

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FISHER & PAYKEL HEALTHCARE LIMITED
Petitioner,

v.

RESMED LIMITED,
Patent Owner.

Case IPR2017-01789
Patent 8,960,196 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 1–22 (the “Challenged Claims”) of U.S. Patent No. 8,960,196 B2 (Ex. 1201, the “’196 patent”). Patent Owner, ResMed Ltd. (“ResMed”), filed a Preliminary Patent Owner Response (Paper 6, “Prelim. Resp.”) to the Petition. We instituted trial on all challenged claims and grounds. *See* Paper 7 (“Dec. on Inst.” or “Institution Decision”), 6–7, 43–44.

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 17 (“Reply”). Oral hearing was conducted for this proceeding on October 5, 2018, and the record contains a transcript of the hearing. Paper 25 (“Tr.”).

Fisher relies on the declaration testimony of Mr. Jason Eaton. Ex. 1206. ResMed relies on the declaration testimony of Mr. Alexander Virr. Ex. 2211.

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 1–22 are unpatentable under 35 U.S.C. § 103.

A. Related Matters

Fisher indicates that the ’196 patent was involved in U.S. International Trade Commission Investigation No. 337–TA–1022, for which ResMed withdrew its complaint, thus terminating the investigation. Pet. 12. Fisher and ResMed are also involved in district court litigation involving the ’196

patent in the Southern District of California, in a case styled *Fisher & Paykel Healthcare Ltd. v. ResMed Corp.*, Case No. 3:16-cv-02068-DMS-WVG (S.D. Cal.). *Id.* at 12–13; Paper 3, 2. Claims 23–86 of the '196 patent were challenged in two earlier-filed *inter partes* review proceedings—IPR2017-00057 and IPR2017-00059. Pet. 13; Paper 3, 2.

B. The '196 Patent

The '196 patent, titled “Mask System with Interchangeable Headgear Connectors,” issued February 24, 2015 with claims 1–86. Ex. 1201, (54), (45), 11:58–18:37. The '196 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 1:14–17. Figures 1A, 1B, and 1C of the '196 patent depict an embodiment of the '196 patent and are reproduced below.

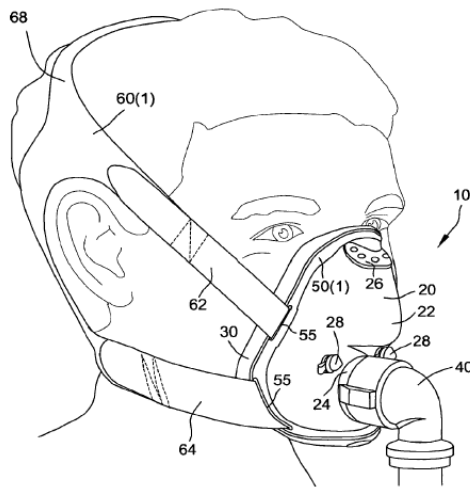


FIG. 1A

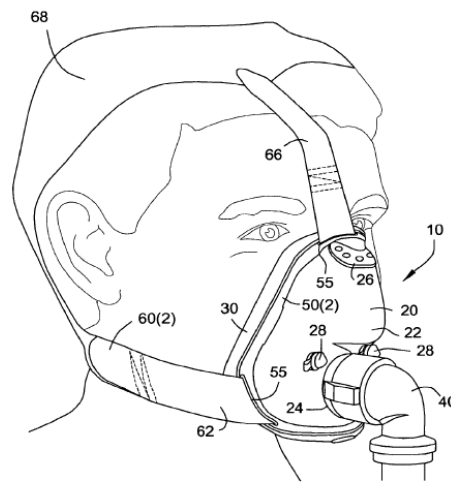


FIG. 1B

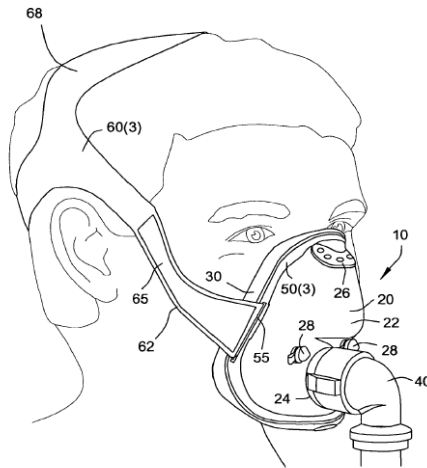


FIG. 1C

Figures 1A, 1B, and 1C depict “a mask system with interchangeable headgear connectors according to an embodiment of the” ’196 patent. Ex. 1201, 2:53–55. Mask system 10 includes frame 20 and cushion 30, which forms a seal where cushion 30 contacts the wearer’s face. *Id.* at 3:29–32. Frame 20 includes main body 22, annular elbow connection seal 24, vent assembly 26, and ports with port caps 28. *Id.* at 3:45–48. Elbow assembly 40 connects to annular elbow connection seal 24 to deliver breathable gas to the mask wearer. *Id.* at 3:32–34.

Mask system 10 also includes headgear connectors 50(1), 50(2), 50(3), depicted in Figures 1A, 1B, and 1C, respectively. Ex. 1201, 3:29–38. Each of headgear connectors 50(1), 50(2), 50(3) includes attachment points that correspond to connection points for headgear 60(1), 60(2), 60(3). *Id.* at 3:36–38. As seen in Figures 1A, 1B, and 1C each headgear 60(1), 60(2), 60(3) configuration differs slightly from the other headgear configurations. *See id.* at Figs. 1A–1C. Headgear connectors 50(1), 50(2), 50(3) removably attach to frame 20, such that the headgear connector corresponding to the

headgear configuration can be attached to the frame to accommodate the headgear. *See id.* at 3:35–67.

Figures 2A and 2B are reproduced below:

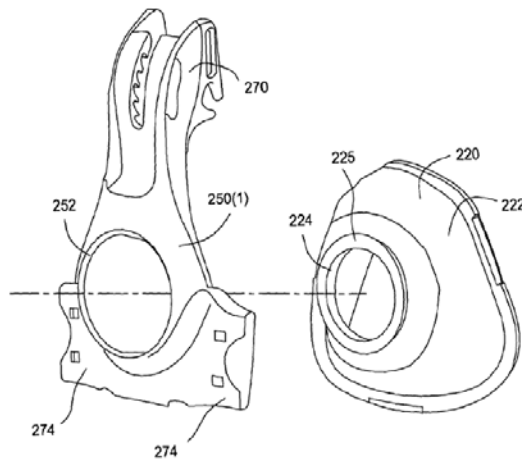


FIG. 2A

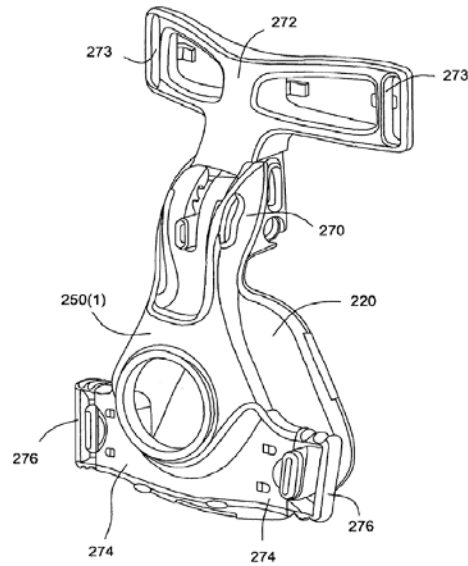


FIG. 2B

Figures 2A and 2B depict an alternative embodiment of the '196 patent's mask assembly. Ex. 1201, 2:58–60. In this embodiment, frame 220 connects with headgear connector 250(1). *Id.* at 6:10–11. Frame 220 includes main body 222 with annular elbow connection seal 224 forming a central bore in frame 220. *Id.* at 6:21–23. Central bore 224 includes interface structure 225, which connects with headgear connector 250(1) at opening 252. *Id.* at 6:28–38.

Headgear connector 250(1) includes structures for attaching a headgear, including openings 273 and clips 276. Ex. 1201, 6:60–7:2. Headgear connector 250(1) includes adjustable forehead support 272. *See id.* at 7:3–16.

C. Challenged Claims

Of the Challenged Claims, claim 1 is the sole independent claim¹ and is reproduced below:

1. A mask for delivering breathable gas to a patient at positive pressure to treat sleep disordered breathing, the mask comprising:

a mask frame having a central bore, said mask frame having no built-in or integral headgear attachment points;

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

a headgear connector adapted to engage the mask frame, said headgear connector including a pair of lower headgear clip anchors adapted to be engaged with respective ones of a pair of lower headgear clips, said headgear connector including a forehead support connected to the headgear connector by an upper support member, said forehead support including a pair of openings adapted to attach to respective ones of a pair of upper side straps, wherein the mask frame is adapted to removably connect to more than one headgear connector, each headgear connector being different in at least one aspect.

Ex. 1201, 11:58–12:8.

¹ We determine that claim 19, although written in a form that resembles an independent claim, is actually a dependent claim. Claim 19 contains a reference to the mask of claim 1 and further limits the subject matter of the claim. See 35 U.S.C. § 112 (“[A] claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed.”); Ex. 1206 ¶ 271 (“Claim 19 depends from Claim 1.”); *cf.* Pet. 106 (considering claim 19 an independent claim). Our analysis herein does not change regardless of whether claim 19 is considered a dependent or independent claim.

D. The Prior Art

We instituted trial on three asserted grounds that rely on the following references:

Ogden	US 5,662,101	Sept. 2, 1997	Ex. 1202
Gunaratnam	US 6,796,308 B2	Sept. 28, 2004	Ex. 1203
Amarasinghe	US 2004/0065328 A1	Apr. 8, 2004	Ex. 1204
Lovell	US 6,631,718 B1	Oct. 14, 2003	Ex. 1205

E. Asserted Grounds of Unpatentability

We instituted trial on the following grounds of unpatentability for the Challenged Claims, each under 35 U.S.C. § 103 (2006):

References	Claims Challenged
Ogden, Gunaratnam, and Amarasinghe	1–3, 6, 7, and 9–22
Ogden, Gunaratnam, Amarasinghe, and Lovell	4, 5, and 8
Gunaratnam, Lovell, and Amarasinghe	1–22

Pet. 16. In support of these asserted grounds of unpatentability, Fisher relies on the testimony of Mr. Jason Eaton. *See* Ex. 1206 (“Eaton Decl.”).

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 ’196 patent pertains is “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. 22 (citing Ex. 1206 ¶ 26). In referencing a “person of ordinary skill in the art,” ResMed cites testimony of its declarant, Mr. Virr. PO Resp. 12 (referencing Ex. 2211 ¶¶ 14–15). Mr. Virr testifies 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.” Ex. 2211 ¶ 15. Mr. Virr adds that additional experience may compensate for less education. *Id.*

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 defines broadly the field of experience as “relevant product design.” 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 the ’196 patent. *See* Exs. 1201–1205, 1212–1230; *see also* Ex. 1206 ¶ 26 (declaring that, based on Mr. Eaton’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 '196 [p]atent.”); Ex. 2211 ¶¶ 14–15 (providing that Mr. Virr’s formulation of the relevant level of ordinary skill in the art is “[b]ased [on] [his] knowledge and experience in [the] area”).

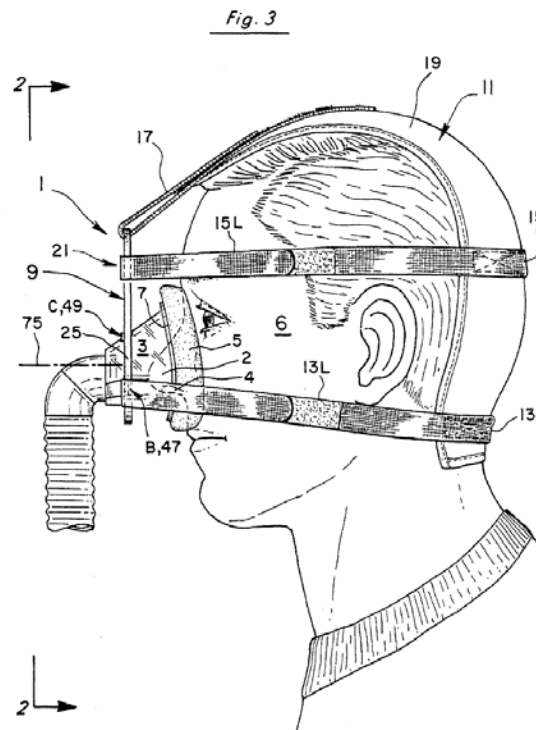
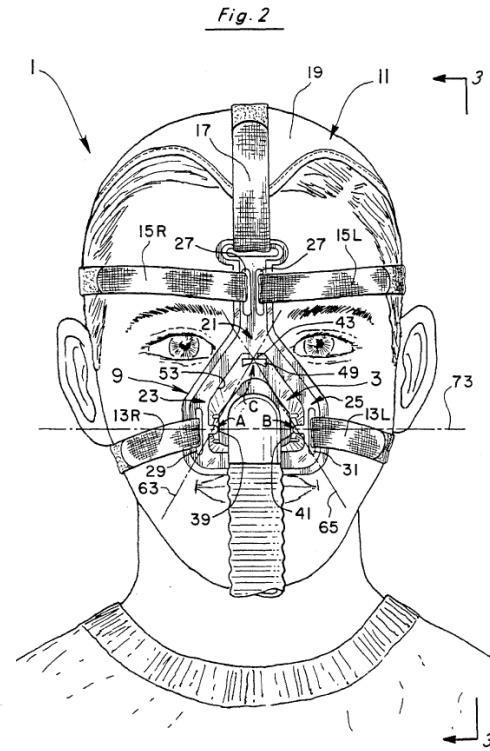
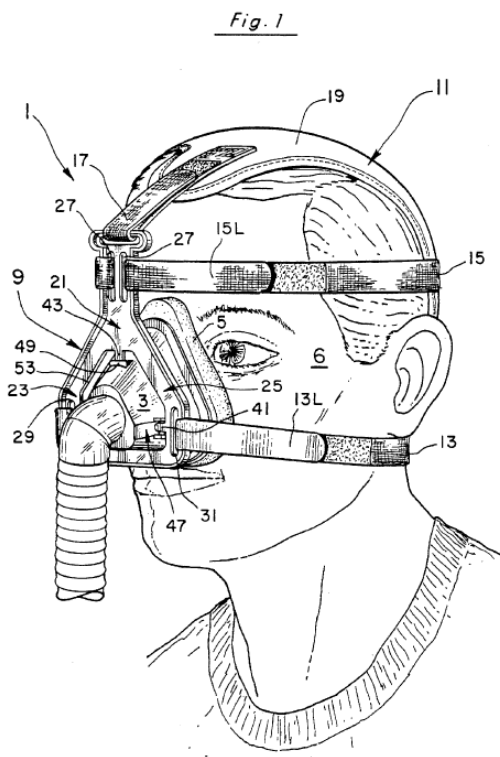
We note that our patentability and claim construction analyses presented below would reach the same findings and determinations under either party’s definition of the level of ordinary skill in the art.

B. Overview of the Asserted Prior Art

The Petition relies on four prior art references in its asserted grounds of unpatentability—Ogden, Gunaratnam, Amarasinghe, and Lovell. We briefly discuss relevant portions of these references, below.

1. Ogden

Ogden, titled “Respiratory Facial Mask,” issued September 2, 1997. Ex. 1202, (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 depicts a perspective view, front view, and side view of Ogden's mask, respectively. Ex. 1202, 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, 32 and channels 45, 47, and 49. Ex. 1202, 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. 1202, 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. Rigid plate 9 rotates relative to 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.

2. Gunaratnam

Gunaratnam, titled “Mask Cushion and Frame Assembly,” issued September 28, 2004. Ex. 1203, (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:

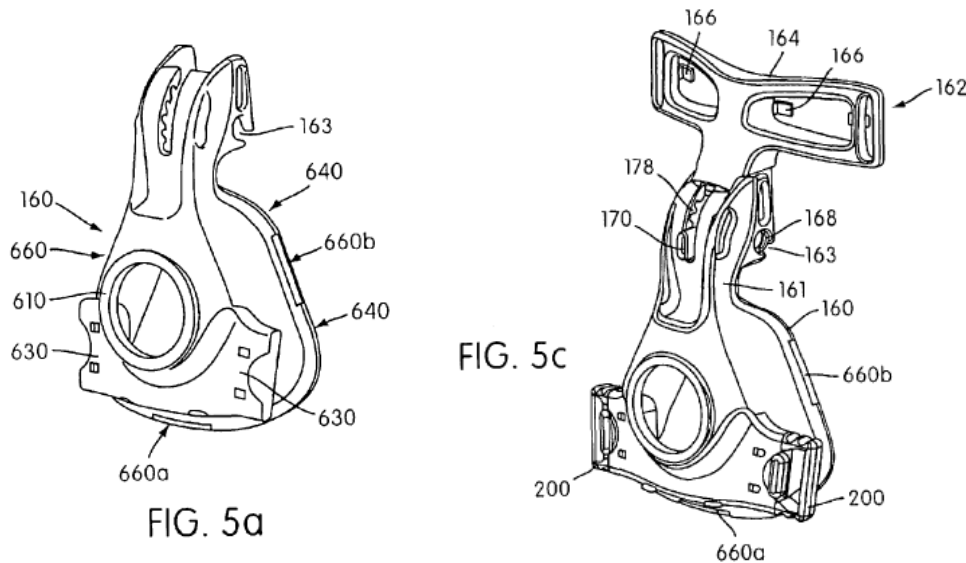


Figure 5a depicts “a front perspective view of a nasal mask frame,” and Figure 5c depicts “a front perspective view of a nasal mask frame and adjustable forehead support.” Ex. 1203, 3:6–12. Frame 160 is generally triangular and fits over a wearer’s nose and forms a breathing cavity. *Id.* at 4:26–30. 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. 1203, 4:46–57. Figure 5c also depicts connector 200 for connecting the mask to a user’s headgear. *Id.* at 4:32–34.

3. Amarasinghe

Amarasinghe, titled “Mask Brace and Mask Assembly,” published April 8, 2004. Ex. 1204 (54), (43). Amarasinghe is directed to “the configuration, fitting and operation of a mask suitable for the delivery of

non-invasive positive pressure ventilation and for nasal CPAP treatment of sleep disordered breathing conditions such as obstructive sleep apnea.” *Id.* at ¶ 2. Fisher states that “[t]he patent that issued from Amarasinghe was submitted during the prosecution of the ’196 [p]atent, but was not cited by the Examiner.” Pet. 26.

Amarasinghe’s Figure 2 is reproduced below.

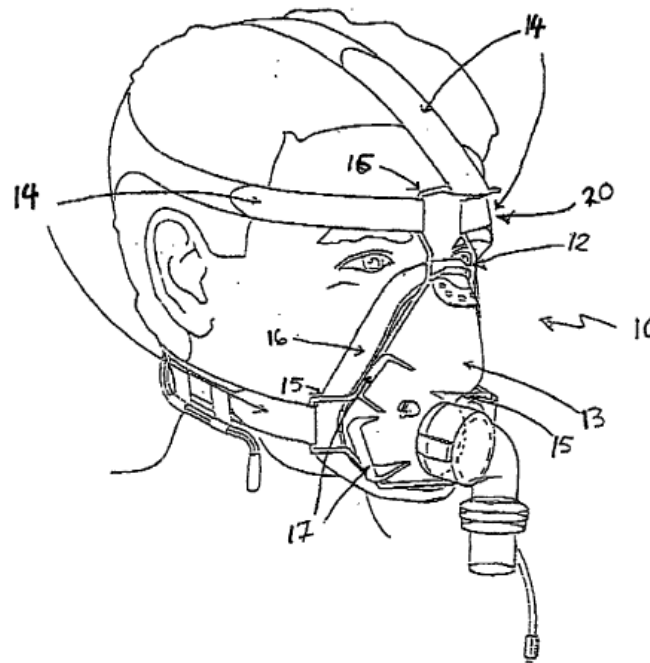


Figure 2 depicts “a mask system incorporating a brace.” Ex. 1204 ¶ 25. Mask system 10 includes “brace 12, mask shell 13, headgear straps 14, brace head strap attachment points 15, mask cushion 16 and mask shell headgear attachment points 17.” *Id.* at ¶ 29.

Amarasinghe discloses that brace 12 provides attachment points for the headgear, rendering any attachment points on mask shell 13 superfluous. Ex. 1204 ¶ 30. Amarasinghe further discloses that, although brace 12 includes attachment points for five headgear straps, “the brace may be configured so as to receive any suitable number.” *Id.* at ¶ 31.

4. Lovell

Lovell, titled “Air Mask with Seal,” issued October 14, 2003. Ex. 1205, (54), (45). Lovell is generally directed to “nasal masks useful for providing pressurized air or therapeutic gas to a patient suffering from an airflow limitation or other respiratory ailment.” *Id.* at 1:6–8. Lovell’s Figures 9, 10A, and 10B are reproduced below:

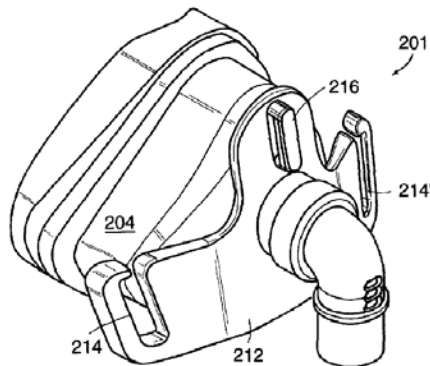


FIG. 9

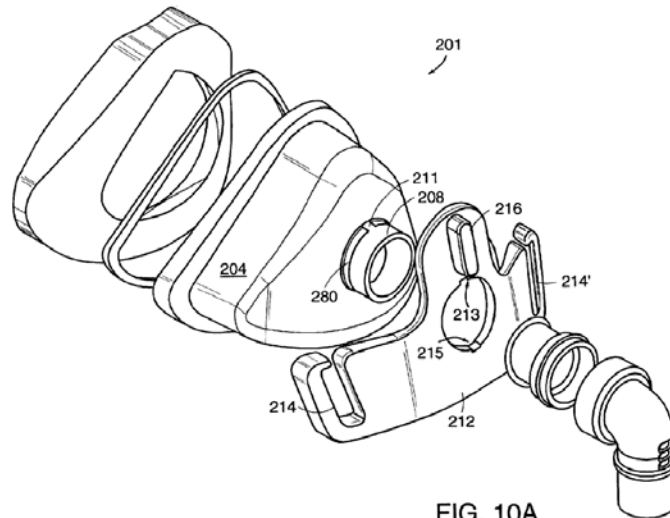


FIG. 10A

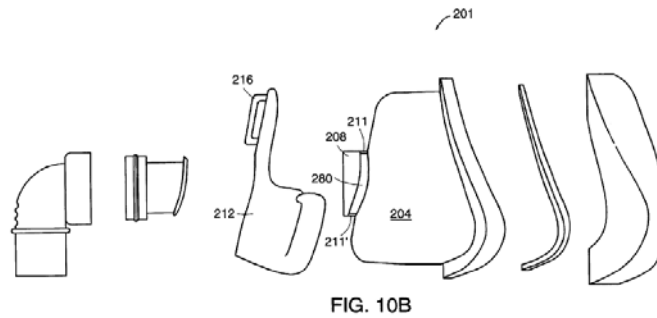


Figure 9 depicts “a schematic perspective view of a nasal mask according to an . . . embodiment of the invention” of Lovell. Ex. 1205, 4:1–2. Figure 10A depicts “a schematic exploded perspective view of the components of the nasal mask depicted in [Figure] 9” and Figure 10B depicts “a schematic exploded side view of the components of the nasal mask depicted in [Figure] 9.” *Id.* at 4:3–6.

Lovell’s mask 201 includes retainer 212, which is contoured to match the surface of shell 204 and is coupled to shell 204 at inlet 208. Ex. 1205, 9:36–46. Retainer 212 includes lower connection points 214, 214’ and upper connection point 216 to connect mask 201 to a user’s headgear. *Id.* at 9:49–51. Retainer 212 includes slots 213, 215 that engage with tabs 211, 211’ of shell 204 such that depressed annular region 280 mates with the edges of the opening in retainer 212. *Id.* at 9:43–66.

Lovell’s mask 201 also includes a cushion (“seal,” not numbered) and a conduit elbow for treatment gas. *See, e.g.,* Ex. 1205, 4:34–40 (discussing seal 2), 5:9–61 (discussing inlet system for treatment gas, including conduit elbow 10), 9:34–36 (disclosing that mask 201 “has many . . . of the features of the nasal mask 1 embodiment shown in [Figures] 1–8.”).

C. Claim Construction

In an *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).² 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 it construes the Challenged Claims “such that the claims are given their broadest reasonable interpretation in light of the specification of the ’196 [p]atent.” *See* Pet. 17. That is, “[a]ll terms [should be given] their ordinary and customary meaning in light of the specification, as commonly understood by those of ordinary skill in the art at the time of the invention.” *Id.* at 18. ResMed agrees that the claim terms of the ’196 patent should be “given [their] broadest reasonable construction in light of the specification in which [they] appear.” PO Resp. 11. Neither party provides an express construction for any term of the Challenged Claims.

² The claim construction standard to be employed in an *inter partes* review recently has changed. *See Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board*, 83 Fed. Reg. 51,340 (Oct. 11, 2018) (to be codified at 37 C.F.R. § 42). That new standard, however, applies only to proceedings in which the petition is filed on or after November 13, 2018. The Petition in this proceeding was filed on July 14, 2017, and we apply the broadest reasonable interpretation standard that was in effect at that time.

We determine that no claim terms need to be expressly construed to resolve the parties' disputes.

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.

Fisher's three grounds of unpatentability are based on obviousness. *See* Pet. 16.

Section 103(a) [of 35 U.S.C. (2006)] 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,

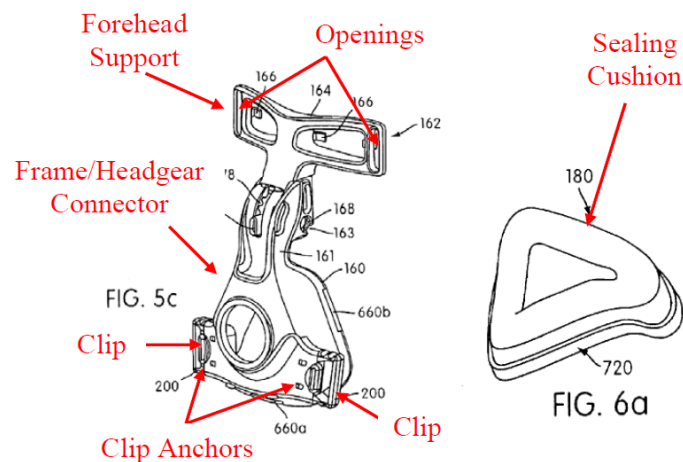
and failure of others. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). We address these underlying factual issues below.³

1. *Claims 1–22 as Allegedly Obvious over Gunaratnam, Lovell, and Amarasinghe*

a. Independent claim 1

The subject matter of claim 1

Fisher contends that Gunaratnam discloses “nearly all” of the subject matter of claim 1. Pet. 73. Fisher provides annotated versions of Gunaratnam’s Figures 5c and 6a, identifying how Gunaratnam discloses this subject matter. We reproduce these annotated figures below.



The annotated figures show Gunaratnam’s mask system of Figure 5c and sealing cushion depicted in Figure 6a and identifies the mask frame, sealing

³ We address the level of ordinary skill in the art in Section II.A., above. ResMed does not argue any evidence of secondary considerations for us to weigh in our obviousness analysis. See *ZUP, LLC v. Nash Mfg., Inc.*, 896 F.3d 1365, 1373 (Fed. Cir. 2018) (“While [the] burden of persuasion remains with the challenger, a patentee bears the burden of production with respect to evidence of secondary considerations of nonobviousness.”).

cushion, headgear connector (as part of the frame) with forehead support and associated openings, and lower headgear clip anchors and clips. *See* Pet. 74. Fisher asserts that “[a]ny differences between the Challenged Claims and Gunaratnam were minor and well-known at the time of the invention and taught by Lovell and/or Amarasinghe.” *Id.* (referencing Ex. 1206 ¶¶ 182–273).

Specifically, claim 1 recites “a mask frame having a central bore, said mask frame having no built-in or integral headgear attachment points.” Ex. 1201, 11:61–62 (the “mask frame” limitation). Fisher contends that the embodiment depicted in Gunaratnam’s Figure 5c discloses mask frame 160, which forms a breathing chamber. Pet. 76. As seen in Gunaratnam’s Figure 5c, above, mask frame 160 includes a central bore.

Fisher acknowledges that the combined mask frame/headgear connector of Gunaratnam has headgear anchors. Pet. 76. Fisher contends that masks with frames separate from headgear connectors and having no headgear anchors were known in the prior art. *Id.* Fisher identifies Lovell as teaching a mask system with frame 204 and separate headgear connector 212, with frame 204 having no headgear anchors. *Id.* at 77. Fisher provides an annotated version of Lovell’s Figure 10A, which we reproduce below.

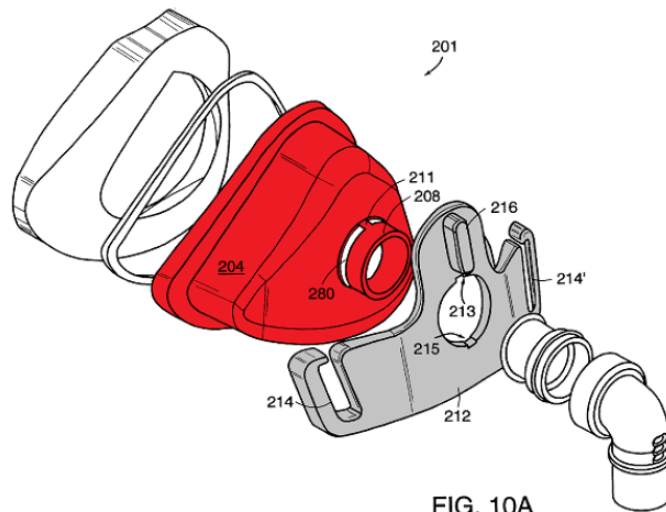


FIG. 10A

The annotated version of Lovell's Figure 10A shows the mask frame in red and separate headgear connector in grey. Pet. 77–78. Fisher contends that modifying Gunaratnam with this teaching of Lovell arrives at a mask system with a separate headgear connector and mask frame, as depicted in the following annotated version of Gunaratnam's Figure 5c:

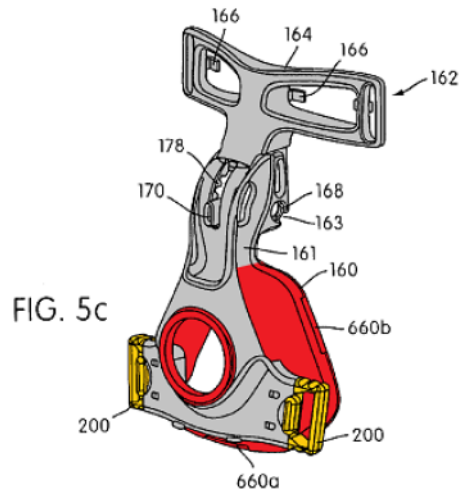


FIG. 5c

Fisher's annotation of Gunaratnam's Figure 5c shows the headgear connector in grey, mask frame in red, and headgear anchors in yellow. Pet. 78. That is, Fisher contends that it would have been obvious, based on

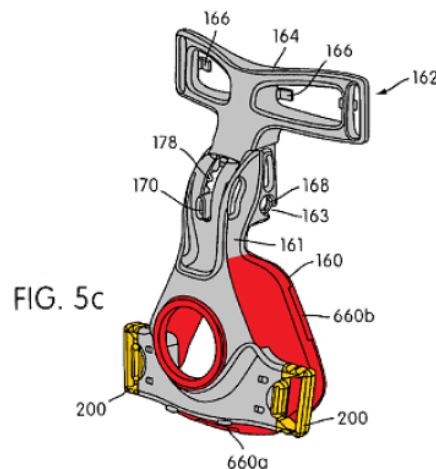
Lovell’s teachings, to modify Gunaratnam’s mask system to separate the red highlighted structure from the grey highlighted structure (which is a unitary structure in Gunaratnam). Based on the complete record, we find that Gunaratnam, as modified by Lovell’s teaching of a headgear connector separate from the mask frame, discloses the subject matter of the “mask frame” limitation of claim 1. That is, the mask frame resulting from separating Gunaratnam’s mask into a mask frame piece and a headgear connector piece results in a mask frame having a central bore and no built-in or integral headgear attachment points. *See id.* (showing the red mask frame with no built-in or integral headgear attachment points); *cf.* Ex. 1201, Fig. 2A (showing mask frame 220 separate from headgear connector 250(1) and resembling Fisher’s proposed modification).

ResMed argues that Amarasinghe, which Fisher relies on for teaching multiple headgear connectors, discloses a mask frame with built-in attachment points. *See* Tr. 46:1–47:2. This argument does not inform us of a deficiency in Fisher’s position. Fisher does not rely on Amarasinghe to teach the mask frame with no built-in attachment points and ResMed fails to explain adequately how Amarasinghe would somehow require such attachment points be used with its brace. Indeed, Amarasinghe characterizes the attachment points on the mask frame as “superfluous,” indicating that these attachment points are not needed. *See* Ex. 1204 ¶ 30.

Claim 1 further recites “a sealing cushion provided to the mask frame and adapted to form a seal with the patient’s face.” Ex. 1201, 11:63–64 (the “sealing cushion” limitation of claim 1). Fisher contends that Gunaratnam discloses sealing cushion 180. Pet. 79. We find, based on the complete record, that Gunaratnam discloses the sealing cushion limitation of claim 1.

See Ex. 1203, 1:32–34 (“The mask may comprise a rigid shell (160), termed a frame, and a soft portion (180), termed a cushion.”); 5:14–29 (describing the mask cushion). ResMed does not dispute that Gunaratnam discloses the “sealing cushion” limitation.

Claim 1 also recites “a headgear connector adapted to engage the mask frame, said headgear connector including a pair of lower headgear clip anchors adapted to be engaged with respective ones of a pair of lower headgear clips.” Ex. 1201, 11:65–12:1 (the “headgear connector” limitation of claim 1). Fisher contends that Gunaratnam, as modified by the teachings of Lovell, results in a headgear connector adapted to engage a mask frame. Pet. 80. Specifically, Fisher contends that Lovell discloses that its separate headgear connector engages its mask frame. *Id.* at 81. Fisher further contends that Gunaratnam, as modified, includes a headgear connector with lower headgear clip anchors to receive lower headgear clips. *Id.* at 82. Fisher provides an annotated version of Gunaratnam’s Figure 5c to illustrate its proposed modification, which we reproduce below.

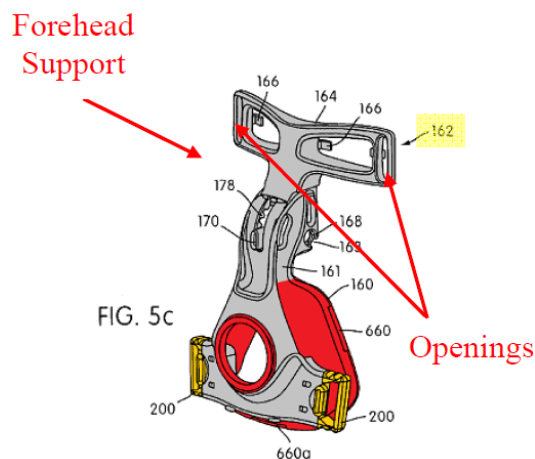


Pet. 80, 82. This annotated figure depicts Gunaratnam with a headgear connector (gray) having a pair of headgear connectors (yellow) and engaged

with the mask frame (red). That is, the headgear connector and mask frame are separate, but engaged to form the complete mask.

We find, based on the complete record, that Gunaratnam, as modified by Lovell, discloses the headgear connector limitation of claim 1. See Ex. 1203, Fig. 5c (depicting a mask with a pair of lower headgear clips). ResMed does not dispute that the combination of Gunaratnam and Lovell discloses the “headgear connector” limitation.

Claim 1 further recites “said headgear connector including a forehead support connected to the headgear connector by an upper support member, said forehead support including a pair of openings adapted to attach to respective ones of a pair of upper side straps.” Ex. 1201, 12:1–5 (the “forehead support” limitation). Fisher contends that Gunaratnam, as modified by Lovell to separate the headgear connector component, discloses a forehead support connected to the headgear connector by an upper support member. Pet. 83. Fisher explains that the forehead support includes a pair of openings through which straps of a headgear may pass. *Id.* The Petition includes the following annotated version of Gunaratnam’s Figure 5c, which we reproduce below.



Pet. 83. This annotated figure depicts Gunaratnam with a headgear connector (gray) engaged with the mask frame (red) and points to the forehead support and openings.

We find, based on the complete record, that the Petition makes the requisite showing that Gunaratnam, as modified by Lovell, discloses the subject matter of the “forehead support” limitation of claim 1. *See* Ex. 1203, Fig. 5c, 4:46–5:2 (describing forehead support 162). ResMed does not dispute that the combination of Gunaratnam and Lovell discloses the “forehead support” limitation.

Finally, claim 1 recites “wherein the mask frame is adapted to removably connect to more than one headgear connector, each headgear connector being different in at least one aspect.” Ex. 1201, 12:6–8 (the “multiple headgear connector” limitation of claim 1). Fisher states that, as discussed above, its proposed modification would result in a mask frame that removably engages a headgear connector, as taught by Lovell. Pet. 84–85. Fisher acknowledges that Gunaratnam does not disclose more than one headgear connector, with each headgear connector being different in at least one aspect as required by the “multiple headgear connector” limitation of claim 1.

Fisher contends that Amarasinghe discloses the subject matter of “multiple headgear connector” limitation. Pet. 86. Specifically, Fisher argues that Amarasinghe discloses a mask system with multiple braces 12 with the different braces 12 having a different number of attachment points for headgear. *Id.* at 87. That is, the braces differ in at least one aspect—the number of attachment points for headgear. Fisher explains that, by having

multiple headgear connectors, a patient could choose a preferred headgear arrangement to attach to their mask. *Id.*

We find, based on the complete record, that Gunaratnam, as modified by the teachings of Lovell and further by the teachings of Amarasinghe, discloses the “multiple headgear connector” limitation of claim 1.

Amarasinghe discloses that, beneficially, different removable headgear connectors can be employed for a single mask structure to allow for attaching different headgears to the same mask. *See* Ex. 1204 ¶ 33 (“A user may be supplied with a number of braces each with a different number of headgear attachment points . . . in order that a suitable choice may be made.”); *see also id.* at ¶ 15 (discussing the benefits of variability in head strap number and attachment position). ResMed does not dispute that Amarasinghe discloses different braces for attaching different headgear configurations to a mask.

*Reasons to combine the teachings of
Gunaratnam, Lovell, and Amarasinghe*

Fisher reasons that a person having ordinary skill in the art would have modified Gunaratnam by separating the mask frame and headgear connector “to provide a breathing chamber, the interior of which is only defined by the frame and cushion.” Pet. 78 (referencing Ex. 1206 ¶¶ 191–193). Fisher contends that “[i]t was common knowledge to provide a separate headgear connector and to connect the mask components at the inlet. *Id.* at 81 (referencing Ex. 1206 ¶ 196); *see also* Ex. 1206 ¶ 196 (identifying Lovell as an exemplary mask with a separate headgear connector and to connect the mask components at the inlet).

Fisher explains that “[a]s modified, the headgear connector would not be exposed to the pressurized gas or the patient’s exhalation, so the headgear

connector would not need to be cleaned or replaced as frequently.” Pet. 78. Fisher continues that “the breathing chamber could be removed for cleaning or replacement, separately and apart from the headgear connector and the headgear” and “[b]ecause the headgear would not have to be removed [from the headgear connector during cleaning], the headgear connector and the headgear could be reattached without requiring strap adjustment.” *Id.* at 78–79.

Fisher further reasons that, in light of Lovell’s teachings, an artisan of ordinary skill “would have recognized that providing a headgear connector that engages the frame at the inlet would provide a simple annular interface, which would simplify manufacturing and manufacturing tolerances by creating engagement around more readily measured cylindrical features that have easier to control tolerances.” Pet. 81 (referencing Ex. 1206 ¶ 197). Fisher continues that “person of skill would have recognized that this connection near the elbow connection would enable additional design features that better secure and seal the elbow to the mask frame.” *Id.*

Mr. Eaton testifies that

a person of skill would have recognized that the modified connection would allow the headgear connector to be connected to the mask frame near the elbow connection and could better secure and seal the elbow to the mask frame. For example, features to hold an elbow to the mask frame could be readily designed and molded onto the headgear connector, which is not required to be airtight. Slots, holes, and other similar features on the part that aid in molding otherwise undercut holding features could not be included in the frame, as these would violate the airtight surfaces of the frame.

Ex. 1206 ¶ 197. Mr. Eaton adds that “[a]dditional design features also become possible, such as allowing the elbow to remain engaged to the

headgear connector when the cushion module is removed, creating a simpler overall assembly and disassembly operation for the end user.” *Id.*

ResMed responds that Fisher’s proposed modification is the product of hindsight, as none of the identified prior art disclose a rigid-to-rigid connection between a mask frame and headgear connector. PO Resp. 48. ResMed argues that Gunaratnam discloses a single-piece, rigid frame and Lovell discloses a two-piece, rigid-to-flexible connection, with the ’196 patent supplying the only disclosure of a two-piece, rigid-to-rigid connection. *Id.* at 49. ResMed adds that a person having ordinary skill in the art would have understood that a flexible mask component behaves differently from a rigid mask component, such that Fisher’s proposed rigid-to-rigid connection lacks any documentary evidence. *Id.* at 49–50.

Fisher replies that ResMed’s argument improperly assumes that Lovell’s connection between its headgear connector and mask frame would have been bodily incorporated into Fisher’s proposed modification. Reply 17. Fisher explains that “the modified headgear connector and the mask frame would ‘engage at the inlet’ and comprise a removable connection in which tabs of the headgear connector removably attach to a peripheral edge of the frame.” *Id.* at 17–18 (referencing Pet. 80–85, 91–93). Fisher continues that “the proposed modification of Gunaratnam adopts the general arrangement shown in Lovell, which may include tabs that engage with corresponding depressions, but does not require Lovell’s exact arrangement.” *Id.* at 18.

Fisher also replies that Lovell’s flexible shell is not critical to the connection between the headgear connector and mask shell. Reply 18. Fisher explains that Lovell employs a flexible mask shell to provide a

custom fit at the seal end of the shell. *Id.* (referencing Ex. 1002, 5:2–8). Fisher adds that removable snap-fit connections were known in the art in 2007 and that Gunaratnam discloses a rigid-to-rigid connection between a mask shell and clip. *Id.* (referencing Ex. 1203, 5:34–38, discussing polycarbonate clip 800 connected to a polycarbonate frame).

Fisher also argues that the limited disclosure in the '196 patent concerning its rigid headgear connector to rigid mask frame confirms that a person having ordinary skill in the art would have known how to connect the two pieces together. Reply 19 (citing *In re Epstein*, 32 F.3d 1559, 1568, (Fed. Cir. 1994) (“[T]hat appellant did not provide the type of detail in his specification that he now argues is necessary in prior art references supports the Board’s finding that one skilled in the art would have known how to implement the features of the references.”)).

Finally, Fisher argues that ResMed’s argument that Fisher’s proposed modification is a product of hindsight lacks evidence. Reply 23. Fisher explains that the prior art, and not the '196 patent provides the support for Fisher’s proposed modification of Gunaratnam. *Id.* Specifically, Fisher

asserts that prior art references such as Lovell, Geist⁴⁴, and Ogden disclose that two-piece frame arrangements were well known prior to the '196 patent. *Id.*

We find that Fisher has the better argument. We recognize that, “[e]ven under [the] ‘expansive and flexible’ obviousness analysis [of *KSR*], we must guard against ‘hindsight bias’ and ‘*ex post* reasoning.’” *St. Jude Med., Inc. v. Access Closure, Inc.*, 729 F.3d 1369, 1381 (Fed. Cir. 2013) (citation omitted). We determine that Fisher’s proposed modification of Gunaratnam, which divides Gunaratnam’s mask into two pieces so that the pieces engage one another, is not the product of hindsight. Instead, we find that Lovell suggests Fisher’s proposed modification, as Lovell teaches a mask shell with no built-in or integral headgear attachment points that engages a separate headgear connector. *See 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*

⁴⁴ U.S. Pat. App. 2006/0042629 A1, pub. Mar. 2, 2006 (“Geist,” Ex. 1217). Mr. Eaton describes Geist a “disclos[ing] a headgear connector 20 that removably mounts to mask frame 12 and seal 14.” Ex. 1206 ¶ 97 (citing Ex. 1217 ¶ 44); *see also id.* at ¶ 190 (indicating Geist discloses a prior art mask assembly “having a separate headgear connector and mask frame.”). Mr. Eaton also relies on teachings in Geist that “it was desirable to provide a headgear connector that was removably mounted to the mask frame to permit detachment of the headgear, ‘which permits the mask and seal to be cleaned separately and apart from the headstraps.’” *Id.* at ¶ 192 (citing Ex. 1217 ¶ 8). Fisher relies on Mr. Eaton’s testimony on cleaning the mask frame separate from the headgear connector to support its obviousness position. *See* Pet. 78–79 (referencing Ex. 1206 ¶ 192).

(a tellingly broad term), or motivations (an equally broad term)—that arise before the time of invention as the statute requires.” (emphasis added)).

Also, we determine that ResMed’s argument that Fisher’s proposed modification of a rigid-to-rigid connection represents a new mask configuration not found in the asserted art improperly incorporates Lovell’s materials into Fisher’s proposed modification. We find that Fisher applies Lovell’s teaching of a two-piece mask frame/headgear connector system in its proposed modification and that Lovell’s materials are not critical to the two-piece system. We agree with Fisher that Lovell’s flexible mask supports a custom fit at the seal end of the mask and the flexible nature of the mask was not selected to connect the headgear connector to the mask frame. *See* Reply 18; Ex. 1205, 5:2–8 (“The combination of the compliant and resilient shell 4 and the malleable element 6 . . . produces a ‘custom-fit’ as desired by a particular user. Because the shell 4 is compliant, the perimeter and overall configuration of the opening of shell 4 can be reformed repeatedly, as necessary, by a particular user.”).

Additionally, we find that Gunaratnam discloses rigid-to-rigid connections, such as the connection between clip 800 and frame 160, both formed from polycarbonate. *See* Ex. 1203, 4:21–25, 5:29–42. That is, Gunaratnam itself discloses the use of rigid-to-rigid connections. Also, we agree with Fisher that the lack of detailed disclosure in the ’196 patent on its rigid-to-rigid connection between the headgear connector and mask frame supports a conclusion that a rigid-to-rigid connection was within the level of ordinary skill. *See also* Tr. 56 10–15 (“MR. KANE [ResMed counsel]: . . . could an engineer develop a snap-fit [between two rigid pieces]? We’re not disputing that.”); Ex. 1211, 341–345 (providing excerpts from “Plastic Part

Design for Injection Molding” and discussing snap-fit joints between two rigid plastic pieces).

ResMed responds that Fisher’s proposed modification of Gunaratnam ignores Gunaratnam’s preference for a one-piece, rigid framed mask. PO Resp. 50–51. Mr. Virr’s testimony mirrors ResMed’s arguments from its response. *See* Ex. 2211 ¶ 91. Mr. Virr adds:

Based on my knowledge and experience in the field and my review of Gunaratnam, Lovell, and Amarasinghe, a [person having ordinary skill in the art] would not have been motivated to implement the proposed modification of dividing Gunaratnam’s one-piece, rigid frame to create a two-piece, rigid-to-rigid, fixed connection. This is especially true in view of the considerable design challenges and performance disadvantages of the proposed combination as compared to Gunaratnam.

Id. ResMed argues that “Gunaratnam’s original solution of a one-piece, rigid frame yields a lighter mask, lower part count, and less work associated with additional parts, interfaces, and assembly.” PO Resp. 51 (referencing Ex. 2211 ¶ 91; Ex. 2212 (deposition testimony from Mr. Eaton), 23:3–27:19, 27:21–25, 28:1–30:15).

Fisher replies that “Gunaratnam does not specifically state a preference for a one-piece frame or any advantages over a multi-piece frame.” Reply 21. We agree. Tellingly, ResMed fails to cite to any disclosure in Gunaratnam expressing a *preference* for a one-piece construction. We do not credit Mr. Virr’s testimony in this regard, as it merely provides a conclusory statement without any further explanation. *See* Ex. 2211 ¶ 91. Although Mr. Virr states that his opinion is “[b]ased on [his] knowledge and experience in the field and [his] review of Gunaratnam, Lovell, and Amarasinghe,” he fails to explain adequately what “considerable design challenges and performance disadvantages” are present in the

proposed modification. *See id.*; *see also* 37 C.F.R. 42.65(a) (“Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.”). Also, Mr. Virr does not testify that the design challenges are beyond the level of ordinary skill in the art.

ResMed next argues that Fisher fails to provide evidence that its proposed modification would result in an operable mask, given Lovell’s reliance on its flexible connection mechanism. PO Resp. 51–52. ResMed appreciates that Fisher’s proposed modification relies on a rigid-to-rigid connection and does not bodily incorporate Lovell’s flexible connection. *See id.* at 52 (“Indeed, Petitioner affirmatively relies on the assumption that Gunaratnam’s harness connector and mask body must be rigid in the proposed modification.”). ResMed argues that a person having ordinary skill in the art would have recognized that Lovell’s connection configuration would not operate in a rigid-to-rigid structure. *Id.* at 52–53. ResMed argues that Lovell never contemplates a rigid-to-rigid connection.

ResMed adds that “the proposed combination fails to provide a ‘mask frame’ that is operable to ‘removably connect’ to a headgear connector.” PO Resp. 55. ResMed argues that Fisher “and Mr. Eaton fail to explain how Lovell’s connection mechanism would be removable if both components were rigid as required in the Petition’s resulting combination.” *Id.*

These arguments does not inform us of a deficiency in Fisher’s position. As ResMed’s counsel admitted, a person having ordinary skill in the art would have understood how to form a rigid-to-rigid, snap-fit, connection between the headgear connector and mask frame. Tr. 56 10–15 (“MR. KANE [ResMed counsel]: . . . could an engineer develop a snap-fit

[between two rigid pieces]? We’re not disputing that.”); see Ex. 1206 ¶¶ 197, 230, 231, 242 (providing Mr. Eaton’s testimony on how the headgear connector would be joined to the mask frame). Given ResMed’s admission, Mr. Eaton’s testimony, and the level of ordinary skill in the art, we find that an artisan of ordinary skill would have known how to make a removable, operable connection (such as a snap-fit connection) between a headgear connector and mask frame, with a reasonable expectation of success. See, e.g., Ex. 1206 ¶ 242 (“[Ex. 1211] describes ‘snap joint assemblies’ as assemblies in which ‘a protruding feature on one component, such as a hook or beam, is deflected briefly during the product assembly operation due to an interference, after which the protruding part recovers elastically, and catches in an undercut or indentation on the mating component.’” (quoting Ex. 1211, 342)); *id.* at ¶ 243 (“A skilled artisan would have recognized snap-fits are configured to permit repeated assembly/disassembly without destroying parts. These modifications would have been a combination of familiar elements according to known methods that does no more than yield predictable results.”).

ResMed next argues that Fisher’s “proposed modifications would have added complexity that outweighed Petitioner’s subsequently theorized benefits.” PO Resp. 57. ResMed asserts that Fisher’s “proposed modification divides Gunaratnam’s one-piece frame and direct connection to a delivery hose into three parts with at least three interfaces” multiplying “the number of interfaces that must be manufactured and assembled/disassembled by at-home users, and the number of locations susceptible to leaks.” *Id.* at 58–59 (referencing Ex. 2211 ¶ 100). We weigh

these considerations against Fisher’s articulated reasons in support of the modification, which we address below.

ResMed argues that Fisher’s articulated reasoning for dividing Gunaratnam’s frame into two pieces is flawed. PO Resp. 63. ResMed argues that Fisher’s reason that a person having ordinary skill in the art “would have been motivated to divide Gunaratnam’s mask so that the frame could be cleaned separately and apart from the headgear straps” lacks proper support. *Id.* ResMed argues that Fisher’s only support for this reason is drawn from the Geist reference and such a basis is flawed. *Id.* at 63–64. ResMed explains that Geist teaches separating the entire mask from the head straps to clean the mask, with the head straps remaining connected to the wearer’s head. *Id.* at 64 (referencing Ex. 1217 ¶ 8). As ResMed’s counsel explained at oral hearing, Geist discloses a structure where the mask can be removed from the headgear straps so, for example, the wearer can remove and re-don the mask without having to adjust the headgear. Tr. 52:2–26. ResMed’s counsel further explained that Geist discloses that the configuration also allows the mask to be cleaned without the headgear straps attached. *Id.* at 53:1–4; *see also* Ex. 1217 ¶ 8 (“It is also believed there is a need in the art for such removable mask and headstrap combination which permits the mask and seal to be cleaned separately and apart from the headstraps.”). Counsel continued that Gunaratnam’s mask, without modification, includes this feature. Tr. 53:5–11; *see also* Ex. 2211 ¶ 105 (“Geist teaches a different solution that would separate a ‘mask’ from ‘headstraps,’ which is no different in function from Gunaratnam’s solution. Geist in no way suggests an advantage in separating Gunaratnam’s rigid frame into multiple pieces as the Petition proposes.”).

Fisher replies that Geist teaches that both the head straps and headgear connector—headstrap retention bracket 20—are separate from the frame, such that Geist teaches the benefits of a mask where the headgear connector and straps may be removed for cleaning. Reply 20.

ResMed criticizes Fisher’s reasoning that engaging the headgear connector and mask frame at the cylindrical, central bore would simplify manufacture as not providing a motivation to make the proposed modification, as a one-piece unit as disclosed in Gunaratnam would not need such an interface. PO Resp. 64–65 (referencing Pet. 81). Fisher replies (and we agree) that this reasoning addressed by ResMed here is not concerned with dividing Gunaratnam’s one-piece mask into two pieces, but rather employing an annular interface to engage the two pieces. Reply 22; *see* Pet. 81.

Next, ResMed argues that Fisher fails to provide any evidence of reasonable success for its proposed modification. PO Resp. 67–68.

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 Royalty Corp. v. Wang*, 202 F.3d 1340, 1349 n.8 (Fed. Cir. 2000) (“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.”).

In weighing the evidence from the complete record, we find that a person having ordinary skill in the art would have been motivated to separate Gunaratnam’s one-piece mask into two pieces and have the mask frame adapted to removably connect to the headgear connector. We find that Fisher has provided persuasive reasons for the proposed modification, with a rational underpinning (which we adopt)—so the headgear connector would not need to be cleaned or replaced as frequently and that the headgear connector and straps could be removed and reattached without the need to adjust the straps. *See* Pet. 78–79; Ex. 1206 ¶¶ 191–193; *KSR Int’l Co.*, 550 U.S. at 418 (stating that, to facilitate the analysis of an obviousness position on appeal, the record should provide “some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”). We also find that Lovell suggests having a headgear connector separate from the mask frame (providing additional support for the proposed modification) and we credit Mr. Eaton’s testimony that the modification is suggested in the prior art, as it is consistent with our reading of the prior art of record. *See* Ex. 1206 ¶ 190; *see, e.g.*, Ex. 1205, Fig. 2A (depicting a headgear connector (retainer 12) separate from the mask frame and cushion (shell 4 and seal 2)); *see also, e.g.*, Ex. 1202 (disclosing a headgear connector (plate 9) removably connected to a frame (shell 3)); Ex. 1204 (disclosing brace 12 removably connected to mask shell 13); Ex. 1217 (disclosing headstrap retention bracket 20 removably connected to mask shell 12).

As to ResMed’s argument that Gunaratnam’s one-piece mask is comparable to Geist’s mask, such that Geist (relied on by Mr. Eaton to

support Fisher's reasons to combine) fails to underpin Fisher's reasoning, we find that this argument is inconsistent with Geist's express teaching. *See* Ex. 1217 ¶ 42 (disclosing that headstrap retention bracket 20 (Geist's headstrap connector) separates from shell 12 and mask seal 14). We credit Mr. Eaton's testimony, as it is consistent with our reading of Geist and other prior art of record. *See* Ex. 1206 ¶ 192; *see also* Ex. 1204 ¶ 44 (disclosing that another benefit of Amarasinghe's removable headgear connector is that the connector and headgear assembly may be removed prior to cleaning the mask shell and cushion). We do not credit Mr. Virr, whose testimony mischaracterizes Geist as teaching separating headgear *straps* from the mask frame. *See* Ex. 2211 ¶ 105.

We recognize that Fisher's proposed modification would result in more parts (at least two pieces as compared to one) and would add some complexity to the mask. We find, however, that the benefits Fisher articulates outweigh this potential added complexity. *See Winner Int'l Royalty Corp.*, 202 F.3d at 1349 n.8. We agree with Fisher that the resulting mask would have been achieved with reasonable success. As we discussed above, the prior art discloses connecting a headgear connector to a mask frame at a central bore, as Fisher proposes, and that such a modification is within the relatively high level of ordinary skill in the art. *See* Ex. 1206 ¶¶ 188–193. This teaching in the prior art supports our finding that a person having ordinary skill in the art would have a reasonable expectation of success in Fisher's proposed modification. *See, e.g.*, Exs. 1202, 1204, 1217 (disclosing masks with separate headgear connectors).

With respect to Fisher's proposed modification driven by Amarasinghe, Fisher reasons that an artisan of ordinary skill "would have

been motivated to include multiple, different versions of the modified Gunaratnam headgear connector, for example with different shapes and/or headgear attachment points, so that the patient would have options for the number and location of the headgear straps attached to the mask.” Pet. 87–88 (referencing Ex. 1204 ¶¶ 29, 33; Ex. 1206 ¶ 215). Fisher continues that a person having ordinary skill in the art “would have understood that patients have different head shapes and different preferences for headgear arrangements” and, for example, Lovell discloses different headgear connector configurations. *Id.* at 88 (referencing Ex. 1205, 6:2–13, 9:36–42; Ex. 1206 ¶¶ 213, 215–216). Fisher adds that “[w]ith multiple different headgear connector options, the patient could select his/her preferred arrangement and use it with the same mask frame, without having to purchase several different entire mask assemblies.” *Id.* at 88. Fisher continues that “[p]roviding slightly modified headgear connectors, for example with different anchor locations and/or slightly different shapes, would have been a minor modification to this easily designed and molded plastic part.” *Id.* at 89 (referencing Ex. 1206 ¶ 218).

ResMed argues that Fisher’s proposed modification ignores Amarasinghe’s express teachings of disadvantages of molded plastic headgear connectors. PO Resp. 69. ResMed continues that Fisher’s modification ignores Amarasinghe’s preference for a flexible wire headgear connector. *Id.* at 70. ResMed argues that Amarasinghe discloses that using molded plastic headgear connectors, rather than inexpensive wire braces, results in relatively expensive tooling to mold the headgear connectors. *Id.* at 71–72. That is, ResMed argues that Amarasinghe teaches away from the proposed modification. *Id.* at 72 (“Simply put, Amarasinghe ‘teaches away’

from the modification of Gunaratnam and Lovell that Petitioner proposes.”). ResMed concludes that Fisher “failed to cite any reference that discloses the actual modification that Petitioner proposes to the modified Gunaratnam mask system—a mask system designed to accommodate different types of rigid headgear connectors.” *Id.* at 73.

ResMed’s arguments do not inform us of a deficiency in Fisher’s position. We find, on the complete record, that Fisher has provided a sufficient reason, with rational underpinning, for modifying Gunaratnam with the teaching of Amarasinghe. Indeed, we find that Amarasinghe provides the express motivation for Fisher’s proposed modification. Amarasinghe discloses:

An approach to headgear attachment which allows for great variability in head strap number and attachment position to the mask *would yield great benefits to the user* in terms of comfort and function, to the mask system manufacturer in terms of facilitating the opportunity to easily experiment with different mask positions and headgear configurations while moving towards the desirable objective of [rationalizing] manufacturer and supplier inventory.

Ex. 1204 ¶ 15 (emphasis added). That is, Amarasinghe expressly states that allowing for variability in attachment number and position provides great benefits to a user. Amarasinghe further discloses that rationalizing manufacturer and supplier inventory is realized by having a removable headgear connector, such that a small variety of mask shells need be produced and kept in inventory. *See id.* ¶¶ 31–33, 40.

We also find that Amarasinghe does not teach away from the proposed modification. “A reference may be said to teach away when a person of ordinary skill, upon reading the reference . . . would be led in a

direction divergent from the path that was taken by the applicant.” *In re Haruna*, 249 F.3d 1327, 1335 (Fed. Cir. 2001) (quoting *Tec Air, Inc. v. Denso Mfg. Mich. Inc.*, 192 F.3d 1353, 1360 (Fed. Cir. 1999)); *see, e.g., In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004) (holding that, to teach away, the prior art must “criticize, discredit, or otherwise discourage the solution claimed”). We find that the language in Amarasinghe relied on by ResMed does not “criticize, discredit, or otherwise discourage” Fisher’s proposed modification. Paragraph 40 in Amarasinghe states that it is expensive to change the location of headgear attachment points *on mask shells*. *See* Ex. 1204 ¶ 40. That is, a manufacturer would need a completely new, retooled mold, for each variation in a *mask shell*. Amarasinghe does not address separate headgear connectors made from polycarbonate. *See id.* We recognize the Amarasinghe does state that the wire brace is “relatively cheap to configure and manufacture” (relative to the mask shell), but this statement does not disparage a removable headgear connector that is made of molded plastic rather than metal. Although we consider Amarasinghe’s preference for metal wire braces, we find that this preference is not entitled to significant weight, given the benefits disclosed in Amarasinghe—benefits that are not tied to the material of Amarasinghe’s headgear connector. *See* Ex. 1206 ¶¶ 215–218; Ex. 1204 ¶¶ 15, 33, 44.

Conclusion as to claim 1

For the reasons discussed above, we determine, based on the complete record, that Fisher has demonstrated, by a preponderance of the evidence, that claim 1 is unpatentable under 35 U.S.C § 103 over Gunaratnam, Lovell, and Amarasinghe.

b. Dependent claims 2–22

Claim 2 depends from claim 1 and recites “wherein the mask frame and the sealing cushion comprise a full-face mask.” Ex. 1201, 12:9–10. Fisher contends that “Gunaratnam expressly discloses both nasal and full-face masks and its disclosed features apply to both nasal and full-face masks.” Pet. 89 (referencing Ex. 1203, 1:21–25, 6:3–13).

We find that Gunaratnam discloses that the mask frame and the sealing cushion is a full-face mask. *See* Ex. 1203, 6:3 (“The invention is also suitable for a full-face mask system.”). ResMed does not dispute Fisher’s contention with respect to claim 2.

Claim 3 depends from claim 2 and recites “wherein the sealing cushion is secured to the mask frame.” Ex. 1201, 12:11–12. Fisher contends that Gunaratnam’s cushion would have been compatible with and secured to the modified mask frame using a tongue and groove connection and/or the clip, as taught by Gunaratnam.” Pet 89 (referencing Ex. 1203 5:14–18, 5:29–46; Ex. 1206 ¶ 220). Fisher adds that “Gunaratnam and Lovell also disclose that it was known to glue or bond the cushion and frame together.” *Id.* (referencing Ex. 1203, 1:49–50).

We find that Gunaratnam discloses a mask where the sealing cushion is secured to the mask frame. *See, e.g.,* Ex. 1203, 5:14–18 (describing how the cushion includes groove 740 that is secured to frame 160 by receiving tongue 620); Ex. 1206 ¶ 220 (“The Gunaratnam cushion would have been compatible with and secured to the modified mask frame using a tongue and groove connection and/or the clip, as taught by Gunaratnam.”). ResMed does not dispute Fisher’s contention with respect to claim 3.

Claim 4 depends from claim 3 and recites “wherein at least a portion of said headgear connector is shaped to conform to a portion of said mask frame.” Ex. 1201, 12:13–15. Fisher contends that “[a]s modified, the Gunaratnam headgear connector would be shaped to conform to an outer surface of the frame.” Pet. 90.

We find that Gunaratnam, as modified as Fisher proposes, discloses a headgear connector with a portion that conforms to the outer surface of the mask frame. See Pet. 90 (providing an annotated version of Gunaratnam’s Figure 5c, illustrating how the headgear connector (gray) would conform to the mask frame (red)); Ex. 1206 ¶ 223 (depicting and describing the same annotated version of Gunaratnam’s Figure 5c). ResMed does not dispute Fisher’s contention with respect to claim 4.

Claim 5 depends from claim 4 and “recites wherein the mask frame includes a peripheral edge to engage the headgear connector.” Ex. 1201, 12:16–17. Fisher contends that the modified mask of Gunaratnam would be connected at the mask frame’s central bore and that the mask frame would include a flange or interfacing structure that would include a peripheral edge. Pet. 91–92. Fisher continues that Lovell discloses this type of interface between a mask frame and headgear connector and “[j]oining the headgear connector and the frame at a peripheral edge would provide a simpler interface, which would simplify manufacturing and manufacturing tolerances by creating engagement around more readily measured cylindrical features.” *Id.* at 92–93.

We find that Gunaratnam’s modified mask would have a mask frame that includes a peripheral edge to engage the headgear connector. We credit Mr. Eaton’s testimony on how the headgear connector would interface with

the mask frame, as his testimony is consistent with the teaching of Lovell. *See* Ex. 1206 ¶¶ 226–231; Ex. 1205, 9:34–10:21 (describing how an embodiment of Lovell’s retainer connects to the mask shell). ResMed does not dispute Fisher’s contention with respect to claim 5.

Claim 6 depends from claim 1 and further requires “an elbow assembly, said elbow assembly being adapted to be connected to an air delivery tube.” Ex. 1201, 12:18–20. Fisher contends that “Gunaratnam discloses that the headgear connector 160 incorporates a gas inlet aperture for connection to a gas delivery conduit of a patient gas delivery system, but does not expressly disclose that the gas delivery conduit is an elbow assembly.” Pet. 94 (referencing Ex. 1203, 4:22–26). Fisher continues that elbow assemblies were common to CPAP masks and that Lovell discloses such an elbow assembly. *Id.* (referencing Ex. 1206 ¶ 234; Ex. 1205, 7:29–32, 9:34–36). Fisher reasons that a person having ordinary skill in the art would have been motivated to use an elbow assembly as “[i]t was well-known at the time of the invention to connect an elbow assembly to mask assemblies to allow the air delivery tube to be routed in different directions based on patient position and preference, while minimizing loads applied to the mask assembly from the air delivery tube.” *Id.* at 95 (referencing Ex. 1206 ¶ 235).

We find that a person having ordinary skill in the art would have included an elbow assembly adapted to connect to an air delivery tube. We credit Mr. Eaton’s testimony, as it is consistent with the prior art of record. *See* Ex. 1206 ¶¶ 232–235; *see also* Ex. 1205, Fig. 10A (depicting an elbow assembly); Ex. 1212 ¶ 151 (disclosing swivel elbow 214); Ex. 1214 ¶ 113

(disclosing swivel elbow 22); Ex. 1217, Fig. 1 (depicting elbow assembly). ResMed does not dispute Fisher's contention with respect to claim 6.

Claim 7 depends from claim 1 and recites "wherein the headgear connector is removably attachable to the mask frame." Ex. 1201, 12:21–22. Fisher contends that "in modifying the Gunaratnam mask frame in view of Lovell, a person of skill would have adopted the removable connection disclosed by Lovell." Pet. 95 (referencing Fisher's analysis for claim 1 and the Gunaratnam ground).

As discussed above in connection with our analysis of claim 1, we determine that, as modified, Gunaratnam's mask would have a headgear connector that is removably attachable to the mask frame. *See supra* (addressing the requirement of claim 1 that "the mask frame [be] adapted to removably connect to more than one headgear connector"). We addressed ResMed's arguments with respect to this subject matter in connection with our analysis of claim 1, concluding that the arguments did not inform us of a deficiency in Fisher's reasoning. *See* PO Resp. 74 (referencing arguments made with respect to claim 1).

Claim 8 depends from claim 7 and recites "wherein when said mask frame and said headgear connector are attached, the mask frame and the headgear connector are not movable relative to one another." Ex. 1201, 12:23–26. Fisher contends that, by implementing a snap-fit connection as taught by Lovell, Gunaratnam's modified mask would include a mask frame and headgear connector that are not movable relative to one another when the two components are attached. Pet. 95–96.

We find that Gunaratnam's mask, as modified, would satisfy the subject matter of claim 8. First, we agree with Fisher and Mr. Eaton that

implementing a connection at the bore hole of the mask frame in a way taught by Lovell would result in a mask with a mask frame that was not movable relative to the headgear connector. *See* Ex. 1206 ¶¶ 237–238. This finding is further supported by the relative shapes of the mask frame and headgear connector, where the two components conform to one another, thus preventing relative rotation. *See, e.g., id.* at ¶ 223 (providing an annotated version of Gunaratnam’s Figure 5c, illustrating how the headgear connector (gray) would conform to the mask frame (red)). ResMed does not dispute Fisher’s contention with respect to the additional subject matter recited in claim 8. *See* PO Resp. 74 (addressing claim 8 only to the extent that it depends from claim 7).

Claim 9 depends from claim 7 and recites “wherein the headgear connector and the mask frame are adapted to be engaged by a snap-fit.” Ex. 1201, 12:27–29. Fisher contends that “the modified Gunaratnam mask assembly would have adopted the removable snap-fit connection disclosed by Lovell.” Pet. 96 (referencing Fisher’s analysis of Gunaratnam and claim 1). As Mr. Eaton explains, Lovell discloses that shell 204 connects to retainer 212 at cylindrical inlet 208. Ex. 1206 ¶ 241.

We find that Fisher’s proposed modified mask would include the headgear connector and the mask frame being adapted to engage by a snap-fit, as taught by Lovell. *See* Ex. 1205, 9:34–10:21. We credit Mr. Eaton’s testimony, in part because it is consistent with the disclosure in Lovell and in part based on the use of snap-fit connections in the art. For example, Gunaratnam itself discloses a rigid-to-rigid snap fit. *See* Ex. 1203, 4:21–25, 5:29–42 (disclosing a snap-fit connection between clip 800 and frame 160, both formed from polycarbonate); *see also* Ex. 1211, 345 (providing

excerpts from “Plastic Part Design for Injection Molding” and discussing snap-fit joints between two rigid plastic pieces). ResMed does not dispute Fisher’s contention with respect to the additional subject matter recited in claim 9. *See* PO Resp. 74 (addressing claim 9 only to the extent that it depends from claim 7).

Claim 10 depends from claim 7 and recites “wherein the headgear connector comprises a plurality of tabs to attach the mask frame with a snap-fit.” Ex. 1201, 12:30–32. Fisher contends that Lovell teaches a snap-fit connection that employs a plurality of tabs. Pet. 98 (referencing Ex. 1205, 9:59–64).

We find that Fisher’s proposed modified mask would include the headgear connector and the mask frame being adapted to engage by a snap-fit, as taught by Lovell, where the snap-fit employs a plurality of tabs. *See* Ex. 1205, 9:34–10:21 (describing connecting retainer 212 with shell 204); Ex. 1206 ¶ 246. ResMed does not dispute Fisher’s contention with respect to the additional subject matter recited in claim 10. *See* PO Resp. 74 (addressing claim 10 only to the extent that it depends from claim 7).

Claim 11 depends from claim 1 and recites “wherein the central bore is located on a main body of the mask frame.” Ex. 1201, 12:33–34. Fisher contends that its modified mask would have a central bore located on the main body of the mask frame. *See* Pet. 100 (referencing Ex. 1206 ¶¶ 253–255).

We find that the modified mask of Gunaratnam would disclose the subject matter of claim 11. *See* Pet. 100 (providing an annotated image of Gunaratnam’s Figure 5c, which depicts a central bore in the mask frame (shown in red)); Ex. 1206 ¶ 253 (explaining the annotated version of

Gunaratnam's Figure 5c). ResMed does not dispute Fisher's contention with respect to claim 11.

Claim 12 depends from claim 1 and further requires the mask to "compris[e] a vent assembly for gas washout." Ex. 1201, 12:35–36. Fisher acknowledges that the embodiment depicted in Gunaratnam's Figure 5c—the embodiment relied on by Fisher in its obviousness assertion—"does not include a vent assembly but other embodiments, such as Figure 15 [of Gunaratnam], disclose an air vent assembly 940 for gas washout." Pet. 101 (reproducing Gunaratnam's Figure 15). Fisher contends that "vent assemblies were frequently included in mask assemblies to release gases exhaled by the user." *Id.* (referencing Ex. 1206 ¶ 44).

We determine that it would have been obvious to include a vent assembly for gas washout in Gunaratnam's modified mask, as at least suggested by Gunaratnam. *See* Ex. 1203, 6:25–29 ("[F]rame (160) . . . includes a gas inlet aperture (910), connection points (920) for headgear straps, an aperture (930) for receiving an air vent (940) (FIG. 15) and ports (950)."). ResMed does not dispute Fisher's contention with respect to claim 12.

Claim 13 depends from claim 1 and recites "wherein the forehead support is T-shaped." Ex. 1201, 12:37–38. Fisher contends that Gunaratnam's Figure 5c depicts a T-shaped forehead support. Pet. 102.

We find that Gunaratnam discloses a T-shaped forehead support. *See* Ex. 1203, Figs. 5c-5f. ResMed does not dispute Fisher's contention with respect to claim 13.

Claim 14 depends from claim 1 and recites "wherein the sealing cushion cannot be easily detached from the mask frame." Ex. 1201, 12:39–

40. Fisher contends that “Gunaratnam discloses that it was known to glue the mask frame to the cushion” and that “Lovell also discloses that the cushion 2 is affixed to the frame 4 by bonding.” Pet. 103 (referencing Ex. 1203, 1:54; Ex. 1205, 4:34–36). Mr. Eaton adds that “[p]roviding a sealing cushion that cannot be easily detached from the mask frame was common in the prior art for CPAP masks prior to the ’196 [p]atent.” Ex. 1206 ¶ 259 (referencing Ex. 1205 (Lovell), 4:34–36 and Ex. 1218, 4:17–26 as exemplary masks).

We find that a sealing cushion that is glued or bonded to a mask frame cannot be easily detached from the mask frame as required by claim 14. We agree with Mr. Eaton that the prior art of record supports a finding that cushions glued or bonded to the mask frame were common in the prior art. *See* Ex. 1206 ¶ 259. ResMed does not dispute Fisher’s contention with respect to claim 14.

Claim 15 depends from claim 1 and recites “wherein the sealing cushion and the mask frame are permanently attached.” Ex. 1201, 12:41–42. Fisher relies on its analysis for claim 14, contending that cushions that are glued or bonded to the mask frame are permanently attached to the mask frame. Pet. 104.

We find that gluing or bonding are forms of permanent attachment, such that a sealing cushion glued or bonded to a mask frame would be permanently attached to the mask frame. *See* Ex. 1206 ¶¶ 259, 261. ResMed does not dispute Fisher’s contention with respect to claim 15.

Claim 16 depends from claim 1 and recites “wherein said headgear connector is constructed of a similar material as the frame.” Ex. 1201, 12:43–44. Claim 17 depends from claim 16 and recites “wherein said

headgear connector and said mask frame are constructed of a substantially rigid, non-malleable plastic material.” *Id.* at 12:45–47. Claim 18 depends from claim 17 and recites “wherein said headgear connector and said mask frame are constructed of polycarbonate.” *Id.* at 12:48–50. Fisher contends that its modified mask would have a polycarbonate headgear connector and polycarbonate mask frame, satisfying the requirements of these three dependent claims. Pet. 104–105.

We find that Fisher’s proposed modification would result in separating the headgear connector component from the mask frame component of Gunaratnam’s one-piece mask construction, resulting in a polycarbonate headgear connector and polycarbonate mask frame. *See* Ex. 1206 ¶¶ 265–266; Ex. 1203, 4:22–24.

ResMed argues that applying Lovell’s teaching would result in a rigid-to-flexible connection, such that the headgear connector would not be the same material as the mask frame. PO Resp. 74–75. As we discussed above in connection with our analysis of claim 1 and Gunaratnam as modified by Lovell, we determine that this argument does not inform us of a deficiency in Fisher’s position. ResMed seeks to bodily incorporate Lovell’s materials into Fisher’s proposed mask. We determine that this argument ignores Fisher’s position that both the headgear connector and mask frame would be polycarbonate. *See* Reply 16 (“Th[e] modification would maintain Gunaratnam’s rigid structure.”). As discussed above, we also determine that a rigid-to-rigid connection was within the skill level of a person having ordinary skill in the art, such that Lovell’s teachings are not limited to a rigid-to-flexible connection.

Claim 19 recites:

A mask system for delivering breathable gas to a patient at positive pressure to treat sleep disordered breathing, the mask system comprising:

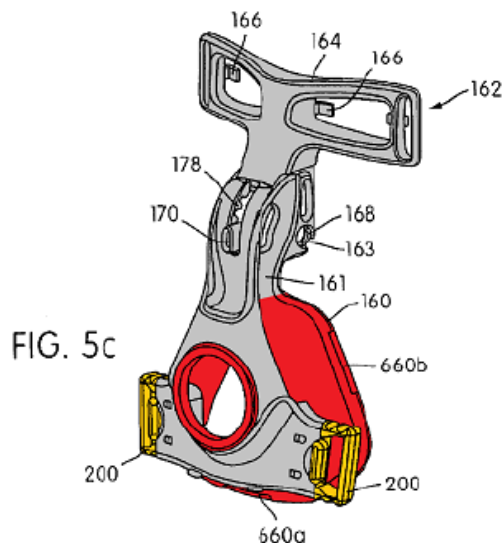
a headgear including a pair of upper side straps, a pair of lower side straps, and a rear portion;

a pair of lower headgear clips adapted to receive respective ones of the pair of lower side straps; and

a mask according to claim 1.

Ex. 1201, 12:51–58. Fisher contends that Gunaratnam discloses “headgear with upper and lower straps [that] would have been used to connect to the upper and lower headgear strap connection points of the Gunaratnam masks.” Pet. 106–107 (referencing Ex. 1206 ¶¶ 272–273). Fisher also contends that, after modifying Gunaratnam, the headgear connector would maintain its lower headgear clips. *Id.* at 107 (providing an annotated version of Gunaratnam’s Figure 5c).

We find that Gunaratnam’s mask, as modified as Fisher proposes, would disclose the subject matter of claim 19. We reproduce Fisher’s annotated version of Figure 5c below:



Pet. 107. The annotated version of Figure 5c depicts the headgear connector in gray, the mask frame in red, and the lower headgear clips in yellow. This image shows that the forehead support includes two openings for a pair of upper side straps and headgear clips for two lower straps. The straps would extend to the back of the wearer's head, such that they would include a rear portion. See Ex. 1206 ¶¶ 271–273. ResMed does not dispute Fisher's contentions with respect to claim 15.

Claim 20 depends from claim 19 and recites “wherein the pair of upper side straps are arranged to extend above the patient's ears and the pair of lower side straps are arranged to extend below the patient's ears.” Ex. 1201, 12:59–62. Claim 21 depends from claim 20 and recites “wherein the rear portion of the headgear is adapted to cup the occiput of the patient's head.” *Id.* at 12:63–65. Fisher contends that the headgear disclosed in Gunaratnam associated with prior art Figure 1 would have upper straps that go above the patient's ear and would have a rear portion that cups the occiput of the patient's head (that is, the back of the skull). Pet. 108–109.

We find that Gunaratnam discloses a headgear system that would have straps corresponding to the connection points for the mask of the embodiment of Figure 5c, such that the upper straps would be above a wearer's ear and the rear portion would cup the occiput of the wearer's head. Compare Ex. 1203, Fig. 1 (showing a prior art headgear arrangement) with Fig. 5c (showing attachment points). Of course, as discussed above in our analysis of claim 1, we determined that it would have been obvious to have multiple headgear connectors that would have been interchangeable to accommodate a wide range of available headgear configurations. ResMed does not dispute Fisher's contentions with respect to claims 20 and 21.

Claim 22 depends from claim 1 and recites “wherein said forehead support is adjustable.” Ex. 1201, 12:66–67. Fisher contends that Gunaratnam discloses an adjustable forehead support. Pet. 109 (referencing Ex. 1203, 4:46–48). We find that Gunaratnam’s forehead support is adjustable. See Ex. 1203, 4:47–48 (“FIGS. 5c-5f also show an adjustable forehead support (162) connected to the frame (160).”). ResMed does not dispute Fisher’s contention with respect to claim 22.

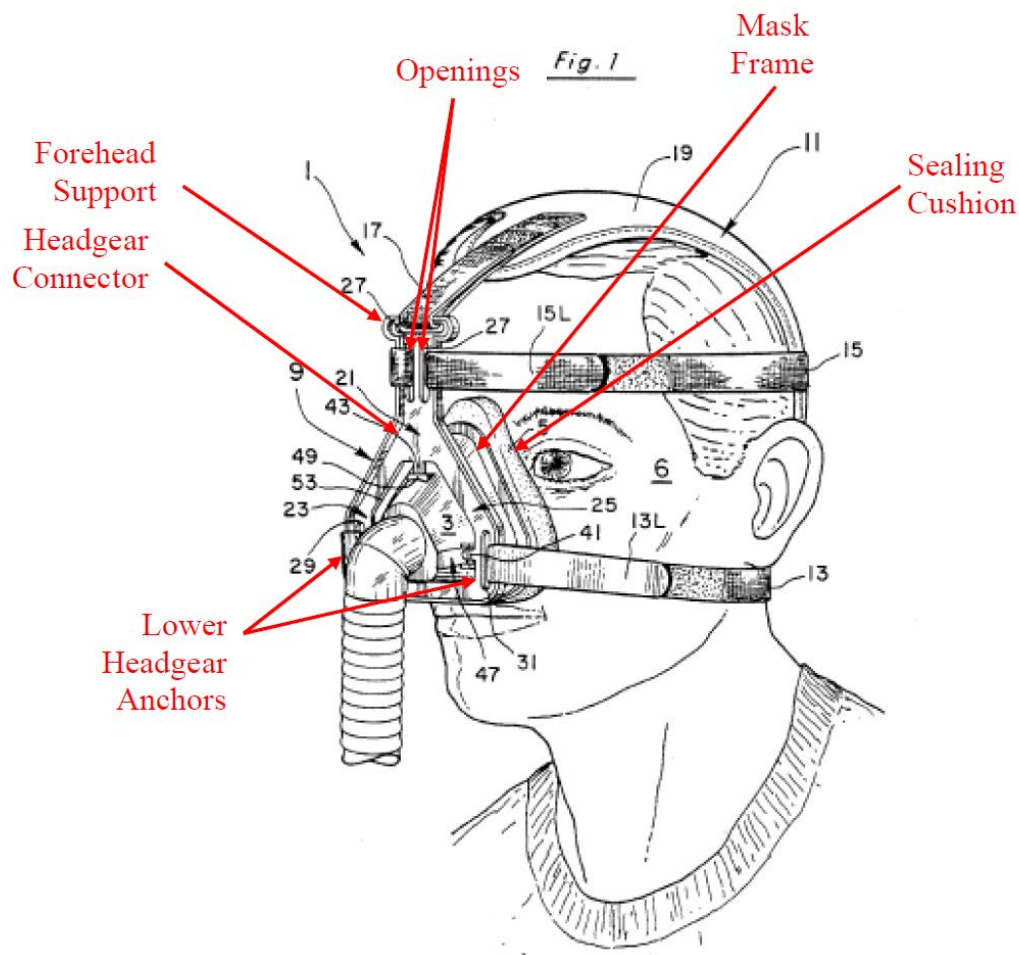
For the reasons discussed above, we determine, based on the complete record, that Fisher has demonstrated, by a preponderance of the evidence, that claims 2–22 are unpatentable under 35 U.S.C § 103 over Gunaratnam, Lovell, and Amarasinghe.

2. Claims 1–3, 6, 7, and 9–22 as Allegedly Obvious over Ogden, Gunaratnam, and Amarasinghe

a. Independent claim 1

The subject matter of claim 1

Fisher contends that Ogden discloses “nearly all” of the subject matter of claim 1. Pet. 27. Fisher provides an annotated version of Ogden’s Figure 1, identifying how Ogden discloses this subject matter. We reproduce this annotated figure below.



The annotated figure shows Ogden’s mask system and identifies the mask frame, sealing cushion, headgear connector with forehead support and associated openings, and lower headgear anchors. *See* Pet. 28. Fisher asserts that “[a]ny differences between [the subject matter of] [c]laims 1–3, 6, 7, and 9–22 and Ogden were minor, well-known, and taught by Gunaratnam and/or Amarasinghe.” *Id.*

Specifically, claim 1 recites “a mask frame having a central bore, said mask frame having no built-in or integral headgear attachment points.” Ex. 1201, 11:61–62 (the “mask frame” limitation). Fisher contends that Ogden discloses mask frame 3, which includes a bore for receiving hose coupling 10. Pet. 31. Fisher further contends that Ogden’s mask frame 3 has no

built-in or integral headgear attachment points. *Id.* We find, based on the complete record, that Ogden discloses the subject matter of the “mask frame” limitation of claim 1. *See* Ex. 1202, Figs. 1, (depicting shell 3 with swivel hose coupling 10 connected to shell 3 at a central bore); 5:35–41; Ex. 1206 ¶¶ 51–54. ResMed does not dispute Fisher’s contention with respect to the “mask frame” limitation.

Claim 1 further recites “a sealing cushion provided to the mask frame and adapted to form a seal with the patient’s face.” Ex. 1201, 11:63–64 (the “sealing cushion” limitation of claim 1). Fisher contends that Ogden discloses soft sealing cushion 5 attached to frame 3, which seals against a wearer’s face. Pet. 33. We find, based on the complete record, that Ogden discloses the subject matter of the “sealing cushion” limitation of claim 1. *See* Ex. 1202, 2:54–57 (“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 to engage and seal against the patient’s face.”); Ex. 1206 ¶ 48. ResMed does not dispute Fisher’s contention with respect to the “sealing cushion” limitation.

Claim 1 also recites “a headgear connector adapted to engage the mask frame, said headgear connector including a pair of lower headgear clip anchors adapted to be engaged with respective ones of a pair of lower headgear clips.” Ex. 1201, 11:65–12:1 (the “headgear connector” limitation of claim 1). Fisher contends that Ogden’s rigid plate 9, which is adapted to engage mask frame 3, corresponds to the recited headgear connector. Pet. 34. Fisher adds that rigid plate 9 includes openings 29 and 31 correspond to the recited lower headgear clip anchors. *Id.* Fisher explains that “Ogden . . .

discloses that ‘snaps and similar arrangements’ could be used for the headgear anchors.” *Id.* (referencing Ex. 1202, 3:10–18).

Alternatively, Fisher contends that Gunaratnam discloses headgear clip anchors, identifying headgear clip anchors 630 that engage clips 200. Pet. 35 (referencing Ex. 1203, 4:32–34, Figs. 5a, 5c). Fisher contends that a person having ordinary skill in the art would have been motivated to employ Gunaratnam’s lower headgear clips in place of Ogden’s lower headgear anchors. *Id.*

We determine that Fisher has demonstrated, by a preponderance of the evidence, that Ogden, as modified by the teachings of Gunaratnam, discloses the subject matter of the “headgear connector” limitation of claim 1. We are not persuaded that Ogden’s disclosure, that “snaps and similar arrangements” could be used to secure headgear straps to plate 9, is sufficient to demonstrate that Ogden discloses the headgear clips recited in the “headgear connector” limitation of claim 1. *See* Ex. 1202, 3:10–18; Ex. 1206 ¶ 59 (“Ogden does not specifically disclose headgear clips.”).

We find, however, that this disclosure in Ogden at least suggests that a wide range of known components may be used to attach straps 13R and 13L to plate 9. One such example are the headgear clips disclosed in Gunaratnam. *See* Ex. 1203, Fig. 5c, 4:31–33 (“On the front surface of the frame, are strap connection points (630) for connection of the mask to patient headgear. Connectors (200) are shown in FIGS. 5c-5f.”). We find that connectors 200 correspond to the recited headgear clips. *See* 1206 ¶ 60. ResMed does not dispute Fisher’s contention with respect to the “headgear connector” limitation and Gunaratnam. We address Fisher’s reasoning for

modifying Ogden with Gunaratnam’s headgear clips below, in a subsection labeled “Reasons to combine Ogden, Gunaratnam, and Amarasinghe.”

Claim 1 further recites “said headgear connector including a forehead support connected to the headgear connector by an upper support member, said forehead support including a pair of openings adapted to attach to respective ones of a pair of upper side straps.” Ex. 1201, 12:1–5 (the “forehead support” limitation). Fisher contends that top portion 21 of plate 9 satisfies the forehead support limitation. Pet. 36–37. Fisher explains that upper side straps 15L and 15R connect with top portion 21 and extend across the user’s forehead and Ogden’s top portion 21 is comparable to the forehead support depicted in Figure 3B of the ’196 patent.

We reproduce Ogden’s Figure 3, below.

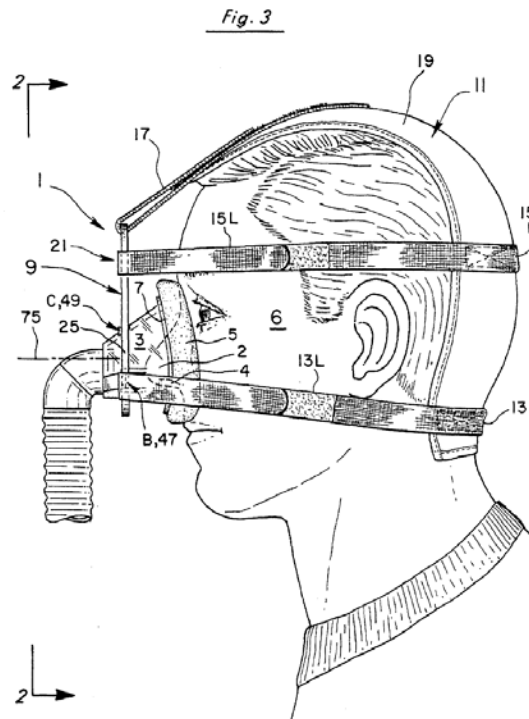


Figure 3 depicts a side view of a person wearing Ogden’s mask. Ex. 1202, 2:20–21. The figure shows that top portion 21 does not contact the wearer’s forehead, and that the straps contact the side of a wear’s head. We are not

persuaded that the proper construction of the term forehead support encompasses a structure (including associated straps) that does not contact or otherwise support the mask on the forehead. *See* PO Resp. 12–14.

Fisher alternatively contends that Gunaratnam discloses the forehead support limitation of claim 1. Pet. 38. Specifically, Fisher contends that Gunaratnam’s forehead support 162, depicted in Gunaratnam’s Figure 5c, corresponds to the subject matter of the forehead support limitation. *Id.* Fisher contends that a person having ordinary skill in the art would have contoured Ogden’s existing structure (the top portion of plate 9) towards the forehead as taught by Gunaratnam. *Id.* at 38–39; *see also* Ex. 1206 ¶ 73 (“[A] person of skill in the art would have contoured the forehead support toward the forehead to provide a greater field of view and a more aesthetically streamlined interface.”).

We find, based on the complete record, that Ogden, as modified by the teaching of Gunaratnam, discloses the subject matter of the “forehead support” limitation of claim 1. ResMed does not dispute that Gunaratnam discloses a forehead support. Again, we address Fisher’s reasoning for modifying Ogden with Gunaratnam’s teachings, as well as ResMed’s responsive arguments, in the subsection labeled “Reasons to combine Ogden, Gunaratnam, and Amarasinghe,” below.

Finally, claim 1 recites “wherein the mask frame is adapted to removably connect to more than one headgear connector, each headgear connector being different in at least one aspect.” Ex, 1201, 12:6–8 (the “multiple headgear connector” limitation of claim 1). Fisher acknowledges that, although Ogden discloses that rigid plate 9 is removable from mask frame 3, that Ogden does not disclose more than one headgear connector,

with each headgear connector being different in at least one aspect, as required by the multiple headgear connector limitation of claim 1. Pet. 40.

Fisher contends that Amarasinghe discloses the subject matter of the “multiple headgear connector” limitation. Pet. 40. Specifically, Fisher argues that Amarasinghe discloses a mask system with multiple brace 12s with the different brace 12s having a different number of attachment points for headgear. *Id.* Fisher contends that a person having ordinary skill in the art would have modified Ogden to have different headgear connectors to accommodate different headgear configurations. *Id.* at 41–42.

We find, based on the complete record, that Ogden, as modified by the teachings of Amarasinghe, discloses the “multiple headgear connector” limitation of claim 1. Amarasinghe discloses that, beneficially, different removable headgear connectors can be employed for a single mask structure to allow for attaching different headgears to the same mask. *See* Ex. 1204 ¶ 33 (“A user may be supplied with a number of braces each with a different number of headgear attachment points . . . in order that a suitable choice may be made.”); *see also id.* at ¶ 15 (discussing the benefits of variability in head strap number and attachment position). ResMed does not dispute that Amarasinghe discloses different braces for attaching different headgear configurations to a mask.

In conclusion, we find that Fisher has demonstrated, by a preponderance of the evidence, that Ogden, as modified by Gunaratnam and Amarasinghe, discloses the subject matter of claim 1.

*Reasons to combine
Ogden, Gunaratnam, and Amarasinghe*

“Headgear connector” limitation. Fisher contends that a person having ordinary skill in the art would have had reason to modify Ogden with

Gunaratnam’s teaching of lower headgear clips to arrive at the subject matter of the “headgear connector” limitation of claim 1. Fisher reasons that “[a] person of skill in the art at the time of the invention would have been motivated to replace the lower headgear anchors of Ogden with lower headgear clips, as taught by Gunaratnam” as “[s]uch a modification would have been a mere substitution of one known feature for another to obtain predictable results.” Pet. 35. Fisher adds that “[a] person of skill would have been motivated to provide lower headgear clips, so the user would not have to force the lower headgear straps over his/her head, and instead would be able to secure the headgear after the mask is properly positioned on the user’s face.” *Id.* at 36 (referencing Ex. 1206 ¶ 63). Fisher continues that “such clips were commonly used to facilitate removal of the headgear straps from the headgear connector during cleaning and reattachment of the headgear straps without requiring any strap length adjustment.” *Id.* (referencing Ex. 1206 ¶ 62).

We find, on the complete record, that Fisher has provided a sufficient reason, with rational underpinning, for modifying Ogden with the teaching of Gunaratnam, to arrive at the subject matter of the “headgear connector” limitation of claim 1. *See KSR Int’l Co.*, 550 U.S. at 418 (providing that, to facilitate the analysis of an obviousness position on appeal, the record should provide “some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”); *see also PAR Pharm., Inc. v. TWI Pharm., 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.”). Our finding is supported, in part, by Ogden’s express disclosure that different types of connections to the

headgear may be used. See Ex. 1202, 3:13–18. ResMed does not dispute Fisher’s contentions with respect to its reasons to modify Ogden with Gunaratnam to arrive at the subject matter of the “headgear connector” limitation of claim 1.

“Multiple headgear connector” limitation. Fisher reasons that an artisan of ordinary skill “would have been motivated to include multiple, different versions of the Ogden headgear connector, for example with different shapes and/or headgear attachment points, so that the patient would have options for the number and location of the headgear straps attached to the mask.” Pet. 42 (referencing Ex. 1204 ¶¶ 29, 33; Ex. 1206 ¶ 89). Fisher continues that a person having ordinary skill in the art “would have understood that patients have different head shapes and different preferences for headgear arrangements” and “[w]ith multiple different headgear connector options, the patient could select his/her preferred arrangement and use it with the same mask frame, without having to purchase several different entire mask assemblies.” *Id.* (referencing Ex. 1206 ¶¶ 90–91). Fisher contends that “[b]ecause the Ogden headgear connector is a simple molded plastic piece, the headgear connector could be easily modified and reproduced into different versions with a reasonable expectation of success.” *Id.* (referencing Ex. 1206 ¶ 92).

ResMed argues that none of Ogden, Gunaratnam, and Amarasinghe discloses multiple, plastic removable headgear connectors. PO Resp. 21. ResMed adds that “Amarasinghe never contemplates any mask system that provides swappable rigid headgear plates.” *Id.* at 22. ResMed argues that Amarasinghe’s wire brace adds *additional* attachment points for headgear straps and the wire brace allows the user to modify the shape of the brace to

accommodate different headgear straps. *Id.* ResMed continues that Amarasinghe's brace could not accommodate headgear clips. *Id.* Finally, ResMed argues that Amarasinghe's brace is not necessary as Ogden's plate 9 already has attachment points at top portion 21. *Id.*

Fisher replies that the combination of Ogden and Amarasinghe results in multiple, rigid, headgear connectors. Reply 5. Fisher asserts that ResMed's arguments are based on bodily incorporating Amarasinghe's brace into Ogden's mask. *Id.* Fisher adds that ResMed's position ignores the relatively high level of ordinary skill in the art. *Id.* at 6.

We find that ResMed's arguments do not inform us of a deficiency in Fisher's reasoning. We agree with Fisher that ResMed's arguments amount to bodily incorporating Amarasinghe's brace into Ogden's mask, ignoring Fisher's obviousness position. *See Allied Erecting & Dismantling Co. v. Genesis Attachments, LLC*, 825 F.3d 1373, 1381 (Fed. Cir. 2016) ("The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference.") (quoting *In re Keller*, 642 F.2d 413, 425 (CCPA 1981)). We also agree with Fisher that ResMed's arguments ignore the level of ordinary skill in the art, treating an artisan of ordinary skill as an automaton. *See KSR, Int'l Co.*, 550 U.S. at 421 ("A person of ordinary skill is also a person of ordinary creativity, not an automaton."). We find that a person having ordinary skill in the art would have used her creativity to apply Amarasinghe's teachings of multiple headgear connectors (albeit metal wire headgear connectors) to Ogden's rigid plate to arrive at a mask with multiple, rigid, plastic headgear connectors. *See* Ex. 1206 ¶¶ 79–88, 92. Indeed, Amarasinghe expressly teaches the benefits of multiple headgear connectors and these benefits are

not limited to the wire nature of Amarasinghe's braces. *See* Ex. 1204 ¶ 15 ("An approach . . . [that] allows for great variability in head strap number and attachment position to the mask would yield great benefits to the user in terms of comfort and function, [and] to the mask system manufacturer in terms of facilitating . . . the desirable objective of [rationalizing] manufacturer and supplier inventory.).

We also find, with respect to ResMed's argument that Amarasinghe teaches *additional* attachment points, that ResMed's argument is contrary to the evidence of record. Amarasinghe expressly discloses that attachment points 17 on mask shell 13 are "superfluous," that is, not needed. Ex. 1204 ¶ 30.

ResMed next argues that Fisher's proposed modification is contrary to Amarasinghe's "preferences and principle of operation." PO Resp. 23 (quoting Ex. 1204 ¶ 40). Fisher replies that Amarasinghe does not teach away from the proposed modification. Reply 6; *see also supra* (finding, in connection with our analysis of claim 1 and the Gunaratnam-Lovell-Amarasinghe ground, that Amarasinghe does not teach away from a rigid headgear connector).

As we discussed above in connection with our analysis of claim 1 and the Gunaratnam-Lovell-Amarasinghe ground, we find that Amarasinghe's paragraph 40 is directed to the cost of producing multiple mask frames, not headgear connectors. *See* Ex. 1204 ¶ 40 (discussing the construction technique for "mask shells"). Although Amarasinghe employs a wire brace that adds certain functionality (such as adapting the brace to add an attachment point), we find that Amarasinghe principle of operation is broader than its wire brace configuration. *See id.* ¶¶ 18–23, 32, 33.

Amarasinghe is directed to employing a versatile headgear connector system that may include multiple connectors with different attachment points. *Cf.* Ex. 1201, 1:39–44 (incorporating by reference Amarasinghe’s disclosure, although the ’196 patent is directed to multiple, rigid headgear connectors). Although we consider Amarasinghe’s preference for metal wire braces, we find that this preference is not entitled to significant weight, given the benefits disclosed in Amarasinghe—benefits that are not tied to the material of Amarasinghe’s headgear connector. *See* Ex. 1204 ¶¶ 15, 33, 44.

Finally, ResMed argues that a person having ordinary skill in the art would not employ multiple headgear connectors on Ogden’s mask, as each connector would need to be positioned at a different point on shell 3—the different plate 9 configurations would not rotate as required by Ogden. PO Resp. 24–25; Ex. 2211 ¶ 46. Mr. Virr provides an example. *See* Ex. 2211 ¶ 47. Mr. Virr declares that, for a configuration where no top/forehead straps were used, plate 9 would need to be moved to balance the forces. *Id.* Mr. Virr provides no additional explanation for his opinion.

Fisher replies that ResMed provides no basis for its position. Reply 7. Fisher explains that Mr. Virr’s opinion is limited to a specific headgear configuration—one with no top headgear straps—a configuration outside the scope of claim 1. *See* Tr. 27:9–28:8.

Although ResMed’s argument may have merit for the limited example that Mr. Virr describes, we find the argument insufficient to inform us of a deficiency in Fisher’s position. First, Mr. Virr fails to provide any support to his position, such that we do not afford his opinion much weight. Second, as Fisher points out, claim 1 requires a pair of upper side straps, so Mr. Virr’s example is based on a mask that is outside the scope of claim 1.

We find, on the complete record, that Fisher has provided persuasive reasoning, with rational underpinning (which we adopt), for modifying Ogden with the teaching of Gunaratnam and Amarasinghe, to arrive at the subject matter of the “multiple headgear connector” limitation of claim 1. Primary support for our finding comes from Amarasinghe itself, which extolls the benefits of multiple, replaceable headgear connectors. *See* Ex. 1204 ¶ 15; *see also* Ex. 1201, 1:39–44 (incorporating by reference Amarasinghe’s disclosure).

“Forehead support” limitation. Fisher contends that a person having ordinary skill in the art would have had reason to modify Ogden with Gunaratnam’s teaching to contour the upper part of Ogden’s plate 9 to contact the wearer’s forehead. Pet. 38. Fisher reasons that “a person [having ordinary] skill in the art would have known that modifying [Ogden’s] support to contact the patient’s forehead would provide additional benefits.” *Id.* (referencing Ex. 1206 ¶¶ 73–75). Fisher continues that an artisan of ordinary skill “would have recognized that, by providing a second contact point between the mask and the patient’s face, the mask would be more stable.” *Id.* at 38–39 (referencing Ex. 1206 ¶ 73). Fisher adds that a person having ordinary skill in the art “would have contoured the forehead support toward the forehead to provide a greater field-of-view around the forehead support and a more aesthetic, streamlined interface.” *Id.* at 39.

Fisher also contends that an artisan of ordinary “skill would have recognized that modifying the Ogden support to contact the forehead would likely affect or limit the relative movement between the headgear connector and the mask frame, but . . . such a person would have known that this relative movement was unnecessary and undesirable.” Pet. 39. Fisher

explains that a person having ordinary “skill would have recognized that modifying Ogden so that the headgear connector is not movable relative to the frame would provide more stability between the headgear connector and the mask frame” and that “it is advantageous to be able to adjust the headgear and headgear connector to apply more or less pressure along the perimeter of the mask to maintain a comfortable and effective seal against the face.” Pet. 71 (referencing Ex. 1206 ¶ 173). Fisher also asserts that “advances in cushion design . . . and manufacturing technology” could provide the same benefits as the relative movement between a headgear connector and frame taught by Ogden. *Id.* We treat this contention as an alternative reasoning. Based on our review of the entire trial record, we conclude that Fisher does not exclusively argue that its modification would fix plate 9 such that it would not move. *See, e.g.*, Ex. 1206 ¶ 75 (“[A] person of skill in the art would have understood that modifying the forehead support of Ogden to contact the forehead of the user would not necessarily fix the position of the headgear connector relative to the mask frame.”); Tr. 23:26–24:4 (“Mr. Eaton in his declaration did say that he didn’t think movability would be desired as of 2007, but if -- if some movability was still desired that there would be still some movability in -- in Ogden, even with the proposed modification of Gunaratnam.”).

ResMed argues that a person having ordinary skill in the art would not have had reason to modify Ogden to contour the top portion 21 of plate 9 to contact a wearer’s face to increase stability, because Ogden teaches that plate 9 should rotate. PO Resp. 14. ResMed continues that top portion 21

contacting would limit the side-to-side rotation of plate 9.⁵ *Id.* at 15. ResMed argues that this limitation on side-to-side rotation would change Ogden's principle of operation. *Id.* at 16. ResMed explains that Ogden expressly teaches that the side-to-side rotation of plate 9 addresses the problem of leaks caused by a wearer moving his or her head during sleep. *Id.* at 16–17.

Fisher responds that, after the proposed modification, Ogden's plate 9 would still be able to move. Reply 2 (referencing Ex. 2212, 91:14–25). In his testimony, Mr. Eaton indicates that the relatively narrow characteristic of the upper portion of plate 9 would allow this movement. *See* Ex. 2212, 91:14–25. Fisher continues that Mr. Virr recognized that the narrow nature of top portion 21 of plate 9 would not eliminate movement of plate 9.

As an initial matter, we find that Ogden's principle of operation is to employ a rigid plate loosely mounted to a rigid shell, such that “in use, the rigid plate is free to move relative to the rigid shell in response to any unequal forces being applied to it by the side straps as the patient, for example, turns his or her head from side-to-side.” Ex. 1202, 1:57–61; *see also id.* at 4:17–20 (disclosing that the loose-fitted rigid plate “rotate[s] to compensate for any unequally applied forces as the patient moves his or her head”), 4:31–38 (disclosing that the rotating action of plate 9 compensates for the forces applied to shell 3 when the wearer moves his or her head from

⁵ ResMed also argues that Fisher's proposed modification would eliminate any up-and-down rotation of plate 9. PO Resp. 14–15. ResMed fails to explain adequately the significance of this change to plate 9. *See id.* at 16–21 (discussing Ogden's teachings as they relate to the benefits of side-to-side rotation). Accordingly, ResMed fails to inform us of a deficiency in Fisher's position due to eliminating the up-and-down rotation of plate 9.

side to side), 4:61–5:3 (describing how Ogden’s facial mask compensates for any unequal applied forces by the side straps through the operation of loosely-mounted rigid plate 9); Fig. 4 (illustrating how the seal at a patient’s face is broken by side-to-side movement with a rigid plate fixedly mounted to a rigid shell); *cf. id.* at 1:16–20 (“[A] common problem often arises that the mask will tend to unseat and leak as the patient turns his or her head (e.g., from side-to-side) or rolls over in bed and the straps contact and are deflected by a pillow, blanket, or other object.”).

We also find that modifying Ogden by contouring top portion 21 of plate 9 so that it contacts the wearer’s forehead would adversely affect this principle of operation. As Fisher itself states, “[a] person of skill would have recognized that modifying the Ogden support to contact the forehead would likely affect or limit the relative movement between the headgear connector and the mask frame.” Pet. 39; *see also* Ex. 2211 ¶ 29 (“[A person having ordinary skill in the art] would have understood that a forehead support would have limited the freedom with which Ogden’s rigid plate 9 would move during use by a patient.”). Indeed, one of Fisher’s reasons for making the proposed modification is to provide greater stability, that is, less movement for the mask. Pet. at 38–39.

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. We also consider, before holding a claimed invention obvious, whether combining references would violate the principle of operation of the modified reference. *See In re Mouttet*, 686 F.3d 1322, 1332 (Fed. Cir. 2012). 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.*, 437 F.3d at 1165 (emphasis added); *see also Winner Int’l Royalty Corp.*, 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.”).

In weighing the benefits, both lost and gained, resulting from Fisher’s proposed modification, we find that Fisher fails to demonstrate, by a preponderance of the evidence, that a person having ordinary skill in the art would have modified top portion 21 of plate 9 to contour the top portion to be in physical contact with the wearer’s forehead. We find that the reduced movement that Ogden’s plate 9 would experience, contrary to Ogden’s principle of operation, outweighs the relatively minimal benefits that Fisher asserts. We must consider a prior art reference for all it teaches, and the primary teaching of Ogden is a mask with a moveable headgear connector that prevents leakage about the seal when the wearer turns his or her head. We must consider this primary teaching in our analysis. *See EWP Corp. v. Reliance Universal Inc.*, 755 F.2d 898, 907 (Fed. Cir. 1985) (“On the issue of obviousness, the combined teachings of the prior art as a whole must be considered.”); *cf.* Ex. 2211 ¶ 35 (“Had a [person having ordinary skill in the art] desired a mask to implement non-rotatable features in a new design, he or she would not have started from Ogden’s original solution, or another rotatable mask design like that shown in Ogden, and then compromised that rotatable functionality.”).

The benefit of a forehead support providing greater stability to a mask is diametrically opposed to Ogden’s principle of operation. *See* Ex. 2211 ¶¶ 29–39 (testifying as to how Fisher’s proposed modification to provide a forehead support conflicts with Ogden’s principle of operation). As to providing “a greater field-of-view around the forehead support and a more aesthetic, streamlined interface,” we find that these benefits are minimal for a CPAP mask typically worn during sleep. *See* Ex. 1201, 1:21–23 (indicating that the mask is for treating sleep disordered breathing); Ex. 1202, 1:9–20 (indicating a leaking concern when the wearer rolls over in bed); Ex. 1203, 1:28–30 (indicating that the mask is for treating sleep disordered breathing), Ex. 1204 ¶ 2 (same); Ex. 1205, 1:30–32 (same). Also, we agree with Mr. Virr that, given the narrow nature of top portion 21, the wearer would experience discomfort to the extent that plate 9 would rotate. *See* Ex. 2211 ¶ 40.⁶

As we recognized above, Fisher provides an alternative path in support of its proposed modification. Fisher contends that, given the advancements in cushion technology between the time that Ogden issued and the application that matured into the ’196 patent was filed, Ogden’s

⁶ We recognize that it was known in the art to include pads on forehead supports to increase comfort. *See* Reply 4. Pads would add depth to the forehead support structure that would further limit rotation and it is unclear whether Mr. Eaton’s testimony considers this added depth. *See* Ex. 1206 ¶ 75.

movement is no longer desirable. Pet. 39.⁷ That is, a person having ordinary skill in the art would have understood that Ogden's principle of operation was not desirable and that the selection of a proper cushion could have achieved the same leak prevention without having plate 9 move. Ex. 1206 ¶¶ 173, 177.

Mr. Eaton explains how Lovell's and Gunaratnam's cushions serve to reduce the opportunity of leakage when the wearer of those masks moves his or her head from side to side. See Ex. 1206 ¶¶ 175–181. Mr. Eaton provides the following testimony in support of his opinion that a person having ordinary skill in the art would have modified Ogden to eliminate the relative movement between shell 3 and plate 9:

A person of skill would have known that the movable headgear connector makes it so that the pressure along the perimeter of the mask cannot be directly or easily controlled by adjusting the headgear. Modifying Ogden so that the headgear connector is not movable would provide stability between the headgear connector and the mask frame so that adjusting the headgear straps would directly apply more or less pressure along the perimeter of the mask in a predictable manner to maintain a comfortable and effective seal. One skilled in the art would additionally be motivated to make a mask with simpler, more intuitive adjustments. With the movable frame of Ogden, a user might be uncertain with respect to which straps to adjust to control pressure along the perimeter of the mask or help resolve a leak. With other known masks with non-movable frames, such as Lovell, a user would intuitively know which straps to tighten

⁷ We do not interpret Fisher's position with respect to claim 1 that Ogden's plate 9 would be fixed at shell 3's borehole, as Fisher contends for claim 8. Instead, we interpret Fisher's position to be that the reduced movement in plate 9 caused by the modified forehead support would be advantageous for certain of the reasons Fisher provides in support of its modification of claim 8. See Pet. 39.

or loosen to resolve seal or pressure problems. Further, because users have unique and differing facial geometries, it would have been advantageous to be able to adjust the headgear to apply more or less pressure along the perimeter of the mask to maintain a comfortable and effective seal against the face. The ability to adjust a mask and headgear to an ideal size and configuration and then maintain that position would appeal to a user's desire for simplicity, ease of use, and predictable performance over time.

Id. at ¶ 173 (citing Ex. 1205, 6:55–7:3). Basically, Mr. Eaton reasons that eliminating the movement of plate 9 would facilitate adjusting the headgear straps because plate 9 would be stable relative to shell 3. Mr. Eaton adds that advances in cushion technology, such as the cushions used in Lovell and Gunaratnam, minimizes leaking even though the headgear connector does not move relative to the mask frame in these masks. *Id.* at ¶¶ 176–179.

Mr. Virr disputes Mr. Eaton's testimony, as he believes the testimony is contrary to Ogden's teachings. Ex. 2211 ¶ 80. Mr. Virr explains that Ogden discloses that, when plate 9 is in its central position, its straps can be properly tightened. *Id.* at ¶¶ 80–81.

We find that Fisher fails to provide a sufficient reason, with rational underpinning, to modify Ogden to arrive at the forehead support limitation, even given advancements in cushion technology. We are not persuaded that eliminating the movement in plate 9 is desirable. First, we agree with Mr. Virr that Ogden discloses that its straps can be properly adjusted with plate 9 in its central position. As Ogden discloses, a wearer “can adjust the side straps 13R and 13L to comfortably apply equal forces to the rigid plate 9” because “[a]ll of the detents 39, 41, and 43 on the rigid plate 9 are . . . pulled back in this position to abut the respective end or rear walls 55, 57, and 59 of the three channels 45, 47, and 49.” Ex. 1202, 4:23–31. That is, in this position, plate 9 is stabilized, allowing for the straps to be adjusted. As

such, Fisher’s proposed reasoning for eliminating movement of plate 9 is not a strong motivating force.

Second, although we credit Mr. Eaton’s testimony about the performance of cushions such as those used in Lovell and Gunaratnam, Fisher fails to provide a reason, other than the alleged benefits of stabilizing plate 9 presented above, for modifying Ogden’s cushion. Mr. Eaton does testify that these advanced cushions are “more effective[]” (we assume as compared to Ogden’s movable plate 9) in adapting to imbalances in headgear strapping forces. *See* Ex. 1206, ¶ 177. Mr. Eaton, however, fails to support his opinion as why the modified configuration is “more effective,” and, as such, we do not afford the testimony in this regard much weight.⁸ *See id.*; 37 C.F.R. 42.65(a) (“Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.”). Instead, we are left to weigh Ogden’s express teaching of the benefits of its movable plate 9 and seal that operates under compressive forces against the performance of Lovell’s or Gunaratnam’s cushion. The only evidentiary support for the performance of these cushions appears to be the inference that, because Gunaratnam and Lovell use these cushions with fixed headgear connectors, the cushions must outperform Ogden’s system. *Id.* at ¶¶ 177–179. Indeed, Mr. Eaton testifies that “a person of [ordinary] skill at the time of the supposed invention would have known that the relative movement disclosed by Ogden was not necessary in view of the improved cushions.” *Id.* at ¶ 179. The fact that Ogden’s mask could have been redesigned to make the movement of plate 9 unnecessary,

⁸ We do afford Mr. Eaton’s testimony some weight in light of his experience in the field, including with certain cushions. *See* Ex. 1206 ¶¶ 3–8, 179.

does not mean that a person having ordinary skill in the art would have been motivated to make such a modification.

Said differently, the issue before us is not whether a person having ordinary skill in the art could have selected a cushion to provide an improved seal over Ogden's seal 5 given the reduced movement in plate 9, but instead, whether Fisher has adequately demonstrated that there was a sufficient reason for that modification. *Cf. KSR Int'l Corp.*, 550 U.S. at 424 ("The proper question to have asked was whether a pedal designer of ordinary skill, facing the wide range of needs created by developments in the field of endeavor, would have seen a benefit to upgrading Asano with a sensor."). We find that Fisher and Mr. Eaton fail to provide persuasive evidence that destroying Ogden's principle of operation would be *outweighed* by employing updated cushions in Ogden's mask.⁹

In conclusion, we find that Fisher fails to prove, by a preponderance of the evidence, that a person having ordinary skill in the art would have had reason to modify top portion 21 of plate 9 to contour that portion to contact the wearer's forehead.

⁹ To be clear, we do not determine that forehead supports, in general, fail to provide advantages to a CPAP mask system. Instead, we find that Fisher's asserted advantages do not outweigh destroying Ogden's principle of operation when considering the limited question of whether it would have been obvious to modify *Ogden's* mask as Fisher proposes on the record in this proceeding.

Conclusion

For the reasons above, we determine, on the complete record, that Fisher fails to demonstrate, by a preponderance of the evidence, that claim 1 is unpatentable over Ogden, Gunaratnam, and Amarasinghe.

b. Dependent claims 2, 3, 6, 7, and 9–22.

Dependent claims 2, 3, 6, 7, and 9–22 depend, directly or indirectly, from claim 1. *See* Ex. 1201, 12:9–67. For the reasons discussed above in connection with our analysis of claim 1 over Ogden, Gunaratnam, and Amarasinghe, we determine, on the complete record, that Fisher fails to demonstrate, by a preponderance of the evidence, that claims 2, 3, 6, 7, and 9–22 are unpatentable over Ogden, Gunaratnam, and Amarasinghe.

3. Claims 4, 5, and 8 as Allegedly Obvious over Ogden, Gunaratnam, Amarasinghe, and Lovell

Dependent claims 4, 5, and 8 depend, directly or indirectly, from claim 1. *See* Ex. 1201, 12:13–26. In asserting that claims 4, 5, and 8 are unpatentable, Fisher relies on its position that claim 1 is unpatentable over Ogden, Gunaratnam, and Amarasinghe. *See* Pet. 65. For the reasons discussed above in connection with our analysis of claim 1 over Ogden, Gunaratnam, and Amarasinghe, we determine, on the complete record, that Fisher fails to demonstrate, by a preponderance of the evidence, that claims 4, 5, and 8 are unpatentable over Ogden, Gunaratnam, Amarasinghe, and Lovell.

III. CONCLUSION

For the reasons discussed above, we determine that Fisher has demonstrated, by a preponderance of the evidence, that claims 1–22 are

unpatentable under 35 U.S.C. § 103(a) over Gunaratnam, Lovell, and Amarasinghe. We additionally determine that Fisher has *not* demonstrated, by a preponderance of the evidence, that claims 1–3, 6, 7, and 9–22 are unpatentable under 35 U.S.C. § 103(a) over Ogden, Gunaratnam, and Amarasinghe or that claims 4, 5, and 8 are unpatentable under 35 U.S.C. § 103(a) over Ogden, Gunaratnam, Amarasinghe, and Lovell.

IV. ORDER

After due consideration of the record before us, it is

ORDERED that claims 1–22 are unpatentable under 35 U.S.C. § 103 over Gunaratnam, Lovell, and Amarasinghe;

FURTHER ORDERED that claims 1–3, 6, 7, and 9–22 have not been shown to be unpatentable under 35 U.S.C. § 103 over Ogden, Gunaratnam, and Amarasinghe;

FURTHER ORDERED that claims 4, 5, and 8 have not been shown to be unpatentable under 35 U.S.C. § 103 over Ogden, Gunaratnam, Amarasinghe and Lovell; and

FURTHER ORDERED that 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.

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Patent 8,960,196 B2

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