2) control ports 200a and 200b, (3) valve body 202 with valve plate segments 232 and 234, and (4) drive mechanism 204. *E.g.*, *id.* at cols. 15, 16.

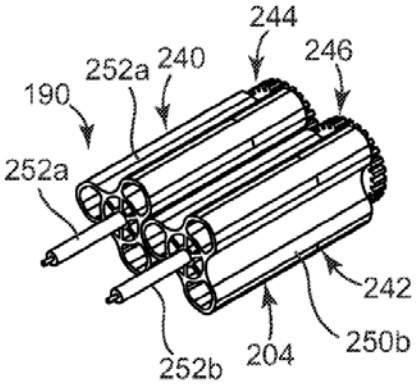
2. Analysis

a. Claim 1

Claim 1 requires, *inter alia*, "a vane configured to rotate the blocking segment between the closed position and the open position in response to the flow of air through the opening." Petitioner's argument concerning Dunsmore's disclosure of a vane appears below:

> Dunsmore teaches that "the valve plate segments 232, 234 [i.e., blocking segments] extend radially from the base 230 that is otherwise configured for affixment to a corresponding component of the *drive mechanism 204" [i.e., vane]*. (*Id.*, 15:64–67; *see also* Fig. 11 and 16:8–9 ("valve body 202 being mounted to the shaft 252a of the first lobe assembly 240").) In this configuration, the "drive mechanism 204 rotates the valve body 202 *in response to exhaled airflow from the patient* to periodically obstruct or close the control ports 200a, 200b" [*i.e.*, the vane is configured to rotate the blocking segment between the closed position and the open position in response to the flow of air through the opening]. (*Id.*, 15:26–29 (emphasis).) Accordingly, Dunsmore teaches the "blocking segment" and "vane" elements of claim 1.

Pet. 22–23 (first emphasis added; second emphasis in original). A depiction of Dunsmore's drive mechanism 204, which Petitioner contends is a vane, *see id.*, is reproduced below from a cropped portion of Figure 9 of Dunsmore.



Ex. 1005, Fig. 9. The cropped portion of Figure 9 shows drive mechanism 204 which includes, *inter alia*, lobe assemblies 240 and 242, gears 244 and 246, and shafts 252a and 252b. *E.g.*, *id.* at 15:40–16:11.

Petitioner asserts that drive mechanism 204, depicted above, constitutes a vane, and not that any particular component (such as a wall of one of the tubes of the lobe assemblies) constitutes a vane. *See* Pet. 22–23 (referring to "drive mechanism 204 [*i.e.*¸ vane]" (internal quotation marks omitted)). Petitioner does not propose a construction for the term "vane," and beyond the assertion that Dunsmore's drive mechanism 204 is a vane because it performs the same function as the vane of claim 1 (i.e., rotating a blocking segment in response to airflow), Petitioner provides no evident explanation as to why a person of ordinary skill in the art would consider the drive mechanism of Dunsmore to be a vane. *See id.*

Claim 1 is directed to an apparatus, and a vane is a structural element of that apparatus. *See, e.g.*, Ex. 1001 at Fig. 12, Fig. 13 (reproduced below). Petitioner does not assert otherwise. "[A]pparatus claims cover what a device *is*, not what a device *does*." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1468 (Fed. Cir. 1990) (emphasis in original). The Parties have not directed us to a definition of "vane" in the '588 patent, but

Patent Owner points out that several figures depict vanes. Figures 12 and 13 are reproduced below as annotated in the Preliminary Response.

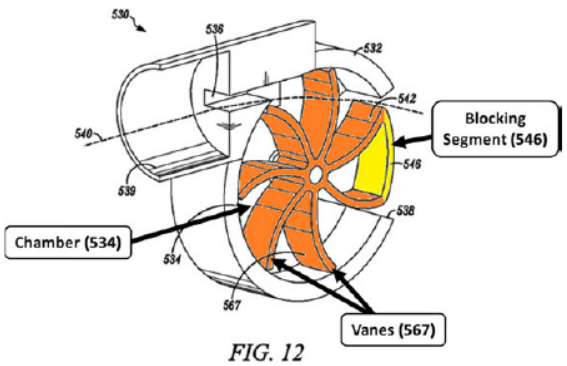


FIG. 12

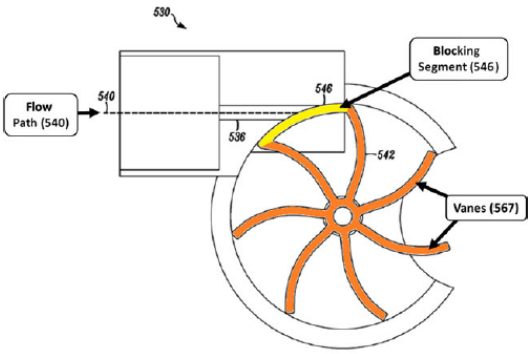


FIG. 13

Prelim. Resp. 11, 37. Figures 12 and 13, above, depict vanes in orange and a blocking segment in yellow.

Patent Owner argues that, consistent with the figures of the '588 patent and the plain meaning of the word, "vane" should be construed as "a blade or plate whose primary purpose is to convert kinetic energy in the form of fluid movement into rotational movement." Prelim. Resp. 37. In support of that proposal, Patent Owner submits a dictionary definition of the word "vane" ("a thin flat or curved object that is rotated about an axis by a flow of fluid or that rotates to cause a fluid to flow or that redirects a flow of fluid," Ex. 2012) and the testimony of William Durgin, Ph.D. Prelim. Resp. 37–38, 42–46; Ex. 2001 ¶¶ 174–183. Dr. Durgin observes that Dunsmore describes drive mechanism 204 as "akin to a reverse roots blower assembly," and Dr. Durgin explains that such an assembly is both functionally and structurally different from a vane. *E.g.*, Ex. 2001 ¶¶ 174–183.

"In an IPR, the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016). We need not

expressly construe the term "vane" to determine that Petitioner has not carried that burden and adequately shown that Dunsmore's drive mechanism 204 constitutes a vane. As noted above, Petitioner appears to assert that the entirety of drive mechanism 204 constitutes a vane. Petitioner provides no explicit claim construction analysis for the term "vane," and we discern no implicit claim construction analysis in Petitioner's discussion of the term "vane" that indicates the structural requirements of a vane and how Dunsmore's drive mechanism 204 meets those requirements. Petitioner provides no discernable explanation or analysis as to why Dunsmore's drive mechanism 204 constitutes a vane in terms of its structure as opposed to its function. *See id.* at 22–23, 26–27. We decline to attempt to provide such an analysis in the first instance ourselves. *Cf. In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) ("[W]e find no support for the PTO's position that the Board is free to adopt arguments on behalf of petitioners that could have been, but were not, raised by the petitioner during an IPR.").

Even assuming that Dunsmore's drive mechanism 204 performs the function of the vane recited by claim 1, that is not enough to show that it possesses the required structure. *Cf. In re Gardiner*, 171 F.2d 313, 315–16 (CCPA 1948) ("It is trite to state that the patentability of apparatus claims must be shown in the structure claimed and not merely upon a use, function, or result thereof."). As noted above, Petitioner does not identify structural requirements of a vane or persuasively explain how drive mechanism 204 meets those structural requirements.

Particularly in the absence of a claim construction analysis, support from an expert, and/or meaningful explanation as to how the prior art

structure falls within the scope of the term "vane,"[7] the information presented in the Petition does not adequately show that a person of ordinary skill in the art would consider Dunsmore's drive mechanism 204 to be a vane. Accordingly, the information presented in the Petition fails to establish a reasonable likelihood that Petitioner would prevail with respect to claim 1. Because claims 2, 7, 8, 13, 14, 20, and 21 also require a vane, either directly or through claim dependency, and Petitioner's analysis of those claims does not remedy the deficiency described above, Petitioner has likewise failed to establish a reasonable likelihood of prevailing as to those claims.

b. Claim 9

Independent claim 9 is reproduced below.

9. A respiratory treatment device comprising:

an inlet configured to receive exhaled air into the device;

an outlet configured to permit air to exit the device;

an opening positioned in an exhalation flow path defined between the inlet and the outlet, the opening having a generally oblong cross-sectional shape comprising a shorter first dimension and an elongated second dimension perpendicular to the first dimension; and,

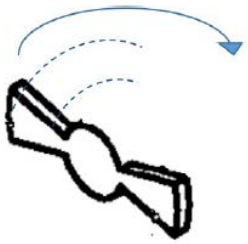
a blocking segment configured to translate relative to the opening along the shorter first dimension between a closed position where the flow of air through the opening is restricted, and an open position where the flow of air through the opening is less restricted;

[7] Our analysis in this decision should not be read to suggest that, to meet the threshold for institution, a petition must always be accompanied by an explicit claim construction analysis and/or expert testimony.

> wherein a size of a blocking surface of the blocking segment is equal to or greater than a size of the opening.

Unlike claim 1, claim 9 does not require a vane. Claim 9 does require, *inter alia*, "a blocking segment configured to translate relative to the opening along the shorter first dimension." Petitioner asserts that, because Dunsmore's valve plates 232 and 234 "*rotate* about vane 252 such that the valve plate segments move along the shorter first dimension [of the opening]," Dunsmore teaches "a blocking segment configured to translate relative to the opening along the shorter first dimension." Pet. 30–31 (emphasis added). Petitioner provides no persuasive analysis of the meaning of the term "translate," and it appears that Petitioner interprets "translate" to have the same meaning as "rotate." *See id.*; *see also, e.g.*, *id.* at 38 (asserting, with no discussion of the words "translate" and "rotate," that claims using the word "translate" rather than "rotate" are "substantially identical" in relevant part).

Patent Owner argues that "to translate relative to the opening" should be interpreted to mean "to move a body along an opening in a manner in which all parts of the body move the same distance in the same amount of time." Prelim. Resp. 38. For support, Patent Owner relies on the testimony of Dr. Durgin, *see* Ex. 2001 ¶¶ 147–154, and a dictionary definition for the word "translatability," Ex. 2014 ("motion, change of place, such that every point moves in the same direction at the same speed"). Patent Owner also gives several illustrations of translational and rotational movement. *E.g.*, Prelim. Resp. 23, 52; Ex. 2001 ¶¶ 149, 150. One of those illustrations is reproduced below.



Prelim. Resp. 52. The illustration above shows the movement of Dunsmore's valve plate, *id.*, which Petitioner alleges is equivalent to the blocking segment of claim 9. The illustration indicates that, in a given period of rotational movement, the portions of the valve plate closest to the axis of rotation move a shorter distance than the portions of the valve plate further from the axis of rotation. *Id.*

We need not expressly construe "translate" to determine that Petitioner has not adequately shown that a person of ordinary skill in the art would consider Dunsmore's blocking segments to be configured to "translate" relative to Dunsmore's control ports. Although neither party directs our attention to any relevant aspects of the written description of the '588 patent, the claims use at least two terms to describe the motion of blocking segments: (1) "rotate," Ex. 1001 at claim 1, and (2) "translate," *id.* at claim 9. That indicates that rotation and translation are not the same thing. *See Nystrom v. TREX Co.*, 424 F.3d 1136, 1143 (Fed. Cir. 2005) ("When different words or phrases are used in separate claims, a difference in meaning is presumed."). The only extrinsic evidence of record concerning the meaning of the term "translate" supports Patent Owner's position that translation requires movement of each point of a body by the same distance in the same time period. *See* Ex. 2014. Moreover, the only expert testimony of record is that Dunsmore's valve plates rotate and do not

translate, *see* Ex. 2001 ¶ 197, which is consistent with Petitioner's assertion that Dunsmore's valve plates rotate, *see* Pet. 30–31.

Particularly in view of the presumption that different words used in different claims have different meanings, Petitioner's conclusory treatment of the two words as being synonymous is unpersuasive and does not adequately show that a person of ordinary skill in the art would have understood the relied-upon portions of Dunsmore to disclose a blocking segment configured to translate relative to an opening. Petitioner provides no discernable analysis as to why translation should be interpreted to have the same meaning as rotation. We decline to attempt to provide such an analysis in the first instance ourselves. The information presented in the Petition fails to establish a reasonable likelihood that Petitioner would prevail with respect to claim 9.

Claims 10–17 depend, directly or indirectly, from claim 9, and the Petitioner's analysis of those claims does not remedy the deficiency identified above. Accordingly, Petitioner has not established a reasonable likelihood of prevailing with respect to those claims.[8]

c. Claim 18

Independent claim 18 is similar to claim 9 and includes the "translate relative to the opening" limitation discussed above. Petitioner argues that "[c]laim 18 is substantially identical to claim 1," but Petitioner does not acknowledge that claim 1 requires *rotation* of the blocking segment, while claim 18—like claim 9—requires *translation* of the blocking segment.

[8] As noted above, claims 13 and 14 also require a "vane," and the Petitioner has not adequately established that the portions of Dunsmore relied on by Petitioner disclose a vane.

Pet. 38–39. In attempting to identify in Dunsmore a disclosure of blocking segment translation, the Petition simply refers back to its analysis of claim 1, which does not require translation of a blocking segment. *Id.* at 39.

For reasons discussed above, and particularly in the absence of a claim construction analysis from Petitioner, we are not persuaded that a person of ordinary skill in the art would have considered translation and rotation to be the same thing. *See Nystrom*, 424 F.3d at 1143; *see also Seachange Int'l, Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1369 (Fed. Cir. 2005) ("[T]here is still a presumption that two independent claims have different scope when different words or phrases are used in those claims." (internal citation omitted)). In view of the Petition's failure to persuasively analyze the differences between the two terms, failure to sufficiently explain how Dunsmore discloses translation of a blocking segment (as opposed to rotation), and in view of our discussion of claim 9 above, we determine that Petitioner does not adequately show that Dunsmore discloses a blocking segment configured to translate relative to an opening, as required by claim 18. Therefore, the information presented in the Petition fails to establish a reasonable likelihood that Petitioner would prevail with respect to claim 18.

Claims 20, 21, 25, and 26 depend, directly or indirectly, from claim 18, and the Petitioner's analysis of those claims does not remedy the deficiency identified above. Accordingly, Petitioner has not established a reasonable likelihood of prevailing with respect to those claims.[9]

[9] As noted above, claims 20 and 21 also require a "vane," and the Petitioner has not adequately established that the portions of Dunsmore relied on by Petitioner disclose a vane.

E. ANTICIPATION BY DUNSMORE (EMBODIMENT 2)

Petitioner asserts that embodiment 2 (Figs. 17–19) of Dunsmore anticipates claims 1, 2, 4, 5, 7, 8, 18–22, 25, and 26. Pet. 40–52.

1. Dunsmore (Embodiment 2)

Figure 19A of Dunsmore is reproduced below.

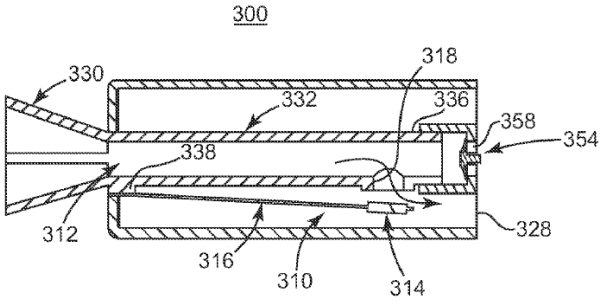


Fig. 19A

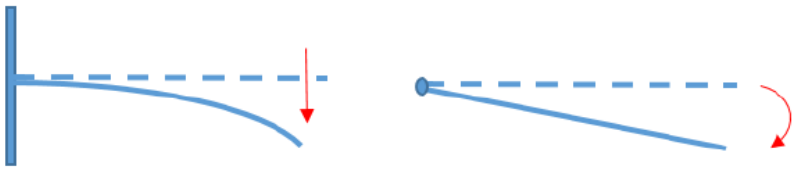
Figure 19A depicts an embodiment of Dunsmore's respiratory therapy device. Ex. 1005 at 4:42–44, 4:48. In particular, Figure 19A shows mouthpiece 330, patient inlet 312, tube 332, control port 318, drive mechanism beam 316, valve body 314, and shoulder 338. *Id.* at 21:1–28. "[T]he shoulder 338 serves as a support or fulcrum for the drive mechanism 316." *Id.* at 19:38–39. Dunsmore discloses that exhaled air enters the device through inlet 312 and is directed to control port 318, where it exerts a force onto valve body 314. *Id.* at 21:14–20. "The drive mechanism beam 316 deflects to permit movement of the valve body 314 in response to the force, pivoting at the shoulder 338." *Id.* at 21:22–24. "As the valve body moves away from the control port 318, pressure drops within the patient inlet 312, and the airflow proceeds to the chamber 310 and then to ambient environment via the opening 328." *Id.* at 21:24–28.

2. Analysis

a. Claim 1

Claim 1 requires, *inter alia*, "a vane configured to rotate the blocking segment between the closed position and the open position in response to the flow of air through the opening." Petitioner asserts that drive mechanism beam 316 is a vane because it allegedly performs the function recited by claim 1, i.e., rotate the blocking segment. Pet. 41. As noted above, Petitioner provides no discernable analysis of how the term "vane" should be construed, and Petitioner does not otherwise identify any structural requirements of a vane. Nor does Petitioner provide relevant expert testimony.

Patent Owner argues that a vane is "a blade or plate whose primary purpose is to convert kinetic energy in the form of fluid movement into rotational movement," and that drive mechanism beam 316 is not a vane. Prelim. Resp. 58. Patent Owner also argues that drive mechanism beam 316 is not configured to, and does not, rotate. *Id.* at 59–60. Patent Owner provides illustrations of deflection and rotation, reproduced below.



(Illustration of deflection) (Illustration of rotation)

Id. at 60. The illustrations above show Patent Owner's assertion of the difference between deflection and rotation.

For reasons similar to those described above, and particularly in the absence of a reasonably discernable analysis of the structural requirements

of the term vane and how Dunsmore meets those requirements, Petitioner has not adequately shown that the cited portions of Dunsmore disclose "a vane configured to rotate the blocking segment." We decline to attempt to provide such an analysis in the first instance ourselves.

Additionally, the Petition does not address the distinction between deflection and rotation, and the Petition fails to adequately establish that a person of ordinary skill in the art would consider (1) Dunsmore's valve body 314 to be configured to "rotate relative to the opening," or (2) Dunsmore's alleged vane to be "configured to rotate the blocking segment," as required by claim 1. The only expert testimony of record is that the elements of Dunsmore relied on by Petitioner deflect rather than rotate. Ex. 2001 ¶¶ 231, 234 ("[C]antilevered beams of this type do not rotate; rather, as confirmed by Dunsmore, they deflect ."). That testimony is consistent with the disclosure of Dunsmore, which describes the movement of beam 316 and valve body 314 as deflection rather than rotation. Ex. 1005 at 21:22–24 ("The drive mechanism beam 316 *deflects* to permit movement of the valve body 314 in response to the force, pivoting at the shoulder 338." (emphasis added)). By noteworthy contrast, Dunsmore describes the movement of valve bodies in other embodiments as rotation. *E.g.*, *id.* at 11:62–63.

For the reasons set forth above, we determine that Petitioner does not adequately show that Embodiment 2 of Dunsmore discloses a vane. Moreover, we determine that Petitioner does not adequately show that Dunsmore's valve body 314 is configured to "rotate relative to the opening," as required by claim 1. Therefore, Petitioner has not established a reasonable likelihood of prevailing with respect to claim 1.

Claims 2, 4, 5, 7, and 8 include the same limitations because they depend, directly or indirectly, from claim 1. Claims 20 and 21 require a vane (but not rotation). Because Petitioner's analysis of those claims fails to remedy the deficiencies described above, Petitioner has likewise failed to establish a reasonable likelihood of prevailing as to those claims.

b. Claim 18

As discussed above, independent claim 18 requires "a blocking segment configured to *translate* relative to the opening" (emphasis added). Petitioner's analysis of claim 18 is silent regarding that requirement. *See* Pet. 48–49. Although unstated in the Petition, which does not use the word "translate" in its discussion of claim 18, *see id.*, Petitioner apparently relies on its analysis of claim 1, which, as described above, requires rotation—not translation.

For essentially the reasons discussed above, Petitioner fails to show that a person of ordinary skill in the art would consider the movement of Dunsmore's valve body 314 to be translation relative to an opening. Petitioner has not established a reasonable likelihood of prevailing with respect to claim 18.

Because claims 19–22, 25, and 26 include the "configured to translate" limitation by their dependence from claim 18, and the Petition's analysis of those claims fails to remedy the deficiency described above, Petitioner likewise has not established a reasonable likelihood of prevailing with respect to those claims.

F. ANTICIPATION BY DUNSMORE (EMBODIMENT 3)

Petitioner asserts that Embodiment 3 (Fig. 20) of Dunsmore anticipates claims 1, 2, 4, 18, and 20–22. Pet. 52–58.

1. Dunsmore (Embodiment 3)

Figure 20 of Dunsmore is reproduced below.

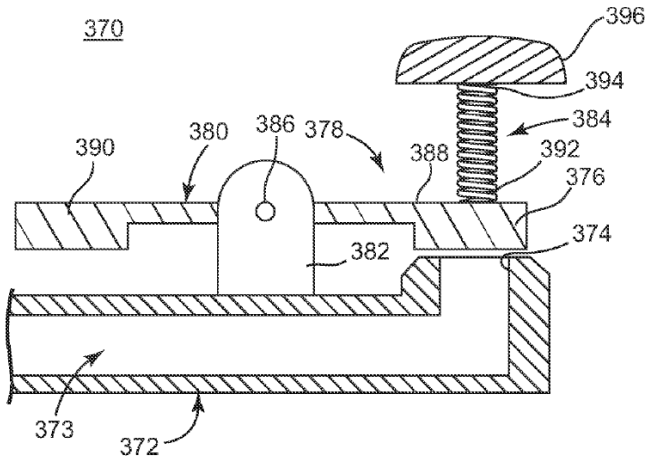


Fig. 20

Figure 20 depicts "an interrupter valve assembly useful with" other embodiments of Dunsmore, including Embodiment 2 discussed above. Ex. 1005 at 4:49–50. Figure 20 shows patient inlet 373, control port 374, valve body 376, first side 388, drive mechanism 378, arm or member 380, pivot point 386, and second side 390. *Id.* at 21:58–22:11. Dunsmore discloses that the elements of the assembly constitute "a rocker-type arrangement" in which, "as the valve body 376 approaches the control port 374, a back pressure is created within patient inlet 373. . . . With this arrangement, then, an oscillatory PEP therapy can be delivered . . . ." *Id.* at 22:20–37.

2. Analysis

a. Claim 1

Claim 1 requires, *inter alia*, "a vane configured to rotate the blocking segment between the closed position and the open position in response to the flow of air through the opening." Petitioner asserts, without meaningful elaboration, that, as depicted in Figure 20, first side 388 is a vane. Pet. 53. As above, Petitioner provides no claim construction analysis, no reasonably discernable discussion of the structural requirements of the term "vane," and no supporting expert testimony. *See id.*

Relying on the same proposed construction of the term "vane" discussed above, Patent Owner argues that the rocker arm of Figure 20 is not a vane, and that it "is simply a support member for positioning the valve body over the control port." Prelim. Resp. 67. Patent Owner also points out that, unlike the vanes disclosed by the '588 patent, Dunsmore's arm "is not exposed to airflow," but "is adjacent and runs parallel to the tube, such that airflow through the tube does not impact the arm." *Id.* at 68. Patent Owner's argument is supported by expert testimony. Ex. 2001 ¶ 263–269.

For reasons essentially the same as those described above, Petitioner has not adequately shown that the cited portions of Dunsmore disclose a vane, particularly in the absence of an analysis of the structural requirements of the term "vane" and how Dunsmore meets those requirements. We decline to attempt to provide such an analysis in the first instance ourselves. Accordingly, Petitioner has not established a reasonable likelihood of prevailing with respect to claim 1. Because claims 2, 4, 20, and 21 also require a vane either directly or due to claim dependency, and Petitioner's analysis of those claims does not remedy the deficiency described above,

Petitioner has likewise failed to establish a reasonable likelihood of prevailing as to those claims.

b. Claim 18

As discussed above, independent claim 18 requires "a blocking segment configured to *translate* relative to the opening" (emphasis added). Petitioner's analysis of claim 18 is again silent regarding that requirement. *See* Pet. 56. As with Ground 2, Petitioner apparently relies on its analysis of claim 1, which, as explained above, requires rotation—not translation.

For essentially reasons stated above in our discussion of other proposed grounds, Petitioner's limited analysis fails to show that a person of ordinary skill in the art would consider the movement of Dunsmore's valve body 376 to be translation relative to an opening. Therefore, Petitioner has not established a reasonable likelihood of prevailing with respect to claim 18.

Because claims 20–22 include the "configured to translate" limitation by their dependence from claim 18, and the Petition's analysis of those claims fails to remedy the deficiency described above, Petitioner likewise has not established a reasonable likelihood of prevailing with respect to those claims.

G. OBVIOUSNESS OVER DUNSMORE

Petitioner asserts that claims 3, 9–17, 23, and 24 would have been obvious over Dunsmore. Pet. 58–69.

1. Claim 3

Claims 3 depends from claim 2, which depends from claim 1. As discussed above, claim 1 requires a vane configured to rotate a blocking

segment. Petitioner's obviousness analysis of claim 3 is deficient for essentially the reasons discussed above. *See* Pet. 58–60. Namely, Petitioner fails to adequately show that a person of ordinary skill would consider beam 550 to teach or suggest a "vane" or would consider valve body 512 to rotate rather than to deflect. *E.g.*, Prelim. Resp. 73; Ex. 2001 ¶ 288–297 ("[T]he beam 550 is not a vane, and . . . the beam does not rotate the alleged blocking segment."). Accordingly, Petitioner fails to establish a reasonable likelihood of prevailing with respect to claim 3.

2. Claims 9–17, 23, and 24

Claims 9–17, 23, and 24 require, either directly or through dependency, "a blocking segment configured to translate relative to the opening." As explained above, Petitioner's anticipation analysis of that limitation is inadequate to establish a reasonable likelihood that Petitioner would prevail as to the claims that include it. In its obviousness analysis, Petitioner appears to continue to treat translation as synonymous with rotation, *see* Pet. 63 (arguing that Dunsmore discloses translation because "valve plate segments 232, 234 rotat[e] about the vane"), and any additional analysis in the Petition related to obviousness focuses on the dimension against which the movement is measured, not on whether the movement itself constitutes translation, *see id.* at 61–64. As above, Petitioner gives no discernable claim construction analysis of the term "translate" and provides no supporting expert testimony for its assertion that Dunsmore's blocking segments translate relative to an opening.

Essentially for reasons set forth above, Petitioner fails to adequately show that rotation is synonymous with translation, or that a person of ordinary skill in the art would have considered Dunsmore's blocking

segments to be configured to translate relative to an opening. Accordingly, Petitioner fails to establish a reasonable likelihood of prevailing as to claims 9–17, 23, and 24.

H. OBVIOUSNESS OVER DUNSMORE AND BLACKER

Petitioner asserts that claim 6 would have been obvious over Dunsmore and Blacker. Pet. 69–71. Claim 6 depends from claim 1 and therefore includes the "vane" requirement of claim 1. Petitioner's analysis of this proposed ground does not remedy the deficiencies described above with respect to whether Dunsmore describes a vane. Petitioner does not rely on Blacker for the disclosure of a vane, and Petitioner does not propose incorporating any potential vane from Blacker into the device of Dunsmore. *See id.* Accordingly, Petitioner fails to establish a reasonable likelihood of prevailing as to this proposed ground.

I. OBVIOUSNESS OVER DUNSMORE AND FOWLER-HAWKINS

Petitioner asserts that claims 11, 23, and 24 would have been obvious over Dunsmore and Fowler-Hawkins. Pet. 71–73. Petitioner's analysis, however, focuses on the shape of the opening and the conduit, and does not remedy the Petition's inadequacies concerning the "configured to translate relative to an opening" limitation that is part of claims 11, 23, and 24 through claim dependency, discussed above. Accordingly, for the reasons set forth above, the Petition does not establish a reasonable likelihood of prevailing as to this proposed ground of unpatentability.

J. ANTICIPATION BY FORAN

Petitioner asserts that Foran anticipates claims 1–4, 6–8, 18, 20, 21, 25, and 26. Pet. 83–90.

1. Foran

Foran, titled "Positive Expiratory Pressure Device," generally concerns PEP therapy devices that "provide[] a variable frequency and variable magnitude positive expiratory pressure by utilizing a nonlinear orifice for adjusting and maintaining a desired positive expiratory pressure oscillation." Ex. 1006 at Abstract. Figure 3 of Foran is reproduced below.

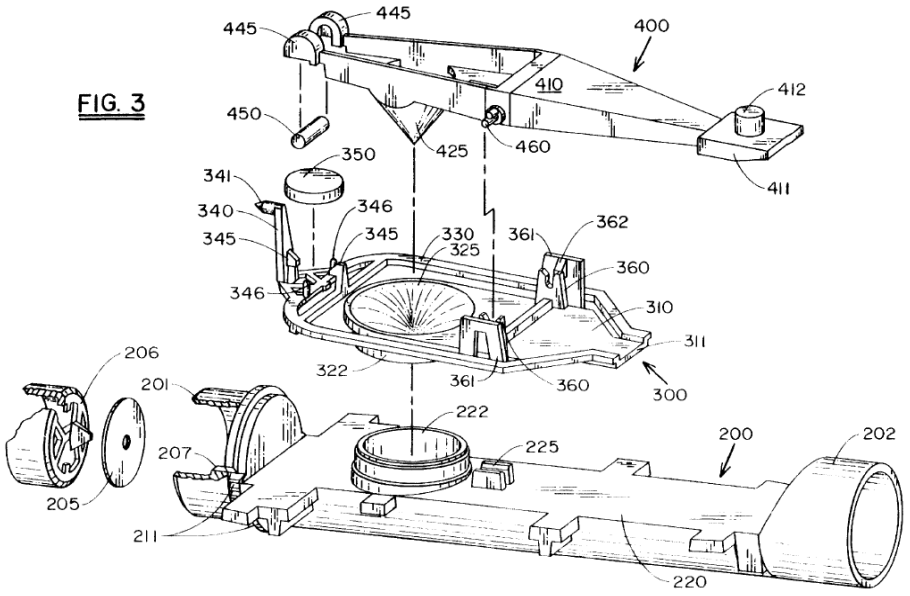


Figure 3 of Foran is "an exploded perspective view of a portion of the invention to better illustrate the manner in which a user produces an oscillatory positive expiratory pressure." *Id.* at 2:48–51. Figure 3 depicts patient input end 202, air flow tube 200, tapered conical interior surface 325, circular opening 326 (*see* Fig. 4), and rocker assembly 400 comprising flow cone 425, rocker platform 410, and pivot pins 460. *Id.* at cols. 3–5. As summarized by Petitioner:

> When a patient exhales into "patient input end 202," air passes through tube 200 and up through opening 326 (Fig. 4) where it is intermittently blocked by "flow cone 425" attached to rocker arm 400; "flow cone 425 is sized and positioned to be inserted into the tapered conical interior 325 . . . for *closing* the circular

> opening 326." (*Id.*, 5:34-37 (emphasis); 7:6-30 (detailing rotation of rocker arm).)

Pet. 14.

2. Analysis

a. Claim 1

Claim 1 requires, inter alia, "a vane configured to rotate the blocking segment between the closed position and the open position in response to the flow of air through the opening." Petitioner argues that Foran's rocker assembly 400 constitutes a vane. Pet. 74. As above, Petitioner provides no claim construction analysis or supporting testimony from an expert, and Petitioner's assertion again appears to be based on functional rather than structural considerations. *See id.* at 77.

Relying on the proposed claim construction for "vane" discussed above and the testimony of Dr. Durgin, Patent Owner argues that Foran's rocker assembly is not a vane because it is not "a blade or plate whose primary purpose is to convert kinetic energy in the form of fluid movement into rotational movement." Prelim. Resp. 84. Patent Owner points out that rocker assembly 400 "is parallel to tube 200 such that air exhaled into the tube does not interact with the rocker platform," and that the rocker platform 410 includes "multiple cut outs . . . which would permit air to move past and avoid interaction with the rocker platform. These are not characteristics of a vane." *Id.* at 84–85 (citing Ex. 2001 ¶ 354). According to Dr. Durgin, "rocker platform 410 and cone 425 are most appropriately described as a pressure relief valve, not a vane." Ex. 2001 ¶ 355.

As above, and for essentially the same reasons, Petitioner has not adequately shown that Foran's rocker assembly constitutes a vane.

Petitioner provides no discernable analysis of the structural requirements of the term "vane" and how Foran meets those requirements. *See* Pet. 74, 77. We decline to attempt to provide such an analysis in the first instance ourselves. Even assuming that Foran's rocker platform performs the function of the vane recited by claim 1, that is not enough to show that it possesses required structure. *Cf. Gardiner*, 171 F.2d at 315–16 ("It is trite to state that the patentability of apparatus claims must be shown in the structure claimed and not merely upon a use, function, or result thereof.").

Accordingly, the information presented in the Petition fails to establish a reasonable likelihood that Petitioner would prevail with respect to claim 1. Because claims 2–4, 6–8, 20, and 21 also require a vane, and Petitioner's analysis of those claims does not remedy the deficiency described above, Petitioner has likewise failed to establish a reasonable likelihood of prevailing as to those claims.

b. Claim 18

Claim 18 requires, inter alia, "a blocking segment configured to translate relative to the opening." Petitioner asserts that "Claim 18 is substantially identical to claim 1," and Petitioner fails to acknowledge or address the fact that claim 1 requires "rotat[ion]," as opposed to the "translat[ion] required by claim 18. The word "translate" or "translation" does not appear in Petitioner's analysis of Foran. *See* Pet. 73–85.

As above, Patent Owner argues that the movement of Foran's blocking segment does not constitute translation, and that Foran's blocking segment is not configured to translate. *See* Prelim. Resp. 86–88.

Petitioner's showing is inadequate because Petitioner does not address a relevant claim limitation ("translate") in its discussion of Foran. Even

were we to treat Petitioner's discussion as incorporating the same analysis of "translate" discussed above with respect to other proposed grounds of unpatentability, i.e., that "translate" is synonymous with "rotate," that analysis is inadequate for the reasons discussed above, particularly in view of the presumption that "translate" means something different from "rotate." *See Nystrom*, 424 F.3d at 1143. We decline to attempt to provide in the first instance ourselves an analysis of why Foran's cone should be considered as "configured to translate relative to the opening." Petitioner fails to establish a reasonable likelihood of prevailing with respect to claim 18.

Claims 20, 21, 25, and 26 depend, directly or indirectly, from claim 18, and Petitioner's analysis of those claims does not remedy the deficiency discussed above. Accordingly, Petitioner likewise fails to establish a reasonable likelihood of prevailing as to those claims.

III. CONCLUSION

For the reasons set forth above, we determine that the Petition fails to demonstrate a reasonable likelihood of prevailing as to any challenged claim.

IV. ORDER

It is hereby:

ORDERED that the Petition is *denied*, and no trial is instituted.

For PETITIONER:

Richard T. Matthews
Andrew R. Shores
WILLIAMS MULLEN, P.C.
rmatthews@williamsmullen.com
ashores@williamsmullen.com

For PATENT OWNER:

David P. Lindner
William H. Frankel
BRINKS GILSON & LIONE
dlindner@brinksgilson.com
wfrankel@brinksgilson.com