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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FISHER & PAYKEL HEALTHCARE LIMITED,
Petitioner

v.

RESMED LIMITED,
Patent Owner

Case No. IPR2017-01659
U.S. Patent No. 9,119,931

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,119,931

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OTHER AUTHORITIES

EXHIBIT LIST

Exhibit No.	Description
1501	U.S. Patent No. 9,119,931
1502	Declaration of Jason Eaton, P.E.
1503	Curriculum Vitae of Jason Eaton, P.E.
1504	Complaint of ResMed Ltd, ResMed Inc., and ResMed Corp. Under Section 337 of the Tariff Act of 1930, as amended, Investigation No. 337-TA-1022
1505	Answer of ResMed Corp. to Complaint for Patent Infringement and Counterclaims, *Fisher &Paykel Healthcare Ltd. v. ResMed Corp*., Case No. 3:16-cv-02068-DMS-WVG (S.D. Cal.)
1506	U.S. Provisional Application No. 61/064,406
1507	U.S. Provisional Application No. 61/071,893
1508	U.S. Provisional Application No. 61/136,617
1509	Excerpts from the File History of U.S. Patent No. 9,119,931
1510	PCT Publication No. WO 2007/041751 (D'Souza)
1511	PCT Publication No. WO 2006/000046 (Hitchcock)
1512	U.S. Publication No. 2007/0044804 (Matula-II)
1513	U.S. Patent No. 6,412,488 (Barnett)
1514	U.S. Patent No. 6,631,718 (Lovell)
1515	U.S. Patent No. 6,851,425 (Jaffre)
1516	Affidavit of Christopher Butler, Ultra Mirage Brochure (Ultra Mirage), dated September 6, 2016

Exhibit No.	Description
1517	Affidavit of Christopher Butler, FlexiFit Instructions (FlexiFit), dated September 6, 2016
1518	Declaration of Fiona Cresswell, dated September 21, 2016
1519	U.S. Publication No. 2004/0226566 (Gunaratnam-II)
1520	U.S. Publication No. 2004/0182398 (Sprinkle)
1521	U.S. Patent No. 7,827,990 (Melidis)
1522	PCT Publication No. WO 2007/045008 (Worboys)
1523	PCT Publication No. WO 2007/147088 (Matula-I)
1524	U.S. Patent No. 6,796,308 (Gunaratnam-I)
1525	PCT Publication No. WO 2005/123166 (Frater)
1526	U.S. Publication No. 2006/0124131 (Chandran)
1527	PCT Publication No. WO 2007/048174 (Ng)
1528	U.S. Publication No. 2005/0011524 (Thomlinson)
1529	U.S. Patent No. 5,662,101 (Ogden)
1530	U.S. Publication No. 2004/0067333 (Amarasinghe)
1531	U.S. Publication No. 2006/0060200 (Ho)
1532	U.S. Publication No. 2005/0155604 (Ging)
1533	PCT Publication No. WO/2005/021075 (McAuley)
1534	U.S. Publication No. 2004/0118406 (Lithgow)
1535	U.S. Publication No. 2006/0042629 (Geist)

Exhibit No.	Description
1536	U.S. Patent No. 5,921,239 (McCall)
1537	U.S. Patent No. 6,435,181 (Jones, Jr.)
1538	U.S. Publication No. 2006/0201514 (Jones)
1539	PCT Publication No. WO 2004/041342 (Berthon-Jones)
1540	PCT Publication No. WO 2006/074515 (Hitchcock-II)
1541	U.S. Patent No. 5,657,752 (Landis)
1542	PCT Publication No. WO2005051468 (Darkin)
1543	Malloy, Robert A., Plastic Part Design for Injection Molding: An Introduction, pp. 336–345 (Hanser Gardner Publications, Inc. 1994) (Malloy)
1544	U.S. Patent No. 6,581,594 (Drew)
1545	U.S. Patent No. 6,561,190 (Kwok)
1546	PCT Publication No. WO 00/50122 (Fecteau)
1547	Excerpt from Webster’s II New College Dictionary
1548	Excerpt from Oxford American College Dictionary

Pursuant to 35 U.S.C. §§ 311–319 and 37 C.F.R. § 42.100 *et seq.*, Petitioner Fisher & Paykel Healthcare Limited ("Petitioner" or "Fisher & Paykel") requests *inter partes* review of Claims 1, 4–8, 10–22, 25, 26, 28–32, 46, 51, 53-56 and 65 ("Challenged Claims") of U.S. 9,119,931 ("'931 Patent") (Ex. 1501), which is purportedly owned by ResMed Limited ("Patent Owner" or "ResMed").

I. INTRODUCTION

Petitioner filed four previous petitions for *inter partes* review of the '931 Patent claims, including the Challenged Claims. *See* Ex. 1509 at 383–485. The Board instituted review of the claims that do not include the "protruding vent arrangement," but denied review of the claims that include this limitation (the Challenged Claims). *Id*. As its basis for denying institution of the "protruding vent arrangement" claims, the Board adopted a construction of this limitation that was not proposed by either party. Specifically, the Board determined that the broadest reasonable interpretation of "a protruding vent arrangement" is "a discrete vent structure that extends above the surrounding surface of the frame and contains a plurality of vent holes." *Id.* at 391–393, 417–419. By adopting this claim construction, the Board then concluded that the prior art presented in the previous petitions did not disclose a "protruding vent arrangement."

Petitioner was surprised by the Board's construction of this limitation that draws a fine distinction between a protruding portion of the frame that includes

vent holes (as readily shown in the asserted prior art), and a "discrete" protruding vent structure. However, even under the Board's unexpectedly narrow construction, the "protruding vent arrangement" claims would have been obvious to a person of skill in the art. Such discrete vent structures that extend above the surrounding surface of the frame were well-known and disclosed in numerous prior art CPAP references. *See infra* § VII(B)(3)(a)(v). Had Petitioner been able to predict that the Board would have crafted and adopted this construction for the "protruding vent arrangement" limitation, which neither party had advanced, Petitioner would have included those other prior art references in its initial petitions.

As shown in the annotated figures, WO 2007/041751 (D'Souza) discloses the same general features as the '931 Patent. Ex. 1502 ¶ 59.

'931 Patent

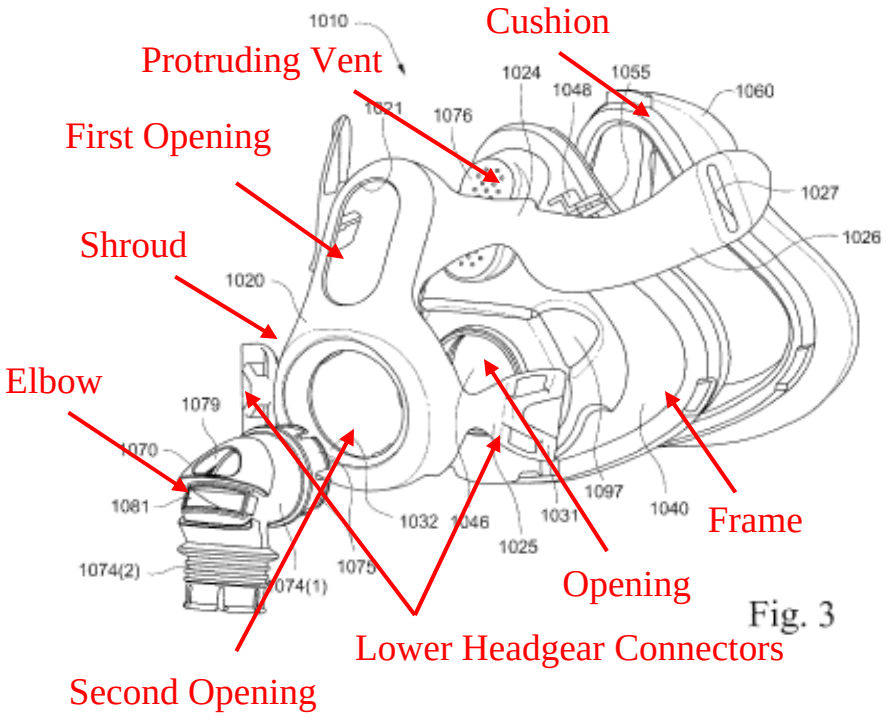


Fig. 3

Prior Art D'Souza (rotated and reversed)

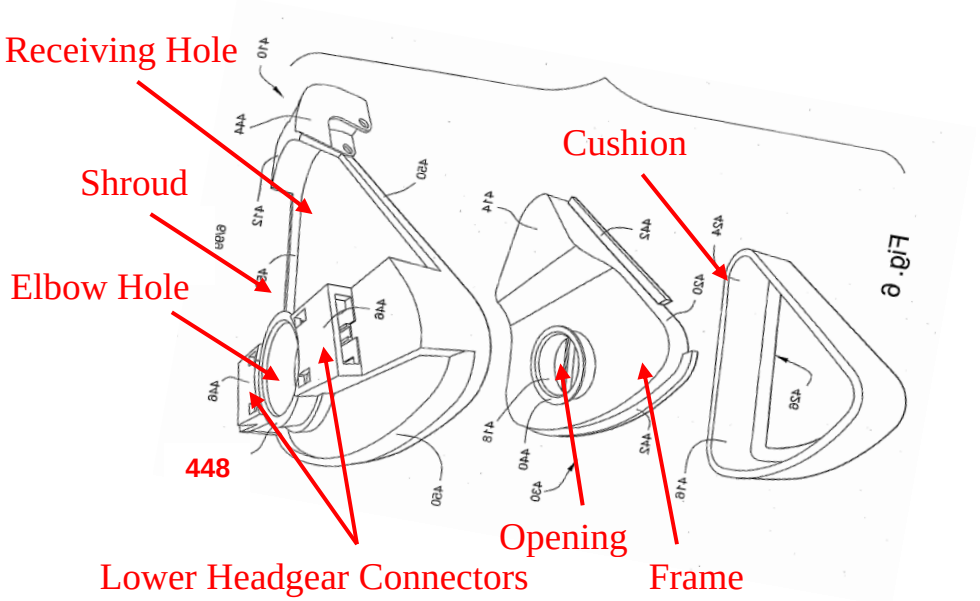


Fig. 8

D'Souza does not disclose a discrete protruding vent, but it was well-known to place such a vent on the frame at the nasal bridge location. *See infra* § VII(B)(3)(a)(v). For example, as shown below, Hitchcock discloses a discrete protruding vent in the nasal bridge location. Ex. 1511 at Fig. 8.

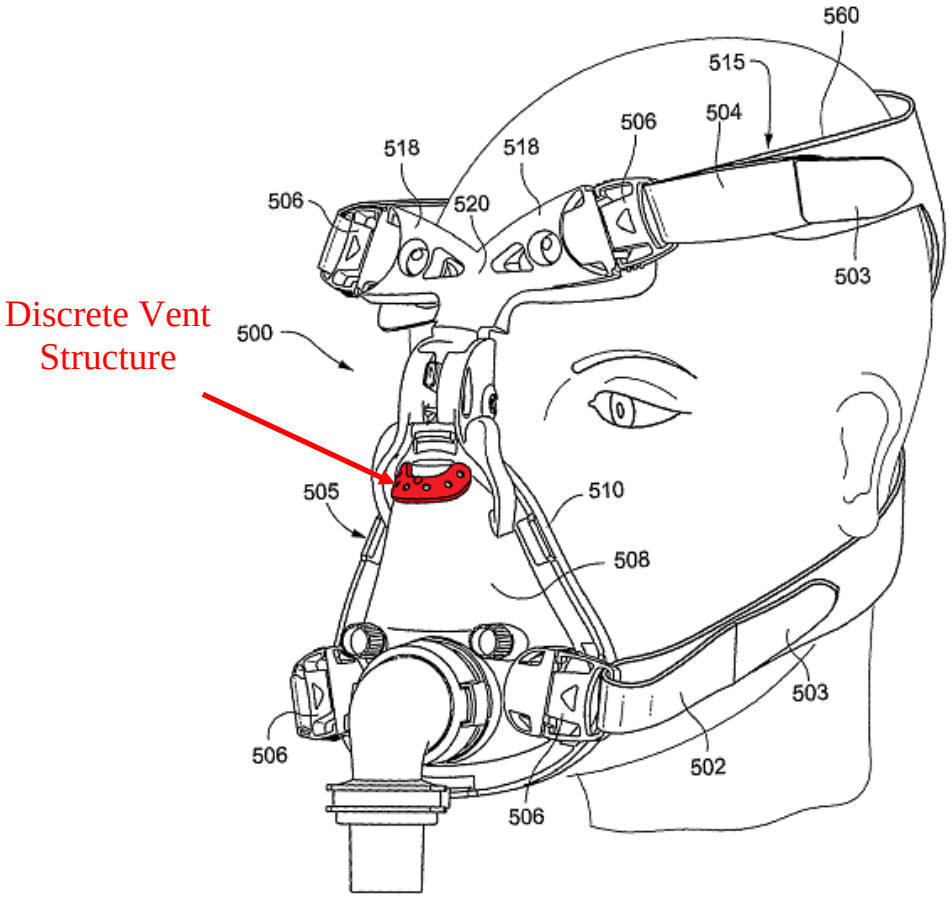


Fig. 8

As explained below, any additional differences between the Challenged Claims and the teachings of D'Souza were similarly well-known and disclosed in other prior art, including ResMed's own publications. *See infra* §§ VII(B)–(L). A person of skill at the time of the purported invention to combine and had a

reasonable expectation of success in combining the features of D'Souza with those of the other prior art CPAP masks.

II. THE BOARD SHOULD DECLINE TO EXERCISE ITS DISCRETION UNDER 35 U.S.C. §§ 314(a) AND 325(d)

This petition is not redundant under 35 U.S.C. § 325(d) with Petitioner's previous and co-pending IPR petitions challenging the '931 Patent. This petition is based on different prior art and challenges only the "protruding vent arrangement" claims that were not instituted in the previous IPRs. Ex. 1509 at 383–485.

The concurrently filed petition relies on Ng (Ex. 1527) and Thomlinson (Ex. 1528), while this petition relies on D'Souza in view of Hitchcock. Because these two concurrently-filed petitions rely on different prior art and obviousness arguments, Petitioner respectfully requests that the Board institute both IPR proceedings. *See ABS Global Inc. v. XY, LLC*, IPR2014-01161, Paper No. 9 at 19 (PTAB Jan. 13, 2015).

The prior art and arguments in this petition are not the same or substantially the same as the previously-filed petitions. In view of the Board's seemingly narrow construction of "protruding vent arrangement," which was not reasonably foreseeable, Petitioner provides different prior art and arguments showing that discrete vent structures were also well-known and a person of skill would have been motivated to include such a vent on the mask frame. For example, Hitchcock

was not used in the previous petitions but is used in each ground of this petition. Thus, the Board should decline to exercise its discretion under § 325(d). *See Valeo North America, Inc. v. Magna Electronics, Inc.*, IPR2014-01204, Paper No. 13 at 11–13 (PTAB Jan. 28, 2015) (finding that the art and arguments in the later petition are not the same or substantially the same where petitioner uses the same primary reference, but a different secondary reference); *Facebook, Inc. v. TLI Communications, LLC*, IPR2015-00778, Paper No. 17 at 26–27 (PTAB Aug. 28, 2015) (instituting review even though there is some overlap with the arguments and prior art of a previous petition challenging the same claims); *Silicon Labs, Inc. v. Cresta Tech Corp.*, IPR2015-00615, Paper 9 at 24-25 (PTAB Aug. 14, 2015) (instituting review where the later challenges rely on different reasoning, despite some commonality); *Wavemarket Inc. v. Locationet Systems Ltd.*, IPR2014-00920, Paper No. 11 at 9–10 (PTAB Dec. 16, 2014) (instituting a later petition based on the same primary reference because it contained new prior art and arguments); *Arista Networks, Inc. v. Cisco Systems, Inc.*, IPR2016-00309, Paper No. 8 at 6–7 (PTAB Jun. 11, 2016).

The Board should also decline to deny institution of this petition based on its broader discretion under 35 U.S.C. § 314(a). This statutory section provides general discretion to the Board to institute IPR petitions, but does not require or compel the Board to institute an IPR. In deciding whether to exercise discretion

under § 314(a), the Board has considered the following factors:

(1) the resources of the Board;

(2) the requirement to issue a final determination not later than 1 year after the date on which the Director notices institution of review;

(3) whether the same petitioner already previously filed a petition directed to the same claims of the same patent;

(4) whether at the time of filing of the first petition the petitioner knew of the prior art asserted in the second petition or should have known about it;

(5) whether at the time of filing of the second petition the petitioner already received patent owner's preliminary response to the first petition or received the Board's decision;

(6) the length of time that elapsed between the time petitioner learned of the prior art asserted in the second petition and filing of the second petition; and

(7) whether petitioner provides adequate explanation for the time elapsed between the filings of multiple petitions directed to the same claims.

Medtronic Xomed, Inc. v. Neurovision Medical Products, Inc., IPR2016-01405, Paper No. 12 at 7 (PTAB Dec. 29, 2016). More recently, the Board broadly evaluated the last factor (7) as "whether the petitioner provides adequate

explanation why we should permit another attack on the same claims of the same patent." *Xactware Solutions, Inc. v. Eagle View Tech., Inc.*, IPR2017-00034, Paper No. 9 at 7–8 (PTAB Apr. 13, 2017).

Regarding factors (1) and (2), the PTAB has already instituted review of many of the claims of the '931 Patent that share nearly all of the same limitations with the Challenged Claims. In fact, the protruding vent arrangement is the only significant limitation addressed in this petition and not a part of the instituted reviews. Any additional burden on the Board caused by institution of these similar claims would be minimal and would not significantly affect the Board's ability to render a final decision. *See Polygroup Ltd v. Willis Electric Co., Ltd.*, IPR2016-00801, Paper No. 8 at 15–16 (PTAB Oct. 17, 2016) (instituting review on grounds similar to a previous petition where the Board is already committed to reviewing similar issues with little additional burden, the parties are engaged in district court litigation, and it would be inefficient for the Board and the district court to have to decide the same issues with respect to the same patent).

Regarding factors (3) and (5), although Petitioner previously filed petitions challenging the same Challenged Claims, Patent Owner did not file any preliminary responses and did not propose any claim constructions. Therefore, Petitioner did not learn from any preliminary response and Patent Owner is not prejudiced by this Petition challenging the claims in view of the Board's claim

construction.

Regarding factors (4) and (6), Petitioner did not think the new prior art references (*e.g.* Hitchcock) were necessary when it filed the earlier petitions relying on a reasonable "ordinary meaning"-type claim construction. Upon receiving the Board's decisions with the unexpected construction of "protruding vent arrangement," Petitioner gathered numerous references that specifically addressed this new construction. Since receiving the earlier decisions, Petitioner has been diligent in preparing and filing this Petition with the new prior art. Moreover, whether the new prior art was available at the time of the first petition is insufficient to justify the Board exercising its discretion. *Facebook*, Paper No. 17 at 26–27 (concluding that petitioner's failure to show the prior art was unavailable is insufficient to exercise discretion under 35 U.S.C. § 314(a)).

Regarding factor (7), there is more than adequate explanation and justification for filing this Petition to outweigh any factors in favor of the Board exercising its discretion. For example, as described above, the Board provided a claim construction of "protruding vent arrangement" in earlier decisions that was unexpected and not proposed by either party. Petitioner believes that its implied "ordinary meaning" construction of this limitation was reasonable, but now requests that the Board allow Petitioner to challenge the claims based on the Board's own construction that it crafted and adopted *sua sponte* in rendering its

recent institution decisions. *See Medtronic Xomed, Inc. v. Neurovision Medical Products, Inc.*, IPR2016-01405, Paper No. 12 at 8–9 (PTAB Dec. 29, 2016) (declining to exercise discretion under 35 U.S.C. §§ 314(a) and 325(d) where the prior petition relied on an improper definition of a claim term and the later petition relied on the correct construction). While the Board is not constrained by the parties' proposed constructions and is free to adopt its own construction, the Board must also give the parties an opportunity to respond. *See SAS Institute, Inc. v. ComplementSoft, LLC,* 825 F.3d 1341, 1351 (Fed. Cir. 2016).

Moreover, this Petition is easily distinguished from the typical follow-on petitions that are denied by the Board for using the preliminary response and institution decision as a road map. In those situations, the original petition is typically deficient (*e.g.*, fails to address a claim limitation, fails to authenticate prior art, etc.). In contrast here, Petitioner's prior petitions challenging the '931 Patent were not deficient, but instead relied on a claim construction that the Board later determined to be incorrect. Thus, Petitioner is not attempting to take multiple bites at the apple and is instead making a first attempt at challenging the claims in view of the Board's own recently adopted claim construction. Congress provided a one-year window for petitioners to request institution of *inter partes* review and the Board should not use its discretion to shorten that window simply because Petitioner has already filed a petition on the same claims earlier in that window.

Silicon Labs, Inc. v. Cresta Tech Corp., IPR2015-00615, Paper 9 at 25 (PTAB Aug. 14, 2015) (concluding that it is not a "prudent exercise of discretion granted by § 325(d) to truncate the ability of a petitioner to make full use of the one-year window Congress expressly provided").

III. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(A)(1)

A. Real Party-In-Interest (37 C.F.R. § 42.8(b)(1))

Petitioner Fisher & Paykel Healthcare Limited is the real party-in-interest. Petitioner provides patients with a broad range of innovative products and systems for use in the treatment of obstructive sleep apnea (OSA) and sells its products in over 120 countries.

B. Related Matters Under 37 C.F.R. § 42.8(b)(2)

ResMed and Fisher & Paykel were involved in proceedings with the United States International Trade Commission in which ResMed asserted that certain Fisher & Paykel products infringe one or more claims of the '931 Patent (Investigation No. 337-TA-1022). Ex. 1504. However, ResMed withdrew its complaint and the investigation was terminated on May 17, 2017.

ResMed and Fisher & Paykel are currently involved in pending litigation in the Southern District of California involving the '931 Patent. *See Fisher & Paykel Healthcare Ltd. v. ResMed Corp.*, Case No. 3:16-cv-02068-DMS-WVG (S.D.

Cal.). ResMed asserted a claim for infringement of the '931 Patent in its counterclaims on September 7, 2016. Ex. 1505.

Fisher & Paykel has concurrently filed an additional petition for *inter partes* review of the '931 Patent that would affect, or be affected by, a decision in this proceeding. Petitioner also previously filed four petitions for *inter partes* review of the '931 Patent (2017-00061, 2017-00062, 2017-00064 and 2017-00065).

C. Lead and Back-up Counsel Under 37 C.F.R. § 42.8(b)(3)

Fisher & Paykel provides the following designation of counsel, all of whom are included in Customer No. 20,995 identified in Fisher & Paykel's Power of Attorney.

Lead Counsel	Back-up Counsel
Brenton R. Babcock (Reg. No. 39,592) 2brb@knobbe.com Postal and Hand-Delivery Address: Knobbe, Martens, Olson & Bear, LLP 2040 Main St., 14th Floor Irvine, CA 92614 Telephone: (949) 760-0404 Facsimile: (949) 760-9502	Benjamin J. Everton (Reg. No. 60,659) 2bje@knobbe.com Postal and Hand-Delivery Address: Knobbe, Martens, Olson & Bear, LLP 2040 Main St., 14th Floor Irvine, CA 92614 Telephone: (949) 760-0404 Facsimile: (949) 760-9502

D. Service Information Under 37 C.F.R. § 42.8(b)(4)

Service information for lead and back-up counsel is provided in the designation of lead and back-up counsel above. Petitioner also consents to service by email at the following address: BoxFPH529-6@knobbe.com.

IV. REQUIREMENTS UNDER 37 C.F.R. § 42.104

A. Grounds for Standing (37 C.F.R. § 42.104(a))

Petitioner hereby certifies that the '931 Patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting *inter partes* review challenging the claims on the grounds identified in this petition.

B. Statement of Relief Requested Under 37 C.F.R. §§ 42.104(b)(1)–(2)

1. Prior Art

Petitioner respectfully requests *inter partes* review of the Challenged Claims of the '931 Patent, filed July 31, 2014, which is a continuation of U.S. Application No. 13/964,280, filed August 12, 2013, which is a continuation of U.S. Application No. 13/745,077, filed January 18, 2013 (U.S. 8,528,561), which is a continuation of U.S. Application No. 12/736,024 (U.S. 8,550,084), filed as PCT Application No. PCT/AU2009/000241 on February 27, 2009, which claims priority benefit of U.S. Provisional Application Nos. 61/064,406, 61/071,893, and 61/136,617 (collectively the "Provisional Applications"), filed March 4, 2008, May 23, 2008, and September 19, 2008, respectively. Ex. 1501 at 1–2. The earliest possible priority date of the '931 Patent is March 4, 2008, but this date does not apply to the Challenged Claims, as explained below.

The Challenged Claims of the '931 Patent would have been obvious in view of the following prior art:

a. WO 2007/041751 ("D'Souza") (Ex. 1510)

D'Souza was filed on January 12, 2006 and published in English on April 19, 2007. Ex. 1510 at 1.

The earliest-filed provisional application from which the '931 Patent claims priority benefit, U.S. Provisional Application No. 61/064,406, disclosed a vent on the elbow or the seal, but did not disclose a vent on the frame. Ex. 1506 ¶¶ 66–69; Ex. 1502 ¶ 31. Indeed, a protruding vent arrangement is not shown or described in any of the Provisional Applications. Ex. 1506; Ex. 1507; Ex. 1508; Ex. 1502 ¶ 31. Thus, the earliest possible priority date for the Challenged Claims is the filing date of the parent application, U.S. Application No. 12/736,024, on February 27, 2009.

Because D'Souza published more than one year before May 23, 2008, D'Souza is prior art under at least 35 U.S.C. § 102(b).[1]

b. PCT Publication No. WO 2006/000046 ("Hitchcock") (Ex. 1511)

Hitchcock published on January 5, 2006. Ex. 1511 at 1. Because Hitchcock published more than one year before the earliest possible priority date, it is prior art under 35 U.S.C. § 102(b).

[1] Reference to 35 U.S.C. §§ 102 and 103 throughout this Petition are to the pre-AIA versions of these statutes, which are applicable to the '931 Patent.

c. U.S. Publication No. 2007/0044804 ("Matula-II") (Ex. 1512)

Matula-II published on March 1, 2007. Ex. 1512 at 1. Because Matula-II published more than one year before the earliest possible priority date, it is prior art under 35 U.S.C. § 102(b).

d. U.S. 6,412,488 ("Barnett") (Ex. 1513)

Barnett issued on July 2, 2002. Ex. 1513 at 1. Because Barnett issued more than one year before the earliest possible priority date, it is prior art under 35 U.S.C. § 102(b).

e. U.S. 6,631,718 ("Lovell") (Ex. 1514)

Lovell issued on October 14, 2003. Ex. 1514 at 1. Because Lovell issued more than one year before the earliest possible priority date, it is prior art under 35 U.S.C. § 102(b).

f. U.S. 6,851,425 ("Jaffre") (Ex. 1515)

Jaffre issued on February 8, 2005. Ex. 1515 at 1. Because Jaffre issued as a patent more than one year before the earliest possible priority date, it is prior art under 35 U.S.C. § 102(b).

g. Ultra Mirage Full Face Mask Brochure ("Ultra Mirage") (Ex. 1516 at 6–7)

Ultra Mirage was publicly available on ResMed's website at least by September 1, 2006 and various pages bear the copyright dates of 2004 and 2005.

Ex. 1516 at 7. The Internet Archive Wayback Machine shows that the public had access to a ResMed webpage containing links to Ultra Mirage by at least September 1, 2006. Ex. 1516 at 8. The authenticity of Ultra Mirage is established by the affidavit of Christopher Butler, attaching Ultra Mirage and testifying as to how the Wayback Machine works and its reliability. Ex. 1516 at 1–2; *see also EMC Corp. v. Personalweb Techs., LLC*, IPR2013-00084, Paper No. 64 at 45 (PTAB May 15, 2014).

The prior art status of Ultra Mirage is further supported by the declaration of Jason Eaton, P.E., explaining that a person of skill in the art would have kept informed about CPAP products on the market and would have visited the websites of well-known CPAP companies providing CPAP products, such as ResMed. Ex. 1502 ¶¶ 176–180.

Because Ultra Mirage was available to the public more than one year before the earliest possible priority date, it is prior art under 35 U.S.C. § 102(b).

h. FlexiFit Series, HC 431 Full Face Mask, Instructions for Use ("FlexiFit") (Ex. 1517 at 9–10)

FlexiFit was publicly available by at least October 16, 2006. Ex. 1517 at 5, 8, 11. The authenticity of FlexiFit is established by the accompanying affidavit of Christopher Butler, attaching FlexiFit and testifying as to how the Wayback Machine works and its reliability. Ex. 1517 at 1–2; *see EMC Corp.*, Paper No. 64

at 45. The Wayback Machine shows that the public had access to a Fisher & Paykel webpage containing links to FlexiFit by at least October 16, 2006. Ex. 1517 at 5, 8, 11.

The authenticity and public availability of FlexiFit is further supported by the declaration of Fiona Cresswell, a Fisher & Paykel employee, testifying to personal knowledge that the documents are authentic and were available. Ex. 1518 at 1–4; *see EMC Corp.*, Paper No. 64 at 45.

The prior art status of FlexiFit is further supported by the declaration of Jason Eaton, P.E., explaining that a person of skill in the art would have kept informed about CPAP products on the market and would have visited the websites of well-known companies providing CPAP products, such as Fisher & Paykel. Ex. 1502 ¶¶ 176–180.

Because FlexiFit was available to the public more than one year before the earliest possible priority date, FlexiFit is prior art under 35 U.S.C. § 102(b).

i. U.S. Publication No. 2004/0226566 ("Gunaratnam-II") (Ex. 1519)

Gunaratnam-II published on November 18, 2004. Ex. 1519 at 1. Because Gunaratnam-II published more than one year before the earliest possible priority date, it is prior art under 35 U.S.C. § 102(b).

j. U.S. Publication No. 2004/0182398 ("Sprinkle") (Ex. 1520)

Sprinkle published on September 23, 2004. Ex. 1520 at 1. Because Sprinkle published more than one year before the earliest possible priority date, it is prior art under 35 U.S.C. § 102(b).

2. Grounds

Fisher & Paykel requests *inter partes* review of Claims 1, 4–8, 10–22, 25, 26, 28–32, 46, 51, 53–56 and 65 of the '931 Patent. Because ResMed claimed a laundry list of well-known features in its many lengthy patent claims, this petition necessarily includes several different prior art references that disclose those various common features. The grounds below are not overlapping in that each challenged claim of the '931 patent is subject to only one ground of unpatentability.

Ground #1. Claims 1, 6–8, 10, 11, 18, 31, and 32 would have been obvious over D'Souza in view of Hitchcock under 35 U.S.C. § 103.

Ground #2. Claims 4, 5, and 26 would have been obvious over D'Souza in view of Hitchcock and Matula-II under 35 U.S.C. § 103.

Ground #3. Claims 12, 14, and 16 would have been obvious over D'Souza in view of Hitchcock and Barnett under 35 U.S.C. § 103.

Ground #4. Claim 13 would have been obvious over D'Souza in view of Hitchcock and Lovell under 35 U.S.C. § 103.

Ground #5. Claim 15 would have been obvious over D'Souza in view of Hitchcock and Jaffre under 35 U.S.C. § 103.

Ground #6. Claim 17 would have been obvious over D'Souza in view of Hitchcock, Barnett, and Ultra Mirage under 35 U.S.C. § 103.

Ground #7. Claims 19, 21, and 25 would have been obvious over D'Souza in view of Hitchcock, FlexiFit, and Gunaratnam-II under 35 U.S.C. § 103.

Ground #8. Claim 20 would have been obvious over D'Souza in view of Hitchcock, FlexiFit, Gunaratnam-II, and Sprinkle under 35 U.S.C. § 103.

Ground #9. Claim 22 would have been obvious over D'Souza in view of Hitchcock, FlexiFit, Gunaratnam-II, and Matula-II under 35 U.S.C. § 103.

Ground #10. Claims 28–30 and 65 would have been obvious over D'Souza in view of Hitchcock, Matula-II, and Barnett under 35 U.S.C. § 103.

Ground #11. Claims 46, 51, and 53–56 would have been obvious over D'Souza in view of Hitchcock, FlexiFit, Barnett, Jaffre, Matula-II, Gunaratnam-II, Ultra Mirage, and Sprinkle under 35 U.S.C. § 103.

C. Claim Construction (37 C.F.R. § 42.104(b)(3))

Solely for the purpose of this review, Petitioner construes the Challenged Claims of the '931 Patent such that the claims are given their broadest reasonable

interpretation in light of the specification of the '931 Patent.[2] 37 C.F.R. § 42.100(b); *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278–79 (Fed. Cir. 2015), *aff'd*, 136 S. Ct. 2131 (2016). All terms have their ordinary and customary meaning in light of the specification, as commonly understood by those of ordinary skill in the art at the time of the invention. *In re Translogic Tech.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). In that light, Petitioner provides the following analyses for the construction of two limitations of the Challenged Claims.

1. "protruding vent arrangement"

Claims 1, 46, and 51 recite "the frame includes a protruding vent arrangement having a plurality of holes." Claim 65 recites, "the frame includes a protruding vent arrangement having a plurality of gas washout holes." In previous decisions, the Board determined that the broadest reasonable interpretation for this feature is "a discrete vent structure that extends above the surrounding surface of the frame and contains a plurality of vent holes." Ex. 1509 at 391–393, 417–419. Although neither party proposed this construction, the analysis provided in this Petition adopts this construction from the Board.

[2] Petitioner's position regarding the scope of the claims should not be taken as an assertion regarding the appropriate claim scope in other adjudicative forums where a different standard of claim construction may apply.

2. "accommodate"

Claims 1, 46, and 51 recite "the shroud module includes a first opening to accommodate said protruding vent arrangement." Claim 65 recites "the shroud module includes an upper opening to accommodate said protruding vent arrangement."

The plain and ordinary meaning of the term "accommodate" in this context is to provide enough space for something. Ex. 1502 ¶¶ 39–41.

The claims themselves do not provide any further description or explanation of how the opening accommodates. The'931 Patent refers briefly to this feature and states "[t]he top end includes an opening or vent receiving hole 1021 to accommodate the vent arrangement 1076 that protrudes from the frame 1040, and the bottom end includes an opening or elbow hole 1032 to accommodate the elbow 1070 and elbow opening into the frame 1040 (e.g., shroud provides no contact with elbow when assembled)." Ex. 1501 at col. 7:21–27. This description refers to Figure 3 (next page) and suggests that the accommodating openings do not have to contact the vent arrangement and elbow when assembled, and that the openings are not constrained by the shape or size of the elbow and vent arrangement. Ex. 1502 ¶ 40.

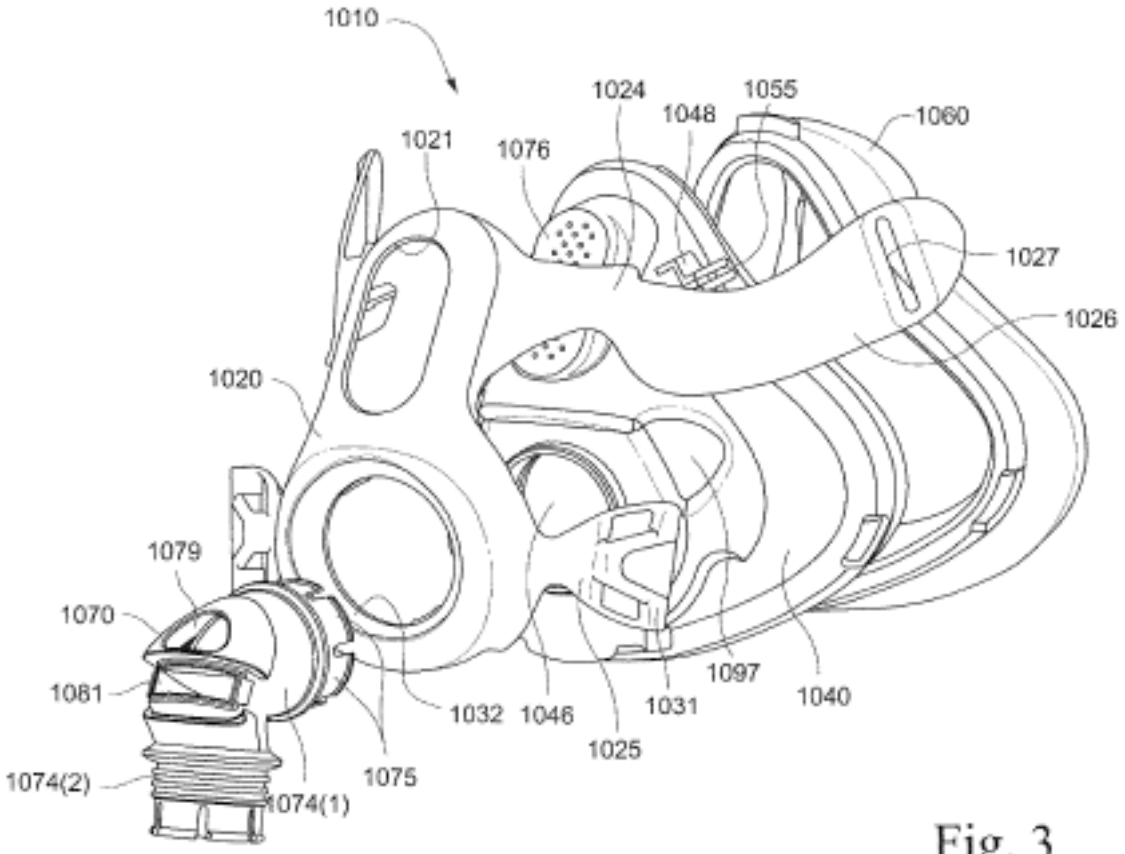


Fig. 3

This interpretation is supported by dictionary definitions, which indicate that an opening "accommodates" when there is "enough space for" or "allow[s] for" another object. Ex. 1544 at 7. Other dictionaries provide similar definitions, such as provide "sufficient space for." Ex. 1545 at 7.

V. THE ’931 PATENT

A. Example Embodiments

The ’931 Patent discloses a CPAP mask system 1010 having a frame 1040 that supports a cushion 1060 and attaches to the shroud 1020, as illustrated below. Ex. 1501 at col. 6:51–54. The shroud 1020 includes an opening 1021 that receives the protruding vent 1076. *Id.* at col. 7:9–23.

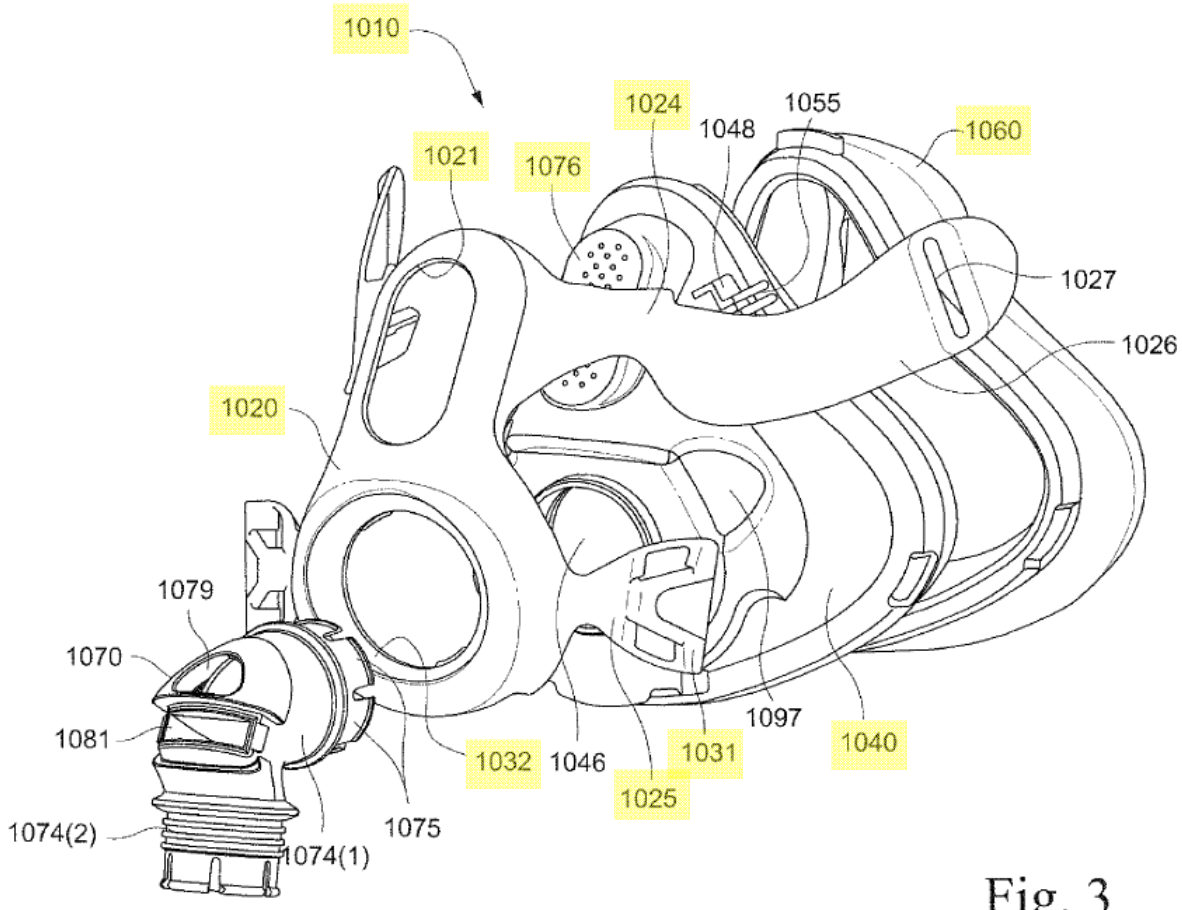


Fig. 3

Upper and lower headgear connectors 1024, 1025 extend from each side of the shroud. *Id.* at col. 7:28–30.

As shown below, the headgear 1090 includes upper and lower straps 1092, 1094. Upper straps 1092 split into top straps 1096. *Id.* at col. 10:52–59.

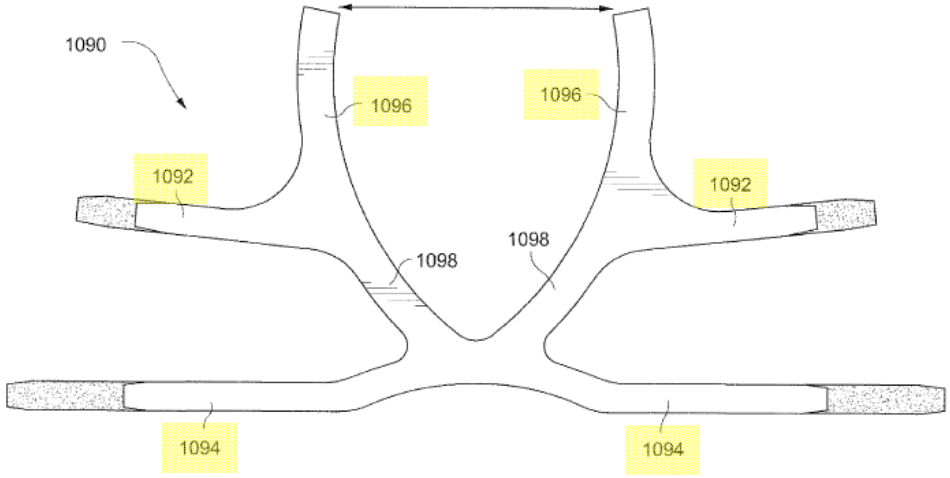


Fig. 9

Frame 1140 is connected to the shroud 1120 by snap fingers 1145(1) that engage the collar 1149, as shown below. *Id.* at col. 18:48–67.

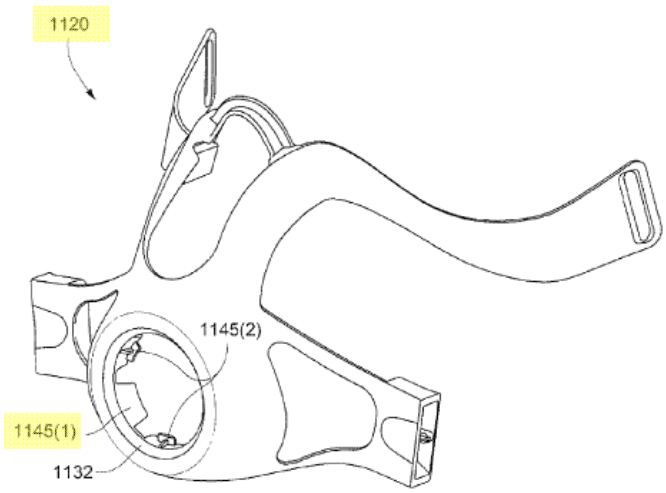


Fig. 14

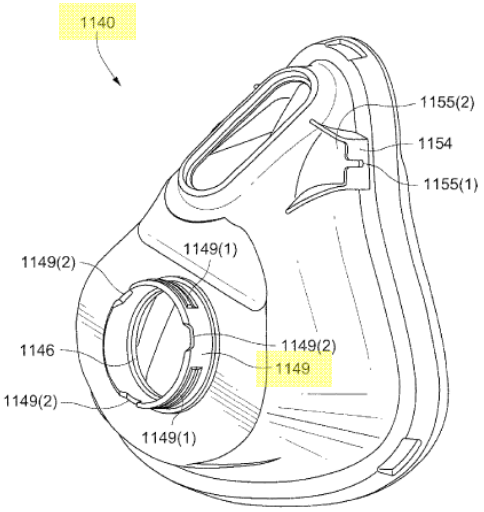


Fig. 11

B. Summary of the Prosecution History of the ’931 Patent

The ’931 Patent was originally filed as U.S. Application No. 14/447,673 on July 31, 2014.

On December 8, 2014, the Examiner rejected all pending claims based on U.S. Publication No. 2006/0272646 (“Ho”) in view of other prior art. Ex. 1509 at 166–171. In response, Applicant amended Claim 1 to include the “non-rotatably coupleable” limitation and added Claims 22–33. *Id.* at 237–243. Claim 29 included, *inter alia*, “a protruding vent arrangement.” *Id.* at 241.

On February 3, 2015, the Examiner rejected almost all the pending claims based on U.S. Publication No. 2006/0042629 (“Geist”) in view of other prior art. *Id.* at 258–272. The Examiner also indicated that Claims 29 and 33 would be allowable if rewritten in independent form. *Id.* at 272. In response, Applicant amended Claim 1 to include the features of Claim 29. *Id.* at 324. Applicant also added Claims 34–83. *Id.* at 331–341. The Examiner issued a notice of allowability on July 15, 2015. *Id.* at 354–361.

VI. LEVEL OF ORDINARY SKILL IN THE ART

A person having ordinary skill in the field at the time of the purported invention of the ’931 Patent would have at least a bachelor’s degree in mechanical engineering, biomedical engineering or other similar type of engineering degree,

combined with at least two years of experience in the field of masks, respiratory therapy, patient interfaces or relevant product design experience. Ex. 1502 ¶ 26.

VII. THE CHALLENGED CLAIMS OF THE '931 PATENT ARE UNPATENTABLE

This Petition explains why the Challenged Claims of the '931 Patent are unpatentable and is supported by the declaration of Jason Eaton, P.E, who has extensive industry experience in CPAP mask design. Ex. 1502 ¶¶ 2–8.

A. Legal Standard for Obviousness

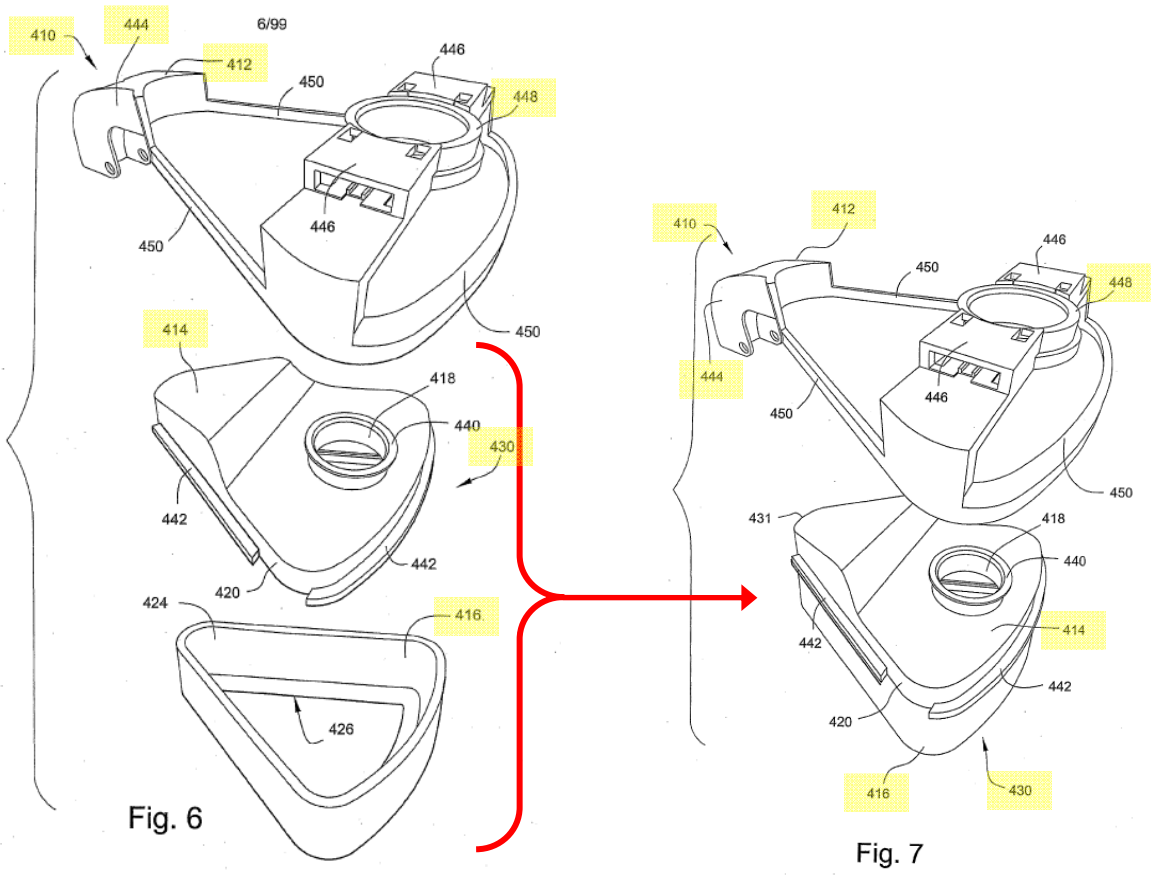
A claim is obvious "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103. The obviousness analysis includes an assessment of the *Graham* factors: (1) the scope and content of the prior art; (2) any differences between the claims and the prior art; (3) the level of ordinary skill in the art; and (4) any objective indicia of nonobviousness. *KSR Int'l v. Teleflex Inc.*, 550 U.S. 398, 406 (2007).

B. Ground 1: Claims 1, 6–8, 10, 11, 18, 31, and 32 would have been obvious over D'Souza in view of Hitchcock

1. Overview of D'Souza (Ex. 1510)

D'Souza was submitted, but not cited, during the prosecution of the '931 Patent. Ex. 1501 at 9.

As shown below, D'Souza discloses a CPAP mask assembly 410 having a skeleton frame 412 that is removably interlocked with a cushion/frame sub-assembly 430. *Id.* ¶¶ 96–100.



The skeleton frame 412 includes an upper support member 444 adapted to support a forehead support (not shown), lower headgear clip receptacles 446 adapted to engage headgear clips (not shown), and an annular elbow connection seal 448 adapted to engage an elbow (not shown). *Id.* ¶ 100.

2. Overview of Hitchcock (Ex. 1511)

Hitchcock was submitted, but not cited, during the prosecution of the ’931 Patent. Ex. 1501 at 1–12.

Hitchcock describes a CPAP mask assembly 500 having a frame 508 adapted to support a cushion 510. Ex. 1511 ¶¶ 4, 35. As shown below, the mask assembly 500 includes headgear connectors and a protruding vent in the nasal bridge region of the frame. *See id.* ¶ 38, Fig. 8; Ex. 1502 ¶ 55.

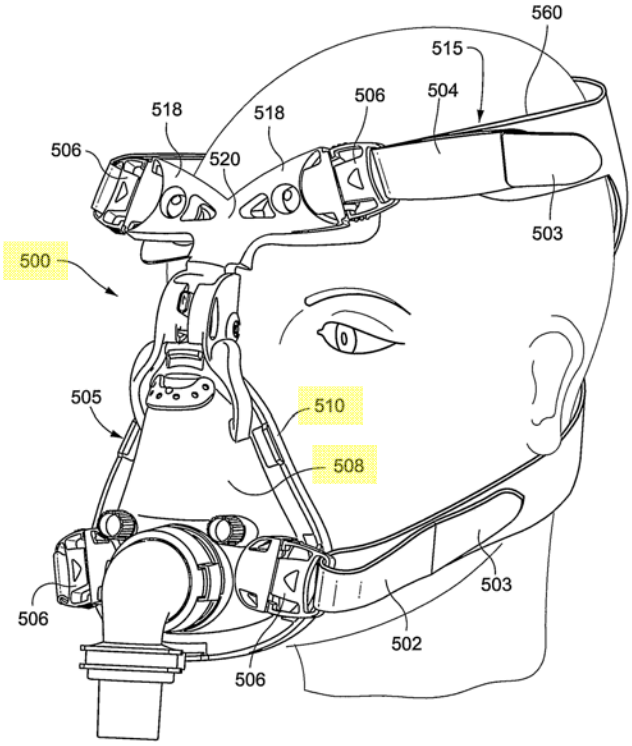
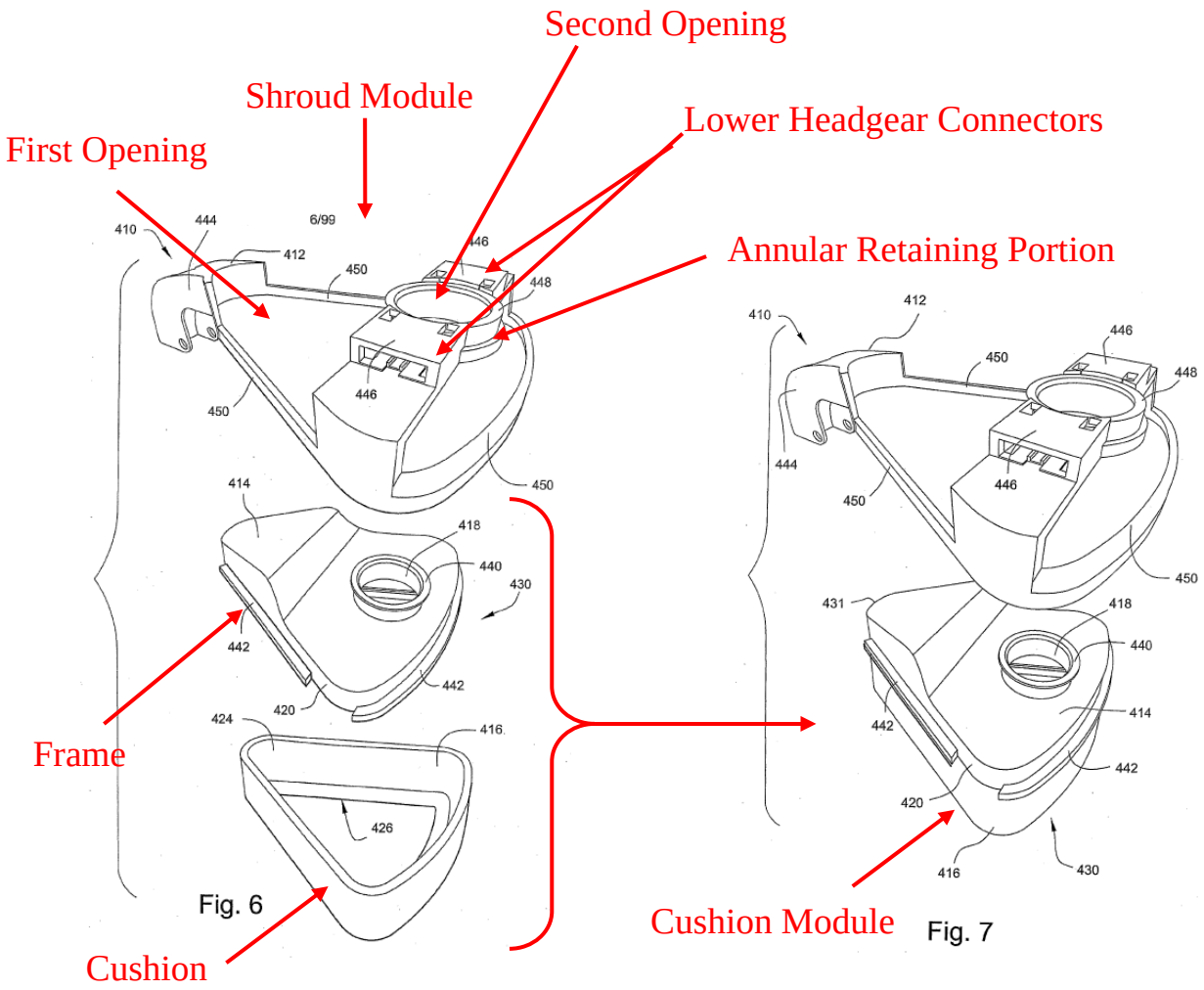


Fig. 8

3. Limitations of Claims 1, 6–8, 10, 11, 18, 31, and 32

Many of the features of Claim 1 are identified in the annotated figures of D'Souza provided below. Ex. 1502 ¶ 59.



As outlined below, any differences between Claims 1, 6–8, 10, 11, 18, 31, and 32 and D'Souza were minor, well-known at the time of the invention, and taught by Hitchcock. *See infra* §§ VII(B)(3)(a)–(i).

Because D'Souza and Hitchcock describe similar CPAP mask assemblies for the treatment of sleep-disordered breathing, the features of Hitchcock would have been readily compatible with and easily incorporated into the D'Souza mask with a reasonable expectation of success. Ex. 1502 ¶ 61. Combining these familiar CPAP mask features according to known methods would have done no more than yield predictable results. *See id.* ¶¶ 61–106; *see also KSR*, 550 U.S. at 416.

a. Limitations of Claim 1

i. "A mask system, comprising:"

As shown below, D'Souza discloses a mask system 410. Ex. 1510 ¶ 96.

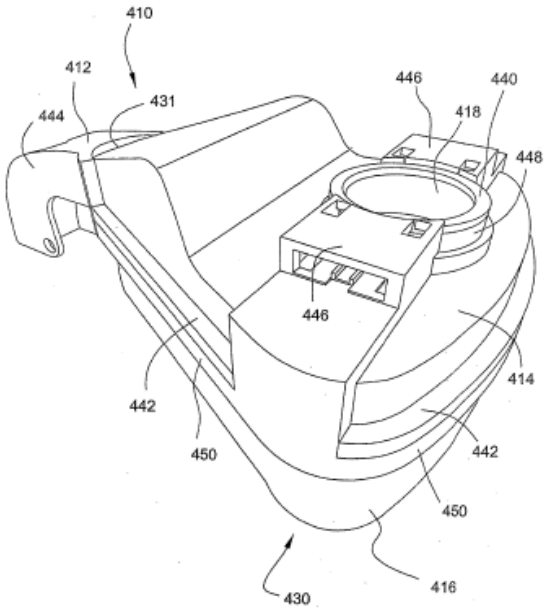


Fig. 8

ii. "(i) a shroud module; wherein the shroud module includes headgear connectors adapted to removably attach to respective headgear straps of headgear; and"

D'Souza discloses a shroud module 412 with headgear connectors 446 adapted to engage clips provided to headgear straps. Ex. 1510 ¶ 100.

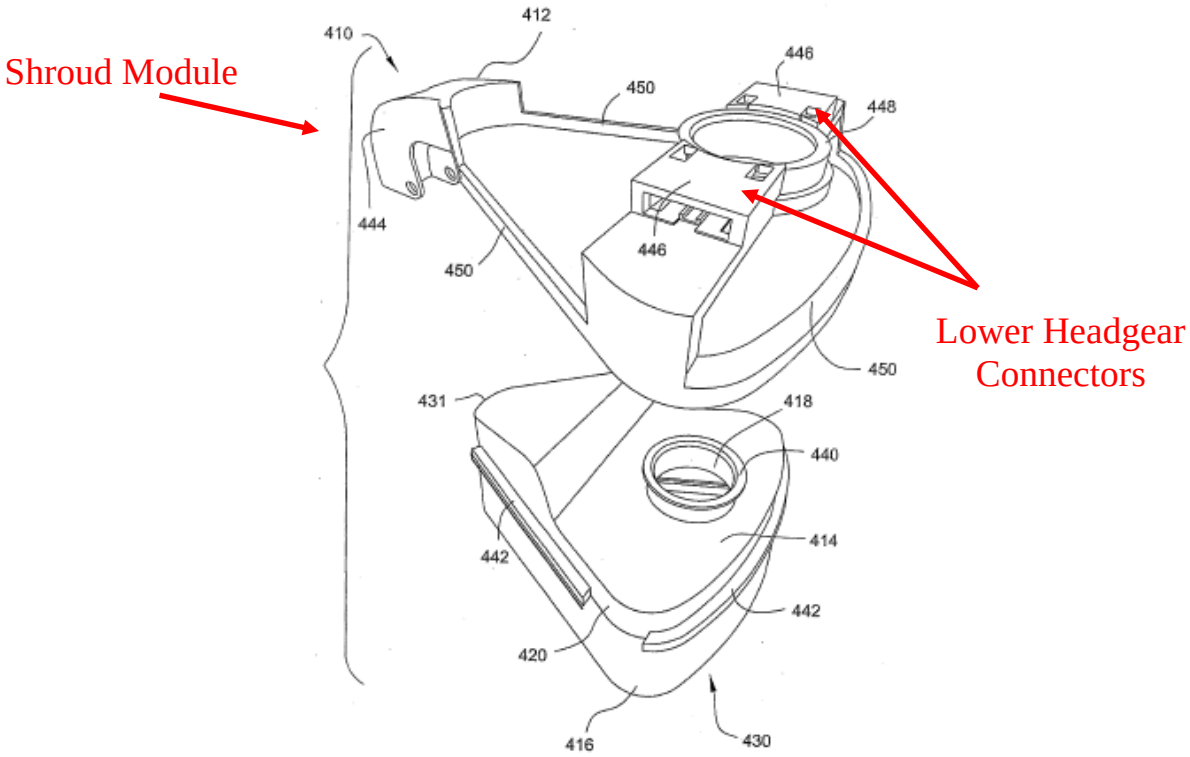


Fig. 7

To the extent D'Souza provides insufficient disclosure for the removability of the headgear straps, this was a common feature so that the mask could be easily removed. Ex. 1502 ¶¶ 64–67. For example, Hitchcock discloses upper and lower straps that are removably connected to the mask. Ex. 1511 ¶ 36.

A person of skill in the art at the time of the invention would have been motivated to provide headgear connectors adapted to removably attach to headgear straps to enable quick and easy mask fitting, separation for cleaning, and convenient removal in an emergency. Ex. 1502 ¶ 67. Further, a person of skill would have recognized that removable headgear allows the mask to be removed without resetting the headgear. *Id.*

iii. "(ii) a cushion module, comprising: a rigid or semi-rigid frame defining a breathing chamber; and a cushion to form a seal with the patient's face in a nasal bridge region, a cheek region and a lower lip/chin region of the patient's face, wherein the cushion is constructed of a first, relatively soft, elastomeric material and the frame is constructed of a second material that is more rigid than the cushion,"

D'Souza discloses a cushion module 430 having a frame 414 attached to a cushion 416, as shown below. Ex. 1510 ¶ 97. The frame 414 is constructed of a rigid polycarbonate material and includes walls 420 that define a breathing chamber. *Id.* ¶ 98. The cushion 416 is constructed of a relatively soft, elastomeric material, liquid silicone rubber, and provides a seal around the patient's nose and

mouth (in a nasal bridge region, a check region and lower lip/chin region). *Id.* ¶¶ 81, 97.

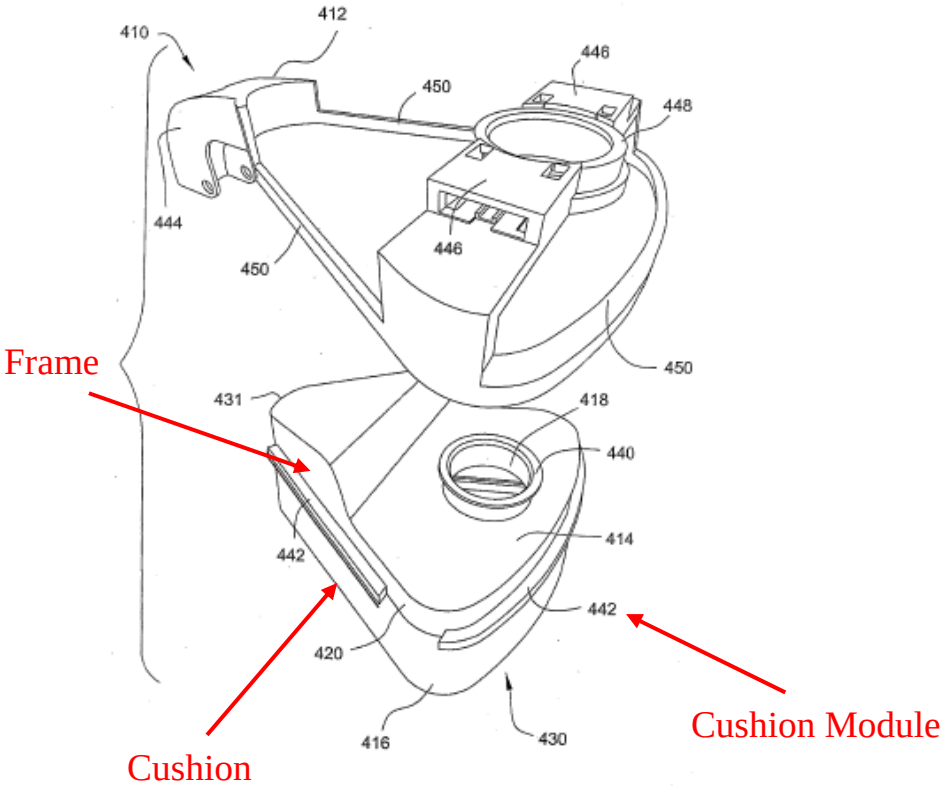


Fig. 7

iv. "wherein the shroud module and the cushion module are configured to be removably and non-rotatably coupleable to one another; and"

The D'Souza shroud module 412 removably interlocks with the cushion module 430, as shown below. Ex. 1510 ¶ 96. They are non-rotatably coupled as the "annular elbow connection seal 448 interlocks with the annular wall 440 . . . upper support member 444 interlocks with a top portion 431 . . . and the elongated frame members 450 interlock with respective protrusions 442." *Id.* ¶ 101.

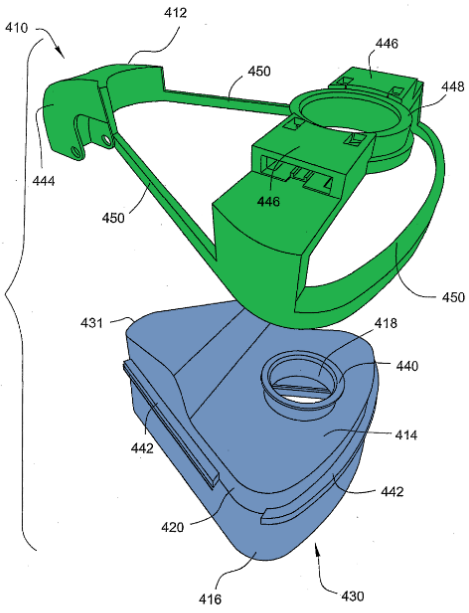


Fig. 7

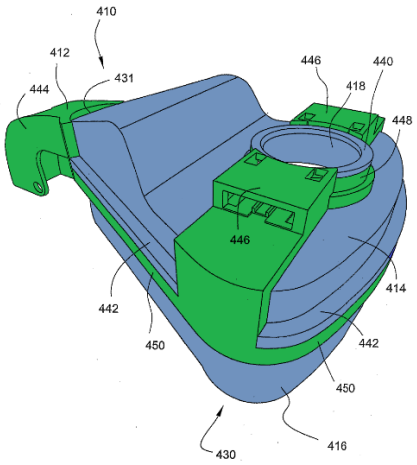


Fig. 8

v. "wherein the frame includes a protruding vent arrangement having a plurality of holes,"

In its previous decisions, the Board construed this limitation to mean "a discrete vent structure that extends above the surrounding surface of the frame and

contains a plurality of vent holes." Ex. 1509 at 391–393, 417–419, 477–479. This type of vent structure was common in CPAP masks and disclosed in numerous prior art references. Ex. 1502 ¶¶ 69–80.

D'Souza does not disclose a discrete protruding vent arrangement on the mask frame. However, Hitchcock and many other prior art references disclose such arrangements. *Id.* ¶¶ 70–80. As shown on the next page, Hitchcock discloses a discrete vent structure with multiple vent holes that extends above the surrounding surface of the frame. Ex. 1511 at Fig. 8; Ex. 1502 ¶ 71.

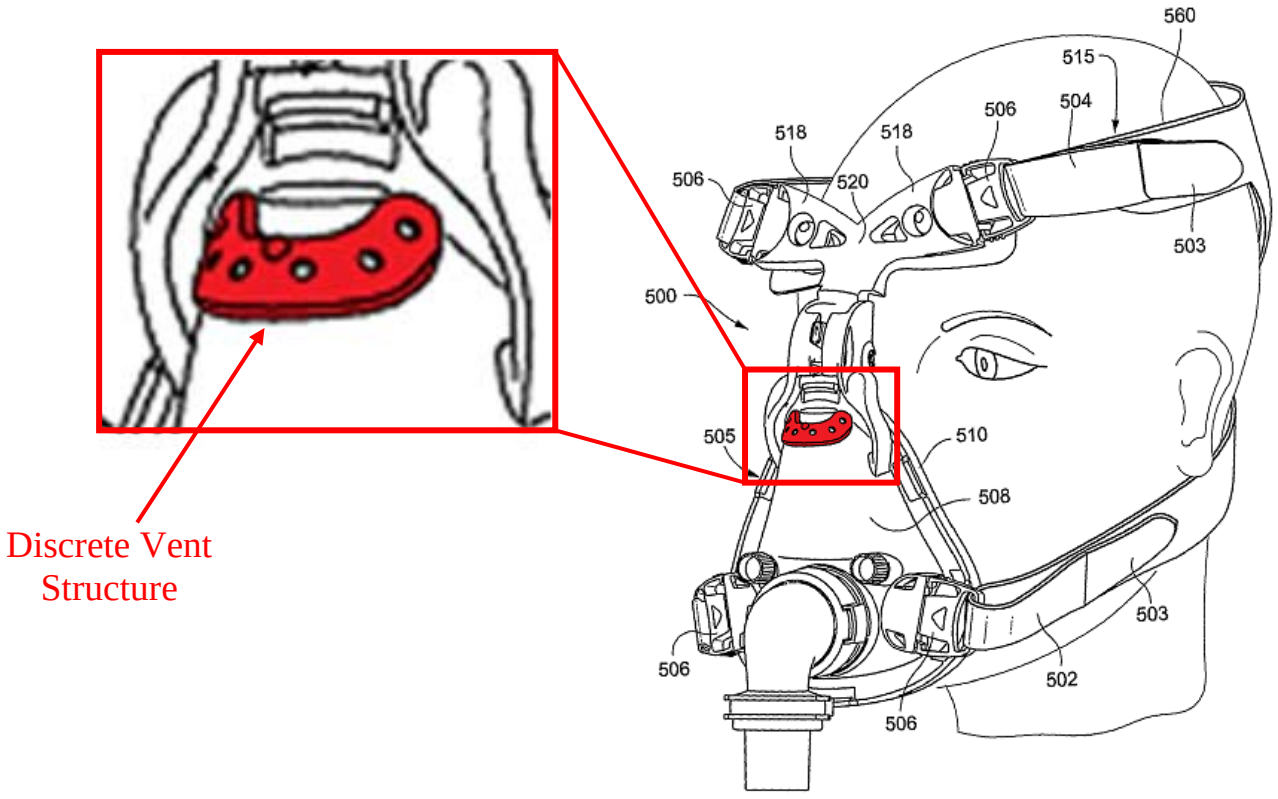
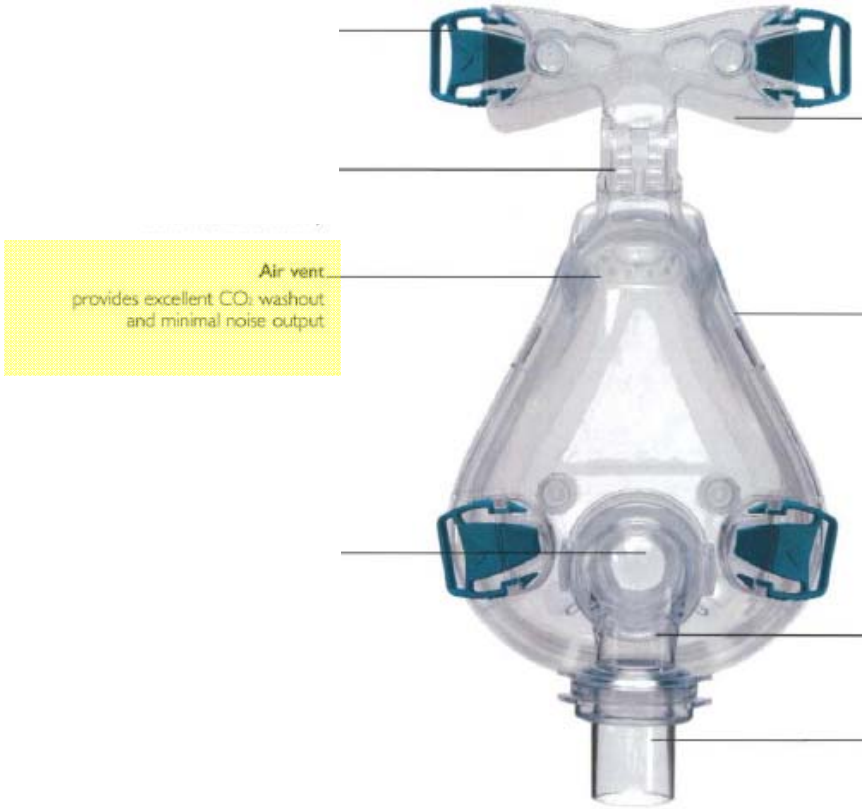


Fig. 8

Hitchcock does not describe the details of the vent structure, but a person of skill would have known that this feature was an air vent with a plurality of holes similar to Ultra Mirage, which also discloses a vent structure on the frame. *See* Ex. 1516 at 6; Ex. 1502 ¶ 72.



A person of skill would have been motivated to provide a protruding vent on the D'Souza frame for CO_2 washout. *See* Ex. 1516 at 6; Ex. 1502 ¶¶ 76–80. In particular, a person of skill would have been motivated to modify the D'Souza frame to include a discrete vent structure, as disclosed by Hitchcock, in the same position shown in Hitchcock (*e.g.*, in the nasal bridge region), as shown in the annotated drawings below. *Id.* ¶¶ 76–77. The discrete vent structure would extend

above the surrounding surfaces of the top portion 431 of the D'Souza frame 414. *Id.* ¶ 76.

D'Souza (reversed) **Hitchcock**

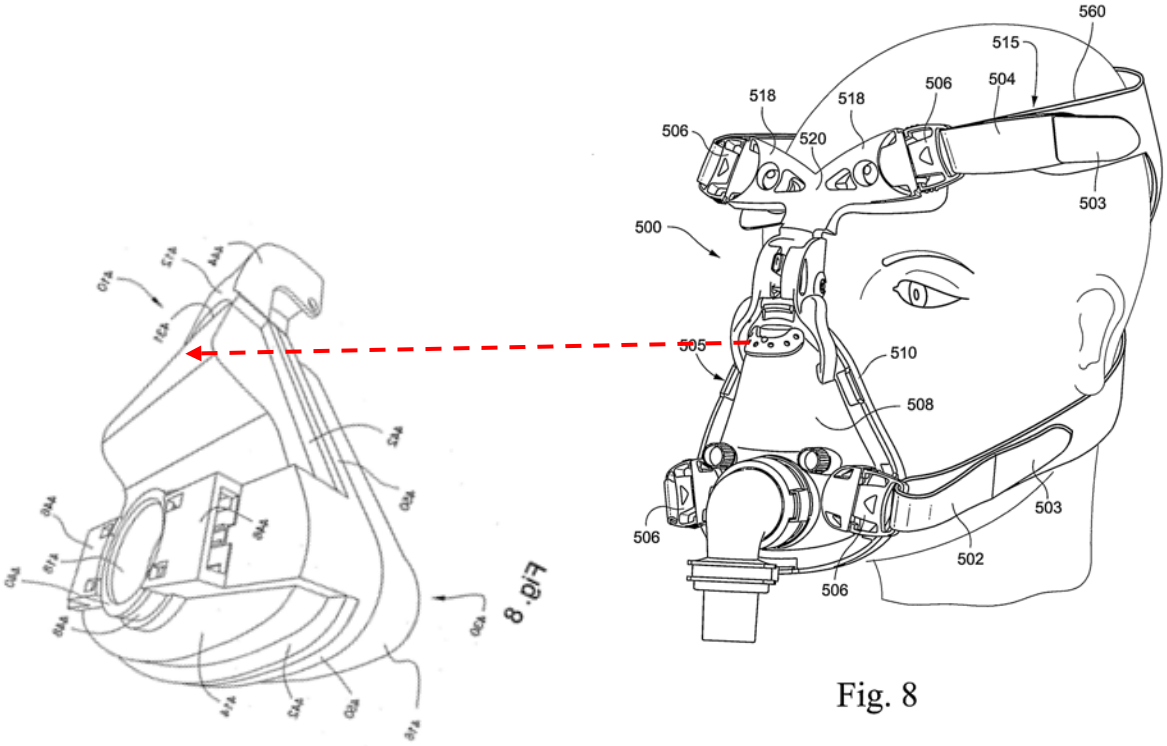


Fig. 8

Positioning the vent in the nasal bridge region of a full-face mask frame was known to promote greater air movement within the dead space from the inlet to the vent and minimize re-breathing of exhaled air. *See* Ex. 1516 at 4, 7; Ex. 1502 ¶ 77.

Further, a person of skill would have been motivated to include the protruding vent arrangement to provide design flexibility for orienting the vent holes in a direction that is independent of the surrounding surface of the frame. Ex. 1502 ¶¶ 78–79. The protruding vent arrangement would provide a thicker wall, which would enable deeper and/or angled holes that better direct the vented air and reduce the velocity of the airflow, which minimizes turbulence, draft, and noise. *Id.*

In instances where the protruding vent arrangement is made from a separate part and joined or assembled to the frame, greater flexibility is afforded in manufacturing techniques, allowing geometry that would be difficult or impossible to form directly on a frame molded by traditional techniques to be readily formed in a mold without undercuts or hidden surfaces. *Id.* ¶ 79.

vi. "wherein the shroud module includes a first opening to accommodate said protruding vent arrangement, and"

D'Souza discloses a first shroud opening (between the elongated frame members 450) that receives the top portion 431 of the frame 414 when the mask is

assembled. Ex. 1510 ¶ 101. With the D'Souza frame modified in view of Hitchcock to have a protruding vent arrangement (*see supra* § VII(B)(3)(a)(v)), the first opening in the D'Souza shroud 412 would receive and allow access to the protruding vent arrangement when the mask is assembled, as shown below. Ex. 1502 ¶ 82.

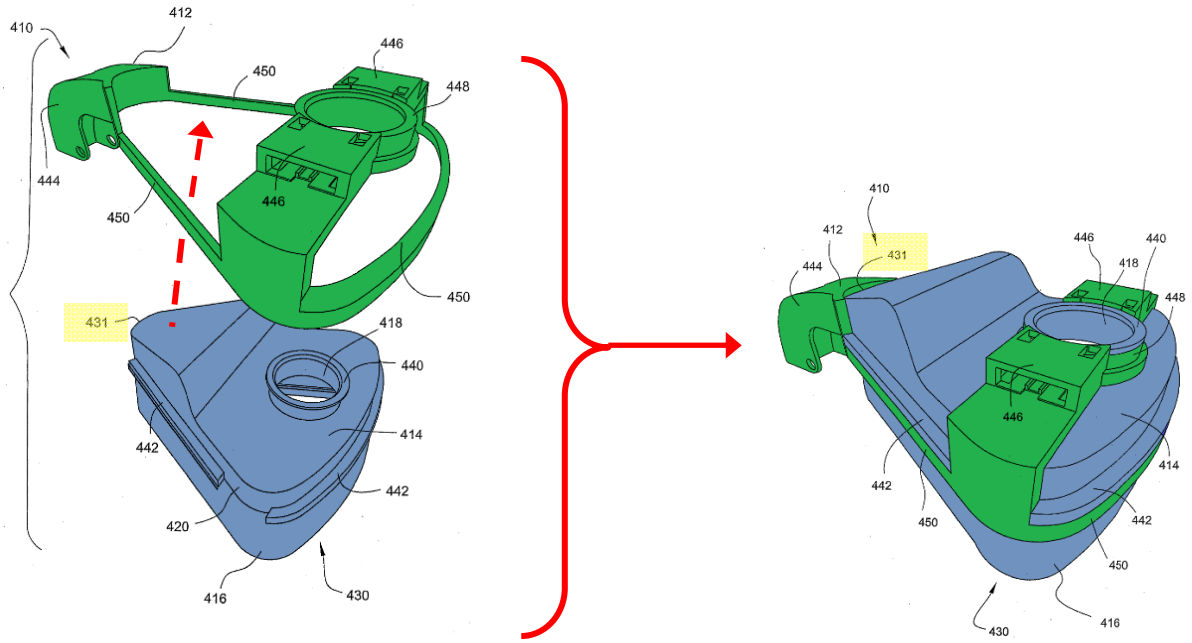


Fig. 7 Fig. 8

As explained above, "accommodate" in this context would include an opening that provides enough space for the protruding vent. *See supra* § IV(C)(2). The first opening of D'Souza would receive and provide enough space for the protruding vent of the modified frame 414. Ex. 1502 ¶ 82. A person of skill

would have known that such an opening is necessary to allow the vented gas to exit the frame without being blocked by the shroud. *Id*.

vii. "further wherein the shroud module includes a second opening positioned to align with a frame opening of the frame leading to the breathing chamber."

As shown below, D'Souza discloses a second shroud opening defined by annular seal 448 that aligns with the frame opening 418 leading to the breathing chamber. Ex. 1510 ¶ 101.

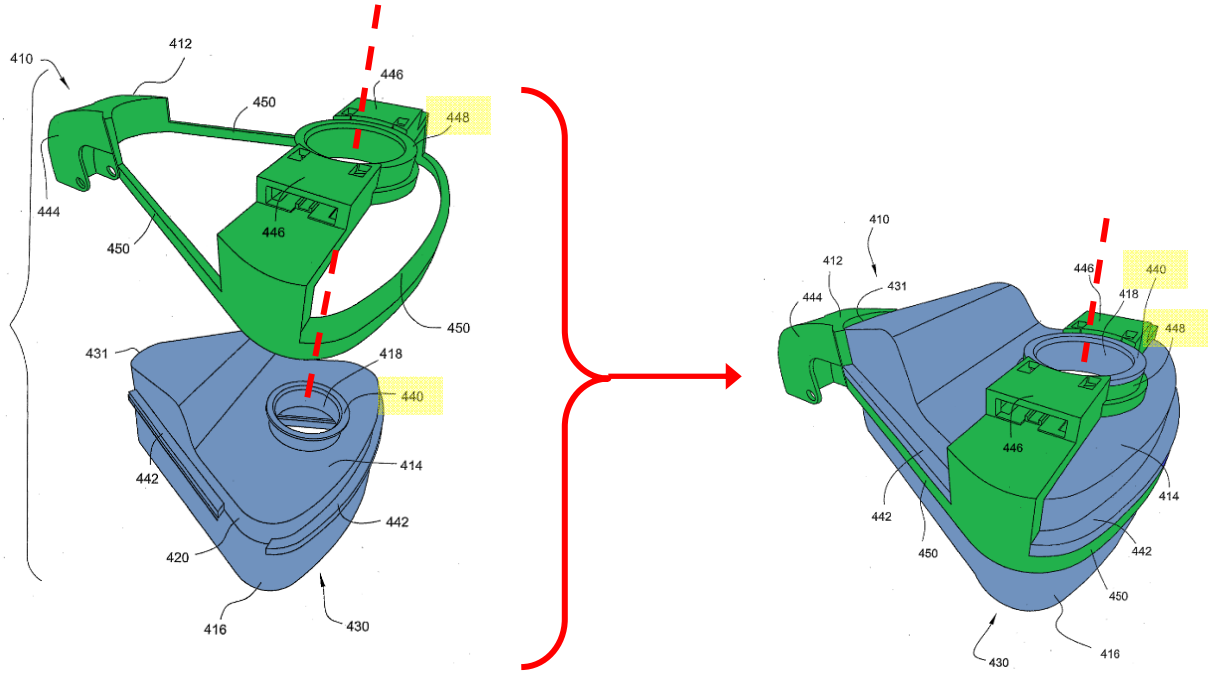


Fig. 7 Fig. 8

b. Dependent Claim 6

Claim 6 depends from Claim 1 and includes:

"wherein the shroud module includes upper and lower headgear connectors on each side of the shroud module."

As shown below, the shroud module 412 includes an upper support member 444 adapted to support a forehead support (not shown) and lower headgear clip receptacles 446. Ex. 1510 ¶ 100.

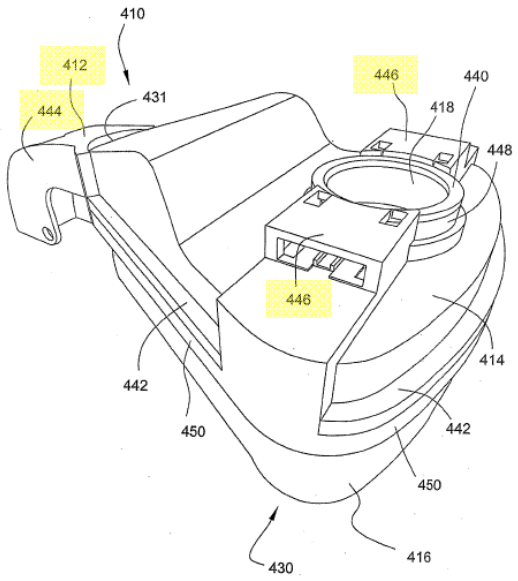


Fig. 8

D'Souza does not show upper headgear connectors, but it was common for prior art masks to have such connectors, especially masks with forehead supports. Ex. 1502 ¶¶ 85–86. For example, as shown below, Hitchcock discloses a shroud having a forehead support with headgear connectors. Ex. 1511 ¶ 36. A skilled artisan would have known to provide upper headgear connectors on the forehead

support to secure the upper portion of the mask assembly and to stabilize the mask assembly. Ex. 1502 ¶ 85.

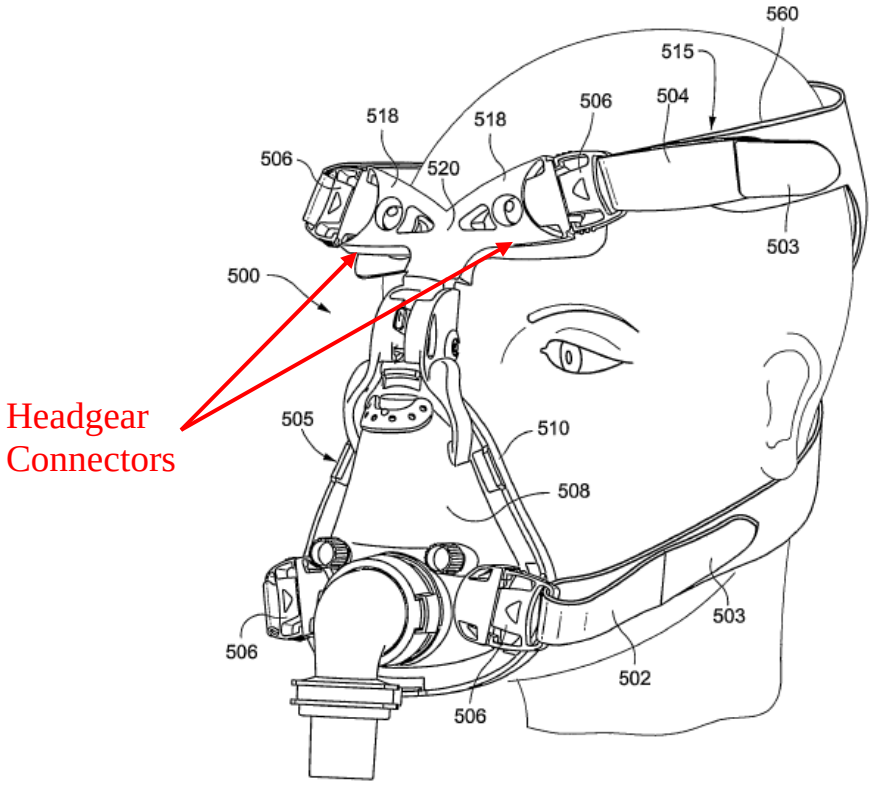


Fig. 8

c. Dependent Claim 7

Claim 7 depends from Claim 6 and includes:

"wherein each upper headgear connector includes a slot adapted to receive a respective headgear strap in use."

D'Souza does not expressly disclose upper headgear connector slots, but such slots were common in masks, as shown in Hitchcock below. Ex. 1511 ¶ 24.

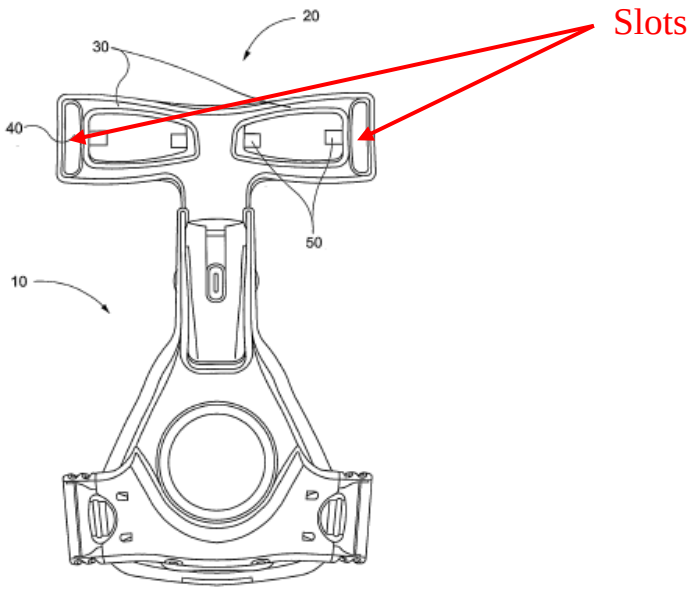


Fig. 1
Prior Art

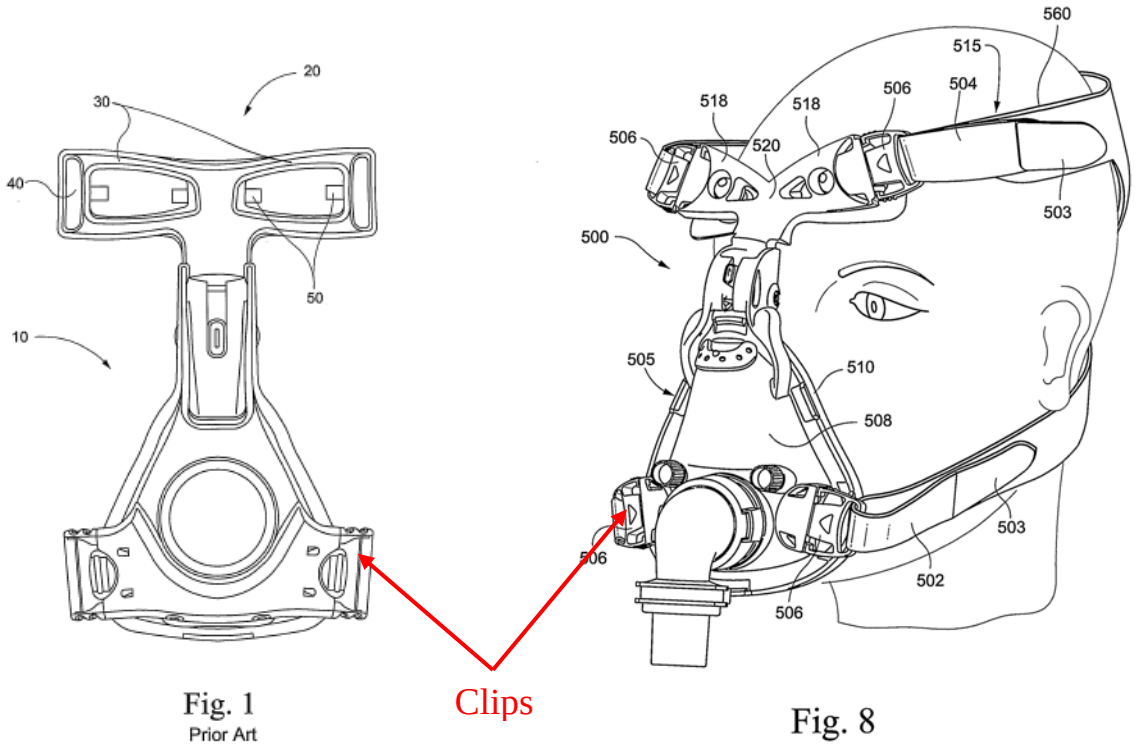
Since upper headgear straps undergo less tension than lower headgear straps when positioning the headgear, a person of skill would have known to include such slots, as taught by Hitchcock, to simplify the design, simplify manufacturing, and reduce parts. Ex. 1502 ¶¶ 90–91.

d. Dependent Claim 8

Claim 8 depends from Claim 7 and includes:

"wherein each lower headgear connector is adapted to be removably interlocked with a headgear clip associated with a respective headgear strap."

D'Souza discloses lower headgear connectors adapted to engage clips, but to the extent D'Souza is insufficient for the removability of the clips, Hitchcock discloses removable lower headgear clips, as shown below. Ex. 1510 ¶ 100; Ex. 1511 ¶ 38.



A person of skill would have provided upper headgear slots and lower headgear clips to make headgear positioning easier. Ex. 1502 ¶¶ 98–100. Unlike

the upper straps, the lower headgear straps undergo tension when the headgear is pulled over a user's head, making it difficult to position the lower headgear straps. *Id.* A person of skill would have been motivated to provide removable lower headgear clips as taught by Hitchcock, so that the user would not have to force the lower headgear straps over his/her head. *Id.*

e. Dependent Claim 10

Claim 10 depends from Claim 1 and includes:

"wherein the shroud module includes an annular or part annular cushion retaining portion structured to retain the cushion module."

As shown below, the D'Souza shroud module 412 includes an annular cushion retaining portion 448 that interlocks with the annular wall 440 of the cushion module 430. Ex. 1510 ¶ 101.

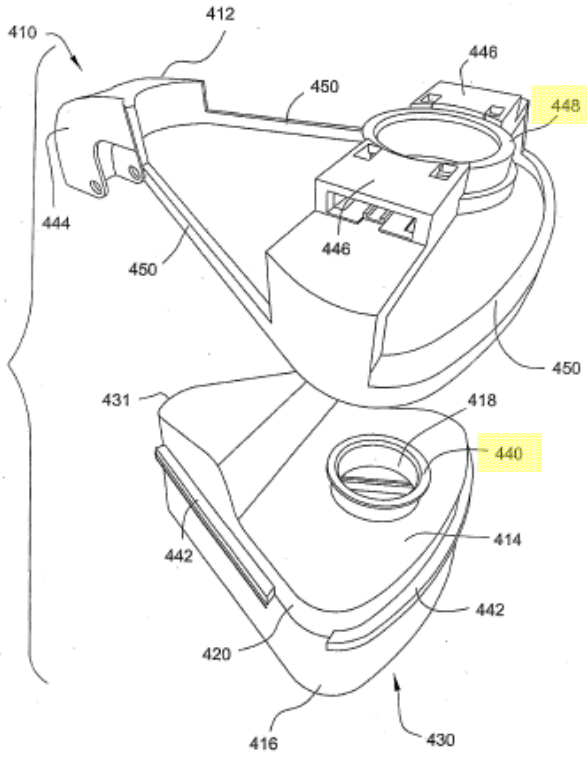


Fig. 7

f. Dependent Claim 11

Claim 11 depends from Claim 1 and includes:

"further comprising an elbow module adapted to be connected to an air delivery tube that delivers breathable gas to the patient."

D'Souza discloses mask assemblies for use with a flow generator and adapted to engage an elbow. Ex. 1510 ¶¶ 3, 100. Although D'Souza may not specify an air delivery tube, it was typical to use tubing to connect an elbow to a flow generator. Ex. 1502 ¶¶ 102–103. For example, Hitchcock discloses delivery of pressurized gas from an air delivery tube via an elbow. Ex. 1511 ¶ 28.

A person of skill would have known to use tubing to connect mask assemblies to flow generators, as taught by Hitchcock. Ex. 1502 ¶¶ 102–103. The D'Souza mask assembly would have been readily compatible with standardized tubing commonly used to deliver breathable air to mask assemblies. *Id.* ¶ 103.

g. Dependent Claim 18

Claim 18 depends from Claim 1 and includes:

"wherein the shroud module and the frame comprise polycarbonate and the cushion comprises silicone."

D'Souza discloses a cushion 416 constructed of liquid silicone rubber and a polycarbonate frame 414. Ex. 1510 ¶¶ 97–98. D'Souza further discloses the shroud being formed of plastic, but does not state that the plastic is polycarbonate. *Id.* ¶ 100. However, it was very common and general knowledge of a person of skill at the time of the invention to construct CPAP components, including the shroud, from polycarbonate. Ex. 1502 ¶ 106.

A person of skill would have used polycarbonate to provide strength, rigidity, and toughness to support the headgear. *Id.* Polycarbonate CPAP components can also be cleaned, disinfected, and/or sterilized by commonly used methods. *Id.*

h. Dependent Claim 31

Claim 31 depends from Claim 1 and includes:

"wherein the frame is rigid."

D'Souza discloses a rigid polycarbonate frame 414. Ex. 1510 ¶ 98, 101; Ex. 1502 ¶¶ 105–106.

i. Independent Claim 32

Independent Claim 32 includes:

"A system for treating a patient with sleep disordered breathing, comprising:"

D'Souza discloses mask assemblies for the treatment of sleep-disordered breathing. Ex. 1510 ¶ 3.

"the mask system of claim 1;"

The mask system of Claim 1 is disclosed by the combination of D'Souza and Hitchcock, as explained above. *See supra* § VII(B)(3)(a).

"a flow generator to generate a supply of air at positive pressure to be delivered to the mask system; and an air delivery tube configured to deliver the supply of air from the flow generator to the mask system."

The D'Souza mask assemblies are "for use with blowers and flow generators in the treatment of sleep disordered breathing (SDB)." Ex. 1510 ¶ 3. Further, as explained above, it was common knowledge to use tubing to connect an elbow to a flow generator, as taught by Hitchcock. *See supra* § VII(B)(3)(f).

C. Ground 2: Claims 4, 5 and 26 would have been obvious over D'Souza in view of Hitchcock and Matula-II

1. Overview of Matula-II (Ex. 1512)

Matula-II was submitted, but not cited, during the prosecution of the '931 Patent. Ex. 1501 at 7.

Matula-II discloses a CPAP mask including a faceplate 36 coupled to a seal member 38. Ex. 1512 ¶¶ 52–53. As shown below, Matula-II discloses a coupling member 46 including a pair of prongs 48 that define a channel 50 to receive the wall of the faceplate 36 and the end of the seal member 38. *Id.* ¶ 53.

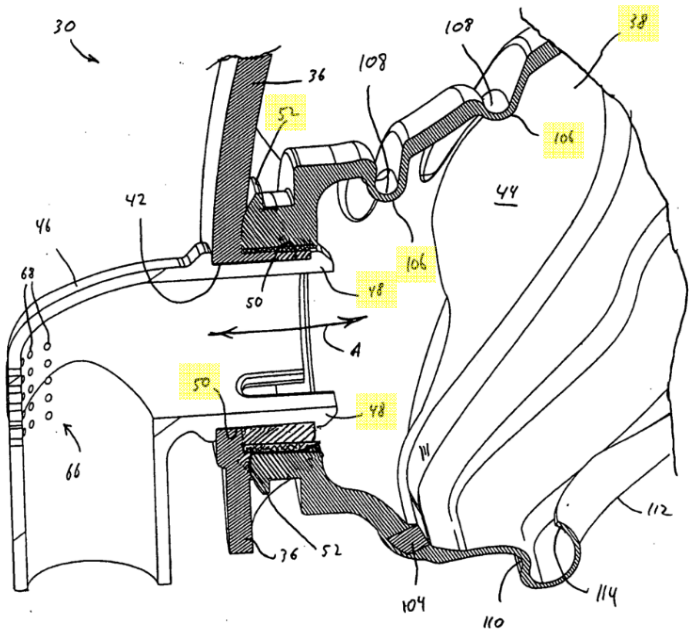


Fig. 4

Additionally, Matula-II discloses seal member 38 with folds 106 provided at an upper portion "so that the seal member has the desired degree of flexibility." *Id.* ¶ 66.

2. Limitations of Claims 4, 5, and 26

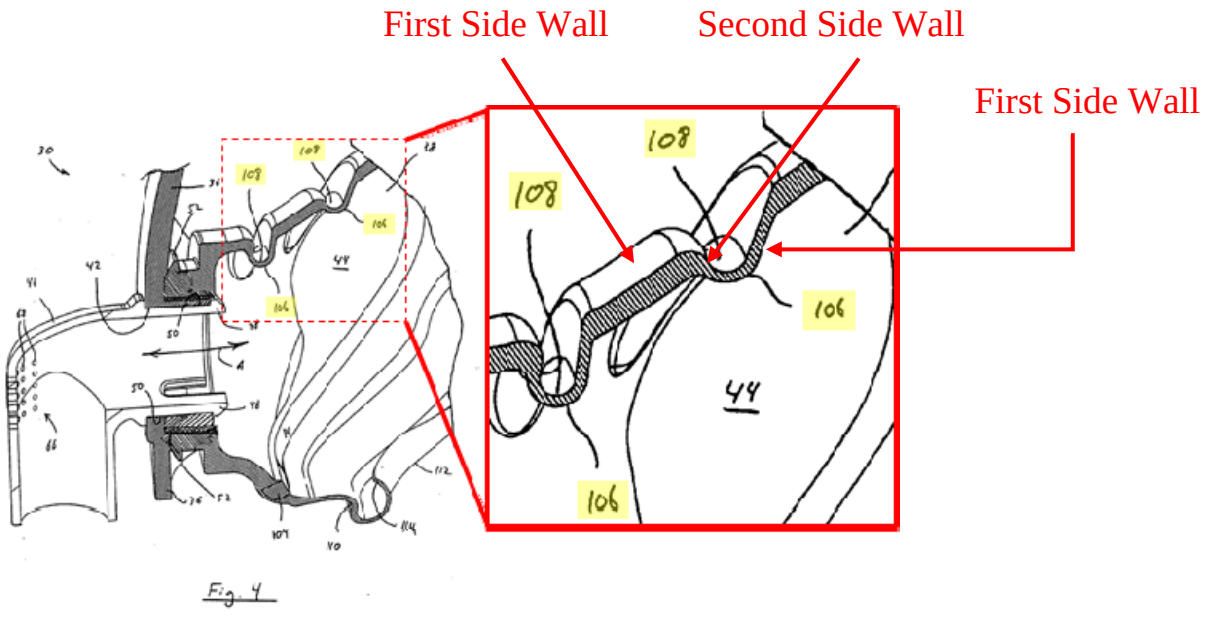
A person of skill in the art would have been motivated to combine D'Souza, Hitchcock, and Matula-II for at least the reasons provided above. *See supra* § VII(B). Because Matula-II discloses a CPAP mask with structurally similar features, its features would have been readily compatible with, and easily incorporated into, the D'Souza mask with a reasonable expectation of success. Ex. 1502 ¶ 111. Combining these familiar features according to known methods would have done no more than yield predictable results. *See id.* ¶¶ 111–138; *see also KSR*, 550 U.S. at 416.

a. Claim 4

Claim 4 depends from Claim 1 and includes:

"wherein a nasal bridge portion of the cushion includes one or more folds to provide in use a higher level of adaptability or flexibility to the nasal bridge region of the cushion module relative to another region of the cushion module; and further wherein each of said one or more folds comprises adjacent first side walls interconnected by a second side wall."

D'Souza does not expressly disclose a fold, but such folds were well-known in the prior art. Ex. 1502 ¶¶ 113–118. For example, as shown below, Matula-II discloses folds 106 in the nasal bridge portion of the cushion 38 to provide "the desired degree of flexibility." Ex. 1512 ¶ 66. The fold 106 has first side walls interconnected by a second side wall. *See id.*; Ex. 1502 ¶ 113.



The Matula-II fold configuration is similar to the fold disclosed in the '931 Patent, which has adjacent first side walls 52(1) interconnected by a second side wall 52(2), as shown below in the annotated Figure 32-3. *See* Ex. 1501 at col. 14:40–42; Ex. 1502 ¶ 114.

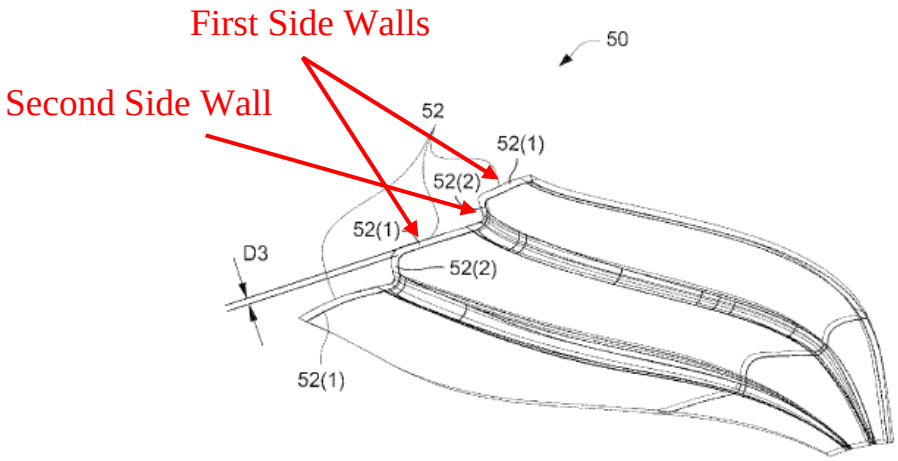


Fig. 32-3

A person of skill in the art at the time of the invention would have been motivated to include the Matula-II fold configuration, to provide higher flexibility in the nasal bridge region. *See* Ex. 1512 ¶ 66; Ex. 1502 ¶ 118. A person of skill would have recognized that this modification would increase patient comfort and optimize the sealing force. *See* Ex. 1512 ¶ 3; Ex. 1502 ¶ 117. By providing more flexibility in the delicate nasal bridge region, less force is transmitted to the nasal bridge region, while more force is transmitted to other areas (*e.g.*, cheeks) that are better suited to support higher pressures. Ex. 1502 ¶ 118.

b. Claim 5

Claim 5 depends from Claim 1 and includes:

"wherein the frame includes a collar surrounding said frame opening, and wherein the shroud includes a retaining portion with a plurality snap fingers structured to engage the collar with a snap-fit."

As shown below, the D'Souza frame 414 has a collar (including 440) surrounding the opening 418. Ex. 1510 ¶ 98.

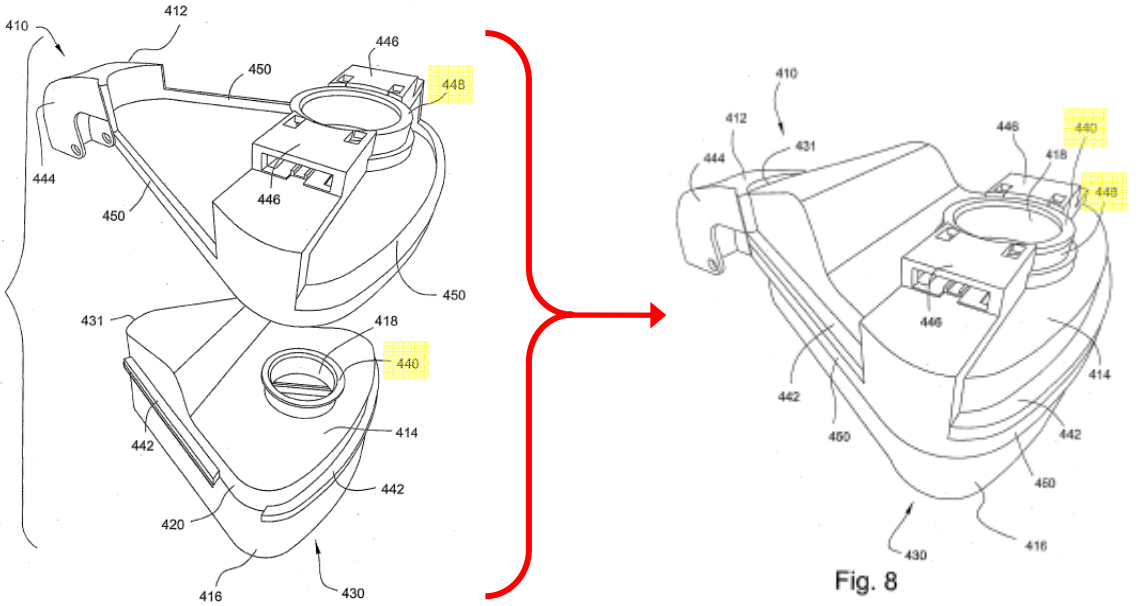


Fig. 7

Fig. 8

The shroud 412 includes a retaining portion 448 structured to engage the collar portion 440. *Id.* ¶ 101. The shroud 412 and frame 414 are constructed from plastic and their assembly would require elastic deformation for the larger diameter collar 440 to pass through the retaining portion 448. Thus, the retaining

portion 448 engages the collar 440 with a snap-fit. *See id.* ¶¶ 98, 100; Ex. 1502 ¶¶ 122–123.

D'Souza does not expressly disclose a plurality of snap fingers, but snap fingers were common in prior art CPAP masks. *Id.* ¶¶ 124–133. For example, as shown on the next page, Matula-II discloses a "pair of prongs 48" structured to mechanically couple the seal member 38 to the faceplate 36. Ex. 1512 ¶ 53. Because the Matula-II faceplate 36 is semi-rigid, the snap-fingers 48 deflect radially inward and elastically recover to mechanically couple the seal member 38 to the faceplate 36 with a snap-fit. *See id.* ¶ 51; Ex. 1502 ¶ 124.

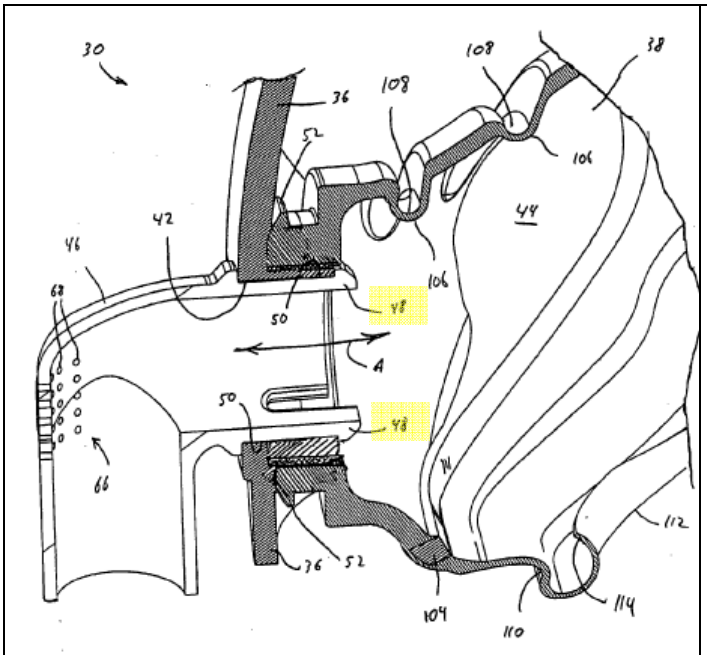


FIG. 4

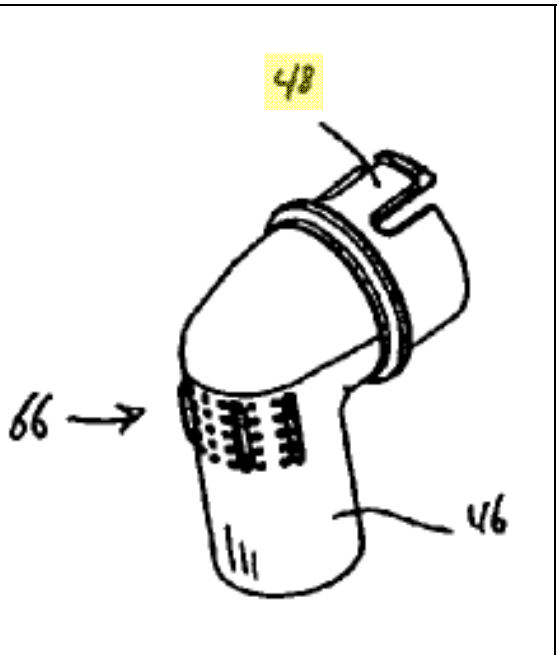


FIG. 5 (PARTIAL)

A skilled artisan would have been motivated to modify the rearward extending retaining portion of D'Souza to include the plurality of rearward

extending snap fingers, as taught by Matula-II, to facilitate formation of the removable snap-fit of D'Souza. Ex. 1502 ¶¶ 125–127. As modified, the snap fingers would extend rearward into the frame opening to engage the underside of the D'Souza collar with a snap-fit, as taught by Matula-II. Ex. 1512 ¶ 125. Alternatively, the snap fingers would extend rearward and engage the outer periphery of the collar. *Id.*

Although the Matula-II snap fingers are on the elbow, it was common knowledge to incorporate snap fingers into the shroud module. *Id.* ¶¶ 126–133. Incorporating snap fingers into the retaining portion of D'Souza would have involved a simple substitution of one known feature for another to obtain predictable results and achieve the same purpose of providing a removable mechanical interlock between the shroud and the cushion module. *See id.* ¶¶ 126–133; *see also KSR*, 550 U.S. at 416.

Besides being a matter of design preference, such a modification would facilitate deformation of the engagement parts and make it easier to join the shroud to the cushion module. Ex. 1502 ¶¶ 132–133. A person of skill would have recognized that it would have been advantageous to provide a plurality of snap fingers on the D'Souza retaining portion to allow for repeated interlocking without destroying the parts. *Id.*

c. Claim 26

Claim 26 depends from Claim 1 and includes:

"wherein the second opening of the shroud module and the frame opening of the frame are aligned along a common longitudinal axis, and wherein the mask system further comprises a snap-fit arrangement to removably snap-fit attach the shroud module and the cushion module to one another by moving the shroud module and the cushion module towards one another along the longitudinal axis."

D'Souza teaches a shroud module 412 having an annular opening with a retaining portion 448 extending rearwardly from the opening. Ex. 1510 ¶ 101.

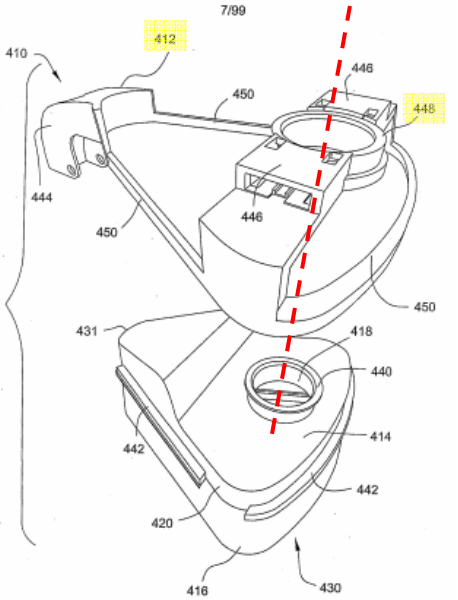


Fig. 7

As explained above, the assembly of the D'Souza arrangement results in a removable, snap-fit interlock between the shroud module and cushion module. *See*

supra § VII(C)(2)(b). Such engagement is formed by moving the shroud module and the cushion module towards one another along the longitudinal axis. Ex. 1502 ¶ 135. However, to the extent D'Souza provides insufficient teachings for a removable snap-fit, Matula-II teaches a plurality of snap fingers that elastically deform to mechanically and removably couple the cushion module to the shroud module, as explained above. *See supra* § VII(C)(2)(b). As modified, the cushion module would engage the shroud module by moving the cushion module and the shroud module towards one another along the longitudinal axis. Ex. 1502 ¶¶ 136–138.

A person of skill in the art would have known that snap-fit connections are desirable because such connections would only require the simple movement of moving the shroud module and the cushion module towards one another by moving along an axis. *Id.* ¶ 137. A person of skill also would have recognized that snap-fit arrangements ensure that the shroud module and the cushion module are securely attached. *Id.* Further, a person of skill would have recognized that snap assemblies are reversible, so the cushion module could be removed or replaced for cleaning. *Id.*

D. Ground 3: Claims 12, 14, and 16 of the ’931 Patent would have been obvious over D’Souza in view of Hitchcock and Barnett

1. Overview of Barnett (Ex. 1513)

Barnett was submitted, but not cited, during the prosecution of the ’931 Patent. Ex. 1501 at 5.

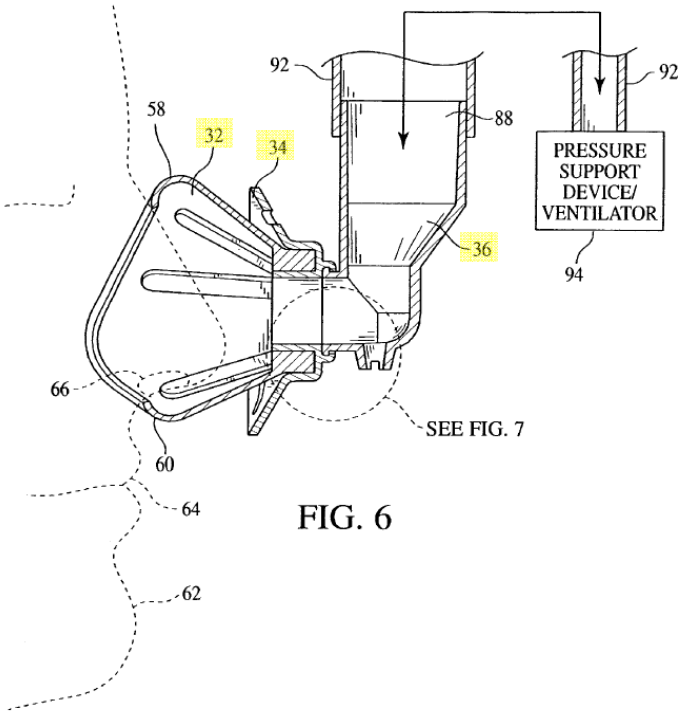


FIG. 6

As shown above, Barnett discloses a CPAP nasal mask assembly 30 with a seal member 32 and a collar 34 that is fixed relative to the seal member 32. Ex. 1513 at col. 3:48–52. An elbow 36 is rotateably mounted to the collar 34. *Id.* at col. 3:52–57.

Additionally, as shown below, Barnett discloses different seal members 32, 32' that can attach to the same collar 34 to accommodate different patient populations. *Id.* at col. 6:1–14, 5:52–67.

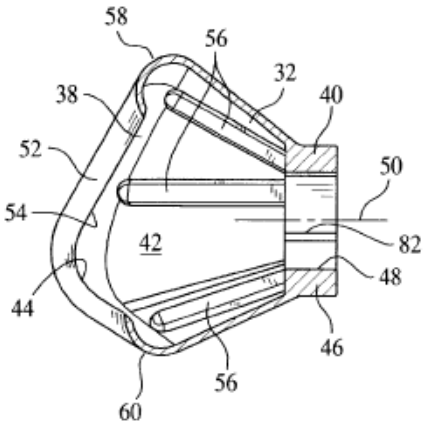


FIG. 2A

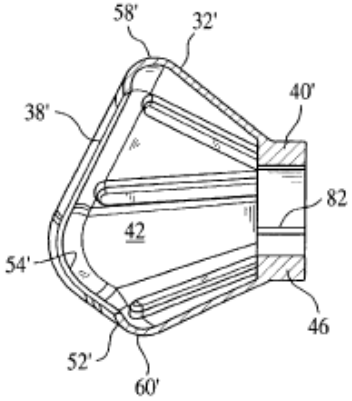


FIG. 3B

2. Limitations of Dependent Claims 12, 14, and 16

A person of skill in the art would have been motivated to combine D'Souza, Hitchcock, and Barnett for at least the reasons provided above. *See supra* § VII(B)(3). Because Barnett discloses a CPAP mask with structurally similar features, its features would have been readily compatible with, and easily incorporated into, the D'Souza mask with a reasonable expectation of success. Ex. 1502 ¶ 141. Combining the teachings of these references would have been a mere combination of familiar elements according to known methods that does no more than yield predictable results. *See id.* ¶¶ 141–159; *see also KSR*, 550 U.S. at 416.

a. Claim 12

Claim 12 depends from Claim 11 and includes:

"wherein the elbow module is provided to the shroud module."

The '931 Patent discloses an elbow connection in which the shroud module accommodates the elbow 1070, but provides no contact with the elbow when assembled. Ex. 1501 at col. 7:21–27.

D'Souza discloses a similar arrangement in which the elbow is only indirectly connected to the shroud (Ex. 1510 ¶ 100). To the extent the term "provided to" is somehow interpreted to require a direct connection between the shroud module and the elbow module, such elbow connections were a known alternative to the indirect connection disclosed by D'Souza. Ex. 1502 ¶¶ 144–149. For example, as shown below, Barnett discloses an elbow 36 that is directly mounted to the shroud 34. Ex. 1513 at col. 3:52–57.

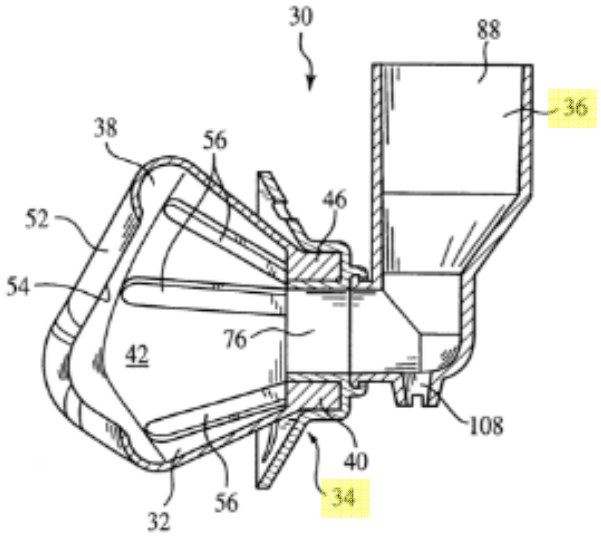


FIG. 1A

A person of skill would have been motivated to modify D'Souza to provide the elbow directly to the shroud module, *e.g.*, by including a flange connection on a front side of the shroud module, as taught by Barnett. *See* Ex. 1513 at col. 9:13–30; Ex. 1502 ¶¶ 144–145. A person of skill would have recognized that this direct connection would make it easier to detach the elbow without affecting the engagement of other mask components and provide more design flexibility. *Id.* ¶¶ 147–149.

b. Claim 14

Claim 14 depends from Claim 11 and includes:

"wherein the elbow module and the shroud module are directly connected with a mechanical interlock while allowing 360 degree rotation of the elbow module."

As explained above, the D'Souza elbow does not directly connect to the shroud, but such elbow connections were a well-known alternative and often included 360° rotation. *See supra* § VII(D)(2)(a).

For example, as shown below, the Barnett elbow 36 is mounted to the shroud 34 and freely rotates 360° in direction A. Ex. 1513 at col. 3:52–57.

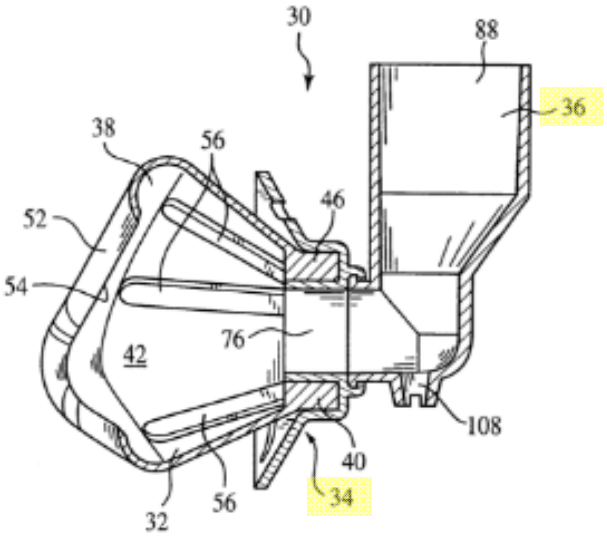


FIG. 1A

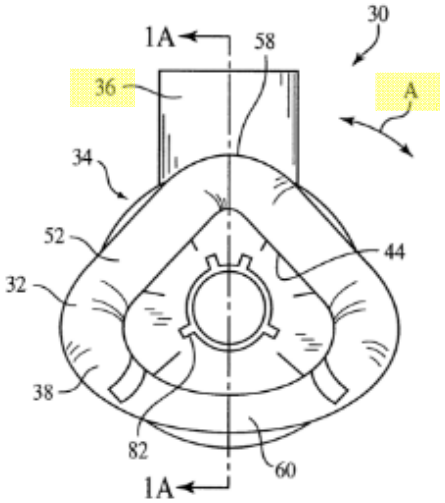


FIG. 1B

For at least the reasons provided above, a person of skill would have been motivated to directly and mechanically interlock the elbow module and the shroud module, as taught by Barnett. *See supra* § VII(D)(2)(a). Further, a person of skill

at the time of the invention would have been motivated to make the elbow rotatable over a 360° range, as taught by Barnett, to provide control over the tubing and to provide the most convenient, comfortable, and low force mask connection. Ex. 1502 ¶¶ 151–155.

c. Claim 16

Claim 16 depends from Claim 1 and includes:

"wherein the cushion module includes at least first and second cushion modules adapted to be provided to the shroud module, said at least first and second cushion modules being different from one another in at least one aspect."

D'Souza does not expressly disclose this feature, but as described above, Barnett discloses different-sized cushion modules 32, 32' that attach to the same shroud 34. Ex. 1513 at col. 6:1–14.

A person of skill would have been motivated to provide different-sized, interchangeable cushions for different patient populations. *See id.*; Ex. 1502 ¶¶ 158–159. A skilled artisan would have recognized that providing different-sized cushion modules to a common shroud would reduce the number of components required (as compared to distinct shrouds for the different cushion modules). Ex. 1502 ¶ 158.

E. Ground 4: Claim 13 would have been obvious over D'Souza in view of Hitchcock and Lovell

1. Overview of Lovell (Ex. 1514)

Lovell was submitted, but not cited, during the prosecution of the '931 Patent. Ex. 1501 at 5.

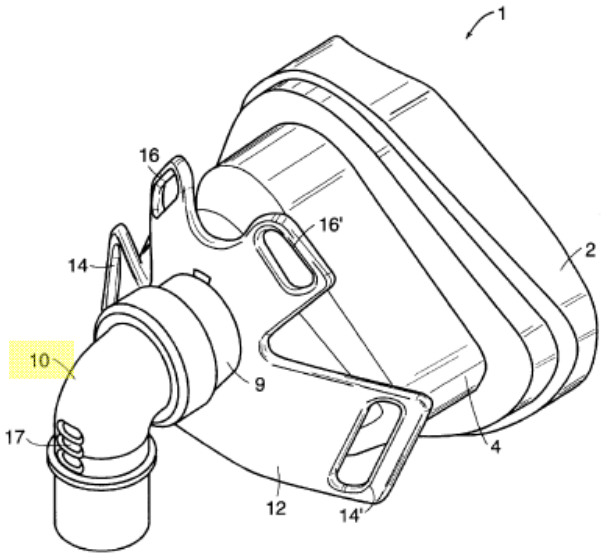


FIG. 1

Lovell discloses CPAP mask assemblies having a shroud, cushion module, and a polycarbonate conduit elbow 10. Ex. 1514 at cols. 1:5–8, 5:29–33.

2. Dependent Claim 13

Claim 13 depends from Claim 11 and includes:

"wherein the elbow module comprises polycarbonate."

D'Souza and Hitchcock each disclose an elbow, but do not specify that it is polycarbonate. However, it was common to use polycarbonate CPAP mask

components, including the elbow, as disclosed by Lovell. *See* Ex. 1514 at cols. 1:5–8, 5:33–35; Ex. 1502 ¶ 162.

Polycarbonate was commonly used for CPAP mask components, including the elbow, to provide strength, rigidity, and toughness to support the air delivery tubing. Ex. 1502 ¶¶ 162–163. Additionally, polycarbonate CPAP components can be cleaned, disinfected, and/or sterilized by most commonly used methods. *Id.* Combining these familiar elements according to known methods would have done no more than yield predictable results. *See id.* ¶ 163; *see also KSR*, 550 U.S. at 416.

F. Ground 5: Claim 15 would have been obvious over D'Souza in view of Hitchcock and Jaffre

1. Overview of Jaffre (Ex. 1515)

Jaffre was submitted, but not cited, during the prosecution of the '931 Patent. Ex. 1501 at 5.

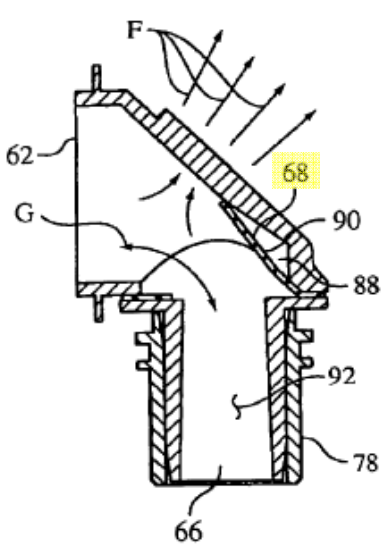


FIG. 8

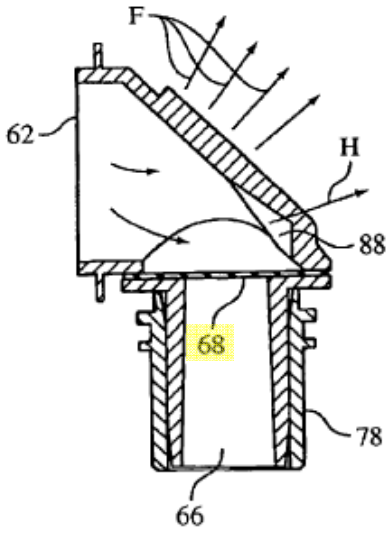


FIG. 9

Jaffre discloses CPAP devices having an exhaust port assembly. Ex. 1515 at col. 1:13–33. As shown above, the exhaust port assembly 62 includes a valve member 68 that flexes to block the opening 88 (Figure 8). *Id.* at col. 10:11–17. If the pressure of the gas in the interior 92 falls below ambient atmosphere, valve member 68 unblocks opening 88 so that the patient has access to ambient atmosphere (see Figure 9). *Id.* at col. 10:23–28.

2. Limitation of Dependent Claim 15

A person of skill in the art at the time of the purported invention would have been motivated to combine the teachings of D'Souza, Hitchcock, and Jaffre for at least the reasons provided above. *See supra* § VII(B)(3). Because Jaffre discloses a CPAP mask with similar mask structures, its features would have been readily compatible with and easily incorporated into the D'Souza mask, as modified by Hitchcock. Ex. 1502 ¶ 166. Combining these familiar mask elements according to known methods would have done no more than yield predictable results. *See id.* ¶¶ 166–172; *see also KSR*, 550 U.S. at 416.

a. Claim 15

Claim 15 depends from Claim 11 and includes:

"wherein the elbow module includes an anti-asphyxia valve and wherein the anti-asphyxia valve includes a flap portion adapted to selectively close a port provided in the elbow module."

D'Souza discloses an elbow, but does not expressly disclose an anti-asphyxia valve (AAV). Ex. 1510 ¶ 100. However, such valve assemblies were common in CPAP elbows, as disclosed in Jaffre. Ex. 1502 ¶¶ 168–172.

As shown below, the Jaffre valve has a flap portion 68 that selectively closes port 88. Ex. 1515 at col. 10:14–28.

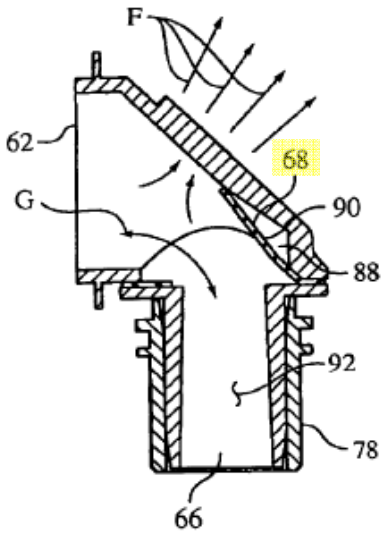


FIG. 8

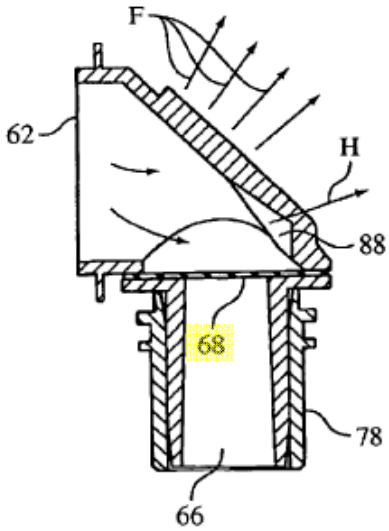


FIG. 9

A person of skill would have known to include the Jaffre AAV in the elbow to provide breathable air when the flow generator does not provide flow. Ex. 1502

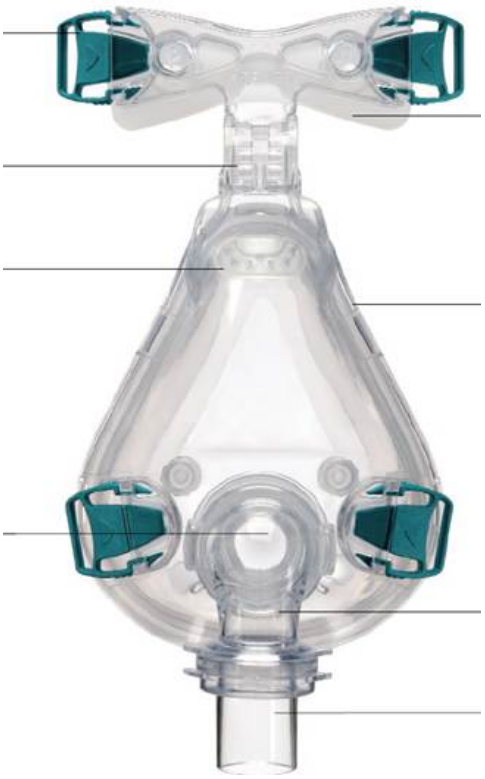
¶ 171. Further, a person of skill would have understood that an AAV using a flap is advantageous because the flap easily moves by change in airflow and pressure. *Id.* ¶ 172.

G. Ground 6: Claim 17 would have been obvious over D'Souza in view of Hitchcock, Barnett and Ultra Mirage

1. Overview of Ultra Mirage (Ex. 1516)

Ultra Mirage was not submitted or cited during the prosecution of the '931 Patent. Ex. 1501 at 1–12.

Ultra Mirage is a brochure for a ResMed full-face CPAP mask. Ex. 1516 at 6. The Ultra Mirage system was available in small, medium, and large sizes. *Id.* at 7.



2. Limitation of Dependent Claim 17

Claim 17 depends from Claim 1 and includes:

"comprising a small cushion module, a medium cushion module and a large cushion module, wherein each of said small cushion module, said medium cushion module and said large cushion module is removably coupleable to the same shroud module."

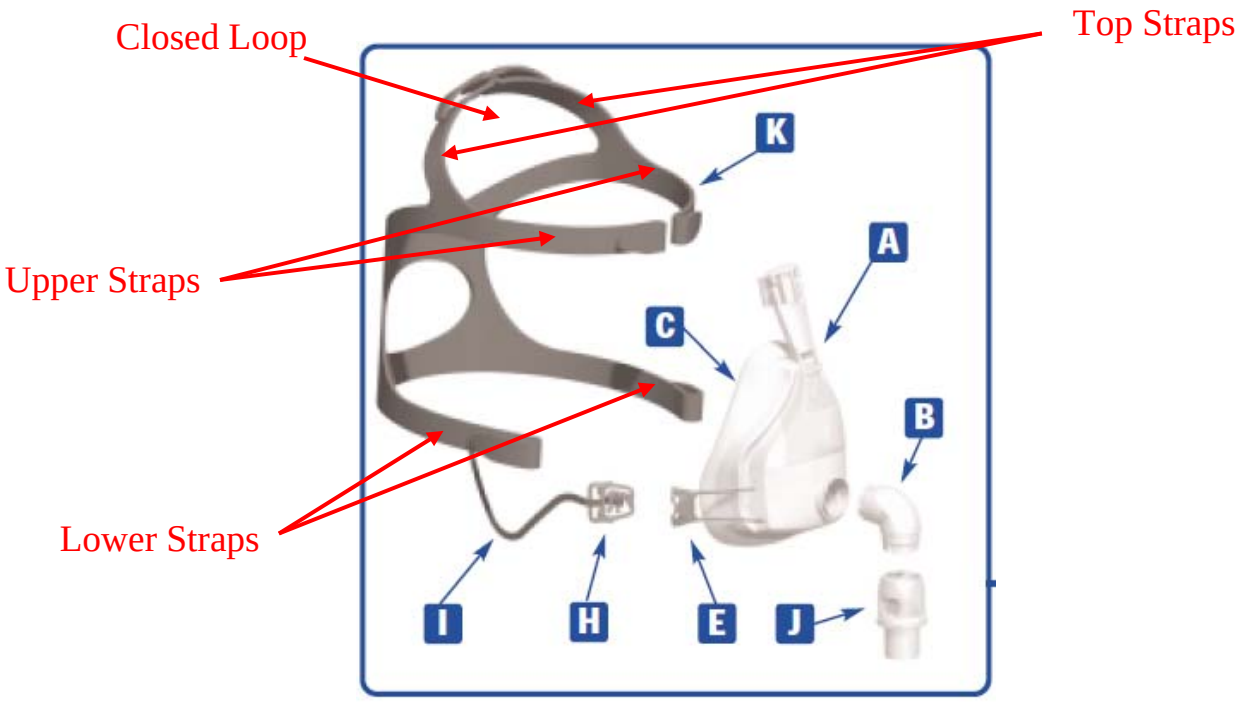
As explained above, Barnett discloses different-sized cushion modules configured for use with a common shroud. *See supra* § VII(D)(2)(c). Ultra Mirage specifically discloses product sizes for small, medium, and large masks. Ex. 1516 at 7.

A person of skill in the art would have been motivated to provide different-sized, interchangeable cushion modules (*e.g.*, small, medium, and large) for at least the reasons provided above. *See supra* § VII(D)(2)(c). Providing different sized cushion modules would have been a combination of familiar elements according to known methods that does no more than yield predictable results. *See* Ex. 1502 ¶¶ 181–187; *see also KSR*, 550 U.S. at 416.

H. Ground 7: Claims 19, 21 and 25 would have been obvious over D'Souza in view of Hitchcock, FlexiFit, and Gunaratnam-II

1. Overview of FlexiFit (Ex. 1517)

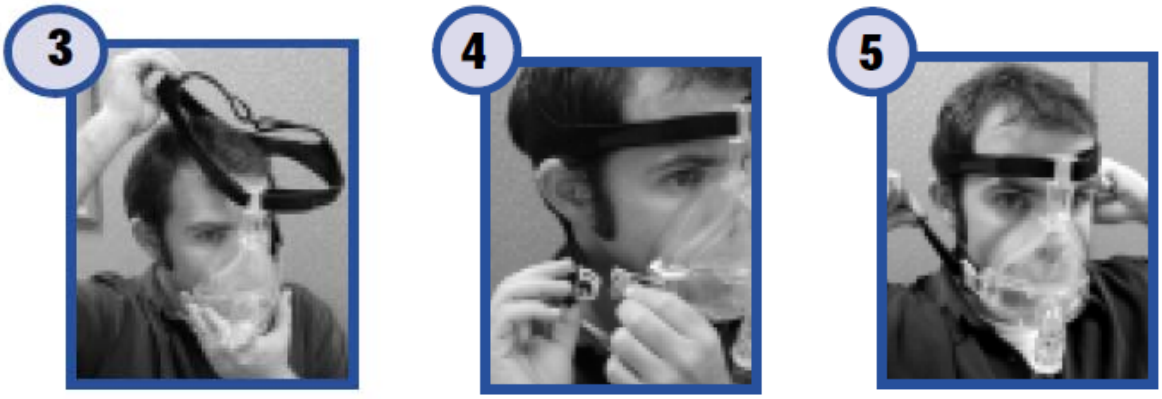
FlexiFit was not submitted or considered during the prosecution of the '931 Patent. Ex. 1501 at 1–12.



As shown above, FlexiFit shows headgear (K) removably coupleable to mask base (A). Ex. 1517 at 10 ("FITTING YOUR MASK"). The headgear (K) has upper horizontal straps and lower horizontal straps. *Id.*

As shown below, the upper horizontal straps attach to corresponding slots in the mask base (A). *Id.* The upper and lower horizontal straps and top crown straps

can be re-adjusted to prevent leaks. *Id.* at 10 ("FITTING YOUR MASK").



2. Overview of Gunaratnam-II (Ex. 1519)

The Examiner cited Gunaratnam-II during prosecution, but for a different feature and as a secondary reference. Ex. 1501 at 6; Ex. 1509 at 271.

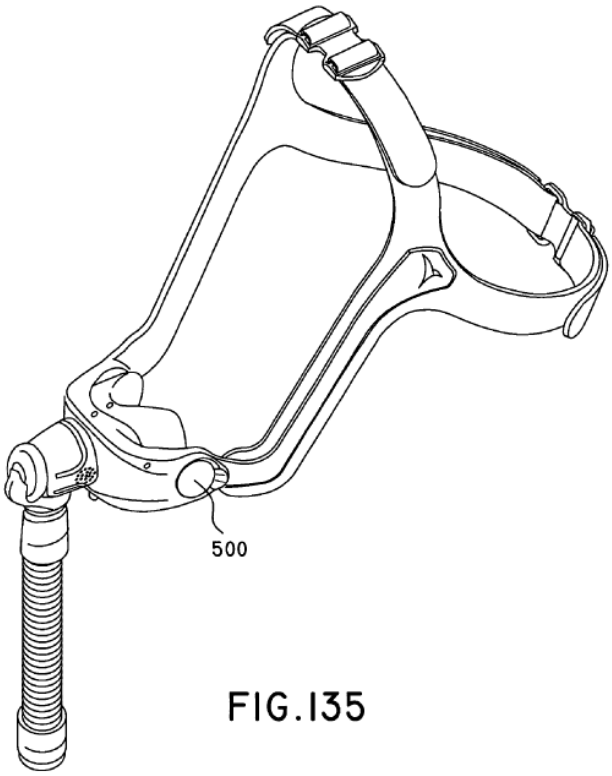


FIG.135

Gunaratnam-II discloses nasal assemblies with a pair of top straps and rear straps, as shown above. Ex. 1519 at Abstract. The top straps are removably and adjustably coupled with a buckle. *Id.* ¶ 316.

3. Limitations of Dependent Claims 19, 21 and 25

A person of skill in the art at the time of the purported invention would have been motivated to combine the teachings of D'Souza, Hitchcock, FlexiFit, and Gunaratnam-II for at least the reasons provided above. *See supra* §§ VII(B)(3).

a. Claim 19

Claim 19 depends from Claim 1 and further recites various headgear features as follows:

"the headgear includes a pair of upper straps and a pair of lower straps, with the upper straps being removably attached to respective ones of the headgear connectors and the lower straps being connected to respective ones of the headgear connectors,"

As explained above, the combination of D'Souza and Hitchcock teaches upper and lower headgear straps removably attached to respective headgear connectors. *See supra* § VII(B)(3)(a)(ii).

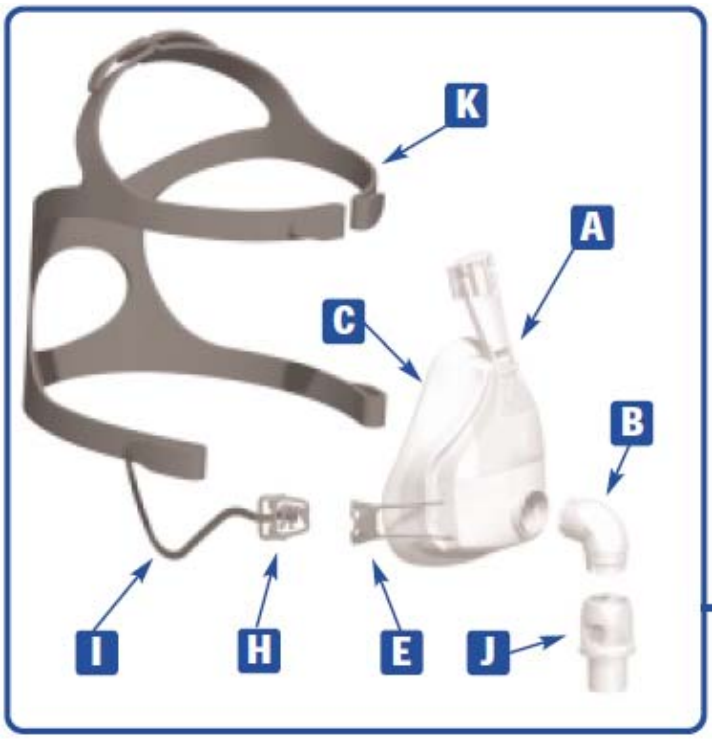
"a free end of each of the upper straps and the lower straps includes a hook tab structured to engage a remainder of the respective upper strap and

respective lower strap to secure the upper and lower straps in place in a length adjustable manner,"

D'Souza does not expressly disclose that each headgear strap includes hook and loop fastening elements, but FlexiFit discloses this common feature with Velcro® tabs on the straps. Ex. 1517 at 10. A person of skill would have known that the Velcro® tabs are positioned at the free ends of the straps, as this was typical in the prior art and a matter of simple design preference to facilitate headgear adjustment. Ex. 1502 ¶¶ 197–199.

"the upper straps split to form a pair of top straps and a pair of rear straps, the top straps being connected together by a buckle and configured to pass over the top of the patient's head in use, the rear straps being adapted to pass behind the patient's head in use,"

D'Souza does not show upper straps that split to form a pair of top straps and a pair of rear straps or a buckle. However, it was common for CPAP headgear to include these features, as shown in the FlexiFit figure below. *See* Ex. 1517 at 10; Ex. 1502 ¶¶ 201–203. The top straps pass over the patient's head and are connected together by a buckle, and the rear straps are adapted to pass behind the patient's head. Ex. 1517 at 10.



Gunaratnam-II also discloses a pair of top straps removably and adjustably threaded through a buckle, as shown below. Ex. 1519 ¶ 316.

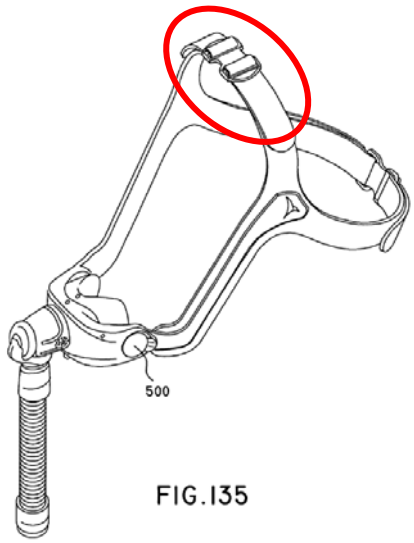


FIG.135

A person of skill in the art would have been motivated to provide the upper strap configuration shown in FlexiFit to better support and secure the upper portion of the mask. Ex. 1502 ¶ 203. Further, a person of skill would have known to join the top straps using a buckle to facilitate adjustments for a better fit and to maintain the straps in a desired position. *Id.* ¶ 207.

"and a free end of each of the top straps has a hook tab threaded through the buckle to engage a remainder of the respective top strap to secure the top straps in place relative to the buckle in a length adjustable manner."

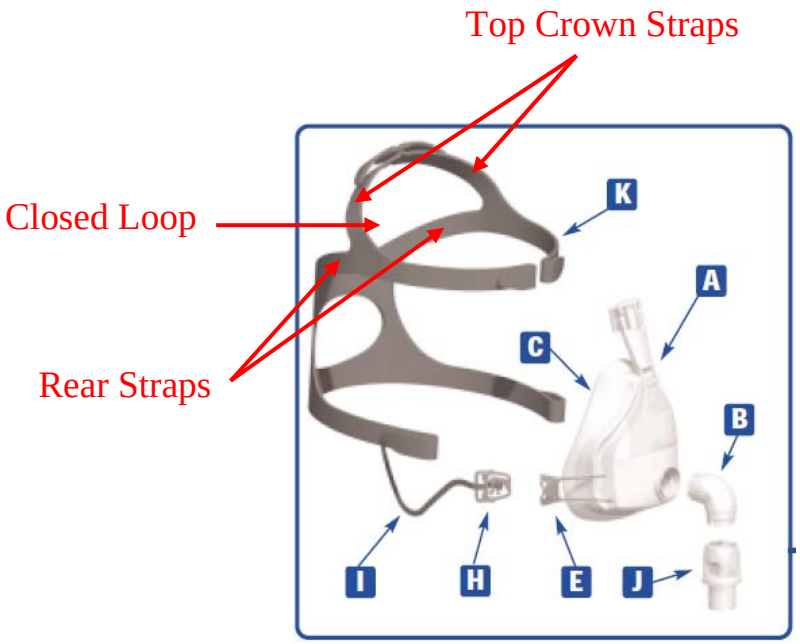
As explained earlier in this section, it was common practice to provide a hook tab on a free end of each strap. A person of skill also would have provided a hook tab on the free end of each top strap. Ex. 1502 ¶ 209.

b. Claim 21

Claim 21 depends from Claim 19 and includes:

"wherein the rear straps and the top straps form a closed loop to encircle a rear portion of the patient's head when in use."

As explained above, a person of skill would have been motivated to provide upper straps that split to form a pairs of top and rear straps. *See supra* § VII(H)(3)(a). Prior art CPAP headgear arrangements had rear and top straps that form a closed loop encircling a rear portion of the patient's head. Ex. 1502 ¶¶ 211–214. For example, as shown below, FlexiFit discloses a rear closed loop. Ex. 1517 at 10. Gunaratnam-II also discloses top straps and a rear portion that form a closed loop. *See* Ex. 1519 at Fig. 135.



A person of skill at the time of the invention would have been motivated to provide a headgear configuration with a rear loop, as taught by FlexiFit, to stabilize

the upper and lower straps, while minimizing the total amount of material required for the headgear. Ex. 1502 ¶ 214.

c. Claim 25

Claim 25 depends from Claim 19 and includes:

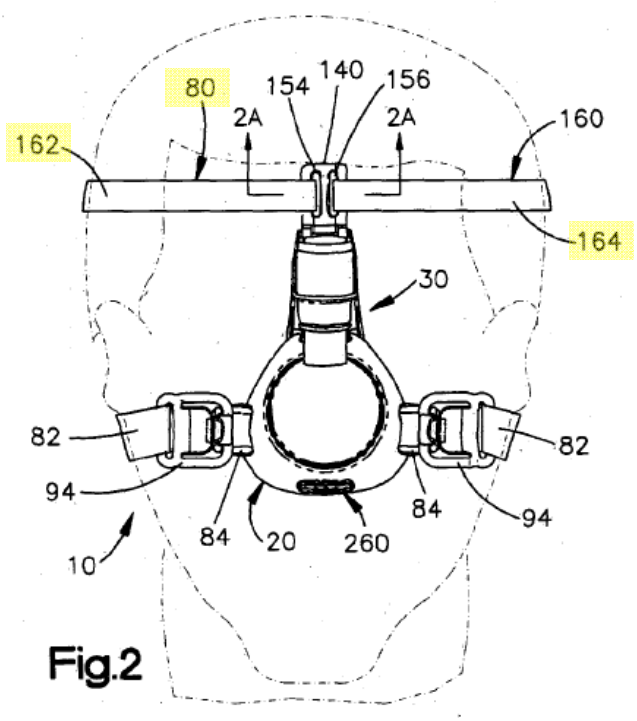
"wherein the frame is rigid."

As explained above, D'Souza discloses a rigid frame. *See supra* § VII(B)(3)(a)(iii).

I. Ground 8: Claim 20 would have been obvious over D'Souza in view of Hitchcock, FlexiFit, Gunaratnam-II, and Sprinkle

1. Overview of Sprinkle (Ex. 1520)

Sprinkle was submitted, but not cited, during the prosecution of the '931 Patent. Ex. 1501 at 6.



As shown above, Sprinkle relates to a mask 10 having headgear straps 162, 164 that provide substantial cushion between the user and the upper headgear connectors of the forehead adjuster 140. Ex. 1520 ¶¶ 72, 74.

a. Claim 20

Claim 20 depends from Claim 19 and includes:

"wherein the upper straps provide padding to the respective headgear connectors of the shroud module on the patient's face in use."

D'Souza does not expressly disclose that the headgear straps provide padding, but straps that provide padding were used in prior art CPAP masks. Ex. 1502 ¶¶ 218–220.

As shown below, Sprinkle discloses a CPAP mask with upper headgear straps that provide a cushion between the headgear connectors of the forehead adjustor 140 and the user's forehead. Ex. 1520 ¶ 74.

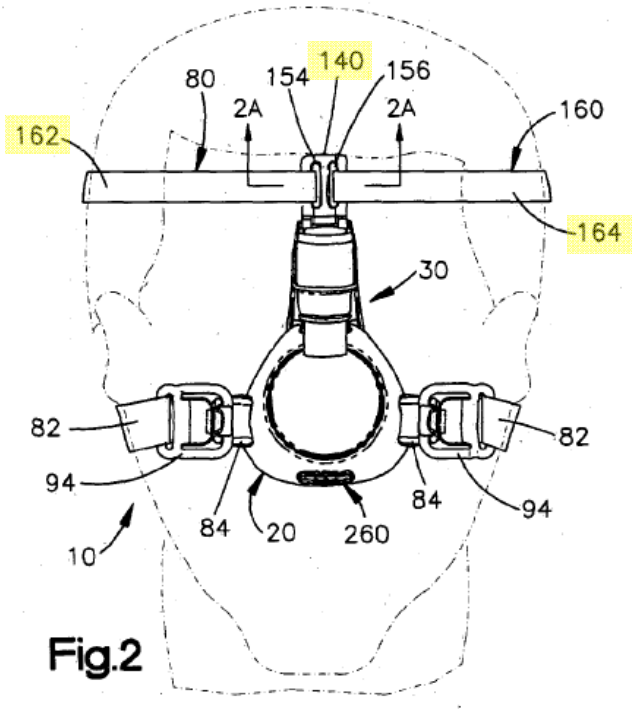


Fig.2

A person of skill would have known to provide padding to the upper straps to provide cushioning between the user's face and the mask assembly. Ex. 1502 ¶ 220.

J. Ground 9: Claim 22 would have been obvious over D'Souza in view of Hitchcock, FlexiFit, Gunaratnam-II, and Matula-II

1. Limitations of Dependent Claim 22

A person of skill in the art at the time of the purported invention would have been motivated to combine the teachings of D'Souza, Hitchcock, FlexiFit, Gunaratnam-II, and Matula-II for at least the reasons provided above. *See supra* §§ VII(B)(3), VII(C)(2), VII(H)(3). Additionally, combining these features would have been a mere combination of familiar elements according to known methods that does no more than yield predictable results. *See KSR*, 550 U.S. at 416.

a. Claim 22

Claim 22 depends from Claim 19 and includes:

"wherein the frame includes a frame opening leading to the breathing chamber, and"

As shown below, the D'Souza frame 414 has a frame opening 418. Ex. 1510 ¶ 98.

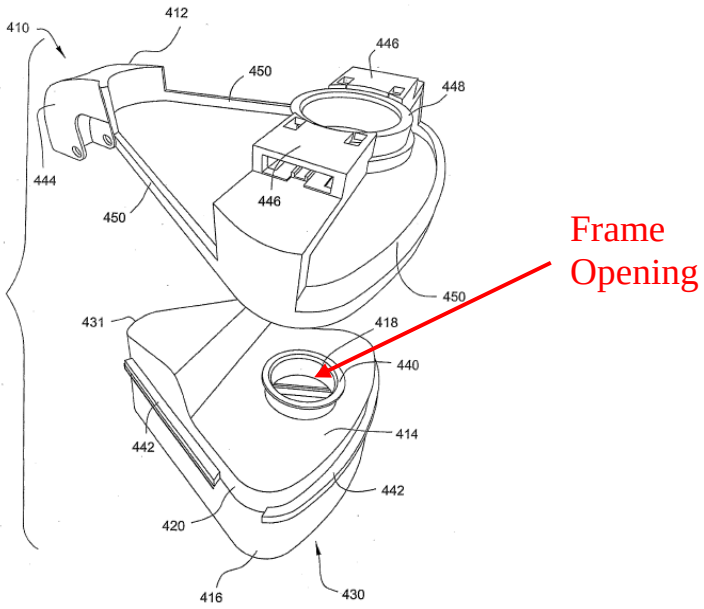


Fig. 7

"wherein the front opening of the shroud module and the frame opening of the frame are aligned along a common longitudinal axis, and wherein the shroud module and the cushion module are removably snap-fit attached to one another by moving the shroud module and the cushion module towards one another along the longitudinal axis."

As explained above, D'Souza, as modified by Matula-II, provides this removable snap-fit arrangement. *See supra* § VII(C)(2)(c).

K. Ground 10: Claims 28–30 and 65 would have been obvious over D'Souza in view of Hitchcock Matula-II, and Barnett

1. Limitations of Claims 28–30 and 65

A person of skill in the art at the time of the purported invention would have been motivated to combine the teachings of D'Souza, Hitchcock Matula-II, and Barnett for at least the reasons provided above. *See supra* §§ VII(B)(3), VII(C)(2), VII(D)(2). Combining these features would have been a mere combination of familiar elements according to known methods that does no more than yield predictable results. *See KSR*, 550 U.S. at 416.

a. Claim 28

Claim 28 depends from Claim 1 and includes:

"the frame includes a collar surrounding said frame opening, and wherein the shroud includes a retaining portion with at least one snap finger structured to engage the collar with a snap-fit,"

As explained above, the combination of D'Souza and Matula-II teaches this snap-fit arrangement. *See supra* § VII(C)(2)(b).

"the shroud module includes upper and lower headgear connectors on each side of the shroud module,"

As explained above, the combination of D'Souza and Hitchcock teaches pairs of upper and lower headgear connectors. *See supra* § VII(B)(3)(b).

"each upper headgear connector includes a slot adapted to receive a respective headgear strap in use,"

As explained above, Hitchcock discloses upper headgear slots. *See supra* § VII(B)(3)(c).

"each lower headgear connector is adapted to be removably interlocked with a headgear clip associated with a respective headgear strap,"

As explained above, D'Souza discloses lower headgear connectors adapted to removably engage clips, as well as Hitchcock. *See supra* § VII(B)(3)(d).

"the mask assembly further comprises an elbow module adapted to be connected to an air delivery tube that delivers breathable gas to the patient, and"

As explained above, D'Souza discloses an elbow module and it was common in the prior art to connect an air delivery tube to the elbow module. *See supra* § VII(B)(3)(f).

"the elbow module is rotatably attached to the shroud module while allowing 360 degree rotation of the elbow module."

As explained above, the combination of D'Souza and Barnett teaches this feature. *See supra* § VII(D)(2)(b).

b. Claim 29

Claim 29 depends from Claim 28 and includes:

"wherein each of the shroud module and the frame comprises polycarbonate, and the cushion comprises silicone."

As explained above, D'Souza discloses a polycarbonate frame with a plastic shroud module, and a silicone cushion. *See supra* §§ VII(B)(3)(a)(iii), VII(B)(3)(g). A person of skill would have known to construct the shroud module of the common polycarbonate material. *Id.*

c. Claim 30

Claim 30 depends from Claim 28 and includes:

"wherein the frame is rigid."

As explained above, D'Souza discloses a rigid frame. *See supra* § VII(B)(3)(a)(iii).

d. Independent Claim 57

Although Claim 57 is not being challenged in this Petition, Claim 57 is discussed below because Claim 65 depends from Claim 57.

Independent Claim 57 includes:

i. "A mask system for treating a patient with sleep disordered breathing with a supply of air at positive pressure, comprising:"

As explained above, D'Souza discloses a mask system for treating sleep-disordered breathing. *See supra* § VII(B)(1).

ii. "headgear including headgear straps"

As explained above, D'Souza discloses headgear straps. *See supra* § VII(B)(3)(a)(ii).

iii. "a shroud module having a pair of upper headgear connectors and a pair of lower headgear connectors adapted to removably attach to the respective headgear straps of the headgear"

As explained above, the combination of D'Souza and Hitchcock teaches pairs of upper and lower headgear connectors adapted to removably attach to headgear straps. *See supra* §§ VII(B)(3)(a)(ii), VII(B)(3)(b).

iv. "the shroud module having a front opening"

As shown below, D'Souza discloses a front shroud opening defined by annular elbow connection seal 448. Ex. 1510 ¶ 101.

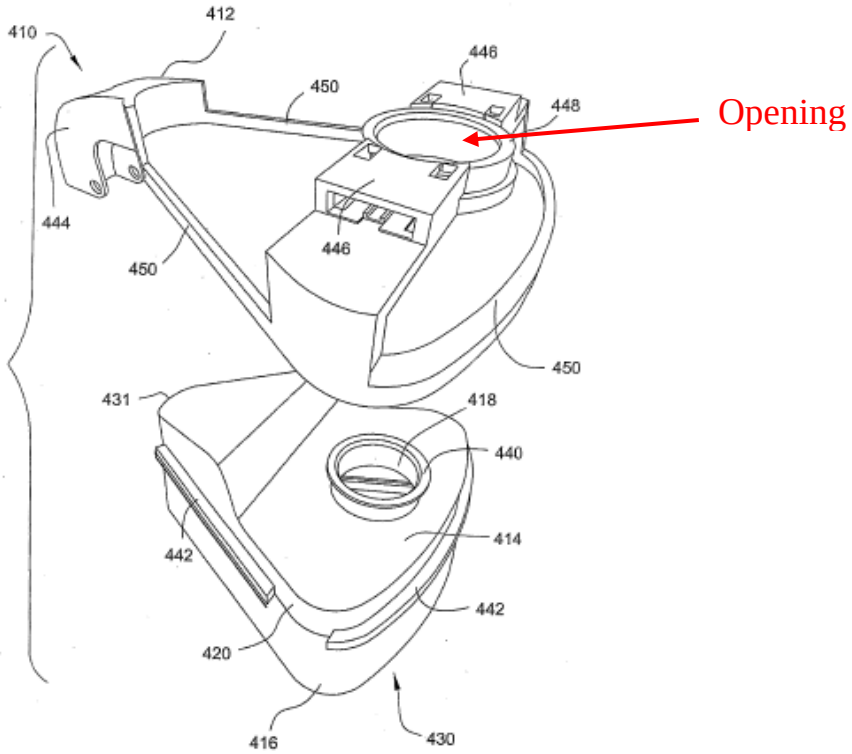


Fig. 7

v. "a rotatable elbow directly attached to the shroud; and"

As explained above, the combination of D'Souza, Hitchcock, and Barnett teaches a rotatable elbow directly attached to the shroud. *See supra* §§ VII(D)(2)(a)–(b).

vi. "a cushion module, the cushion module comprising a frame defining a breathing chamber, the frame having a frame opening leading to the breathing chamber; and"

As explained above, D'Souza discloses a cushion module having a frame with an opening 418 and a full-face cushion. *See supra* § VII(B)(3)(a)(iii).

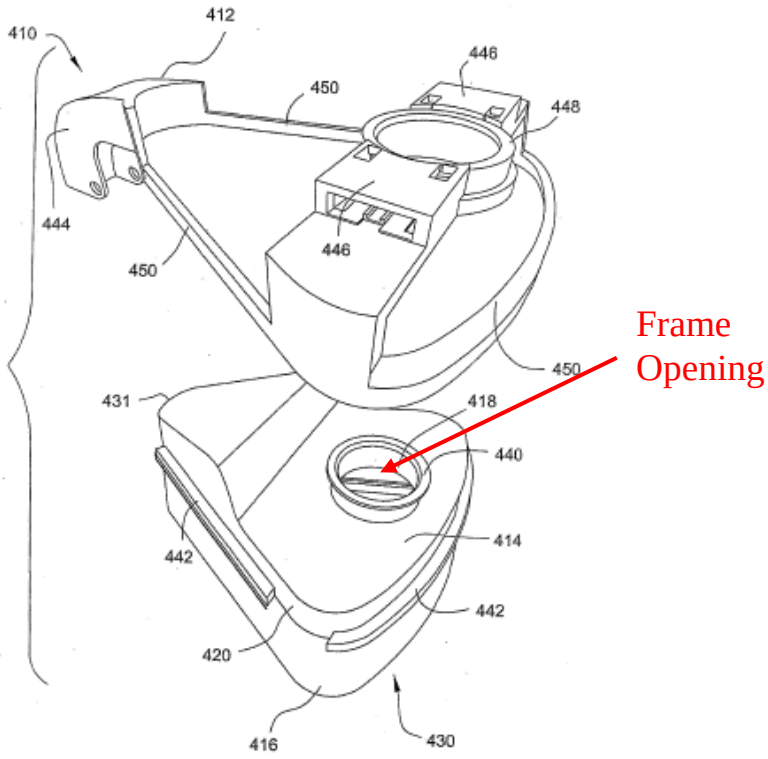


Fig. 7

vii. "a cushion to form a seal with the patient's face, wherein the cushion comprises a first, relatively soft, elastomeric material and the frame comprises a second material that is more rigid than the cushion"

As explained above, D'Souza discloses a polycarbonate frame that is more rigid than the silicone cushion. *See supra* §§ VII(B)(3)(a)(iii), VII(B)(3)(g).

viii. "wherein: the front opening of the shroud module and the frame opening of the frame are aligned along a common longitudinal axis, and wherein the shroud module and the cushion module are structured and

arranged to be removably snap-fit attached to one another by moving the shroud module and the cushion module towards one another along the longitudinal axis, and the shroud module includes a retaining portion positioned rearwardly of the front opening, towards the frame, and structured to snap fit with the cushion module."

As explained above, the combination of D'Souza, Hitchcock, and Matula-II teaches this removably snap-fit arrangement. *See supra* § VII(C)(2)(b).

e. Dependent Claim 65

Claim 65 depends from Claim 57 and includes:

"wherein the frame includes a protruding vent arrangement having a plurality of gas washout holes, wherein the shroud module includes an upper opening to accommodate said protruding vent arrangement."

As explained above, the combination of D'Souza and Hitchcock teaches a discrete protruding vent arrangement. *See supra* §§ VII(B)(3)(a)(v)–(vi).

L. Ground 12: Claims 46, 51, and 53–56 would have been obvious over D'Souza in view of Hitchcock, FlexiFit, Barnett, Jaffre, Matula-II, Gunaratnam-II, Ultra Mirage, and Sprinkle

1. Limitations of Claims 46, 51, and 53–56

A person of skill in the art at the time of the purported invention would have been motivated to combine the teachings of D'Souza, Hitchcock, FlexiFit, Barnett, Jaffre, Matula-II, Gunaratnam-II, Ultra Mirage, and Sprinkle for at least the reasons provided above. *See supra* §§ VII(B)–(D), VII(F)–(K). Combining these features would have been a mere combination of familiar elements according to known methods that does no more than yield predictable results. *See KSR*, 550 U.S. at 416.

Although Claim 43 is not being challenged in this Petition, Claim 43 is discussed below because Claim 46 depends from Claim 43.

a. Independent Claim 43

i. "A mask system for delivery of a supply of air at positive pressure to a patient's airway, the mask system comprising:"

As discussed above, D'Souza discloses a mask system for treating sleep disordered breathing with positive pressure. *See supra* VII(B)(1).

ii. "a cushion module comprising a frame defining a breathing chamber configured to receive the positive

pressure air, and a cushion to form a seal with the patient's face in a nasal bridge region, a cheek region and a lower lip/chin region of the patient's face,"

As discussed above, D'Souza discloses a cushion module with a frame and a full-face cushion. *See supra* § VII(B)(3)(a)(iii).

iii. "wherein the cushion is constructed of a first, relatively soft, elastomeric material and the frame is constructed of a second material that is more rigid than the cushion"

As discussed above, D'Souza discloses a soft cushion and a rigid frame. *See supra* § VII(B)(3)(a)(iii).

iv. "the frame including a washout vent"

As discussed above, the combination of D'Souza and Hitchcock teaches the frame including a washout vent. *See supra* § VII(B)(3)(a)(v).

v. "the frame including an opening"

As discussed above, the D'Souza frame includes an opening. *See supra* § VII(B)(3)(a)(vii).

vi. "headgear to maintain the mask system in a desired position on the patient's face, the headgear comprising a pair of upper headgear straps each

configured to extend above a respective one of the patient's ears in use and a pair of lower headgear straps each configured to extend below a respective one of the patient's ears in use"

As discussed above, the combination of D'Souza and Hitchcock teaches headgear with pairs of upper and lower headgear straps. *See supra* § VII(H)(3)(a).

vii. "wherein a free end of each of the upper headgear straps and the lower headgear straps includes a hook tab structured to engage a remainder of the respective upper headgear strap and respective lower headgear strap to secure the upper and lower straps in place in a length adjustable manner"

As discussed above, FlexiFit teaches headgear with a hook tab on a free end of each strap that would be compatible with D'Souza. *See supra* § VII(H)(3)(a).

viii. "wherein the headgear includes a pair of top straps and a pair of rear straps, each said top strap being configured to extend from generally above a respective ear of the patient such that the top straps cross over the top of the patient's head in use, the rear

straps being adapted to pass behind the patient's head in use, and"

As discussed above, FlexiFit teaches pairs of top and rear straps that would be compatible with D'Souza. *See supra* § VII(H)(3)(a).

ix. "wherein the rear straps and the top straps together at least partly form a closed loop to encircle a rear portion of the patient's head when in use"

As discussed above, FlexiFit teaches a rear closed loop that would be compatible with D'Souza. *See supra* § VII(H)(3)(b).

x. "a shroud module including headgear connectors adapted to removably attach to the headgear"

As discussed above, D'Souza and Hitchcock disclose headgear connectors adapted to removably attach to the headgear. *See supra* § VII(B)(3)(a)(ii).

xi. "wherein the headgear connectors include two upper connectors associated with the upper headgear straps"

As discussed above, the combination of D'Souza and Hitchcock teaches two upper headgear connectors. *See supra* § VII(B)(3)(b).

xii. "the shroud module having an opening of circular shape, and two lower connectors associated with the lower headgear straps"

As shown below, D'Souza discloses a circular shroud opening and two lower headgear connectors 446 associated with headgear straps. Ex. 1510 ¶ 100.

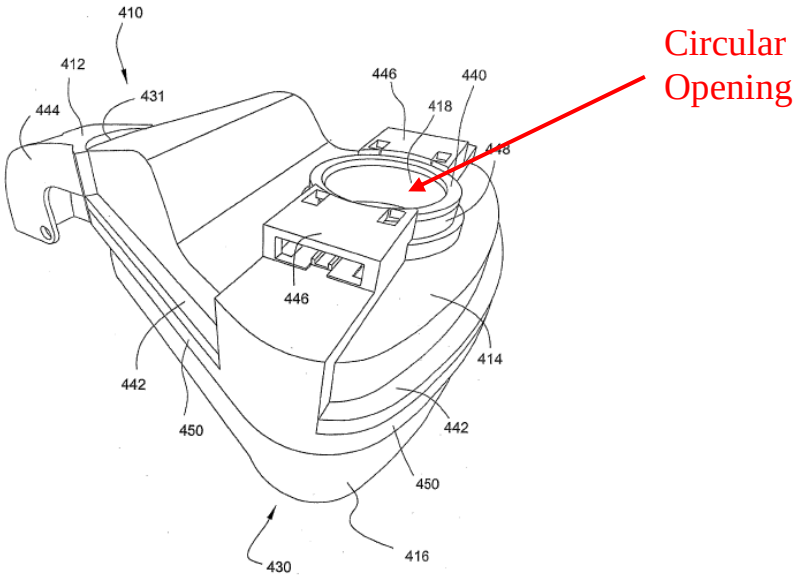


Fig. 8

xiii. "each said upper headgear connector including a slot or receiving hole adapted to receive one of the upper headgear straps"

As explained above, the combination of D'Souza and Hitchcock teaches upper headgear connectors with slots. *See supra* § VII(B)(3)(c).

xiv. "wherein the shroud module and the frame of the cushion module are configured to be removably snap-

fit attached to one another in a non-rotatable manner by pushing the shroud module towards the frame along a longitudinal axis of both the opening of the frame and the opening of the shroud"

As explained above, D'Souza discloses the shroud module and the frame are attached in a non-rotatable manner. *See supra* § VII(B)(3)(a)(iv). Further, as explained above, the combination of D'Souza and Matula-II teaches a removable snap-fit connection formed by pushing the shroud module towards the frame. *See supra* § VII(C)(2)(c).

xv. "and an elbow rotatably attached to and carried by the shroud module or the frame of the cushion module, the elbow being configured to deliver the positive pressure air to the breathing chamber"

As explained above, the combination of D'Souza and Barnett teaches an elbow rotatably attached to and carried by the shroud module. *See supra* §§ VII(D)(2)(a)–(b).

xvi. "the elbow including a swivel adapted to connect to an air delivery tube"

D'Souza does not disclose an elbow including a swivel, but swivels were well-known prior to the '931 Patent. Ex. 1502 ¶¶ 238–242. For example, Ultra

Mirage discloses a quick release swivel. Ex. 1516 at 6. A person of skill would have been motivated to provide the swivel to facilitate easy adjustment and disconnection of the air delivery tube. *See* Ex. 1516 at 6; Ex. 1502 ¶ 242.

xvii. "the elbow including an anti-asphyxia valve (AAV) and a port that is selectively closed by a flap portion of the AAV."

As explained above, the combination of D'Souza and Jaffre discloses an elbow with an AAV that is selectively closed by a flap portion of the AAV. *See supra* § VII(F)(2)(a).

b. Dependent Claim 46

Claim 46 depends from Claim 43 and includes:

"wherein: the elbow is rotatably attached the shroud module,"

As explained above, the combination of D'Souza, Hitchcock, and Barnett teaches an elbow that is rotatably attached to the shroud module. *See supra* §§ VII(D)(2)(a)–(b).

"the upper headgear straps provide padding to the respective headgear connectors of the shroud on the patient's face in use,"

As explained above, the combination of D'Souza, FlexiFit, and Sprinkle teaches upper headgear straps that provide padding. *See supra* § VII(I)(1)(a).

"the frame includes a protruding vent arrangement having a plurality of holes, wherein the shroud module includes a first opening to accommodate said protruding vent arrangement,"

As explained above, the combination of D'Souza and Hitchcock teaches a protruding vent arrangement. *See supra* §§ VII(B)(3)(a)(v)–(vi).

"further wherein the shroud module includes a second opening to accommodate the elbow,"

As explained above, a person of skill would modify D'Souza to directly couple the elbow and shroud module. *See supra* §§ VII(D)(2)(a)–(b). As modified, the second opening would accommodate the elbow. Ex. 1502 ¶ 144–149, 234.

"the frame includes an opening and the frame further includes a collar surrounding said opening, and wherein the shroud module includes a retaining portion with one or more rearward extending snap fingers structured to engage the collar with a snap-fit, and"

As explained above, the combination of D'Souza and Matula-II discloses this snap-fit arrangement. *See supra* § VII(C)(2)(b).

"the top straps are connected together with a buckle allowing independent adjustment of each of the top straps."

As explained above, the combination of D'Souza, FlexiFit, and Gunaratnam-II teaches top straps connected together with a buckle. *See supra* § VII(H)(3)(a).

c. Independent Claim 51

Claim 51 consists of a subset of the claim limitations recited in Claims 43 and 46. *See supra* §§ VII(L)(1)(a)–(b).

d. Dependent Claim 53

Claim 53 depends from Claim 51 and includes:

"wherein the second shroud opening and the frame opening are aligned along a common longitudinal axis, and wherein the shroud and the frame are removably snap-fit attached to one another by moving the shroud and the frame towards one another along the longitudinal axis."

As explained above, the combination of D'Souza and Matula-II teaches this snap-fit arrangement. *See supra* § VII(C)(2)(c).

e. Dependent Claim 54

Claim 54 depends from Claim 51 and includes:

"wherein the frame is semi-rigid or rigid."

As explained above, D'Souza discloses a rigid frame. *See supra* § VII(B)(3)(a)(iii).

f. Dependent Claim 55

Claim 55 depends from Claim 54 and includes:

"wherein the frame is rigid."

As explained above, D'Souza discloses a rigid frame. *See supra* § VII(B)(3)(a)(iii).

2. Independent Claim 56

Independent Claim 56 includes:

"A system for treating a patient with sleep disordered breathing, comprising:"

D'Souza discloses mask assemblies for the treatment of sleep-disordered breathing. Ex. 1510 ¶ 3.

"the mask system of claim 51;"

As explained above, the combination of D'Souza, Hitchcock, FlexiFit, Barnett, Jaffre, Matula-II, Gunaratnam-II, Ultra Mirage, and Sprinkle teaches the features of Claim 51. *See supra* § VII(L)(1)(c).

"and a flow generator to generate a supply of air at positive pressure to be delivered to the mask system, wherein the air delivery tube is configured to deliver the supply of air from the flow generator to the mask system."

As explained above, D'Souza discloses a flow generator, and it was common knowledge to use an air delivery tube to deliver air from the flow generator to the mask system. *See supra* § VII(B)(3)(f).

VIII. SECONDARY CONSIDERATIONS

Secondary considerations should be taken into account, but they do not control the obviousness conclusion. *Newell Cos., Inc. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988). Where a strong *prima facie* obviousness showing exists, as here, the Federal Circuit has repeatedly held that even relevant secondary considerations supported by substantial evidence may not dislodge the primary conclusion of obviousness. *See, e.g., Leapfrog Enters. Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007). Further, a showing of secondary considerations requires a nexus between the evidence of the secondary consideration and a novel feature of the claims of the ’931 Patent. *See, e.g.*, *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010).

Patent Owner has not presented any evidence of secondary considerations in any of the instituted reviews of the ’931 Patent. Further, Petitioner does not believe that any potential evidence of secondary considerations could outweigh the strong prima facie case of obviousness. In the event that the Patent Owner puts forth any allegations regarding secondary considerations, Petitioner will address those allegations in due course.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: June 22, 2017

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CERTIFICATE OF TYPE-VOLUME LIMITATIONS UNDER 37 C.F.R. § 42.24

Pursuant to 37 C.F.R. § 42.24(d), Counsel for Petitioner Fisher & Paykel Healthcare Limited hereby certifies that this document complies with the type-volume limitation of 37 C.F.R. § 42.24(a)(1)(i). According to Microsoft Office Word 2010's word count, this document contains approximately 13,838 words, including any statement of material facts to be admitted or denied in support, and excluding the table of contents, table of authorities, mandatory notices under § 42.8, exhibit list, certificate of service or word count, or appendix of exhibits or claim listing.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: June 22, 2017

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CERTIFICATE OF SERVICE

I hereby certify that true and correct copies of the foregoing **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT 9,119,931** and **Fisher & Paykel Healthcare Exhibits 1501-1548** are being served on June 22, 2017, via FedEx Priority Overnight service on counsel of record for U.S. Patent 9,119,931 patent owner **RESMED LIMITED** at the address below:

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