

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FISHER & PAYKEL HEALTHCARE LIMITED,
Petitioner,

v.

RESMED LIMITED,
Patent Owner.

Case IPR2017-00501
Patent 9,027,556 B2

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

MAYBERRY, *Administrative Patent Judge*.

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

I. INTRODUCTION

Petitioner, Fisher & Paykel Healthcare Ltd. (“Fisher”), filed a Petition (Paper 1, “Pet.”) requesting *inter partes* review of claims 1–66 (the “Challenged Claims”) of U.S. Patent No. 9,027,556 B2 (Ex. 1001, the “’556 patent”). Patent Owner, ResMed Ltd. (“ResMed”), filed a Preliminary Patent Owner Response to the Petition. Paper 7 (“Prelim. Resp.”). We instituted trial on claims 61–64 and 66 only. See Paper 8 (“Dec. on Inst.” or “Institution Decision”), 42–43 (instituting trial on claims 61–64 and 66 on four of the twelve asserted grounds); *cf.* Pet. 9–10 (listing the twelve asserted grounds).

After we instituted trial, ResMed filed a Patent Owner Response. Paper 14 (“PO Resp.”). Fisher filed a Reply to ResMed’s Patent Owner Response. Paper 18 (“Reply”). Oral hearing was conducted for this proceeding on February 21, 2018, and the record contains a transcript of the hearing. Paper 28 (“Tr.”).

On April 24, 2018, the Supreme Court held that a decision to institute under 35 U.S.C. § 314 may not institute on less than all claims challenged in the petition. *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348 (2018). In response to this decision, on May 3, 2018, we modified our Institution Decision to institute trial on all Challenged Claims and all grounds. See Paper 27, 2.

ResMed filed a Supplemental Patent Owner Response (“Supp. PO Resp.”) to address the claims and grounds added to trial in response to SAS. Paper 31. Fisher filed a Supplemental Reply (“Supp. Reply”) addressing the Supplemental Patent Owner Response and our Institution Decision with respect to the added claims and grounds. Paper 32. With our authorization,

ResMed filed a Sur-Reply to the Supplemental Reply. Paper 35. ResMed also filed a Motion for Observation (“Mot. for Obs.”) directed to testimony cited in the Supplemental Reply and Fisher filed a Response to the Motion for Observation (“Resp. to Mot. for Obs.”). Papers 34, 37.

On June 12, 2018, we conducted a supplemental oral hearing to address the added claims and grounds, and the record includes a transcript of that hearing. Paper 40 (“Supp. Tr.”).

Fisher relies on the declaration testimony of Mr. Richard Lordo and Mr. Jason Eaton. Exs. 1009; 1023.¹ ResMed relies on the declaration testimony of Mr. Geoffrey Sleeper. Ex. 2003.

The Board has jurisdiction under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons that follow, we conclude that Fisher has demonstrated, by a preponderance of the evidence, that claims 61–64 are unpatentable under 35 U.S.C. § 103. We also conclude that Fisher fails to demonstrate, by a preponderance of the evidence, that claims 1–60, 65, and 66 are unpatentable under 35 U.S.C. § 103.

A. Related Matters

Fisher indicates that the ’556 patent is involved in district court litigation in the Southern District of California, in a case styled *Fisher & Paykel Healthcare Ltd. v. ResMed Corp.*, Case No. 3:16-cv-02068-DMS-

¹ Mr. Eaton’s declaration was generated for IPR2017-00064. IPR2017-00064 was filed by the same Petitioner and concerned ResMed’s U.S. Patent 9,119,931, which is related to the ’556 patent. See Ex. 1023, 1; compare Ex. 1001, 1:5–12 with IPR2017-00064, Ex. 1201, 6–16. ResMed did not object to Fisher’s use of this evidence, so we need not determine if its use is proper in this proceeding under the Federal Rules of Evidence.

WVG (S.D. Cal.). Pet. 5; *see also* Paper 4, 2 (identifying the litigation). Fisher indicates that it has filed a second petition for *inter partes* review challenging claims 1–66 of the ’556 patent. Pet. 5; *see also* Paper 4, 2 (identifying the *inter partes* review as IPR2017–00504); IPR2017-00504, Paper 25 (providing the Final Written Decision for that proceeding); IPR2017-00504, Paper 26 (providing Petitioner’s Notice of Appeal of the Final Written Decision).

B. The ’556 Patent

The ’556 patent, titled “Mask System,” issued May 12, 2015, with claims 1–66. Ex. 1001, (54), (45), 9:65–20:40. The ’556 patent is generally directed “to a mask system used for treatment, e.g., of Sleep Disordered Breathing (SDB) with Continuous Positive Airway Pressure (CPAP) or Non-Invasive Positive Pressure Ventilation (NIPPV).” *Id.* at 1:16–19. Figures 1, 2, and 4 of the ’556 patent depict an embodiment of the ’556 patent’s mask system and are reproduced below.

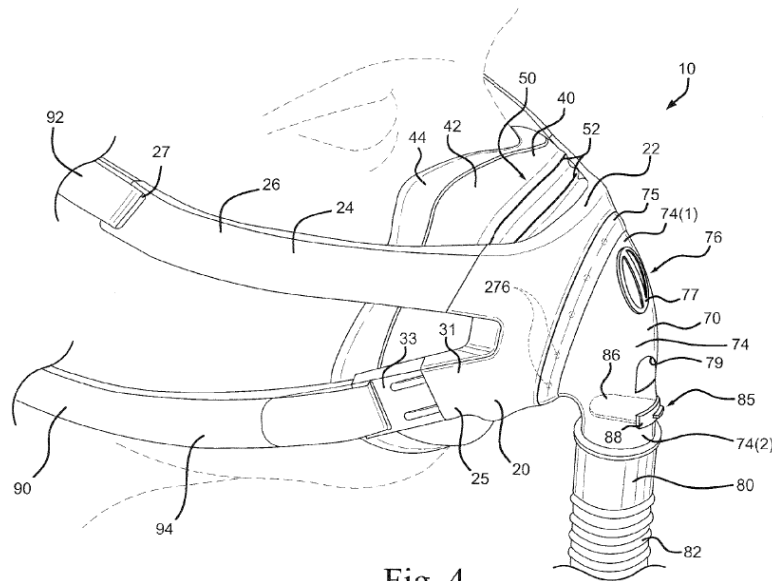


Fig. 4

Figure 1 depicts “a front perspective view of a mask system according to an embodiment of the” ’556 patent, Figure 2 depicts “an exploded view of the mask system shown in [Figure] 1,” and Figure 4 depicts “a side view of the mask system shown in [Figure] 1.” Ex. 1001, 2:11–12, 2:13–14, 2:17. In the embodiment of Figures 1, 2, and 4, mask system 10 includes frame module 20, cushion module 40, elbow module 70, and headgear 90. *Id.* at 2:61–3:4. Cushion module 40 forms a seal with the wearer’s face, elbow 70 delivers breathing gas to the wearer, and headgear 90, which may be removably attached to frame module 20, maintains mask system 10 in position on the wearer’s face. *Id.*

Cushion module 40 includes main body 42 and cushion 44. Ex. 1001, 4:1–2. Main body 42 attaches to frame 20. *Id.* at 4:2–4. Main body 42 and cushion 44 may form a one-piece, integrated component, such as by co-molding the two separate components. *Id.* at 5:2–4. Main body 42 may be molded from a material that is more rigid than the material used to mold cushion 44, so that main body 42 may interface with frame 20 and cushion 44 may be relatively soft to allow it to seal to a wearer’s face. *Id.* at 5:5–12.

In the embodiment of Figures 1, 2, and 4, interfacing structure 23 of frame 20 removably connects to interfacing structure 48 of main body 42 to connect frame 20 to cushion module 40. Ex. 1001, 5:25–33. The '556 patent describes that alternative connections may be used, such as friction fit connections, snap-fit connections, and mechanical interlocks. *Id.* at 5:33–36.

C. Challenged Claims

Claims 1, 14, 22, 32, 54, and 61 of the '556 patent are independent. Claims 1, 54, and 61 are representative and are reproduced below:

1. A mask system for delivery of a supply of gas at positive pressure to a patient for medical treatment, the mask system comprising:

a frame module;

a cushion module provided to the frame module and adapted to form a seal with the patient's face;

an elbow module rotatably attached to the frame module such that the frame module acts as a carrier and bearing surface for the elbow module, the elbow module being rotatably attached to the frame module such that the elbow module is rotatable 360° relative to the frame module in use, and the elbow module being adapted to be connected to an air delivery tube that delivers breathable gas to the patient; and

headgear removably attachable to the frame module to assist in maintaining the mask system in a desired adjusted position on the patient's face, wherein:

the cushion module includes a main body and a cushion, the main body at least partly defining a breathing chamber,

the frame module and the main body having shapes that prevent relative rotation when the frame module is attached to the main body,

an outer portion of the main body is exposed and remains uncovered by the frame module when the frame module and the main body are attached, and

the main body and cushion together comprise an integrated component, the main body comprising a molded material that interfaces with the frame module and the cushion comprises a molded silicone material adapted to interface with patient's face, and the molded material of the main body is a more rigid material than the molded silicone material of the cushion.

Ex. 1001, 9:65–10:31.

54. An oro-nasal mask system for treatment of respiratory disorder with Continuous Positive Airway Pressure equipment suitable to generate a supply of gas at positive pressure to be delivered to a patient's airways, the mask system comprising:

a frame module;

a cushion module having (i) a cushion adapted to form a seal with the patient's nose and mouth and (ii) a main body;

an elbow module adapted to be connected to an air delivery tube to deliver breathable gas to the patient; and

headgear removably attachable to the frame module,

wherein:

the frame module includes two headgear connectors to connect with the headgear,

the main body comprises a relatively harder material and the cushion comprises relatively softer material provided to the main body,

the cushion is an oro-nasal cushion adapted to engage the patient's face generally along nasal bridge, cheek, and chin regions of the patient's face,

a vent arrangement is provided for gas washout,

the elbow module includes a first end portion and a second end portion, the first end portion being attached to the

frame module, the second end portion being provided to a swivel joint adapted to be connected to the air delivery tube,

the elbow module includes an elbow and an anti-asphyxia valve provided to the elbow,

the elbow includes a port that is selectively closed by a flap portion of the anti-asphyxia valve depending on the presence of pressurized gas, and a structure to attach the anti-asphyxia valve,

the elbow module is rotatably attached to the frame module, [and]

the elbow module and the frame module are mechanically interlocked to form a combined elbow and frame module that is releasably snap-fitted to the cushion module, in a non-rotatable manner, with a snap-fit attachment mechanism.

Ex. 1001, 17:50–18:23.

61. A full-face mask system for delivering a supply of breathable gas at positive pressure to a patient's airways to treat a respiratory disorder, the mask system comprising:

a frame module;

a cushion module that engages the frame module, the cushion module including a main body and a full-face cushion adapted to engage the patient's face generally along nasal bridge, cheek, and chin regions of the patient's face, the main body at least partly defining a breathing chamber;

an elbow directly attached to the frame module in a rotatable manner such that the elbow and the frame module are 360° rotatable, the elbow being adapted to be connected to an air delivery tube to deliver breathable gas to the patient; and

headgear directly or indirectly attachable to the frame module in a removable manner, wherein:

the frame module and the main body are joined with a snap-fit,

the frame module includes an opening, the elbow including a distal end inserted into the opening of the frame module to retain the elbow with the frame module, and

the frame module and the main body having shapes that prevent relative rotation when the frame module is snap-fitted to the main body.

Ex. 1001, 19:1–25.

Relevant to our analysis herein, claims 1, 14, 22, 32, and 54 require the material of the main body of a cushion module be more rigid (or harder) than the material of the cushion of the cushion module. As seen above, claim 1 includes the recitation “the molded material of the main body is a more rigid material than the molded silicone material of the cushion.” Independent claims 14 (*see id.* at 13:4–6), 22 (*see id.* at 14:8–10), and 32 (*see id.* at 16:11–13) recite similar language. As seen above, claim 54 uses slightly different language: “the main body comprises a relatively harder material and the cushion comprises relatively softer material provided to the main body.” *See id.* at 17:65–67. The parties agree that, in interpreting the claims, the subject matter encompassed by the “more rigid material” recitation is comparable to the subject matter encompassed by the recitation of “a relatively harder material.” *See* Supp. Tr. 7:7–9 (providing Petitioner’s counsel stating that, “we do not think there is a difference . . . between harder and more rigid”), 15:5–7 (providing Patent Owner’s counsel stating that, “we also don’t contend that relatively harder has any different meaning in this context than more rigid does”).

In addition to not including the material rigidity/hardness requirement, Claim 61 differs from claim 1 by (1) requiring the main body of a cushion module to snap-fit to a frame module; and (2) requiring the cushion of the cushion module to be a full-face cushion.

D. The Prior Art

We instituted trial on twelve (12) grounds of unpatentability for the Challenged Claims that rely on the following references:

Barnett	US 6,412,488 B1	July 2, 2002	Ex. 1002
Ogden	US 5,662,101	Sept. 2, 1997	Ex. 1003
Lithgow	US 2004/0118406 A1	June 24, 2004	Ex. 1004
Namey	US 2002/0020416 A1	Feb. 21, 2002	Ex. 1005
Jaffre	US 6,851,425 B2	Feb. 8, 2005	Ex. 1006
Gunaratnam	US 6,796,308 B2	Sept. 28, 2004	Ex. 1007
Ging	US 2005/0155604	July 21, 2005	Ex. 1008

E. Alleged Grounds of Unpatentability

We instituted trial on twelve (12) grounds of unpatentability for the Challenged Claims, each of which is based on 35 U.S.C. § 103(a)²:

Grounds³	Claims Challenged
(1) Barnett and Ogden	1, 2, 4, 7, 14–16, 19, 22, 23, 25, 29, 32, 35, 36, 43, 45–47, 49, 52, 61, and 64
(2) Barnett, Ogden, and Lithgow	6, 17, 18, 27, and 37–42
(3) Barnett, Ogden, and Namey	44
(4) Barnett, Ogden, and Jaffre	3, 24, 50, 51, 54, 57, 58, and 62
(5) Barnett, Ogden, and Gunaratnam	33, 34, 48, 63, and 65
(6) Barnett, Ogden, Gunaratnam, and Ging	5 and 26

² The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, 125 Stat. 284, 296–307 (2011), took effect on September 16, 2012. Because the application for the patent at issue in this proceeding has an effective filing date before that date, we refer to the pre-AIA versions of the statute.

³ For convenience, we use the same numbering scheme for the grounds as appears in the Petition. See Pet. 9–10.

Grounds ³	Claims Challenged
(7) Barnett, Ogden, Gunaratnam, and Lithgow	53
(8) Barnett, Ogden, Gunaratnam, and Namey	9–13, 20, 21, 30, and 31
(9) Barnett, Ogden, Gunaratnam, and Jaffre	55 and 66
(10) Barnett, Ogden, Gunaratnam, Jaffre, and Namey	59
(11) Barnett, Ogden, Gunaratnam, Jaffre, and Lithgow	56 and 60
(12) Barnett, Ogden, Jaffre, Lithgow, and Ging	8 and 28

Pet. 9–10.

II. ANALYSIS

A. Level of Ordinary 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). Fisher asserts that the level of ordinary skill in the art to which the ’556 patent pertains is “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. 13–14 (citing Ex. 1009 (Decl. of Richard Lordo) ¶ 26). Mr. Sleeper, ResMed’s declarant, states that a person having ordinary skill in the art “would have at least a bachelor’s degree in mechanical engineering, biomedical engineering, or a similar technical field, with at least two years of relevant product design experience. An increase in experience could compensate for less education, and an increase in

education could likewise compensate for less experience.” Ex. 2003 (Decl. of Geoffrey Sleeper) ¶¶ 11–12.

Factual indicators of the level of ordinary skill in the art include “the various prior art approaches employed, the types of problems encountered in the art, the rapidity with which innovations are made, the sophistication of the technology involved, and the educational background of those actively working in the field.” *Jacobson Bros., Inc. v. United States*, 512 F.2d 1065, 1071 (Ct. Cl. 1975); *see also Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1011 (Fed. Cir. 1983) (quoting with approval *Jacobson Bros.*).

We find both parties assert very similar definitions of the level of ordinary skill in the art. Both definitions include a degreed engineer with two years of experience. Fisher identifies the field of experience narrowly as “masks, respiratory therapy, patient interfaces or relevant product design” and ResMed, through Mr. Sleeper, defines broadly the field of experience as “relevant product design.” Mr. Sleeper declares that additional experience may compensate for less education and additional education may compensate for less experience.

We find, based on our review of the complete record, that the evidence of record supports a level of ordinary skill in the art consistent with the parties’ definitions—a person having a bachelor’s degree in mechanical engineering, biomedical engineering, or other similar type of engineering degree combined with two years of experience in the field of masks, respiratory therapy, patient interfaces, or other relevant product design experience. We also find that additional experience may compensate for less education and additional education may compensate for less experience. Our findings are supported by the level of ordinary skill in the art reflected

by the prior art of record and '556 patent. *See* Exs. 1002–1008, 1011–1015; *see also* Ex. 1009 ¶ 26 (declaring that, based on Mr. Lordo's experience in the field of patient interface masks, "[t]his education and industry background provides the necessary training and understanding of the mask systems described in the '556 [p]atent."); Ex. 2003 ¶¶ 11–12 (declaring that Mr. Sleeper's formulation of a level of ordinary skill in the art is "[b]ased []on [his] knowledge and experience in [the] area" and indicating that he "underst[ood] that one can consider the types of problems encountered in the art, the prior solutions to those problems found in prior art references, the speed with which innovations were made at that time, the sophistication of the technology, and the level of education of active workers in the field").

We note that our patentability and claim construction analyses presented below would reach the same findings and determinations under either party's definition of the level of ordinary skill in the art.

B. Claim Construction

In this *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b) (2016). Under the broadest reasonable construction standard, claim terms 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. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Also, we are careful not to read a particular embodiment appearing in the written description into the claim if the claim language is broader than the embodiment. *See In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993) ("[L]imitations are not to be read into the claims from the specification.").

Fisher contends that the terms of the Challenged Claims should be “given their broadest reasonable interpretation in light of the [S]pecification of the ’556 [p]atent” and does not offer any express constructions for any term in the Challenged Claims. *See* Pet. 10. ResMed also contends that no term needs to be expressly construed. *See* PO Resp. 14–15; *see also* PO Supp. Resp. *generally* (addressing claims 1–60 and not providing any express claim constructions for those claims).

We determine that we need not construe expressly any terms of the Challenged Claims to resolve the controversy between the parties. *See Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (construing explicitly only those claim terms in controversy and only to the extent necessary to resolve the controversy).

C. Overview of the Asserted Prior Art

The Petition relies on seven prior art references in its asserted grounds of unpatentability against the Challenged Claims. We provide an overview of these references below.

1. Barnett

Barnett, titled “Low Contact Nasal Mask and System Using Same,” issued July 2, 2002. Ex. 1002, (54), (45). Barnett is generally directed to “a low contact nasal mask that includes a one-piece, lightweight seal member defining a nose receiving cavity, a collar coupled to the seal member, and a

conduit coupling member, and to a system for supplying a flow of gas to a patient.” *Id.* at 1:9–12. Barnett’s Figure 1A is reproduced below:

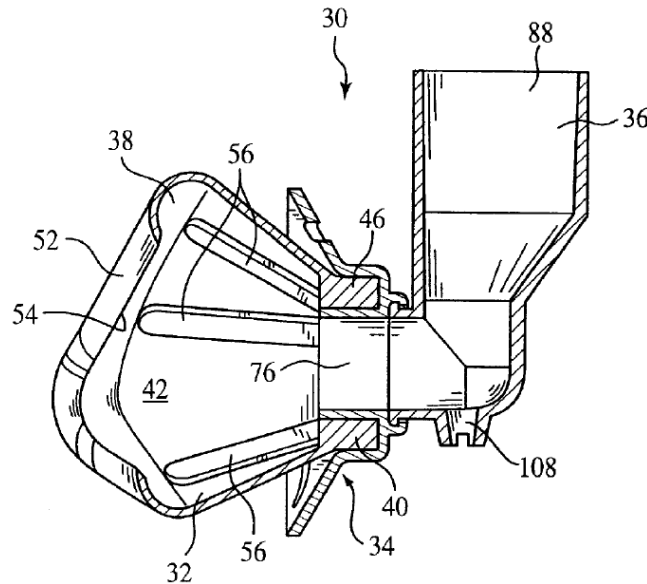


FIG. 1A

Figure 1A depicts “a sectional side view of a low contact nasal mask assembly according to the principles of” the mask system disclosed in Barnett. Ex. 1002, 2:65–66. Nasal mask assembly 30 communicates breathing gas to a patient from a pressure generating device, such as a ventilator, CPAP device, or other device. *Id.* at 3:33–43. Nasal mask assembly 30 includes seal member 32, collar 34, and conduit coupling member 36. *Id.* at 3:48–50. Seal member 32 is fixed to collar 34 and conduit coupling member 36 is rotatably mounted on collar 34 so that conduit coupling member 36 freely rotates about a central axis of collar 34. *Id.* at 3:50–56. Barnett discloses that seal member 32 may be replaced with seal member 32', where seal member 32' is “specifically designed to correspond to the facial features of smaller patients, such as children, but is otherwise similar to seal member 32.” *Id.* at 6:1–14.

“Seal member 32 includes [] neck portion 46.” Ex. 1002, 4:11. Neck portion 46 is integrally formed with seal member 32 and is formed of the same material as seal member 32, however, Barnett discloses that, for an alternative embodiment, neck portion 46 may be formed of a different material and bonded to seal member 32. *Id.* at 4:20–26. Seal member 32 also includes ribs 56 on the sidewalls of seal member 32, to provide additional support to the relatively flexible material of seal member 32. Ex. 1002, 5:8–12. Barnett discloses that, preferably, ribs 56 are made of the same material as, and integrally formed with, seal member 32. *Id.* at 5:17–19. Barnett also discloses that, alternatively, the ribs may be formed of a different material. *Id.* at 5:22–24.

Barnett’s Figures 3A and 4A are reproduced below.

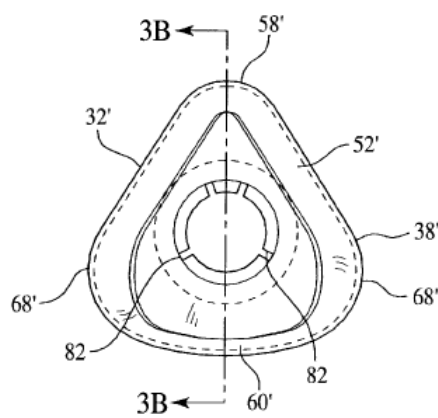


FIG. 3A

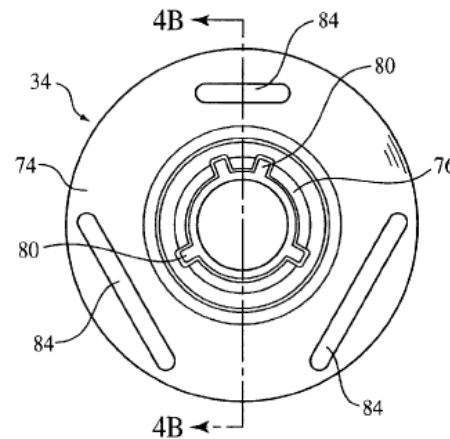


FIG. 4A

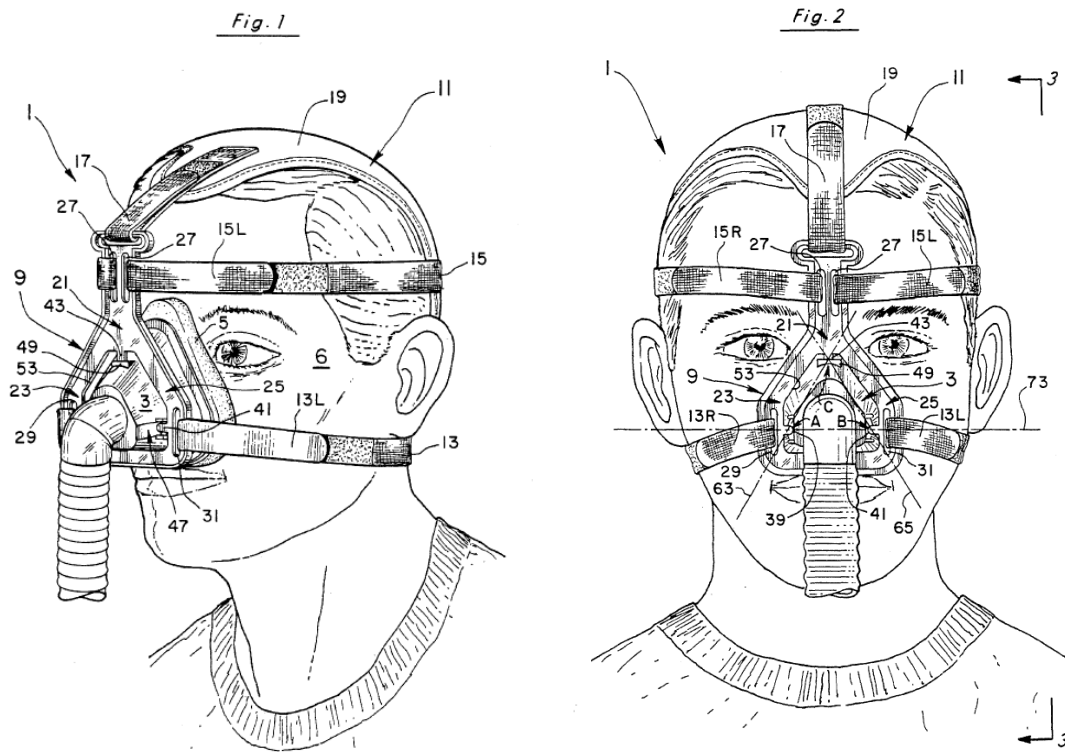
Figure 3A depicts “a front view of an alternative configuration for the seal member” and Figure 4A depicts “a rear view of a collar in the low contact nasal mask assembly” depicted in Figure 1A. Ex. 1002, 3:6–7, 3:11–12. Barnett discloses that neck portion 46 of seal member 32 is coupled to first mounting member 76 of collar 34 by a friction fit. *Id.* at 7:17–21. Barnett also discloses that, in addition, a tongue and groove or

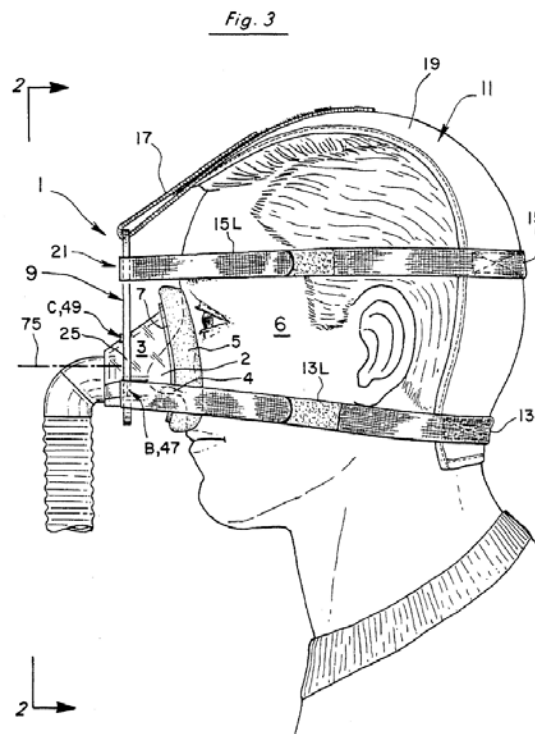
other coupling structure could be used to couple neck portion 46 and first mounting member 76. *Id.* at 7:28–33.

Barnett discloses that seal member 32, 32' includes channels 82 as part of neck portion 46, which receive protrusions 80 of collar 34 to secure seal member 32, 32' to collar 34 and prevent relative rotational movement between seal member 32, 32' and collar 34. *See id.* at 7:35–45.

2. Ogden

Ogden, titled “Respiratory Facial Mask,” issued September 2, 1997. Ex. 1003, (54), (45). Ogden is generally directed to “respiratory facial masks” such as those used in respiratory care and therapy. *Id.* at 1:5–10. Ogden’s Figures 1–3 are reproduced below:





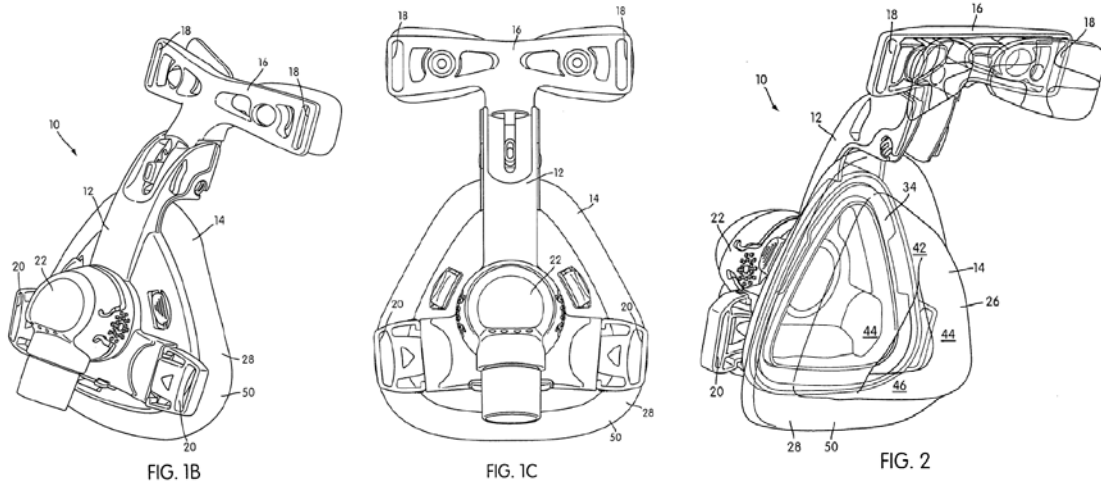
Figures 1, 2, and 3 depict a perspective view, front view, and side view of Ogden's mask, respectively. Ex. 1003, 2:17–21. Mask assembly 1 covers a user's nose with rigid, cup-shaped shell 3. *Id.* at 2:46–54. Soft, pliable seal 5 is attached to cup 3 and forms a seal at the patient's face. *Id.* at 2:54–57. Shell 3 is held in position by rigid plate 9 and harness arrangement 11. *Id.* at 2:58–61.

Rigid plate 9 is planar and attaches to cup 3 at locations A, B, and C using detents 39, 41, 43 and channels 45, 47, and 49. Ex. 1003, 3:26–29. Plate 9 provides five-point attachment to harness arrangement 11—an opening at the top of plate 9 for strap 17, two adjacent openings (loops 27) for straps 15R and 15L, and openings 29, 31 for straps 13R and 13L. *See id.* at 2:62–3:24.

Channels 45 and 47 for plate 9 are positioned on the sides of shell 3 and “loosely receive” detents 39 and 41 of rigid plate 9. Ex. 1003, 3:30–33. Channel 49 is located at the top ridge of shell 3 and “loosely receives” detent 43. *Id.* at 3:34–37. Channel 49 differs from channels 45 and 47 in that it maintains detent 43 within four end walls 55 of the channel. *Id.* at 3:43–46. Channel 45 and 47 have close walls 57 and 59, respectively, but are open ended at the front. *Id.* at 3:46–49. Accordingly, rigid plate 9 rotates relative to the rigid shell 3 about axes 63 and 65 “to compensate for any unequal forces applied to [] rigid plate 9, as for example, by side straps 13R and 13L as the patient turns his or her head from side-to-side.” *Id.* at 3:49–55.

3. *Lithgow*

Lithgow, titled “Cushion for a Respiratory Mask Assembly,” published June 24, 2004. Ex. 1004, (54), (43). Lithgow is generally directed to “a cushion for a respiratory mask assembly used for providing ventilator support, e.g., for treatment of Sleep Disordered Breathing . . . with Non-invasive Positive Pressure Ventilation.” *Id.* ¶ 2. Lithgow’s Figures 1B, 1C, and 2 are reproduced below:



Figures 1B, 1C, and 2 depict a front perspective view, a front view, and a rear perspective view of Lithgow's mask, respectively. Ex. 1004 ¶ 40–42. Respiratory mask assembly 10 includes frame 12, cushion 14, which may be removably connected to frame 12, and forehead support 16, movably mounted to frame 12. *Id.* ¶ 111. Intermediate portion 28 of cushion 14 includes gusset 50, which allows portion 26 to move relative to portion 28. *Id.* ¶ 124.

4. *Namey*

Namey, titled “Two-Shot Injection Molded Nasal/Oral Mask,” published February 21, 2002. Ex. 1005, (54), (43). Namey is generally directed to “a mask in which both the mask body and at least a portion of a mask seal are formed and joined using a two-shot injection molding process.” *Id.* ¶ 2. Namey's Figures 1 and 2 are reproduced below:

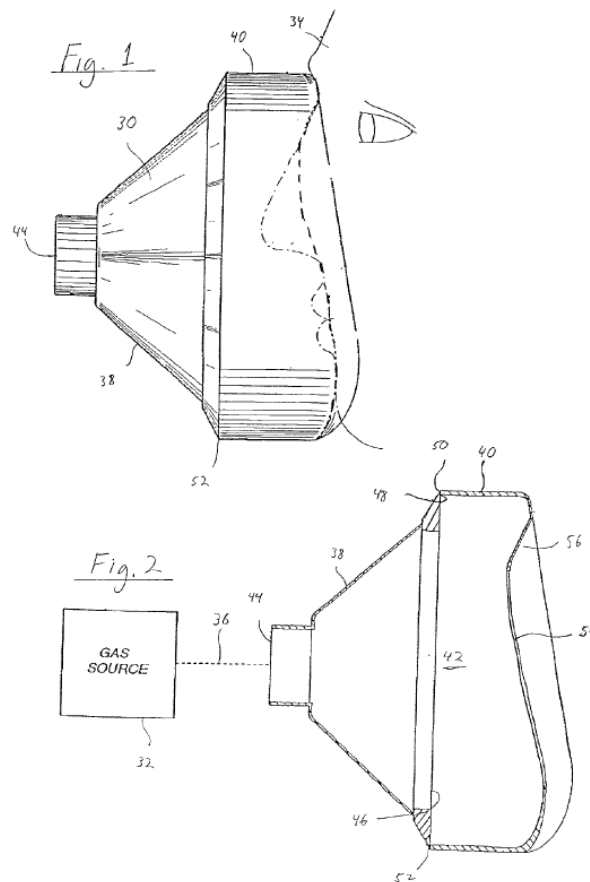


Figure 1 depicts “a side view of a mask manufactured in accordance with the two-shot injection molding technique of” Namey and Figure 2 depicts “a cross-sectional view of the mask of [Figure] 1.” Ex. 1005 ¶¶ 11–12. Mask 30, including main body 38 and mask seal member 40, is used to provide breathing gas to a patient. *Id.* ¶¶ 19–20. “Mask body 38 supports seal member 40 and is typically formed from a material that is more rigid than the seal member, such as a rigid or semi-rigid plastic.” *Id.* ¶ 21.

5. Jaffre

Jaffre, titled “Exhaust Port Assembly for a Pressure Support System,” issued February 8, 2005. Ex. 1006, (54), (45). Jaffre is generally directed “to an exhaust port assembly with enhanced noise reduction and gas diffusion capabilities, while also minimizing size” such as those used in

mask systems used in non-invasive positive pressure support therapy. *Id.* at 1:15–17, 21–30. Jaffre’s Figures 7, 8, and 9 are reproduced below:

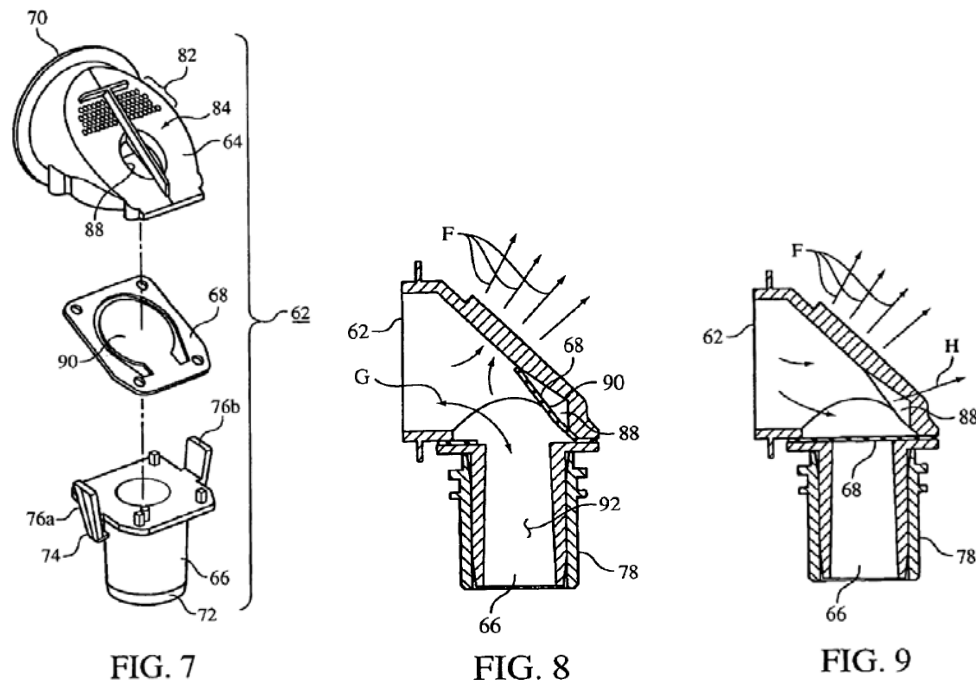


Figure 7 depicts “an exploded view of [an] exhaust port assembly” of an embodiment of Jaffe’s invention. Ex. 1006, 6:46–47. Figure 8 depicts “a cross-sectional view of the exhaust port assembly showing a first position of the valve member” and Figure 9 depicts “a cross-sectional view of the exhaust port assembly showing a second position of the valve member.” *Id.* at 6:48–52. Exhaust port assembly 62 of Figures 7, 8, and 9 provides a patient access to ambient air when the patient wears a mask system employing the disclosed valve system. *Id.* at 10:11.

Exhaust port assembly 62 includes auxiliary opening 88 having a diameter greater than the diameter of holes 82, and valve member 68. Ex. 1006, 10:12–14. During normal use of a mask system employing exhaust assembly 62 (that is, when the pressure of the gas within interior 92 of the exhaust port assembly is greater than ambient atmospheric pressure),

cantilever member 90 associated with valve member 68 blocks auxiliary opening 88—it is deflected up against opening 88. *Id.* at 10:14–20. In this position, cantilever member 90 enables gas to flow between the patient and gas system. *Id.* at 10:20–22. If the pressure of the gas in interior 92 drops below the ambient air pressure, such as from a failure of the gas system, cantilever member 90 unblocks auxiliary opening 88 and blocks gas from flowing towards the gas system. *Id.* at 10:23–34.

6. *Gunaratnam*

Gunaratnam, titled “Mask Cushion and Frame Assembly,” issued September 28, 2004. Ex. 1007, (54), (45). Gunaratnam is generally directed to connecting a mask used in the treatment of sleep disordered breathing (SDB) with a nasal or full-face mask cushion. *Id.* at 1:21–25. Gunaratnam’s Figures 5a and 5c are reproduced below:

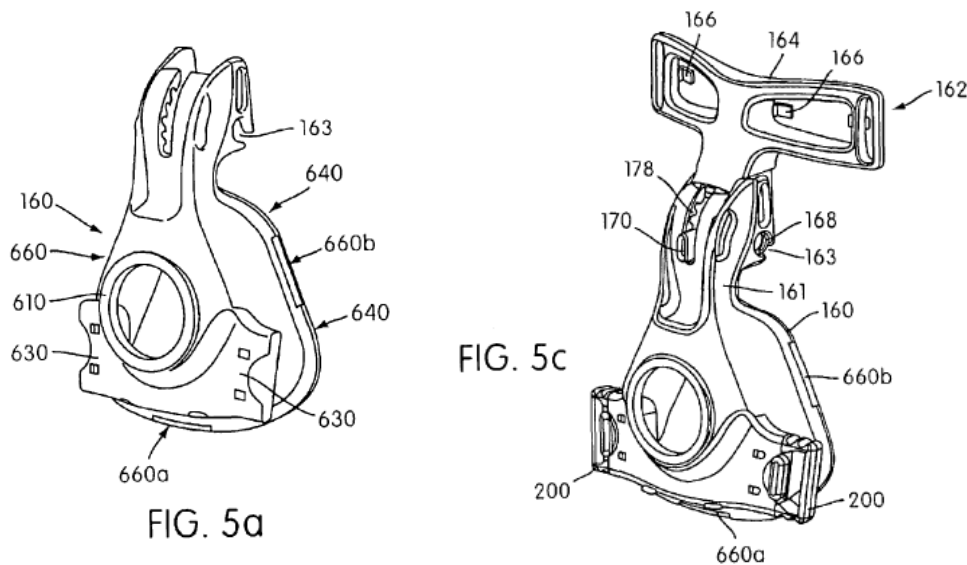


Figure 5a depicts “a front perspective view of a nasal mask frame,” and Figure 5c depicts “a front perspective view of a nasal mask frame and adjustable forehead support.” Ex. 1007, 3:6–12. Frame 160 is generally

triangular and fits over a wearer's nose and forms a breathing cavity. *Id.* at 4:26–30. Frame 160 includes gas inlet aperture 610, which connects to a conduit that delivers gas to the wearer. *Id.* at 4:21–25. The frame includes a front portion with connection points 630 for headgear.

The embodiment of Figure 5c includes adjustable forehead support 162 coupled to frame 160. Ex. 1007, 4:46–57. Figure 5c also depicts connector 200 for connecting the mask to a user's headgear. *Id.* at 4:32–34.

7. *Ging*

Ging, titled “Respiratory Mask Assembly with Magnetic Coupling to Headgear Assembly,” published July 21, 2005. Ex. 1008, (54), (43). Ging is generally directed to “a nasal mask for use in the delivery of Non-invasive Positive Pressure Ventilation . . . and for nasal continuous positive airway pressure . . . therapy of sleep disordered breathing . . . conditions such as obstructive sleep apnea (OSA).” *Id.* ¶ 2. Ging's Figure 1 is reproduced below.

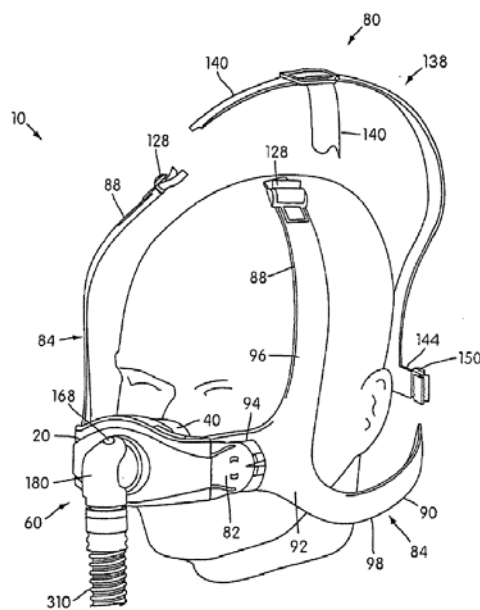


FIG. 1

Figure 1 depicts a perspective view of Ging's nasal mask assembly. Ex. 1008 ¶ 30. Nasal mask assembly 10 includes frame 20 and cushion 40, attached to frame 20, including by co-molding. *Id.* ¶ 110. Swivel elbow assembly 60 and a headgear assembly 80 are also attached to frame 20. *Id.* Frame 20 includes central bore 24 (not identified in Figure 1) to connect with swivel elbow assembly 60. *Id.* ¶ 112.

Ging's Figure 5c and Figures 27a, 27b, and 27c are reproduced below.

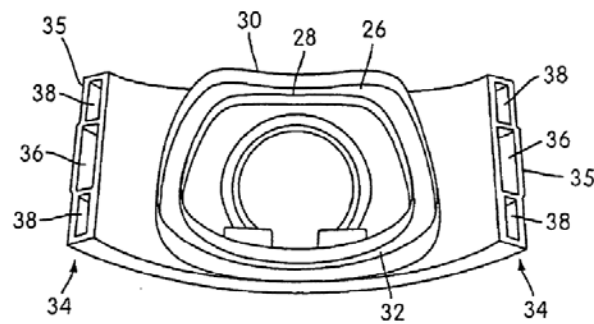


FIG. 5c

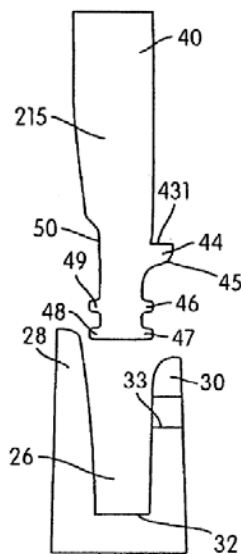


FIG. 27a

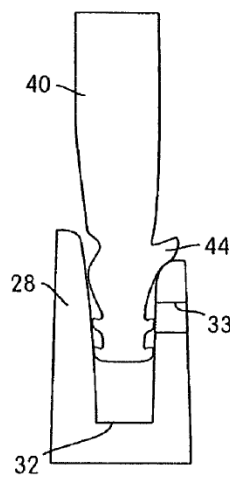
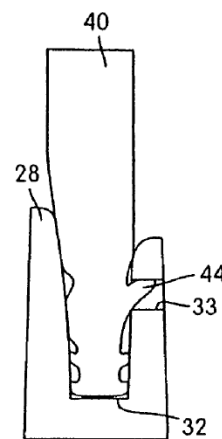


FIG. 27b



cushion 40. *Id.* ¶ 88. As seen in Figure 5c, frame 30 connects with cushion 40 through channel 26, including inner wall 28 and outer wall 30. *Id.* ¶ 114. To connect cushion 40 with frame 20, leading edge 45 of retention lip 44 engages outer wall 30 and deforms. *Id.* ¶ 207. Cushion 40 is then inserted into channel 26 until it contacts channel floor 32, with sealing lips 46–49 in full contact with inner and outer walls 28 and 30 retention lip 44 entered into undercut 33. *Id.*

D. Asserted Grounds of Unpatentability

In *inter partes* reviews, a petitioner bears the burden of proving unpatentability of the challenged claims, and the burden of persuasion never shifts to the patent owner. *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail in this proceeding, Fisher must support its challenge by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). Accordingly, all of our findings and conclusions are based on a preponderance of the evidence.

Each of Fisher’s asserted grounds against the Challenged Claims is based on 35 U.S.C. § 103(a).

Section 103(a) [of 35 U.S.C.] 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, secondary

considerations, 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). We address these underlying factual issues with respect to each asserted ground, below.⁴

1. *Claims 1, 2, 4, 7, 14–16, 19, 22, 23, 25, 29, 32, 35, 36, 43, 45–47, 49, 52, 61, and 64 as allegedly obvious over Barnett and Ogden*

a. Independent claim 1.

“cushion module” limitation

Independent claim 1 recites, in relevant part, “the cushion module includes a main body and a cushion . . . the main body and cushion together comprise an integrated component, the main body comprising a molded material that interfaces with the frame module and the cushion comprises a molded silicone material adapted to interface with patient’s face.” Ex. 1001, 10:15–29 (the “cushion module” limitation of claim 1).

Fisher contends that Barnett’s seal member 32 corresponds to the recited cushion module, with first end portion 38 corresponding to the recited cushion and neck 46 and ribs 56 corresponding to the recited main body. Pet. 26 (referencing Ex. 1002, 3:67–4:3, 4:11–26, 5:8–18). Fisher identifies these structures in an annotated version of Barnett’s Figure 1A, which we reproduce below.

⁴ We address the level of ordinary skill in the art in Section II.A., *supra*. ResMed does not argue or provide any evidence of secondary considerations.

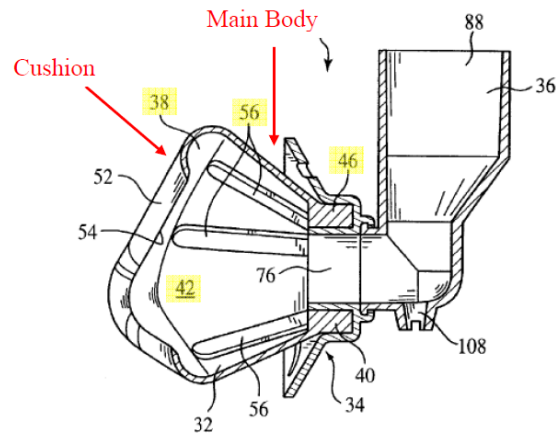


FIG. 1A

Id. The annotated version of Figure 1A highlights the reference numerals for first end portion 38, receiving cavity 42, neck 46, and ribs 56 and also identifies the cushion and main body.

Fisher also contends that Barnett discloses that seal member 32 may be integrally formed and first end portion 38 may be made of silicone. Pet. 29 (citing Ex. 1002, 3:62–67, 4:19–22, 5:18–20). Fisher also contends that a person having ordinary skill in the art would have recognized that seal member 32 includes molded material. *Id.* (referencing Ex. 1009 ¶ 60). Mr. Lordo declares that “[m]ost CPAP masks were and are constructed of molded materials and it was common practice in the art to mold components of a breathing mask assembly, including the main body and cushion.” Ex. 1009 ¶ 60. Fisher and Mr. Lordo identify Namey as disclosing an example of a mask with a cushion module made of molded material. Pet. 29; Ex. 1009 ¶ 64.

We find that Fisher sufficiently demonstrates that Barnett discloses a cushion module comprising a main body and cushion, where the main body and cushion together comprise an integrated component and the cushion is

made of silicone. *See, e.g.*, Ex. 1002, 3:62–67 (disclosing that seal member 32 may be made of silicone), 4:20–22 (describing neck 46 as integral with seal member 32), 5:17–19 (disclosing that ribs 56 are integrally formed with seal member 32).

On the complete record before us, we also determine that Fisher demonstrates, by a preponderance of the evidence, that Barnett discloses a cushion module where the main body comprises a molded material and the cushion is molded silicone, as required by claim 1’s “cushion module” limitation. Fisher’s principal support for its contention that Barnett discloses this subject matter is that molding these products was “common practice,” relying on the testimony of Mr. Lordo. Pet. 29 (citing Ex. 1009 ¶60). Mr. Lordo supports his testimony by stating that Namey “teaches the use of molded materials for both the main body and the cushion.” Ex. 1009 ¶ 64. In finding that Fisher adequately proves its contention, we credit Mr. Lordo’s testimony, based on his industry experience and other record evidence. *See id.* ¶¶ 3–8 (providing Mr. Lordo’s education and experience); Ex. 1019, 6, 10 (providing “agreed common knowledge” by the parties in a related United Kingdom dispute and stating that “[s]ilicone cushions can be made by compression [molding] or injection [molding].”). We discern no countervailing evidence.

ResMed does not dispute Fisher’s contentions with respect to the cushion module limitation of claim 1.

“more rigid material” limitation

Claim 1 further recites “the molded material of the main body is a more rigid material than the molded silicone material of the cushion.” Ex. 1001, 10:29–31 (the “more rigid material” limitation). Fisher asserts

alternative positions with respect to this limitation: 1) that Barnett discloses the subject matter of the “more rigid material” limitation (or renders the subject matter obvious) and 2) the subject matter of the “more rigid material” limitation would have been obvious over Barnett in view of Ogden’s teachings. See Pet. 30–32; Supp. Reply 2–4. We address each of these positions in turn.

*“more rigid material” limitation and
Barnett alone*

We reproduce below the entirety of the Petition with respect to the “more rigid material” limitation and Barnett’s disclosure:

Barnett discloses that main body portions 46, 56 provide structural support to the silicone cushion 38. Ex. 1002 at cols. 4:17–19, 5:8–18. Further, Barnett discloses that main body portions 46, 56 can include materials different from the cushion 38. *Id.* at cols. 4:22–26, 5:22–24. Thus, Barnett recognizes the desirability of main body portions 46, 56 being more rigid than cushion 38. Ex. 1009 ¶ 65.

Pet. 30. In its Supplemental Reply, Fisher again argues that “Barnett recognizes that the main body (at least neck 46 and ribs 56) requires more rigidity than the cushion (end portion 38).” Supp. Reply 2. Fisher adds, for the first time, that “Barnett states that ‘the ribs can be eliminated in favor of increasing the thickness of the entire side wall, or a major portion of the side wall, of the seal member to provide the side wall support function.’” *Id.* at 3 (referencing Ex. 1002, 5:33–37). Fisher continues that “Barnett teaches that the ribs and neck—the same portions that Barnett teaches should be more rigid—can be made from a different material.” *Id.* (relying on Ex. 1002, 4:22–26, 5:22–24).

We find that this presentation in the Petition accurately reflects Barnett’s disclosure. Barnett discloses that neck 46 and ribs 56 provide

structural support to sealing member 38. Specifically, Barnett discloses that “[i]n the illustrated embodiment, neck portion 46 is relatively thick as compared to a remainder of the seal member to provide a solid mounting base for the seal member.” Ex. 1002, 4:17–19. Barnett also discloses that:

In the illustrated exemplary embodiment, ribs 56 extend from second end portion 40 toward first end portion 38 and provide structural support for the sides of the seal member so that the seal member does not collapse when a strapping force sufficient to minimizes [sic] leaks at the mask-patient interface is applied on second end portion 40.

Id. at 5:12–18. Barnett also discloses that, instead of using ribs, the entire wall thickness of seal member 32 could be thickened. *Id.* at 5:33–37. Barnett discloses that neck 46 and ribs 56 may be made of a material different than the remainder of seal member 38. *Id.* at 4:22–25 (“[N]eck portion 46 can be made from a substance different from that of the remainder of the seal member.”); *Id.* at 5:23–25 (“[R]ibs 56 can be made from substances that differ from that used to define seal member 32.”).

Fisher concludes its assertion in the Petition by stating that “[t]hus, Barnett recognizes the desirability of main body portions 46, 56 being more rigid than cushion 38.” Pet. 30 (referencing Ex. 1009 ¶ 65). Again, we agree with this assertion—Barnett discloses that neck 46 and ribs 56 are thicker (and, thus, relatively more rigid) than the remainder of seal member 38. Ex. 1002, 4:17–19, 5:12–18. Significantly, however, claim 1 does not require the main body structurally to be more rigid than the cushion—it requires that the molded material of the main body be *a more rigid material* than the molded silicone material of the cushion. That is, the claim requires the molded material of which the main body is comprised 1) be different

than the silicone material of the cushion and 2) possess the material property that its rigidity is greater than the rigidity of silicone.

Fisher fails to explain adequately, in the very limited discussion in the Petition, how Barnett teaches using a different material that is more rigid than silicone for neck 46 and ribs 56. The Petition lays out certain factual statements, *but draws no conclusion from those statements*, leaving us to somehow connect the dots.

ResMed argues that “Barnett does not disclose what Petitioner has asserted as Barnett’s ‘main body’ is made of a material that is more rigid or harder than the material for Barnett’s ‘cushion.’” Supp. PO Resp. 2. ResMed explains that “Barnett discloses . . . that the neck portion 46 and ribs 56 can be made out of different materials, and that a [person having ordinary skill in the art] would not have understood from Barnett’s disclosure that these different materials must necessarily be more rigid than Barnett’s seal member 32.” *Id.* ResMed concludes that neither Fisher nor Mr. Lordo “identify any suggestions in Barnett regarding the desirability for these portions to be made out of a more rigid material, and they also fail to explain why the same or a less rigid material could not be used.” *Id.*

Fisher does cite to Mr. Lordo’s testimony. Mr. Lordo’s paragraph 65 states:

Barnett teaches that different materials can be used in the main body and the cushion, and recognizes the benefit of additional rigidity in the main body. [footnoting a citation to Ex. 1002, 5:22–25] Ogden specifically teaches the use of a more rigid material in the main body than in the cushion. [footnoting a citation to Ex. 1002, 2:50–57] A person of skill in the art would have been motivated, *consistent with the teachings of Barnett and Ogden*, to include a molded cushion with a rigid main body so as to allow the cushion to be made using readily available

materials and utilizing an inexpensive, well-developed manufacturing process.

Ex. 1009 ¶ 65. As can be seen from this testimony, Mr. Lordo is opining on how the combination of the teachings of Barnett and Ogden arrives at the subject matter of the “more rigid material” limitation (which we discuss, below). This testimony is *silent* on whether Barnett alone discloses or suggests employing a different material that is more rigid than silicone for neck 46 and ribs 56. Instead, like Fisher, Mr. Lordo testifies that Barnett teaches that different materials may be used and that Barnett recognizes that neck 46 and ribs 56 should have additional rigidity as compared to the remainder of the seal member. Again, these statements are accurate characterizations of the statements in Barnett, but fail to present a conclusion that the different material would have a higher rigidity than silicone.

We agree with ResMed that Fisher fails to satisfy its evidentiary burden in demonstrating that Barnett teaches constructing neck 46 and ribs 56 from a material that differs from silicone *and* has a rigidity greater than silicone. See Supp. PO Resp. 2 (“These failures of proof by Petitioner and Mr. Lordo are telling.”). As ResMed alludes, a material with the same rigidity as silicone could be used for the neck and ribs, with the neck and ribs constructed as disclosed in Barnett. Alternatively, a material with less rigidity than silicone could be used for the neck and ribs, with the neck and ribs being made thicker than the embodiment in Barnett. Under this alternative, the increased thickness could potentially be balanced by using a lower density material, such as a foamed material, to not adversely impact weight. Or, the proposed modification could increase the weight, with other favorable trade-offs. Accordingly, although there may be some suggestion in Barnett of using a material for the neck and ribs that is more rigid than

silicone (given the desire for support in the ribs and neck), this suggestion is not sufficient to carry Fisher's burden. We find that the suggestion in Barnett is not strong enough to demonstrate, by a preponderance of the evidence, that Barnett discloses the "more rigid material" limitation.

Fisher argues that Barnett's disclosures must be considered in the proper context—that "[t]he disclosures regarding the use of different materials are directly related to the discussions of additional rigidity needed in the side walls and neck." Supp. Reply 5. Fisher concludes that "a [person having ordinary skill in the art] would heed Barnett's suggestion to use a different material and would select a more rigid material . . . to achieve Barnett's desired rigidity." *Id.* This argument overstates Barnett's disclosure. With respect to neck 46, Barnett states that "[t]he present invention contemplates, however, that neck portion 46 can be made from a substance different from that of the remainder of the seal member and bonded thereto to define the illustrated seal member." Ex. 1002, 4:22–26. That is, Barnett merely states that, as an alternative to forming neck 46 as an integral part of seal member 32 made from the same material, the disclosed invention "contemplates" forming neck 46 from a different material and bonding that material to seal member 32. We find, based on the express language in Barnett quoted above, that Barnett's disclosure of "a substance different from that of the remainder of the seal member" merely expresses that the breadth of Barnett's invention goes beyond an integrally-formed seal member 32 made of the same material. We find nothing in the language of Barnett, nor does Fisher identify any specific language, that directly relates the different substance to the rigidity of neck 46. *See id.* at 4:17–26.

The similar disclosure for ribs 56 further supports our finding. Barnett states that “[i]t can be appreciated, however, that ribs 56 can be made from substances that differ from that used to define seal member 32 and preferably fixedly secured thereto.” Ex. 1002, 5:22–24. Again, we find, based on the express language of Barnett, that forming ribs 56 from “substances that differ from that used to define seal member 32” is merely an expression of the breadth of Barnett’s invention. Nothing in this language suggests that this statement about different substances directly relates to the structural support aspect of Barnett, as Fisher alleges. *See id.* at 5:12–27.

In its Supplemental Reply, Fisher elaborates on (or adds to) its position. Fisher argues that a person having ordinary skill in the art (“POSITA”):

would have understood Barnett to suggest an alternative main body with a different, more rigid material to provide the desired rigidity and support. *See* Pet. at 30; Ex. 1009 ¶ 61. To achieve Barnett’s goal of rigidity at the ribs and neck, a POSITA would have selected a different, more rigid material, not one equally or less rigid. *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007) (“When there is a design need . . . and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp.”).

Supp. Reply 3–4. Tellingly, in support of its assertion that “a POSITA would have selected a different, more rigid material, not one equally or less rigid,” Fisher cites to *KSR Int’l Co.*, and not to any *evidence* of record. *Id.*

See also Supp. Tr. 9:8–9 (“[W]e look at the [*KSR Int’l Co.*] standard – we’ve got the classic situation of a finite number of predictable solutions.”).⁵

From this presentation, we understand Fisher’s position (or at least one alternative position) to be that a person having ordinary skill in the art would have found it obvious to try a material with more rigidity than silicone, as there were a finite number of solutions: a material with more rigidity, less rigidity, or the same rigidity. *See* Supp. Tr. 8:25–11:4. Importantly, however, in formulating its “obvious to try” rationale, the Supreme Court states that, “[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill [in the art] has good reason to pursue the known options within his or her technical grasp.” *KSR Int’l Co.*, 550 U.S. at 421.

Here, Fisher fails to articulate that there is a design need or market pressure to solve a problem and, specifically, what that problem is. Absent such argument and evidence, Petitioner fails to carry its burden to

⁵ Patent Owner’s counsel asserts that this obviousness rationale was not in the Petition and that Patent Owner was not provided adequate notice of this argument. *See* Supp. Tr. 19:12–15 (“I was going to make the point and will make it now that Petitioner’s belated argument that there are a finite number of materials that could be used either less rigid or more rigid wasn’t presented in the Petition and, therefore, shouldn’t be adopted.”). Petitioner points to page 30 of the Petition and paragraph 65 of Mr. Lordo’s declaration in support of this position in the original Petition. *See id.* at 10:1–7. Although we agree with Patent Owner that this obviousness position was not in the original Petition or Mr. Lordo’s declaration, we address it here because we find the position insufficient to carry Fisher’s burden of proving the claim limitation obvious, such that ResMed is not harmed.

demonstrate that it would have been obvious to try a material with more rigidity than the silicone cushion based on design need or market pressure. *See Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1361 (Fed. Cir. 2011) (“[A] combination is only obvious to try if a person of ordinary skill has ‘a good reason to pursue the known options.’”) (emphasis added); *see also In re Enhanced Sec. Research, LLC*, 739 F.3d 1347, 1366 (Fed. Cir. 2014) (addressing “obvious to try” and stating that “the Board identifies no ‘problem’ that one of ordinary skill was trying to solve at the time of the invention.”) (O’Malley, dissenting).

Further, we are not persuaded that there are only three solutions. Instead, there are an unspecified number of materials that may be used other than silicone. These unspecified materials are the potential solutions and Fisher fails to demonstrate adequately that this set of materials is finite and small. *See In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1072 (Fed. Cir. 2012) (“Evidence of obviousness, especially when that evidence is proffered in support of an ‘obvious-to-try’ theory, is insufficient unless it indicates that the possible options skilled artisans would have encountered were ‘finite,’ ‘small,’ or ‘easily traversed,’ and that skilled artisans would have had a reason to select the route that produced the claimed invention.”). Indeed, Fisher fails to cite to any record evidence in support of its position.

Fisher also argues that “[c]onsidering Barnett in its entirety, a POSITA would heed Barnett’s suggestion to use a different material and would select a more rigid material *as a matter of common sense* to achieve Barnett’s desired rigidity.” Supp. Reply 5 (referencing Pet. at 30; Ex. 1009 ¶ 65). However, the Federal Circuit has “repeatedly explained that

obviousness findings ‘grounded in “common sense” must contain explicit and clear reasoning providing some rational underpinning why common sense compels a finding of obviousness.’” *In re Van Os*, 844 F.3d 1359, 1361 (Fed. Cir. 2017); *see also Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1377 (Fed. Cir. 2012) (“The mere recitation of the words ‘common sense’ without any support adds nothing to the obviousness equation.”). Again, Fisher fails to provide any persuasive evidence of record that supports its contention that it was a matter of common sense to select a material with a greater rigidity than silicone for the ribs and neck.

We find, based on the complete record before us, that Barnett does not expressly disclose the subject matter of the “more rigid material” limitation. As we discussed above, we find that Barnett does disclose that its neck and ribs may be made from a different material and that the neck and ribs provide structural support to seal member 32. However, we determine that Fisher fails to prove, by a preponderance of the evidence, that a person having ordinary skill in the art would have understood from this disclosure that Barnett discloses an alternative where the neck and ribs are made from a different material and that material has a greater rigidity than silicone. Further, we determine that Fisher has not demonstrated, by a preponderance of the evidence, that it would have been obvious to make Barnett’s neck 46 and ribs 56 from a material that has a rigidity property greater than that for silicone, based on the disclosure of Barnett alone, as Fisher has failed to provide adequate support for its “obvious to try” and “common sense” theories.

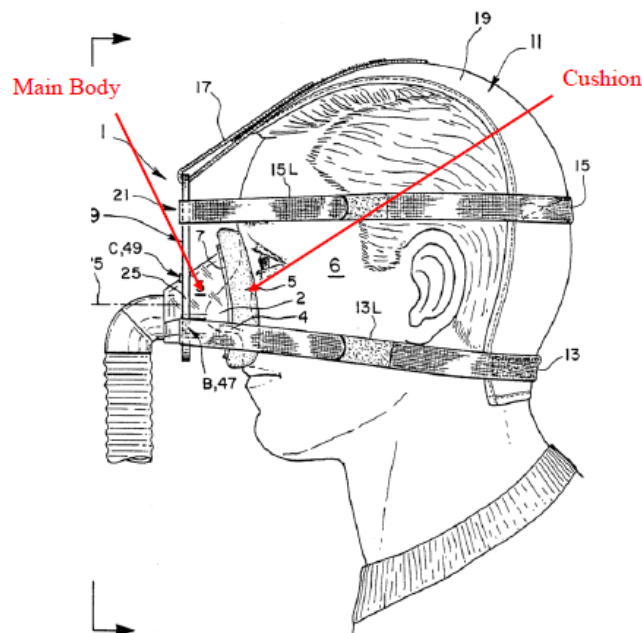
*“more rigid material” limitation and
Barnett in combination with Ogden*

Fisher alternatively contends that Barnett, combined with the teachings of Ogden, renders the “more rigid material” limitation obvious.

Pet. 30–31. The Petition states:

To the extent Barnett provides insufficient disclosure for the main body having a more rigid molded material, this feature was well-known by those skilled in the art and common in CPAP prior art. *Id.* ¶¶ 62–64. For example, as shown in annotated Fig. 3 below, Ogden discloses a main body 3 made of hard plastic that is more rigid than the soft, pliable cushion 5. Ex. 1003 at col. 2:50–57.

Pet. 30–31. The Petition also provides an annotated version of Ogden’s Figure 3, which we reproduce below.



Id. at 31. This annotated figure indicates Ogden’s pliable seal 5 as corresponding to the “cushion” and rigid, cup-shaped shell 3 as the “main body.” *See id.*; *see also* Ex. 1003, 2:51–61 (“[F]acial mask assembly 1 . . . includes a rigid, cup-shaped shell 3 made of hard plastic A soft, pliable

seal 5 of elastomer, urethane foam, or rubber is attached (e.g., glued or press fit) about the rear perimeter portion 7 of the rigid shell 3 The rigid, cup-shaped shell 3 with its seal 5 (see FIGS. 1-3) is attached or secured in its sealing position enclosing the nose 2 and nares 4 of the patient 6 by the rigid plate 9 and harness arrangement 11.”).

We find, consistent with Fisher’s assertion, that Ogden teaches a mask with a cushion module that includes a cushion (seal 5) and a main body (shell 3) that forms an integrated component, with shell 3 made of a material that is different from the material of seal 5 and more rigid than the material of seal 5. *See* Ex. 1003, 2:51–61.

Fisher contends that “[a] person of skill in the art at the time of the invention would have been motivated to incorporate a more rigid molded material for the main body to provide support for the cushion, *as suggested by Barnett.*” Pet. 31 (referencing Ex. 1002, 4:17–19, 5:8–18; Ex. 1009 ¶¶ 65–66) (emphasis added). We interpret this statement to mean that a reason behind the motivation for the proposed modification of Barnett with Ogden’s teachings is based on a suggestion in Barnett. This suggestion is that neck 46 and ribs 56 should be more rigid than the remainder of seal member 32, including cushion 38, and made of a different material. *See* Supp. Reply 3 (“[A] POSITA would have understood Barnett to suggest an alternative main body with a different, more rigid material to provide the desired rigidity and support.”); *See also* Pet. 30 (“Thus, Barnett recognizes the desirability of main body portions 46, 56 being more rigid than cushion 38.”); *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1365 (Fed. Cir. 2008) (“The [teaching-suggestion-motivation] test, flexibly applied, . . . assures that the obviousness test proceeds on the basis of

evidence—teachings, suggestions (a tellingly broad term), or motivations (an equally broad term)—that arise before the time of invention as the statute requires.”). Fisher reasons that “[a] more rigid main body, as disclosed in Ogden, would also maintain the shape of the cushion and would ease assembly by providing a rigid portion that can be grasped and manipulated by the user.” Pet. 31–32 (referencing Ex. 1009 ¶ 66).

Mr. Lordo declares that “[a] person of skill in the art would have been motivated, consistent with the teachings of Barnett and Ogden, to include a molded cushion with a rigid main body so as to allow the cushion to be made using readily available materials and utilizing an inexpensive, well-developed manufacturing process.” Ex. 1009 ¶ 65. Mr. Lordo provides no additional support for this specific testimony in his declaration. *See id.* Mr. Lordo continues:

A person of skill would have also recognized that a more rigid material would maintain the shape of the cushion module and breathing chamber. During transport, the use of a more rigid material would prevent the cushion modules from deforming when packaged with multiple components. During use, the more rigid material would provide a secure attachment and reliable seal between the cushion module and the frame module. Because the cushion would not be able to deform in the area of the rigid material, the sealing surfaces would remain in intimate contact. A more flexible material could bow or otherwise deflect and not fully seat against the frame. Adopting the rigid main body of Ogden would also ease the assembly of the cushion module by providing a rigid portion that could be grasped and manipulated by the user.

Id. ¶ 66.

Fisher also relies on testimony from Mr. Eaton, a declarant in a different *inter partes* review proceeding.⁶ Supp. Reply 8.

Mr. Eaton testified that a POSITA would have recognized that “internal positive air pressure would cause a cushion module of a unitary soft material to deform under pressure, thus leading to undesired displacement of the mask assembly and its seal,” and would have known that a more rigid frame material would resist such displacement.

Id. Fisher added that “Mr. Eaton also testified that a POSITA would have used a more rigid main body material in Barnett ‘to provide structure to the cushion module and provide an effective attachment structure for the shroud.’” *Id.*

Fisher also references deposition testimony from Mr. Sleeper, ResMed’s declarant. Supp. Reply 7. Fisher argues that “Mr. Sleeper[] testified that his company’s Tiara mask shells ‘were made out of polycarbonate, so they were rigid’” and “that rigid shells ‘[p]rovided good support for the cushion.’” *Id.* (referencing Ex. 1018, 26:9–21, 27:1–10).

From Mr. Lordo’s declaration testimony, Mr. Eaton’s declaration testimony from IPR2017-00064, and Mr. Sleeper’s deposition testimony, Fisher asserts that, “[t]hus, in addition to Barnett’s desire for a more rigid main body, all of the experts testified that more rigid main body material

⁶ As stated in footnote 1, ResMed did not object to Fisher’s use of this evidence, so we need not determine if its use is proper in this proceeding under the Federal Rules of Evidence.

was a known option for providing this rigidity, and the unrebutted expert testimony provides specific reasons for using that option.”⁷ Supp. Reply 8.

ResMed argues that Fisher “and Mr. Lordo provided mere conclusory and generic assumption as to why a POSITA would have been motivated to modify Barnett’s flexible and unitary seal member to have a rigid main body in view of Ogden.” Supp. PO Resp. 4. ResMed explains that Fisher “and Mr. Lordo simply alleged generic benefits that might be provided by a more rigid mask body without any connection to Barnett’s specific mask.” *Id.* at 5. ResMed argues that Fisher fails to meet its burden because Fisher fails to provide articulated reasoning with a rational underpinning for modifying Barnett with Ogden’s teachings. *Id.* ResMed also argues that the Petition fails to explain adequately how Barnett’s mask, as modified with Ogden’s teaching of a rigid shell, achieves the asserted benefits. *Id.* at 6.

ResMed continues that a person having ordinary skill in the art would not have modified Barnett with Ogden’s teachings as proposed by Fisher. Supp. PO Resp. 7. ResMed argues that Barnett’s mask, as disclosed, maintains a seal even under forces from the wearer moving his or her head. *Id.* (referencing Ex. 2004, 25:7–26:7). ResMed argues that the Petition fails to explain how this sealing advantage of Barnett’s mask is maintained once modified by Ogden. *Id.*

ResMed adds that:

⁷ We note that Fisher’s use of “unrebutted” is somewhat disingenuous. As we did not originally institute on claims with the “more rigid material” limitation (or similar claims in IPR2017-00064), there was no need for Mr. Sleeper to include any testimony in his declaration for this proceeding nor any need to cross examine Mr. Lordo or Mr. Eaton on the subject.

Mr. Lordo's deposition testimony casts doubt as to whether Barnett's mask would have been modified in view of Ogden's teachings without having to additionally incorporate Ogden's "pivoting" face plate in order to maintain Barnett's sealing advantages, which would frustrate several of Barnett's other objectives, such as having lightweight and small form factor mask.

Supp. PO Resp. 8 (referencing Ex. 2004, 65:21–66:2).

Fisher replies that "[a] POSITA would appreciate that a seal member design rarely optimizes all characteristics, but represents a trade-off between competing characteristics such as increased support and increased weight." Supp. Reply 6 (citing *Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349 n.8 (Fed. Cir. 2000)).

In reaching our obviousness determination, we "look with care at a patent . . . that claims as innovation the combination of two known devices according to their established functions." *KSR Int'l Co.*, 550 U.S. at 418. Importantly, "obviousness must be determined in light of *all the facts*, and . . . a given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate motivation to combine." *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (emphasis added); see also *Winner Int'l*, 202 F.3d at 1349 n.8 ("The fact that the motivating benefit comes at the expense of another benefit, however, should not nullify its use as a basis to modify the disclosure of one reference with the teachings of another. Instead, the benefits, both lost and gained, should be weighed against one another."). Accordingly, we weigh Fisher's and ResMed's evidence with respect to whether a person having ordinary skill in the art would have been motivated to modify Barnett with Ogden's teaching of a main body of a cushion module using a material that is more

rigid than the material used for the cushion, and evaluate their arguments based on that evidence. *See PAR Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1196 (Fed. Cir. 2014) (“The presence or absence of a motivation to combine references in an obviousness determination is a pure question of fact.”).

We evaluate Fisher’s multiple reasons for its proposed modification in turn. First, Fisher reasons that a person having ordinary skill in the art would have modified Barnett in view of Ogden’s teachings to make neck 46 and ribs 56 out of Ogden’s hard shell material (or, at least, a material that is more rigid than silicone) because such a modification is suggested in Barnett. Pet. 31. As we discuss above, in connection with our analysis of whether Barnett *alone* discloses the subject matter of the “more rigid material” limitation, we found that Fisher fails to prove, by a preponderance of the evidence, that a person having ordinary skill in the art would have understood Barnett as disclosing making neck 46 and ribs 56 out of a material that is more rigid than silicone. We do find, however, that, *in view of Ogden’s teaching* of a main body of a cushion module that is made of a more rigid material than its cushion, that there is at least some suggestion for the proposed modification and weigh this evidence in Fisher’s favor.

Fisher next reasons that its modified mask would maintain the shape of the cushion and would ease assembly by providing a rigid portion that can be grasped and manipulated by the user. Pet. 31–32. These two reasons are taken from Mr. Lordo’s testimony. *See* Ex. 1009 ¶ 66. We give this specific testimony from Mr. Lordo little weight for the reasons discussed below. As an initial matter, Mr. Lordo provides no support for his testimony. *See* 37 C.F.R. § 42.65(a). Further, to the extent that Fisher proposes making

neck 46 and ribs 56 out of a rigid material similar to Ogden's shell 3, we find these reasons to be inconsequential in light of Barnett's express teaching. Barnett teaches that neck 46 and ribs 56 add rigidity to Barnett's overall structure, to allow the mask to maintain its shape and have a portion that can be grasped by the user. *See* Ex. 1002 4:17–19, 5:12–18.

To the extent that Fisher proposes substituting the region of seal member 32 that includes ribs 56 and neck 46 with a hard plastic shell similar to Ogden's shell 3, then we find that such a modified mask would be more likely to maintain its shape as compared to Barnett's disclosed structure and also would be easier to grasp. Such a substitution, however, would also include disadvantages, which we discuss in greater detail below.

Mr. Lordo's testimony includes additional reasoning. *See* Ex. 1009 ¶¶ 65–66. We likewise give this additional testimony little weight, both because Mr. Lordo fails to support persuasively his reasoning and because his reasoning is divorced from the disclosure in Barnett. For example, Mr. Lordo testifies that Fisher's proposed modification allows the cushion to be made using readily available materials and would use an inexpensive, well-developed manufacturing process. *Id.* ¶ 65. Again, Mr. Lordo provides no support for this statement. Indeed, he does not identify the material or manufacturing process used. Further, he does not provide any evidence that compares the proposed modification with the materials and manufacturing processes used.

Similarly, Mr. Lordo testifies that using more rigid materials would prevent deformation of the mask during transport. Ex. 1009 ¶ 66. Mr. Lordo fails to address, however, Barnett's express disclosure that its mask is flexible when a deformation force is applied *but returns to its original shape*

when the force is removed. Ex. 1002, 3:62–66. Based on this express disclosure, we find that a person having ordinary skill in the art would not be concerned with mask deformation during transport. Mr. Lordo provides no testimony whether deformation during transport is somewhat different than the deformation disclosed in Barnett, such that the deformation would impair the subsequent use of the mask. There is no evidence in the record addressing why a mask that may deform during transportation would not recover upon removal from its packaging, as Barnett discloses. Again, this lack of evidence or additional explanation on Mr. Lordo’s part, coupled with Barnett’s disclosure, garners this testimony very little weight.

Mr. Lordo’s additional testimony suffers from similar deficiencies. He fails to explain adequately why a more rigid material would provide a secure attachment and reliable seal between the cushion module and the frame module. Mr. Lordo appears to explain that “[b]ecause the cushion would not be able to deform in the area of the rigid material, the sealing surfaces would remain in intimate contact [and a] more flexible material could bow or otherwise deflect and not fully seat against the frame.” Ex. 1009 ¶ 66. Mr. Lordo fails to explain persuasively how the interference fit of neck 46, made from silicone, and collar 34, allows for material to bow or deflect, and how a rigid material-to-rigid material interference fit performs better than Barnett’s fit. *Cf.* Ex. 2003 ¶ 50 (“Barnett describes a hard-to-soft connection between its rigid frame (collar 34) and its soft cushion module (seal member 32 and neck 46 made of a flexible material, like silicone) to provide retention and a seal”). Although the modified structure may provide a secure attachment and reliable seal, the strength of this fact *as a motivating force* for the modification would depend on the relative performance of the

attachment and seal of the modified mask and that of Barnett's mask.

Neither Fisher nor Mr. Lordo persuasively address this issue.

Mr. Eaton's testimony on this point is similarly deficient. As an initial matter, he too fails to provide the underlying bases for his opinion. *See* Ex. 1023 ¶¶ 71–72 (relied on by Fisher in Supp. Reply 8). Mr. Eaton testifies that a person having ordinary skill in the art would have replaced Barnett's ribs and neck with Ogden's shell 3 "to provide structure to the cushion module and provide an effective attachment structure for the shroud." *See id.* ¶ 71. Mr. Eaton fails to address that, as taught by Barnett, ribs 56 provide structure to seal member 32 and neck 46 provides an effective attachment to collar 34. *See* Ex. 1002 4:17–19, 5:12–18.

Mr. Eaton testifies that "[t]he internal positive air pressure would cause a cushion module of a unitary soft material to deform under pressure, thus leading to undesired displacement of the mask assembly and its seal." Ex. 1023 ¶ 72. This testimony is presented generically and does not specifically identify Barnett's mask, with its ribs 56, as having this issue. Also, as ResMed indicates, Mr. Lordo testifies that the soft material nature of Barnett's mask helps to provide an effective seal. *See* Supp. PO Resp. 7 (referencing Ex. 2004, 25:25–26:3). Given that Mr. Eaton's testimony is not directed to Barnett expressly and is not supported by Mr. Lordo's testimony, we afford Mr. Eaton's testimony little weight.

Although we find Mr. Lordo's and Mr. Eaton's testimony deserves little weight, we do accord it some weight. We credit these two declarants' industry experience as providing at least some basis for their opinions. *See* Ex. 1009 ¶¶ 3–8; Ex. 1017; Ex. 1023 ¶¶ 2–9.

We find that Barnett’s express teachings weigh against Fisher’s proposed modification. *Cf.* Supp. PO Resp. 7 (“The Petition never explains how the improved sealing advantages of Barnett’s seal member 32 would be maintained under Petitioner’s proposed modification to Barnett, which would eliminate Barnett’s advantageous flexible and unitary structure.”). Barnett expresses a *preference* for seal member 32 to be “defined from a unitary piece of elastomeric material that is relatively flexible when a deformation force is applied” to the mask. Ex. 1002, 3:62–64. Barnett also discloses that, “[i]n a preferred embodiment . . . ribs 56 are integrally formed with the seal member, and, therefore are formed from the same material.” *Id.* at 5:18–20. Although Barnett contemplates other materials for the ribs and neck, it expresses a preference that the seal member be a unitary structure with the ribs made of the same material as the face-contacting portion of seal member 32. *See Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1069 (Fed. Cir. 2018) (“[A reference’s] statements regarding preferences are relevant to a finding regarding whether a skilled artisan would be motivated to combine that reference with another reference.”).

Fisher replies that ResMed’s argument touting Barnett’s preference for a unitary structure ignores the disclosed alternatives, which include a non-unitary structure employing different materials for seal member 32. *See* Supp. Reply 4–5. We appreciate that Barnett’s disclosure goes beyond its preferred embodiments. Fisher’s argument, however, fails to address persuasively Barnett’s expressed *preference* for a unitary structure.

We additionally find that Ogden’s teachings weigh against Fisher’s proposed modification, to the extent that Fisher proposes substituting shell 3 for the rib-contacting and neck portions of seal member 32. Ogden discloses

that a rigid shell attached fixedly to a plate, such as may be the case if Ogden's shell 3 is substituted in for the rib-contacting and neck portions of seal member 32, may encounter sealing issues when a wearer turns his or her head from side to side. Ex. 1003, 3:56–4:12, Fig. 4. Barnett expressly discloses that an objective of its invention is to maintain a seal. See Ex. 1002, 1:41–50.

Ogden does provide a solution to the loss of seal—providing a connection between the hard plastic shell and plastic plate that pivots. See Ex. 1003, 4:13–5:34. Fisher does not explain adequately how (or even if) such a feature would have been incorporated into Barnett's structure or how its modified mask would maintain its seal. Considering Ogden's disclosure as a whole, we find that it weighs against the proposed modification.

As a final point, we note that the Petition fails to address whether its modified structure, based on the teachings of Ogden, would include a molded material that interfaces with Barnett's collar, as required by claim 1. See Ex. 1001, 10:27–27. That is, neither Fisher nor Mr. Lordo indicate whether Ogden discloses a main body of a molded material and whether, once modified, the modified structure would satisfy the “molded material” limitation.⁸

In weighing all of the evidence for and against Fisher's proposed modifications of Barnett based on Ogden's teachings of a rigid shell forming the main body of a cushion module, we find that the evidence fails to show,

⁸ Mr. Lordo does testify that Namey and Ging disclose co-molding or over-molding a cushion and main body of a cushion module, but he fails to indicate whether Ogden discloses this molding process or how Namey's and Ging's teachings relate to his obvious position for the “more rigid material” limitation of claim 1 over Barnett and Ogden. See Ex. 1009 ¶ 64.

by a preponderance of the evidence, that a person having ordinary skill in the art would have modified Barnett as Fisher proposes.

Conclusion

We determine, based on the complete trial record, that Fisher fails to demonstrate, by a preponderance of the evidence, that it would have been obvious, based on Barnett alone, to make neck 46 and ribs 56 out of a material having more rigidity than the silicone face contacting portion of seal member 32. We also determine, based on the complete trial record, that Fisher fails to demonstrate, by a preponderance of the evidence, that it would have been obvious, based on the combination of Barnett and Ogden, to modify seal member 32 to incorporate a hard plastic material as taught by Ogden. We make this determination in consideration of two possible modifications: 1) replacing Barnett's neck 46 and ribs 56 with the hard plastic of Ogden's shell 3 or 2) substituting shell 3 for the rib-contacting and neck portions of seal member 32.

Accordingly, we determine that Fisher fails to demonstrate, by a preponderance of the evidence, that claim 1 is unpatentable under 35 U.S.C. § 103 over Barnett and Ogden.

b. Dependent claims 2, 4, and 7.

Claims 2, 4, and 7 depend directly from claim 1. Ex. 1001, 10:32–11:21. In asserting that claims 2, 4, and 7 are unpatentable over Barnett and Ogden, Fisher relies on its positions with respect to how the combination of Barnett and Ogden renders claim 1 obvious. See Pet. 49 (addressing claim 2), 50–51 (addressing claim 4), 52 (addressing claim 7). For the reasons provided above in connection with our analysis of claim 1 over Barnett and Ogden, we determine that Fisher fails to demonstrate, by a preponderance of

the evidence, that claims 2, 4, 7 are unpatentable under 35 U.S.C. § 103 over Barnett and Ogden.

c. Claims 14–16 and 19.

Independent claim 14 recites, in relevant part, “wherein the molded material of the main body is a more rigid material than the molded silicone material of the cushion.” Ex. 1001, 13:7–9. Fisher references its positions with respect to claim 1 for how this requirement is satisfied by the combination of Barnett and Ogden. Pet. 36. As discussed above in connection with our analysis of claim 1, we determine, based on the complete record, that Fisher fails to demonstrate, by a preponderance of the evidence, that it would have been obvious, based on the teachings of Barnett alone or the combination of Barnett and Ogden, to make Barnett’s neck 46 and ribs 56 from a more rigid material than the silicone of the face-contacting portion of seal member 32.

Accordingly, we determine that Fisher fails to demonstrate, by a preponderance of the evidence, that claim 14 is unpatentable under 35 U.S.C. § 103 over Barnett and Ogden.⁹

Claims 15, 16, and 19 depend, directly or indirectly, from independent claim 14. Ex. 1001, 13:11–41. In asserting that claims 15, 16, and 19 are unpatentable over Barnett and Ogden, Fisher relies on its positions with respect to how the combination of Barnett and Ogden renders claims 1 and 14 obvious. See Pet. 33–37 (addressing claim 14), 49 (addressing claim 15),

⁹ Claim 14 also includes, among other limitations, a requirement that the “cushion module snap-fit to the frame module.” Ex. 1001, 12:54. We address this subject matter and the parties dispute as to this subject matter in connection with our analysis of claim 61, *infra*.

53 (addressing claim 16), 54 (addressing claim 19). For the reasons provided above in connection with our analysis of claims 1 and 14 over Barnett and Ogden, we determine that Fisher fails to demonstrate, by a preponderance of the evidence, that claims 15, 16, and 19 are unpatentable under 35 U.S.C. § 103 over Barnett and Ogden.

d. Claims 22, 23, 25, and 29.

Independent claim 22 recites, in relevant part, “the molded material of the main body is a more rigid material than the molded silicone material of the cushion.” Ex. 1001, 14:8–10. Fisher references its positions with respect to claim 1 for how this requirement is satisfied by the combination of Barnett and Ogden. *See* Pet. 37–43. As discussed above in connection with our analysis of claim 1, we determine, based on the complete record, that Fisher fails to demonstrate, by a preponderance of the evidence, that it would have been obvious, based on the teachings of Barnett alone or the combination of Barnett and Ogden, to make Barnett’s neck 46 and ribs 56 from a more rigid material than the silicone of the face-contacting portion of seal member 32.

Accordingly, we determine that Fisher fails to demonstrate, by a preponderance of the evidence, that claim 22 is unpatentable under 35 U.S.C. § 103 over Barnett and Ogden.

Claims 23, 25, and 29 depend directly from independent claim 22. Ex. 1001, 14:28–15:63. In asserting that claims 23, 25, and 29 are unpatentable over Barnett and Ogden, Fisher relies on its positions with respect to how the combination of Barnett and Ogden renders claims 1 and 22 obvious. *See* Pet. 37–43 (addressing claim 22), 49 (addressing claim 23), 50 (addressing claim 25), 54 (addressing claim 29). For the reasons

provided above in connection with our analysis of claims 1 and 22 over Barnett and Ogden, we determine that Fisher fails to demonstrate, by a preponderance of the evidence, that claims 23, 25, and 29 are unpatentable under 35 U.S.C. § 103 over Barnett and Ogden.

e. Claims 32, 35, 36, 43, 45–47, 49, and 52.

Independent claim 32 recites, in relevant part, “a cushion module comprising a cushion of one material adapted to form a seal with the patient’s face, and a main body of a different, more rigid material.” Ex. 1001, 16:11–15. Fisher references its positions with respect to claim 1 for how this requirement is satisfied by the combination of Barnett and Ogden. *See* Pet. 43.

As discussed above in connection with our analysis of claim 1, we determine, based on the complete record, that Fisher fails to demonstrate, by a preponderance of the evidence, that it would have been obvious, based on the teachings of Barnett alone or the combination of Barnett and Ogden, to make Barnett’s neck 46 and ribs 56 from a more rigid material than the silicone of the face-contacting portion of seal member 32.

Accordingly, we determine that Fisher fails to demonstrate, by a preponderance of the evidence, that claim 32 is unpatentable under 35 U.S.C. § 103 over Barnett and Ogden.

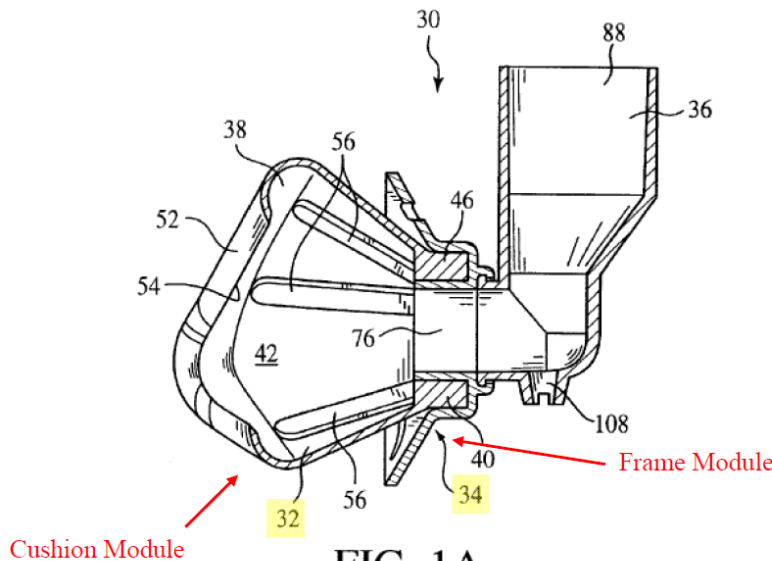
Claims 35, 36, 43, 45–47, 49, and 52 depend, directly or indirectly, from independent claim 32. Ex. 1001, 16:34–17:22. In asserting that claims 35, 36, 43, 45–47, 49, and 52 are unpatentable over Barnett and Ogden, Fisher relies on its positions with respect to how the combination of Barnett and Ogden renders claims 1 and 32 obvious. *See* Pet. 43–45 (addressing claim 32), 55–56 (addressing claim 35), 56 (addressing claim 36), 57

(addressing claim 43), 57 (addressing claim 45), 58–59 (addressing claim 46), 60 (addressing claim 47), 61 (addressing claim 49), 62 (addressing claim 52). For the reasons provided above in connection with our analysis of claims 1 and 32 over Barnett and Ogden, we determine that Fisher fails to demonstrate, by a preponderance of the evidence, that claims 35, 36, 43, 45–47, 49, and 52 are unpatentable under 35 U.S.C. § 103 over Barnett and Ogden.

f. Independent claim 61.

“frame module” limitation

Claim 61 recites “[a] full-face mask system . . . comprising: a frame module.” Ex. 1001, 19:1–4 (the “frame module” limitation of claim 61). Fisher contends that Barnett’s collar 34 corresponds to the recited frame module. Pet. 20–21, 46 (referencing the analysis of claim 1 for the frame module limitation of claim 61). We find, based on the complete record, that the Petition adequately demonstrates that Barnett discloses the recited frame module. *See id.*; Ex. 1002, Figs. 1A, 1C, 4B, 6 (depicting collar 34). We reproduce one of Fisher’s annotated versions of Barnett’s Figure 1A, below.



Pet. 21. This annotated figure indicates seal module 32 as the cushion module and collar 34 as the frame module. *See also* Ex. 1009 ¶ 52 (presenting annotated versions of Barnett’s Figs. 1A and 4A, showing collar 34 as the frame module). ResMed does not dispute Fisher’s position with respect to Barnett disclosing a frame module.

“cushion module” limitation

Claim 61 also recites “a cushion module that engages the frame module, the cushion module including a main body and a full-face cushion adapted to engage the patient’s face generally along nasal bridge, cheek, and chin regions of the patient’s face, the main body at least partly defining a breathing chamber.” Ex. 1001, 19:5–10 (the “cushion module” limitation of claim 61). Fisher contends that Barnett’s seal member 32 corresponds to the recited cushion module. Pet. 21, 46–47 (referencing the analysis of claim 1 for aspects of the “cushion module” limitation of claim 61). Fisher explains that seal member 32 is attached to collar 34 (the asserted frame module) and is adapted to seal with a patient’s face. *Id.* at 21.

Fisher explains that Barnett’s seal member 32 defines nose receiving cavity 32 (the apparent breathing cavity) and that neck portion 46 and ribs 56 (the asserted main body) at least partially form the cavity, as they are part of sealing member 32. Pet. 26.

As to the requirement for a “full-face cushion,” Fisher contends that Barnett discloses that both nasal and full-face masks are used for pressure support therapies. Pet. 46 (referencing Ex. 1002, 1:26–29). We find, based on the complete record, that Fisher fails to demonstrate, by a preponderance of the evidence, that Barnett expressly discloses that sealing member 32 includes a full-face cushion. Barnett expressly discloses that sealing

member 32 is part of *nasal* mask assembly 30. Ex. 1002, 3:48–52. Barnett also discloses that “[s]eal member 38 is sized such that at least the distal end portion of the patient’s nose, including the patient’s nares, are disposed within nose receiving cavity 42.” *Id.* at 4:5–8. We determine that Fisher’s reference to a “nasal/oral mask” in the Background of the Invention is insufficient to demonstrate, by a preponderance of the evidence, that Barnett discloses a full-face cushion. *See* Pet. 47; Ex. 1002, 1:26–29.

Alternatively, Fisher contends that a person having ordinary skill in the art “would have known that nasal mask features and designs are generally interchangeable with full-face masks.” Pet. 46–47 (referencing Ex. 1009 ¶ 79). Fisher indicates that both Ogden and the ’556 patent support this contention. *Id.* at 47. Fisher states that “Ogden discloses that nasal mask features are ‘equally applicable to full face masks covering the patient’s nose and mouth’” and that “[t]he ’556 [p]atent itself recognizes that the disclosed full-face embodiments may be adapted for use as nasal masks.” *Id.* (referencing Ex. 1003, 2:46–50; Ex. 1001, 2:48–51). Mr. Lordo also declares that “Gunaratnam teaches that a breathing mask can be provided in nasal or full-face forms.” Ex. 1009 ¶ 79 (referencing Ex. 1007, 6:3–7).

We interpret Fisher’s position to be that modifying a mask from a nasal mask to a full-face mask represents a simple substitution—nasal mask configuration for a larger, full-face configuration—and this substitution would have been within the level of ordinary skill with a reasonable expectation of success. We determine, on the complete record, that Fisher demonstrates, by a preponderance of the evidence, that it would have been obvious to substitute a full-face mask configuration for a nasal mask configuration. *See KSR Int’l Co.*, 550 U.S. at 416 (“The combination of

familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.”). ResMed does not dispute Fisher’s contention.

“elbow” limitation

Claim 61 also recites “an elbow directly attached to the frame module in a rotatable manner such that the elbow and the frame module are 360° rotatable, the elbow being adapted to be connected to an air delivery tube to deliver breathable gas to the patient.” Ex. 1001, 19:11–15 (the “elbow” limitation of claim 61). Fisher contends that Barnett’s elbow module 36 corresponds to the recited elbow. Pet. 22 (providing analysis of how Barnett discloses the “elbow” limitation of claim 1), 47 (referencing its analysis of the “elbow” limitation of claim 1 for claim 61). Fisher explains that Barnett discloses that elbow module 36 “‘rotates over a range of 360° about a central axis’ of the frame module 34.” *Id.* at 22 (citing Ex. 1002, 3:52–57). Fisher explains that “elbow module 36 is attached to [] air delivery tube 92 ‘which carries a flow of breathing gas generated by [] flow generating device 94, such as a ventilator or pressure support device, to nasal mask assembly 30.’” *Id.* at 23 (citing Ex. 1002, 8:48–54). Fisher annotates Barnett’s Figs. 1A and 1B to indicate the elbow module. *See id.* at 22 (showing the annotated figures). We find, on the complete record, that Barnett discloses the “elbow” limitation of claim 61. *See* Ex. 1002, 3:52–57 (indicating that coupling member 36 (the asserted elbow) is mounted on collar 34 (the asserted frame module) and freely rotates about 360°), 8:48–55 (“Conduit coupling portion 88 attaches conduit coupling member 36 to a patient circuit 92, such as a flexible conduit, which carries a flow of breathing gas generated by a flow generating device 94, such as a ventilator or pressure

support device, to nasal mask assembly 30.”). ResMed does not dispute Fisher’s contentions with respect to the “elbow” limitation of claim 61.

“headgear” limitation

Claim 61 also requires “headgear directly or indirectly attachable to the frame module in a removable manner.” Ex. 1001, 19:16–17 (the “headgear” limitation of claim 61). Fisher contends that Barnett’s collar 34 (the asserted frame module) includes cutouts 84 to attach headgear. Pet. 24 (analyzing the “headgear” limitation of claim 1), 47 (referencing the analysis of the “headgear” limitation of claim 1 for claim 61). We find, on the complete record, that Barnett discloses headgear directly or indirectly attachable to the frame module in a removable manner. *See* Ex. 1002, 7:45–8:37 (explaining the function of cutouts 84 to receive headgear straps), Fig. 4A (depicting collar 34 (the asserted frame module) with cutouts 84 to connect headgear). ResMed does not dispute Fisher’s contentions with respect to the “headgear” limitation.

“snap-fit” limitation

Claim 61 recites “the frame module and the main body are joined with a snap-fit.” Ex. 1001, 19:17–19 (the “snap-fit” limitation of claim 61). Fisher contends that Barnett discloses this “snap-fit” subject matter. Pet. 33–34 (providing an analysis of the “snap-fit” limitation of claim 14), 48 (referencing its analysis of the “snap-fit” limitation of claim 14 for claim 61). Fisher explains that Barnett’s collar 34 (the asserted frame module) includes retaining portion 76, which engages neck portion 46 (part of the asserted main body) of sealing member 32 with a friction fit. *Id.* at 33. Fisher explains that Barnett discloses that its friction fit engagement may be replaced by a tongue-and-groove engagement between neck portion 46 and

collar 34. *Id.* at 34 (referencing Ex. 1002, 7:28–33). Fisher contends that “[a] person of [ordinary] skill would have recognized that the interlocking structures of the tongue and groove of Barnett would provide a snap-fit” between neck portion 46 and collar 34. *Id.* (referencing Ex. 1009 ¶ 70).

Mr. Lordo declares that such a person “would have understood such a tongue and groove structure to include an annular protrusion that can deflect or deform during attachment and then engages an annular groove or recess.” Ex. 1009 ¶ 70. Mr. Lordo continues that “[t]his tongue and groove structure would be configured to hold the cushion and frame parts in the assembled position to prevent the cushion module from being pulled off the frame module [and that] Barnett recognizes that tongue and groove structures provide interlocking components.” *Id.*

As it is relevant to the parties’ dispute, we reproduce the entire paragraph of Barnett describing how neck portion 46 of seal member 32 connects with collar 34:

In the illustrated embodiment, first mounting member 76 is sized and configured to insert within second opening 48 in neck portion 46 of seal member 32 with the friction between first mounting member 76 and neck portion 46 preventing the seal member from being readily pulled off of the collar. It is to be understood, however, that the present invention contemplates other configurations for coupling collar 34 and seal member 32. For example, neck portion 46 of seal member 32 and mounting member 76 of collar 34 can be configured such that the neck portion inserts within mounting member rather than mounting member 76 inserting within neck portion 46, as shown. *In addition, a tongue and groove or other coupling structure can be provided on neck portion 46 of seal member 32 and mounting member 76 of collar 34 to maintain the neck portion in an engaged relation with the mounting member in addition to or in place of the friction engagement discussed above.*

Ex. 1002, 7:17–33 (emphasis added). We also reproduce the two paragraphs directly following the above paragraph, as it is relevant to one of ResMed’s arguments:

To prevent rotational movement of seal member 32 relative to collar 34, mounting member 76 includes a plurality of protrusions 80 and neck portion 46 includes an equal number of channels 82 adapted to receive protrusion 80 when seal member 32, 32’ is properly positioned on collar 34. In addition to preventing rotation of seal member 32 relative to collar 34, protrusions 80 and channels 82 serve as guides for properly locating seal member 32, 32’ on collar 34. Thus, it is preferable that protrusions 80 and channels 82 are configured and arranged such that they only align if seal member 32, 32’ is properly positioned relative to collar 34.

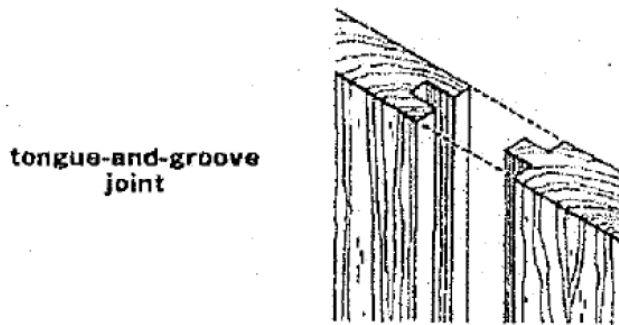
While FIG. 4A illustrates four (4) protrusions 80 symmetrically disposed on mounting member 76 and FIGS. 1B and 3B illustrate four (4) channels 82 symmetrically disposed in the neck portions of seal members 32 and 32’, respectively, it is to be understood that the present invention contemplates other configurations for protrusions 80 and channels 82, as well as increasing or decreasing the number of protrusions 80 and channels 82. *For example, the present invention contemplates that a single protrusion and a single associated channel is sufficient to provide the rotation prevention and guide functions discussed above.* In addition, the present invention contemplates reversing the placement of protrusions 80 and channels 82 so that the protrusion(s) is provided on the seal member and the reciprocal channel(s) is defined in the mounting member, or combinations thereof.

Id. at 7:34–59 (emphasis added); *see also id.* at Figs. 2A, 3A, 3B (depicting channels 82), Fig. 4A (depicting protrusions 80).

ResMed argues that Barnett’s disclosure of a tongue and groove connection between seal member 32 and collar 34 is not a snap-fit connection. PO Resp. 18. ResMed complains that “[t]he Petition relies on

no meaningful documentary evidence, and instead solely relies on conclusory and self-serving statements from the Petition, which are copied with no additional explanation in Lordo Declaration.” *Id.*

First, ResMed argues that the ordinary use of the term “tongue and groove” does not support Fisher’s interpretation of Barnett’s disclosure. PO Resp. 19. ResMed argues that general dictionaries define “tongue and groove” as “a joint *between two boards* in which a raised area on the edge of one board fits into a corresponding groove in the edge of the other to produce a flush surface,” (citing Ex. 2005, 1994) and “joint made by a tongue *on one edge of a board* fitting into a corresponding groove on the edge of another board” (citing Ex. 2006, 1242). *Id.* (emphasis added). ResMed provides a depiction of a tongue and groove connection provided in Ex. 2005, which we reproduce below:



Id. at 20 (referencing Ex. 2005, 1994; Ex. 2003 ¶ 32). ResMed asserts that “[e]ngineering and scientific dictionaries from the relevant time frame provide similar definitions” of tongue and groove. *Id.* (referencing Ex. 2007, 519; Ex. 2008, 2041; Ex. 2003 ¶ 33). ResMed argues that this extrinsic evidence demonstrates that a person having ordinary skill in the art would understand a tongue and groove connection as not constituting a snap fit.

Fisher replies that ResMed's use of dictionary definitions "involve a different context than the tongue and groove contemplated by Barnett – planar boards vs. overlapping cylinders – and therefore do not describe [Barnett's tongue and groove's] particular function." Reply 3–4. As Fisher explains, "[h]owever, the interrelation of such a tongue that fits within a groove would result in a snap-fit if implemented *in the context of Barnett* and taking into consideration the direction of assembly." *Id.* at 4 (emphasis added). Fisher explains that "Barnett states that the tongue and groove 'maintain[s] the neck portion in an engaged relation with the mounting member in addition to or in place of the friction engagement discussed above.'" *Id.* (referencing Ex. 1002, 7:28–34).

We find that the weight of the evidence supports Fisher's position. We agree that ResMed's dictionary definitions are inapposite to Barnett's disclosure, as they concern a tongue and groove, side-to-side, connection of two flat boards, not two annular components. Barnett, however, discloses the connection of one annular structure with another annular structure. *See* Ex. 1002, 7:28–33.

Next, ResMed argues that Barnett's disclosure of a tongue and groove connection relied on by Fisher "is merely an introduction of the protrusion 80/channel 82 feature in the following two paragraphs of Barnett." PO Resp. 21 (referencing Ex. 1002, 7:17–60; Ex. 2003 ¶ 35). ResMed argues that the language in Barnett reproduced above that includes the reference to "tongue and groove" provides "that the 'tongue and groove or other coupling structure' is being provided 'in addition to or in place of' the *specific* frictional engagement between the annular surfaces of the neck portion 46 and the first mounting member 76 described earlier in that paragraph of

Barnett.” *Id.* at 23. ResMed continues that a person having ordinary skill in the art:

would have understood that the “in addition to or in place of” language means the tongue and groove coupling maintain engagement between the seal member 32 and the collar 34 either alone (“in place of”) or in combination with (“in addition to”) the specific frictional engagement between the annular surfaces of the neck portion 46 and the first mounting member 76.

Id. (referencing Ex. 2003 ¶ 38). We agree with ResMed’s characterization of the “in addition to or in place of” language. First, we find that Barnett expressly teaches that first mounting member 76 (of collar 34) and neck portion 46 are connected through a friction fit in the “illustrated embodiment.” *See* Ex. 1002, 7:10–21. In the same paragraph, Barnett discloses that “[i]n addition, a tongue and groove or other coupling structure can be provided on neck portion 46 . . . and mounting member 76.” *Id.* at 7:28–30. In that same portion of the paragraph, Barnett states that the purpose of the tongue and groove or other coupling structure is to “maintain the neck portion in an engaged relation with the mounting member in addition to or in place of the friction engagement.” *Id.* at 7:31–33. That is, the tongue and groove or other coupling structure may be used with the friction fit or instead of the friction fit to maintain the neck portion in engagement with the mounting member. In this way, Barnett discloses three alternative embodiments: 1) a friction engagement between first mounting member 76 and neck portion 46 (the “illustrated embodiment”); 2) a tongue and groove or some other coupling structure coupling first mounting member 76 and neck portion 46; or 3) a friction engagement *and* a tongue and groove or some other coupling structure coupling first mounting member 76 and neck portion 46.

This understanding is consistent with Fisher’s interpretation of Barnett—indeed, it is the basis for Fisher’s snap-fit contention. *See* Pet. 33–34; Ex. 1009 ¶ 70. Mr. Lordo declares:

Barnett also teaches that a tongue and groove structure can be provided on main body portion 46 of the cushion module and the retaining portion 76, *in addition to or in place of the friction engagement*. A person of skill in the art would have understood such a tongue and groove structure to include an annular protrusion that can deflect or deform during attachment and then engages an annular groove or recess. This tongue and groove structure would be configured to hold the cushion and frame parts in the assembled position to prevent the cushion module from being pulled off the frame module. Barnett recognizes that tongue and groove structures provide interlocking components. A person of ordinary skill in the art would have recognized that this frame module 34 that removably attaches to a cushion module 32 by way of a tongue and groove connection provides a snap-fit attachment.

Ex. 1009 ¶ 70 (emphasis added). We credit Mr. Lordo’s testimony as it is consistent with the plain language of Barnett.

ResMed continues that “Barnett’s very next sentence [after the ‘in addition to or in place of the friction engagement’ language] mentions the protrusions 80 and the channels 82 *for the first time*.” POResp. 24 (referencing Ex. 1002, 7:35–40). ResMed argues that a person having ordinary skill in the art “would have understood that the protrusions 80 and channels 82 are ‘tongue and groove’ in accordance with the ordinary usage of this phrase, as described above in the analysis of the dictionary definitions (i.e, a sliding/frictional fit between the mating surfaces—not a ‘snap-fit’ as recited in the claims).” *Id.* (referencing Ex. 2003 ¶¶ 35–38).

In support of this reading of Barnett, ResMed argues that Mr. Lordo agrees that a person having ordinary skill in the art would interpret

protrusions 80 and channels 82 as tongue and groove couplings. PO Resp. 24 (referencing Ex. 2004, 41:23–42:2). We find, however, that this testimony provides little support to ResMed’s position, as it concerns protrusions 80 and channels 82 in the abstract, not whether protrusions 80 and channels 82 are the tongue and groove coupling structure disclosed in Barnett.

ResMed cites to Mr. Sleeper’s declaration for additional support. See PO Resp. 24 (referencing Ex. 2003 ¶¶ 35–38). Mr. Sleeper testifies that “it is clear that a [person having ordinary skill in the art] would have understood that ‘tongue and groove’ ([Ex. 1002,] 7:28–29) is referencing the protrusions 80 and channels 82 (or similar structures) based on the ordinary use of this term, as described above with regard to the dictionary definitions of tongue and groove.” Ex. 2003 ¶ 37. Mr. Sleeper continues that “there is no discussion in Barnett with regard to ‘tongue and groove’ ([Ex. 1002,] 7:28–29) of an annular protrusion or an annular groove, or any structures that would form an interference, deflection, and at least a substantial elastic recovery that typifies a snap-fit.” *Id.*

Fisher replies that “Barnett never states or suggests that this additional tongue and groove is the protrusions 80 and channels 82, but instead uses different names for these features, which are discussed in different paragraphs.” Reply 6. Fisher argues that “Barnett discusses the protrusions 80 and channels 82 in a paragraph that only describes these features as functioning to prevent relative rotation, not to maintain the parts in an engaged axial relation.” *Id.* (referencing Ex. 1002, 7:35–45). Fisher continues that, “[i]n contrast, the paragraph describing the tongue and groove discusses a friction fit and other configurations for retaining the

module connection, the tongue and groove being an additional or alternative option.” *Id.* (referencing Ex. 1002, 7:17–34).

We are not persuaded in a deficiency in Fisher’s position by ResMed’s argument, as we determine that ResMed misinterprets Barnett’s disclosure. First, as Fisher points out, the discussion of protrusions 80 and channels 82 are in a separate paragraph from the discussion of the tongue and groove coupling structure. *See* Ex. 1002, 7:28–35. Also, we do not credit ResMed’s argument or Mr. Sleeper’s testimony as it ignores the plain language in Barnett. Barnett begins the discussion of protrusions 80 and channels 82 by stating “[t]o prevent rotational movement of seal member 32 relative to collar 34, mounting member 76 includes a plurality of protrusions 80 and neck portion 46 includes an equal number of channels 82 adapted to receive protrusion 80.” *Id.* at 7:35–38. That is, the clear, unambiguous language of Barnett states the purpose of protrusions 80 and channels 82—to prevent relative rotation between seal member 32 and collar 34. Neither ResMed nor Mr. Sleeper accounts for this discussion. *See, e.g.*, Ex. 2003 ¶¶ 35–37 (not addressing the “[t]o prevent rotational movement” language); *cf. id.* ¶ 22 (stating that “channels 82 and the protrusions 80 are designed so that they line up with each other as the collar 34 slides onto the seal member 32 to prevent rotation of the collar 34 with regard to the seal member 32” without stating that these structures are used to couple seal member 32 with collar 34). Barnett also discloses that protrusions 80 and channels 82 function to properly align seal member 32 and collar 34 and that a single protrusion 80/channel 82 would be sufficient both to align the components and prevent relative rotation. *See* Ex. 1002, 7:40–56. This wording makes clear that Barnett does not consider protrusions 80 and channels 82 as the

tongue and groove structure for maintaining engagement between neck 46 and collar 34.

Further, Barnett makes clear that the tongue and groove coupling structure is an *additional* structure to the illustrated embodiment—that is, it is not in the illustrated embodiment. *See* Ex. 1002, 7:17–34. However, protrusions 80 and channels 82 *are in the illustrated embodiment*. *See, e.g., id.* at Figs. 1B, 2A, 2B, 3A, 3B, 4A, 4B (each depicting one or more protrusions 80 or channels 82). That is, the illustrated embodiment would not depict a tongue and groove coupling structure, as it is an additional structure. Because Barnett’s depicted embodiment includes protrusions 80 and channels 82, these structures cannot be the disclosed tongue and groove coupling structure. *See id.*

ResMed also argues that additional references to “tongue and groove” in Barnett supports its reading. PO Resp. 25–30. ResMed argues that the connection between flanges 100 and 102, which connects male mating member 98 with female mating member 96 (which Mr. Lordo testified would be like the annular tongue and groove connection between neck 46 and first mounting member 76), is distinct from a “tongue and groove” connection as Barnett uses the term. *Id.* at 25–27. ResMed explains that Barnett discloses that a “tongue and groove” connection would be an alternative engagement mechanism to flanges 100 and 102. *Id.* at 27–28.

Fisher replies that “Mr. Lordo explained that this second instance suggests that ‘you can also use a tongue and groove in another arrangement between 98 and 96,’ and it ‘doesn’t disavow that the annular snap is a tongue and groove.’” Reply 7 (referencing Ex. 2004, 48:21–49:17).

We find that this second reference to “tongue and groove” does not support ResMed’s reading of Barnett. Flanges and tongue-and-groove structures have similarities, but are also different, distinct structures, such that one may be an alternative to another. As seen in Barnett’s Figure 7, flanges 100 and 102 are structures that, *at the end of one leg of a structure*, forms roughly a right angle with that leg. This depiction of a flange is consistent with our understanding of what constitutes a “flange.” In contrast, the tongue component of a tongue and groove structure may form roughly a right angle on the leg at a position other than the edge. *See, e.g.*, PO Resp. 20 (showing tongue in the middle of the end of a board).

These two types of structures are distinct as to where the protruding element (flange end or tongue) would interface the mating component. The flange structure would interface the mating component closer to the end than the tongue and groove component. In this way, the structures are different. However, they both have similarities. Importantly, they both allow for rotation of conduit coupling member 36. *See* Ex. 1002, 9:12–43. They both would also snap into place, as the projection would deflect, then recover, when inserted into a groove.

ResMed argues that Barnett’s use of the term “tongue and groove” in its claims supports ResMed’s interpretation that protrusions 80 and channels 82 represent the referred-to tongue and groove coupling structure. PO Resp. 28–30. ResMed argues that Barnett’s claims 1 and 14, from which claims 8 and 21 depend, require a friction fit. *Id.* at 28; *see also* Ex. 1002, 11:4–8 (reciting “a neck portion that is sized and configured so as to selectively engage the mounting member of the collar and to remain engaged therewith due to friction between the neck portion and the mounting member”), 12:38–

42 (reciting “a neck portion that is sized and configured so as to selectively engage the mounting member of the collar and to remain engaged therewith due to friction between the neck portion and the mounting member”).

ResMed argues that claims 8 and 21 demonstrate that “tongue and groove” is a narrower species of friction fit. PO Resp. 28–29. ResMed argues that a person having ordinary skill in the art would have understood from this claim structure “that Barnett’s ‘tongue and groove’ assembly is a frictional engagement in accordance with the ordinary usage of this phrase, as described above in the analysis of the dictionary definitions.” *Id.* at 29 (referencing Ex. 2003 ¶ 42).

ResMed’s argument concerning Barnett’s use of the phrase “tongue and groove” in its claims does not inform us of a deficiency in Fisher’s position, as ResMed improperly interprets the claim language. Barnett’s claim 8 recites “[a] patient interface device according to claim 1, wherein the neck portion and the mounting member *include* a tongue and groove assembly.” Ex. 1002, 11:52–54 (emphasis added). Similarly, Barnett’s claim 21 recites “[a] system according to clam [sic] 14, wherein the neck portion and the mounting member include a tongue and groove assembly.” *Id.* at 13:22–24. This claim language does not indicate that a tongue and groove is a narrowing species of a friction fit. Instead, it merely requires the neck portion and the mounting member to *include* a tongue and groove assembly and Barnett expressly discloses a configuration with *both* a friction fit *and* a tongue and groove coupling structure. *See id.* at 7:17–34. ResMed improperly reads claims 8 and 21 to recite something more than the plain language suggests, such as “wherein the friction engagement is accomplished using a tongue and groove assembly.”

Based on our review of the complete evidence of record, we find, based on a preponderance of the evidence, that Barnett discloses the “snap-fit” limitation of claim 61. We agree with Fisher and Mr. Lordo that a person having ordinary skill in the art would understand Barnett’s reference to a “tongue and groove” is an annular tongue and groove that would require the tongue to deflect then return in a snap-fit. See Ex. 1009 ¶¶ 67–71. We credit Mr. Lordo’s testimony as it is consistent with the plain language in Barnett. Barnett is clearly discussing an alternative or additional *coupling structure* to its illustrated friction fit between neck portion 46 and collar 34. See Ex. 1002, 7:17–34. Neck portion 46 and collar 34 join at overlapping cylindrical, or annular, structures. See *id.* at 7:17–21; see also Figs. 3A and 4A (showing cylindrical structures), 6 (showing seal member 32 coupled with collar 34). Given that these mating structures are cylindrical or annular, the type of tongue and groove connection would be an annular tongue and groove, which would require a snap-fit to join. See Ex. 1009 ¶¶ 70–71. Barnett’s clear disclosure that protrusions 80 and channels 82 function to prevent rotation between seal member 32 and collar 34 and align these components, with absolutely no tie of this disclosure to its disclosure of a tongue and groove coupling structure, further supports Mr. Lordo’s and Fisher’s interpretation of Barnett. Again, as we find Mr. Sleeper’s testimony to ignore the express language in Barnett concerning protrusions 80 and channels 82, we do not credit his testimony.

Fisher provides an alternative basis for addressing the “snap-fit” limitation of claim 61, stating that “[t]o the extent Barnett does not sufficiently disclose a snap-fit between the frame module and cushion module, such connections were common knowledge of a person of skill at

the time of the invention.” Pet. 35. As we find that Barnett sufficiently discloses the “snap-fit” limitation of claim 61, we need not address this alternative.

“frame opening”

Claim 61 also requires that “the frame module includes an opening, the elbow including a distal end inserted into the opening of the frame module to retain the elbow with the frame module” (the “frame opening” limitation of claim 61) and also requires “the frame module and the main body having shapes that prevent relative rotation when the frame module is snap-fitted to the main body.” Ex. 1001, 19:20–25 (the “relative rotation” limitation of claim 61).

Fisher contends that “Barnett discloses that coupling portion 90 of the elbow module 36 is received by and attaches with coupling portion 78 of frame module 34.” Pet. 48 (citing Ex. 1002, 8:66—9:1). On the complete record, we find that Barnett’s collar 34 includes an opening and that coupling portion 90 of conduit coupling member 36 (the asserted elbow module) is inserted into the opening and retained by collar 34 as required by the “frame opening” limitation. *See, e.g.*, Ex. 1002, Fig. 4A (depicting opening in collar 34), Figs. 6 and 7 (depicting coupling portion 90 snap-fitting into opening of collar 34). ResMed does not dispute Fisher’s contentions with respect to the “frame opening” limitation of claim 61.

Fisher also contends that Barnett discloses that collar 34 and neck portion 46 have shapes that prevent relative rotation when the frame module is snap-fitted to the main body. Pet 27 (addressing the “relative rotation” limitation of claim 1), 49 (referencing the analysis of the “relative rotation” limitation of claims 1 and 14 for claim 61). Specifically, Fisher contends

that Barnett discloses “that main body portion 46 includes channels 82 adapted to receive protrusions 80 on the frame module 34 to prevent relative rotational movement.” Pet. 27 (referencing Ex. 1002, 7:34–39). Fisher explains that protrusions 80 and channels 82 are shapes such that they prevent relative motion between the frame module 34 and the cushion module 32. *Id.* We find, based on the complete record, that Barnett discloses the subject matter of the “relative rotation” limitation. *See, e.g.*, Ex. 1002, 7:35–40 (“To prevent rotational movement of seal member 32 relative to collar 34, mounting member 76 includes a plurality of protrusions 80 and neck portion 46 includes an equal number of channels 82 adapted to receive protrusion 80 when seal member 32, 32' is properly positioned on collar 34.”); *see also* Ex. 1009 ¶ 45 (describing the function of protrusions 80 and channels 82); Ex. 2003 ¶ 22 (“Barnett further describes that the seal member 32 and the collar 34 can use a spline-and-channel mating arrangement to prevent rotation of the collar 34 with regard to the seal member 32.”).

ResMed does not dispute Fisher’s contentions with respect to the “relative rotation” limitation of claim 61 (except for the “snap-fit” requirement, which we have addressed above).

Accordingly we determine, on the complete record, that Fisher has demonstrated, by a preponderance of the evidence, that claim 61 is unpatentable under 35 U.S.C. § 103 over Barnett and Ogden.

g. Dependent claim 64.

Claim 64 depends from claim 61 and recites:

wherein the mask system is provided with a plurality of differently sized cushion modules each having a full-face cushion and a main body, the main body of each cushion module

including a universal configuration for interfacing with the frame module, thus providing a modular arrangement that allows the frame module to be selectively and removably coupled to each of the plurality of differently sized cushion modules, and wherein the plurality of differently sized cushion modules include different size full-face cushions, including small, medium, and large.

Ex. 1001, 19:37–20:6. Fisher contends that Barnett discloses the recited subject matter of claim 64. Pet. 41–43, 63. Fisher contends that Barnett discloses sealing members 32, and 32' (the asserted cushion modules) that interface with collar 34. *Id.* at 41. Fisher explains that “[c]ushion module 32' includes a main body portion 46 that is ‘substantially the same size and configuration’ as main body portion 46 of cushion module 32 and can be used with the same frame module 34.” *Id.* (citing Ex. 1002, 6:1–14). Fisher further explains that cushion module 32' differs from module 32 in its size and shape, such that module 32' may be used for small adults and children. *Id.* at 42.

Fisher recognizes that Barnett does not disclose small, medium, and large sealing members 32. Pet. 42. Fisher contends that “[i]t was common knowledge of a person of skill in the art to provide . . . different-sized cushion modules, including small, medium, and large.” *Id.* (referencing Ex. 1009 ¶ 44). Fisher reasons that “[a] person of skill would have been motivated to provide different-sized, interchangeable cushions (*e.g.*, small, medium, and large) to accommodate different-sized patient populations.” *Id.* (citing Ex. 1002, 6:1–14; Ex. 1009 ¶ 44). Fisher continues that “[a] skilled artisan would have known that providing different-sized, interchangeable cushion modules to fit a common frame module would reduce the number of components required (as compared to distinct frame

module sizes to match distinct cushion module sizes).” *Id.* at 42–43 (referencing Ex. 1009 ¶ 44).

On the complete record, we find that Fisher has made the requisite showing that the subject matter of claim 64 would have been obvious over Barnett and Ogden. We find that Barnett expressly discloses including different sized sealing members to accommodate different sized faces. *See* Ex. 1002, 6:1–67. We also find that a person having ordinary skill in the art would have had reason to size sealing member 32, 32' as small, medium, and large. *See id.*; Ex. 1009 ¶ 44. We credit Mr. Lordo’s testimony as to the reason for modifying Barnett to arrive at a large, medium, and small mask, in part, as the modification is suggested by Barnett itself, which discusses the need for different mask sizes, and other prior art of record. *See* Ex. 1002, 6:1–6; *see also* Ex. 1008 ¶ 184 (indicating that Ging’s cushion is designed to accommodate most patients, preferably in one to three sizes).

ResMed does not dispute Fisher’s contentions with respect to claim 64.

Accordingly, we determine, based on the complete record, that Fisher has demonstrated, by a preponderance of the evidence, that claim 64 is unpatentable under 35 U.S.C. § 103(a) over Barnett and Ogden.

h. Conclusion as to claims 1, 2, 4, 7, 14–16, 19, 22, 23, 25, 29, 32, 35, 36, 43, 45–47, 49, 52, 61, and 64 as allegedly obvious over Barnett and Ogden.

For the reasons discussed above, we determine that Fisher fails to demonstrate, by a preponderance of the evidence, that claims 1, 2, 4, 7, 14–16, 19, 22, 23, 25, 29, 32, 35, 36, 43, 45–47, 49, and 52 are unpatentable under 35 U.S.C. § 103 over Barnett and Ogden. We also determine that

Fisher has demonstrated, by a preponderance of the evidence, that claims 61 and 64 are unpatentable under 35 U.S.C. § 103 over Barnett and Ogden.

2. Claims 6, 17, 18, 27, and 37–42 as allegedly obvious over Barnett, Ogden, and Lithgow

Claims 6, 17, 18, 27, and 37–42 depend, directly or indirectly, from independent claims 1, 14, 22, and 32. *See* Ex. 1001, 11:16–16:60. In asserting that these claims are unpatentable, Fisher relies, in part, on its positions as to why independent claims 1, 14, 22, and 32 are unpatentable. *See* Pet. 66–71.

As discussed above in connection with our analysis of claims 1, 14, 22, and 32 over Barnett and Ogden, we determine that Fisher fails to demonstrate, by a preponderance of the evidence, that these claims are unpatentable as obvious. Fisher does not assert that Lithgow cures the deficiencies we identified in our analyses. *See* Pet. 66–71.

Accordingly, we determine that Fisher fails to demonstrate, by a preponderance of the evidence, that claims 6, 17, 18, 27, and 37–42 are unpatentable under 35 U.S.C. § 103 over Barnett, Ogden, and Lithgow.

3. Claim 44 as allegedly obvious over Barnett, Ogden, and Namey

Claim 44 depends indirectly from claim 32. Ex. 1001, 16:63–64. In asserting that claim 44 is unpatentable, Fisher relies, in part, on its positions as to why independent claim 32 is unpatentable. *See* Pet. 73–74.

As discussed above in connection with our analysis of claim 32 over Barnett and Ogden, we determine that Fisher fails to demonstrate, by a preponderance of the evidence, that claim 32 is unpatentable as obvious. Fisher does not assert that Namey cures the deficiencies we identified in our analysis. *See* Pet. 73–74.

Accordingly, we determine that Fisher fails to demonstrate, by a preponderance of the evidence, that claim 44 is unpatentable under 35 U.S.C. § 103 over Barnett, Ogden, and Namey.

4. Claims 3, 24, 50, 51, 54, 57, 58, and 62 as allegedly obvious over Barnett, Ogden, and Jaffre

a. Claims 3, 24, 50, and 51

Claims 3, 24, 50, and 51 depend, directly or indirectly, from independent claims 1, 22, and 32. Ex. 1001, 10:40–17:18. In asserting that these claims are unpatentable, Fisher relies, in part, on its positions as to why independent claims 1, 22, and 32 are unpatentable. See Pet. 76–82.

As discussed above in connection with our analysis of claims 1, 22, and 32 over Barnett and Ogden, we determine that Fisher fails to demonstrate, by a preponderance of the evidence, that these claims are unpatentable as obvious. Fisher does not assert that Jaffre cures the deficiencies we identified in our analyses. See Pet. 76–82.

Accordingly, we determine that Fisher fails to demonstrate, by a preponderance of the evidence, that claims 3, 24, 50, and 51 are unpatentable under 35 U.S.C. § 103 over Barnett, Ogden, and Jaffre.

b. Claims 54, 57, and 58

Independent claim 54 recites, in relevant part, “the main body comprises a relatively harder material and the cushion comprises relatively softer material provided to the main body.” Ex. 1001, 17:65–67 (the “relatively harder material” limitation of claim 54). As discussed above in Section I.C, the parties agree that, in interpreting the claims, the subject matter encompassed by the “more rigid material” limitation of claim 1 is comparable to the subject matter encompassed by the “relatively harder material” limitation of claim 54. See Supp. Tr. 7:7–9, 15:5–7. In asserting

that claim 54 is unpatentable, Fisher relies on its analysis of how Barnett alone or the combined teaching of Barnett and Ogden renders the subject matter of the “more rigid material” limitation of claim 1 obvious in addressing the “relatively harder material” limitation of claim 54. Pet. 83.

As discussed above in connection with our analysis of claim 1 we determine that Fisher fails to demonstrate, by a preponderance of the evidence, that Barnett and Ogden renders obvious the “more rigid material” limitation of claim 1. Fisher does not assert that Jaffre cures the deficiencies we identified in our analysis. See Pet. 83.

Accordingly, we determine that Fisher fails to demonstrate, by a preponderance of the evidence, that independent claim 54 is unpatentable under 35 U.S.C. § 103 over Barnett, Ogden, and Jaffre.

Claims 57 and 58 depend, directly or indirectly, from claim 54. Ex. 1001, 18:32–41. In asserting that these claims are unpatentable, Fisher relies, in part, on its positions as to why independent claim 54 is unpatentable. See Pet. 86. Accordingly, for the reasons discussed above, we determine that Fisher fails to demonstrate, by a preponderance of the evidence, that claims 57 and 58 are unpatentable under 35 U.S.C. § 103 over Barnett, Ogden, and Jaffre.

c. Claim 62

Claim 62 depends from claim 61 and recites “a vent arrangement is provided for gas washout.” Ex. 1001, 19:27. Fisher contends that “Barnett discloses a vent 108 in the elbow module 36 that ‘allows the patient’s exhaled gases to escape to atmosphere.’” Pet. 77 (citing Ex. 1002, 10:22–23).

Claim 62 further requires “the elbow [to] include[] a swivel joint adapted to be connected to the air delivery tube.” Ex. 1001, 19:28–29. Fisher recognizes that Barnett does not expressly disclose a swivel joint connected to an air delivery tube. Pet. 79. Fisher contends that Ogden discloses such a structure and it would have been obvious to modify Barnett with the teachings of Ogden. *Id.* at 79–80. Specifically, Fisher contends that Ogden discloses that its tube 20, which is connected to section 16 of elbow 10, rotates relative to section 16. *Id.* at 79; *see also* Ex. 1003, 5:44–47 (“[T]ube 20 with the end of hose 12 press fit over it is mounted to the second rigid section 16 so the hose 12 and tube 20 can rotate relative to section 16 about a second axis 22.”), Fig. 8 (depicting elbow 10).

Fisher reasons that “[a] person of skill in the art at the time of the invention would have been motivated to provide the swivel joint of Ogden to the elbow of Barnett for additional freedom of movement relative to the patent interface assembly and to eliminate torque from the patient tubing.” *Id.* at 80 (referencing Ex. 1009 ¶ 120); *see also* Ex. 1003, 5:47–61 (discussing the benefit of allowing rotation of elbow about axes 18, 22, and 24).

Claim 62 further recites “the elbow includes an anti-asphyxia valve and a port that is selectively closed by a flap portion of the anti-asphyxia valve depending on the presence of pressurized gas.” Ex. 1001, 19:30–32. Fisher contends that Jaffre discloses an anti-asphyxia valve (AAV) with a flap portion. Pet. 82 (identifying AAV 68 with flap portion 90, as depicted in Jaffre’s Figures 8 and 9). Fisher reasons that a person having ordinary skill in the art would have had reason to modify Barnett with Jaffre’s AAV because “an AAV using a flap is advantageous because the flap easily

moves by airflow and pressure.” *Id.* (referencing Ex. 1009 ¶ 123). Fisher also states that “[a] person of skill at the time of the invention would have known to include an AAV as a safety precaution to provide breathable air to the user when the flow generator does not provide flow.” *Id.* at 78 (referencing Ex. 1009 ¶¶ 113–116).

Mr. Lordo explains that:

A person of skill in the art would have known that it is necessary to include an anti-asphyxia valve in full face mask systems. The risk of asphyxiation upon loss of mask pressurization was readily recognized in the art at the time of the invention. Indeed, the international standard for CPAP masks ISO 17510-2:2007 published in 2007 requires the use of an anti-asphyxia valve in full face masks, and such a feature was necessary for FDA clearance. This standard is widely used in the CPAP mask industry. The standard was public before the earliest priority date of the ’556 [p]atent and one of skill would have known of the standard before 2007. Prior to the alleged invention, CPAP products on the market, including Respironics’ Spectrum full-face mask, included an anti-asphyxia valve.

As such, a person of ordinary skill in the art at the time of the invention would have been motivated to provide an AAV with a flap portion as taught by Jaffre to the mask system of Barnett, or to use an elbow with an AAV as a safety precaution against asphyxiation, particularly when the flow generator does not provide flow.

Ex. 1009 ¶¶ 114–115.

We find, based on the entire record, that the combination of Barnett, Ogden, and Jaffre discloses the subject matter of claim 62. *See* Ex. 1002, 10:22–23 (disclosing exhaust port 108, which “allows the patient’s exhaled gases to escape to atmosphere”); Ex. 1003, 5:44–47 (disclosing that elbow 10 includes a swivel joint connecting air delivery tube 20); Ex. 1006, 7:21–10:46 (disclosing generally anti-asphyxia valve and a port closed by a flap

depending on the presence of pressurized gas, including valve member 68 and cantilever member 90), 10:11–22 (disclosing the function of cantilever 90 (the asserted flap) in response to changing pressures), Figs. 4–9 (depicting the structure and function of the AAV).

We also find, based on the complete record, that Fisher articulates reasons, with rational underpinnings, for its proposed modifications. We find, based on Fisher’s reasoning, which we adopt here, that a person having ordinary skill in the art would have been motivated to make the proposed modifications to Barnett’s elbow.

ResMed does not dispute Fisher’s contentions.

Accordingly, we determine that Fisher has demonstrated, by a preponderance of the evidence, that claim 62 is unpatentable under 35 U.S.C. § 103 over Barnett, Ogden, and Jaffre.

d. Conclusion as to claims 3, 24, 50, 51, 54, 57, 58, and 62

For the reasons discussed above, we determine that Fisher fails to demonstrate, by a preponderance of the evidence, that claims 3, 24, 50, 51, 54, 57, and 58 are unpatentable under 35 U.S.C. § 103 over Barnett, Ogden, and Jaffre. We also determine that Fisher has demonstrated, by a preponderance of the evidence, that claim 62 is unpatentable under 35 U.S.C. § 103 over Barnett, Ogden, and Jaffre.

5. Claims 33, 34, 48, 63, and 65 as allegedly obvious over Barnett, Ogden, and Gunaratnam

a. Claims 33, 34, and 48

Claims 33, 34, and 48 depend, directly or indirectly, from independent claim 32. Ex. 1001, 16:29–17:10. In asserting that these claims are unpatentable, Fisher relies, in part, on its positions as to why independent claim 32 is unpatentable. See Pet. 89–93.

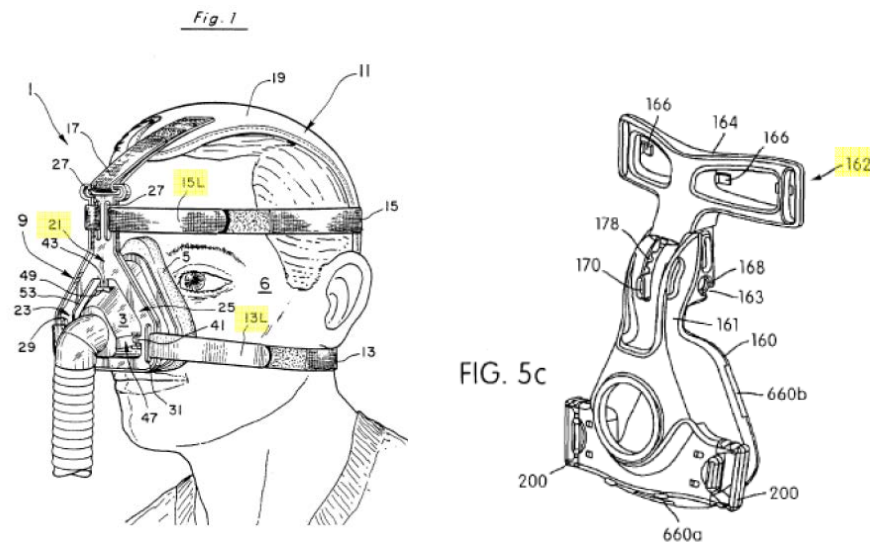
As discussed above in connection with our analysis of claim 32 over Barnett and Ogden, we determine that Fisher fails to demonstrate, by a preponderance of the evidence, that claim 32 is unpatentable as obvious. Fisher does not assert that Gunaratnam cures the deficiencies we identified in our analysis. *See* Pet. 89–93.

Accordingly, we determine that Fisher fails to demonstrate, by a preponderance of the evidence, that claims 33, 34, and 48 are unpatentable under 35 U.S.C. § 103 over Barnett, Ogden, and Gunaratnam.

b. Claims 63 and 65

Claim 63

Claim 63 depends from claim 61 and further recites “the frame module includes a forehead support and four headgear connectors that are attached to the frame module to connect with the headgear.” Ex. 1001, 19:33–36. Fisher contends that the combination of Barnett, Ogden, and Gunaratnam discloses the recited subject matter. Pet. 58–59, 89–90, 93. Fisher contends that both Ogden and Gunaratnam disclose forehead supports. *Id.* at 89–90. We reproduce Fisher’s annotated versions of Ogden’s Figure 1 and Gunaratnam’s Figure 5c, below.



Pet. 89–90. These annotations on these figures highlight Ogden’s frame with forehead section and straps and Gunaratnam’s forehead support.

Fisher reasons that “[a] person of skill in the art at the time of the invention would have been motivated to incorporate a forehead support, as taught by Ogden and Gunaratnam, into the mask of Barnett [to] stabilize the upper portion of the mask assembly.” *Id.* at 90 (referencing Ex. 1009 ¶ 131).

Mr. Lordo declares that

[a] person of skill in the art at the time of the invention would have been motivated to modify the mask assembly in Barnett to include forehead support as disclosed in Gunaratnam to stabilize the upper portion of the mask assembly and to provide a more secure attachment as the wearer moves during sleep.

Ex. 1009 ¶ 131.

Fisher contends that “Ogden discloses two upper headgear connectors 27 and two lower headgear connectors 29, 31 on each side of the frame module 9.” Pet. 58–59 (citing Ex. 1003, 3:2–7). Fisher reasons that “[a] person of skill in the art at the time of the invention would have been motivated to utilize upper and lower headgear connectors on each side of the frame module to provide additional support and reduce the likelihood of the

mask dislodging during sleep.” *Id.* at 59 (citing Ex. 1009 ¶ 85). Further, Barnett suggests that other headgear connections may be used with its frame. *See* Ex. 1002, 8:15–24 (providing, in part, that “the present invention contemplates that cutouts 84 can have any configuration suitable to attach a headgear to the collar”); Ex. 1009 ¶ 83. That is, Barnett expressly teaches that the number of headgear connectors may be modified to adapt to a headgear.

ResMed argues that “[t]he two purported reasons provided in the Petition to modify Barnett to incorporate the forehead support from Ogden or Gunaratnam were already accomplished by Barnett alone.” PO Resp. 47. With respect to the first reason (to stabilize the upper portion of the mask assembly), ResMed argues that “Barnett describes that the specific size and configuration of the circular collar 34 . . . and its three cutouts 84 shown in the Figures . . . is already stable and ‘provides a firm contact point’ for the relatively large headgear straps commonly used with patient interface device.” *Id.* at 48 (referencing Ex. 1002, 8:9–15).

Fisher replies that “ResMed provides no evidence that a forehead support would not improve the stability and provide a more secure attachment.” Reply 20. Fisher continues that “[a] ‘firm contact point’ does not suggest that the mask has achieved maximum stability or that a second contact point provided by a forehead support would not improve stability.” *Id.* Fisher also argues that Mr. Sleeper testified that a forehead contacting portion could improve mask stability. *Id.* at 21 (referencing Ex. 1018, 39:18–22).

Fisher asserts that “[t]he Petition and Mr. Lordo analyzed Barnett, Ogden, and Gunaratnam in detail and explained that a forehead support

would improve the stability and attachment of Barnett, as disclosed in the prior art.” Reply 21 (referencing Pet. 89–90; Ex. 1009 ¶¶ 130–131). Fisher adds that the masks designed and sold by Mr. Sleeper included forehead contacting portions. *Id.* (referencing Ex. 1018, 35:16–37:20).

ResMed also argues that Barnett achieves providing a more secure attachment as the wearer moves during sleep. PO Resp. 49. ResMed explains that “Barnett explicitly calls out concerns related to comfort and seal for ‘patient interface devices [being] typically worn for an extended period of time,’ such as concerns that stem from ‘the patient normally wear[ing] the patient interface device all night long while he or she sleep’” and that one of Barnett’s objectives was to overcome these concerns. *Id.* (referencing Ex. 1002, 1:33–45, 1:53–2:12).

We determine, on the complete trial record, that ResMed’s arguments fails to show a deficiency in Fisher’s reasoning. As Fisher correctly states, Barnett’s disclosure that its collar 34 with cutouts 84 provides a firm contact point does not cut against providing stability through a forehead support. We base our determination, in part, on Mr. Lordo’s testimony, which we credit as consistent with the evidence of record. *See, e.g.*, Ex. 1018, 39:18–22 (providing that a forehead support could provide stability), 35:16–37:20 (providing that masks designed and sold by Mr. Sleeper included, as an option, forehead supports).

ResMed also argues that modifying Barnett to include a forehead support would frustrate a main purpose of Barnett—to provide a small, lightweight mask that is comfortable and provides a good seal. PO Resp. 51. ResMed argues that Fisher’s proposed modification would add size and weight to Barnett’s mask. *Id.* ResMed explains that Barnett discloses that

its collar and the position of its three head gear connectors allows for seal member to be made small and provides a proper seal. *Id.* at 51–52. ResMed continues that Barnett explains that a small seal member is advantageous. *Id.* at 52.

Fisher replies that adding a forehead support would not change the size of the seal member, such that Barnett would still realize those advantages. Reply 22. Fisher continues that nothing in Barnett suggests that positioning cutouts 84 within the diameter of collar 34 is a purpose of Barnett. *Id.* Fisher concludes that ResMed fails to support that Barnett’s purpose is to be small and lightweight. *Id.*

Fisher argues that “[a]lthough Barnett discloses an embodiment without a forehead support, Barnett also recognizes that the collar 34 could be modified to have other headgear attachment points.” Reply 23. Fisher adds that modifying Barnett to add “a forehead support would not add significant weight or size. For example, Gunaratnam discloses a small nasal mask similar to Barnett that includes a forehead support that still allows the patient to see.” *Id.* (referencing Ex. 1007, Figs. 5a–5f).

We agree with Fisher that ResMed fails to demonstrate that a forehead support would frustrate the purpose of Barnett’s mask. Although we agree with ResMed that Barnett touts the benefits of a small *seal member* (see Ex. 1002, 4:54–65), ResMed fails to explain adequately how adding a forehead support would require a larger *seal member*. Although a forehead support would increase the overall weight and size of the mask, we interpret Barnett’s advantages as focusing on the *seal member*, not the overall mask.

ResMed also argues that Mr. Lordo testified that a commercial embodiment of Barnett’s mask employed headgear straps, rather than a

forehead support, to stabilize the mask. PO Resp. 54–55 (referencing Ex. 2004, 62:6–24). ResMed argues that this testimony supports a finding that “a [person having ordinary skill in the art,] would not have incorporated a forehead support into Barnett, and would have instead opted to use lighter and less obtrusive headgear straps.” *Id.* at 55 (referencing Ex. 2003 ¶ 59).

Fisher replies that ResMed mischaracterizes Mr. Lordo’s testimony. Fisher explains that “Mr. Lordo testified that the commercial [embodiment of Barnett’s mask] included ‘a forehead-contacting element’ that supported the headgear at the forehead.” Reply 24 (referencing Ex. 2004, 60:25–61:9). Fisher continued that “Mr. Lordo testified that the commercial Barnett headgear support structure may have simplified the *headgear* itself and not the actual mask, as providing a forehead support on the frame would not require additional parts.” *Id.* (referencing Ex. 2004, 62:20–22).

As an initial point, we determine that ResMed’s characterization of Mr. Lordo’s testimony is appropriate. Mr. Lordo clearly testifies that the “forehead contacting element” was a strap that came up from the collar. *See* Ex. 2004, 60:25–62:5. This testimony is consistent with Barnett itself, which shows a cutout 84 at the “12 o’clock” position on collar 34, which would support a strap that went up to the forehead between the wearer’s eyes and over the top of the head. *See* Ex. 1002, Fig. 4A.

We determine, however, the ResMed’s argument does not show a deficiency in Fisher’s position. The fact that a commercial embodiment of the mask in Barnett did not employ a forehead support structure does not mean that a person having ordinary skill in the art would not have had reason to modify Barnett’s mask.

In weighing all of the evidence and evaluating the supporting arguments, we determine that Fisher demonstrates, by a preponderance of the evidence, that a person having ordinary skill in the art would have had reason to modify Barnett's mask to include a forehead support for improved stability. Our determination is based, in part, on the prior art disclosure in Gunaratnam, which shows a forehead support on a small nasal mask, and other commercial uses of a forehead support. *See* Ex. 1007, Figs. 5a–5f; *see also* Ex. 1018, 5:16–37:20 (providing testimony from Mr. Sleeper that masks designed and sold by him included, as an option, forehead supports); Ex. 1019, 6, 11 (providing “agreed common knowledge” by the parties in a related United Kingdom dispute and stating that “[a] forehead support, if used, [stabilizes] the mask on the face, enabling a more consistent seal” but also including shortcomings of a forehead support). We also credit Mr. Lordo's testimony, which is consistent with Mr. Sleeper's deposition testimony. *See* Ex. 1009 ¶ 131; Ex. 1018, 39:18–22.

We are not persuaded that the proposed modification would defeat the overall purpose of Barnett as ResMed argues. PO Resp. 51–54. Barnett's purposes of comfort and a good seal are realized through its seal member 32 and ResMed fails to demonstrate persuasively that a forehead support would result in a larger, less comfortable, seal member 32. *See* Ex. 1002, 54–65.

Accordingly, we determine, on the complete record, that Fisher demonstrates, by a preponderance of the evidence, that claim 63 is unpatentable under 35 U.S.C. § 103 over Barnett, Ogden, and Gunaratnam.

Claim 65

Claim 65 depends from claim 61 and further recites “wherein the main body and full-face cushion together comprise an integrated component,

the main body comprising a molded polycarbonate material that interfaces with the frame module and the full-face cushion comprises a molded elastomeric material adapted to interface with patient's face." Ex. 1001, 20:7–12.

As a foundation to its position that claim 65 is unpatentable over Barnett, Ogden, and Gunaratnam, Fisher states that "[a]s discussed above, Barnett and Ogden disclose a more rigid main body material . . . , but do not expressly disclose a molded polycarbonate material." Pet. 94 (cross referencing its position with respect to the "more rigid material" limitation of claim 1).

As we discussed above in connection with our analysis of the "more rigid material" limitation of claim 1, we found Fisher's positions that Barnett alone or Barnett, in combination with Ogden, renders the subject matter of this limitation obvious, deficient. Fisher fails to explain adequately how Gunaratnam cures the deficiency. Fisher contends that "polycarbonate was one of a short-list of materials used in CPAP masks at the time of the invention" and that "Gunaratnam discloses that mask assembly components forming the breathing cavity *can* be constructed from polycarbonate." Pet. 94 (emphasis added). Fisher fails to explain persuasively, however, why a person having ordinary skill in the art *would have looked* to Gunaratnam for its teaching of polycarbonate other than the reasoning we analyzed in conjunction with the "more rigid material" limitation of claim 1.

Accordingly, we determine, on the complete record, that Fisher fails to demonstrate, by a preponderance of the evidence, that claim 65 is unpatentable under 35 U.S.C. § 103 over Barnett, Ogden, and Gunaratnam.

c. Conclusion as to claims 33, 34, 48, 63, and 65

For the reasons discussed above, we determine that Fisher fails to demonstrate, by a preponderance of the evidence, that claims 33, 34, 48, and 65 are unpatentable under 35 U.S.C. § 103 over Barnett, Ogden, and Gunaratnam. We further determine that Fisher has demonstrated, by a preponderance of the evidence, that claim 63 is unpatentable under 35 U.S.C. § 103 over Barnett, Ogden, and Gunaratnam.

6. Claims 5 and 26 as allegedly obvious over Barnett, Ogden, Gunaratnam, and Ging

Claims 5 and 26 depend directly from independent claims 1 and 22, respectively. *See* Ex. 1001, 10:59–15:7. In asserting that these claims are unpatentable, Fisher relies, in part, on its positions as to why independent claims 1 and 22 are unpatentable. *See* Pet. 95–101.

As discussed above in connection with our analyses of claims 1 and 22 over Barnett and Ogden, we determine that Fisher fails to demonstrate, by a preponderance of the evidence, that claims 1 and 22 are unpatentable as obvious. Fisher does not assert that Gunaratnam or Ging cures the deficiencies we identified in our analysis. *See* Pet. 95–101.

Accordingly, we determine that Fisher fails to demonstrate, by a preponderance of the evidence, that claims 5 and 26 are unpatentable under 35 U.S.C. § 103 over Barnett, Ogden, Gunaratnam, and Ging.

7. Claim 53 as allegedly obvious over Barnett, Ogden, Gunaratnam, and Lithgow

Claim 53 depends directly from claim 32. Ex. 1001, 17:23–49. In asserting that claim 53 is unpatentable, Fisher relies, in part, on its positions as to why independent claim 32 is unpatentable. *See* Pet. 102.

As discussed above in connection with our analysis of claim 32 over Barnett and Ogden, we determine that Fisher fails to demonstrate, by a preponderance of the evidence, that claim 32 is unpatentable as obvious. Fisher does not assert that Gunaratnam or Lithgow cures the deficiencies we identified in our analysis. *See* Pet. 102.

Accordingly, we determine that Fisher fails to demonstrate, by a preponderance of the evidence, that claim 53 is unpatentable under 35 U.S.C. § 103 over Barnett, Ogden, Gunaratnam, and Lithgow.

8. Claims 9–13, 20, 21, 30, and 31 as allegedly obvious over Barnett, Ogden, Gunaratnam, and Namey

Claims 9–13, 20, 21, 30, and 31 depend, directly or indirectly, from independent claims 1, 14, and 22. Ex. 1001, 12:24–16:8. In asserting that these claims are unpatentable, Fisher relies, in part, on its positions as to why independent claims 1, 14, and 22 are unpatentable. *See* Pet. 103–107.

As discussed above in connection with our analysis of claims 1, 14, and 22 over Barnett and Ogden, we determine that Fisher fails to demonstrate, by a preponderance of the evidence, that these claims are unpatentable as obvious. Fisher does not assert that Gunaratnam or Namey cures the deficiencies we identified in our analyses. *See* Pet. 103–107.

Accordingly, we determine that Fisher fails to demonstrate, by a preponderance of the evidence, that claims 9–13, 20, 21, 30, and 31 are unpatentable under 35 U.S.C. § 103 over Barnett, Ogden, Gunaratnam, and Namey.

9. Claims 55 and 66 as allegedly obvious over Barnett, Ogden, Gunaratnam, and Jaffre

a. Claim 55

Claim 55 depends directly from claim 54. Ex. 1001, 18:24–25. In asserting that claim 55 is unpatentable, Fisher relies, in part, on its positions as to why independent claim 54 is unpatentable. *See* Pet. 107.

As discussed above in connection with our analysis of claim 54 over Barnett, Ogden, and Jaffre, we determine that Fisher fails to demonstrate, by a preponderance of the evidence, that claim 54 is unpatentable as obvious. Fisher does not assert that Gunaratnam cures the deficiencies we identified in our analysis. *See* Pet. 107.

Accordingly, we determine that Fisher fails to demonstrate, by a preponderance of the evidence, that claim 55 is unpatentable under 35 U.S.C. § 103 over Barnett, Ogden, Gunaratnam, and Jaffre.

b. Claim 66

Claim 66 depends from claim 61 and recites a list of additional claim limitations, limitations that are present in dependent claims 62, 63, 64, and 65 (as noted by our annotation of each limitation):

a vent arrangement is provided for gas washout [recited in claim 62],

the elbow includes a swivel joint adapted to be connected to the air delivery tube, the elbow includes an anti-asphyxia valve and a port that is selectively closed by a flap portion of the anti-asphyxia valve depending on the presence of pressurized gas [recited in claim 62],

the frame module includes a forehead support and four headgear connectors that are attached to the frame module to connect with the headgear [recited in claim 63],

the mask system is provided with a plurality of differently sized cushion modules each having a full-face cushion and a main body, the main body of each cushion module including a

universal configuration for interfacing with the frame module, thus providing a modular arrangement that allows the frame module to be selectively and removably coupled to each of the plurality of differently sized cushion modules [recited in claim 64],

the plurality of differently sized cushion modules include different size full-face cushions, including small, medium, and large, and the main body and full-face cushion together comprise an integrated component [recited in claim 64],

the main body comprising a molded polycarbonate material that interfaces with the frame module and the full-face cushion comprises a molded elastomeric material adapted to interface with patient's face [recited in claim 65].

Ex. 1001, 20:13–39.

Fisher incorporates its analyses with respect to claims 62–65 in asserting that claim 66 is unpatentable. Pet. 107. As we stated above in connection with our analysis of claim 65, we determine that Fisher fails to demonstrate, by a preponderance of the evidence, that the subject matter of claim 65 is obvious over Barnett, Ogden, and Gunaratnam. Fisher does not assert that Jaffre cures the deficiencies we identified in our analysis of claim 65.

Accordingly, we determine, based on the complete record, that Fisher fails to demonstrate that claim 66 is unpatentable under 35 U.S.C. § 103(a) over Barnett, Ogden, Gunaratnam, and Jaffre.

10. Claim 59 as allegedly obvious over Barnett, Ogden, Gunaratnam, Jaffre, and Namey

Claim 59 depends indirectly from claim 54. Ex. 1001, 18:42–48. In asserting that claim 59 is unpatentable, Fisher relies, in part, on its positions as to why independent claim 54 is unpatentable. See Pet. 108.

As discussed above in connection with our analysis of claim 54 over Barnett, Ogden, and Jaffre, we determine that Fisher fails to demonstrate, by

a preponderance of the evidence, that claim 54 is unpatentable as obvious. Fisher does not assert that Gunaratnam or Namey cures the deficiencies we identified in our analysis. *See* Pet. 108.

Accordingly, we determine that Fisher fails to demonstrate, by a preponderance of the evidence, that claim 59 is unpatentable under 35 U.S.C. § 103 over Barnett, Ogden, Gunaratnam, Jaffre, and Namey.

11. Claims 56 and 60 as allegedly obvious over Barnett, Ogden, Gunaratnam, Jaffre, and Lithgow

Claims 56 and 60 depend, directly or indirectly, from independent claim 54. Ex. 1001, 18:26–67. In asserting that these claims are unpatentable, Fisher relies, in part, on its positions as to why claim 54 is unpatentable. *See* Pet. 109–111.

As discussed above in connection with our analysis of claim 54 over Barnett, Ogden, and Jaffre, we determine that Fisher fails to demonstrate, by a preponderance of the evidence, that claim 54 is unpatentable as obvious. Fisher does not assert that Gunaratnam or Lithgow cures the deficiencies we identified in our analysis. *See* Pet. 109–111.

Accordingly, we determine that Fisher fails to demonstrate, by a preponderance of the evidence, that claims 56 and 60 are unpatentable under 35 U.S.C. § 103 over Barnett, Ogden, Gunaratnam, Jaffre, and Lithgow.

12. Claims 8 and 28 as allegedly obvious over Barnett, Ogden, Jaffre, Lithgow, and Ging

Claims 8 and 26 depend directly from independent claims 1 and 22, respectively. Ex. 1001, 11:33–15:7. In asserting that these claims are unpatentable, Fisher relies, in part, on its positions as to why independent claims 1 and 22 are unpatentable. *See* Pet. 111–112.

As discussed above in connection with our analyses of claims 1 and 22 over Barnett and Ogden, we determine that Fisher fails to demonstrate, by a preponderance of the evidence, that claims 1 and 22 are unpatentable as obvious. Fisher does not assert that Jaffre, Lithgow, or Ging cures the deficiencies we identified in our analysis. *See* Pet. 111–112.

Accordingly, we determine that Fisher fails to demonstrate, by a preponderance of the evidence, that claims 8 and 26 are unpatentable under 35 U.S.C. § 103 over Barnett, Ogden, Jaffre, Lithgow, and Ging.

III. CONCLUSION

For the foregoing reasons, we conclude that Fisher has demonstrated, by a preponderance of the evidence, that claims 61–64 are unpatentable under 35 U.S.C. § 103. We further conclude that Fisher fails to demonstrate, by a preponderance of the evidence, that claims 1–60, 65, and 66 are unpatentable under 35 U.S.C. § 103.

IV. ORDER

After due consideration of the record before us, it is:

ORDERED that claims 1, 2, 4, 7, 14–16, 19, 22, 23, 25, 29, 32, 35, 36, 43, 45–47, 49, and 52 have *not* been shown to be unpatentable under 35 U.S.C. § 103 over Barnett and Ogden;

FURTHER ORDERED that claims 61 and 64 are unpatentable under 35 U.S.C. § 103 over Barnett and Ogden;

FURTHER ORDERED that claims 6, 17, 18, 27, and 37–42 have *not* been shown to be unpatentable under 35 U.S.C. § 103 over Barnett, Ogden, and Lithgow;

FURTHER ORDERED that claim 44 has *not* been shown to be unpatentable under 35 U.S.C. § 103 over Barnett, Ogden, and Namey;

FURTHER ORDERED that claims 3, 24, 50, 51, 54, 57, and 58 have *not* been shown to be unpatentable under 35 U.S.C. § 103 over Barnett, Ogden, and Jaffre;

FURTHER ORDERED that claim 62 is unpatentable under 35 U.S.C. § 103 over Barnett, Ogden, and Jaffre;

FURTHER ORDERED that claims 33, 34, 48, and 65 have *not* been shown to be unpatentable under 35 U.S.C. § 103 over Barnett, Ogden, and Gunaratnam;

FURTHER ORDERED that claim 63 is unpatentable under 35 U.S.C. § 103 over Barnett, Ogden, and Gunaratnam;

FURTHER ORDERED that claims 5 and 26 have *not* been shown to be unpatentable under 35 U.S.C. § 103 over Barnett, Ogden, Gunaratnam, and Ging;

FURTHER ORDERED that claim 53 has *not* been shown to be unpatentable under 35 U.S.C. § 103 over Barnett, Ogden, Gunaratnam, and Lithgow;

FURTHER ORDERED that claims 9–13, 20, 21, 30, and 31 have *not* been shown to be unpatentable under 35 U.S.C. § 103 over Barnett, Ogden, Gunaratnam, and Namey;

FURTHER ORDERED that claims 55 and 66 have *not* been shown to be unpatentable under 35 U.S.C. § 103 over Barnett, Ogden, Gunaratnam, and Jaffre;

FURTHER ORDERED that claim 59 has *not* been shown to be unpatentable under 35 U.S.C. § 103 over Barnett, Ogden, Gunaratnam, Jaffre, and Namey;

FURTHER ORDERED that claims 56 and 60 have *not* been shown to be unpatentable under 35 U.S.C. § 103 over Barnett, Ogden, Gunaratnam, Jaffre, and Lithgow;

FURTHER ORDERED that claims 8 and 28 have *not* been shown to be unpatentable under 35 U.S.C. § 103 over Barnett, Ogden, Jaffre, Lithgow, and Ging; 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.

IPR2017-00501
Patent 9,027,556 B2

For PETITIONER:

John B. Sganga, Jr.
Brenton R. Babcock
Benjamin J. Everton
KNOBBE, MARTENS, OLSON & BEAR, LLP
2jbs@knobbe.com
2brb@knobbe.com
2bje@knobbe.com

For PATENT OWNER:

Michael T. Hawkins
Michael J. Kane
Christopher C. Hoff
Stephen R. Schaefer
Roger A. Denning
FISH & RICHARDSON P.C.
hawkins@fr.com
kane@fr.com
hoff@fr.com
schaefer@fr.com
denning@fr.com
IPR36784-0059IP1@fr.com
PTABInbound@fr.com