IN THE 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

Patent No. U.S. 9,808,588
Filing Date: March 8, 2017
Issue Date: November 7, 2017

Title: OSCILLATING POSITIVE RESPIRATORY PRESSURE DEVICE

Inter Partes Review No.: Unassigned

PETITION FOR *INTER PARTES* REVIEW OF CLAIMS 1-26 UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.100 *et seq.*

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I. INTRODUCTION

Pursuant to 35 U.S.C. § 311 and 37 C.F.R. § 42.100, Petitioner D R Burton Healthcare LLC ("Petitioner") petitions for *inter partes* review of claims 1-26 of U.S. Patent No. 9,808,588 (Exhibit 1001, "the '588 Patent"; Listing of Claims 1-26, Exhibit 1002). The '588 Patent was filed in the name of, and originally assigned to, Trudell Medical International ("Patent Owner").

Patent Owner, Petitioner, and several other companies sell positive pressure respiratory devices that variably and/or at least partially restrict the airflow of a user for therapy purposes. The '588 Patent family's original application was Application Ser. No. 12/472,215, now U.S. 8,539,951, having its only independent claim 1 directed to an embodiment disclosed in the figures and requiring a "restrictor member rotatably mounted within the interior chamber . . . having an axis of rotation substantially perpendicular to the exhalation flow path . . . ***and being rotatable through a complete revolution***." Similarly, all three independent claims in the next family member (U.S. 9,636,473) require a "restrictor member [that] has an axis of rotation substantially perpendicular to a flow of air passing through the inlet and is ***rotatable through a complete revolution***."

When Petitioner's product entered the market in November 2016, the '588 Patent family's claims altered course. Notably absent from the '588 Patent is a requirement of any "restrictor member . . . rotatable through a complete

revolution." Instead, the '588 Patent's claims require "a blocking surface of [a] blocking segment . . . equal to or greater than a size of the opening." This drastic change in scope is important when considering the TrackOne prosecution of the '588 Patent and the 191 references of record, especially where Petitioner's primary references (Dunsmore and Foran) include at least five distinct embodiments that invalidate the '588 Patent.

This Petition demonstrates a reasonable likelihood that Petitioner will prevail with respect to at least one of the challenged claims. Thus, a trial for *inter partes* review on all of the challenged claims 1-16 should be instituted. *See SAS Inst., Inc. v. Iancu*, 584 U.S. ___, ___, 2018 WL 1914661 at *10 (April 24, 2018). Evidence in this Petition demonstrates that claims 1-26 of the '588 Patent are unpatentable under 35 U.S.C. (pre-AIA) § 102 and/or § 103. Petitioner respectfully requests that claims 1-26 of the '588 Patent be rejected and cancelled.

II. MANDATORY NOTICES (37 C.F.R. § 42.8(B))

A. Real Parties in Interest (§ 42.8(b)(1))

The real party in interest for this Petition is D R Burton Healthcare LLC.

B. Related Matters (§ 42.8(b)(2))

The '588 Patent is asserted against Petitioner in *Trudell Medical International v. D R Burton Healthcare LLC*, Case No. 4:18-CV-00009, filed in the U.S. District Court for the Eastern District of North Carolina on January 29, 2018 (the "District Court Litigation"). (Exhibit 1003.)

C. Counsel and Service Information (§§ 42.8(b)(3)-(4) and 42.10(a))

Petitioner appoints Richard T. Matthews (Reg. No. 53,284) as lead counsel and Andrew R. Shores (Reg. No. 72,108) as back-up counsel. Contact information for each is included below:

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A power of attorney with designation of counsel is filed herewith in accordance with 37 C.F.R. § 42.10(b).

D. Service of Petition (§ 42.105)

As the attached Certificate of Service indicates, this Petition and all supporting evidence is being served in accordance with § 42.105.

III. PAYMENT OF FEES FOR *INTER PARTES* REVIEW (§ 42.15(A))

This petition for *inter partes* review of all 26 claims of the '588 Patent is accompanied by a fee payment of $39,900.00, which includes the $15,500.00 *inter partes* review request fee, the $1,800.00 fee for requesting review of each claim in excess of 20, the $15,000.00 *inter partes* review post-institution request fee, and the $6,600.00 post-institution fee for review of each claim in excess of 15. § 42.15(a). The Commissioner is authorized to charge any fees required by

§ 42.15(a) and not submitted with the petition to Deposit Account No. 50-0766 (Ref. 078332.0001).

IV. CERTIFICATION OF STANDING AND CONTESTABILITY OF PATENT (§ 42.104(A))

The '588 Patent was filed on March 8, 2017 and granted on November 7, 2017 and is therefore eligible for *inter partes* review. § 42.102(a)(2). Further, the '588 Patent is currently asserted in the District Court Litigation and this Petition is filed within one year of Petitioner being served with the Complaint. § 42.101(b); *see also* Exhibit 1003 (Complaint). Petitioner certifies that the '588 Patent is available for *inter partes* review and that Petitioners are not barred or estopped from requesting *inter partes* review challenging the '588 Patent's claims on the grounds identified herein.

V. IDENTIFICATION OF CHALLENGE AND REQUESTED RELIEF (§§ 42.104(B) & 42.22)

Petitioner requests that the Patent Trial and Appeal Board institute trial on claims 1-26 of the '588 Patent, and cancel those claims as invalid on the following grounds:

Ground 1	Claims 1-2, 7-21, 25-26	35 U.S.C. § 102	Dunsmore (U.S. 8,025,054) (first embodiment, Figs. 9-16)
Ground 2	Claims 1-2, 4-6, 7-8, 18-21, 25-26	§ 102	Dunsmore (second embodiment, Figs. 17-19)

Ground 3	Claims 1-2, 4, 18, 20-22	§ 102	Dunsmore (third embodiment, Fig. 20)
Ground 4	Claims 3, 5, 9-17, 23-24	§ 103	Dunsmore
Ground 5	Claim 6	§ 103	Dunsmore in view of Blacker (U.S. 7,905,228)
Ground 6	Claims 11, 23-24	§ 103	Dunsmore in view of Fowler-Hawkins (U.S. 6,702,769)
Ground 7	Claims 1-4, 6-8, 18, 20-21, 25-26	§ 102	Foran (U.S. 6,581,598)

Section VIII below identifies the evidence in support of the above challenges and identifies where each claim element is found in the identified prior art.

This Petition complies with all statutory and other requirements under 37 C.F.R. §§ 42.104, 42.105, and 42.15, and should therefore be accorded a filing date as of the filing date of this Petition. § 42.106.

VI. OVERVIEW OF THE '588 PATENT

A. Priority Date

The '588 Patent issued on November 7, 2017 from Application No. 15/453,767, filed on March 8, 2017. The '588 Patent purports to be a continuation of Application No. 13/966,759, filed on August 15, 2013, now Patent No. 9,636,473, which is a continuation of application No. 12/472,215, filed on May 25, 2009, now Patent No. 8,539,951, which claims priority to Provisional Application No. 61/056,358, filed on May 27, 2008. Thus, the earliest possible effective filing date for purposes of 35 U.S.C. § 102 is **May 27, 2008**.

B. Summary of Claimed Subject Matter

The ’588 Patent discloses an oscillating positive respiratory pressure apparatus and method for using the same. (’588 Patent, Abstract.) Oscillating positive expiratory pressure (“OPEP”) therapy, or the oscillation of exhalation pressure during exhalation, transmits an oscillating back pressure to the lungs, which may be used to open obstructed airways and loosen secretions contributing to bronchial obstructions. (*Id.*, 1:29-40.)

To generate the oscillating back-pressure, the ’588 Patent discloses different apparatuses that include a housing with an interior chamber, an inlet, an outlet, an exhalation flow path between the inlet and outlet, an opening along the flow path, and a restrictor member rotatably mounted within the interior chamber that moves between an open position allowing air to flow freely through the opening, and a closed position blocking the flow of air through the opening. (*See id.*, 1:59 to 2:5.) As the restrictor member moves between the open and closed positions, respiratory pressure at the chamber inlet oscillates between a minimum when the restrictor member is in the open position and a maximum when the restrictor member is in the closed position. (*Id.*, 2:5-8.)

Devices with these components were not new as of the ‘588 priority date, as several similar devices containing the same components and operating in the same manner were already known in the art.

C. Prosecution History

A copy of the ’588 Patent’s prosecution history is attached as Exhibit 1004. On March 8, 2017, Patent Owner filed the ’759 Application along with a TrackOne Request seeking prioritized examination. Two days later, on March 10, 2017, Patent Owner submitted a lengthy Information Disclosure Statement (“IDS”) identifying approximately 191 references for consideration during the TrackOne process. Buried among these were Dunsmore and Foran, the primary references in Petitioner’s grounds for rejection.

The Examiner issued a Non-Final Rejection on April 6, 2017, rejecting each claim over references not included in the IDS. Patent owner amended the claims to add the limitation “wherein a size of a blocking surface of the blocking segment is equal to or greater than a size of the opening.” (Ex. 1004 at p.82, June 30, 2017 Amendment at 2.) In the August 15, 2017 Notice of Allowability, the Examiner identified Haber (5,372,128), Brown (2008/0053456), and Yoshimoto (6,607,008) as the “closest prior art of record,” but indicated that none of those references teach the new limitation. (*Id.*, p.62, ¶5.) The Examiner did not address Dunsmore or Foran, Petitioner’s primary references. Claims 1-26 of the ’588 Patent are invalid over these references.

D. Claim Construction

The ’588 Patent has not expired, and therefore its claims are given the “broadest reasonable construction in light of the specification of the patent in which it appears” to a person having ordinary skill in the art (“PHOSITA”). § 42.100(b); *see also SAP America, Inc. v. Versata Dev. Grp., Inc.*, Case CBM2012-00001, Final Written Decision, p.23 (P.T.A.B. 2013). Under this “BRI” standard, “the claims must be interpreted as broadly as their terms reasonably allow. . . . This means that the words of the claim must be given their plain meaning unless the plain meaning is inconsistent with the specification.” MPEP § 2111.01 (citing cases); *see also In re Am. Acad. of Sci. Tech Ctr.*, 367 F.3d 1359, 1369 (Fed. Cir. 2004).

Petitioner’s claim construction under the “BRI” standard is not binding in litigation related to the ’588 Patent. For this *inter partes* review only, 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.

VII. SUMMARY OF APPLIED REFERENCES

A. U.S. Patent 8,025,054 to Dunsmore

The Dunsmore patent (Exhibit 1005) was filed February 2, 2007, and is a continuation of U.S. Application No. 11/559,288 filed on Nov. 13, 2006 (now U.S. 7,779,841). Dunsmore is prior art under 35 U.S.C. pre-AIA §102(e).

Dunsmore teaches various embodiments of respiratory therapy devices that provide oscillatory positive expiratory pressure ("OPEP" or "oscillatory PEP") like the device in the '588 Patent. (*See generally* Ex. 1001, '588 Patent at 5:9-37; *see also id.*, 1:66 to 2:5 ("many oscillatory positive expiratory pressure [] therapy devices utilize the patient's breath alone to drive an oscillatory fluid flow restriction").)

Dunsmore teaches a "respiratory therapy device 30" that generally includes a "patient inlet 36," an "exhaust outlet 40," a "chamber 38," and an "interrupter valve assembly 34." (*Id.*, 5:38-46; Fig. 1 (below).) The "interrupter valve assembly 34" can include "at least one control port 44" (*i.e.*, an opening) and a "valve body 46" (*i.e.*, a blocking segment). (*Id.*, 5:46-48.) "The control port(s) 44 fluidly connects the patient inlet 36 and the chamber 38, whereas the valve body 46 is adapted to selectively obstruct or interrupt fluid flow through the control port(s) 44." (*Id.*, 5:49-52; *see also* Fig. 4A; 7:49 to 8:14 (teaching an exhalation flow path from patient inlet 70, through interrupter valve assembly 34 (including the "control port" (opening) and "valve body" (blocking segment), to exhaust outlet 112 (open to ambient)).) The patient's exhaled breath causes the valve body to selectively obstruct the fluid flow through control port(s) 44. (*See, e.g.*, *id.*, 5:57-62.) These features are present in Dunsmore's various embodiments.

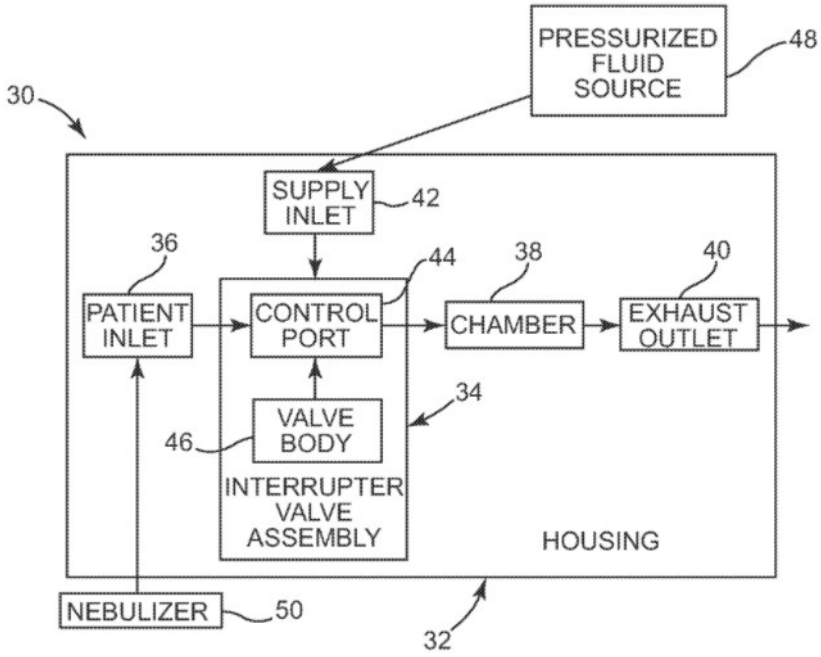


Fig. 1

In the first Dunsmore embodiment, shown in Figs. 2-16, interrupter valve assembly 190 (*e.g.*, Figs. 9 & 12 (excepted below)) includes "one or more control ports 200a, 200b, a valve body 202, and a drive mechanism 204." (*Id.*, 15:25-26.) "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." (*Id.*, 15:27-29.) "[F]luid flow between the patient inlet 210 and the first chamber 212 is via the control port(s) 200a, 200b." (*Id.*, 15:37-39.)

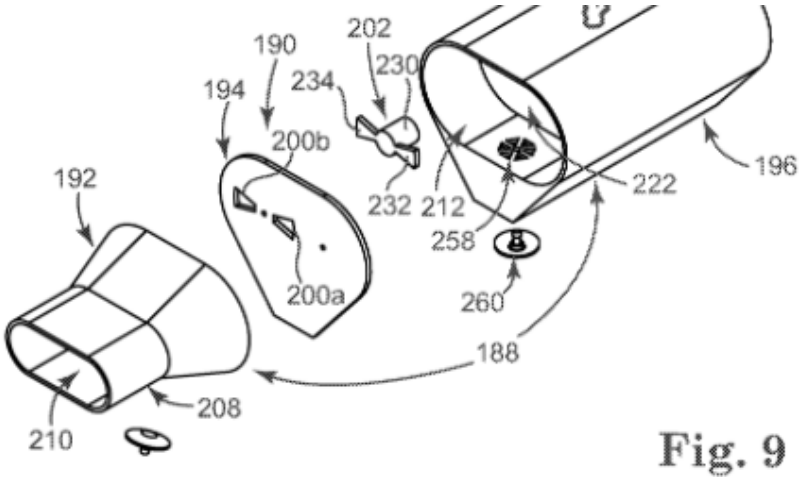


Fig. 9

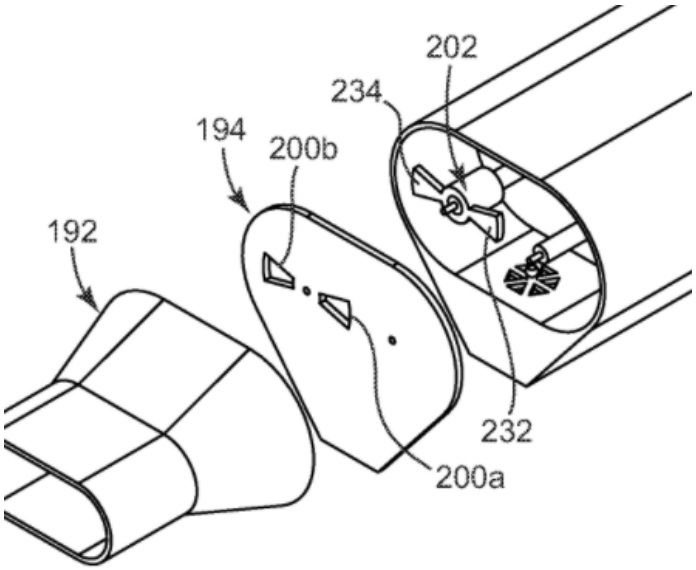


Fig. 12

Valve body 202 can include valve plate segments 232, 234 that are "shaped and sized in accordance with the control ports 200a, 200b such that when aligned, the valve plate segments 232, 234 can simultaneously obstruct or 'block' the control ports 200a, 200b." (*Id.*, 15:57-66; *see also* 9:5-8 (valve plate segments "can be identical, slightly smaller ***or slightly larger*** than a size and/or shape of the control ports.").)

In the second Dunsmore embodiment, shown in Figs. 17-19, the interrupter valve assembly includes "valve body 314, a drive mechanism or member 316 and a control port 318." (*Id.*, 18:59-61.) "The drive mechanism 316 selectively controls movement of the valve body 314 toward and away from the control port 318, for example in response to air exhaled by a patient during an expiratory phase of a breathing cycle, so as to establish a periodic back pressure within the patient inlet 312." (*Id.*, 18:65 to 19:4.)

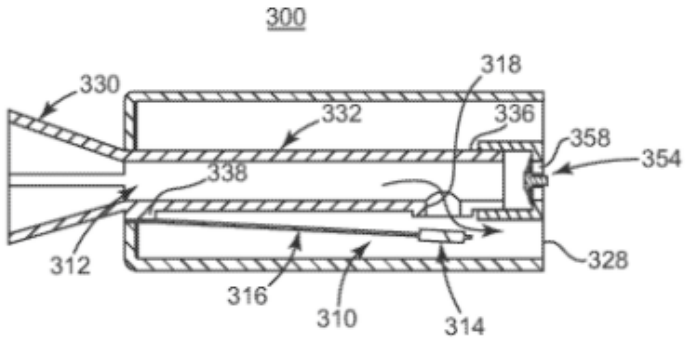


Fig. 19A

In the third Dunsmore embodiment (Fig. 20), the interrupter valve assembly 370 may employ a "rocker-type arrangement," and include a "valve body 376 and a drive mechanism 378." (*Id.*, 21:63-65.) "The valve body 376 is sized in accordance with a size of the control port 374 (*e.g.*, identical, slightly smaller, or slightly larger), and is maintained or driven by the drive mechanism 378." (*Id.*, 21:65 to 22:1.)

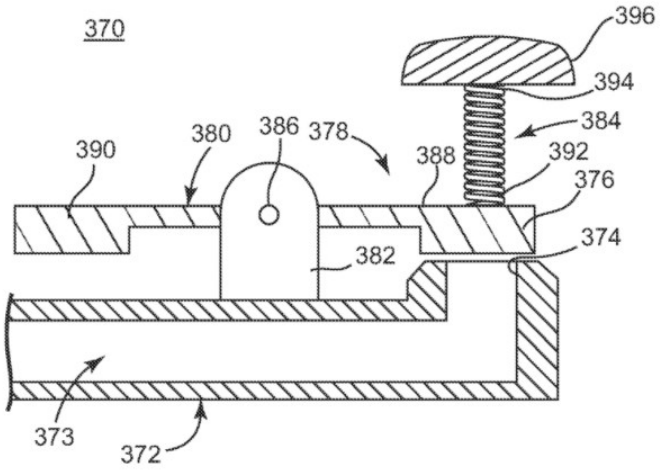


Fig. 20

A fourth Dunsmore embodiment (Figs. 23-28) teaches an interrupter valve assembly that includes a control port 510 and valve body 512. Like control ports 200a, 200b shown in Fig. 12 above, control port 510 may have a non-circular shape, such as generally rectangular (*e.g.*, Fig. 24 (below)).

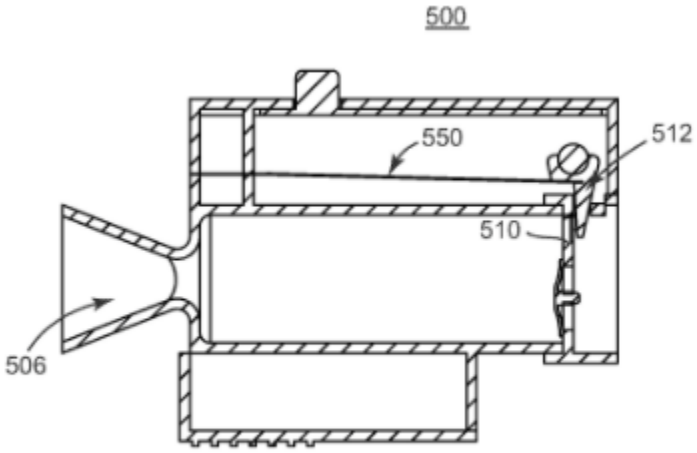


Fig. 27A

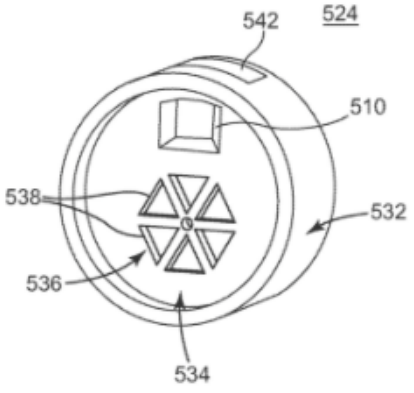


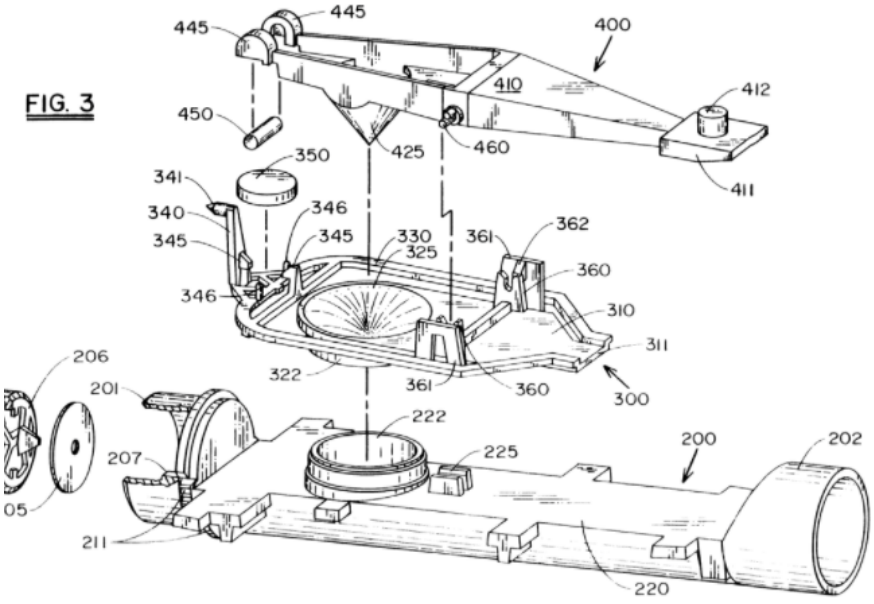
Fig. 24

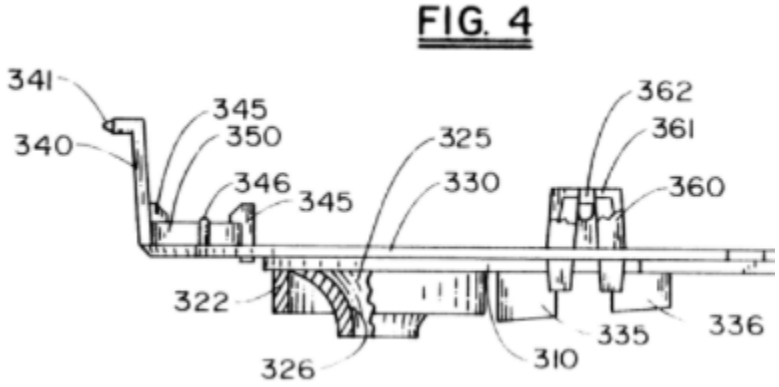
B. U.S. Patent 6,581,598 to Foran

The Foran patent (Exhibit 1006) was filed on Nov. 24, 1999 and issued June 24, 2003. Foran is prior art under 35 U.S.C. (pre-AIA) § 102(b).

Foran teaches a "PEP therapy device which provides . . . positive expiratory pressure by utilizing a nonlinear orifice for adjusting and maintaining a desired positive expiratory pressure oscillation in accordance with . . . a patient's expiratory air." (Foran, Abstract.) Fig. 3 below illustrates Foran's "air driven oscillatory rocker assembly." (*See* Figs. 4-9; 3:35-38.) 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).)

FIG. 3





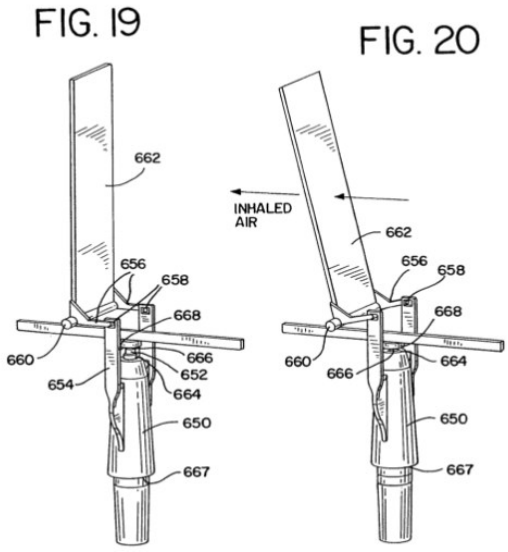
C. U.S. 7,905,228 to Blacker

The Blacker patent (Exhibit 1007) was filed on October 3, 2006, and claims priority to multiple applications, including the original provisional application filed on March 20, 2001. Blacker is therefore prior art under 35 U.S.C. (pre-AIA) § 102(e).

Blacker relates to a nebulizer apparatus and method for reliably delivering aerosolized fluid to an inhaling patient. Nebulizer devices were considered in the art to be closely related to respiratory therapy devices generally. (*See, e.g.*, Ex. 1008, Cook Decl. at ¶5.) Indeed, the '588 Patent teaches use of the disclosed embodiment with nebulizer apparatuses. (*E.g.*, '588 Patent at 2:32-41.) Blacker is therefore analogous art that would have been known to a PHOSITA at the time of the invention.

Blacker teaches, among other things, a blocking mechanism (650) that can be biased during a period of no airflow through an opening by the weight of

gravity alone. (*See, e.g.*, Blacker, Figs. 19 (closed during no airflow) & 20 (open when airflow present).)



D. U.S. 6,702,769 to Fowler-Hawkins

The Fowler-Hawkins patent (Exhibit 1009) was filed October 21, 2002, and claims priority to a provisional application filed January 7, 2002. The Fowler-Hawkins patent issued March 9, 2004, and is therefore prior art under 35 U.S.C. (pre-AIA) § 102(b).

Fowler-Hawkins is directed to a respiratory therapy device similar to that disclosed in the ’588 Patent. Fowler-Hawkins teaches, among other things, the use of non-circular conduits and openings in such devices.

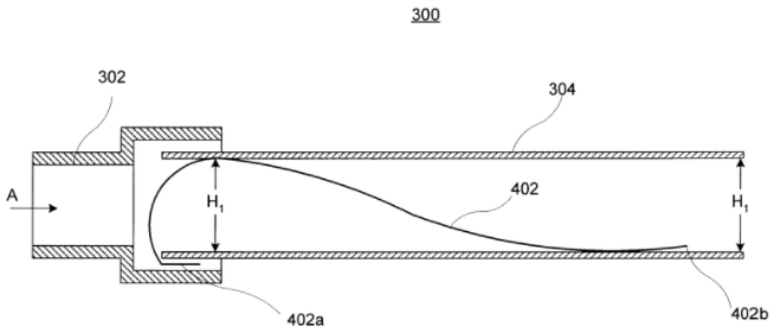


Figure 4

E. Level of Ordinary Skill in the Art

A PHOSITA of respiratory devices at the time of the invention disclosed in the ’588 Patent 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. (Cook Decl. at ¶6.) The 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.*) The relevant person at the time of the invention disclosed in the ’588 Patent would have been familiar with the various devices taught in at least Dunsmore, Foran, Blacker, and Fowler-Hawkins.

VIII. REASONABLE LIKELIHOOD EXISTS THAT THE CHALLENGED CLAIMS ARE UNPATENTABLE

Dunsmore and Foran are the primary references in this Petition. Petitioner cites two additional references, Blacker and Fowler-Hawkins, for features in dependent claims. This Petition asserts seven independent and distinct grounds for invalidity under §§ 102, 103.

Dunsmore and Foran teach several different embodiments of respiratory therapy devices. Each embodiment anticipates different claim groupings, and therefore should be given separate treatment.

Blacker and Fowler-Hawkins teach additional features found in some dependent claims. Blacker teaches that it was well-known at the time of the invention to bias blocking segments in respiratory therapy devices during a period of no air flow using gravity alone. Fowler-Hawkins demonstrates that it was well-known to use non-circular conduits and/or openings in respiratory therapy devices (*e.g.*, generally oblong, rectangular conduits and openings). These references provide a more complete view of the prior art landscape that was not considered during prosecution.

To facilitate "just, speedy and inexpensive resolution" in the spirit of § 42.1(b), Petitioners have diligently minimized both the number of references and the number of invalidity positions against Claims 1-26. The Petition therefore meets the requirements of § 42.1(b). For dependent claims identified in the below grounds, please also refer to the citations associated with the underlying claims from which they depend; for ease of reference, subject matter is generally not repeated.

A. Ground 1: Claims 1-2, 7-21, and 25-26 Are Each Unpatentable Under 35 U.S.C. (pre-AIA) § 102(e) as Anticipated by Dunsmore's *First Embodiment*.

Dunsmore teaches multiple embodiments of a passive respiratory therapy device like that disclosed in the '588 Patent. Dunsmore's *first embodiment* (Figs. 2-16) discloses each limitation of:

- Independent claim 1, and dependent claims 2, 7-8;
- Independent claim 9, and dependent claims 10-17; and
- Independent claim 18, and dependent claims 19-21, 25-26.

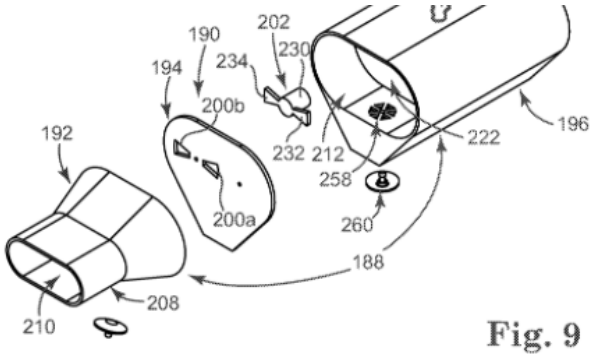


Fig. 9

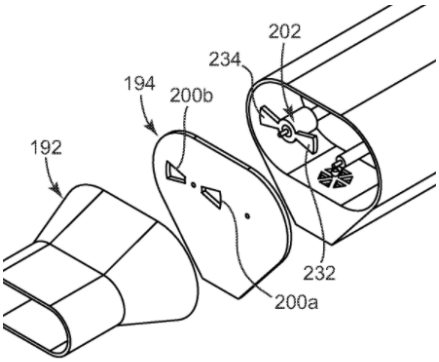


Fig. 12

1. Independent Claim 1

Claim 1 requires a "respiratory treatment device" that includes "an inlet configured to receive exhaled air into the device"; "an outlet configured to permit air to exit the device"; and "an opening positioned in an exhalation flow path defined between the inlet and the outlet." Claim 1 also requires "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." Dunsmore teaches each of these limitations.

Dunsmore's embodiments generally include "a respiratory therapy device 30" that includes a "patient inlet 36" and an "exhaust outlet 40," with an "interrupter valve assembly 34" therebetween. (Dunsmore, 5:38-46; Fig. 1 (below).) "The interrupter valve assembly 34 includes at least one control port 44 [*i.e.*, opening] and a valve body 46 [*i.e.*, blocking segment]. The control port(s) 44 fluidly connects the patient inlet 36 and the chamber 38, whereas the valve body 46 is adapted to selectively obstruct or interrupt fluid flow through the control port(s) 44." (*Id.*, 5:47-52; 54-55 (Valve body 46 may "selectively obstruct (partially or completely) the control port(s) 44").)

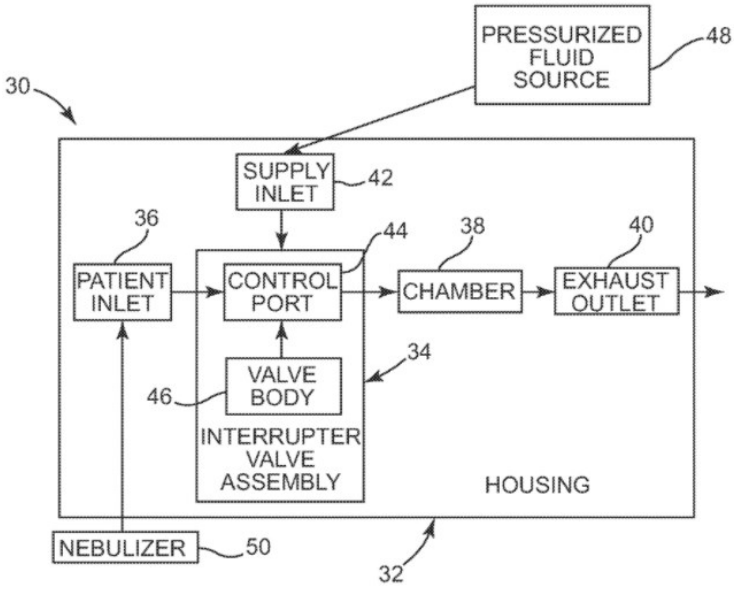


Fig. 1

More particularly, and referring now to a first embodiment shown Figs. 9-16,[1] Dunsmore teaches an "oscillating positive respiratory pressure device" that includes "a patient inlet 210" [*i.e.*, an inlet] configured to receive exhaled air into the device as required by claim 1. (*Id.*, 17:6-8 ("During the expiratory phase, exhaled air from the patient is directed through the patient inlet 210 and toward the plate 194.").)

Dunsmore teaches that with "the valve body 202 arrangement relative to the control ports 200a, 200b [*i.e.*, an opening] of Figs. 14A and 14B, the valve plate segments 232, 234 [*i.e.*, a blocking segment] are not aligned with the control ports 200a, 200b such that the patient's exhaled air flows from the patient inlet 210 through the control ports 200a, 200b [*i.e.*, openings], and into the first chamber 212." (*Id.*, 17:14-19.) "The first chamber 212 is fluidly connected to the second chamber 220 . . . [which] is fluidly connected to an exhaust chamber 254 . . . [which] is open to ambient at an exhaust outlet 262" [*i.e.*, "an outlet configured to permit air to exit the device"]. (*Id.*, 16:46-57.)

[1] Figs. 2-8 are similar to Figs. 9-16, but include supply inlets (74) and nozzles (100a, 100b) that may be connected to external air supply lines not found in the '588 Patent. PHOSITAs would have recognized that most elements taught in Figs. 2-8 and 9-16 are interchangeable. (Col. 15:18-20 ("device 186 [Fig. 9] is similar in many respects to . . . device 60 (Fig. 2)").

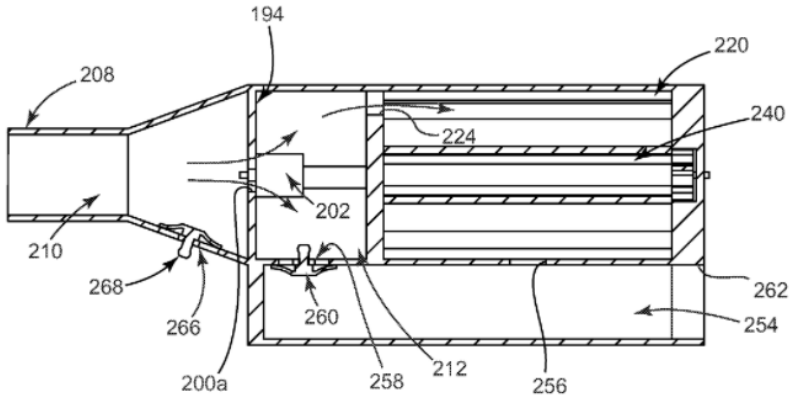


Fig. 14A

Accordingly, Dunsmore teaches the "inlet," "outlet," and "opening" elements of claim 1.

Claim 1 further requires "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," and that "a size of a blocking surface of the blocking segment is equal to or greater than a size of the opening." Dunsmore's first embodiment teaches these limitations.

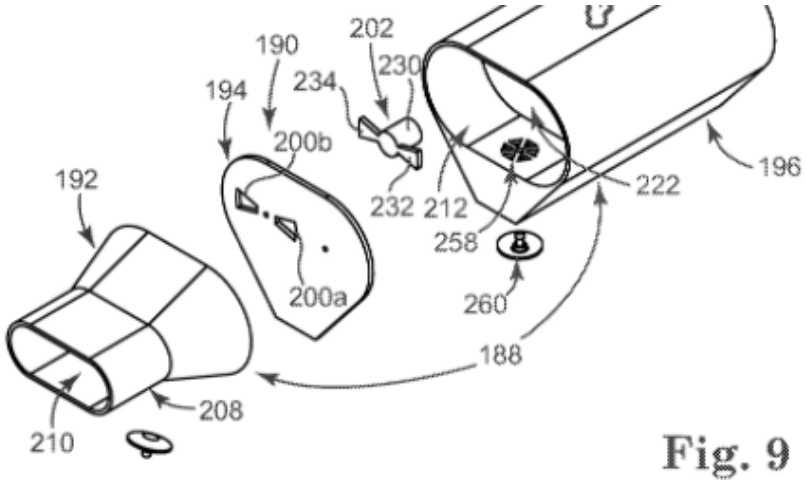
Referring first to Figs. 9 and 11, Dunsmore's "valve body 202" includes "valve plate segments 232, 234" [*i.e.*, blocking segments] that are "shaped and sized in accordance with the control ports 200a, 200b [*i.e.*, opening] such that when aligned, the valve plate segments 232, 234 can simultaneously obstruct or 'block' the control ports 200a, 200b." (*Id.*, 15:60-64.) Importantly, 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

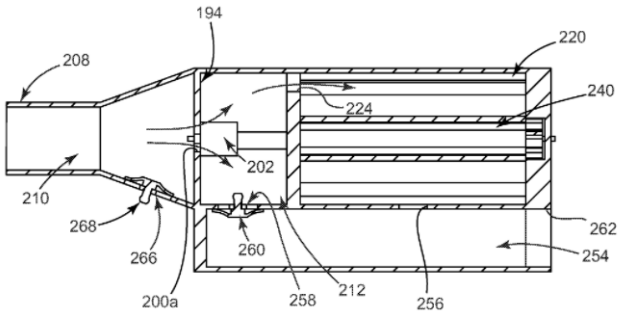
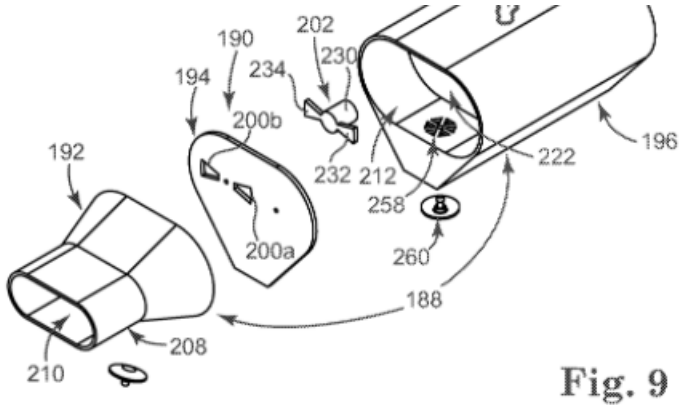
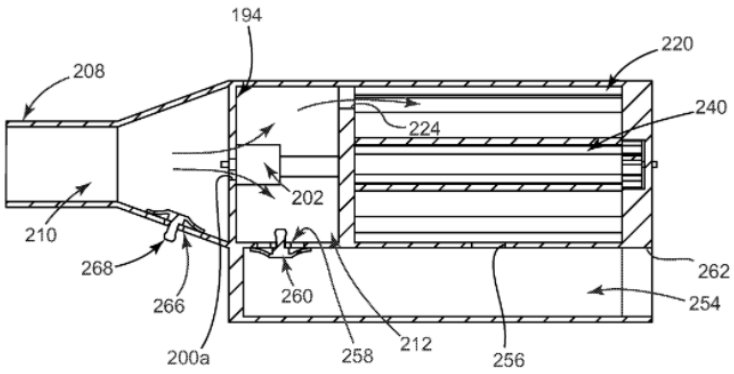
corresponding component of the drive mechanism 204" [*i.e.*, vane]. (*Id.*, 15:64-67; *see also* Fig. 11 and 16:8-9 ("valve body 202 being mounted to the shaft 252a of the first lobe assembly 240").) In this configuration, the "drive mechanism 204 rotates the valve body 202 ***in response to exhaled 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.

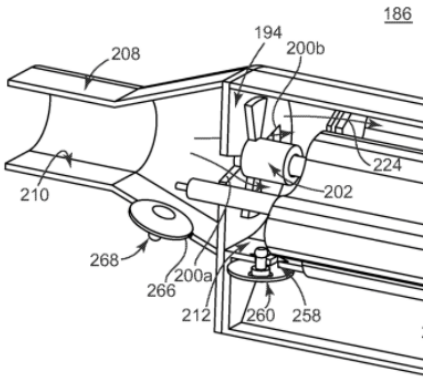
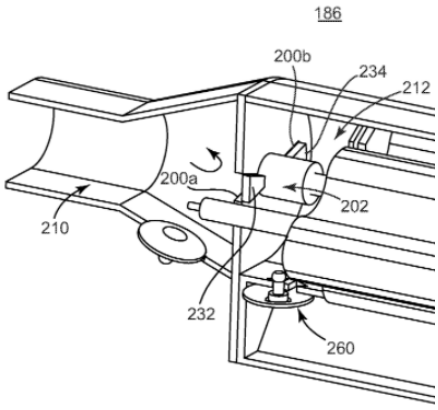
Finally, Dunsmore discloses the final element – "a size of a blocking surface of the blocking segment is equal to or greater than a size of the opening." (*Id.*, 9:5-8 ("a size and/or shape of the valve plate segments 132, 134 [*i.e.*, valve plate segments 232, 234][2] can be ***identical***, slightly smaller ***or slightly larger*** than a size and/or shape of the control ports 78a, 78b [*i.e.*, control ports 200a, 200b]." (emphasis)).)

Accordingly, Dunsmore anticipates claim 1.

[2] Dunsmore teaches that "valve body 202 is similar to valve body 80 (Fig. 2) previously described," which include valve plate segments 132, 134. (*Id.* at 15:57-58; *see also supra* note 1.)

Claim 1	
1. A respiratory treatment device comprising:	"Passive Respiratory Therapy Device" ('588 Patent Title; Abstract). "With the above understanding in mind, FIG. 1 is a block diagram illustrating features of ***a respiratory therapy device 30*** in accordance with some aspects of the present disclosure." (*Id.*, 5:38-40.) "an alternative embodiment respiratory therapy device 186 is shown in exploded form in FIG. 9." (*Id.*, 15:17-18.)  Fig. 9
an inlet configured to receive exhaled air into the device;	"During the expiratory phase, exhaled air from the patient is directed through the patient inlet 210 and toward the plate 194." (*Id.*, 17:6-8.)

an outlet configured to permit air to exit the device;	"the exhaust chamber 254 is open to ambient at an exhaust outlet 262." (*Id.*, 16:56-57.)  Fig. 14A
an opening positioned in an exhalation flow path defined between the inlet and the outlet;	"the patient's exhaled air flows from the patient inlet 210 through the control ports 200a, 200b [*i.e.*, openings], and into the first chamber 212." (*Id.*, 17:14-19; *see also* 16:46-57 (teaching fluid connection from inlet to opening to outlet).)  Fig. 9  Fig. 14A

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	"valve body 202" includes "valve plate segments 232, 234" [*i.e.*, blocking segments] that are "shaped and sized in accordance with the control ports 200a, 200b [*i.e.*, opening] such that when aligned, the valve plate segments 232, 234 can simultaneously obstruct or 'block' the control ports 200a, 200b." (*Id.*, 15:60-64; *see also id.*, 15:26-29 (explaining rotation of segments between open and closed positions).)  **Fig. 14B**  **Fig. 15B**

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;	"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.*, a vane]. (*Id.*, 15:64-67.) "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" (*Id.*, 15:26-29.)
wherein a size of a blocking surface of the blocking segment is equal to or greater than a size of the opening.	"a size and/or shape of the valve plate segments 132, 134 [equivalent to valve plate segments 232, 234] can be ***identical***, slightly smaller ***or slightly larger*** than a size and/or shape of the control ports 78a, 78b [equivalent to control ports 200a, 200b]." (*Id.*, 9:5-8.)

2. Claim 2

Claim 2 depends from claim 1 and requires that "the blocking segment is mounted on the vane." Claim 1 specifies that the "vane" is "configured to rotate the blocking segment . . . in response to a flow of air through the opening."

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").) The drive mechanism 204 rotates in response to the patient's exhaled air and, via shaft 252, causes the blocking segments 232, 234 to rotate between the open and closed positions. (*Id.*, 16:1-11.)

The drive mechanism 204 and shaft 252a therefore correspond to the claimed "vane" under the BRI of that element.

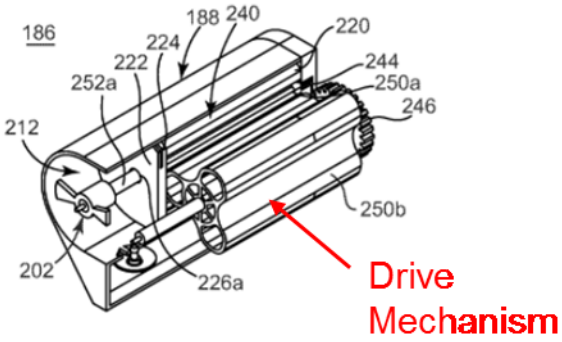


Fig. 11

Accordingly, Dunsmore anticipates claim 2.

3. Claim 7

Claim 7 depends from claim 1, and requires that "the flow of air through the opening is completely blocked when the blocking segment is in the closed position."

Dunsmore teaches that "valve body 80 is constructed such that ***all*** of the control port(s) 78 can simultaneously be obstructed (*e.g.*, ***completely blocked*** or less than completely blocked) by the valve body 80." (*Id.*, 9:33-37 (emphasis added); 6:46-50 ("The valve body 80 . . . is located in close proximity to the control ports 78 such that rotation of the valve body 80 selectively opens and closes (*e.g.*, partial ***or complete obstruction***) the control ports 78 relative to the first chamber 72 and the patient inlet 70." (emphasis)).)

Accordingly, Dunsmore anticipates claim 7.

4. Claim 8

Claim 8 depends from claim 1, and requires that "the blocking surface of the blocking segment contacts the opening when the blocking segment is in the closed position."

Dunsmore teaches that the "valve body 202 defines a ***contact*** face [*i.e.*, blocking surface] . . . positioned to ***interact*** with the control ports 200a, 200b." (*Id.*, 16:32-34 (emphasis).) Further, valve plate segment 232 is pictured as being ***in contact with*** control port 200a and wall 194 (*see* Fig. 14B). (*See* Fig. 15A (below-left and enlarged below-right).)

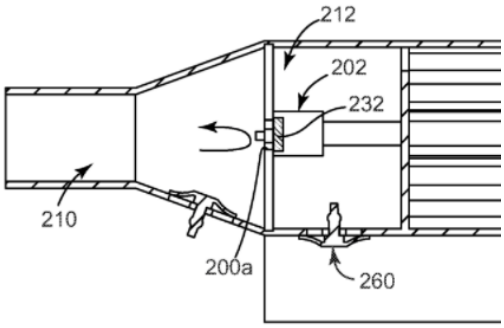
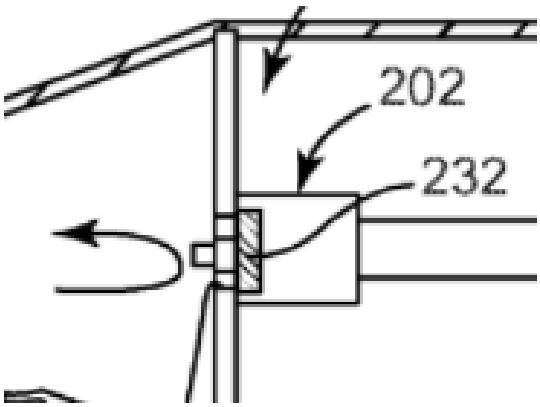


Fig. 15A



Accordingly, Dunsmore anticipates claim 8.

5. Independent Claim 9

Claim 9 is identical to independent claim 1, but rather than requiring the "vane" element, it requires that the "opening" have "a generally oblong cross-sectional shape comprising a shorter first dimension and an elongated second

dimension perpendicular to the first dimension." Claim 9 further requires that the blocking segment "translate relative to the opening along the shorter first dimension."

Dunsmore teaches that the "control port(s) 44 [*i.e.*, opening] fluidly connects the patient inlet 36 and the chamber 38." (*Id.*, 5:49-50.) Importantly, Dunsmore does not limit the control port to any particular shape. Instead, control ports 200a, 200b may take on any number of shapes, including a generally oblong cross-sectional shape having a shorter first dimension (relatively vertical in Fig. 12 below) and an elongated second dimension (relatively horizontal and perpendicular to the shorter first dimension in Fig. 12 below). The control ports are therefore "generally oblong" within the element's BRI.

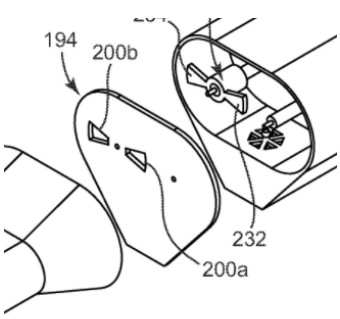
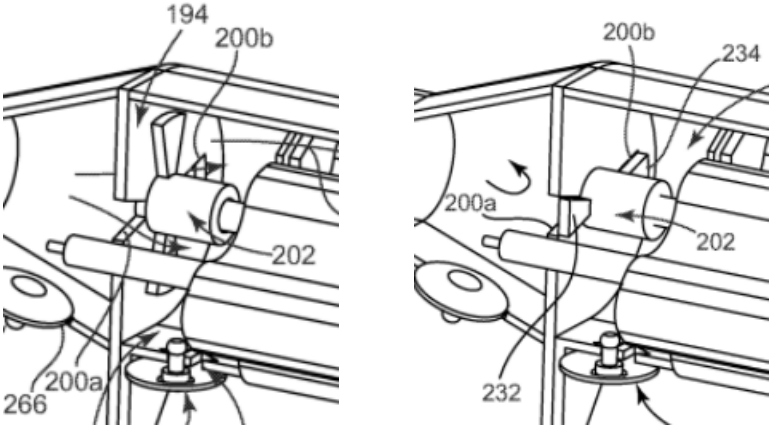


Fig. 12

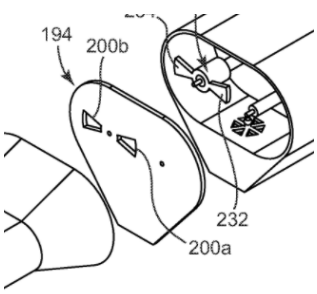
In this arrangement, the valve plate segments 232, 234 [*i.e.*, blocking segments] rotate about vane 252 such that the valve plate segments move along the shorter first dimension. (*Compare* Fig. 14B (below-left, valve plate segments in

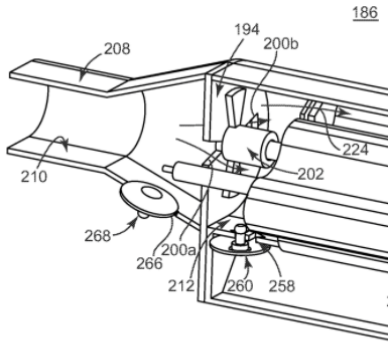
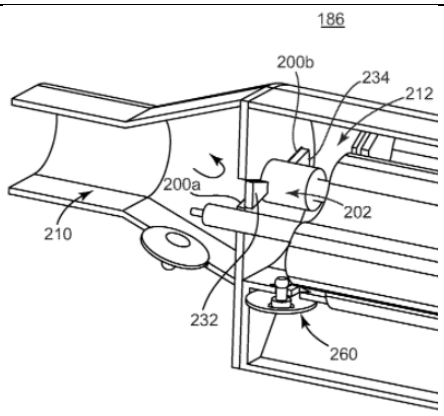
open configuration allowing air to pass through (see arrows passing through 200a, 200b)), *with* Fig. 15B (below-right, valve plate segments in closed configuration blocking the flow of air (see arrow reversed at control ports 200a, 200b)). Dunsmore therefore teaches the valve plate segments translating relative to the opening along the shorter first dimension within the BRI of that element (*i.e.*, valve plate segments translate substantially along the shorter axis (vertically in the figures) of control ports 200a, 200b). *See also* col. 16:65 to 17:3 ("Rotation of the first lobe assembly 240 causes the valve body 202 to similarly rotate, thus periodically moving the valve plate segments 232, 234 into and out of alignment with corresponding ones of the control ports 200a, 200b.")



Accordingly, Dunsmore anticipates claim 9.

Claim 9	
9. A respiratory treatment device comprising:	*See* Claim 1 above.
an inlet configured to receive exhaled air into the device;	*See* Claim 1 above.

an outlet configured to permit air to exit the device;	*See* Claim 1 above.
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	*See* Claim 1 above. *See also, e.g.*, Fig. 12 (illustrating exemplary shape of control ports 200a, 200b that include an oblong cross-sectional shape having a shorter first dimension (vertically in the figures pasted below) and an elongated second dimension (horizontal and perpendicular to the shorter first dimension in the figures below).  Fig. 12 
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; and	*See* Claim 1 above. *See also, e.g.*, Figs 14B and 15B (valve plate segments 232, 234 [*i.e.*, blocking segments] rotate about vane 252 such that the valve plate segments translate relative to the opening along the shorter first dimension (vertical dimension in figures below)).

	 Fig. 14B  Fig. 15B
wherein a size of a blocking surface of the blocking segment is equal to or greater than a size of the opening.	*See* Claim 1 above.

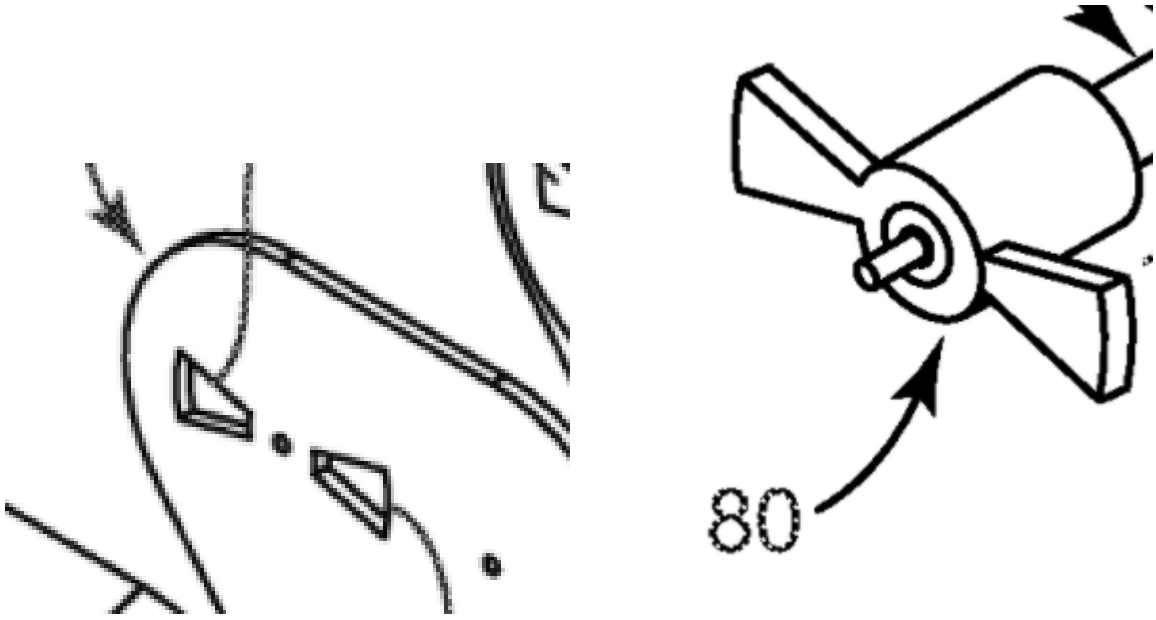
6. Claim 10

Claim 10 depends from claim 9, and requires that the "oblong cross-sectional shape is generally rectangular." An oblong trapezoidal shape like that pictured for example in Fig. 12 is "generally rectangular" under the BRI of that term.

As discussed immediately above, the control ports 200a, 200b may take on any shape, including an oblong, generally rectangular or trapezoidal shape as pictured in, for example, Fig. 12. The shape of valve plate segments 232, 234 in Figs. 12 (excerpted below-left) and Fig. 5B (excerpted below-right) also demonstrate the generally rectangular or trapezoidal shape of control ports 200a,

200b, as Dunsmore teaches that a size and/or shape of the valve plate segments 132, 134 [*i.e.*, valve plate segments 232, 234] can be ***identical***, slightly smaller or slightly larger than a size and/or shape of the control ports 78 a, 78 b [*i.e.*, control ports 200a, 200b] ." (*Id.*, 9:5-8 (emphasis added).)

Accordingly, Dunsmore anticipates claim 10.



7. Claims 11-12

Claim 11 depends from claim 9, and requires "a conduit having a length terminating at the opening, wherein a cross-sectional shape of the conduit along the length matches the cross-sectional shape of the opening." Claim 12 depends from claim 11, and requires that the cross-sectional area of the conduit is less than a cross-sectional area of an opening associated with a patient interface located upstream of the conduit. Dunsmore anticipates both claims.

Dunsmore teaches that a "plate 194 separates the patient inlet 210 and the first chamber 212, and forms the one or more control ports 200a, 200b." (*Id.*, 15:33-35.) The BRI of this element does not include a minimal length, and therefore an opening having any thickness forms a conduit. For example, in Fig. 14B (annotated below), plate 194 has a thickness T. Accordingly, Dunsmore teaches the claimed conduit having a length (*i.e.*, length equivalent to thickness T), terminating at the claimed opening (*i.e.*, control ports 200a, 200b), wherein the cross-sectional shape of the conduit along the length matches the cross-sectional shape of the opening (*i.e.*, the cross-sectional shape of control ports 200a, 200b).

Accordingly, Dunsmore anticipates claim 11.

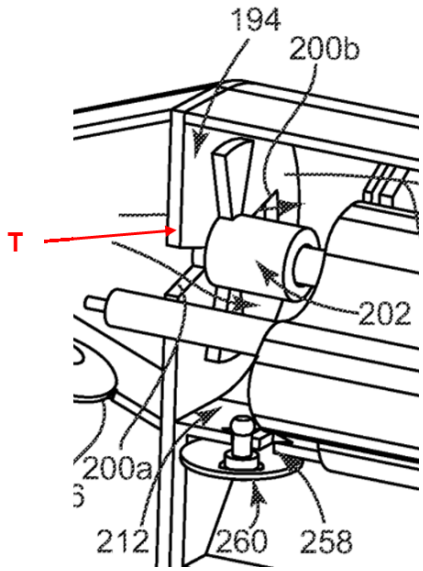


Fig. 14B (enlarged)

Dunsmore further discloses a "mouthpiece 86" (*see* Fig. 2) that is "sized for placement in the patient's mouth." (*Id.*, 6:65-66.) Fig. 2, for example, makes clear

that the cross-sectional area of the openings (*e.g.* control ports 78a, 78b) is plainly less than that of the mouthpiece 86. *See also id.*, 15:35-39 (teaching that "any" number of control ports, "either ***lesser*** or greater" than that shown in Fig. 2, are acceptable).)

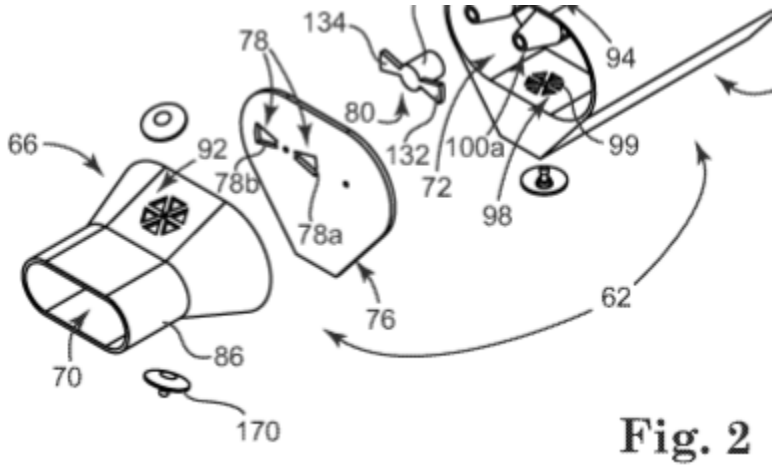


Fig. 2

Dunsmore therefore anticipates claim 12.

8. Claims 13-14 and 16-17

Claim 13-14 and 16-17 depend directly or indirectly from independent claim 9, and require limitations identical to those required by corresponding claims 1, 2, 7, and 8.[3] (*See* Secs. VIII.A.1-4.) For at least those reasons, Dunsmore's first embodiment similarly anticipates claims 13-14 and 16-17.

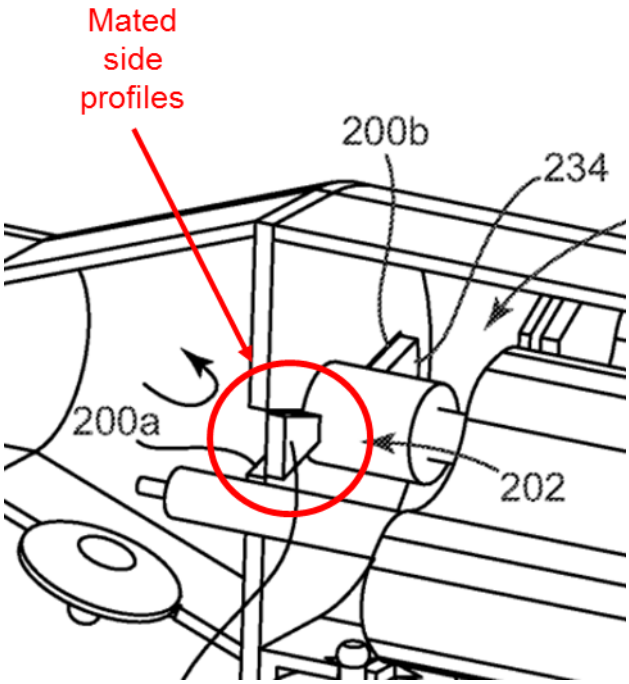
9. Claim 15

Claim 15 depends from 9, and requires that "a side profile of the blocking segment, in the direction of the elongated second dimension, is shaped to mate

[3] Claim 13 uses the term "move" rather than "rotate." The BRI of "move" encompasses "rotate," and therefore the arguments above hold.

with a side profile of the opening, when the blocking segment is in the closed position."

Dunsmore teaches in Fig. 15B that a side profile of the blocking segment (*i.e.*, valve plate segment 232), in the direction of the elongated second dimension (*i.e.*, generally horizontal in Fig. 15B along a line from an outer edge of valve plate segment 232 to an outer edge of valve plate segment 234), is shaped to mate with a side profile of the opening (*i.e.*, control port 200a). This is further supported in the specification. (*Id.*, 9:5-8 (the size and/or shape of the valve plate segments "can be ***identical***" (emphasis)).)



Accordingly, Dunsmore anticipates claim 15.

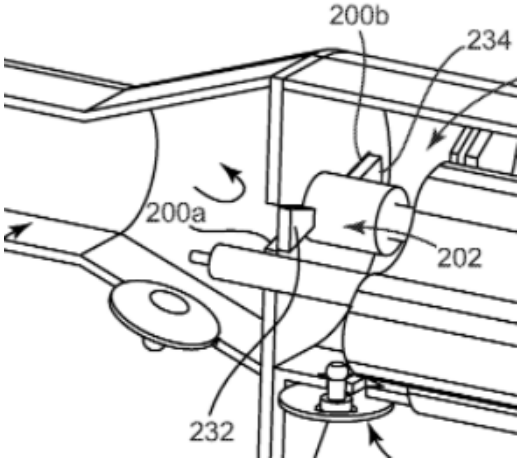
10. Independent Claim 18

Claim 18 is substantially identical to claim 1, except rather than the vane element, it requires that "a side profile of the blocking segment is shaped to mate with a side profile of the opening, when the blocking segment is in the closed position." Under the BRI, this limitation requires the side profiles to have similar shapes and lengths, *i.e.*, shape and length of opening is approximately equal to shape and length of blocking segment.

As discussed with respect to at least claim 15 above, Dunsmore's first embodiment (*e.g.*, Fig. 15B (above)) teaches that a side profile of the blocking segment (*i.e.*, valve plate segment 232) is shaped to mate with a side profile of the opening (*i.e.*, control port 200a). This is further supported in the specification – the size and/or shape of the valve plate segments "can be ***identical***, slightly smaller or slightly larger than a size and/or shape of the control ports." (*Id.*, 9:5-8 (emphasis added).)

For these reasons and those discussed with respect to claim 1, claim 18 is anticipated by Dunsmore.

Independent Claim 18	
18. A respiratory treatment device comprising:	*See* Claim 1 above.
an inlet configured to receive exhaled air into the device;	*See* Claim 1 above.

an outlet configured to permit air to exit the device;	*See* Claim 1 above.
an opening positioned in an exhalation flow path defined between the inlet and the outlet; and	*See* Claim 1 above.
a blocking segment configured to translate 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;	*See* Claim 1 above.
wherein a side profile of the blocking segment is shaped to mate with a side profile of the opening, when the blocking segment is in the closed position; and,	*See* Claim 15 above; *see also* col. 9:5-8 (valve plate segments "can be ***identical***, slightly smaller or slightly larger than a size and/or shape of the control ports."); Fig. 15B (illustrating side profiles having shapes that permit mating when in closed position). 

wherein a size of a blocking surface of the blocking segment is equal to or greater than a size of the opening.	*See* Claim 1 above.

11. Claims 20-21 and 25-26

Claims 20-21 and 25-26 depend directly or indirectly from claim 18, and include limitations identical to those in corresponding claims 1-2 and 7-8.[4] (*See* Sec. VIII.A.1-4.) For at least those reasons, claims 20-21 and 25-26 are similarly anticipated by the first embodiment of Dunsmore.

B. Ground 2: Claims 1-2, 4-8, 18-21, and 25-26 Are Each Unpatentable Under § 102 as Being Anticipated by Dunsmore's *Second Embodiment.*

Dunsmore also teaches a second embodiment of the disclosed respiratory device in Figs. 17-19. This second embodiment includes each and every limitation of, at least:

- Independent claim 1, and dependent claims 2, 4-8; and
- Independent claim 18, and dependent claims 19-21, 25-26.

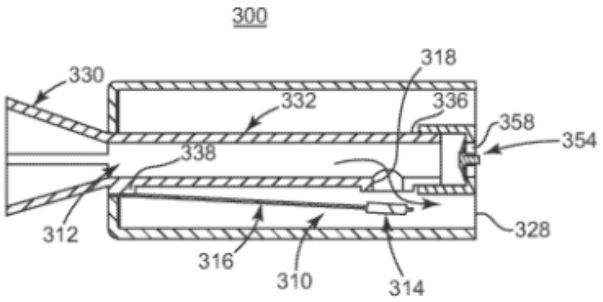


Fig. 19A

[4] *See supra* note 3.

1. Independent Claim 1

The limitations of claim 1 are set forth above. The general disclosure of those elements in relation to Dunsmore Fig. 1 (*see, e.g.*, Sec. VIII.A.1) also apply to the second embodiment. Dunsmore's second embodiment is a therapy device 300 (*e.g.*, Fig. 19A above) where "exhaled air from the patient is forced through the patient inlet 312 [*i.e.*, an inlet configured to receive exhaled air] and toward the distal section 336 of the tube 332." (*Id.* at 21:14-16) "[E]xhaled airflow is directed to and through the control port 318" [*i.e.*, an opening positioned in an exhalation flow path]. (*Id.*, 21:18-19). "[A]irflow exiting the control port 318 exerts a force onto the valve body 314 [*i.e.*, blocking segment configured to rotate relative to the opening] in a direction away from the tube 332 (and thus away from the control port 318), as shown by arrows in FIG. 19A." (*Id.*, 21:19-22).

"The drive mechanism [or member][5] 316 [*i.e.* the vane] selectively controls movement of the valve body 314 toward and away from the control port 318 for example, in response to air exhaled by a patient [*i.e.*, a vane configured to rotate the blocking segment between the closed and open positions in response to flow of air] . . . , so as to establish a periodic back pressure within the patient inlet 312." (*Id.*, 18:65 to 19:3.) "As the valve body 314 moves away from the control port 318 [*i.e.*, to an open position], pressure drops within the patient inlet 312, and the

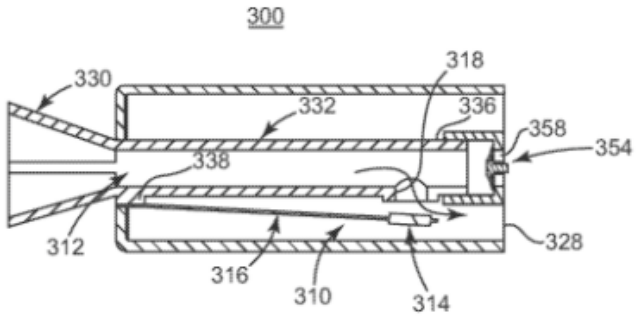
[5] Dunsmore, col. 18:60-61.

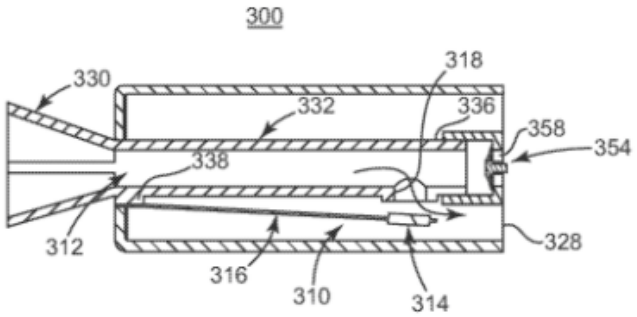
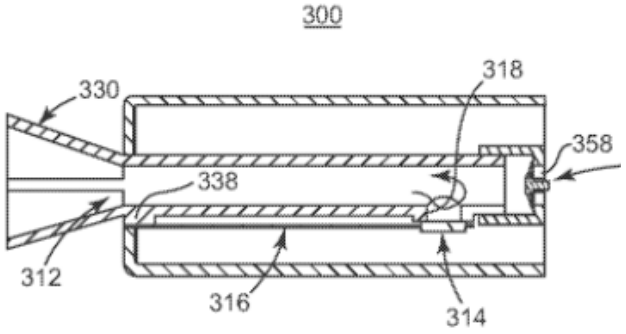
airflow proceeds to the chamber 310 and then to ambient environment via the opening 328 [*i.e.*, an outlet configured to permit air to exit the device]." (*Id.*, 21:24-28.)

The movement of valve member 314 in conjunction with member 316 about the "shoulder [or hinge or pivot point] 338" is a "rotation" within the BRI of that element (*i.e.*, oscillating between two positions about a fixed rotation point is the same as "rotating" between two positions).

Valve member 314 can be "a disc having a size and shape commensurate with a size and shape of the control port 318 (*e.g.*, the valve body 314 can have the same shape dimensions as the control port 318, ***or can be larger*** or smaller than the control port 318)." (*Id.*, 19:49-53 (emphasis).) Dunsmore's second embodiment thus teaches the blocking surface of the blocking segment being equal to or greater than a size of the opening.

Accordingly, Dunsmore's second embodiment anticipates claim 1.

Claim 1	
1. A respiratory treatment device comprising:	"Passive Respiratory Therapy Device" ('588 Patent Title; Abstract). "With the above understanding in mind, FIG. 1 is a block diagram illustrating features of ***a respiratory therapy device 30*** in accordance with some aspects of the present disclosure." (*Id.*, 5:38-40.) "Yet another alternative embodiment respiratory therapy device 300 in accordance with principles of the present disclosure is shown in [Figs. 17-20]." (*Id.*, 18:51-53.)  **Fig. 19A**
an inlet configured to receive exhaled air into the device;	"exhaled air from the patient is forced through the patient inlet 312" (*Id.*, 21:14-16)
an outlet configured to permit air to exit the device;	"the airflow proceeds to the chamber 310 and then to ambient environment via the opening 328." (*Id.*, 21:24-28.)
an opening positioned in an exhalation flow path defined between the inlet and the outlet;	From the inlet, "exhaled airflow is directed to and through the control port 318," and on to the outlet. (*Id.*, 21:18-19).

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	"The drive mechanism 316 selectively controls movement of the valve body 314 toward and away from the control port 318 . . . so as to establish a periodic back pressure within the patient inlet 312." (*Id.*, 18:65 to 19:3; *see also* Figs. 19A (open position) and 19B (closed position)).)  **Fig. 19A**  **Fig. 19B**
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;	"The drive mechanism [or member] 316 [*i.e.* the vane] selectively controls movement of the valve body 314 toward and away from the control port 318 . . . in response to air exhaled by a patient" (*Id.*, 18:65 to 19:3.)

wherein a size of a blocking surface of the blocking segment is equal to or greater than a size of the opening.	Valve body 314 can be "a disc having a size and shape commensurate with a size and shape of the control port 318 (*e.g.*, the valve body 314 can have the same shape dimensions as the control port 318, ***or can be larger*** . . . .)." (*Id.*, 19:49-53.)

2. Claim 2

Claim 2 depends from claim 1, and requires that "the blocking segment is mounted on the vane."

Dunsmore teaches that the "drive mechanism 316 selectively controls movement of the valve body 314 toward and away from the control port 318." (*Id.*, 18:65 to 19:2.) Fig. 19A, for example, illustrates valve member 314 [*i.e.*, blocking member] mounted on drive mechanism 316 [*i.e.*, vane].

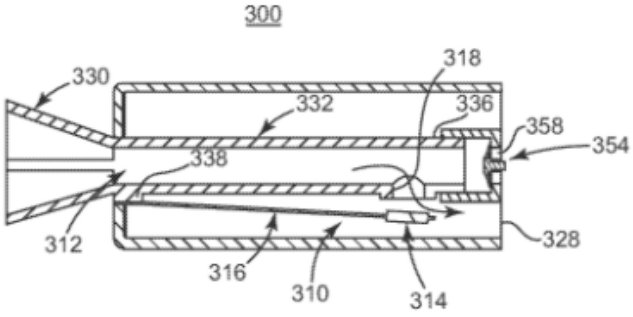


Fig. 19A

Accordingly, Dunsmore anticipates claim 2.

3. Claim 4

Claim 4 depends from claim 1, and requires that "the blocking segment and the vane are rotatable about an axis of rotation perpendicular to a direction of the flow of air through the opening."

Dunsmore teaches that the "airflow exiting the control port 318 exerts a force onto the valve body 314 in a direction away from the tube 332 (and thus away from the control port 318), as shown by arrows in FIG. 19A." (*Id.*, 21:19-22.) "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.*, 21:22-24.)

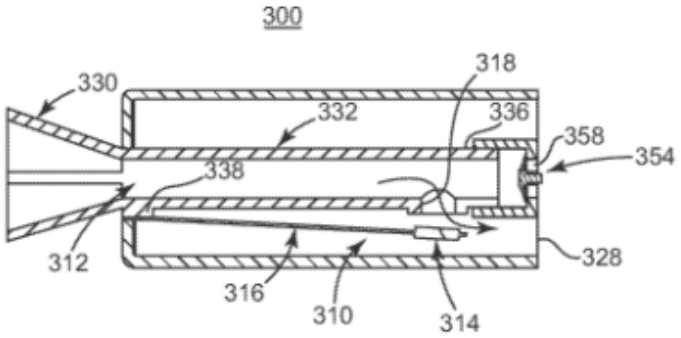


Fig. 19A

Dunsmore's "axis of rotation" is therefore an axis at shoulder 338 in Fig. 19A (*i.e.*, a pivot point) running into and out of the page, which is perpendicular to the direction of airflow moving downward through the control port 318. This pivoting motion is a "rotation" within the BRI of this limitation.

Accordingly, Dunsmore anticipates claim 4.

4. Claim 5

Claim 5 depends from claim 1, and requires that "the blocking segment and the vane have a combined center of gravity offset from the axis of rotation."

The drive mechanism 316 [*i.e.*, vane] and valve member 314 [*i.e.*, blocking segment] "pivot at a shoulder 338." (*Id.*, 21:23-24.) This functions as a "cantilevered-type device," in which the mass of the drive mechanism 316 and valve member 314 extend away from pivot point 338. (*Id.*, 19:64 to 20:2; Fig. 19A.) Thus, Dunsmore teaches a blocking segment and vane with a combined center of gravity offset from the axis of rotation.

Accordingly, Dunsmore anticipates claim 5.

5. Claims 7-8

Dunsmore teaches that "valve body 46" can "selectively obstruct (partially ***or completely***) the control port(s) 44." (*Id.*, 5:53-57 (emphasis).) Further, Fig. 19B illustrates the second embodiment of Dunsmore in the "closed position." As shown in Fig. 18B (below), a gap 362 between "first surface 340" and "surface 344" of control port 318 is disclosed, with the gap having various sizes, ***including zero*** (*i.e.*, surface 340 and surface 344 are in contact when gap is zero). (*Id.*, 20:28-44 ("elimination" of gap 362).) Dunsmore also teaches that "the first surface 340 [of valve body 314] is configured to generally mate with an exterior surface 344 of the inner housing portion 308 at which the control port 318 is defined." (*Id.*, 19:61-63.)

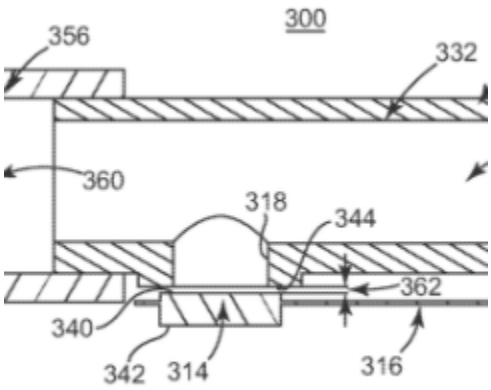


Fig. 18B

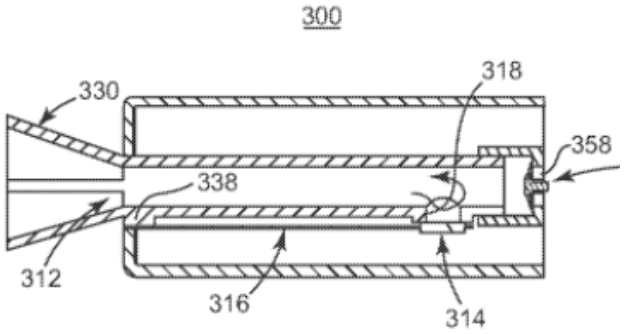


Fig. 19B

Accordingly, as seen in Fig. 19B, Dunsmore teaches that the valve body 314 can completely block the control port 318 when the valve body 314 is in the closed position as required by claim 7 (*e.g.*, when gap 362 is "eliminated" (*id.*, 20:28-44) and "the first surface 344 is configured to generally mate with an exterior surface 344" (*id.*, 19:61-63)). Dunsmore therefore anticipates claim 7.

With gap 362 eliminated, Dunsmore also teaches that valve body 314 [*i.e.*, blocking segment] contacts control port 318 [*i.e.*, opening] in the closed position as required by claim 8. (*Id.*) Dunmore therefore anticipates claim 8.

6. Independent Claim 18

As noted above, claim 18 replaces the "vane" element of claim 1 with "a side profile of the blocking segment is shaped to mate with a side profile of the opening, when the blocking segment is in the closed position."

Dunsmore teaches that "the first surface 340 [of valve body 314] is configured to generally mate with an exterior surface 344 of the inner housing

portion 308 at which the control port 318 is defined." (*Id.*, 19:61-63; *see also id.*, 19:48-53 ("The valve body 314 is . . . a disc having a size and shape commensurate with a size and shape of the control port 318 (*e.g.*, the ***valve body 314 can have the same shape dimensions as the control port 318***, or can be larger . . .)" (emphasis).) Dunsmore therefore teaches that the blocking segment (valve body 314) has a side profile shaped to mate with a side profile of the opening (control port 318). For these reasons and those set forth above with respect to claim 1 (Sec. VIII.B.1), Dunsmore's second embodiment anticipates claim 18.

7. Claim 19

Claim 19 depends from claim 18, and requires that the "side profile of the blocking segment and the side profile of the opening are curved to mate with one another."

Dunsmore teaches that "the first surface 340 can assume a different shape, such as a ***hemispherical***, conical, etc." and "[r]egardless, the first surface 340 is configured to generally mate with an exterior surface of the inner housing portion 308 at which the control port 318 is defined." (*Id.*, 19:58-63.)

Under the BRI of this claim element, Dunsmore anticipates claim 19.

8. Claims 20-21

Claim 20 depends from claim 18, and requires "a vane" identical to that required by claim 1. Claim 21 depends from claim 20, and requires that "the blocking segment is mounted on the vane."

As discussed above (sec. VIII.B.1), Dunsmore teaches that the "drive mechanism 316 [*i.e.* the vane] selectively controls movement of the valve body 314 [*i.e.*, blocking segment] toward and away from the control port 318 [opening], for example in response to air exhaled by a patient." (*Id.*, 18:65 to 19:3.)

Accordingly, Dunsmore anticipates claim 20.

Further, as explained above (sec. VI.B.2 (valve body 314 attached to beam or member 316 (Fig. 19A below)), Dunsmore anticipates claim 21 as well.

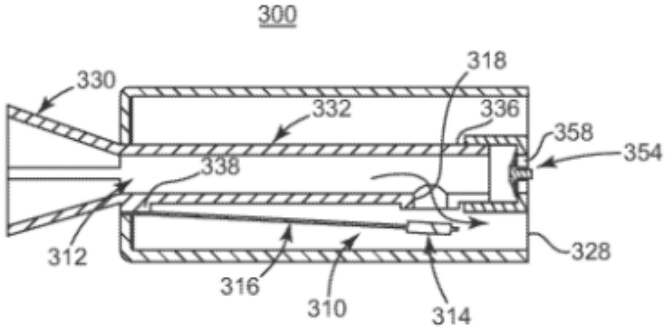
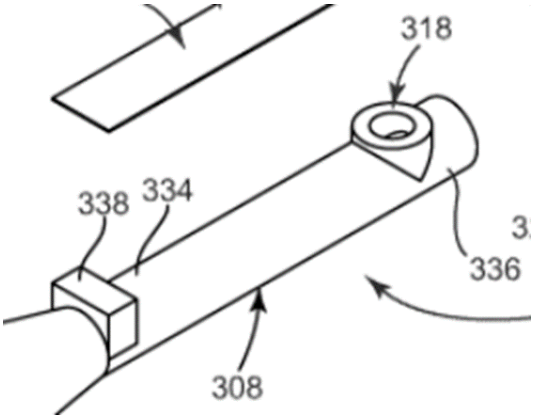


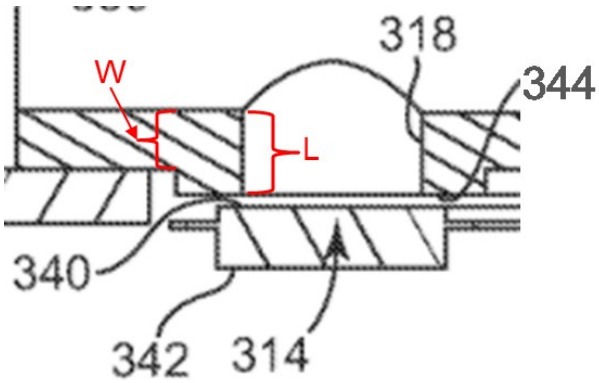
Fig. 19A

9. Claim 22

Claim 22 depends from claim 18, and recites "a conduit having a length terminating at the opening, wherein a cross-sectional shape of the conduit along the length matches a cross-sectional shape of the opening."

As illustrated in Figs. 17 (below-left) & 18B (below-right), respiratory device 300 includes a conduit of length L terminating at control port 318 [*i.e.*, the opening]. The conduit extends from "tube 332" (Figs 17, 18B) to "exterior surface 344 of the inner housing portion 308 at which the control port 318 is defined." (*Id.* at 19:62-63.) Further, the conduit has a length L that is greater than a width W of "tube 332." (*See* Fig. 18B (below-right).) Therefore, under the element's BRI, Dunsmore's second embodiment teaches a conduit having a length [*i.e.*, length L] terminating at the opening [*i.e.*, exterior surface 344 defining control port/opening 318]. Dunsmore's conduit also has a cross-sectional shape along the length that matches a cross-sectional shape of the opening. (*Id.*)





Accordingly, Dunsmore anticipates claim 22.

10. Claims 25-26

Claims 25-26 each depend directly from claim 18, and include limitations identical to those claimed in corresponding claims 7-8. (*See* sec. VIII.B.5.) For at

least those reasons, Dunsmore's second embodiment similarly anticipates claims 25-26.

C. Ground 3: Claims 1-2, 4, 18, and 20-22 Are Unpatentable Under § 102(e) as Being Anticipated by Dunsmore's *third embodiment*.

Dunsmore also teaches a third embodiment of the disclosed respiratory device. (*See* Fig. 20 (below).) The third embodiment replaces the "cantilever-type resonator interrupter valve assembly 304" taught in the second embodiment with an alternative "rocker-type arrangement." (*Id.*, 21:55-64.) The remaining components identified in the second embodiment (Figs. 17-19) can remain substantially the same. (*Id.*)

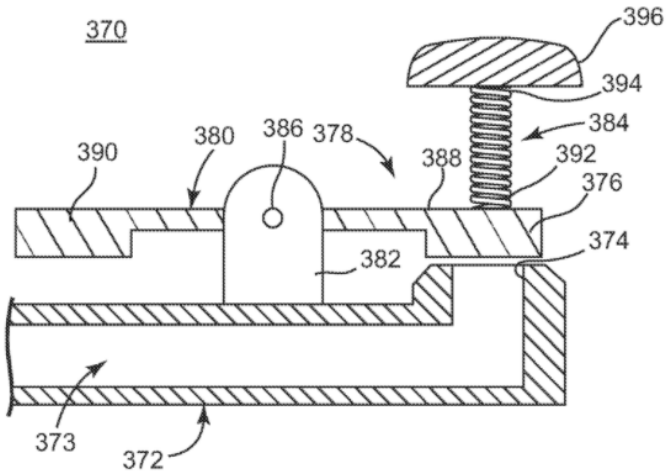


Fig. 20

As demonstrated below and in combination with the second embodiment discussed above (*i.e.*, everything other than the cantilevered interrupter assembly), Dunsmore's third embodiment discloses each and every limitation of, at least:

- Independent claim 1, and dependent claims 2, 4; and

- Independent claim 18, and dependent claims 20-22.

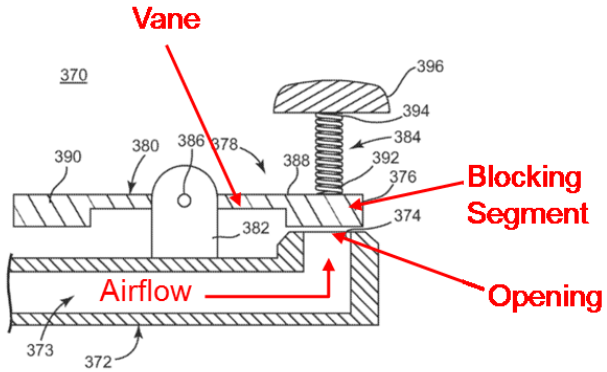
1. Independent claim 1

Referring to Sec. VIII.B.1 above, the general elements of claim 1 are disclosed, including the "inlet" and the "outlet." *See also id.*, 21:61-63 ("the tube 372 of Fig. 20 is akin to the tube 332 of Fig. 18A.").) The rocker-type interrupter valve assembly 370 includes "valve body 376" (*i.e.*, blocking segment). (*Id.*, 21:64-67.) A drive mechanism 378 having an arm 380 pivotably mounted to support 382 and at a pivot point 386 is also included. (*Id.*, 22:1-11 ("arm 380 includes a first side 388 [*i.e.* vane] at which the valve body 376 [*i.e.* blocking segment] is formed or affixed.").) As before, the "valve body 376 is sized in accordance with a size of the control port 374 (*e.g.*, ***identical***, slightly smaller, ***or slightly larger***)." (*Id.*, 21:65-67 (emphasis).) Dunsmore's third embodiment therefore teaches each of these elements under the limitations' BRI.

"During use, the valve body 376 limits airflow from the patient inlet 373/control port 374, with the distance or gap between the valve body 376 and the control port 374 (and thus the resistance to expiratory airflow) being cyclically dictated by the biasing device 384." (*Id.*, 22:22-27.) "Once again, as the valve body 376 approaches the control port 374 [*i.e.*, a closed position], a back pressure is created within patient inlet 373 (in conjunction with continued airflow from the patient . . .)." (*Id.*, 22:27-31.) As the pressure builds, valve body 376 is pushed

away from control port 374 (*i.e.*, to an open position). (*Id.*, 2212-19.) A biasing device 384 then returns valve body 376 to a closed position, and the process repeats. (*Id.*)

Considering the BRI of each of the claimed elements, Dunsmore's third embodiment teaches each of the elements of claim 1. Accordingly, Dunsmore's third embodiment anticipates claim 1.

Claim 1	
1. A respiratory treatment device comprising:	*See* Sec. VIII.B.1 (Claim 1); *see also generally* col. 21:55 to 22:37 (discussing third embodiment).
an inlet configured to receive exhaled air into the device;	*See* Sec. VIII.B.1 (Claim 1).
an outlet configured to permit air to exit the device;	*See* Sec. VIII.B.1 (Claim 1).
an opening positioned in an exhalation flow path defined between the inlet and the outlet;	"FIG. 20 schematically illustrates an alternative embodiment interrupter valve assembly 370 in connection with a tube 372 otherwise forming a patient inlet 373 and a control port 374 [*i.e.*, an opening in the exhalation flow path]." (Col. 21:58-61)  Fig. 20

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	"the interrupter valve assembly 370 employs a rocker-type arrangement" (*Id.*, 21:63-64.) "the valve body 376 [blocking segment] limits airflow from the patient inlet 373/control port 374, with the . . . resistance to expiratory airflow . . . being cyclically dictated by the biasing device 384." (*Id.*, 22:22-27.)
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;	"arm 380 includes a first side 388 [*i.e.* vane] at which the valve body 376 [*i.e.* blocking segment] is formed or affixed." (Col. 22:5-7.) "The arm 380 maintains the valve body 376 and is pivotally mounted to the support 382 at a pivot point 386." (Col. 22:4-6.) *See also* Figs. 21A-21B (illustrating motion of blocking segment relative to opening in response to air flow from patient).
wherein a size of a blocking surface of the blocking segment is equal to or greater than a size of the opening.	"valve body 376 is sized in accordance with a size of the control port 374 (*e.g.*, ***identical***, . . . ***or slightly larger***)." (*Id.*, 21:65-67.)

2. Claim 2

Claim 2 requires the "blocking segment [be] mounted on the vane." Dunsmore teaches that "the arm 380 includes a first side 388 [*i.e.* vane] at which the valve body 376 [*i.e.* blocking segment] is formed or affixed." (*Id.*, 22:5-7.)

Accordingly, Dunsmore anticipates claim 2.

3. Claim 4

Claim 4 depends from claim 1, and requires that "the blocking segment and the vane are rotatable about an axis of rotation perpendicular to a direction of the flow of air through the opening."

As shown in Fig. 20, rocker-type interrupter valve assembly 370 pivots about pivot point 386. (*See also id.*, 22:4-5.) This movement is within the BRI of the claimed limitation. The axis of rotation, therefore, extends in to and out of the page at pivot point 386. That axis is perpendicular to the direction of air flowing upwards through control port 374.

Accordingly, Dunsmore anticipates claim 4.

4. Independent claim 18

Claim 18 replaces the vane element of claim 1 with "a side profile of the blocking segment is shaped to mate with a side profile of the opening, when the blocking segment is in the closed position."

Dunsmore teaches that "valve body 376 is sized in accordance with a size of the control port 374 (*e.g.*, ***identical***, slightly smaller, or slightly larger)." (*Id.*, 21:65-67.) For at least this reason, and those discussed regarding claim 1 (*see* Sec. VIII.A.1 and B.1) and claim 18 (*see* Sec. VIII.A.10 and B.6), Dunsmore anticipates claim 18.

5. Claims 20-21

Claim 20 depends from claim 18, and requires "a vane" identical to that required by claim 1. Claim 21 depends from claim 20, and requires that "the blocking segment is mounted on the vane."

As discussed with respect to claim 1, the rocker-type interrupter valve assembly 370 includes a vane [arm 380, first side 388) configured to move the blocking segment [376] between the closed position and the open position in response to the flow of air through the opening. (*See* Sec. VIII.C.1.) Further, Dunmore teaches that "the arm 380 includes a first side 388 [*i.e.* vane] at which the valve body 376 [*i.e.* blocking segment] ***is formed or affixed***." (*Id.*, 22:5-7 (emphasis).)

Accordingly, claims 20-21 are again anticipated by Dunsmore.

6. Claim 22

Like Dunsmore's second embodiment, the third embodiment also teaches the required "conduit."

Fig. 20 (annotated below) discloses an interrupter valve assembly that includes a conduit having a length ("L") terminating at an opening [*i.e.*, control port 374]. Dunsmore also teaches that the cross-sectional shape of the conduit along the length matches a cross-sectional shape of the opening [*i.e.*, control port 374]. Accordingly, Dunsmore anticipates claim 22.

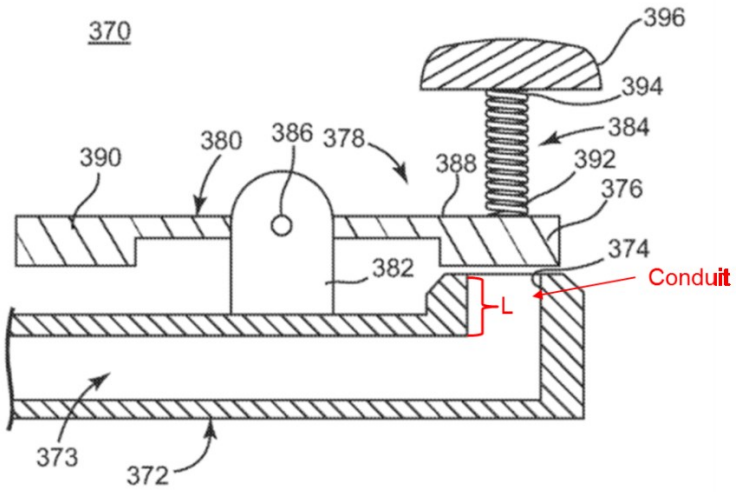


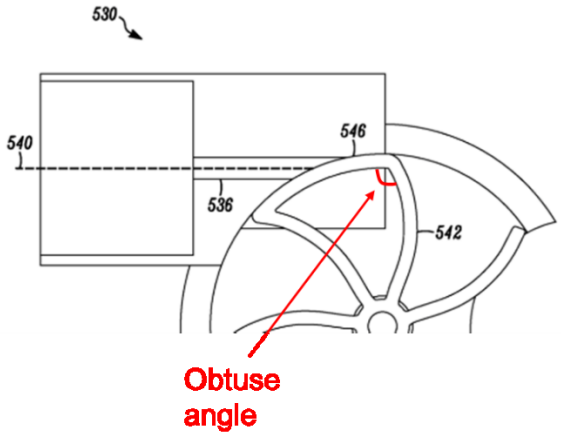
Fig. 20

D. Ground 4: Claims 3, 5, 9-17, and 23-24 Are Unpatentable Under 35 U.S.C. § 103 in view of Dunsmore.

This Petition has thus far demonstrated that most of the '588 Patent's claims are anticipated by Dunsmore. Several claims would have also been obvious in view of Dunsmore.

1. Claim 3

Claim 3 depends from claim 1, and requires that "the blocking segment is mounted to the vane at an obtuse angle." (*E.g.*, '588 Patent, Fig. 12 below.)



Referring to Figs. 23-28, Dunsmore also teaches an interrupter valve assembly having a valve body 512 (*i.e.*, blocking segment) and control port 510. As illustrated in Figs. 24, 27A (annotated/enlarged below), and discussed further below, valve body 512 is mounted to the vane ("beam or member 550")[6] at an obtuse angle.

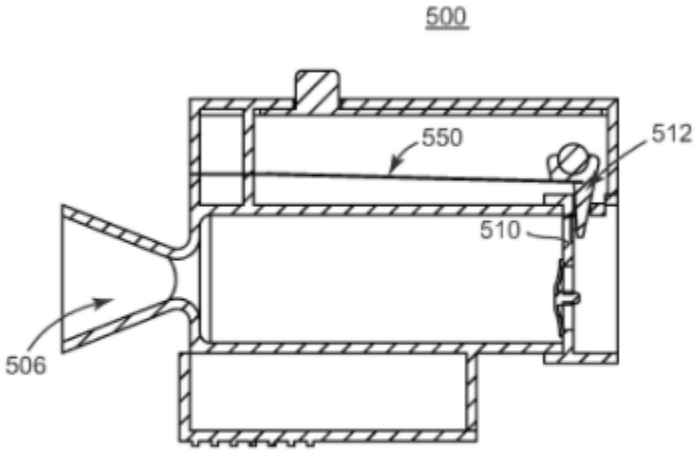


Fig. 27A

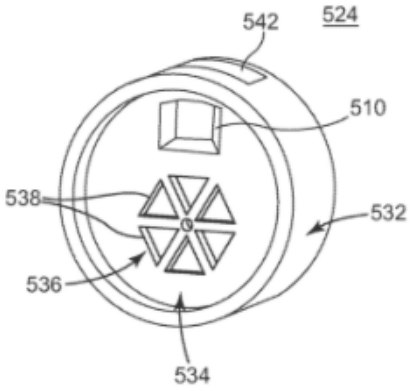
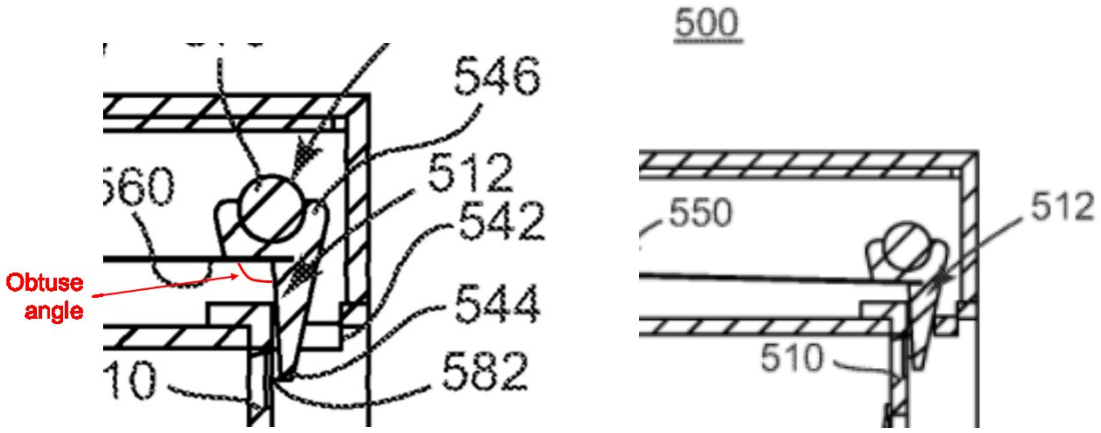


Fig. 24



[6] Like "member 316" discussed above (Sec. VIII.B.1), "beam or member 550" is a "vane" within the BRI of that term.

Dunsmore teaches that "the valve body 512 . . . includes a leading segment 544 and a trailing segment 546," and the "leading segment 544 . . . ***has a tapered shape***." (*Id.*, 25:17-21 (emphasis).) Indeed, as illustrated in Figs. 26A, 27A (enlarged above), this tapered shape is ***necessary*** in order to adequately block the flow of exhaled air through control port 510. As the beam 550 pivots downward, the beam angles away from the horizontal. If the blocking surface of valve member 512 (*i.e.*, the surface of valve member 512 nearest control port 510) were mounted at a right angle to beam 550, leading segment 544 would be closer to port 510 than the trailing segment 546, resulting in a non-uniform blocking surface in the closed position. The "tapered shape" (*i.e.*, obtuse angle) avoids this pitfall, thereby resulting in a uniform blocking surface across port 510. (*Id.*, 25:19-21.)

It would have been obvious to a PHOSITA at the time of the disclosure in the '588 Patent to adopt the tapered valve body 512 in embodiments where a non-uniform blocking surface might otherwise result. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007) (holding that when "there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp.")

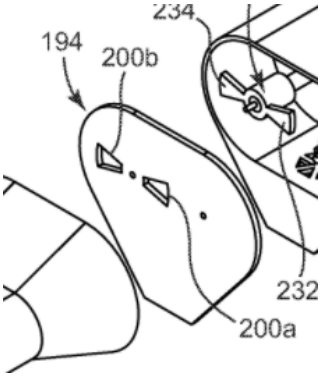
Accordingly, claim 3 is obvious over Dunsmore.

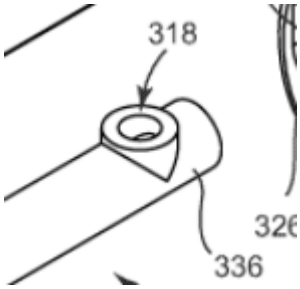
2. Independent Claim 9 and dependent claim 10

Claim 9 is substantially identical to claims 1 and 18, but for requiring that the "opening positioned in an exhalation flow path. . . hav[e] a generally oblong cross-sectional shape comprising a shorter first dimension and an elongated second dimension perpendicular to the first dimension." As discussed above, Dunsmore's first embodiment teaches a generally oblong opening. (*See* Sec. VIII.A.1 (citing, *e.g.*, Fig. 9).) Claim 9 further requires that the blocking segment be "configured to translate relative to the opening along the shorter first dimension" between the closed position and open position. Under the BRI, this means that the blocking segment moves principally in a direction matching the shorter first dimension rather than principally along the longer second dimension. Dependent claim 10 adds the limitation that the "generally oblong cross-sectional shape" is "generally rectangular." For the reasons below, claims 9 and 10 are unpatentable over Dunsmore.

Dunsmore teaches that control port 44 (*i.e.*, opening, Fig. 1) can be any shape or configuration so long as it fluidly connects the patient inlet to the outlet. (*Id.*, 5:47-50.) For example, the opening may take on the generally oblong cross-sectional shape shown in Figs. 9, 12 (*see* control ports 200a, 200b (which are "generally rectangular" under the BRI of that phrase)); the generally circular

control ports shown in Figs. 17 (port 318), 18B (port 318), and 20 (port 374); and the generally rectangular control port shown in Fig 24 (port 510).





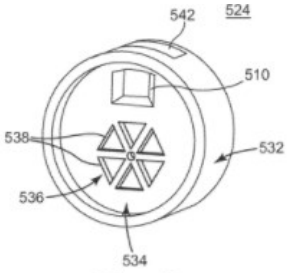


Fig. 24

Dunsmore also teaches that there is no limitation on the shape of the control port, indicating on multiple occasions that the "plate segments 132, 134 . . . each have a size and shape commensurate with a size and shape of a corresponding one the control ports 78a, 78b, [and may be] a size and/or shape . . . identical, slightly smaller or slightly larger than a size and/or shape of the control ports 78a, 78b." (*Id.*, 9:2-8; *accord* 21:65-67; 22:46-49.)

Accordingly, while the second/third embodiments of Dunsmore (Secs. VIII.B, VIII.C) illustrate exemplary circular openings, it would have been obvious to a PHOSITA at the time of the '588 Patent disclosure to modify the shape of the openings to include generally oblong cross-sectional shaped openings as taught, for example, in Fig. 9, and/or generally rectangular shaped openings as taught, for example, in Fig. 24. *See KSR*, 550 U.S. at 421; *see also* MPEP § 2144 (citing *In re Dailey*, 357 F.2d 669 (CCPA 1966) (finding disposable plastic nursing container's

configuration was a matter of choice which a PHOSITA would have found obvious absent persuasive evidence that the particularly claimed container configuration was significant)).

The ’588 Patent makes no indication that the claimed “generally oblong cross-sectional” opening has ***any*** significant advantage over circular openings; only that the opening is shaped to align with the shape of the blocking segment. (Col. 5:34-38 (“restrictor member 142 . . . could be any number of shapes, so long as it may be positionable such that at least one blocking segment 146 . . . is capable of at least partially blocking the chamber inlet 136”); 7:11-14 (“the relative size or shape of the blocking segments . . . may vary”).) Indeed, regarding the second/third embodiments, the “tube 332 can assume a variety of different constructions.” (Dunsmore, 19:34-35.)

Further, Dunsmore’s first embodiment (*e.g.*, Fig. 9) and third embodiment (*e.g.*, Fig 24) teaches that the blocking segment is configured to translate relative to the opening along the shorter first dimension between the open and closed positions as required by claim 9. (*See* Sec. VIII.A.5 (citing Figs. 14B, 15B illustrating valve plate segments 232, 234 rotating about the vane and translating relative to the opening (*i.e.*, control ports 200a, 200b) along the shorter first dimension); *see also* Dunsmore, 27:27-30, Figs. 24, 26B (“the beam 550 resonates, causing the valve body 512 to move back and forth . . . (*e.g.*, up and down [])

relative to the control port 510 [illustrated in Fig. 24 as having a shorter vertical dimension relative to a longer horizontal dimension]").)

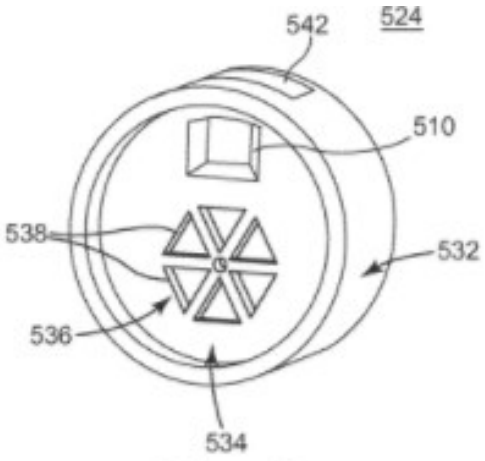


Fig. 24

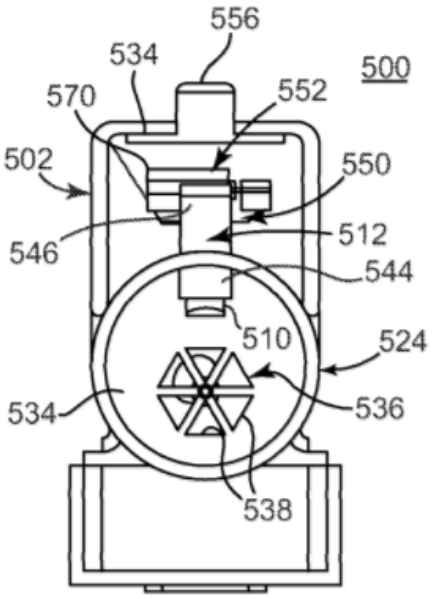


Fig. 26B

The '588 Patent is silent on any benefits of translating the blocking segment along a shorter first dimension rather than a longer second dimension, and therefore the relative shapes of the opening would have no unique performance impact. (*See, e.g.*, '588 Patent at 7:11-14.) Thus, because the shape was known in the art to be variable, the feature would have been obvious to a PHOSITA at the time of the invention. *See Gardner v. TEC Syst., Inc.*, 725 F.2d 1338 (Fed. Cir. 1984) (where only difference between prior art and claims is a recitation of relative dimensions, and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device is not patentably distinct); *see also KSR*, 550 U.S. at 421.

Accordingly, claims 9 and 10 would have been obvious over Dunsmore.

3. Claims 11 and 23

Claim 11 depends from claim 9, and requires "a conduit having a length terminating at the opening, wherein a cross-sectional shape of the conduit along the length matches the cross-sectional shape of the opening." Thus, claim 11 includes all the limitations discussed with respect to claim 22 above (*see* Secs. VIII.B.9, VIII.C.6), but for the opening having a "generally oblong cross-sectional shape." Similarly, claim 23 depends from claim 22 (depending from claim 18), and requires that the opening and corresponding conduit have a "generally oblong cross-sectional shape" as in claim 9.

As noted above, an opening having a "generally oblong cross-sectional shape" would have been obvious to a PHOSITA at the time of the invention. (*See* Sec. VIII.D.2.) Further, as discussed with respect to claim 22 above, it would have been obvious from Dunsmore's embodiments to have the conduit employ a cross-sectional shape that matches the opening (*see, e.g.*, Figs. 18B (below-left); 20 (below-right). *See KSR*, 550 U.S. at 421; MPEP § 2144.

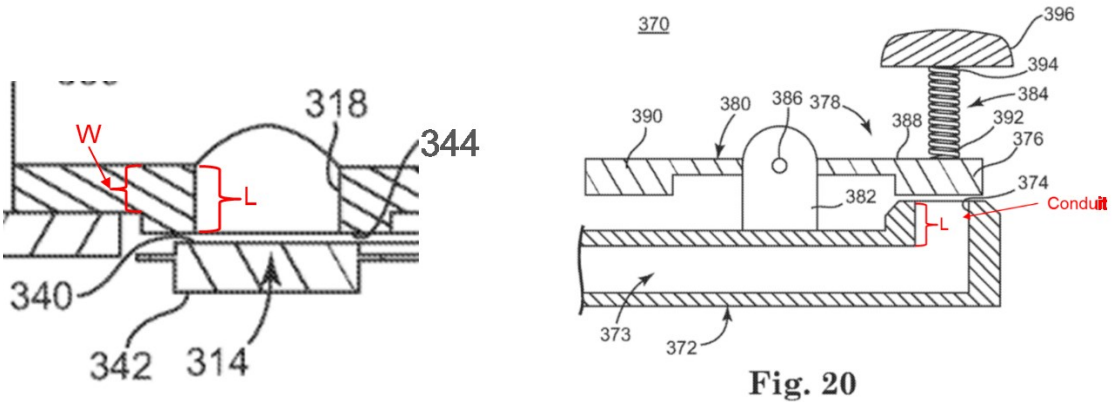


Fig. 20

Accordingly, claims 11 and 23 would have been obvious over Dunsmore.

4. Claim 24

Claim 24 depends from claim 23, and requires that "the blocking segment is configured to translate relative to the opening along the shorter first dimension between the closed position and the open position." For at least the reasons discussed with respect to claim 9 (Sec. VIII.D.2), Dunsmore teaches this limitation and it would have been obvious to a PHOSITA at the time of the invention.

Accordingly, claim 24 would have been obvious over Dunsmore.

5. Claim 12

Claim 12 depends from claim 11, and recites "a cross-sectional area of the conduit is less than a cross-sectional area of an opening associated with a patient interface located upstream of the conduit." Claim 11 is unpatentable over Dunsmore (Sec. VIII.D.3), and the additional limitation of claim 12 would have been obvious in view of Dunsmore. (*See also* Sec. VIII.A.7 (finding claim 12 anticipated by the first embodiment of Dunsmore.)

Figs. 17 (below-left), 19A (below-right) show that the device includes a "mouthpiece 330" and a separate "tube 332." (*Id.*, 19:24-33.) "The mouthpiece 330 is adapted for convenient placement within a patient's mouth . . . and thus can have . . . an oval-like shape." (*Id.*) As this description and Figs. 17, 19A make clear, the enlarged, mouth-sized mouthpiece has a cross-sectional area greater than a cross-sectional area of the opening (*e.g.*, control port 318).

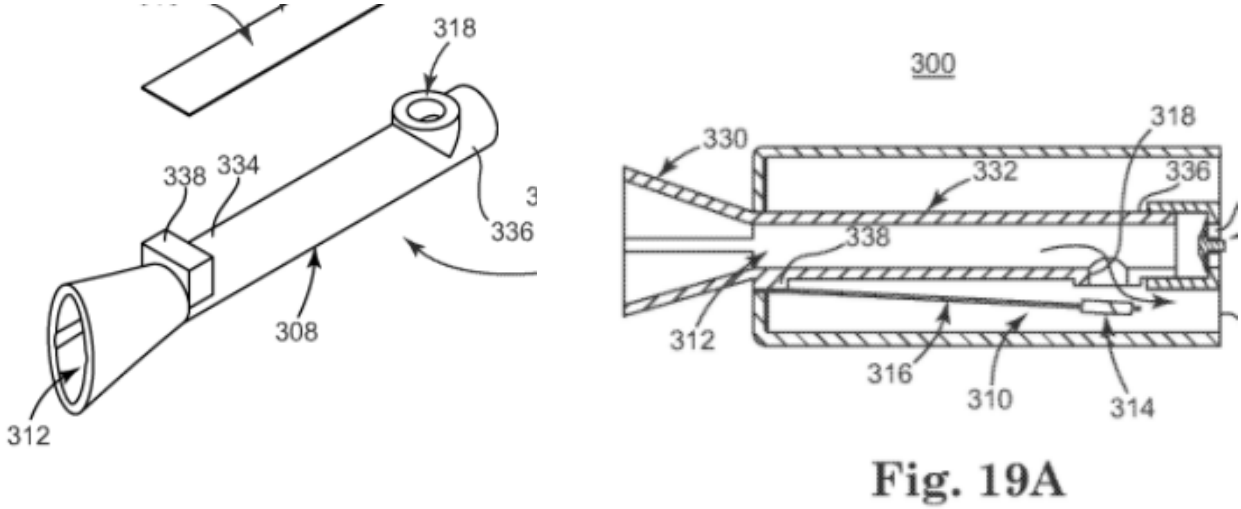


Fig. 19A

Modifying the cross-sectional area of the mouthpiece to be greater than the cross-sectional area of a conduit would have also been obvious to a PHOSITA at the time of the invention. *See Gardner*, 725 F.2d 1338 (device not patentably distinct where it performs in same manner and only differs in recitation of relative dimensions); *see also* MPEP § 2144 (citing *In re Rose*, 220 F.2d 459, 105 U.S.P.Q. 237 (C.C.P.A. 1955) (finding claims directed to a lumber package "of appreciable size and weight requiring handling by a lift truck" unpatentable over prior art

lumber packages which could be lifted by hand because limitations relating to the size of the package were not sufficient to patentably distinguish over the prior art)).

Nothing in the '588 Patent indicates that the enlarged cross-sectional area of the mouthpiece offers any advantage. Accordingly, claim 12's limitations are nothing more than a design choice which would have been obvious over Dunsmore.

6. Claims 13-14 and 16-17

Claims 13-14 and 16-17 depend directly or indirectly from claim 9, and contain limitations substantially identical to claims 1-2, and 7-8 discussed above.[7] For the reasons set forth above explaining why independent claim 9 is unpatentable (*see* Sec. VIII.D.2), and the reasons why claims 1-2, and 7-8 are unpatentable (*see, e.g.*, Secs. VIII.A.1-4), claims 13-14 and 16-17 are similarly unpatentable over Dunsmore.

7. Claim 15

Claim 15 is substantially similar to independent claim 18, but for the limitation that the opening has a "generally oblong cross-sectional shape."

As discussed above regarding claim 18 (*see* Secs. VIII.A.10, VIII.B.7, and VIII.C.4), and the discussion immediately above explaining the unpatentability of claim 9's "generally oblong cross-sectional shape" element (Sec. VIII.D.2), claim

[7] *See supra* note 3.

15 would similarly have been obvious to a PHOSITA at the time of the invention, and is therefore unpatentable over Dunsmore.

E. Ground 5: Claim 6 Is Unpatentable Under § 103 Over the first embodiment of Dunsmore in view of Blacker

Claim 6 depends from claim 1, and requires that the "blocking segment and the vane are biased during a period of no air flow through the opening solely by a weight of gravity." The '588 Patent accomplishes this by having a restrictor member on only one vane. (*See, e.g.*, Fig. 14.)

In Dunsmore's first embodiment (*e.g.*, Figs. 9-16), valve plate segments 232, 234 mounted on valve body 202 can have a "propeller-like" construction. (Dunsmore, 8:64-67.) The drive mechanism 204 includes "lobe assemblies 240, 242" which are designed to rotate "in response to exhaled air entering the second chamber 220," thereby causing the valve body 202 to rotate." (*See id.*, 17:47-49.)

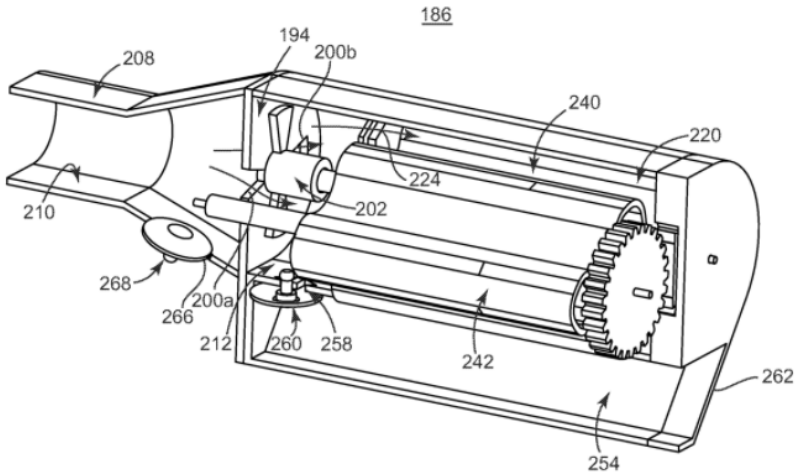
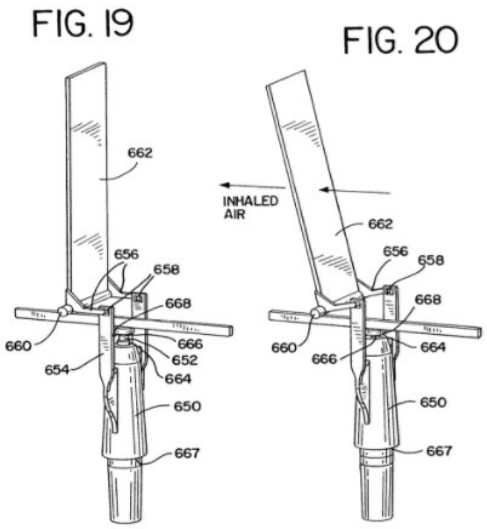


Fig. 14B

Dunsmore acknowledges, however, that there may be a need to "account for instances in which the valve body 202 is initially aligned with control ports 200a, 200b (and thus may impede desired airflow into the second chamber 200 sufficient to initiate rotation of the lobe assembles 240, 242)." (*Id.*, 17:49-53.) Dunsmore then notes that a "means (not shown)" may be provided to overcome such initial conditions and initiate rotation of the lobes. (*Id.*)

One solution to this problem, which was known by a PHOSITA at the relevant time, would be to use gravity to bias the lobe assemblies such that in the absence of exhaled air flow, the respiratory device would settle in an open configuration such as that shown in Fig. 14B.

Blacker teaches such a configuration, with a nebulizer apparatus that includes "a nozzle cover 650" designed to "close off the fluid inlet 667 so that substantially no fluid may flow into the fluid passage . . . when the nebulizer is in the non-actuated position." (Blacker at 11:21-36 and Fig. 19.) Such an arrangement stops the flow of medicine except when the patient is inhaling, thereby minimizing medicinal waste. (*See id.*, 1:49-52.) Importantly, Blacker teaches that "the ***weight of the nozzle cover 650*** . . . may keep the nozzle cover in the non-actuated position at rest and during exhalation." (*Id.*, 11:33-36.) While Blacker needed to bias the mechanism closed, the same principle (*i.e.*, using gravity to bias a blocking member) could have been used to bias a mechanism open if desired.



It would therefore have been obvious to a PHOSITA at the time of the invention to look to analogous art such as Blacker (Cook Decl., ¶¶5-7) and combine the idea of using gravity to bias a respiratory device into a desired configuration (*e.g.*, bias the lobe assemblies 240, 242 and/or valve body 202 into an "open" configuration in the absence of airflow through the opening). Indeed, it would have been "obvious to try" such a solution in this context given such use in analogous art. *See* MPEP § 2143 (explaining that a claim element is obvious if merely chosen from a "finite number of identified, predictable solutions with a reasonable expectation of success).

Accordingly, claim 6 is unpatentable over Dunsmore in view of Blacker.

F. Ground 6: Claims 11 and 23-24 Are Unpatentable Under § 103 Over Dunsmore In View of Fowler-Hawkins

As discussed above, the conduit having the "generally oblong cross-sectional shape" required by claims 11, 23-24 provides no advantage over circular

conduits and is therefore only a design choice that would have been obvious to a PHOSITA at the time of the invention. (*See* Secs. VIII.D.3, D.4.)

Fowler-Hawkins demonstrates that generally oblong cross-sectional shape conduits were known in the art at the time of the invention. Like Dunsmore, Fowler-Hawkins relates generally to a PEP device for inducing back-pressure in a patient's lungs to reduce the viscosity of mucus contained therein. (Fowler-Hawkins, 1:13-17.)

Referring to Fowler-Hawkins Fig. 4, the device 300 includes a housing 304 that includes a patient inlet 302 and an opening (end of housing 304 adjacent the inlet 302), and a reed 402 (*i.e.*, a blocking segment). (*See* 5:64 to 6:4.) "As the air passes in the direction A over the reed 402, the free end 402b of the reed 402 vibrates up and down." (*Id.*, 7:11-15.) "The vibration produces an acoustical shockwave within the housing 304." (*Id.*)

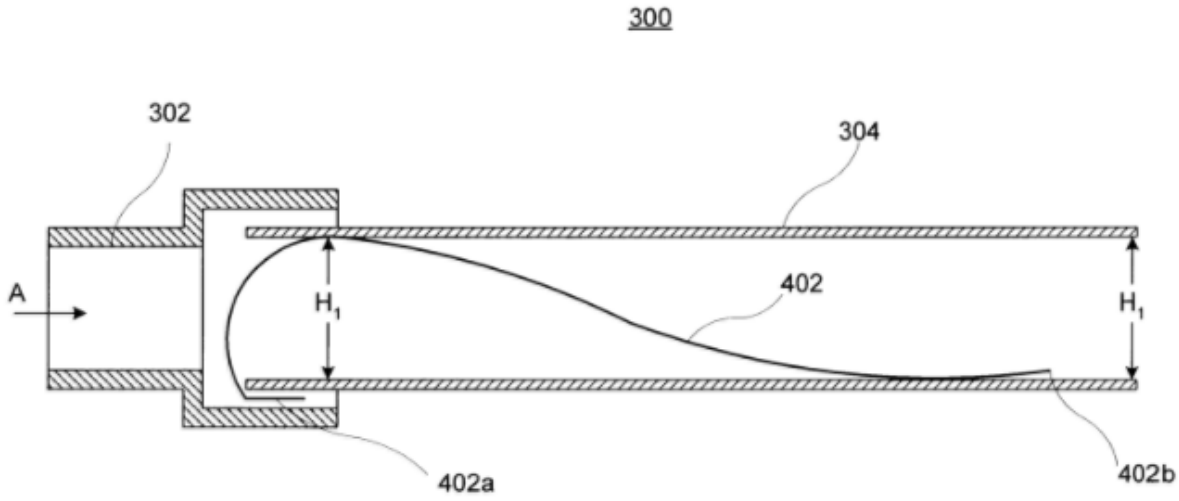


Figure 4

Notably, the "housing 304 ***can comprise a rectangular or square shape*** to minimize air flow around the reed 402." (*Id.*, 6:34-42 (emphasis).) As discussed above, this desire to maximize the air flow interaction with the blocking segment ***is the same reason*** Dunsmore teaches varying shapes and sizes of control ports (*i.e.* openings), conduits, and correspondingly sized valve bodies (*i.e.* blocking segments); the device works best when the air flow maximally engages the blocking segment (*i.e.*, when blocking segment "completely blocks" the opening). (*See* Dunsmore, 5:53-57 ("by controlling or operating the valve body 46 to selectively obstruct (partially ***or completely***) the control port(s) 44, the interrupter valve assembly 34 alters airflow/pressure characteristics to and/or from the patient inlet 36." (emphasis).)

Accordingly, because a PHOSITA at the time of the invention would have known of rectangular or square conduits like that taught in Fowler-Hawkins, it would have been obvious to incorporate such shapes into the device taught by Dunsmore (to the extent such variations in shape for the same purpose are not already obvious in view of Dunsmore itself (*see* Sec. VIII.D.3-4)). Therefore, claims 11, 23-24 are unpatentable over Dunsmore in view of Fowler-Hawkins.

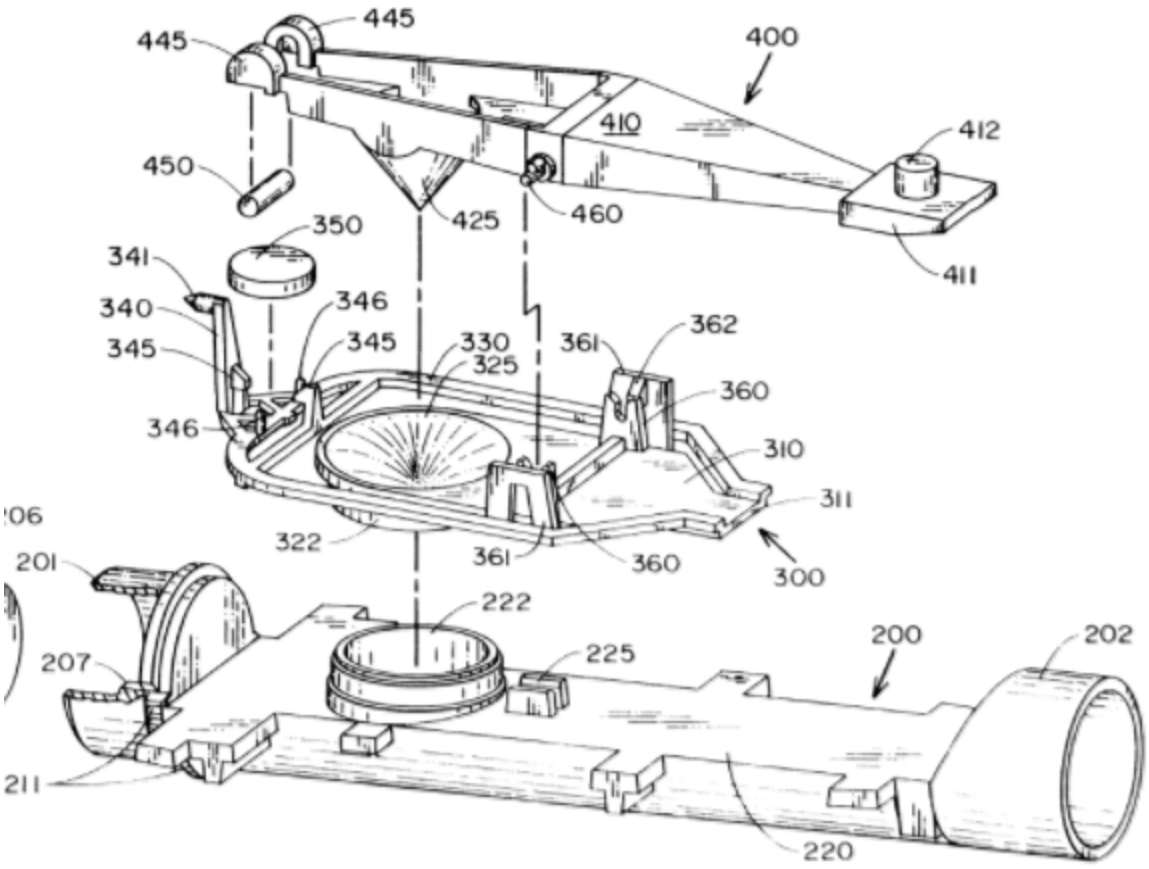
G. Ground 7: Claims 1-4, 6-8, 18, 20-21, and 25-26 Are Each Unpatentable Under § 102 As Being Anticipated by Foran

Many of the challenged claims are also anticipated by Foran's respiratory therapy device.

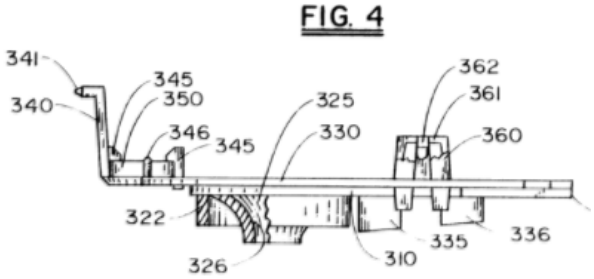
1. Independent claim 1

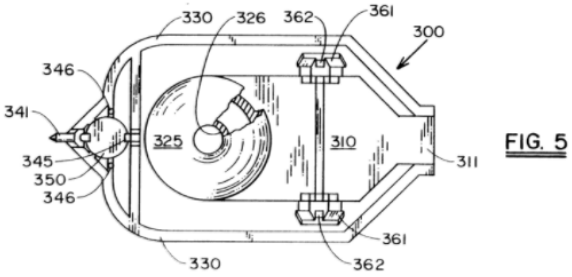
The limitations of claim 1 are set forth above. In general terms (*see* Foran at 6:64 to 7:43; Fig. 3 (below)), Foran teaches an "enhanced PEP therapy device" (*see* Abstract) that includes "a patient input end 202 through which a patient . . . discharges expiratory air [*i.e.* an inlet]" (*id.*, 3:38-41), that directs exhaled air flow through an "opening 326." (*Id.*, 7:6-8.) There, the exhaled air flow encounters cone 425 (*i.e.*, blocking segment) "which forms a closure of the opening 326" (*i.e.*, closed position). (*Id.*, 7:6-10.) "The pressure of the patient expiratory air will raise the cone 425, causing the rocker assembly 400 (*i.e.*, vane configured to rotate the blocking segment) to pivot about its pivot pins 460."[8] (*Id.*, 7:10-12.) As cone 425 moves upwardly (*i.e.*, to an open position), the effective discharge area increases which reduces the force of air on the cone 425. (*See id.*, 7:15-19.) Cone 425 then returns, via at least the venturi effect, to its closed position, and the cycle repeats. (*See id.*, 7:19-29.)

[8] The discussion about magnet 350 is omitted here because Foran teaches that the magnetic components are not required for operation of the device. (Col. 5:66 to 6:8.)



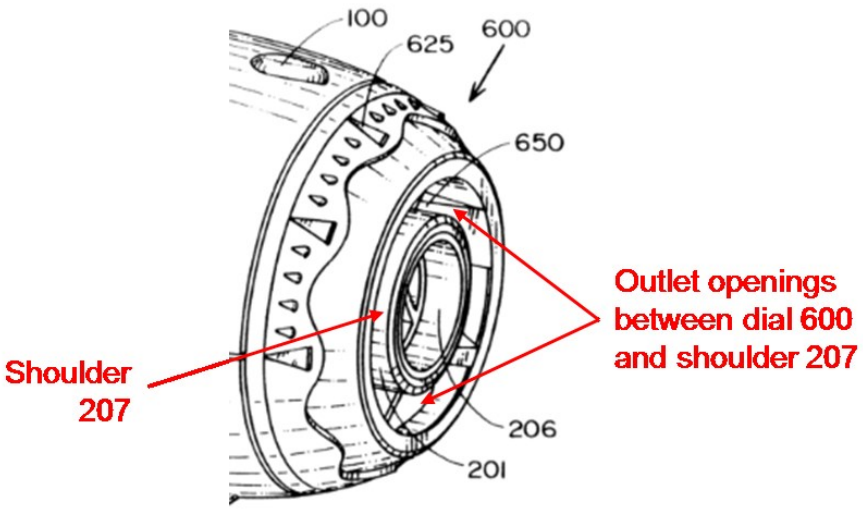
Regarding the opening, "the tapered conical interior surface 325 closes the air passage into the air flow tube 200 ***except for a circular opening 326*** which extends downwardly . . . through the collar 222 into . . . tube 200." (*Id.*, 4:14-19 (emphasis).) Therefore, all air exhaled into the device by a patient through the inlet (*i.e.*, patient input end 202) passes through the opening 326 before being discharged. (*See id.*, 7:1-2 ("The patient's expiratory air . . . ***must pass through the opening 326*** . . .").)





After discharging through opening 326, the discharged air exits the device to ambient through openings in the rotatable adjusting dial 600 [*i.e.*, an outlet]. (*See, e.g.*, Fig. 1 (excerpted/annotated below, illustrating openings between adjusting dial 600 and shoulder 207 of air intake end 201).)[9]

[9] While not identified by number in Figs. 1, 10, housing openings are illustrated and necessarily present because otherwise exhaled air would fill the device and no air would flow through the opening as required. *See Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003) ("a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference"); *see also* Cook Decl., ¶8. Further, a continuation-in-part application following Foran, now U.S. 7,059,324 to "Pelerossi," explicitly teaches the outlet openings in relation to an identical embodiment. (*See* Exhibit 1010, Pelerossi at col. 4:14-17 ("After the expiratory air is applied to the rocker assembly 400, the air thereafter exits from the device 1000 through openings in the rotatable adjusting dial 350 carried in the housing 300.").) To the extent the Board finds Foran lacking disclosure of this "outlet," Petitioner asserts claim 1 is obvious under § 103 over Foran in view of Pelerossi.



The blocking segment (*i.e.*, cone 425) is mounted to a vane (*i.e.*, rocker platform 410) that is configured to rotate the cone 425 between the closed and open position in response to air flowing through the opening. (*Id.*, 5:33-37 ("The flow cone 425 is sized and positioned to be inserted into the tapered conical interior 325 of the coupling 322 ***for closing the circular opening 326*** into the air tube 200." (emphasis added); *id.*, 7:6-10 ("forms a closure of the opening 326."); *id.*, 7:24-29.)

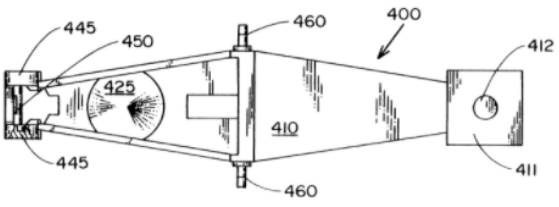


FIG. 8

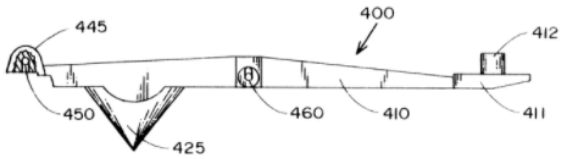


FIG. 7

Finally, Foran teaches that cone 425 (*i.e.* blocking segment and blocking surface) is equal to or greater than a size of opening 326. (*See* Figs. 3-6 and 5:33-37 ("flow cone 425 is sized and positioned to be inserted into the tapered conical interior 325 of the coupling 322 ***for closing the circular opening 326***") (emphasis added).)

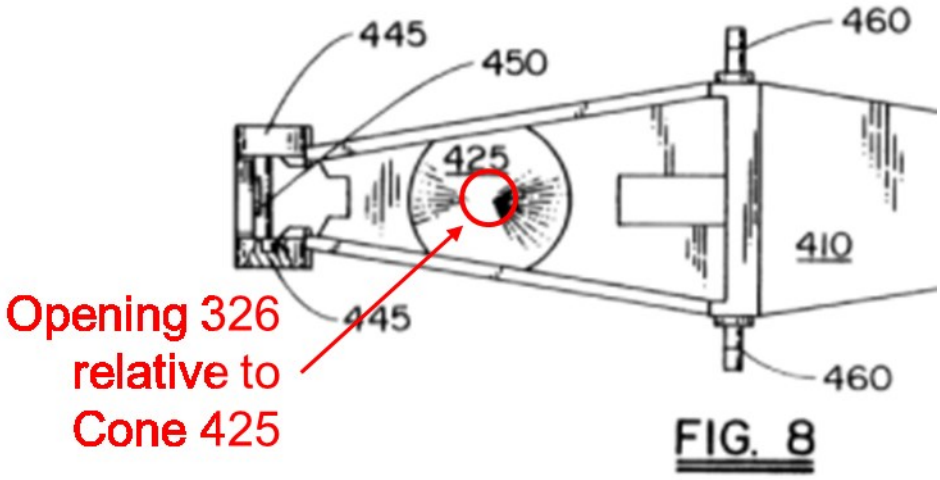
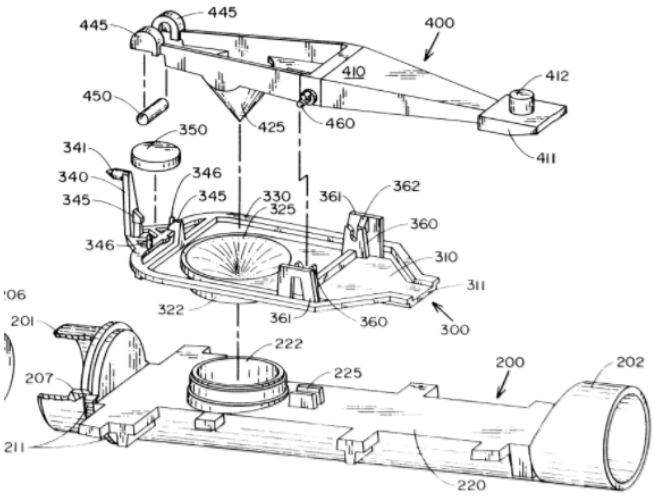
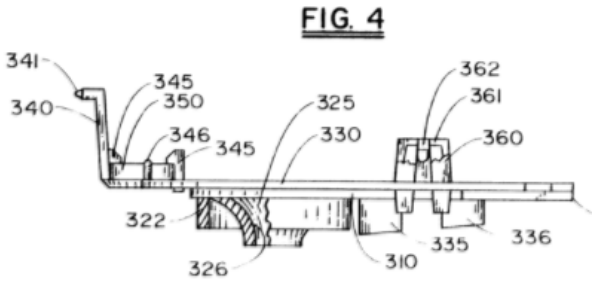
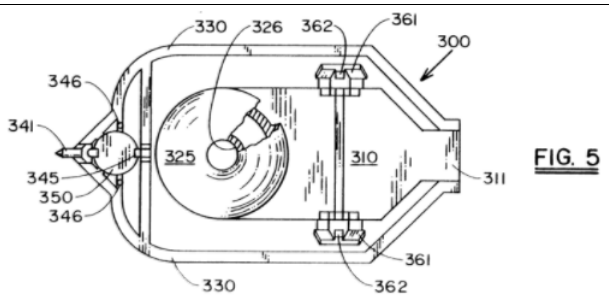
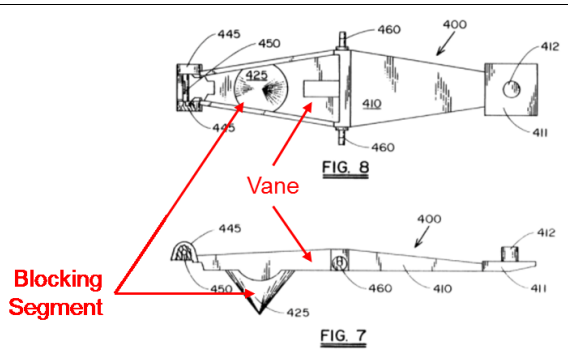
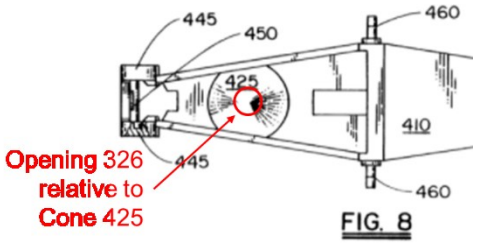


FIG. 8

Accordingly, Foran anticipates claim 1.

Claim 1	
1. A respiratory treatment device comprising:	"enhanced PEP therapy device" (Abstract) "This invention relates in general to a . . . positive expiratory pressure respiratory therapy device." (Col. 1:6-9.) 
an inlet configured to receive exhaled air into the device;	"a patient input end 202 through which a patient . . . discharges expiratory air." (*Id.*, 3:38-41.)
an outlet configured to permit air to exit the device;	Air passing through the opening 326 discharges to ambient through openings in the housing (*e.g.*, between dial 650 and shoulder 207).
an opening positioned in an exhalation flow path defined between the inlet and the outlet;	"The patient's expiratory air is then discharged into the patient input end 202, ***but must pass through the opening 326***. . . ." (Col. 7:1-5.) 

	 FIG. 5
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	"air pressure is applied through the opening 326 against the cone 425 of the rocker assembly 400 which forms a closure of the opening 326." (Col. 7:7-10; *see generally id.* 7:6-31 (detailing rotation of the blocking segment relative to opening between open and closed positions); 7:21-23.)
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.	"flow cone 425 is sized and positioned to be inserted into the tapered conical interior 325 of the coupling 322 ***for closing the circular opening 326***" (Col. 5:33-37.)  FIG. 8

2. Claim 2

Claim 2 requires that "the blocking segment is mounted on the vane."

As illustrated in Figs. 7, 8 above, cone 425 (*i.e.* blocking segment) is mounted on rocker assembly 400 (*i.e.* the vane).

Foran therefore anticipates claim 2.

3. Claim 3

Claim 3 depends from claim 1, and requires that "the blocking segment is mounted to the vane at an obtuse angle."

The blocking cone 425 taught by Foran is mounted to the rocker assembly (*i.e.*, vane) at an obtuse angle. (*See* Fig. 7 (annotated below).)

Accordingly, Foran anticipates claim 3.

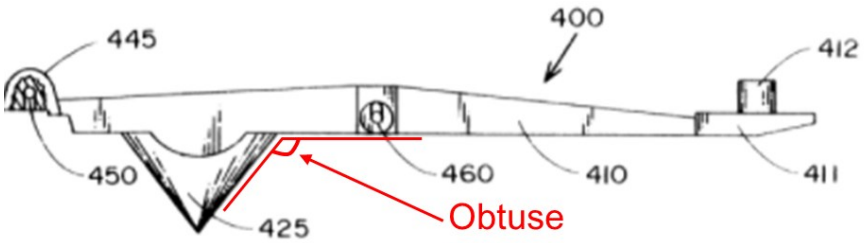


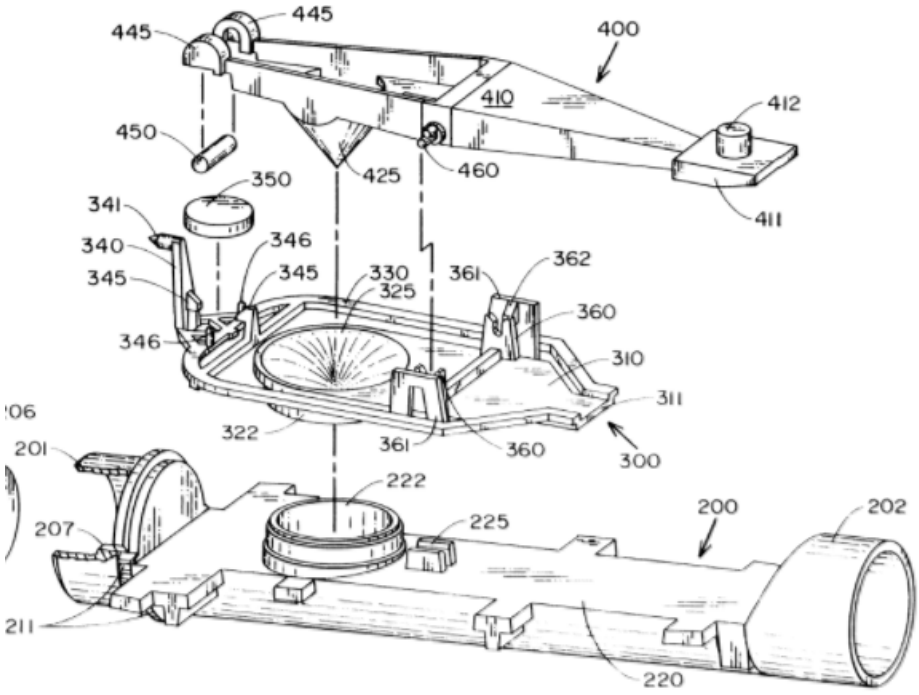
FIG. 7

4. Claim 4

Claim 4 depends from claim 1, and requires that "the blocking segment and the vane are rotatable about an axis of rotation perpendicular to a direction of the flow of air through the opening."

"[A]djustable orifice platform 310 includes . . . pivot supports 360 ***forming a pivot axis***." (*Id.*, 5:12-16.) Exhaled air travels through tube 200 and up through opening 326 in a direction perpendicular to pivot axis. (*Id.*, 7:10-12.)

Foran therefore anticipates claim 4.



5. Claim 6

Claim 6 depends from claim 1 and requires the "blocking segment and vane [to be] biased during a period of no air flow through the opening solely by a weight of gravity."

Foran's claim 3 (and others) requires "an orifice closure" (*i.e.*, blocking segment) "***normally closing*** said non-linear discharge orifice" (*i.e.*, opening) that is "operable to open . . . in response to [exhaled air]." The BRI of "***normally*** closing" would include an "orifice closure" that defaults to (or is "normally" in) the closed

position. Other than a magnet 350, the only available force to provide this necessary bias is gravity.

Importantly, Foran teaches that the device is operable ***without*** magnet 350. (*See* col. 5:66 to 6:8.) Further, independent claim 3 does not require a magnet. Instead, claim 4 (which depends from claim 3) introduces a magnet element, meaning that the required "orifice closure normally closing said non-linear discharge orifice" can be biased to the "normally clos[ed]" position without a magnet (*i.e.*, by the force of gravity alone). *See Schering*, 339 F.3d at 1377.

Accordingly, Foran anticipates claim 6.

6. Claims 7-8

Claim 7 depends from claim 1, and requires "the flow of air through the opening [be] completely blocked when the blocking segment is in the closed position." Claim 8 also depends from claim 1, and requires that "the blocking surface of the blocking segment contacts the opening when the blocking segment is in the closed position."

Foran teaches that the "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; *see also id.*, 7:6-9 ("***closure of the opening 326***"); *id.*, 7:21-23 ("***closing off the expiratory air flow through the opening 326***") (emphasis); *e.g.*, claims 1, 3, 7.)

Foran's teaching that cone 425 is sized to "close" circular opening 326 and "clos[e] off" the airflow through the opening means that the blocking segment completely blocks the opening, and by necessity, contacts the opening. (*Id.*; *see also, e.g.*, claim 2 ("includes an orifice closure normally closing said non-linear discharge orifice").) Even if it were not explicitly taught, it is inherent that the cone 425 of Foran must contact the opening 326 in order to "close off" the flow of air through the opening. *See Schering*, 339 F.3d at 1377.

Accordingly, Foran anticipates claims 7-8.

7. Independent claim 18

Claim 18 is substantially identical to claim 1, except that rather than require the vane element, it requires that "a side profile of the blocking segment is shaped to mate with a side profile of the opening, when the blocking segment is in the closed position."

As discussed above, cone 425 is "sized and positioned to be inserted into the tapered conical interior 325 of the coupling 322 for closing the circular opening 326." (*See* Sec. VIII.G.5 (citing Foran at 5:34-37).) Referring, for example, to Fig. 5, opening 326 is circular and therefore has a circular side profile. Similarly, the side profile of cone 425 where it contacts the perimeter of circular opening 326 is also circular (*i.e.*, a slice of a cone is a circle) and identically sized. For this reason,

and the reasons explained above with reference to the identical limitations in claim 1 (Sec. VIII.G.1), Foran anticipates claim 18.

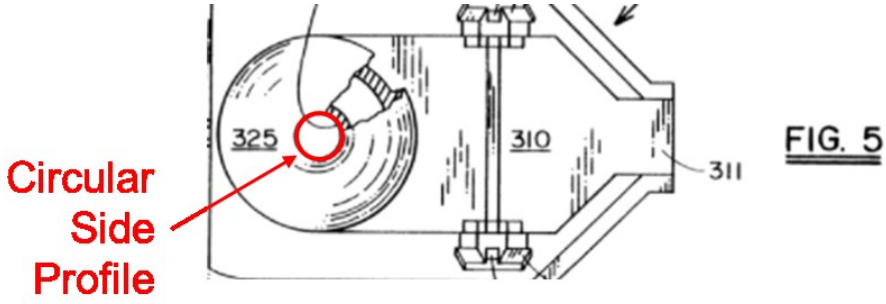


FIG. 5

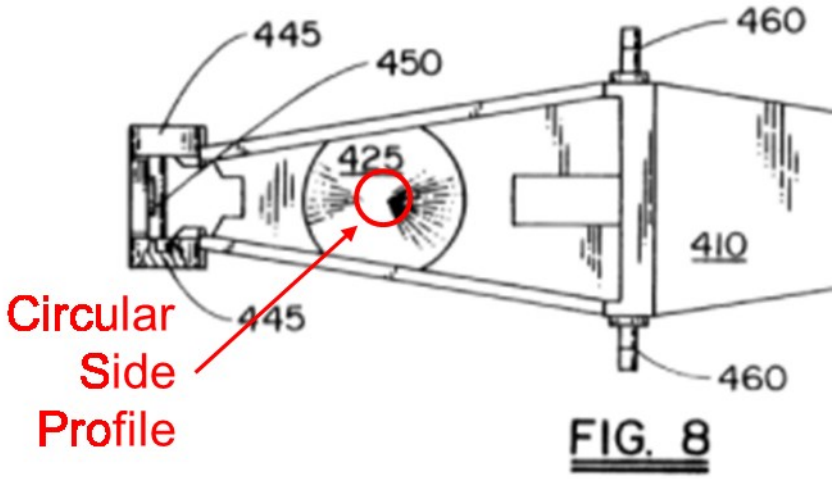


FIG. 8

8. Claims 20-21 and 25-26

Claims 20-21 and 25-26 depend directly or indirectly from claim 18, and include limitations identical to those claimed in corresponding claims 1-2 and 7-8.[10] (*See* Secs. VIII.G.1-2, 5.) For at least those reasons, Foran similarly anticipates claims 20-21 and 25-26.

[10] *See supra* note 3.

IX. CONCLUSION

In view of at least the above prior art, Petitioner is reasonably likely to prevail in their challenge of patentability for claims 1-26 of the '588 Patent. Petitioner respectfully requests that a trial for *inter partes* review of claims 1-26 be instituted and that the challenged claims be rejected and cancelled.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I caused to be served this 4th day of May, 2018, a true and correct copy of the foregoing PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,808,588 and accompanying exhibits and other supporting materials via Priority Mail Express on:

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WORD COUNT CERTIFICATION

I hereby certify that the foregoing PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,808,588, exclusive of table of contents, table of authorities, mandatory notices under § 42.8, certificate of service, word count certification, and the appendix of exhibits and claim listing, consists of 13,997 words and does not exceed the 14,000-word limit set forth in 37 C.F.R. § 42.24.

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