

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 BARRY L. GROSSMAN, BEVERLY M. BUNTING, and
JAMES J. MAYBERRY, *Administrative Patent Judges*.

GROSSMAN, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

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

Petitioner raised five separate and distinct challenges to patentability. Pet. 15–16. We instituted review on the four grounds listed below:

1. claims 57, 58, 61, 68, 69, 71, and 77–79 would have been obvious based on D’Souza², Ultra Mirage³, Barnett⁴, and Matula-II⁵;
2. claim 60 would have been obvious based on D’Souza Ultra Mirage, Barnett, Matula-II, and FlexiFit⁶;
3. claims 62–64 would have been obvious based on D’Souza, Ultra Mirage, Barnett, Matula-II, FlexiFit, and Gunaratnam-II⁷; and

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

² WO 2007/041751 A1, pub. Apr. 19, 2007 (Ex. 1102, “D’Souza”).

³ ResMed product brochure describing the “Ultra Mirage™ Full Face Mask” (Ex. 1103, “Ultra Mirage”). Petitioner has submitted 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).

⁴ US 6,412,488 B1, iss. July 2, 2002 (Ex. 1107, “Barnett”).

⁵ US 2007/0044804 A1, pub. Mar. 1, 2007 (Ex. 1105, “Matula-II”).

⁶ 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).

⁷ US 2004/0226566 A1, pub. Nov. 18, 2004 (Ex. 1110, “Gunaratnam-II”).

4. claims 43, 48–50, and 70 would have been obvious based on D’Souza, Ultra Mirage, FlexiFit, Barnett, Jaffre⁸, and Matula-II. Paper 7, 36 (“Dec. Inst.”) (collectively, the claims for which trial was instituted are referred to as the “Instituted Claims”).

We did not institute trial on challenged claims 46, 51, 53–56, and 65, which included a “protruding vent arrangement.” See Dec. Inst. 19–21, 34–35.

Patent Owner filed a Response to the Petition (Paper 17, “PO Resp.”), and Petitioner filed a Reply (Paper 23, “Pet. Reply”).

Petitioner submitted 26 exhibits (Exs. 1101–1126). Petitioner relies, in part, on the Declaration testimony of Jason Eaton, P.E. (Ex. 1113).

Patent Owner submitted 7 exhibits (Exs. 2001–2007). Patent Owner relies, in part, on the Declaration testimony of Geoffrey Sleeper (Ex. 2002).

A joint hearing with related IPR2017-00061 was held December 18, 2017. Paper 33 (“Tr.”).

We have jurisdiction under 35 U.S.C. § 6. We enter this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

Petitioner has the burden of proving unpatentability of a claim by a preponderance of the evidence. 35 U.S.C. § 316(e). Based on the findings and conclusions below, we determine that Petitioner has proven by a preponderance of the evidence that claims 43, 48–50, 57, 58, 60–64, 68–71, and 77–79 would have been obvious.

⁸ US 6,851,425 B2, iss. Feb. 8, 2005 (Ex. 1112, “Jaffre”).

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. This case is still pending. See Ex. 3001 (District Court Order entered May 23, 2017 denying Plaintiff's motion to lift a stay).⁹ The parties also indicate that the '931 patent is involved in U.S. International Trade Commission Investigation No. 337–TA–1022. Pet. 7; Paper 4, 2.

In addition to the case before us, 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 challenging the '931 patent are summarized in the chart below.

⁹ As summarized in Ex. 3001, the parties have patent disputes pending in three fora (district court, ITC, and PTAB) involving numerous patents. Ex. 3001, 1–2.

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 ¹⁰	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
Status	Final Written Decision (3/21/18) finding unpatentable claims 33–37, 40–42	Final Written Decision (3/29/18) finding unpatentable claims 43, 48–50, 57, 58, 60–64, 68–71, and 77–79	Decision (4/11/17) denying institution of IPR	Decision (4/11/17) denying institution of IPR

C. The '931 Patent

Sleep apnea is a sleep disorder in which breathing repeatedly stops and starts. A common way of treating sleep apnea is to use a continuous

¹⁰ 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.

positive airway pressure (CPAP) machine. CPAP machines deliver pressurized air through a mask placed over the nose and mouth while the patient sleeps. The increased air pressure is intended to keep upper airway passages open, preventing repeated apneas. *See* Ex. 1102 ¶¶ 2–3.

It is well-known in the prior art that the mask used with CPAP machines typically includes a soft patient-contacting portion, such as a cushion, and a rigid shell or frame. *See id.* ¶ 3. In use, the prior art masks are held in a sealing position by headgear so as to enable a supply of air at positive pressure to be delivered to the patient’s airways. *See id.*

The ’931 patent relates generally to the mask system used with a CPAP machine. Ex. 1101, 1:21–24. This is a highly-developed technology, as represented by the eleven pages of references cited in the ’931 patent. *Id.* at (56)¹¹.

The ’931 patent includes 81 sheets of illustrations, with more than 100 figures illustrating the disclosed mask system. The written description includes 23 full columns of text. The dispute between the parties in this proceeding, however, focuses on two specific features of the mask system: (1) a “snap-fit” connection between the “cushion module” contacting the patient’s face and the “shroud module,” or headgear, that attaches the entire mask system to the patient’s head; and (2) an “elbow” conduit rotatably

¹¹ The citation “(56)” is to the INID code on the front page of the ’931 patent. “INID” is an acronym for “Internationally agreed Numbers for the Identification of Data.” *See* MPEP 901.05(b). INID code “56” identifies “prior art documents” or references cited. *Id.* INID codes are used by most patent offices and have been applied to U.S. patents since August 4, 1970. *Id.*

attached to the “shroud module” for delivering positive pressure air to the patient.

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

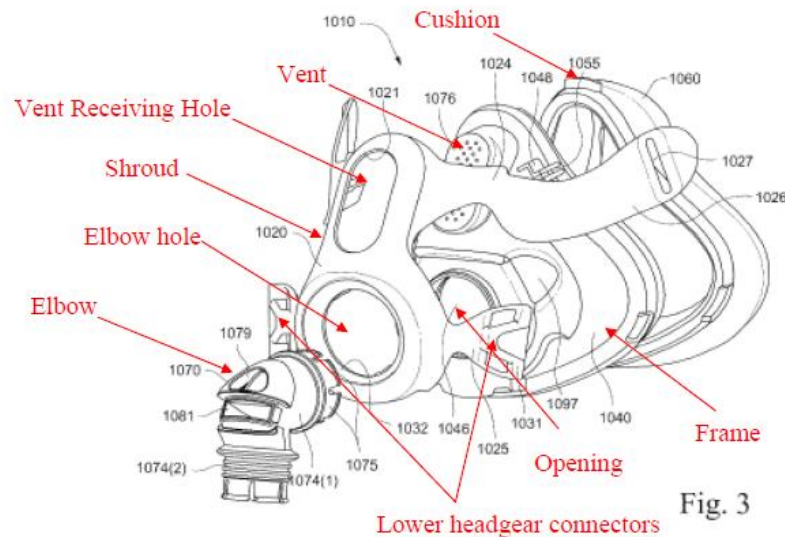


Fig. 3

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

Figure 3 of the '931 patent shows the four basic components of mask system 1010. These are: shroud 1020, frame 1040, cushion 1060, and elbow 1070. *Id.* at 6:51–53. Patent Owner’s declarant, Mr. Sleeper, provides the following colored version of Figure 3, reproduced below, which highlights these four basic components.

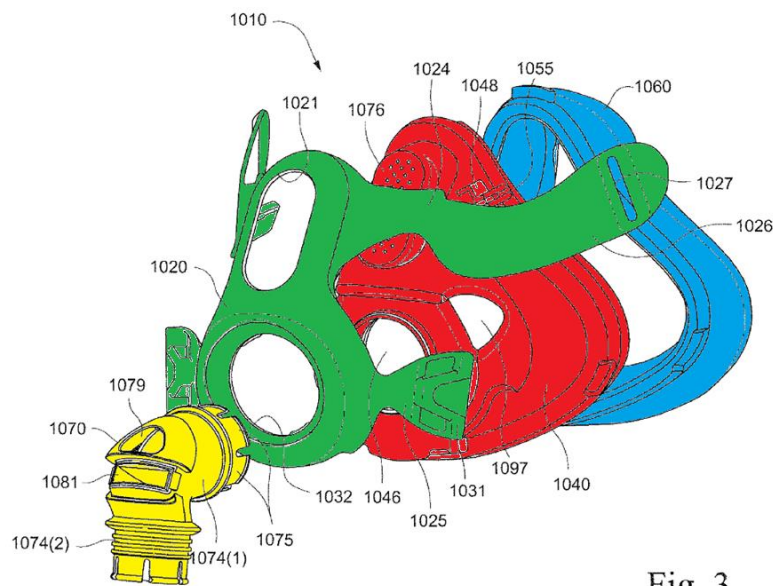


Fig. 3

Colored version of Fig. 3, as annotated by Mr. Sleeper, showing frame 1040 (red) that interfaces with shroud 1020 (green) and cushion 1060 (blue). Elbow 1070 (yellow) also is shown. *See* Ex. 2002 ¶ 17.

The mask system provides a modular design that allows different styles and/or sizes of the frame (also referred to as a frame module), shroud (also referred to as a shroud module), cushion (also referred to as a cushion module), and/or elbow (also referred to as an elbow module) to be interchanged or mixed and matched with one another to provide a more customized mask system for the patient. *Ex. 1101, 17:19–25.* In addition, the modular design allows selected modules to be replaced easily, for example, if treatment requirements change or parts are worn out or damaged. *Id.* at 17:25–27.

Frame 1040 defines a breathing chamber adapted to receive the patient's nose and mouth. *Id.* at 6:60–64. Frame 1040 includes opening 1046 that communicates with elbow 1070. *Id.* Upper headgear connectors 1024 extend from each side of the upper portion of shroud 1020 and lower headgear connectors 1025 extend from each side of the lower portion of the

shroud. *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.

In a preferred embodiment, shroud 1020 is constructed of a resilient material, including but not limited to plastic or nylon. *Id.* at 7:11–13. However, the shroud may be constructed of other suitable materials, such as polycarbonate, polypropylene, or thermoplastic elastomer. *Id.* at 7:13–16.

The parties dispute whether the applied references disclose or suggest a combination of features that include a snap-fit between the shroud and frame. *E.g.*, PO Resp. 21, 66. The parties also dispute whether the references disclose or suggest the shroud to elbow rotatable connection, as claimed. *E.g.*, *id.* at 57.

Regarding the snap-fit between the shroud and frame, the Specification discloses that, as shown in Figures 11, 14, 15, 17, and 21, opening 1132 of shroud 1120 may include structure adapted to engage collar 1149 surrounding frame opening 1146 “with a snap-fit.” Ex. 1101, 18:54–57. As illustrated in Figure 14 and described in the related Specification, shroud 1120 includes “snap fingers 1145(1)” and “sandwich tabs 1145(2)” that extend from opening 1132. *Id.* at 18:57–60. In use, snap fingers 1145(1) resiliently deflect and engage protrusions 1149(1) provided on collar 1149 (e.g., see Figure 22) to provide an initial retention of shroud 1120 to frame 1140 to facilitate assembly and disassembly. *Id.* at 18:62–67.

Regarding the shroud to elbow rotatable connection, the Specification discloses that, as shown in Figures 27–30, the shroud is structured to maintain the elbow in an operative position with respect to the patient’s face. *Id.* at 15:59–61. Also, the elbow may be rotated 360° relative to the shroud

in use. *Id.* at 16:1–4. The Specification also states this same connection/rotational arrangement between the elbow and *frame*.
Id. at 16:5–21.

Of the Instituted Claims, claims 43 and 57 are independent.

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 (emphases added).

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 (emphases added).

II. ANALYSIS

A. Claim Construction

Neither Petitioner nor Patent Owner assert any specific construction for the claims. Pet. 16; PO Resp. 20.

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); *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. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). The correct inquiry in giving a claim term its broadest reasonable interpretation in light of the specification is “an interpretation that corresponds with what and how the inventor describes his invention in the specification, *i.e.*, an interpretation that is ‘consistent with the specification.’” *In re Smith Int’l, Inc.*, 871 F.3d 1375, 1382–83 (Fed. Cir. 2017) (citations omitted). The broadest *reasonable* interpretation differs from the “broadest *possible* interpretation.” *Id.*

Only terms that are in controversy need to be construed expressly, and then only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

We determine that a specific construction of the claims is not necessary to resolve the issues in this proceeding.

Because claim terms generally are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure, we consider the level of ordinary skill in the art as part of claim construction.

B. Level of Skill in the Art

The level of skill in the art is “a prism or lens” through which we view the prior art and the claimed invention. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

Factors pertinent to a determination of the level of ordinary skill in the art include: (1) educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology, and (6) educational level of workers active in the field. *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696–697 (Fed. Cir. 1983) (citing *Orthopedic Equip. Co. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 1381–82 (Fed. Cir. 1983)). Not all such factors may be present in every case, and one or more of these or other factors may predominate in a particular case. *Id.* Moreover, these factors are not exhaustive but are merely a guide to determining the level of ordinary skill in the art. *Daiichi Sankyo Co. Ltd, Inc. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007).

In determining a level of ordinary skill, we also may look to the prior art, which may reflect an appropriate skill level. *Okajima*, 261 F.3d at 1355. Additionally, the Supreme Court informs us that “[a] person of ordinary skill is also a person of ordinary creativity, not an automaton.” *KSR Int’l v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

Neither party presents a detailed evidentiary showing of factors typically considered in determining the level of ordinary skill.

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 (quoting Ex. 1113 ¶ 27). Mr. Eaton mentions the factors he considered (Ex. 1113 ¶ 25), but does not explain how these factors influenced his opinion on the level of ordinary skill in the art (*id.* at ¶ 27).

Patent Owner does not propose a specific level of skill in its Response, nor does Patent Owner comment in its Response on the level of skill proposed by Petitioner. In its Response, Patent Owner neither argues nor cites to Mr. Sleeper’s declaration, which proposes a level of skill. See Ex. 2002 ¶¶ 11–12.

At the hearing in this proceeding, counsel for Patent Owner stated “[t]here is no dispute over the substance” of Petitioner’s proposed level of skill.” Tr. 18:4–9; see also Ex. 2002 ¶¶ 11–12 (providing Patent Owner’s declarant’s definition of the level of ordinary skill in the art, which is consistent with Petitioner’s definition).

We have not been directed to any evidence in the record concerning the educational level of the inventors of the '913 patent or the educational level of workers active in the field.

We find that the prior art has used many of the same solutions to the problems addressed by the disclosure and claims in the '931 patent. *See e.g.*, Ex. 1102 ¶ 3 (disclosing a “mask assembly,” “a soft patient contacting portion, such as a cushion,” “a rigid shell or frame,” all “held in a sealing position by headgear”). The prior art reflects a knowledge of human anatomy and respiratory therapy, and delivery of pressurized air to a person’s airway for the purpose of treating sleep apnea. *Id.*

Based on the evidence before us, we find that Petitioner’s asserted level of skill in the art is reasonable and we adopt that proposed level of skill. Accordingly, we find a person having ordinary skill in the art 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.

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

The first ground for which we instituted trial is whether 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. Dec. Inst. 36.

Section 103(a) forbids issuance of a patent when “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 to which said

subject matter pertains.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007).

The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) when available, evidence such as commercial success, long-felt but unsolved needs, and failure of others. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966); *see KSR*, 550 U.S. at 407 (“While the sequence of these questions might be reordered in any particular case, the [Graham] factors continue to define the inquiry that controls.”). The Court in *Graham* explained that these factual inquiries promote “uniformity and definiteness,” for “[w]hat is obvious is not a question upon which there is likely to be uniformity of thought in every given factual context.” 383 U.S. at 18.

The Supreme Court made clear that we apply “an expansive and flexible approach” to the question of obviousness. *KSR*, 550 U.S. at 415. Whether a patent claiming the combination of prior art elements would have been obvious is determined by whether the improvement is more than the predictable use of prior art elements according to their established functions. *Id.* at 417. To reach this conclusion, however, it is not enough to show merely that the prior art includes separate references covering each separate limitation in a challenged claim. *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011). Rather, obviousness additionally requires that a person of ordinary skill at the time of the invention “would have selected and combined those prior art elements in the normal course of research and development to yield the claimed invention.” *Id.*

Moreover, in determining the differences between the prior art and the claims, the question under 35 U.S.C. § 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 164 (Fed. Cir. 1985) (“It is elementary that the claimed invention must be considered as a whole in deciding the question of obviousness.”) (citation omitted); *see also Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1537 (Fed. Cir. 1983) (“[T]he question under 35 U.S.C. § 103 is not whether the differences themselves would have been obvious. Consideration of differences, like each of the findings set forth in *Graham*, is but an aid in reaching the ultimate determination of whether the claimed invention as a whole would have been obvious.”) (citation omitted).

“A reference must be considered for everything it teaches by way of technology and is not limited to the particular invention it is describing and attempting to protect.” *EWP Corp. v. Reliance Universal Inc.*, 755 F.2d 898, 907 (Fed. Cir. 1985).

As a factfinder, we also must be aware “of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning.” *KSR*, 550 U.S. at 421. This does not deny us, however, “recourse to common sense” or to that which the prior art teaches. *Id.*

Against this general background, we consider the references, other evidence, and arguments on which the parties rely.

1. Scope and Content of the Prior Art

a. Overview of D’Souza (Ex. 1102)

The D’Souza reference is indicated as being owned by the Patent Owner in this proceeding, ResMed Limited. Ex. 1102 (71) (“Applicant”).

Two of the inventors listed in the D'Souza reference (Messrs. D'Souza and Eves) also are named as inventors in the '931 patent. *Compare* Ex. 1101 (72) ("Inventors") with Ex. 1102 (72) ("Inventors").

D'Souza, like the '931 patent, discloses a CPAP full-face mask assembly. Ex. 1102 ¶¶ 2, 15, 96. D'Souza, like the '931 patent, discloses a method and apparatus for securing a face-contacting portion of a patient interface, such as a cushion, to a frame or shell of the patient interface. *Id.*; ¶¶ 7–11, 15, 96, 97. D'Souza, like the '931 patent, includes a comprehensive disclosure, including 107 figures and 28 pages of written description. Ex. 1102.

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

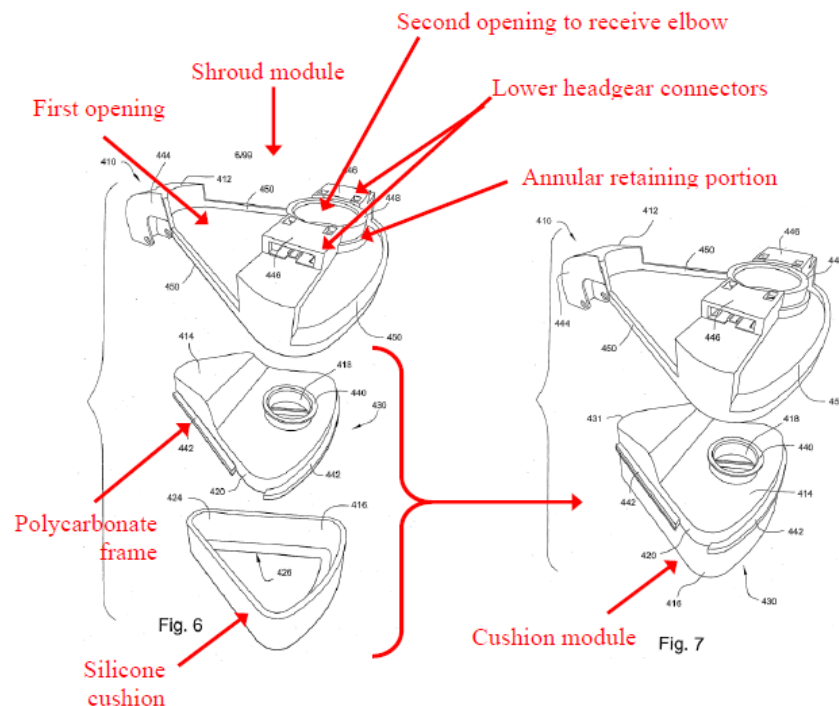


Fig. 6 from D'Souza is a top perspective view of a mask assembly
Fig. 7 is the mask assembly in a partially assembled condition,
as annotated by Petitioner. See Pet. 28.

The figures above depict D’Souza’s mask assembly 410 comprising skeleton frame 412 (asserted “shroud module,” see Pet. 26), frame 414, and cushion 416. Ex. 1102 ¶¶ 96–97. As illustrated in the figures, and as disclosed in the related written description, 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 (Ex. 1103)

Ultra Mirage discloses a full face CPAP mask with top and bottom removable headgear clips, an air vent to provide CO₂ washout, and a rotating elbow with a quick release swivel. See Pet. 23–24; Ex. 1103, 6. This reference is a marketing brochure for a product commercialized by Patent Owner ResMed. Ex. 1103, 4. A figure in Ultra Mirage, which is reproduced below, illustrates the mask.

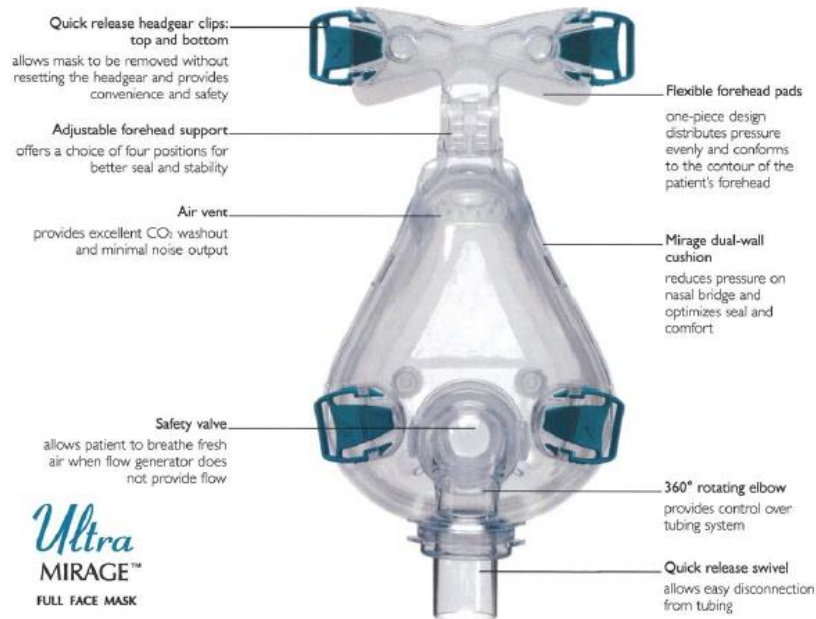
Ultra Mirage™ Full Face Mask

The ultimate solution for mouth leak



Mouth breathing and leak are common problems for CPAP and bilevel therapy users. These problems result in ineffective therapy, discomfort and disrupted sleep—all of which can cause patients to be noncompliant or to abandon therapy altogether.

ResMed's Ultra Mirage™ Full Face Mask covers both the nose and mouth so patients receive effective therapy even in the presence of mouth breathing and leak.



Front view of the Ultra Mirage mask,
with components identified. Ex. 1103, 6.

See Pet. 23–24; Ex. 1103, 6. Various elements of the mask, including a “360° rotating elbow” connected to air supply tubing, are identified in the Ultra Mirage figure. See Ex. 1103, 6.

c. Overview of Barnett (Ex. 1107)

Barnett discloses a CPAP mask. Ex. 1107, 1:5–32. Petitioner’s annotated Figure 6 from Barnett (Pet. 24) is reproduced below.

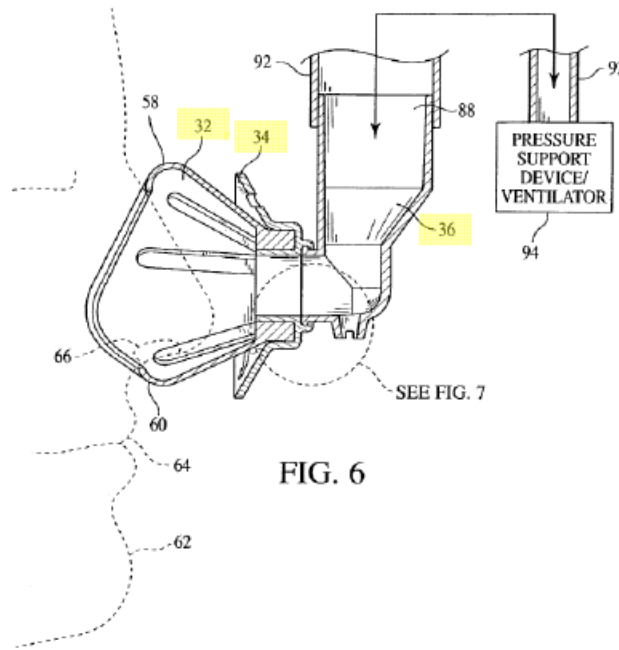


FIG. 6 is a side sectional view of a nasal mask assembly schematically illustrating the nasal mask assembly in a system for delivering a gas to a patient, as annotated by Petitioner.

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 (Ex. 1105)

Petitioner's annotated Figure 4 from Matula-II (Pet. 25) is reproduced below.

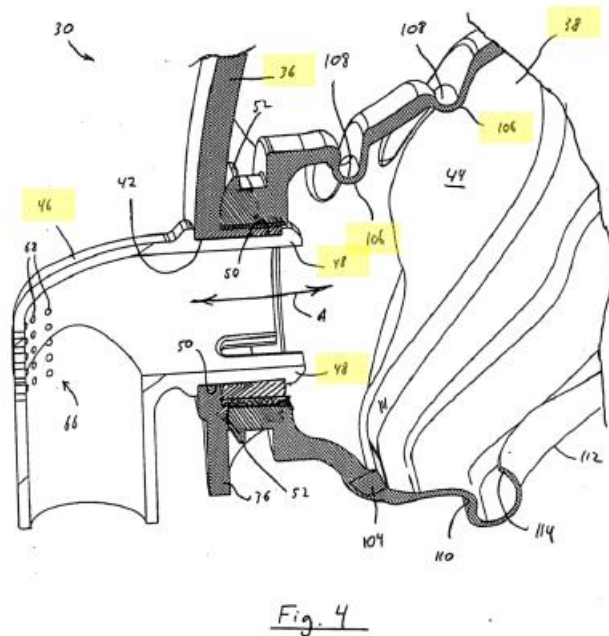


Fig. 4 from Matula-II is a sectional view of a seal member and faceplate coupling configuration in a patient interface, as annotated by Petitioner. Pet. 25.

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, 71, 77–79,” for which we instituted trial on this asserted

ground. Pet. 26; *see also id.* at 83–94 (containing claim charts for these claims). According to Petitioner:

skeleton frame 412 in D’Souza corresponds to shroud 1020 in the ’931 patent (Pet. 26, 64 (claim chart));

frame 414 in D’Souza corresponds to frame 1040 in the ’931 patent (*id.* at 59 (claim chart));

cushion 416 in D’Souza corresponds to cushion 1060 in the ’931 patent (*id.*); and

an elbow inlet conduit for pressurized air (unnumbered) in D’Souza (Ex. 1102 ¶ 100 (“and an annular elbow connection seal 448 adapted to engage an inlet conduit, e.g., elbow”)) corresponds to elbow 1070 in the ’931 patent (*id.* at 69 (claim chart)); Pet. Reply 2 (“Although D’Souza does not show an elbow-to-shroud connection, Mr. Sleeper testified that D’Souza suggests such a connection and admitted that a POSITA was capable of providing such a connection.”).

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 (Ex. 1113 ¶ 59) supports Petitioner’s position.

Patent Owner takes a different view. According to Patent Owner, “the differences between the prior art and the instituted claims are significant and numerous.” PO Resp. 1. Patent Owner also argues that Petitioner’s proposal “to modify the primary reference (D’Souza) ignores critical facts and the unsatisfactory consequences from such modifications.” *Id.* Of the asserted “significant and numerous” differences, however, Patent Owner argues only two such differences: (1) “the snap fit features” of the Instituted

Claims (*e.g.*, *id.* at 21 (“the Petition has not carried its burden to show that D’Souza or Matula-II discloses the snap-fit features of the asserted claims”)); and (2) the “elbow-module to shroud-module connection” (*e.g.*, *id.* at 57 (“Petitioner has not carried its burden to show that a POSITA would have been prompted to modify D’Souza in view of Barnett to incorporate a ‘direct’ connection between the elbow and shroud”))).

We discuss these two arguments below. First, however, because Petitioner has the burden of proof in this proceeding, we discuss other elements in independent claim 57 that are not specifically contested by Patent Owner. Our Scheduling Order (Paper 8) advised Patent Owner that “any arguments for patentability not raised in the response will be deemed waived.” Paper 8, 3.

Claim 57 recites “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. 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.

Claim 57 also recites that the cushion comprises a first, relatively soft, elastomeric material and the frame comprises a second material that is more rigid than the cushion. Ex. 1101, 30:64–67. D’Souza discloses that cushion 416 is constructed of a relatively soft liquid silicone rubber (Ex. 1102 ¶ 97), whereas frame 414 is constructed of a more rigid polycarbonate (*id.* ¶ 98).

Ex. 1113 ¶ 60; *see also id.* ¶ 3 (“Patient interfaces, such as a mask assembly, for use with blowers and flow generators in the treatment of sleep disordered breathing (SDB) typically include a soft patient contacting portion, such as a cushion, and a rigid shell or frame.”).

For these elements uncontested by Patent Owner, the preponderance of the evidence – including: the applied references as set forth in Petitioner’s claim charts (Pet. 59–94); Mr. Eaton’s declaration testimony (Ex. 1113), Mr. Sleeper’s declaration testimony (Ex. 2002), and the deposition testimonies of Mr. Eaton (Ex. 2003) and Mr. Sleeper (Ex. 1125) – supports our findings that these uncontested elements are disclosed or suggested by the prior art and that one of ordinary skill in the art would have been motivated to combine the teachings of the references as argued by Petitioner.

a. Snap Fit

Independent claim 57 recites that:

the *shroud module* [1020] and the *cushion module* [1060] 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*.

Ex. 1101, 31:4–11 (emphases added).

The Specification discloses various embodiments of the claimed snap-fit connection. One embodiment is that the upper portion of frame 1040 “includes an interfacing structure 1048 adapted to interface or otherwise removably connect to the shroud 1020.” Ex. 1101, 6:66–7:2. This structure, however, connects the shroud and frame, *not* the shroud and cushion, as

recited in claim 57. Moreover, the Specification repeats that “the shroud 1020 is connected to the frame 1040.” *Id.* at 7:9–10. This apparent inconsistency is explained in claim 57, however, because claim 57 defines the “cushion module” as “comprising a frame.” *Id.* at 30:61–67.

Figures 11 and 14 from the '931 patent are reproduced below.

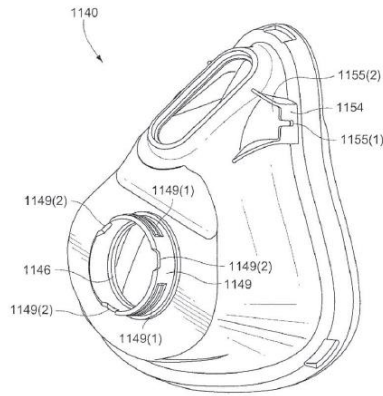


Fig. 11

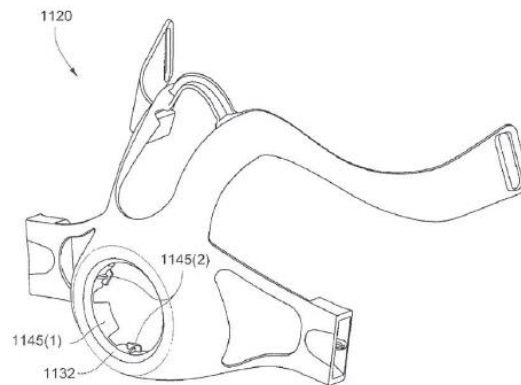


Fig. 14

Figure 11 is a front perspective view showing the frame of the mask system. Figure 14 is a front perspective view showing the shroud of the mask system.

As shown in Figures 11 and 14, and as further explained in the Specification, opening 1132 of shroud 1120 may include structure adapted to engage collar 1149 surrounding opening 1146 in frame 1140 “with a snap-fit.” Ex. 1101, 18:54–57.

As shown in Figure 14, and as described in the related Specification, shroud 1120 includes “snap fingers 1145(1)” and “sandwich tabs 1145(2)” that extend from opening 1132. *Id.* at 18:57–60. In use, snap fingers 1145(1) resiliently deflect and engage protrusions 1149(1) provided on collar 1149 (see Figure 22) to provide an initial retention of shroud 1120 to frame 1140 to facilitate assembly and disassembly. *Id.* at 18:62–67.

In an alternative embodiment, as shown in Figure 24, the shroud's lower section may be structured to clip to a single point below the collar. *Id.* at 19:14–16. As illustrated, the lower end of shroud 1320 includes snap finger 1345 that is engaged or clipped onto protrusion 1349(1) spaced below collar 1349 of frame 1340 with a snap-fit. *Id.* at 19:16–19.

Although the disclosed snap-fit connections are preferred embodiments, they are not critical. The Specification discloses that “other suitable arrangements for attaching the frame 40 to the shroud 20 are possible, e.g., friction fit, snap-fit, mechanical interlock, or other suitable attachment mechanism[s].” *Id.* at 19:45–48.

Petitioner asserts that the claimed snap-fit connection is disclosed in D’Souza. Pet. 32 (“D’Souza expressly discloses that the shroud and frame are adapted to removably interlock, and a person of skill would understand that this assembly comprises a removable snap-fit”). Alternatively, Petitioner asserts that “[t]o the extent D’Souza provides insufficient teachings for a snap-fit, . . . Matula-II teaches a plurality of snap fingers 48 that facilitate elastic deformation to mechanically and removably couple the seal member 38 to the faceplate 36. *Id.* at 33 (citing Ex. 1105 ¶ 53). Because we find that the asserted ground relying on D’Souza and Matula II for the snap fit is dispositive, we address this asserted ground.

Regarding the asserted snap fit in D’Souza, Petitioner argues:
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 (annular elbow connection seal 448 and opening 418 are arranged to be removably snap-fit by moving the skeleton frame 412 and the cushion/frame sub-assembly 430 along the longitudinal axis). [Ex. 1102] ¶ 101].

The shroud module includes a retaining portion (annular elbow connection seal 448) positioned rearwardly of the front opening, towards the frame, and structured to snap fit with the cushion module. *Id.*

Pet. 27; *see also id.* at 32–33 (“D’Souza expressly discloses that the shroud and frame are adapted to removably interlock, and a person of skill would understand that this assembly comprises a removable snap-fit”). Petitioner relies on the declaration testimony of Mr. Eaton. *Id.* at 32–33 (citing Ex. 1113 ¶¶ 69–70).

As shown in Figure 6 of D’Souza, reproduced below, and as described in D’Souza, skeleton frame, or “shroud module,” 412 is engaged with cushion 416 and frame 414. Ex. 1102 ¶ 101. There are several connection points among D’Souza’s mask components. Cushion 416 and frame 414 combine to form cushion/frame sub-assembly 430. *Id.* ¶ 97; *see* Fig. 7. A first connection point is that cushion/frame sub-assembly 430 connects to shroud 412 by annular elbow connection seal 448 interlocking with annular wall 440 of the cushion/frame sub-assembly 430. Ex. 1102 ¶ 101. Annular wall 440 surrounds opening 418. *Id.* ¶ 98. A second connection point is that upper support member 444 interlocks with top portion 431 of cushion/frame sub-assembly 430. *Id.* ¶ 101. A third connection point is that elongated frame members 450 interlock with respective protrusions 442 provided around the perimeter of cushion/frame sub-assembly 430. *Id.*

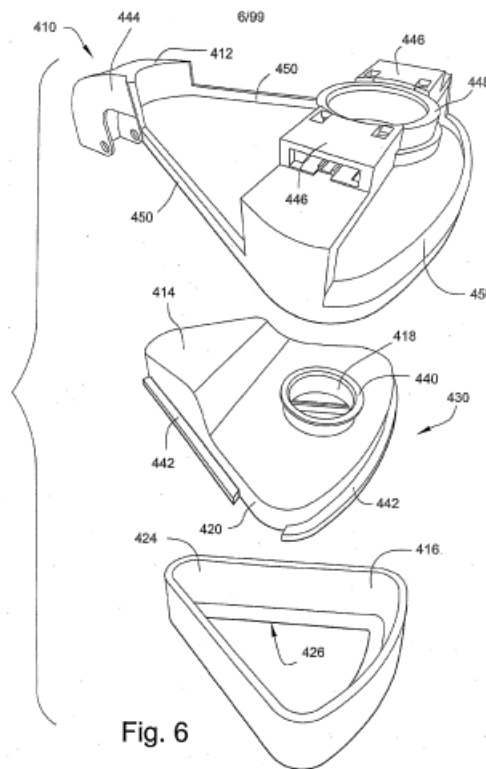


Fig. 6 is an exploded top perspective view of the D'Souza mask in a pre-assembled condition.

Petitioner relies only on the first connection, which is the connection between connection seal 448 and annular wall 440, in asserting unpatentability. Pet. 33 (“[T]he collar 440 passes through the retaining portion 448 and removably interlocks with the retaining portion 448 in a snap-fit manner.” (citing Ex. 1113 ¶ 70)).

Mr. Eaton testifies that “a person of skill in the art would have understood that the collar 440 and the retaining portion 448 interlock with a snapfit as the collar 440 passes through the annular opening of the shroud 412 and releases to interlock with the front side of the retaining portion 448.” Ex. 1113 ¶ 70. Mr. Eaton also states:

[a]lthough D'Souza does not describe this process in detail, it would have been clear to one of skill in the art that in this arrangement the collar 440 snaps into its final interlocked

position with the retaining portion 448. Such an assembly operation, with the parts undergoing interference, deflection, and elastic recovery to achieve the interlocked assembly, would have been understood to be a snap-fit.”

Id.

As part of the snap fit connection, claim 57 also recites that “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.” Ex. 1101, 31:9–11. Petitioner asserts that annular elbow connection seal 448 in D’Souza corresponds to the claimed “retaining portion.” Pet. 33 (“collar 440 passes through the retaining portion 448 and removably interlocks with the retaining portion 448 in a snap-fit manner”).

Patent Owner, and its Declarant, Mr. Sleeper, agree with the basic snap fit structure disclosed in D’Souza as discussed above. According to Patent Owner, the engagement between annular wall 440 of cushion/frame subassembly 430 and annular elbow connection seal 448 “involves the annular wall 440 passing through annular elbow connection seal 448.” PO Resp. 10 (citing Ex. 2002 ¶¶ 23–24). Patent Owner also acknowledges that “annular wall 440 includes an annular protrusion (‘flange’) extending radially from the front end of the annular wall.” *Id.* When interlocked with annular elbow connection seal 448, Patent Owner also acknowledges that the flange (unnumbered) extends beyond and covers the front facing surface of annular elbow connection seal 448, which is a tubular member. *Id.* (citing Ex. 2002 ¶¶ 23–24).

Mr. Sleeper provides the following colored version of D’Souza’s Figure 8, which shows the flange (unnumbered) of annular wall 440

extending beyond and covering the front facing surface of annular elbow connection seal 448, which is a tubular member.

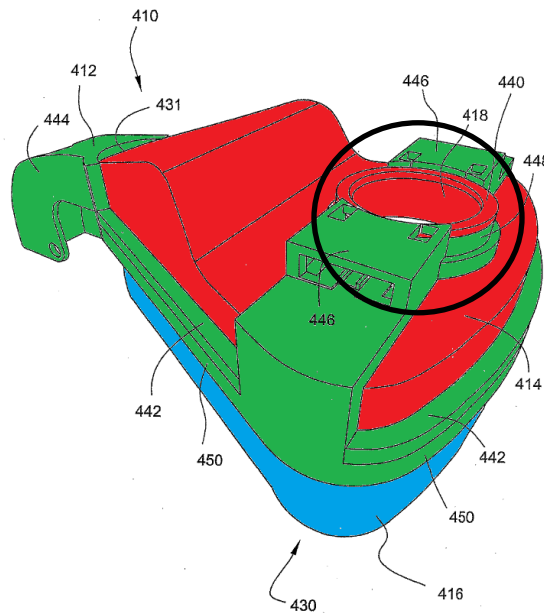


Fig. 8

Figure 8 of D'Souza colored by Mr. Sleeper. Ex. 2002 ¶ 22 (annotated).

In Mr. Sleeper's colored Figure 8, skeleton frame, or shroud, 412 is shown in green; frame 414 is shown in red; and cushion 416 is shown in blue.¹² As shown, the flange (unnumbered) of annular wall 440 of frame 414 is shown in red extending beyond and covering the front facing surface of annular elbow connection seal 448, which is a tubular member shown in green. The figure is annotated with a black circle to highlight the described structure.

Notwithstanding Patent Owner's acknowledgement of the structure and function of D'Souza's interlocking connection between the shroud and cushion/frame module, as discussed above, Patent Owner asserts that

¹² For a similar colored figure of the structure disclosed in the '931 patent, see Ex. 2002 ¶ 17.

“Petitioner has not established that there is a snap-fit between D’Souza’s annular wall 440 and annular elbow connection seal 448.” PO Resp. 23. Patent Owner points out that Mr. Eaton, Petitioner’s Declarant, allegedly contradicts his testimony as to what a person of ordinary skill would do or understand from D’Souza. *Id.* at 23–24. Patent Owner focuses (*id.*) on the following testimony from Mr. Eaton regarding the snap fit in D’Souza:

A skilled artisan seeking to practice the arrangement described in D’Souza would have recognized that the degree of deformation required to allow assembly of the collar [440] and the rearward extending retaining portion [448], as shown in the figures, *appears to exceed acceptable material strain limits of commonly used rigid plastics* such as polycarbonate, *and thus could have made it difficult or even impossible to assemble these components.*

Ex. 1113 ¶ 93 (emphasis added). Patent Owner asserts that this contradictory testimony “undermines Petitioner’s assertion that there is a snap-fit disclosed by D’Souza.” PO Resp. 24 (citing Ex. 2002, ¶¶ 35–36).

In its Reply, Petitioner asserts “a POSITA would have modified the annular interlock of D’Souza that connects the frame to the shroud to include a snap-fit with snap fingers on the shroud.” Pet. Reply 3. We note that claim 57 does *not* recite “snap fingers on the shroud.”¹³ Here, Petitioner is focusing on its *alternative* position, in which Petitioner asserted that it would have been obvious to combine D’Souza and Matula-II. Pet. 33 (“To the extent D’Souza provides insufficient teachings for a snap-fit, such removable snap-fit arrangements were common and well-known in CPAP

¹³ Claim 69, dependent from claim 57, recites that the retaining portion of the shroud includes a plurality of snap fingers. We address claim 69 below.

masks. For example, Matula-II teaches a plurality of snap fingers 48.”). Thus, we address this alternative position argued by Petitioner for claim 57.

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).

According to Petitioner, “[b]ased on the teachings of Matula-II, a skilled artisan would have been motivated to incorporate such snap fingers into the removable interlocking arrangement of D’Souza. *Id.* (citing Ex. 1113 ¶¶ 71–72). Mr. Eaton testifies that “a skilled artisan would have been motivated to include a plurality of snap-fit fingers in the D’Souza arrangement to allow for deformation and to facilitate insertion of the rigid collar 440 through the rigid retaining portion 448, resulting in a removable snap-fit. Ex. 1113 ¶ 72.

Petitioner also asserts that the proposed modification of D’Souza to include the plurality of snap fingers would “make it easier to join the shroud to the cushion module. Pet. 42 (citing Ex. 1113 ¶¶ 93–94). Additionally, Petitioner asserts that although the Matula-II snap fingers are on the elbow, incorporating snap fingers in the retaining portion of D’Souza would have achieved the same purpose of providing a more efficient removable mechanical interlock between the shroud and the cushion module. *Id.* at 43.

Mr. Eaton further explains that the rationale for why a person of ordinary skill in the relevant technology would have made the proposed modification is to avoid exceeding the deformation or strain limits of the elements when creating the snap fit between seal 448 and wall 440 in D’Souza. Mr. Eaton testifies that one way of avoiding strain limits of the snap fit in D’Souza, other than to use appropriately flexible materials, would

have been to use a “well-known solution to the problem of snap fit features exceeding material strain limits.” Ex. 1113 ¶ 93. This “well-known solution” would have been “to create slots that segment the interfering features on one or both mating parts into one or more fingers or beams.” *Id.* As explained by Mr. Eaton, “[t]hese fingers or beams can deform along the length of the finger or beam by bending, and allow greater deflection than could be achieved by the radial compression/expansion of cylindrical features, such as those depicted in D’Souza.” *Id.* Mr. Eaton further testifies that, to solve the problems he identified for D’Souza’s snap fit, a person having ordinary skill “would have known” to look at other CPAP mask assemblies, such as Matula II, wherein “mating cylindrical features were intended to axially engage in a snap fit.” *Id.* at 94.

Mr. Eaton recognizes that the snap fingers of Matula-II are located in the elbow. *Id.* It is his opinion, however, that one of ordinary skill in the art—a degreed engineer with at least two years of experience in the field of masks, respiratory therapy, patient interfaces or relevant product design experience— would have recognized that it would have been advantageous to add snap fingers to the shroud rather than the mask frame “based on the simplicity of molding the required snap finger geometry without compromising the airtight surfaces of the mask frame.” *Id.*

Patent Owner asserts that “Matula-II’s alleged snap-fit structures (prongs 48) are not on the shroud and also are not rearwardly positioned from the front opening,” as required by claim 57. PO Resp. 28. Petitioner acknowledges this distinction. See Ex. 1113 ¶ 94 (“While the snap fingers of Matula-II are located in the elbow . . .”). Petitioner’s modification, however, is to incorporate Matula-II’s snap fingers “into the retaining

portion of D’Souza.” *Id.* (“A skilled artisan at the time of the invention would have been motivated to modify the rearward extending retaining portion of D’Souza to include a plurality of rearward extending snap fingers on the retaining portion, based on the teaching of Matula-II.”); Pet. 85. Mr. Eaton concludes that this is “simply substituting one known feature for another with a predictable result.” *Id.*

Mr. Sleeper, Patent Owner’s Declarant, testifies that snap-fits were known at the time of the invention claimed in the ’931 patent. Ex. 1125, 186:7–24. Mr. Sleeper also testifies that the snap-fit could be positioned on either the elbow or the shroud:

Q · A person of skill in the art in 2007 would have been capable of reversing a snap-fit from, let’s say, an elbow to a shroud, correct?

A · Yeah, I’ll say correct.

Ex. 1125, 186:25–187:3.

We find that Mr. Eaton’s testimony, discussed above, provides substantial evidence that a person having ordinary skill in the art would have had good reason to modify D’Souza’s snap fit as proposed by Petitioner. We also find that a preponderance of the evidence establishes that it was within the skill and creativity of a person of ordinary skill to modify D’Souza to include a shroud that includes a retaining portion positioned rearwardly of the front opening, towards the frame, and structured to snap fit with the cushion, as suggested by the snap fit structure in Matula-II.

b. “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).

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.*

Patent Owner asserts that “Petitioner has not carried its burden to show that a POSITA would have been prompted to modify D’Souza in view of Barnett to incorporate a ‘direct’ connection between the elbow and

shroud.” PO Resp. 57. Patent Owner does not dispute, however, that Barnett discloses an example of an elbow connected directly to the shroud. For example, Mr. Sleeper, Patent Owner’s Declarant, acknowledges that Barnett discloses a direct elbow to shroud connection. Ex. 2002 ¶ 62 (“Petitioner and Mr. Eaton do not disclose sufficient detail of *how* D’Souza would have been modified *in view of Barnett’s teachings regarding a direct elbow-to-shroud connection.*” (emphasis added)); see also Ex. 1125, 210:9–211:10 (agreeing that Barnett discloses an elbow-to-shroud arrangement).

Mr. Sleeper, Patent Owner’s Declarant, also testified that a person of ordinary skill would have recognized that one could attach the elbow to either D’Souza’s frame or shroud. Ex. 1125, 219:15–220:19.

Mr. Sleeper stated that the function of the connection of the elbow to shroud in Barnett is the same function as the elbow to shroud in the ’931 patent. *Id.* at 221:15–20.

As a reason why it would have been obvious to add the rotatable elbow of Barnett to the shroud of D’Souza, Petitioner asserts that connecting the elbow directly to the shroud allows the two engagements to be entirely independent, as disclosed in Barnett. Pet. Reply 23 (citing Ex. 1113 ¶ 89). Mr. Eaton testifies that directly attaching the elbow to the shroud module as taught in Barnett would “make it easier for a patient to detach the elbow from the shroud without affecting the engagement of other mask components.” Ex. 1113 ¶ 89.

We find, based on the Barnett disclosure and the testimony of Mr. Eaton and Mr. Sleeper, cited and discussed in the preceding paragraphs, that a preponderance of the evidence establishes that it was within the skill and creativity of a person of ordinary skill to modify D’Souza to include a

rotatable elbow directly attached to the shroud, as suggested by the structure in Barnett. A preponderance of the evidence establishes that this direct connection makes it easier for a patient to detach the elbow from the shroud without affecting the engagement of other mask components. *See* Ex. 1113 ¶ 89.

c. Dependent Claims 58, 61, 68, 69, 71, and 77–79

Unless indicated otherwise, Patent Owner has not presented persuasive argument or evidence against Petitioner’s challenge to claims 58, 61, 68, 69, 71, and 77–79. For these claims, uncontested by Patent Owner, the preponderance of the evidence, including – the disclosure in the applied references as set forth in Petitioner’s claim charts (Pet. 59–94), Mr. Eaton’s declaration testimony (Ex. 1113), Mr. Sleeper’s declaration testimony (Ex. 2002), and deposition testimonies of Mr. Eaton (Ex. 2003) and Mr. Sleeper (Ex. 1125) – supports Petitioner’s position that these claims would have been obvious. We address these claims below.

Claim 58 depends from claim 57 and recites that the shroud and cushion are detachable from one another by moving the shroud and cushion away from one another along the longitudinal axis. D’Souza clearly discloses this claimed structure and function. Pet. 86; Ex. 1102, Figs. 6–8 and related text.

Claim 61 depends from claim 57 and recites that the elbow is adapted to be connected to an air delivery tube that delivers breathable gas to the patient. Petitioner relies on Ultra Mirage for this claim element. Pet. 88, 71; Ex. 1103, 6 (disclosing a “quick release swivel” connected to the elbow to allow easy disconnection from the air delivery tubing), 7 (referring to a flow generator providing air flow to the Ultra Mirage Mask). This also is the

fundamental way CPAP masks operate. *See, e.g.*, Ex. 1105 ¶ 6 (“Non-invasive ventilation and pressure support therapies involve the placement of a patient interface, which is typically a nasal or nasal/oral mask, on the face of a patient to interface the ventilator or pressure support system with the airway of the patient so that a flow of gas can be delivered from the pressure/flow generating device to the airway of the patient.”). We find that the features recited in claim 61 were well-known and commonly used.

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).

Matula-II's seal member 38 "includes at least one pleat 106 (which can also be referred to as a fold or gusset) provided at a portion of the seal member so that the seal member has the desired degree of flexibility." Ex. 1105 ¶ 66. Pleats 106 are provided at an upper portion of the seal member so that this portion of the seal member can expand and contract with adjustment of the adjustment mechanism. *Id.* The number, size, configuration, and location of the pleats on the seal member can also be varied so that the seal member flexes where desired. *Id.* Matula-II also discloses a pleat 110 at or near a patient contacting portion 112 of the seal member to control the collapsibility of the patient contacting portion of the seal. *Id.* at ¶ 67.

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). Based on a preponderance of the evidence, we agree with, and adopt as our finding, Petitioner's position regarding a reason to combine.

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. This claim, unlike claim 57, specifically recites that the snap fit connection includes "a plurality of snap fingers." 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.*

In discussing the snap fit limitation in claim 57, we discussed Petitioner's proposed modification of D'Souza to include snap fingers, as disclosed in Matula-II. We also considered Patent Owner's arguments and evidence directed to the snap fit using snap fingers. Our analysis of the snap fit limitation in claim 57 included an analysis of the evidence as to why it would have been obvious to a person of ordinary skill to implement the proposed modification of D'Souza based on Matula-II. Our findings related to claim 57 are equally applicable to claim 69.

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 D'Souza discloses that frame 414 is constructed of polycarbonate. Pet. 40 (citing Ex. 1102 ¶ 98) (“frame 414 is constructed of polycarbonate”). D'Souza also discloses that skeleton frame or shroud 412 is formed of plastic, but does not expressly disclose that the plastic is polycarbonate. *Id.* ¶ 100 (“[S]keleton frame 412 is formed of plastic and has an integral one-piece construction.”). Petitioner asserts 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 testifies that “[i]t was well-known in the industry at the time of the invention to construct CPAP components, including the shroud, from polycarbonate.” Ex. 1113 ¶ 84. Mr. Eaton cites prior art, not applied in the asserted ground of unpatentability, as representative of the knowledge of a person of ordinary skill about the use of polycarbonate in CPAP masks. *Id.*

Mr. Eaton further testifies that polycarbonate provides a high degree of transparency, which makes a mask less visually obtrusive to the patient and allows visual inspection for contamination; provides good mechanical properties of strength, rigidity, and toughness; meets the biocompatibility testing standards with which masks for sleep disordered breathing must comply; and can be cleaned, disinfected, and/or sterilized by most commonly used methods without significant degradation of material properties. *Id.* ¶ 95. Mr. Eaton concludes that a person of ordinary skill in the art at the time of the invention would have been motivated to construct the shroud of D’Souza from polycarbonate plastic. *Id.*; *see also id.* ¶ 84.

Based on a preponderance of the evidence, we find that the use and benefits of polycarbonate for CPAP mask components were well-known at the time of the invention claimed in the ’931 patent, and would have been obvious to use for both the shroud and frame.

Claims 77 depends from claim 57 and recites that the frame is semi-rigid or rigid. Claim 78 depends from claim 77 and recites that the frame is rigid. We discussed above the use of various plastic materials for mask components. D’Souza discloses that these materials are known to be “rigid.” Ex. 1102 ¶ 3.

Claim 79 depends from claim 57 and recites that a flow generator supplies air at positive pressure to the mask system, and that an air delivery tube is configured to deliver the supply of air from the flow generator to the mask system. We have discussed these limitations in our analysis of claim 61.

3. Conclusion for Ground 1

In summary, based on the analysis above and the record before us, we determine that a preponderance of the evidence establishes that 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.

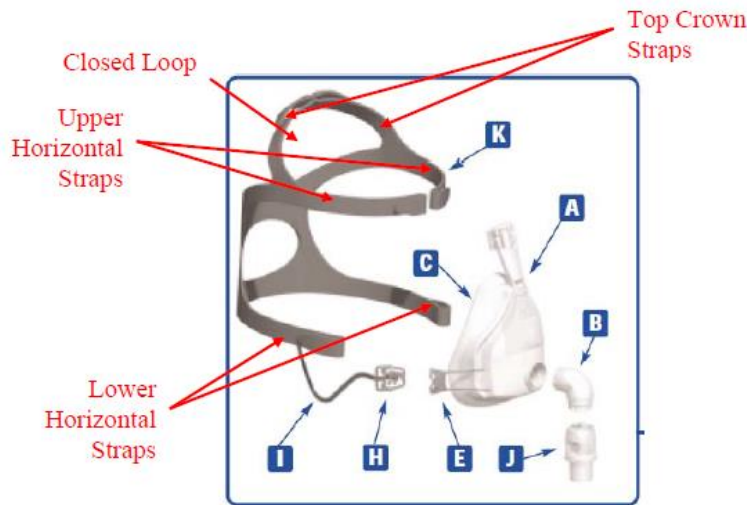
D. Patentability of Claim 60 in View of D’Souza Ultra Mirage, Barnett, Matula-II, and FlexiFit

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 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 shows an exploded view of a mask and headgear from FlexiFit. Pet. 44.

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.

Patent Owner does not provide any persuasive evidence or argument addressing the challenge to the patentability of claim 60.

Based on the analysis above and the evidence of record, we determine that a preponderance of the evidence establishes that claim 60 would have been obvious 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.

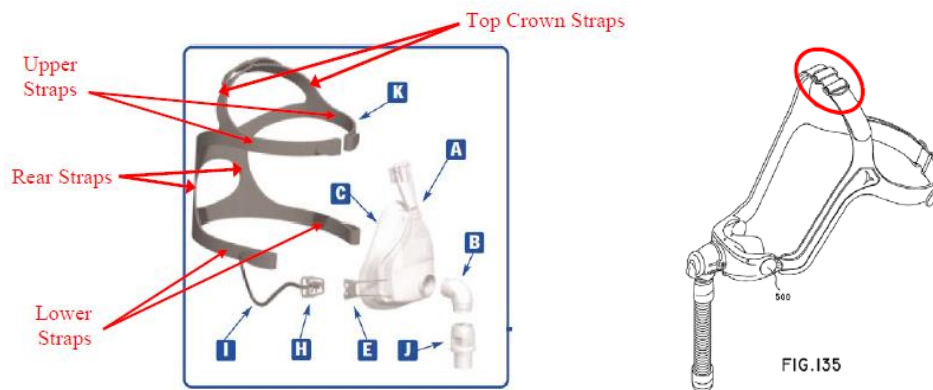
Claim 64 recites that the rear straps and the top straps form a closed loop to encircle a rear portion of the patient's head.

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 are removably attached to upper headgear connectors 1024 and lower straps 1094 are 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)).

Petitioner’s annotated figures from FlexFit (Pet. 49) and Gunaratnam-II (*id.* at 50) are reproduced below.

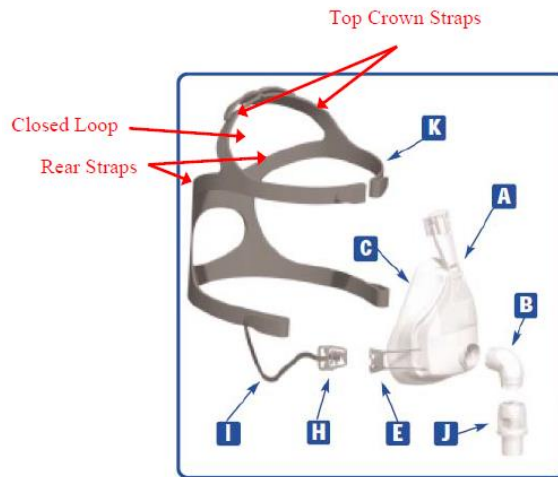


The figure on the left is an annotated exploded view of the FlexFit mask (Pet. 49). The figure on the right is an annotated Figure 135 from Gunaratnam-II (*id.* at 50) showing top straps threaded through a buckle.

As shown in Figure 135 of Gunaratnam-II, Gunaratnam-II discloses a pair of top straps removably and adjustably threaded through a buckle. Ex. 1110 ¶ 316; Fig. 135. *See also* Pet. 50 (citing Ex. 1113 ¶ 107). Gunaratnam-II discloses that each top strap is wrapped around a respective cross-bar associated with the buckle. Ex. 1110 ¶ 316.

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. Pet. 51 (citing Ex. 1113 ¶ 110).

Petitioner relies on FlexiFit for the disclosure of the “closed loop” recited in claim 64, as identified in Petitioner's annotated figure from FlexFit, reproduced below. *Id.* at 52 (citing Ex. 1113 ¶ 111).



Petitioner's annotated exploded view figure from FlexFit, identifying top and rear straps and a closed loop. Pet. 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).

Patent Owner does not provide any persuasive evidence or argument addressing the challenge to the patentability of claims 62–64.

Based on the analysis above and the evidence of record, we determine that a preponderance of the evidence establishes that claims 62–64 would have been obvious 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 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.

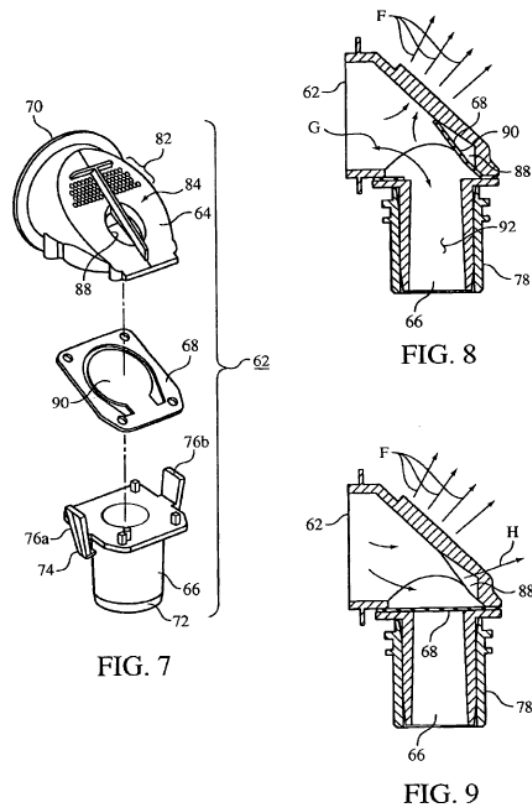


Figure 7 from Jaffre is an exploded view of exhaust port assembly 62. Figures 8 and 9 are cross-sectional views of the exhaust port assembly. Ex. 1112.

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 rotatably 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 7:41–42.

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. Based on our analysis, above, we agree with Petitioner that D’Souza, Ultra Mirage, FlexiFit, Barnett, and Matula-II

disclose or suggest 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.

*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 360° 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 a person of ordinary skill would have modified D’Souza in view of Ultra Mirage, Petitioner asserts the swivel elbow facilitates easy adjustment and disconnection from the tubing. Pet. 58 (citing Ex. 1103, 6; Ex. 1113 ¶ 123). Regarding the AAV, Petitioner asserts it 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 ¶ 106¹⁴; 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 evidence of record, we determine that a preponderance of the evidence establishes that claims 43, 48–50, and 70 would have been obvious based on D’Souza, Ultra Mirage, FlexiFit, Barnett, Jaffre, and Matula-II.

III. CONCLUSION

We recognize that in the highly developed field of CPAP mask systems, small differences may produce a nonobvious advance. *See Outside the Box Innovations, LLC v. Travel Caddy, Inc.*, 695 F.3d 1285, 1298 (Fed. Cir. 2012); *see also Unigene Labs.*, 655 F.3d at 1360–61 (providing that the inquiry under § 103 is not whether the claimed invention is “sufficiently simple to appear obvious to judges after the discovery is finally made”). We also recognize that “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *KSR*, 550 U.S. 418. Most, if not all, inventions “rely upon building blocks long since uncovered,” and “claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” *Id.* at 418–419.

¹⁴ 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.

Here, Petitioner has relied on several references to assert unpatentability. Based on the evidence, we have determined that combining the disclosures of these several references would have been obvious and is not based on hindsight. As noted in *KSR*, “in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle.” *Id.* at 420. A preponderance of the evidence establishes that this is the situation in the case before us.

The structural and functional details recited in the Instituted Claims are all disclosed in the prior art. The level of ordinary skill is high – 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. As discussed above, a preponderance of the evidence establishes that assembling the puzzle of prior art to meet the desired functional needs of a CPAP mask system of effective, efficient, comfortable use by a patient would have been obvious to this highly skilled person. A preponderance of the evidence discussed above supports the conclusion that combining familiar elements of a CPAP mask, as recited in the Instituted Claims, is no more than the predictable use of prior art elements according to their established functions. *KSR*, 550 U.S. at 417. A preponderance of the evidence also provides persuasive reasons why these elements would have been combined, thus supporting the legal conclusion of obviousness.

Accordingly, we determine that a preponderance of the evidence establishes that claims 43, 48–50, 57, 58, 60–64, 68–71, and 77–79 are unpatentable because the subject matter of each of these claims, considered

as a whole, would have been obvious to a person having ordinary skill in the relevant technology of CPAP mask systems.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that

- A. claims 57, 58, 61, 68, 69, 71, and 77–79 are unpatentable under 35 U.S.C. § 103(a) in view of D’Souza, Ultra Mirage, Barnett, and Matula-II;
- B. claim 60 is unpatentable under 35 U.S.C. § 103(a) in view of D’Souza Ultra Mirage, Barnett, Matula-II, and FlexiFit;
- C. claims 62–64 are unpatentable under 35 U.S.C. § 103(a) in view of D’Souza, Ultra Mirage, Barnett, Matula-II, FlexiFit, and Gunaratnam-II;
- D. claims 43, 48–50, and 70 are unpatentable under 35 U.S.C. § 103(a) in view of D’Souza, Ultra Mirage, FlexiFit, Barnett, Jaffre, and Matula-II; and

FURTHER ORDERED because this is a Final Written Decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

IPR2017-00062
Patent 9,119,931 B2

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