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Paper 7
Entered: March 31, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FISHER & PAYKEL HEALTHCARE LIMITED,
Petitioner,

v.

RESMED LIMITED,
Patent Owner.

Case IPR2017-00062
Patent 9,119,931 B2

Before RICHARD E. RICE, BARRY L. GROSSMAN, and JAMES J. MAYBERRY, *Administrative Patent Judges.*

GROSSMAN, *Administrative Patent Judge*.

DECISION
Instituting Inter Partes Review
37 C.F.R. § 42.108

I. INTRODUCTION

A. Background

Fisher & Paykel Healthcare Limited ("Petitioner") filed a Petition (Paper 1, "Pet.") requesting an *inter partes* review of claims 43, 46, 48–51, 53–58, 60–65, 68–71, and 77–79 of U.S. Patent No. 9,119,931 B2 (Ex. 1101, "the '931 Patent"). ResMed Limited ("Patent Owner") did not file a preliminary response to the Petition.[1]

Under 35 U.S.C. § 314, an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). The Board considers the Petition on behalf of the Director. 37 C.F.R. § 42.4(a).

Upon considering the Petition and the evidence filed therewith, we determine that Petitioner has shown a reasonable likelihood that it would prevail with respect to claims 43, 48–50, 57, 58, 60, 61–64, 68, 69, 70, 71, and 77–79. Petitioner has *not* shown a reasonable likelihood that it would prevail with respect to claims 46, 51, and 53–56, and 65. Accordingly, we institute an *inter partes* review of claims 43, 48–50, 57, 58, 60, 61–64, 68, 69, 70, 71, and 77–79.

B. Related Matters

The parties identify a related federal district court case involving the '931 Patent: *Fisher & Paykel Healthcare Ltd. v. ResMed Corp.*, Case No. 3:16-cv-02068-GPC-WVG (S.D. Cal.). Pet. 7–8; Paper 4, 2. The parties

[1] *See* 37 C.F.R. § 42.107 (providing that filing a preliminary response to the petition is not obligatory).

also indicate that the '931 Patent is involved in U.S. International Trade Commission Investigation No. 337–TA–1022. Pet. 7; Paper 4, 2.

Petitioner has filed three additional petitions for *inter partes* review of the '931 Patent. *See* IPR2017-00061, IPR2017-00064, IPR2017-00065; Pet. 8; Paper 4, 2. The reviews sought in the four petitions by Petitioner challenging the '931 Patent are summarized in the chart below.

Case No.	IPR2017-00061	IPR2017-00062	IPR2017-00064	IPR2017-00065
Challenged Claims	1, 4–8, 10–22, 25, 26, 28–37, and 40–42	43, 46, 48–51, 53–58, 60–65, 68–71, and 77–79	33–37, 40–43, 48–50, 57, 58, 60–64, 68–71, and 77–79	1, 4–8, 10–22, 25, 26, 28–32, 46, 51, 53–56, and 65
References Asserted[2]	D'Souza, Ultra Mirage, Matula-II, FlexiFit, Barnett, Lovell, Jaffre, and Gunaratnam-II	D'Souza, Ultra Mirage, Matula-II, FlexiFit, Barnett, Jaffre, and Gunaratnam-II	Barnett, Ogden, Gunaratnam-I, Gunaratnam-II, Worboys, Matula-II,	Barnett, Ogden, Gunaratnam-I, Gunaratnam-II, Worboys, Matula-II, Matula-I, and Lovell

C. The '931 Patent

The '931 Patent, titled "Mask System," issued on September 1, 2015, and claims priority based on a series of applications dating back to February 27, 2009, as well as several provisional applications dating back to

[2] We use the shorthand identification used in each Petition to identify the references asserted. Not all references are asserted against all claims in each case. As necessary, in other sections of this Decision, we provide complete citations of the specific references asserted against each claim.

September 19, 2008. Ex. 1101, 1:6–17. The '931 Patent relates generally to a mask system for treatment of "Sleep Disordered Breathing" using "Continuous Positive Airway Pressure ['CPAP']" or "Non-Invasive Positive Pressure Ventilation." *Id.* at 1:21–24. This is a highly-developed technology, as represented by the eleven pages of references cited in the patent. *Id.* at 2–12.

Figure 3 of the '931 Patent, as annotated by Petitioner (Pet. 3), is reproduced below.

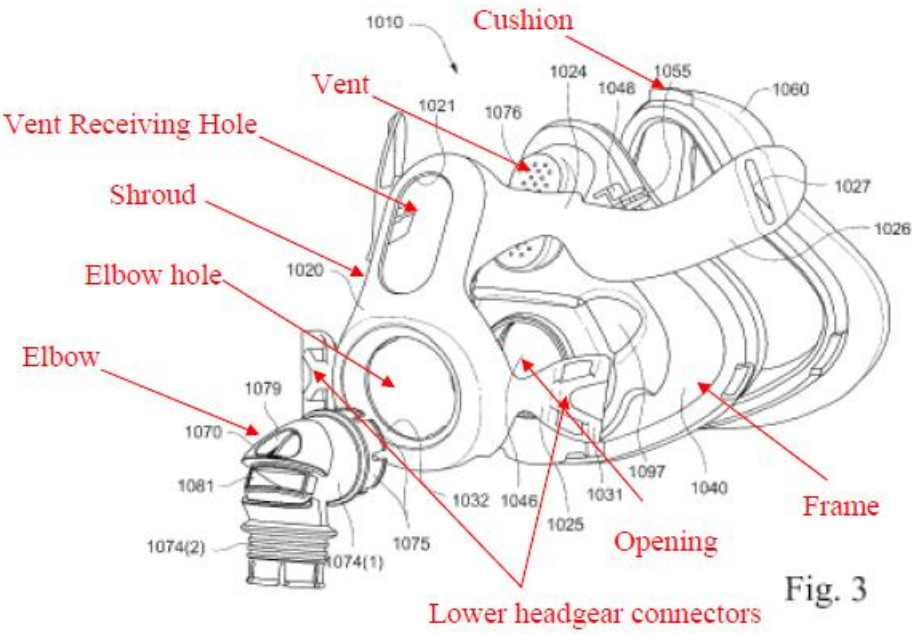


Fig. 3

Figure 3 is an exploded perspective view of the disclosed mask system showing the frame, cushion, shroud, and elbow, as annotated by Petitioner.

Figure 3 depicts mask system 1010 comprising frame 1040, mask cushion 1060, shroud 1020, and elbow 1070. *Id.* at 6:51–53. The frame defines a breathing chamber adapted to receive the patient's nose and mouth and includes an opening 1046 that communicates with elbow 1070. *Id.* at 6:60–64. The frame 1040 also includes vent arrangement 1076, shown in

Figure 3, which protrudes from frame 1040. *Id.* at 7:22–23. Opening or vent receiving hole 1021 in shroud 1020 accommodates the protruding vent arrangement. *Id.* at 7:21–23. Upper headgear connectors 1024 extend from each side of the top portion of the shroud and lower headgear connectors 1025 extend from each side of the lower portion. *Id*. at 7:28–30. Each lower headgear connector 1025 includes clip receptacle 1031 at the free end that interlocks with a headgear clip on a headgear strap (*see* Figure 9 showing headgear strap 1090). *Id*. at 8:29–32.

Of the challenged claims, claims 43, 51, and 57 are independent. Representative claims 43 and 57 are reproduced below:

> 43. A mask system for delivery of a supply of air at positive pressure to a patient's airway, the mask system comprising:
>
> 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, 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, the frame including a washout vent, the frame including an opening;
>
> 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, 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, 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 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;

a shroud module including headgear connectors adapted to removably attach to the headgear, wherein the headgear connectors include two upper connectors associated with the upper headgear straps, the shroud module having an opening of circular shape, and two lower connectors associated with the lower headgear straps, each said upper headgear connector including a slot or receiving hole adapted to receive one of the upper headgear straps, 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; 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, the elbow including a swivel adapted to connect to an air delivery tube, the elbow including an anti-asphyxia valve (AAV) and a port that is selectively closed by a flap portion of the AAV.

Ex. 1101, 27:55–28:39.

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

headgear including headgear straps;

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, the shroud module having a front opening;

a rotatable elbow directly attached to the shroud; and

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 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;
>
> 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.

Id. at 30:52–31:11.

Independent claim 51 includes the limitations of claim 43 and its dependent claim 46, reciting additional details of the straps and frame.

D. The Asserted Grounds

Petitioner challenges claims 43, 46, 48–51, 53–58, 60–65, 68–71, and 77–79 on the following five grounds (Pet. 15–16):

Reference(s)	Basis	Claims Challenged
D'Souza[3], Ultra Mirage[4], Barnett[5], and Matula-II[6]	§ 103(a)	57, 58, 61, 65, 68, 69, 71, and 77–79

[3] WO 2007/041751 Al, pub. Apr. 19, 2007 (Ex. 1102, "D'Souza").
[4] ResMed product brochure describing the "Ultra Mirage™ Full Face Mask" (Ex. 1103, "Ultra Mirage"). Petitioner has proffered evidence to establish that the brochure was publicly available by September 1, 2006. Pet. 11–12 (citing Ex. 1103, 1–2, 7–8; Ex. 1113 ¶¶ 48–50).
[5] US 6,412,488 B1, iss. July 2, 2002 (Ex. 1107, "Barnett").
[6] US 2007/0044804 Al, pub. Mar. 1, 2007 (Ex. 1105, "Matula-II").

Reference(s)	Basis	Claims Challenged
D'Souza, Ultra Mirage, Barnett, Matula-II, and FlexiFit[7]	§ 103(a)	60
D'Souza, Ultra Mirage, Barnett, Matula-II, FlexiFit, and Gunaratnam-II[8]	§ 103(a)	62–64
D'Souza, Ultra Mirage, FlexiFit, Barnett, Jaffre[9], and Matula-II	§ 103(a)	43, 48–50, and 70
D'Souza, Ultra Mirage, FlexiFit, Barnett, Jaffre, Matula-II, and Gunaratnam-II	§ 103(a)	46, 51, and 53–56

II. ANALYSIS

A. Level of Skill in the Art

Petitioner asserts that a person having ordinary skill in the art ("PHOSITA") "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." Pet. 20 (citing Ex. 1113 ¶ 27). Based on our review of the Petition and evidence, including Mr. Eaton's testimony, we find that

[7] Fisher & Paykel Healthcare Corporation Limited product brochure describing the "FlexiFit™431 Full Face Mask" (Ex. 1106, "FlexiFit"). Petitioner has proffered evidence to establish that the brochure was publicly available by October 16, 2006. Pet. 12–14 (citing Ex. 1106, 5, 8, 11; Ex. 1113 ¶¶ 48–50; Ex. 1116, 1–4).
[8] US 2004/0226566 A1, pub. Nov. 18, 2004 (Ex. 1110, "Gunaratnam-II").
[9] US 6,851,425 B2, iss. Feb. 8, 2005 (Ex. 1112, "Jaffre").

Petitioner's asserted level of skill in the art is reasonable and, for the purposes of this Decision, we adopt that definition.

B. Claim Construction

In an *inter partes* review, the Board gives claim terms in an unexpired patent their broadest reasonable interpretation in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *see Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under that standard, a claim term generally is given its ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

Petitioner does not assert any specific construction for the claims. Pet. 16. Petitioner states the claims should be given 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. *Id.* We determine that it will be helpful to our analysis and decision to construe one claim phrase, which we do below.

1. "a protruding vent arrangement having a plurality of holes" (claim 1)

Claim 65 recites "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." Ex. 1101, 31:55–59 (emphasis added).

In its obviousness analysis, Petitioner argues that the "protruding vent arrangement" claim term would be satisfied by adding the vent of Ultra Mirage in the nasal bridge region of D'Souza and thus on the protruding

portion of D'Souza. Pet. 34–35. As such, Petitioner contends, implicitly, that the "protruding vent arrangement" claim term broadly encompasses vent holes in a portion of the frame that extends through an opening in the shroud module.

We disagree. Petitioner's implicit claim construction is contrary to the plain language of claim 65, which requires the frame to have a "vent arrangement" that is "protruding" (rather than reciting that the frame has a protruding portion that includes a vent arrangement having a plurality of holes). Petitioner's implicit construction also is inconsistent with the Specification. As described in the Specification and depicted in Figure 3 (reproduced above), protruding vent arrangement 1076 is a discrete vent structure that extends above the surrounding surface of frame 1040 and contains a plurality of vent holes. Ex. 1001, 7:18–23 ("The top end of the shroud 1020 . . . includes an opening or vent receiving hole 1021 to accommodate *the vent arrangement 1076 that protrudes from the frame 1040*" (emphasis added)), Fig. 3. Contrary to Petitioner's implicit claim construction, protruding vent arrangement 1076 is described in the Specification as extending from the surface of the frame, and not merely as extending through an opening in shroud 1020. *See id.*

Further, claim 65 also recites that "the shroud module" includes an upper opening to accommodate the protruding vent arrangement. That language would be rendered superfluous under Petitioner's implicit construction that "a protruding vent arrangement" is a portion of the frame with vent holes that extends through an opening in the shroud. *See Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006) (stating that "claims are interpreted with an eye toward giving effect to all terms in the

claim," so that physical structures and characteristics specifically described in a claim are not rendered "merely superfluous").

We determine that the broadest reasonable interpretation consistent with the Specification of the "a protruding vent arrangement having a plurality of gas washout holes," as recited in claim 65 is a discrete vent structure that extends above the surrounding surface of the frame and contains a plurality of vent holes.[10]

The parties are hereby given notice that claim construction, in general, is an issue to be addressed at trial. Claim construction will be determined at the close of all the evidence and after any hearing. The parties are expected to assert all their claim construction arguments and evidence in the Petition, Patent Owner's Response, Petitioner's Reply, or otherwise during trial, as permitted by our rules.

C. Patentability of Claims 57, 58, 61, 65, 68, 69, 71, and 77–79 in view of D'Souza, Ultra Mirage, Barnett, and Matula-II

1. Scope and Content of the Prior Art

a. Overview of D'Souza

Petitioner's annotated versions (Pet. 28) of Figures 6 and 7 of D'Souza are reproduced below.

[10] We note that this consistent with the claim interpretation of a substantially similar phrase in claim 1 of the '931 Patent construed in IPR2017-00061.

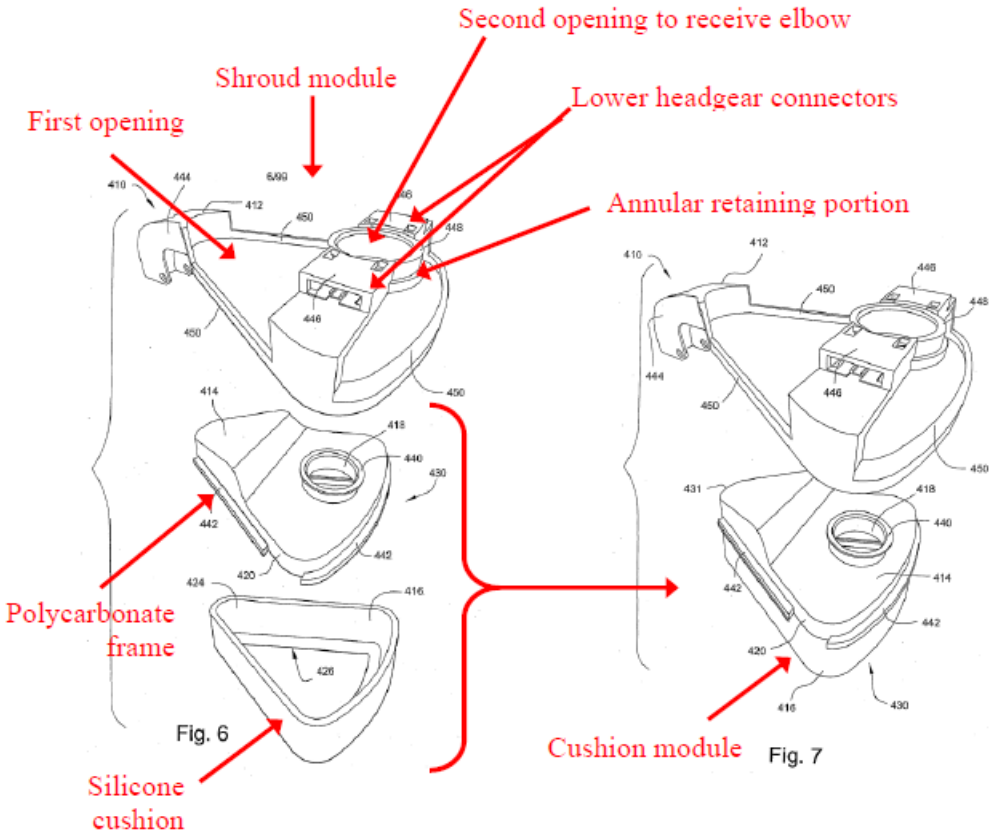


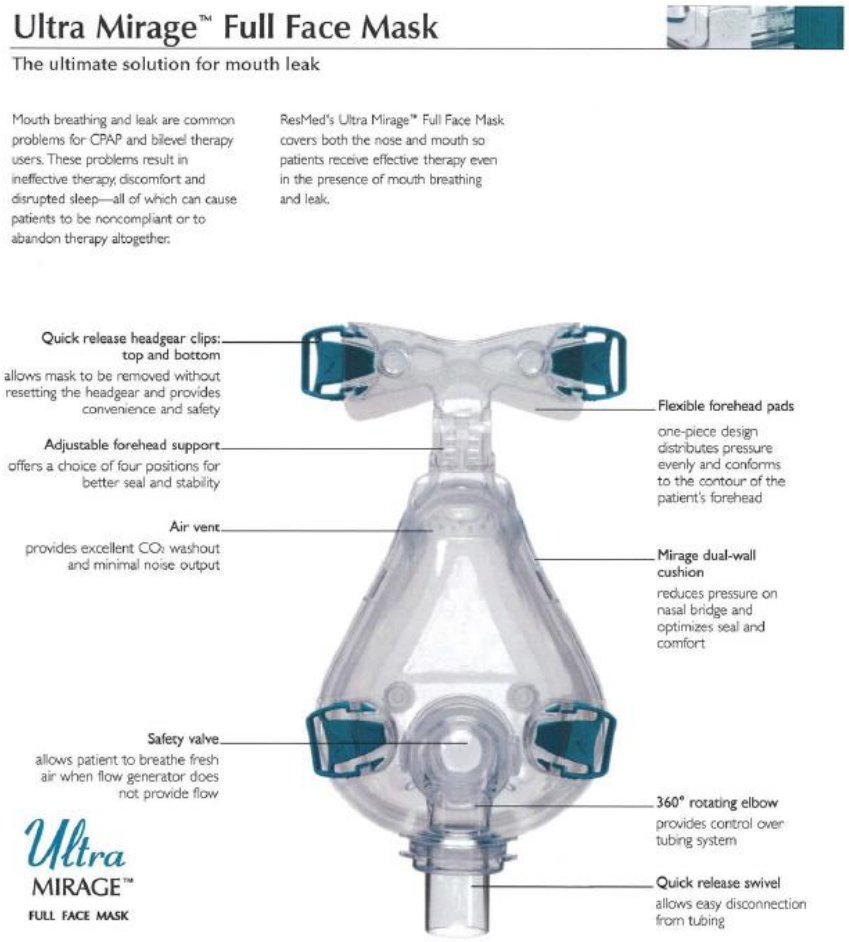
Fig. 6 is a top perspective view of a mask assembly
Fig. 7 is the mask assembly in a partially assembled condition,
as annotated by Petitioner.

See Ex. 1102, Figs. 6, 7. The figures above depict D'Souza's mask assembly 410 comprising skeleton frame 412 (asserted "shroud module"), frame 414, and cushion 416. Ex. 1102 ¶¶ 96–97. As illustrated in the figures, frame 414 interlocks with cushion 416 to form cushion/frame sub-assembly 430. *Id.* D'Souza discloses that cushion 416 is constructed of liquid silicone rubber (*id.* ¶ 97), whereas frame 414 is constructed of polycarbonate (*id.* ¶ 98).

b. Overview of Ultra Mirage

Ultra Mirage discloses a full face CPAP mask with top and bottom removable headgear clips, an air vent to provide CO_2 washout, and a rotating

elbow with a quick release swivel. *See* Pet. 23–24; Ex. 1103, 6. A figure in Ultra Mirage, which is reproduced below, illustrates the mask.



Front view of the Ultra Mirage mask, with components identified.

See Pet. 23–24; Ex. 1103, 6. Various elements of the mask, including the air vent, are identified in the Ultra Mirage figure.

c. Overview of Barnett

Petitioner's annotated Figure 6 from Barnett (Pet. 24) is reproduced below.

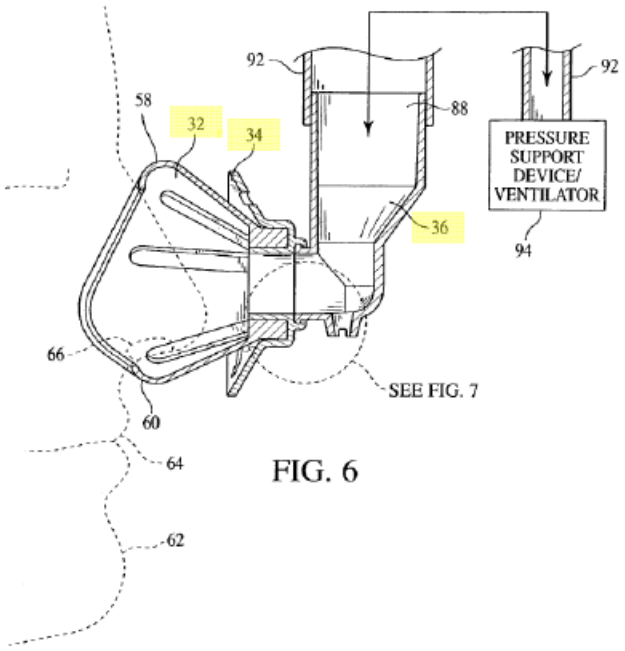


FIG. 6

FIG. 6 is a side sectional view of a nasal mask assembly schematically illustrating the nasal mask assembly in a system for delivering a gas to a patient, as annotated by Petitioner.

As shown above in Petitioner's annotated Figure 6, Barnett discloses nasal mask assembly 30 with seal member 32 that contacts the patient's face and collar 34 that is fixed and not movable relative to seal member 32. *Id.* at 25 (citing Ex. 1107, 3:48–52). Conduit coupling member or elbow 36 is rotatably mounted to collar 34 and freely rotates 360° about a central axis of collar 34. *Id*. (citing Ex. 1107, 3:52–56).

d. Overview of Matula-II

Petitioner's annotated Figure 4 from Barnett (Pet. 25) is reproduced below.

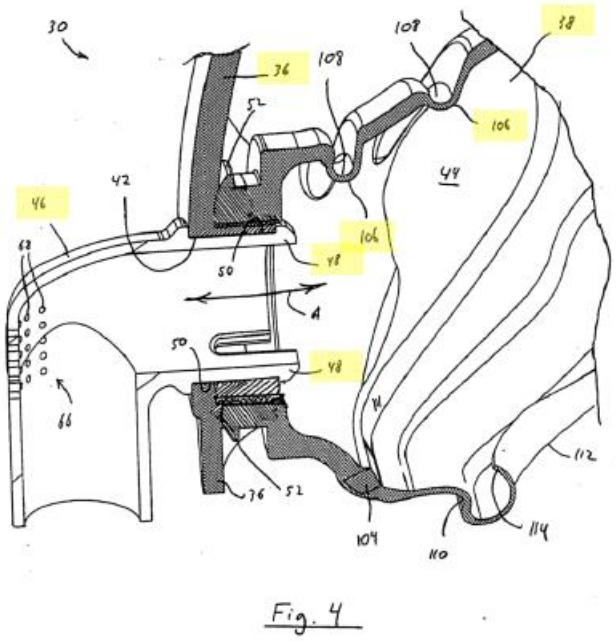


Fig. 4

Fig. 4 is a sectional view of a seal member and faceplate coupling configuration in a patient interface, as annotated by Petitioner.

Matula-II discloses a CPAP interface including faceplate 36 mechanically coupled to seal member 38. Pet. 25 (citing Ex. 1105 ¶¶ 52–53). As shown in Figure 4, according to Petitioner, coupling member 46 includes a pair of prongs 48 that define channel 50 to receive the wall of faceplate 36 and the end of seal member 38. *Id*. at 26 (citing Ex. 1105 ¶ 53. Petitioner also asserts that Matula-II discloses seal member 38 having at least one fold 106 provided at an upper portion of the seal member "so that the seal member has the desired degree of flexibility." *Id*. (citing Ex. 1105 ¶ 66).

2. Differences Between Prior Art and Challenged Claims, and Analysis

Petitioner asserts "D'Souza discloses nearly all of the limitations of Claims 57, 58, 61, 65, 71, 77–79." Pet. 26. It is Petitioner's position that

any differences between the challenged claims and the disclosure of D'Souza are "minor, well-known, and disclosed in other prior art CPAP masks." *Id.* (citing Ex. 1113 ¶ 59). Mr. Eaton's cited testimony supports Petitioner's position.

a. Snap Fit

Independent claims 57 and 79 recite that "the shroud module and the cushion module are structured and arranged to be removably snap-fit attached to one another." *E.g.* Ex. 1101, 31:4–6.

As shown in Figure 8 of D'Souza, reproduced below, skeleton frame 412 is engaged with cushion/frame sub-assembly 430 such that annular elbow connection seal 448 interlocks with annular wall 440 of the cushion/frame sub-assembly 430, upper support member 444 interlocks with top portion 431 of cushion/frame sub-assembly 430, and elongated frame members 450 interlock with respective protrusions 442 provided around the perimeter of cushion/frame sub-assembly 430. Ex. 1105 ¶ 101.

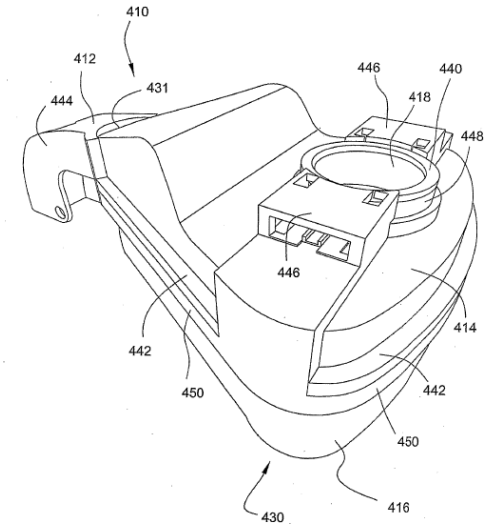


Fig. 8

Fig. 8 is a top perspective view of the D'Souza mask in an assembled condition;

Alternatively, Petitioner asserts Matula-II teaches a plurality of snap fingers 48 that facilitate elastic deformation to mechanically and removably couple seal member 38 to faceplate 36. Pet. 33 (citing Ex. 1105 ¶ 53.

Based on the record before us, for purposes of this Decision, we are persuaded that each of D'Souza and Matula-II disclose a snap-fit as recited in the claims.

b. Upper Headgear Connectors

Claims 57 and 79 recite "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." *E.g.*, Ex. 1101, 30:56–59. As disclosed in the '931 Patent, and as shown generally in Figure 3 of the patent, upper headgear connectors 1024 extend from each side of the top portion of the shroud and lower headgear connectors 1025 extend from each side of the lower portion. Ex. 1101, 7:28–30. Each lower headgear connector 1025 includes clip receptacle 1031 at the free end that interlocks with a headgear clip on a headgear strap (*see* Figure 9 showing headgear strap 1090). *Id*. at 8:29–32.

D'Souza discloses that skeleton frame 412 provides attachment points for a forehead support, a headgear assembly, and an inlet conduit. Ex. 1102 ¶ 101. As best shown in Figures 6 and 7 of D'Souza (*see* Section II(C)(1)(a) above), skeleton frame 412 includes upper support member 444 adapted to support a forehead support, lower headgear clip receptacles 446 adapted to be engaged with clips provided to straps of a headgear assembly (not shown). *Id*.

Petitioner acknowledges that D'Souza "does not expressly disclose upper headgear connectors." Pet. 29. Petitioner asserts, however, that Ultra

Mirage discloses "a shroud having a forehead support with upper and lower headgear connectors. *Id.* (citing Ex. 1103, 6) (*see* figure with identification of "Quick release headgear clips: top and bottom"). As stated in Ultra Mirage, the headgear clips allow the mask "to be removed without resetting the headgear and provides convenience and safety." Ex. 1106, 6

Petitioner asserts that "to the extent the removability of the headgear in D'Souza is unclear, Ultra Mirage discloses this feature." Pet. 30. Based on the record before us, for purposes of this Decision, we are persuaded that Ultra Mirage discloses upper and lower headgear connectors as recited in the claims.

As a rationale for the proposed modification, Petitioner asserts a person of ordinary skill in the art at the time of the invention would have been motivated to modify D'Souza to add upper headgear connectors as taught by Ultra Mirage to provide stability to the mask assembly. Pet. 48 (citing Ex. 1113 ¶ 86). Mr. Eaton testifies that the proposed modification also would have been obvious to provide ease in manufacturing, assembly, and ease of use. Ex. 1113 ¶ 86.

For purposes of this Decision, on the record before us, we agree with Petitioner.

c. "a rotatable elbow directly attached to the shroud"

Claims 57 and 79 include "a rotatable elbow directly attached to the shroud." *E.g.* Ex. 1101, 30:60.

Petitioner acknowledges that D'Souza "does not expressly disclose a rotatable elbow directly attached to the shroud or the elbow being connected to an air delivery tube [*see* claim 61]". Pet. 30–31. Petitioner asserts, however, that D'Souza "discloses mask assemblies for use with a flow

generator and adapted to engage an elbow." *Id.* at 30 (citing Ex. 1102 ¶ 3 (disclosing use with flow generators); Ex. 1102 ¶ 100 (disclosing an annular elbow connection seal 448 adapted to engage an inlet conduit, e.g., elbow").

Petitioner asserts Ultra Mirage discloses a "360° rotating elbow" on a CPAP mask to provide control over a tubing system. Pet. 31 (citing Ex. 1103, 6; Ex. 1113 ¶ 66). Petitioner also asserts Barnett discloses a rotatable elbow as claimed. *Id.* (citing Ex. 1107, 3:52–57).

Based on the record before us, for purposes of this Decision, we are persuaded that Ultra Mirage and Barnett each disclose a rotatable elbow directly attached to the shroud as recited in the claims.

As a rationale for the proposed modification, Petitioner asserts a person of skill in the art at the time of the invention would have been motivated to modify the references as proposed to allow the wearer to position the tubing to provide the most convenient, comfortable, and low force mask connection. *Id.* at 31 (citing Ex. 1113 ¶ 87). Petitioner also asserts a skilled person would have been motivated to directly attach the elbow to the shroud as taught in Barnett to make it easier to detach the elbow without affecting the engagement of the mask components. *Id*. (citing Ex. 1113 ¶ 89). According to Petitioner, attaching the elbow directly to the shroud instead of the frame would also have provided more design flexibility. *Id*.

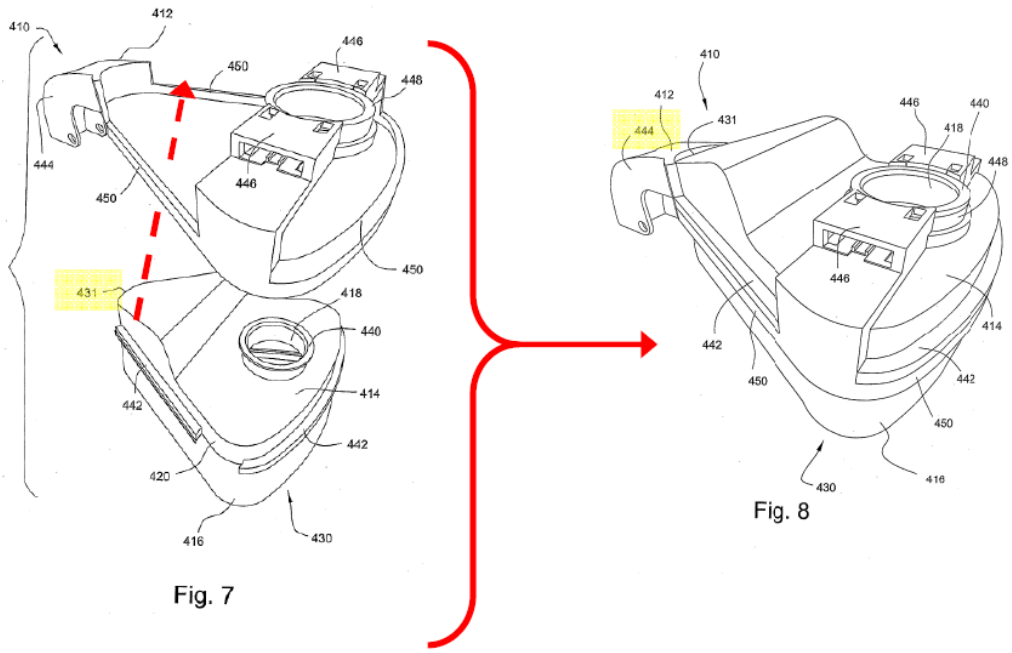
For purposes of this Decision, on the record before us, we agree with Petitioner.

d. "Protruding Vent Arrangement"

Claim 65 depends from Claim 57 and further recites that "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." Ex. 1101, 31:55–59.

With respect to this claim requirement, Petitioner asserts: "As shown in Figs. 7–8 of D'Souza, reproduced below with Petitioner's annotations, when the mask assembly 410 is assembled, the top portion 431 (nasal bridge region) of the frame 414 protrudes through the opening (between the elongated frame members 450) in the shroud 412." Pet. 34 (citing Ex. 1102 ¶ 101); Ex. 1102, Figs. 7, 8.



Figures 7 and 8 are a top perspective views of the D'Souza mask. Figure 7 is partially assembled; Figure 8 is fully assembled, as annotated by Petitioner.

Petitioner acknowledges that D'Souza "does not expressly disclose a vent on the protrusion." Pet. 34. Petitioner asserts, however, that "vents positioned in the region of the D'Souza protrusion (nasal bridge region) were common in prior art CPAP masks." *Id.* (citing Ex. 1113 ¶ 74). Petitioner further argues that "Ultra Mirage teaches an air vent positioned in

the nasal bridge region to provide CO_2 washout and minimize noise output." *Id.*34–35 (citing Ex. 1103, 6). Petitioner concludes a skilled artisan "would have been motivated to provide the vent of Ultra Mirage in the same nasal bridge region of D'Souza, and thus on the protruding portion of D'Souza." *Id.* (citing Ex. 1113 ¶¶ 74, 90). We disagree with Petitioner's analysis, as discussed below.

Petitioner's argument, that adding a plurality of vent holes to a portion of D'Souza's frame 414 that extends through an opening in shroud 412 would satisfy the claim requirement, is based on an improper claim construction, as discussed above. *See supra* Section II.B.1. Under our claim interpretation, the claim term requires a discrete vent structure that extends above the surrounding surface of the frame and contains a plurality of vent holes. *See id.* Petitioner does not contend that Ultra Mirage teaches or suggests "a protruding vent arrangement having a plurality of vent holes." Rather, Petitioner contends that Ultra Mirage teaches positioning a plurality of vent holes in the nasal bridge region of a mask. Merely positioning a plurality of vent holes in the nasal bridge region of D'Souza's mask would not result in a discrete vent structure that extends above the surrounding surface of the frame and contains a plurality of vent holes, as required under our claim interpretation. The vent holes would be flush with the surrounding surface of the nasal bridge region. We are unpersuaded, therefore, that the combination of D'Souza and Ultra Mirage teaches or suggests "a protruding vent arrangement having a plurality of holes."

For the reasons given, we determine that Petitioner has not established a reasonable likelihood of prevailing on its challenge that claim 65 would have been obvious based on D'Souza, Ultra Mirage, Barnett, and Matula-II.

e. "One or More Folds"

Claim 68 depends from Claim 57 and further recites "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." Ex. 1101, 32, 5–9. Claim 68 also recites that each of the one or more folds comprises adjacent first side walls interconnected by a second side wall.

The Specification of the '931 Patent states that, as best shown in Figures 30 and 33, a "concertina" section 50 may be provided in a nasal bridge region of the cushion and/or frame "to enhance the flexibility of the cushion in use." Ex. 1101, 14:19–25. Concertina section 50 includes a bellows structure with one or more folds 52 that provide a higher degree of flexibility, movement, or adaptability to the nasal bridge region of the cushion/frame. *Id.* at 14:25–32. In one disclosed embodiment, as shown in Figure 32-3, each fold 52 includes first side wall 52(1) and second side wall 52(2) that interconnect adjacent side walls 52(1). *Id.* at 14:40–42.

Petitioner acknowledges that "D'Souza does not expressly disclose a fold" as claimed. Pet. 36. Petitioner relies on Matula-II for the disclosure of fold 106 in the nasal bridge portion of the cushion 38 to provide "the desired degree of flexibility." *Id.* (citing Ex. 1105 ¶ 66).

Petitioner asserts a skilled artisan would have known to incorporate the folds taught by Matula-II with the D'Souza cushion to provide a higher degree of flexibility in the delicate nose bridge region compared to other regions. Pet. 42 (citing Ex. 1113 ¶ 92).

For purposes of this Decision, on the record before us, we agree with Petitioner.

f. "Plurality of Snap Fingers"

Claim 69 depends from Claim 57 and further recites "the frame includes a collar surrounding said frame opening" and "the retaining portion of the shroud includes a plurality of snap fingers structured to engage the collar with a snap-fit." Ex. 1101, 32:14–18.

The '951 patent discloses that, as shown in Figures 14, 15, 17, and 21, opening 1132 of shroud 1120 may include snap fingers 1145(1) adapted to engage the collar 1149 surrounding the frame opening 1146 with a snap-fit. Ex. 1101, 18:54–58.

Petitioner acknowledges that D'Souza does not expressly disclose a plurality of snap fingers. Pet. 39. According to Petitioner, however, snap fingers "were common in prior art CPAP masks." *Id*. (citing Ex. 1113 ¶ 82). As an example of the common snap fingers, Petitioner asserts Matula-II discloses prongs, or snap fingers, 48 that mechanically couple seal member 38 to the faceplate. *Id.*

As a rationale for the proposed modification, Petitioner asserts it would have been obvious to a person of ordinary skill to facilitate repeated insertion of the collar 440 through the rigid retaining portion 448 without destroying the parts. *Id*. at 42–43. According to Petitioner, this would provide a more effective removable mechanical interlock between the shroud and the cushion module. *Id.* at 43.

For purposes of this Decision, on the record before us, we agree with Petitioner.

g. Polycarbonate Frame

Claim 71 depends from Claim 57 and further recites that the shroud module and the frame comprise polycarbonate. Ex. 1101, 32:23–25.

Petitioner states that D'Souza discloses a plastic shroud being formed of plastic, but acknowledges that D'Souza "does not expressly disclose polycarbonate. Pet. 49. According to Petitioner, however, it was common at the time of the invention to construct CPAP components, including the shroud, from polycarbonate. *Id.* (citing Ex. 1113 ¶ 84). Mr. Eaton's testimony supports Petitioner's argument.

For purposes of this Decision, on the record before us, we agree with Petitioner.

3. Conclusion

In summary, based on the analysis above and the record before us, we determine that it is reasonably likely Petitioner will prevail on it challenge to the patentability of Claims 57, 58, 61, 68, 69, 71, and 77–79 in view of D'Souza, Ultra Mirage, Barnett, and Matula-II. Accordingly, we institute trial on this ground. Based on the analysis above and the record before us, we determine that it is *not* reasonably likely Petitioner will prevail on its challenge to claim 65. Accordingly, we do *not* institute trial on claim 65.

D. Patentability of Claim 60 in View of D'Souza Ultra Mirage, Barnett, Matula-II, and FlexiFit

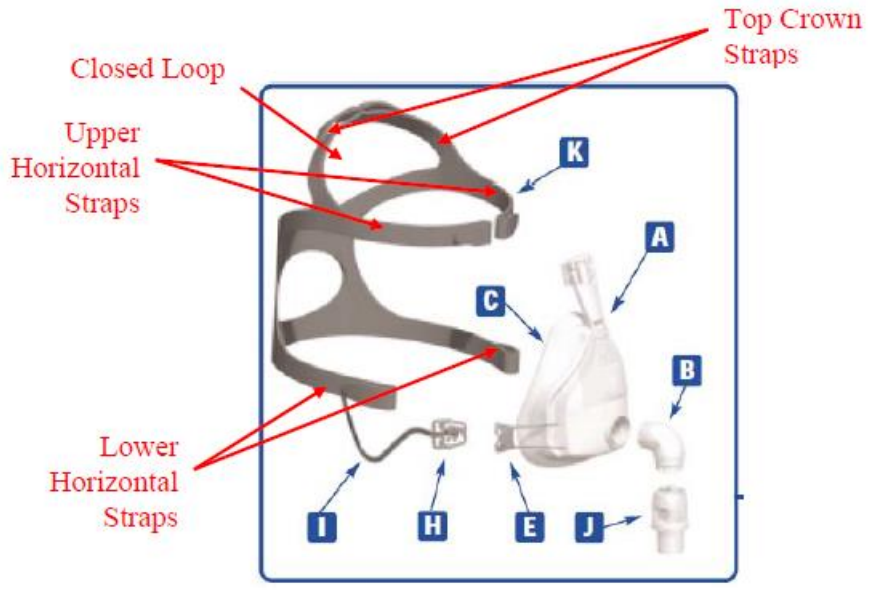
Claim 60 depends from claim 57 and further recites that "each upper headgear connector includes a slot adapted to receive a respective headgear strap in use; and wherein each lower headgear connector is adapted to be removably interlocked with a headgear clip associated with a respective headgear strap."

As disclosed in the Specification, and as shown in Figure 3, each upper headgear connector 1024 includes elongated arm 1026 and slot or receiving hole 1027 at the free end of arm 1026 adapted to receive a

respective headgear strap. Ex. 1101, 7:34–37. Each lower headgear connector 1025 includes an abbreviated arm and a clip receptacle 1031 at the free end of the arm adapted to be removably interlocked with a headgear clip associated with a respective headgear strap. *Id.* at 8:29–32. The clips allow for easier positioning or donning/removal of the mask system. *Id.* at 8:32–34.

Figures 27–30 illustrate lower headgear clip 33 adapted to be removably interlocked with clip receptacle 31. *Id.* at 8:37–38. As best shown in Figure 28, clip 33 includes spring arms 35 adapted to interlock with clip receptacle 31 with a snap-fit, and slot 37 adapted to receive a respective headgear strap in use. *Id.* at 8:39–42.

Petitioner provides (Pet. 44) an annotated figure from FlexiFit, reproduced below.



Petitioner's annotated figure of an exploded view of a mask and headgear from FlexiFit.

According to Petitioner, FlexiFit shows headgear (K), which can be coupled to mask base (A). Pet. 43 (citing Ex. 1106, 10). As shown in the figure and identified by Petitioner's annotations, Headgear (K) has upper horizontal straps and lower horizontal straps. *Id.*

As explained in the "Fitting Your Mask" instructions for FlexiFit, a user fits the mask by unclipping headgear (K) from Glider™ strap (E) by pulling release cord (I) downwardly. Ex. 1106, 10. The user then fits the mask comfortably over the user's head. *Id.* The user re-attaches headgear clip (H) to the Glider™ strap, and adjusts the top and lower horizontal straps, and the top crown straps. *Id.*

Petitioner asserts D'Souza discloses lower headgear connectors adapted to engage clips, but argues that to the extent D'Souza provides insufficient teachings for the "removability" of the clips, Ultra Mirage and FlexiFit both disclose removable lower headgear clips. Pet. 46 (citing Ex. 1102 ¶ 100; Ex. 1103, 6; Ex. 1106, 10). Why would it have been obvious to a person of ordinary skill to make the proposed modification? Petitioner's answer to this question is that at the time of the invention, a skilled artisan would have been motivated to provide removable lower headgear clips, as disclosed in FlexiFit, "so that the user would not have to force the lower headgear straps over his/her head," and "a simpler design option" of upper headgear connectors with slots, as taught by FlexiFit, to "simplify manufacturing and reduce parts." *Id.* at 46–47 (citing Ex. 1113 ¶ 101). Mr. Eaton testifies that the proposed modification:

> improves ease of donning/doffing, as a user would not have to overcome strap tension while holding the mask away from the face and sliding it down from the top of the head. This advantage would have been minimal at the top headgear connection because

> those straps are only brought into tension as they near the worn position. Thus, as an alternative design option, a skilled artisan would have known to provide slots at the upper headgear connectors, instead of clips. Although clip attachments have their own advantages, such as quick release, a person of skill in the art would have also recognized simple slots on the frame as a design option with its own advantages.

Ex. 1113 ¶ 101.

Based on the analysis above and the record before us, we determine that it is reasonably likely Petitioner will prevail on it challenge to the patentability of claim 60 based on D'Souza Ultra Mirage, Barnett, Matula-II, and FlexiFit.

E. Patentability of Claims 62–64 in view of D'Souza, Ultra Mirage, Barnett, Matula-II, FlexiFit, and Gunaratnam-II

Claim 62 depends from independent claim 57. Claims 63 and 64 depend from claim 62. All three claims concern specific structure for the upper and lower straps and for the top and rear straps of the headgear. Claim 62 recites:

> the headgear includes upper straps and lower straps,
>
> 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,
>
> 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, 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.

Claim 63 recites that the upper straps provide padding to the headgear connectors of the shroud module on the patient's face.

Claim 64 recites that the rear straps and the top straps form a closed loop to encircle a rear portion of the patient's head.

As disclosed in the Specification, and as shown in Figure 9, headgear 1090 includes a pair of upper and lower straps 1092, 1094. Ex. 1101, 10:41–42. Upper straps 1092 removably attached to upper headgear connectors 1024 and lower straps 1094 removably attached to lower headgear connectors 1025. *Id.* at 10:42–45. The free end of each strap may include a VELCRO® tab structured to engage the remainder of the strap to secure the strap in place. *Id.* at 10:45–47. Upper straps 1092 split at the crown of the patient's head to form top straps 1096 adapted to pass over the top of the patient's head and rear straps 1098 adapted to pass behind the patient's head. *Id.* at 10:52–57.

Petitioner relies on FlexiFit for the strap system recited in claim 62 (Pet. 48–49), and on Gunaratnam-II for the specific disclosure of a buckle connector for the top straps, as shown in Figure 135 of Gunaratnam-II (*id.* at 50) (citing Ex. 1110 ¶ 316; Ex. 1113 ¶ 107).

Concerning claim 63, Petitioner asserts that FlexiFit discloses that the flexible headgear strap between the upper headgear connector and the user's face provides padding. *Id.* at 51 (citing Ex. 1113 ¶ 110).

Petitioner relies on FlexiFit for the disclosure of the "closed loop" recited in claim 64. *Id.* at 52.

Petitioner's rationale for the proposed combination is that a person of skill in the art would have recognized the comfort benefits, without adding additional parts, of using the FlexiFit headgear in connection with upper

headgear connectors to provide padding between the upper headgear connectors and the user's face. *Id*. at 53–54 (citing Ex. 1113 ¶¶ 110, 114). Petitioner also asserts it would have been obvious to a person of ordinary skill to use a rear loop for stability and a buckle for adjustability based on the prior art disclosures. *Id.* at 54 (citing Ex. 1113 ¶¶ 114, 115).

Based on the analysis above and the record before us, we determine that it is reasonably likely Petitioner will prevail on its challenge to the patentability of claims 62–64 based on D'Souza, Ultra Mirage, Barnett, Matula-II, FlexiFit, and Gunaratnam-II

F. Patentability of Claims 43, 48–50, and 70 Based on D'Souza, Ultra Mirage, FlexiFit, Barnett, Jaffre, and Matula-II

Independent claim 43 is similar to independent claim 57, discussed above, in that both claims are directed to a mask system including a cushion module, headgear, a shroud module, and an elbow assembly. Claim 43 includes substantial additional structure not recited in claim 57.

In claim 57, the frame of the cushion module includes a "frame opening" leading to the breathing chamber, which is not recited in claim 43. In claim 57, the headgear is recited very broadly, as merely including "headgear straps," whereas claim 43 recites the headgear in detail, incorporating substantial portions from dependent claims 62 and 64 discussed above. In claim 57, the shroud module is recited broadly, as merely including upper and lower headgear connectors, whereas claim 43 recites the shroud module in additional detail, such as including a slot in the headgear connector similar to dependent claim 60 discussed above. Claim 57 also recites the rotatable elbow attached to the frame very broadly, whereas claim 43 also recites that the elbow includes a swivel adapted to

connect to an air delivery tube and also includes an anti-asphyxia valve (AAV) and a port that is selectively closed by a flap portion of the AAV. This list of differences between independent claim 43 and independent claim 57 is exemplary, not exhaustive.

As described in the ’931 Patent, and as shown generally in Figure 3, elbow 1070 includes slot 1081, which receives an anti-asphyxia valve (AAV). Ex. 1101, 16:42–43. Anti-asphyxia valve 85 is shown generally in Figure 27 of the ’931 Patent. Elbow 1070 also includes port 1079 that is selectively closed by flap 86 of the AAV depending on the presence of pressurized gas. *Id.* at 16:43–45; 65–67.

Jaffre is newly asserted in this ground of unpatentability. We first discuss its scope and content. Petitioner relies on Jaffre for its disclosure of an exhaust port assembly. Pet. 55.

Jaffre discloses an exhaust port assembly with enhanced noise reduction and gas diffusion capabilities, while also minimizing size. Ex. 1112, 1:15–17. It has particular applicability to a patient interface mask in a CPAP machine. *Id.* at 7:8–12; 1:20–28. Exhaust port assembly 62 is shown in detail in Figures 4–9 and described in the related text. Figures 7, 8, and 9 from Jaffre are reproduced below.

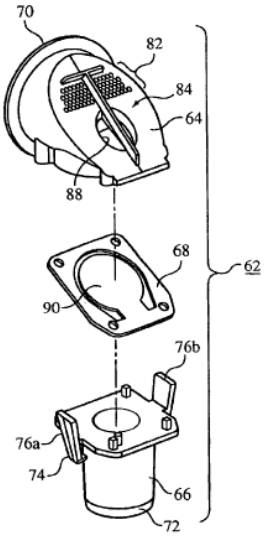


FIG. 7

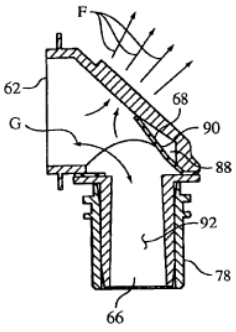


FIG. 8

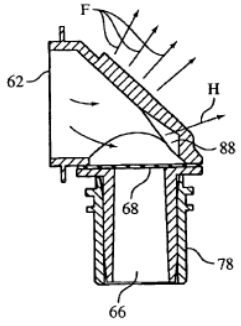


FIG. 9

Figure 7 is an exploded view of exhaust port assembly 62. Figures 8 and 9 are cross-sectional views of the exhaust port assembly.

As shown in Figures 7–9, exhaust port assembly 62 includes vent 64, conduit coupling member 66, and valve 68. Ex. 1112, 7:21–23. Vent 64 and conduit coupling member 66 define a conduit having first end 70 that is coupled to patient interface device, or mask, 46 (*see id.* Figure 3) and a second end 72 that is coupled to patient circuit 52 (*id.*). *Id.* at 7:35–38. Patient circuit 52 is connected to pressure generating system 32, 32′. *Id.* at 7:8–15; Figure 3. First end 70 is rotateably and permanently attached to patient interface device 46 using any conventional technique. *Id.* at 7:38–41. Second end 72 is selectively attachable to patient circuit 52. *Id.* at 41–42.

To provide automatic access to the ambient atmosphere, exhaust port assembly 62 includes auxiliary opening 88 defined in the conduit and having a relatively large diameter. *Id.* at 10:11–14. During normal use, cantilever member 90 of valve 68 flexes, as shown to Figure 8, to block auxiliary opening 88, so that gas is able to flow between the patient and the pressure generating system, as indicated by arrow G in Figure 8. *Id.* at 10:14–22. If, however, the pressure of the gas in interior 92 is not greater than ambient atmosphere, cantilever member 90 returns to its normal, undeflected position shown in Figure 9 and unblocks auxiliary opening 88 so that the patient has access to the ambient atmosphere as indicated by arrow H in Figure 9. *Id.* at 10:23–27. In this Figure 9 position, cantilever member 90 also blocks gas from flowing through the conduit toward the pressure support system. *Id.* at 10:28–30. The spring force of cantilever member 90 tends to urge it toward the unflexed position shown in Figure 9 to ensure that auxiliary opening 88 becomes unblocked if the pressure support system fails to provide an adequate supply of breathing gas. *Id.* at 10:30–33.

The operation of valve 68 to block and unblock auxiliary opening 88 and the patient circuit does not affect the operation of holes 82 allowing a continuous flow F of gas from the patient circuit, as shown in Figures 8 and 9. *Id.* at 10:35–38.

Petitioner asserts D'Souza discloses "nearly all" of the limitations of claims 43, 48–50, and 70. Pet. 55. According to Petitioner, "[a]ny differences were well-known at the time of the invention and taught by other prior art CPAP masks." *Id.* (citing Ex. 1113 ¶ 117). Petitioner relies on D'Souza, Ultra Mirage, FlexiFit, Barnett, and Matula-II, as discussed above in our analysis of claims 57, 60–62, and 65, for "most of the features of"

claims 43, 48–50, and 70. We agree with Petitioner that our analysis above addresses most of the elements recited in challenged claims 43, 48–50, and 70. Claim 48 recites that the frame is semi-rigid or rigid. Claim 49 recites that the frame is rigid. Claim 50 adds a flow generator and delivery tube to the mask of claim 43. These limitations have been addressed above.

We discuss below the two elements of claims 43, 48–50, and 70 that Petitioner acknowledges are not disclosed in D'Souza, Ultra Mirage, FlexiFit, Barnett, and Matula-II – an "elbow including a swivel" and an anti-asphyxia valve.

1. Differences Between Prior Art and Challenged Claims, and Analysis

Independent claim 43 recites "the elbow including a swivel adapted to connect to an air delivery tube." D'Souza discloses an elbow adapted to engage the mask, but, as acknowledged by Petitioner, D'Souza "does not expressly disclose the elbow including a swivel." Pet. 56 (citing Ex. 1102 ¶ 100). Petitioner correctly asserts that Ultra Mirage discloses a 360º rotating elbow. *Id.* (citing Ex. 1103, 6).

Independent claim 43, and claim 70, dependent from claim 57, each recite that the elbow includes an AAV and a port that is selectively closed by a flap portion of the AAV. Petitioner correctly asserts that Jaffre disclosures an AAV as recited in claims 43 and 70. Pet. 57.

As a reason why the proposed modifications would have been obvious to a person of ordinary skill, Petitioner asserts the swivel elbow facilitates easy adjustment and disconnection from tubing. Pet. 58 (citing Ex. 1103, 6; Ex. 1113 ¶ 123). Regarding the AAV, Petitioner asserts would have been obvious to a person of ordinary skill to adapt the AAV of Jaffre to the D'Souza modified elbow "to allow patients to breathe fresh air when the

flow generator does not provide flow." Pet. 58 (citing Ex. 1103, 6; Ex. 1109 ¶ 106[11]; Ex. 1113 ¶ 124). Mr. Eaton testifies that one skilled in the art would have recognized that a safety valve such as the AAV in Jaffre "would be a requirement of the full-face mask of D'Souza" and "would have been motivated to include this structure." Ex. 1113 ¶ 124.

Based on the analysis above and the record before us, we determine that it is reasonably likely Petitioner will prevail on its challenge to the patentability of claims 43, 48–50, and 70 based on D'Souza, Ultra Mirage, FlexiFit, Barnett, Jaffre, and Matula-II.

G. Patentability of Claims 46, 51, and 53–56 Based on D'Souza, Ultra Mirage, FlexiFit, Barnett, Jaffre, Matula-II, and Gunaratnam-II

Claim 46 depends from claim 43 and adds details about the elbow, headgear straps, and frame. In particular, it recites that the frame includes a "protruding vent arrangement" having holes, and that the shroud module includes an opening to accommodate the protruding vent. Independent claim 51 combines independent claim 43 and dependent claim 46. As such, claim 51 recites the same "protruding vent arrangement" limitations as are recited in claim 46. Claims 53–56 depend directly or indirectly from claim 51. Thus, all the claims in this group include the "protruding vent arrangement" limitations recited in claim 46.

The "protruding vent arrangement" limitations in claims 46, 51, and 53–56 are substantially identical to the "protruding vent arrangement" limitations in claim 65 discussed above. Claim 65 refers to the "holes" in

[11] Ex. 1109 is PCT Publication No. WO 2007/045008, published April 26, 2007. It is not relied on as a reference in the asserted ground of unpatentability.

the protruding vent as "gas washout" holes, and refers to the opening in the shroud module as an "upper" opening. These are distinctions without a substantive difference based on the record before us.

Petitioner relies on its analysis of claim 65 to assert that the "protruding vent arrangement" limitations of claims 46, 51, and 53–56 would have been obvious based on the cited references. *E.g.*, Pet. 73–74. We rely on our analysis of claim 65 in rejecting that assertion. For the reasons discussed above in connection with claim 65, we are unpersuaded that the combination of D'Souza and Ultra Mirage teaches or suggests "a protruding vent arrangement having a plurality of holes," as recited in claims 46, 51, and 53–56.

Accordingly, we determine that Petitioner has not established a reasonable likelihood of prevailing on its challenge that claims 46, 51, and 53–56 would have been obvious based on D'Souza, Ultra Mirage, FlexiFit, Barnett, Jaffre, Matula-II, and Gunaratnam-II.

III. CONCLUSION

For the reasons give, Petitioner has shown a reasonable likelihood that it would prevail in establishing unpatentability of claims 43, 48–50, 57, 58, 60, 61–64, 68, 69, 70, 71, and 77–79. Accordingly, as set out in the Order below, we institute a trial of these claims.

Petitioner has *not* shown a reasonable likelihood of prevailing in establishing unpatentability of claims 46, 51, and 53–56, and 65. Accordingly, we do *not* institute a trial of these claims.

This is a decision to institute an *inter partes* review under 35 U.S.C. § 314. Our factual findings and determinations at this stage of the proceeding are preliminary, and based on the evidentiary record developed

thus far. This is not a final decision as to the patentability of claims for which *inter partes* review is instituted. Our final decision will be based on the record as fully developed during trial.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is hereby instituted based on the following grounds:

A. claims 57, 58, 61, 68, 69, 71, and 77–79 would have been obvious in view of D'Souza, Ultra Mirage, Barnett, and Matula-II;

B. claim 60 would have been obvious in view of D'Souza Ultra Mirage, Barnett, Matula-II, and FlexiFit;

C. claims 62–64 would have been obvious in view of D'Souza, Ultra Mirage, Barnett, Matula-II, FlexiFit, and Gunaratnam-II;

D. claims 43, 48–50, and 70 would have been obvious in view of D'Souza, Ultra Mirage, FlexiFit, Barnett, Jaffre, and Matula-II; and

FURTHER ORDERED that no other ground of unpatentability asserted in the Petition is authorized for this *inter partes* review; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial; the trial will commence on the entry date of this Decision.

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