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Fisher & Paykel Healthcare Limited
By: Brenton R. Babcock
Benjamin J. Everton
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street, 14th Floor
Irvine, CA 92614
Tel.: (949) 760-0404
Fax: (949) 760-9502
Email: BoxFPH533-3@Knobbe.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FISHER & PAYKEL HEALTHCARE LIMITED**,**
Petitioner

v.

RESMED LIMITED**,**
Patent Owner

Case No. IPR2017-01789
Patent 8,960,196

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT 8,960,196

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EXHIBIT LIST

Exhibit No.	Description
1201	U.S. Patent No. 8,960,196
1202	U.S. Patent No. 5,662,101 (Ogden)
1203	U.S. Patent No. 6,796,308 (Gunaratnam)
1204	U.S. Publication No. 2004/0065328 (Amarasinghe)
1205	U.S. Patent No. 6,631,718 (Lovell)
1206	Declaration of Jason Eaton
1207	Curriculum Vitae of Jason Eaton
1208	Excerpts from the File History of U.S. Patent No. 8,960,196
1209	Complaint of ResMed Ltd., ResMed Inc., and ResMed Corp. Under Section 337 of the Tariff Act of 1930, as amended, Investigation No. 337-TA-1022
1210	Answer of ResMed Corp. to Complaint for Patent Infringement and Counterclaims, *Fisher &Paykel Healthcare Ltd. v. ResMed Corp*., Case No. 3:16-cv-02068-DMS-WVG (S.D. Cal.)
1211	Excerpts from *Plastic Part Design for Injection Molding*, Robert A. Malloy (1994)
1212	PCT Publication No. WO 2006/130903 (Lubke)

Exhibit No.	Description
1213	Affidavit of Christopher Butler, Ultra Mirage Brochure (Ultra Mirage), dated September 6, 2016
1214	U.S. Publication No. 2004/0118406 (Lithgow)
1215	PCT Publication No. WO 2007/048174 (Ng)
1216	Affidavit of Christopher Butler, ResMed Mask Frames (Sullivan-I), dated July 6, 2017
1217	U.S. Publication No. 2006/0042629 (Geist)
1218	U.S. Patent No. 6,412,488 (Barnett)
1219	U.S. Publication No. 2004/0182398 (Sprinkle)
1220	U.S. Publication No. 2002/0020416 (Namey)
1221	PCT Publication No. WO/2005/021075 (McAuley)
1222	PCT Publication No. WO 2006/000046 (Hitchcock)
1223	PCT Publication No. WO 2004/041342 (Berthon-Jones)
1224	Affidavit of Christopher Butler, FlexiFit Instructions (FlexiFit), dated September 6, 2016
1225	PCT Publication No. WO 2005/123166 (Frater)

Exhibit No.	Description
1226	U.S. Publication No. 2007/0044804 to (Matula-II)
1227	U.S. Publication No. 2005/0011524 (Thomlinson)
1228	U.S. Publication No. 2004/0255949 (Lang)
1229	U.S. Publication No. 2004/0067333 (Amarasinghe-II)
1230	U.S. Patent No. 7,178,525 (Matula)

Pursuant to 35 U.S.C. §§ 311–319 and 37 C.F.R. § 42.100 *et seq.*, Petitioner Fisher & Paykel Healthcare Limited ("Petitioner" or "Fisher & Paykel") requests *inter partes* review of Claims 1–22 ("Challenged Claims") of U.S. 8,960,196 ("'196 Patent") (Ex. 1201), which is purportedly owned by ResMed Limited ("Patent Owner" or "ResMed"). Petitioner authorizes the Patent and Trademark Office to charge any required fees to Deposit Account No. 11-1410, including the fee as set forth in 37 C.F.R. § 42.15(a) and any excess claim fees.

I. INTRODUCTION

Petitioner filed two previous petitions for *inter partes* review of Claims 23–86 of the '196 Patent. The Board instituted review of Claims 23–86 on grounds that these claims were obvious over Ogden in view of other prior art. Ex. 1208 at 250–280. The Board denied institution of these same claims on grounds that they were obvious over Gunaratnam. *Id.* at 221–249. This petition challenges the remaining claims of the '196 Patent (Claims 1–22) on grounds similar to the previous petitions.

As shown below in Figure 2A, the '196 Patent discloses a mask frame 220 adapted to attach to a headgear connector 250(1). The Challenged Claims (1–22) of this petition only differ from the already instituted claims (Claims 23–86) in that the Challenged Claims include a mask frame that is adapted to removably connect

to more than one headgear connector, each headgear connector being different in at least one aspect.

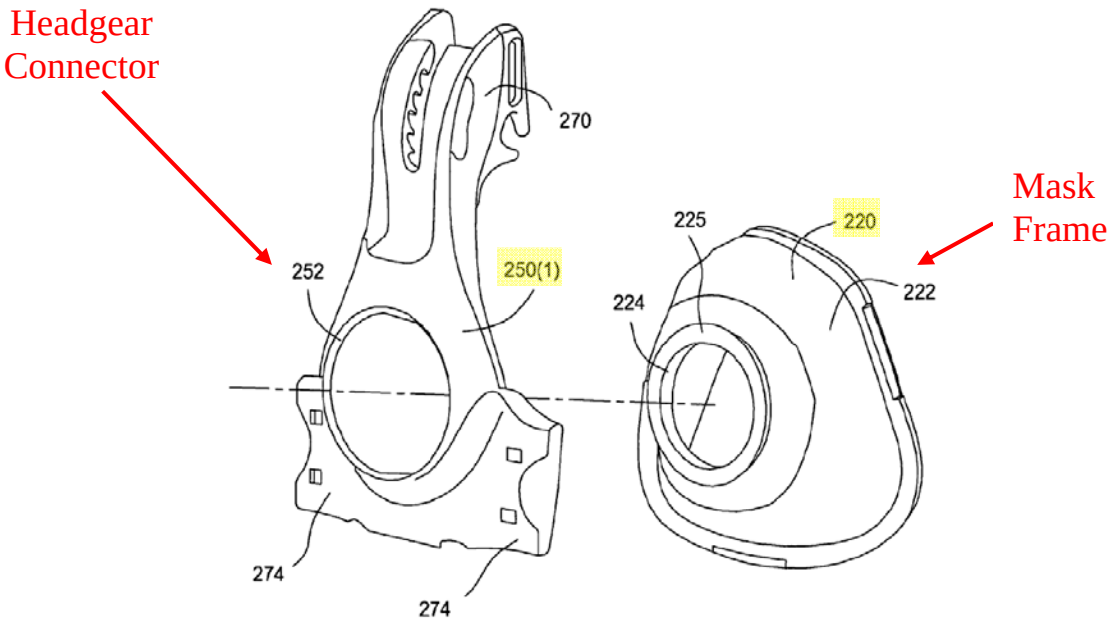
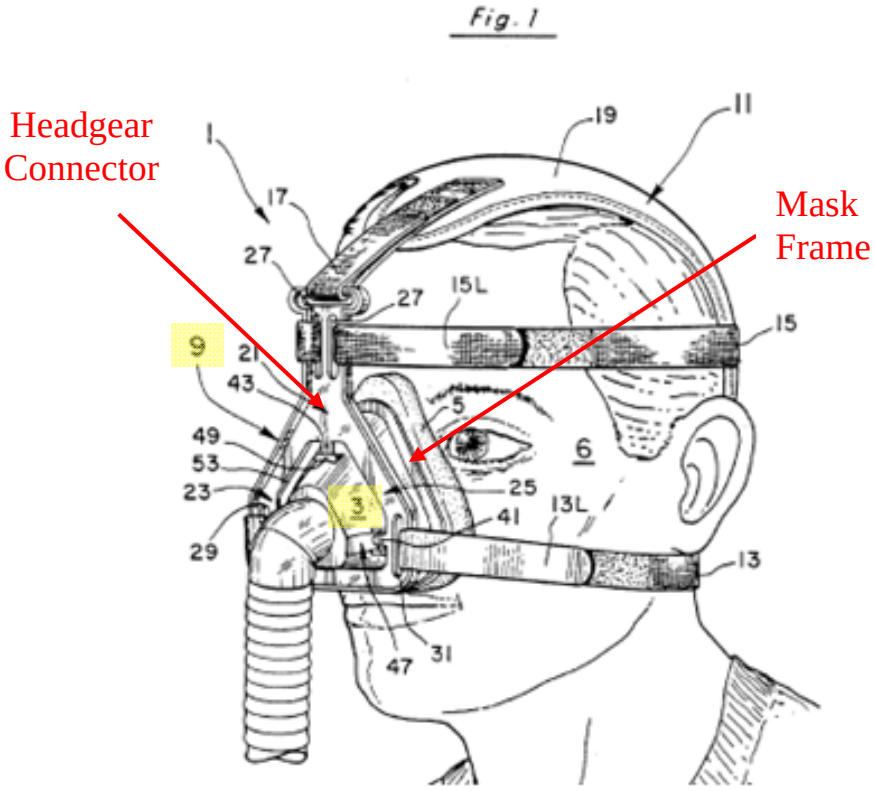


FIG. 2A

As explained in detail below, the claimed mask arrangement, with a separate headgear connector that engages the mask frame, was well-known prior to the earliest priority date of the '196 Patent. *See infra* §§ VII.B.4.a., VII.D.1.a.

For example, Ogden provides a mask assembly having nearly all of the features of the Challenged Claims, including a separate headgear connector 9 that engages the mask frame 3, as shown below in Figure 1. Ex. 1202 at col. 2:57–61.



As another example, ResMed's own prior art patent, Gunaratnam, discloses a mask assembly that is nearly identical to the relevant embodiments disclosed in the '196 Patent. Gunaratnam discloses a frame 160, shown below in Figure 5c, that is essentially the same as the mask frame 220 and headgear connector 250(1), shown below in Figure 2B of the '196 Patent.

Challenged '196 Patent (Ex. 1201)

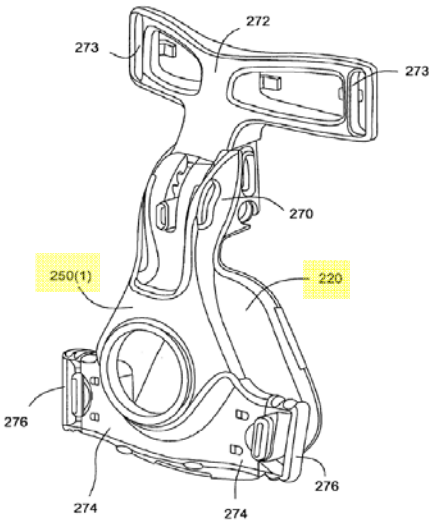


FIG. 2B

Prior Art Gunaratnam (Ex. 1203)

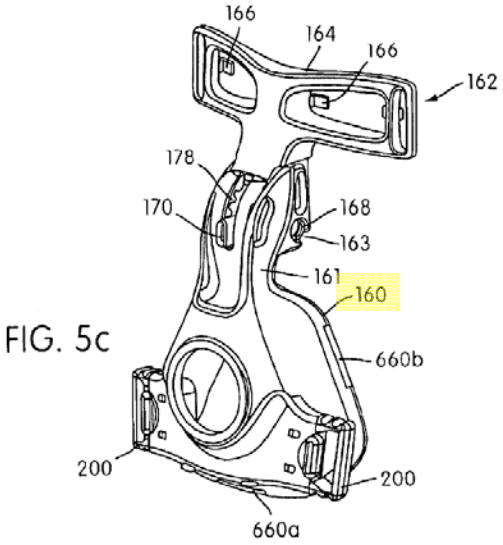


FIG. 5c

The only difference between the prior art frame of Gunaratnam and the frame of the ’196 Patent is that the unitary frame of Gunaratnam has been divided into two parts in the ’196 patent. But this modification to provide a separate headgear connector was common in the prior art, as shown below in Lovell. *See infra* § VII.D.1.a.ii.

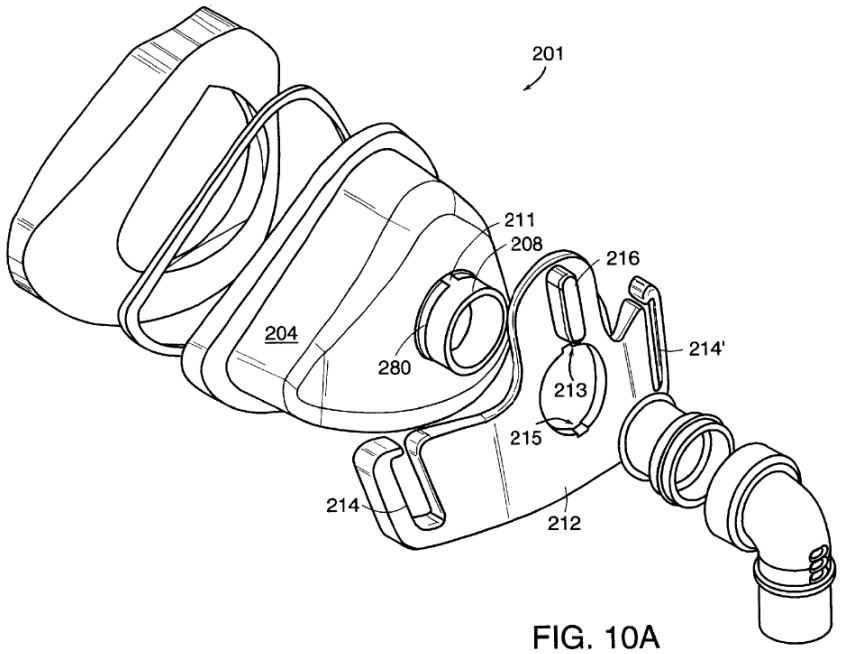


FIG. 10A

Although Ogden and Gunaratnam do not specify that the mask frame connects to multiple different headgear connectors, this feature was also disclosed in the prior art and common knowledge to a person of skill. For example, Amarasinghe discloses multiple headgear connectors with different headgear attachment points for use with the same mask frame. Ex. 1204 ¶ 33. A person of skill would have known to provide multiple headgear connectors with different

shapes and attachment points so that the patient has various choices for headgear arrangements without needing to purchase multiple entire mask assemblies. *See infra* § VII.B.4.a.vi.

As explained below, any additional differences between the Challenged Claims and the masks of Ogden and Gunaratnam were minor, well-known, and disclosed in prior art CPAP masks. *See infra* §§ VII.B.–D. Because the claimed features are simple mechanical features commonly used in CPAP masks, a skilled artisan would have had a reasonable expectation of success in combining the features of Ogden and Gunaratnam with those of the other prior art CPAP masks.

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

This petition is not redundant under 35 U.S.C. § 325(d) with Petitioner's previous IPR petitions challenging the '196 Patent because it challenges different claims. This petition challenges Claims 1–22 which were not included in the previous petitions, have not been challenged in an IPR proceeding, and have not been asserted against Petitioner. The Board should not exercise its discretion under either §§ 314(a) or 325(d) where the claims are different and not previously challenged. *See Silicon Labs, Inc. v. Cresta Tech Corp.*, IPR2015-00615, Paper 9 at 24–25 (PTAB Aug. 14, 2015) (declining to exercise discretion where the petitioner later challenged the remaining claims before it was barred from doing so); *see also Emerson Electric Co. v. IP Co.*, IPR2017-00252, Paper 7 at 9–10 (PTAB May 31, 2017) (declining to exercise discretion under §§ 314(a) and 325(d) on claims that were not previously asserted or challenged); *see also Ford Motor Co. v. Paice LLC*, IPR2015-00799, Paper 11 at 6–7 (PTAB Nov. 9, 2015) (declining to exercise discretion because the later petition challenges different dependent claims from the same patent).

Also, this petition is based on additional prior art and arguments to address the limitation unique to Claims 1–22 ("mask frame is adapted to removably

connect to more than one headgear connector, each headgear connector being different in at least one aspect"). For example, Amarasinghe is used in each of the grounds in this petition, but it was not used in the previous petitions. Thus, the Board should decline to exercise its discretion under § 325(d). *See Valeo North America, Inc. v. Magna Electronics, Inc.*, IPR2014-01204, Paper No. 13 at 11–13 (PTAB Jan. 28, 2015) (declining to exercise discretion where petitioner uses the same primary reference as a previous petition, but a different secondary reference); *Facebook, Inc. v. TLI Communications, LLC*, IPR2015-00778, Paper No. 17 at 26–27 (PTAB Aug. 28, 2015) (instituting review even though there is some overlap with the arguments and prior art of a previous petition challenging the same claims).

The Board should also decline to deny institution of this petition based on its broader discretion under 35 U.S.C. § 314(a). This statutory section provides general discretion to the Board to institute IPR petitions. In deciding whether to exercise this discretion, the Board has considered the following factors:

(1) the resources of the Board;

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

(3) whether the same petitioner already previously filed a petition

directed to the same claims of the same patent;

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

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

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

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

Medtronic Xomed, Inc. v. Neurovision Medical Products, Inc., IPR2016-01405, Paper No. 12 at 7 (PTAB Dec. 29, 2016). More recently, the Board broadly evaluated the last factor (7) as "whether the petitioner provides adequate explanation why we should permit another attack on the same claims of the same patent." *Xactware Solutions, Inc. v. Eagle View Tech., Inc.*, IPR2017-00034, Paper No. 9 at 7–8 (PTAB Apr. 13, 2017).

Regarding factors (1) and (2), the PTAB has already instituted review of

most of the claims of the ’196 Patent, which share nearly all of the same limitations with the Challenged Claims. Any additional burden on the Board caused by institution of these similar claims would be minimal and would not significantly affect the Board’s ability to render a final decision. *See Polygroup Ltd v. Willis Electric Co., Ltd.*, IPR2016-00801, Paper No. 8 at 15–16 (PTAB Oct. 17, 2016) (instituting review on grounds similar to a previous petition where the Board is already committed to reviewing similar issues with little additional burden, and it would be inefficient for the Board and the district court to have to decide the same issues with respect to the same patent).

Regarding factors (3) and (5), the Challenged Claims (Claim 1–22) were not included in the previous petitions. Patent Owner did file a patent owner response in the previously instituted review of the ’196 Patent, but that was related to different claims. This petition is the first time these claims are being challenged and Patent Owner is not prejudiced by this petition challenging these new claims.

Regarding factors (4) and (6), Petitioner did not include the Amarasinghe reference in the previous petitions challenging the ’196 Patent because it was not necessary for the claims challenged therein. Instead, the Amarasinghe reference used in this petition relates to the multiple different headgear connectors limitation that is not in the previously challenged claims. Moreover, whether the new prior

art was available at the time of the first petition is insufficient to justify the Board exercising its discretion. *Facebook*, Paper No. 17 at 26–27 (concluding that petitioner's failure to show the prior art was unavailable is insufficient to exercise discretion under 35 U.S.C. § 314(a)).

Regarding factor (7), unlike the claims challenged in the previous petitions, ResMed has not asserted the Challenged Claims in the ITC or the district court. Petitioner filed this petition to challenge these unasserted claims of the '196 Patent that Patent Owner could possibly assert in the future before Petitioner is barred from doing so by 35 U.S.C. § 315(b). *See Silicon Labs*, Paper 9 at 24–25.

Moreover, this petition is easily distinguished from the typical follow-on petitions that are denied by the Board for using the preliminary response and institution decision as a road map. In those situations, the original petition is typically deficient (*e.g.*, fails to address a claim limitation, fails to authenticate prior art, etc.). In contrast here, Petitioner's prior petitions challenging the '196 Patent were not deficient, but instead challenged different claims of the '196 Patent. Thus, Petitioner is not attempting to take multiple bites at the apple and is instead making a first attempt at challenging Claims 1–22. Congress provided a one-year window for petitioners to request institution of *inter partes* review, and the Board should not use its discretion to shorten that window simply

because Petitioner has already filed a petition challenging different claims of the same patent earlier in that window. *Silicon Labs*, Paper 9 at 25 (concluding that it is not a "prudent exercise of the discretion granted by § 325(d) to truncate the ability of a petitioner to make full use of the one-year window Congress expressly provided").

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

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

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

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

ResMed and Fisher & Paykel were involved in proceedings with the United States International Trade Commission in which ResMed asserted that certain Fisher & Paykel products infringe one or more claims of the '196 Patent (Investigation No. 337-TA-1022). Ex. 1209. However, ResMed withdrew its complaint and the investigation was terminated on May 17, 2017.

ResMed and Fisher & Paykel are currently involved in pending litigation in the Southern District of California involving the '196 Patent. *See Fisher & Paykel*

Healthcare Ltd. v. ResMed Corp., Case No. 3:16-cv-02068-DMS-WVG (S.D. Cal.). ResMed asserted a claim for infringement of the '196 Patent in its counterclaims on September 7, 2016. Ex. 1210.

Fisher & Paykel previously filed two other petitions for *inter partes* review of Claims 23–86 of the '196 Patent (IPR2017-00057 and IPR2017-00059).

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

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

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

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

Service information for lead and back-up counsel is provided in the designation of lead and back-up counsel above. Petitioner also consents to service by email at the following email address: BoxFPH533-3@knobbe.com.

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

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

Fisher & Paykel hereby certifies that the ’196 Patent is available for *inter partes* review and that Fisher & Paykel is not barred or estopped from requesting *inter partes* review challenging the patent claims on the grounds identified herein.

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

1. Prior Art

Petitioner respectfully requests *inter partes* review of Claims 1–22 of the ’196 Patent, filed May 29, 2013, which is a continuation of U.S. Application No. 12/010,680 (now U.S. 8,517,023), filed January 29, 2008, which claims priority benefit of U.S. Provisional Application No. 60/898,108, filed January 30, 2007. Ex. 1201 at 1. The earliest possible priority date of the ’196 Patent is **January 30, 2007**.

The Challenged Claims of the ’196 Patent would have been obvious in view of the following prior art:

- U.S. 5,662,101 (“Ogden”) (Ex. 1202) issued on September 2, 1997. Ex. 1202 at 1. Because Ogden issued more than one year before the earliest

possible priority date of the ’196 Patent, it is prior art under 35 U.S.C. § 102(b).[1]

- U.S. 6,796,308 (“Gunaratnam”) (Ex. 1203) issued on September 28, 2004. Ex. 1203 at 1. Because Gunaratnam issued more than one year before the earliest possible priority date of the ’196 Patent, it is prior art under 35 U.S.C. § 102(b).
- U.S. Publication No. 2004/0065328 (“Amarasinghe”) (Ex. 1204) published on April 8, 2004. Ex. 1204 at 1. Because Amarasinghe published more than a year before the earliest possible priority date of the ’196 Patent, it is prior art under 35 U.S.C. § 102(b).
- U.S. 6,631,718 (“Lovell”) (Ex. 1205) issued on October 14, 2003. Ex. 1205 at 1. Because Lovell issued more than one year before the earliest possible priority date of the ’196 Patent, it is prior art under 35 U.S.C. § 102(b).

[1] Reference to 35 U.S.C. §§ 102 and 103 throughout this Petition are to the pre-AIA versions of these statutes, which are applicable to the ’196 Patent.

2. Grounds

Ground #1. Claims 1–3, 6, 7, and 9–22 of the ’196 Patent would have been obvious over Ogden in view of Gunaratnam and Amarasinghe under 35 U.S.C. § 103.

Ground #2. Claims 4, 5, and 8 of the ’196 Patent would have been obvious over Ogden in view of Gunaratnam, Amarasinghe, and Lovell under 35 U.S.C. § 103.

Ground #3. Claims 1–22 of the ’196 Patent would have been obvious over Gunaratnam in view of Lovell and Amarasinghe under 35 U.S.C. § 103.

3. Grounds 1 and 2 are not Redundant with Ground 3

Grounds 1 and 2 are significantly different from Ground 3 because they are based on different prior art. Grounds 1 and 2 rely on Ogden as the primary reference instead of Gunaratnam. As explained in Grounds 1 and 2, Ogden expressly discloses a mask system having a separate headgear connector, but may not teach other features of the claimed mask system. However, a person of skill would have been motivated to modify Ogden to include those mask features, as taught by the other prior art. *See infra* §§ VII.B.–C.

In contrast, the obviousness analysis of Ground 3 is based on Gunaratnam in view of Lovell and Amarasinghe. Gunaratnam is a prior art ResMed patent that

discloses mask systems nearly identical to the mask systems of the ’196 Patent. A person of skill would have been motivated to modify the Gunaratnam masks to include a separate mask frame and headgear connector arrangement, as taught by Lovell. *See infra* § VII.D.

Because these grounds present different primary references that disclose different features of the Challenged Claims, Petitioner respectfully requests that the Board institute IPR proceedings on all three grounds. *See Thorley Indus. LLC v. Kolcraft Enterprises, Inc.*, IPR2016-00352, Paper 14 at 20–21 (PTAB June 23, 2016); *see also Ricoh Corp., Xerox Corp., and Lexmark Intl. v. MPHJ Tech. LLC*, IPR2014-00539, Paper 7 at 17 (PTAB Aug. 25, 2014).

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

Solely for the purpose of this review, Petitioner construes the Challenged Claims of the ’196 Patent such that the claims are given their broadest reasonable interpretation in light of the specification of the ’196 Patent.[2] 37 C.F.R. § 42.100(b); *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278–79 (Fed. Cir.

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

2015), *aff'd*, 136 S. Ct. 2131 (2016). All terms have their ordinary and customary meaning in light of the specification, as commonly understood by those of ordinary skill in the art at the time of the invention. *In re Translogic Tech.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

V. THE ’196 PATENT

A. Example Embodiments

The ’196 Patent discloses a mask system including “a common frame . . . and at least first and second headgear connectors adapted to be provided to the frame.” Ex. 1201 at Abstract.

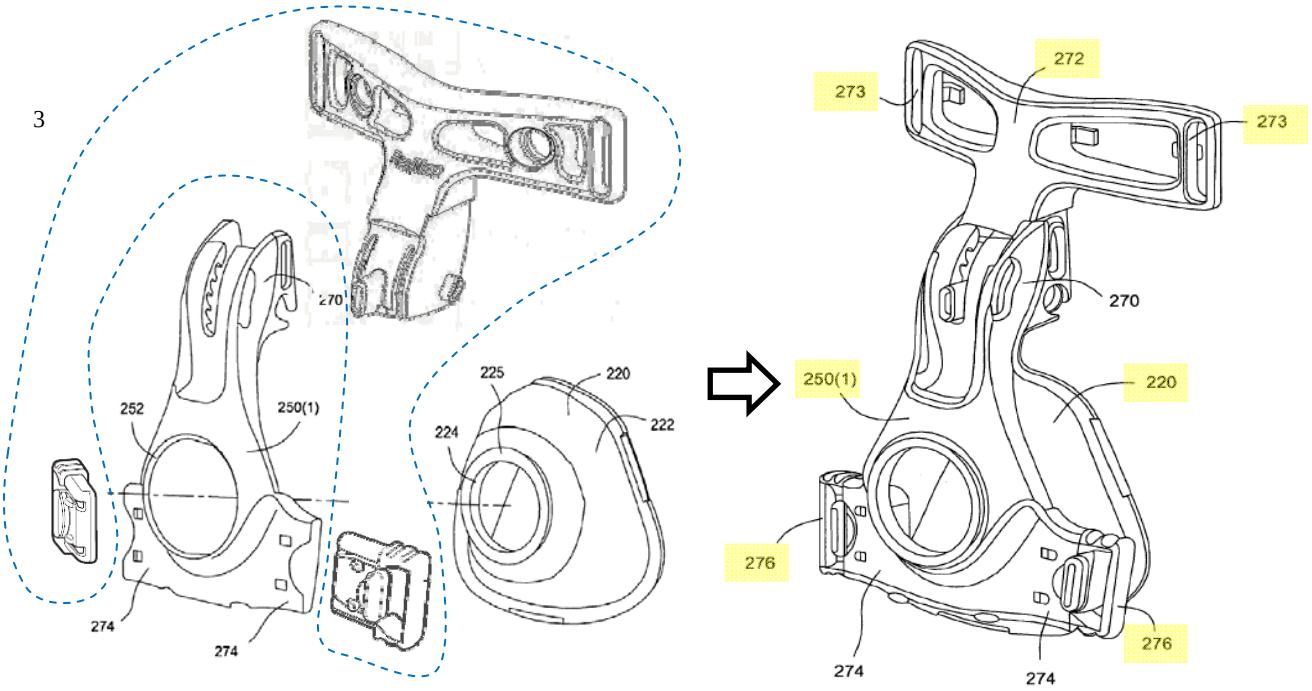


FIG. 2B

[3] Drawings of mask components circumscribed by dashed blue line, adapted from commercial ResMed product literature, used for illustration purposes. The mask frame 220 and headgear connector 250(1) are from the ’196 Patent.

The ’196 Patent describes various headgear connectors that engage a common mask frame. *Id.* at col. 6:10–20, Figs. 2A–5B. Figure 2B of the ’196 Patent (previous page) illustrates a mask system that includes a headgear connector 250(1) attached to a frame 220 and a forehead support 272 adjustably mounted to the headgear connector 250(1). *Id.* at col. 7:3–12. The headgear connector 250(1) includes an opening adapted to engage the interfacing structure of the frame 220 with a snap-fit or other suitable attachment mechanism. *Id.* at col. 6:32–38.

B. Summary of the Prosecution History of the ’196 Patent

The ’196 Patent was originally filed as U.S. Application No. 13/904,748 (“’748 Application”) on May 29, 2013, and the claims were allowed after a single Office Action dated July 1, 2014. The only rejection in the Office Action was a nonstatutory double patenting rejection over Claims 45–66 of U.S. 8,517,023, which is the parent of the ’196 Patent. Ex. 1208 at 68. ResMed overcame this rejection by filing a terminal disclaimer on September 29, 2014 and also added new claims. *Id.* at 134–135. The ’748 Application was allowed on October 10, 2014 without any substantive rejections under 35 U.S.C. §§ 102 or 103. *See id.* at 154–158. After allowance, ResMed submitted a Request for Continued Examination on November 25, 2014, adding Claims 42–87 (Claims 41–86 of the

issued ’196 Patent). *Id.* at 165–182. Another Notice of Allowance was issued on December 22, 2014 without any substantive rejections under 35 U.S.C. §§ 102 or 103. *See id.* at 188–192.

VI. LEVEL OF ORDINARY SKILL IN THE ART

A person having ordinary skill in the field at the time of the purported invention of the ’196 Patent would have at least a bachelor’s degree in mechanical engineering, biomedical engineering or other similar type of engineering degree, combined with at least two years of experience in the field of masks, respiratory therapy, patient interfaces or relevant product design experience. Ex. 1206 ¶ 26.

VII. CLAIMS 1–22 OF THE ’196 PATENT ARE UNPATENTABLE

This petition explains, in detail, why the Challenged Claims of the ’196 Patent are unpatentable and is supported by the declaration of Jason Eaton, P.E. (Ex. 1206).

A. Legal Standard for Obviousness

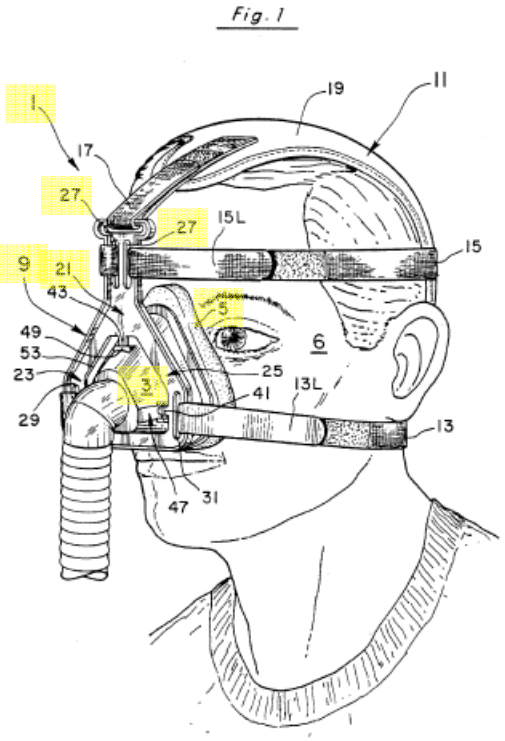
A claim is obvious “if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” 35 U.S.C.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

B. Ground 1: Claims 1–3, 6, 7, and 9–22 would have been obvious over Ogden in view of Gunaratnam and Amarasinghe

1. Overview of Ogden (Ex. 1202)

Ogden was submitted during the prosecution of the ’196 Patent, but was not cited by the Examiner. Ex. 1201 at 4.

Ogden describes CPAP mask assemblies for use in respiratory care and therapy. Ex. 1202 at col. 1:5–12.



As shown above in Figure 1, the mask assembly 1 includes a rigid, cup-shaped shell 3 made of hard plastic and provided with a soft seal 5. *Id.* at col. 2:50–57. The shell 3 and seal 5 are secured in a sealing position by a rigid

plate 9 and headgear arrangement 11. *Id.* at col. 2:57–61. The rigid plate 9 includes a top portion 21 that includes headgear anchors 27. *Id*. at col. 3:7–10.

As shown below in Figures 2 and 6 of Ogden, the rigid plate 9 attaches to the rigid shell 3 by detents 39, 41, and 43 that are received into channels 45, 47 (not shown), and 49 on the rigid shell 3. *Id.* at col. 3:25–34. Ogden discloses that the detent-channel 43, 49 "is preferably dimensioned to snap together to hold or maintain the rigid plate 9 on the rigid shell 3." *Id*. at col. 5:15–18.

Fig. 2

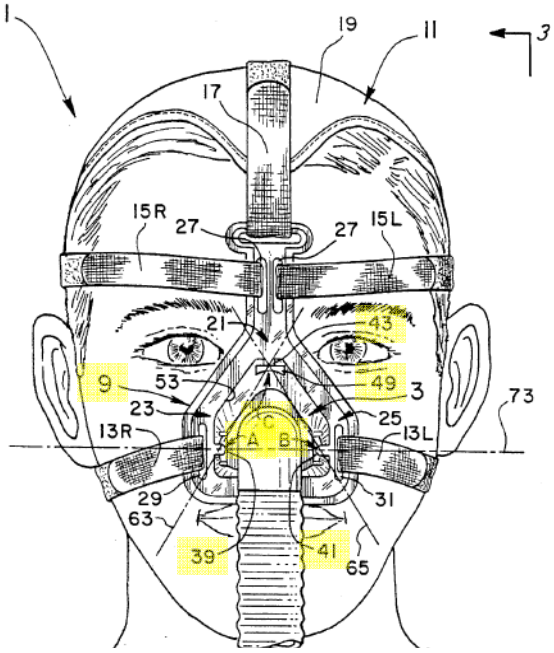
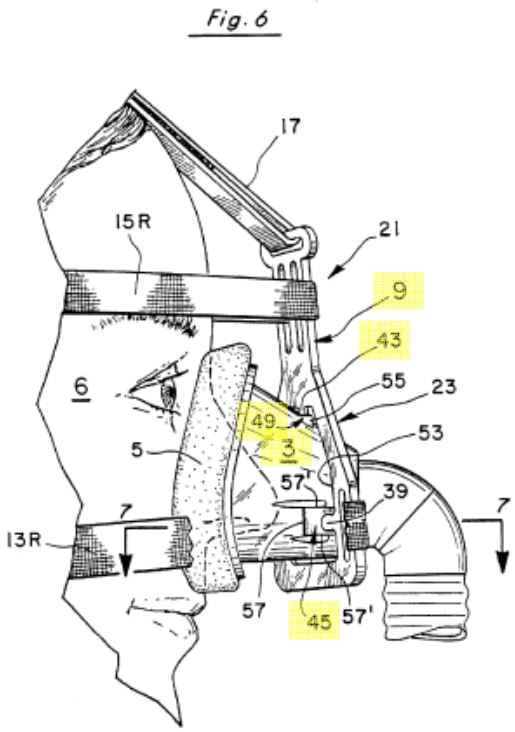


Fig. 6



2. Overview of Gunaratnam, (Ex. 1203)

Gunaratnam was submitted during the prosecution of the ’196 Patent, but was not cited by the Examiner. Ex. 1201 at 5.

Gunaratnam discloses nasal and full-face CPAP masks for treating sleep-disordered breathing. Ex. 1203 at col. 1:21–25.

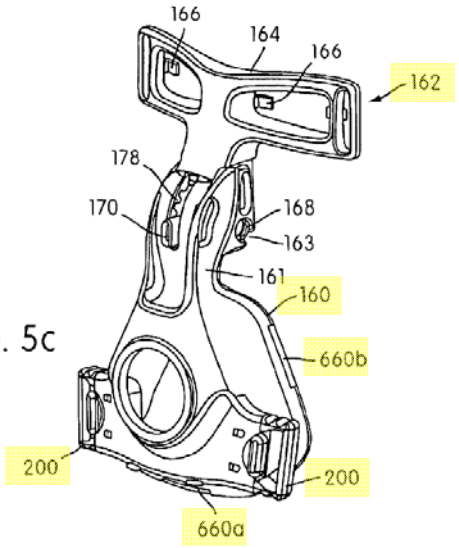


FIG. 5c

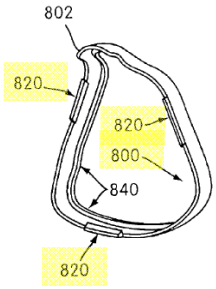


FIG. 7a

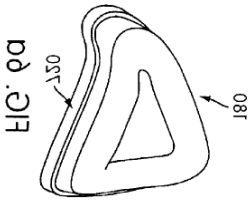


FIG. 6a

(rotated, reversed)

Figure 5c (above) illustrates a T-shaped headgear connector 160/162 with headgear strap connection points and a forehead support 162. *Id.* at col. 4:32–48.

Figure 6a (above) illustrates a face-contacting cushion 180 that is formed of soft material such as silicone. *Id.* at 5:22–24. Figure 7a (above) illustrates a clip 800 that holds the cushion in secure engagement with the frame. *Id.* at 5:31–47.

3. Overview of Amarasinghe (Ex. 1204)

The patent that issued from Amarasinghe was submitted during the prosecution of the ’196 Patent, but was not cited by the Examiner. Ex. 1201 at 6.

As shown below in Figure 2, Amarasinghe discloses a mask system 10 including a brace 12 (shaded red) that supports the mask shell 13 and provides headgear strap attachment points 15 for the headgear straps 14. Ex. 1204 ¶ 29.

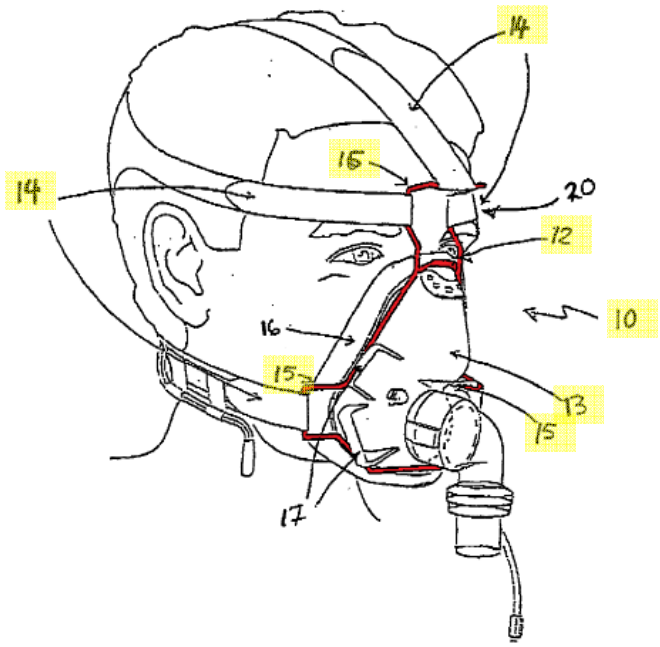


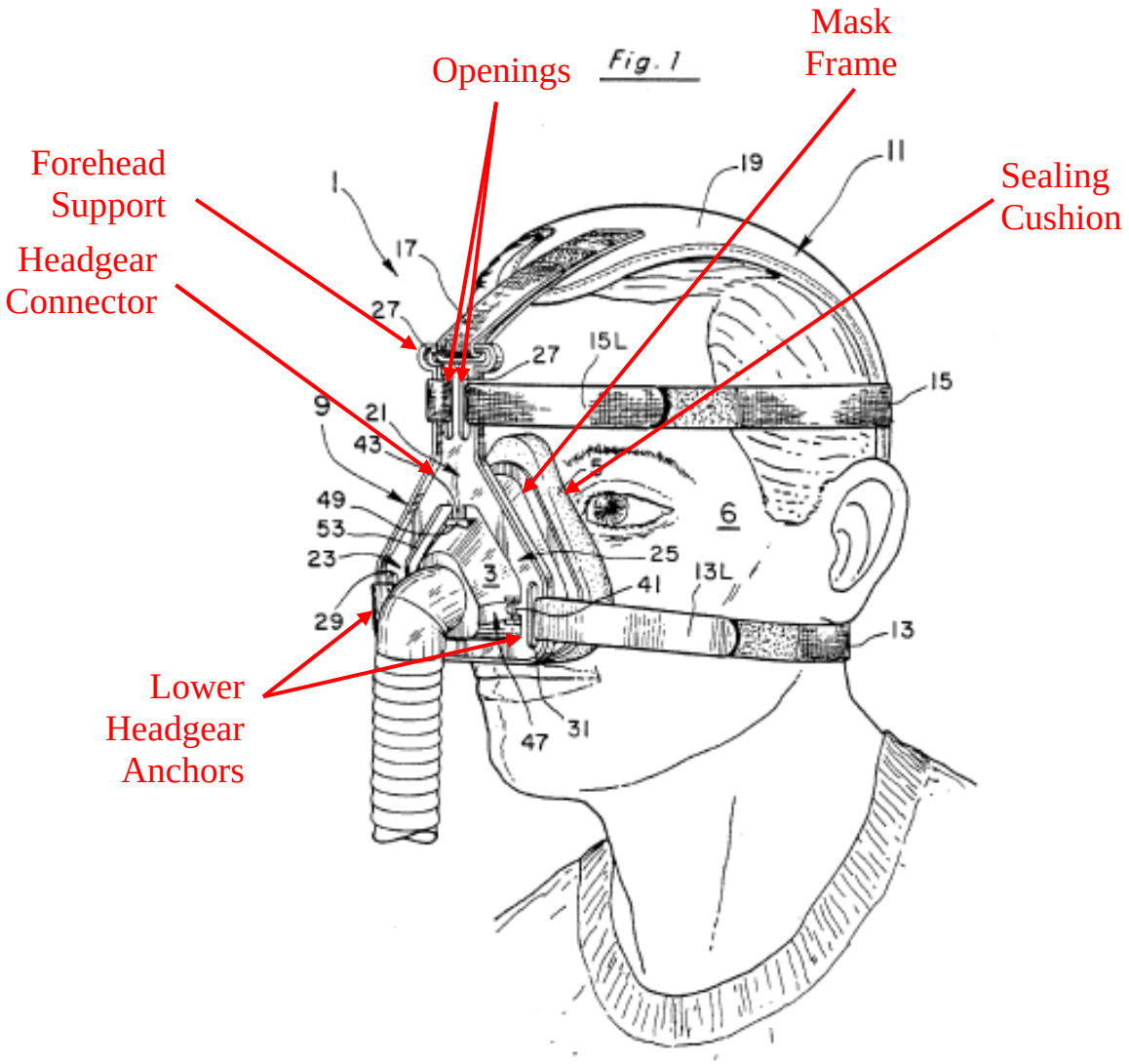
Fig. 2

The user can be supplied with multiple braces, each with a different number of headgear attachment points or different locations, that can attach to the shell 13. *Id*. ¶ 33.

4. Limitations of Claims 1–3, 6, 7, and 9–22

As explained in detail below, Ogden describes a CPAP mask assembly having nearly all of the limitations of independent Claim 1. Specifically, Ogden discloses a mask for delivering breathable gas to a patient, the mask comprising: a mask frame (rigid shell 3), said mask frame having no built-in or integral headgear attachment points; a sealing cushion (seal 5) provided to the mask frame and adapted to form a seal with the patient's face; and a headgear connector (rigid plate 9) adapted to engage the mask frame, said headgear connector including a pair of lower headgear anchors (openings 29, 31), said headgear connector including a forehead support (top portion 21) connected to the headgear connector by an upper support member, said forehead support including a pair of openings (loops 27) adapted to attach to respective ones of a pair of upper side straps (straps 15R, 15L). *See* Ex. 1202 at cols. 2:50–61, 3:7–30, 5:14–19; Ex. 1206 ¶¶ 47–48.

Many of these claimed features are identified below in Figure 1 of Ogden. Ex. 1206 ¶ 49.



Any differences between Claims 1–3, 6, 7, and 9–22 and Ogden were minor, well-known, and taught by Gunaratnam and/or Amarasinghe. Ex. 1206 ¶¶ 50–146. Because Ogden, Gunaratnam, and Amarasinghe all teach structurally similar CPAP masks for the treatment of sleep-disordered breathing, their features would have been readily compatible with and easily incorporated into Ogden with a reasonable

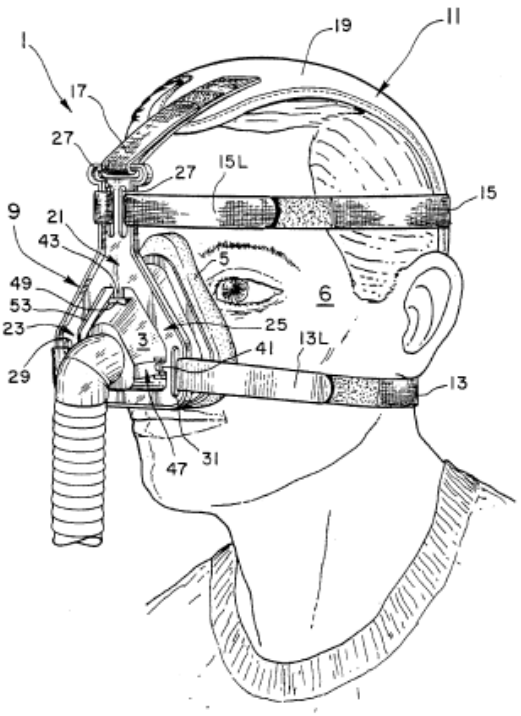
expectation of success. *Id.* ¶ 50. Combining these familiar CPAP mask features according to known methods would have done no more than yield predictable results. *See id.*; *see also KSR*, 550 U.S. at 416.

a. Independent Claim 1

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

Ogden discloses masks that deliver breathable pressurized gas from a CPAP device, as shown below in Figure 1. Ex. 1202 at col. 1:9–12. The mask receives breathable gas at positive pressure from a flexible hose 12 connected to a ventilator or CPAP device. *Id.* at col. 5:41–44.

Fig. 1



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

Ogden discloses a mask frame 3 with a bore for receiving hose coupling 10. Ex. 1202 at cols. 2:50–54, 5:35–41. The mask frame 3 has no built-in or integral headgear attachment points, as shown below in Figures 1 and 8. Instead, the headgear attachment points are on the headgear connector 9. *Id.* at col. 3:13–22.

The '196 Patent does not define "central," but only uses this term to describe bores on nasal mask frames in which the bores appear to be positioned near the centroid of the mask frame and aligned with the vertical axis of the mask and nose of the patient, as shown below in Figure 2A. Ex. 1201 at col. 6:21–23.

'196 Patent

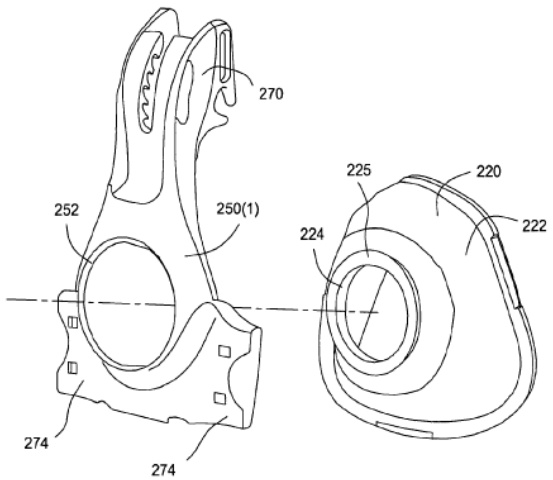
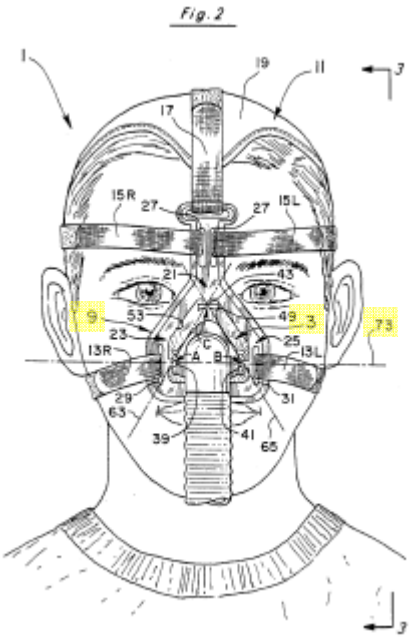
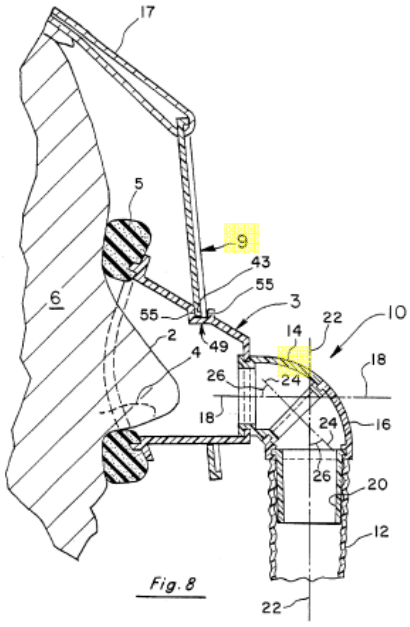


FIG. 2A

Under a broadest reasonable interpretation in view of the specification, a "central bore" would include bores that are centrally located in the horizontal dimension, but not necessarily centered in all dimensions. Ex. 1206 ¶¶ 52–53. Under this interpretation, the bore of Ogden is a central bore as it is centrally located on the horizontal axis 73 and aligned with the vertical axis of the mask and the patient's nose. *Id.* ¶ 54.





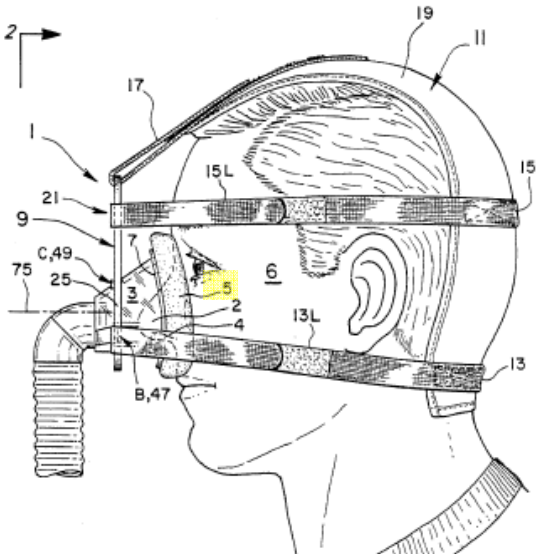
To the extent "central bore" is construed more narrowly to be limited to bores that are centered in the horizontal and vertical dimensions of the mask frame, such a bore position would have been common knowledge to a person of skill in the art. *Id.* ¶ 55. A person of skill would have been motivated to position the bore at or very near the centroid of the triangular mask frame so that the elbow would

attach at the point furthest from the patient's face to allow the air conduit to swivel 360º about the bore axis without being obstructed by other parts of the mask frame. *Id.* ¶ 56. Positioning the bore and elbow connection at the center of the mask frame would also provide a central application point for hose pull forces. *Id.* Reaction forces from cushion contact with the face, and from headgear tension, can most effectively counter hose loads in all orientations when the hose loads are centrally applied. *Id.*

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

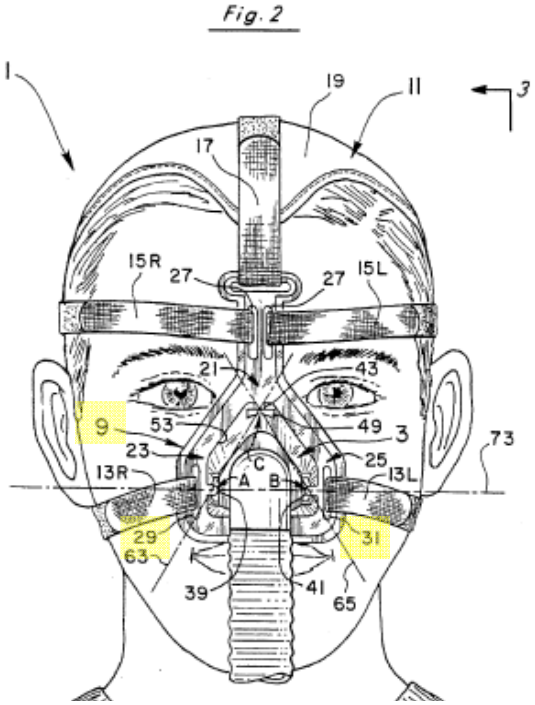
The Ogden mask includes a soft sealing cushion 5 attached to the frame 3 that seals against the patient's face, as shown below in Figure 3. Ex. 1202 at col. 2:54–61.

Fig. 3



iv. "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,"

The Ogden mask includes a headgear connector 9 adapted to engage the mask frame 3, as shown below in Figure 1. The headgear connector 9 includes a pair of lower headgear anchors 29, 31 that receive lower headgear straps 13R, 13L. Ex. 1202 at col. 3:10–18. Ogden also discloses that "snaps and similar arrangements" could be used for the headgear anchors. *Id*.



To the extent Ogden's disclosure is insufficient for the "headgear clip anchors" or "headgear clips," such headgear clips were well-known and common in CPAP mask assemblies. Ex. 1206 ¶¶ 59–61. For example, Gunaratnam discloses lower headgear clip anchors 630 and clips 200 for connecting the headgear, as shown below in Figures 5a and 5c. Ex. 1203 at col. 4:32–34.

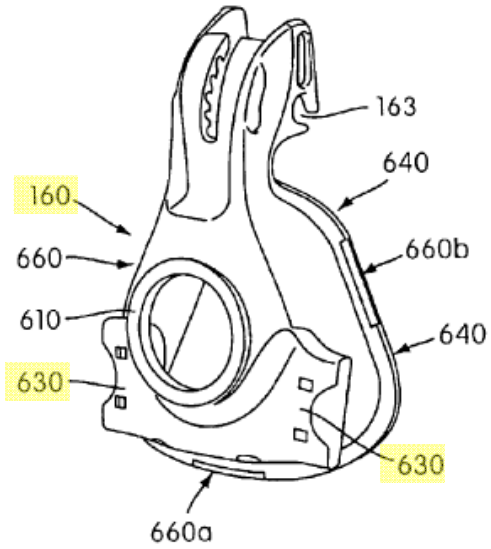


FIG. 5a

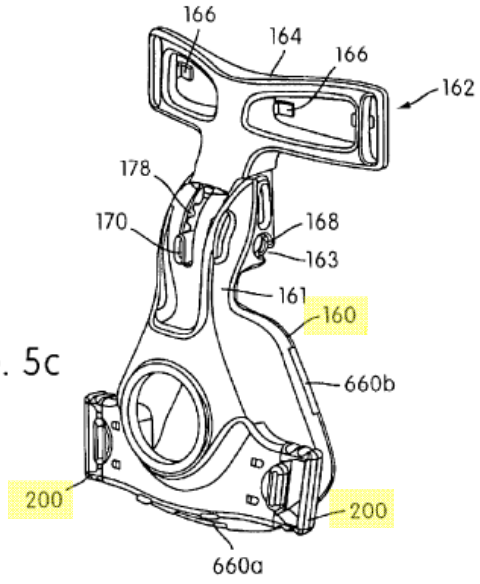


FIG. 5c

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. Ex. 1206 ¶¶ 62–63. Such a modification would have been a mere substitution of one known feature for another to obtain predictable results. *Id.* ¶ 62; *see also KSR*, 550 U.S. at 416.

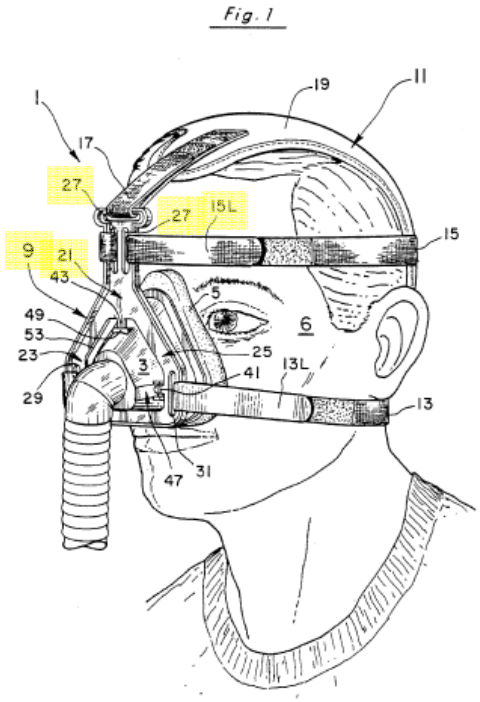
The lower headgear straps undergo significant tension when the headgear is pulled over a user's head, making it difficult to position the lower headgear straps. Ex. 1206 ¶ 63. A person of skill would have been motivated to provide lower headgear clips, so the user would not have to force the lower headgear 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.* Further, 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.* ¶ 62.

v. "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"

The Ogden headgear connector 9 includes a support adjacent to the forehead (top portion 21) that is connected to the headgear connector by an upper support member. Ex. 1206 ¶ 65. The support 21 includes a pair of openings 27 that receive upper side straps 15R, 15L. Ex. 1202 at col. 3:7–10. The headgear connector configuration shown in Figure 1 of Ogden (below, left) is similar to that

shown in Figure 3B of the ’196 Patent (below, right), which shows a headgear connector 250(2) connected to a fixed forehead support 272. Ex. 1201 at col. 7:17–26.

Ogden



’196 Patent

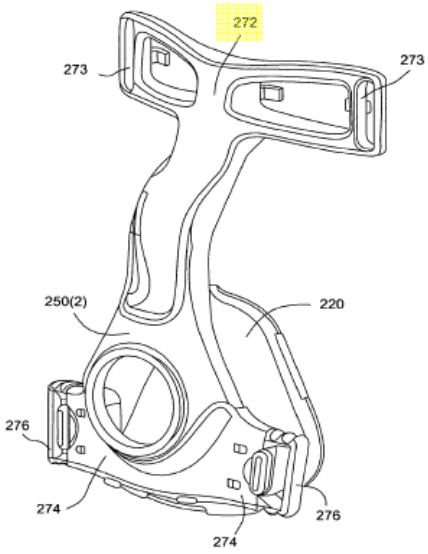


FIG. 3B

To the extent "forehead support" is interpreted narrowly to require that the forehead support directly contact the user's forehead, such forehead-contacting supports were also well-known and used in prior art CPAP masks. Ex. 1206 ¶¶ 66–72. For example, as shown in Figure 5c (below, left), Gunaratnam discloses a contoured forehead support 162 similar to the forehead support 272 shown in Figure 2B of the '196 Patent (below, right). *See* Ex. 1203 at col. 1:29–35.

Gunaratnam

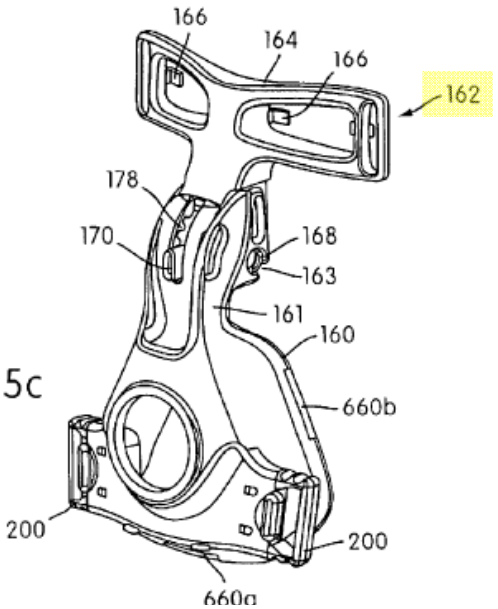


FIG. 5c

'196 Patent

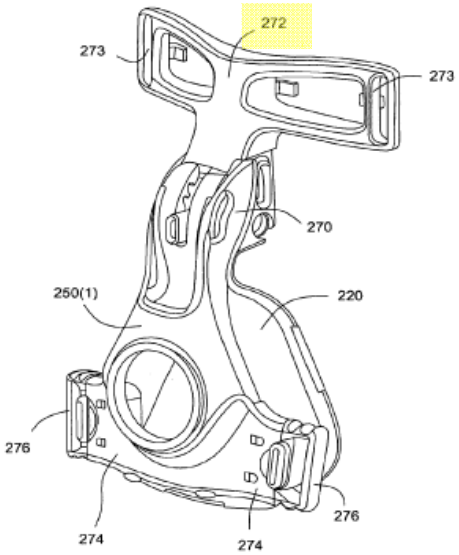


FIG. 2B

Although Ogden already includes a support adjacent the forehead, a person of skill in the art would have known that modifying the support to contact the patient's forehead would provide additional benefits. Ex. 1206 ¶¶ 73–75. A person of 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.* ¶ 73. Also, a person of skill 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.* 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, but as discussed below with respect to Claim 8, such a person would have known that this relative movement was unnecessary and undesirable. *See infra* § VII.C.2.c.

Under a broadest reasonable interpretation of "connected to," the support 21 of Ogden is integral with and connected to the headgear connector. However, to the extent "connected to" is more narrowly interpreted to require a separate component, a person of skill would have also been motivated to incorporate the removability features of the Gunaratnam forehead support into the Ogden headgear connector, for example to provide an adjustable forehead support. *Id.* ¶ 74.

vi. "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."

Ogden discloses a headgear connector 9 that engages the frame 3 and is removable by slightly stressing the detent 43 over the front wall 55 of the channel 49. Ex. 1202 at col. 5:14–22; Ex. 1206 ¶ 78. Ogden does not expressly disclose more than one headgear connector, where the headgear connectors are different in at least one aspect. However, such mask arrangements were well-known and disclosed in the prior art. Ex. 1206 ¶¶ 78–88.

For example, Amarasinghe discloses a mask frame 13 that is adapted to removably connect to multiple headgear connectors 12 (shaded red) with different head strap attachment points 15, as shown on the next page. Ex. 1204 ¶¶ 29, 33. Amarasinghe discloses headgear connectors "each with a different number of headgear attachment points or at least having a set number of headgear attachment points positioned in a variety of configurations with respect to the mask shell in order that a suitable choice may be made." *Id.* ¶ 33. Thus, the patient could choose a preferred headgear connector 12 from the various different headgear connectors for use with the same mask frame 13. Ex. 1206 ¶ 80.

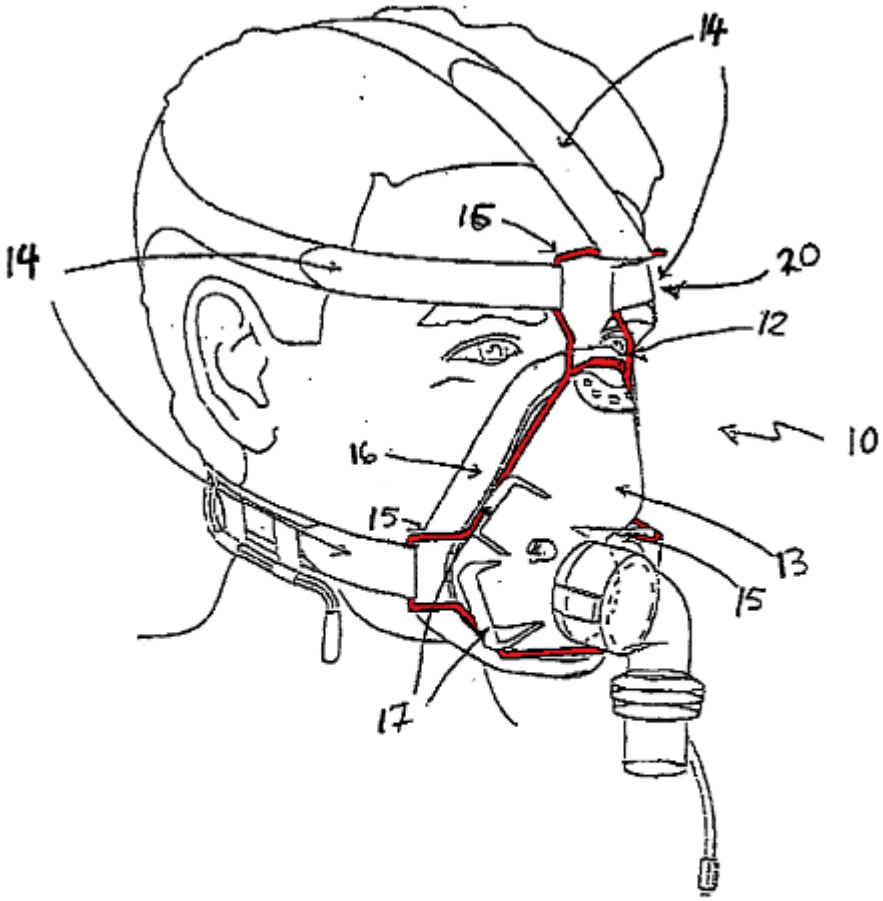


Fig. 2

Although the mask frame 13 of Amarasinghe includes headgear attachment points, those attachment points are not used for headgear and are replaced by the headgear attachment points 15 of the headgear connector 12, as shown above in Figure 2. *Id.* ¶ 81. Therefore, a person of skill would have understood that this

same concept of multiple different headgear connectors could be used with frames that do not include headgear anchors, such as the Ogden mask assembly, without diminishing the benefits and functionality of the mask system. *Id.*

A person of 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. *See* Ex. 1204 ¶¶ 29, 33; Ex. 1206 ¶ 89. A person of skill would have understood that patients have different head shapes and different preferences for headgear arrangements. Ex. 1206 ¶ 90. With 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*. ¶ 91.

Because 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*. ¶ 92. Providing 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.*

b. Dependent Claim 2

Claim 2 depends from Claim 1 and includes "wherein the mask frame and the sealing cushion comprise a full-face mask."

The masks shown in Ogden are nasal masks, but Ogden expressly discloses that the mask arrangements are equally applicable to full-face masks covering the patient's nose and mouth. Ex. 1202 at col. 2:46–50. A person of skill in the art would have been motivated to modify the nasal masks of Ogden to cover both the nose and mouth, particularly for patients who breathe through their mouths when they sleep. Ex. 1206 ¶ 50. Each of the features described above in Claim 1 would have been readily compatible with a full-face mask. *Id.*

c. Dependent Claim 3

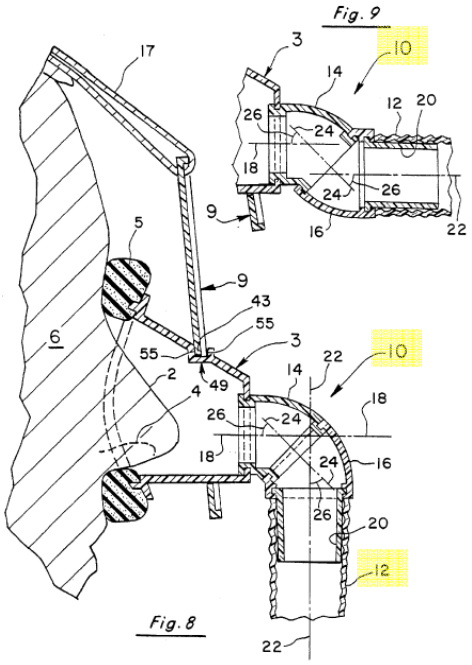
Claim 3 depends from Claim 2 and includes "wherein the sealing cushion is secured to the mask frame."

Ogden discloses that the sealing cushion is secured to the mask frame around the rear perimeter by adhesive or press fit. Ex. 1202 at col. 2:54–57.

d. Dependent Claim 6

Claim 6 depends from Claim 1 and includes "comprising an elbow assembly, said elbow assembly being adapted to be connected to an air delivery tube."

The Ogden mask assembly includes an elbow assembly 10 that connects to an air delivery tube 12, as shown below in Figure 8. Ex. 1202 at col. 5:35–47.



e. Dependent Claim 7

Claim 7 depends from Claim 1 and includes "wherein the headgear connector is removably attachable to the mask frame."

The Ogden mask assembly is assembled by slightly stressing the detent 43 on the headgear connector 9 over the front wall 55 to position the detent 43 in the channel 49 of the frame 3 (see Figure 8 below). Ex. 1202 at col. 5:14–22. A person of skill would have known that the headgear connector 9 could be removed from the frame 3 by flexing the detent 43 back over the front wall 55 and out of the channel 49. Ex. 1206 ¶¶ 94–95. There are no features on the Ogden frame 3 that prevent the headgear connector 9 from being removed. *Id.*

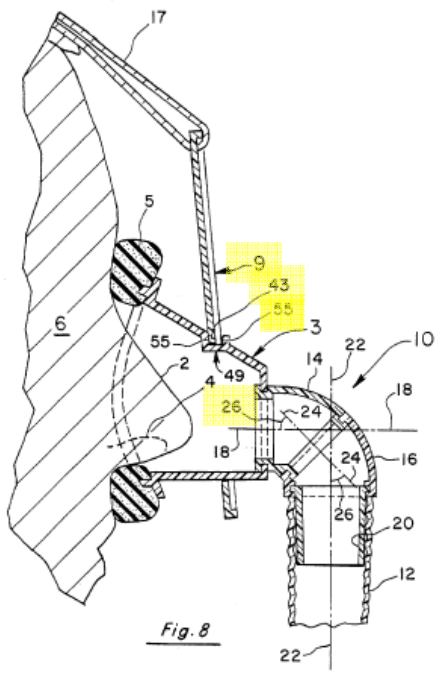


Fig. 8

However, to the extent Ogden somehow provides insufficient teachings for this limitation, such removable attachments were well-known in CPAP masks. *Id.* ¶¶ 96–97. For example, Gunaratnam discloses that "the detents ([820]) may be forced outwardly against their natural resilience to release the recesses (660) and ride over the outer edge of flange (640). Ex. 1203 at col. 5:39–43.

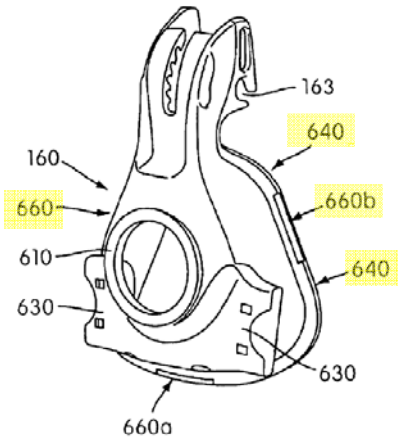


FIG. 5a

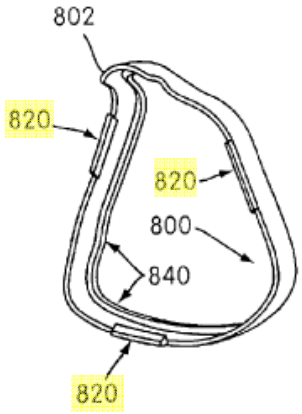


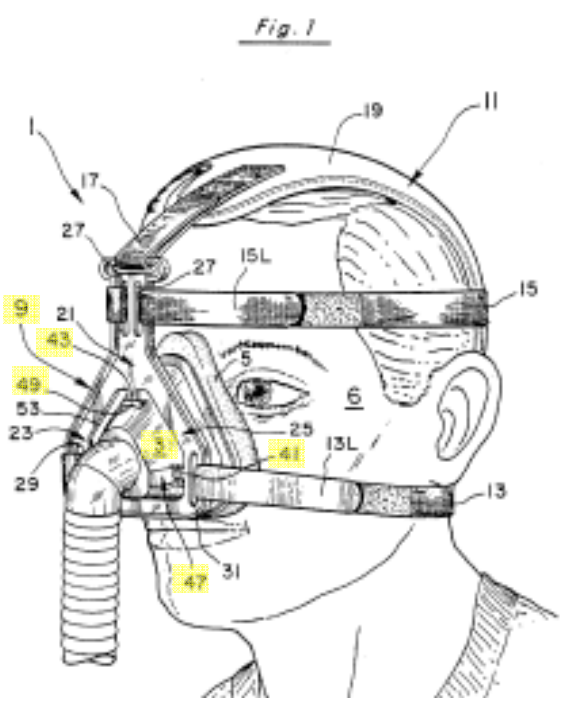
FIG. 7a

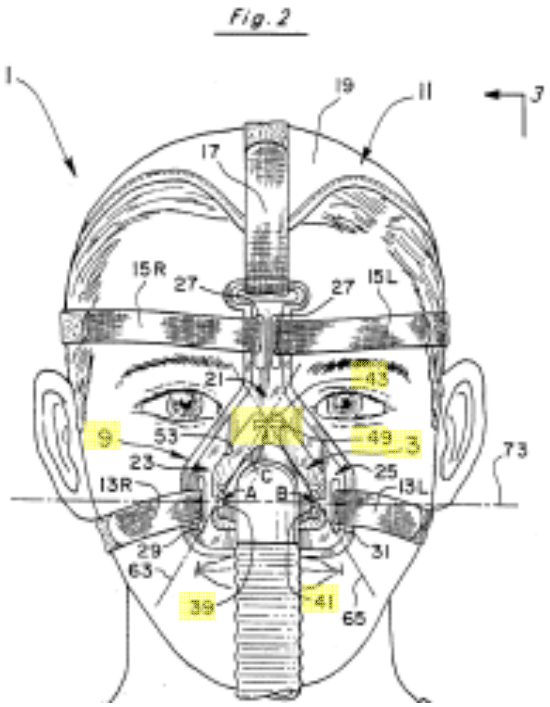
A person of skill in the art at the time of the invention would have been motivated to provide a headgear connector that is removably attachable to a mask frame to allow for easy removal of the mask frame and cushion for cleaning or replacing mask components. *See id.* at col. 5:34–43; Ex. 1206 ¶¶ 98–99.

f. Dependent Claim 9

Claim 9 depends from Claim 7 and includes "wherein the headgear connector and the mask frame are adapted to be engaged by a snap-fit."

The Ogden headgear connector 9 and mask frame 3 are adapted to be engaged by a snap-fit, as shown below in Figures 1 and 2. The headgear connector 9 includes three tabs or detents 39, 41, and 43 that are received into channels 45, 47, and 49 on the mask frame 3, in a snap-fit arrangement. Ex. 1202 at col. 3:10–30; Ex. 1206 ¶ 101. "[T]he detent-channel 43, 49 at the top of the shell 3 at the third location C is preferably dimensioned to snap together to hold or maintain the rigid plate 9 on the rigid shell 3." Ex. 1202 at col. 5:14–19.





A person of skill would have recognized that the assembly of Ogden, with at least one tab undergoing interference, deflection, and elastic recovery to achieve the interlocked position, is a snap-fit. Ex. 1206 ¶¶ 102–104.

g. Dependent Claim 10

Claim 10 depends from Claim 7 and includes "wherein the headgear connector comprises a plurality of tabs to attach the mask frame with a snap-fit."

The Ogden headgear connector 9 includes a plurality of tabs or detents 39, 41, and 43 that are received into channels 45, 47, and 49 on the mask frame, and the detent 43 snaps into the channel 49. *See* Ex. 1202 at col. 5:14–19. Thus, the plurality of tabs 39, 41 and 43 engage the mask frame 3 and attach the headgear connector 9 with a snap-fit. Ex. 1206 ¶¶ 101–104, 106.

To the extent this limitation is somehow interpreted narrowly to require that each of the plurality of tabs engages the mask frame with a snap-fit, a person of skill in the art would have known to and been motivated to construct the other tabs of Ogden to also snap with the frame. *Id.* ¶¶ 107–114.

For example, Lovell discloses that the headgear connector 212 includes tabs (extending between slots 213, 215) that each engage the depressed annular regions 280 on the frame 204 in a snap-fit. Ex. 1205 at col. 9:59–64.

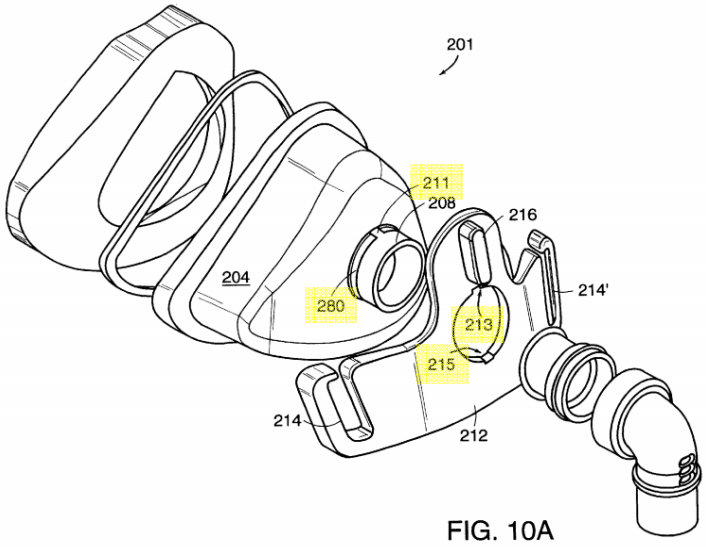


FIG. 10A

A person of skill would have been motivated to make each of the plurality of tabs in Ogden snap with the mask frame to provide a more secure attachment and to limit unwanted movement between the headgear connector and the mask frame. Ex. 1206 ¶ 110. Although the Ogden headgear connector is movable relative to the frame, a person of skill at the time of the purported invention would have understood that this feature was no longer necessary in view of advances in seal design and manufacturing technology. *Id.* ¶ 111. A person of skill would have known that it was desirable to prevent relative movement between the headgear

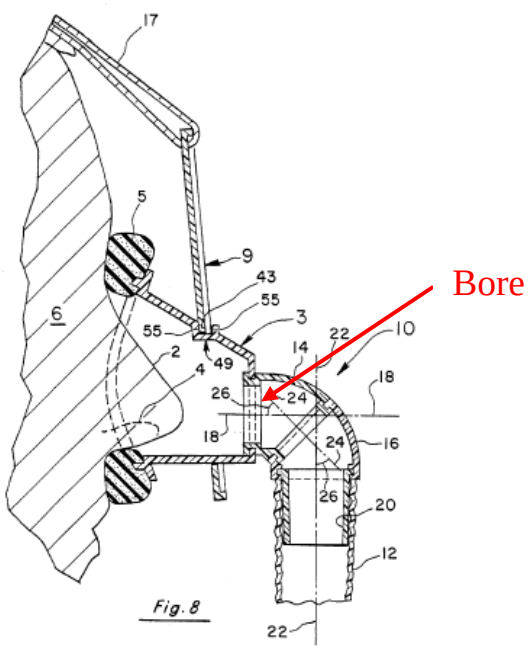
connector and the frame for at least the reasons provided below in the discussion of Claim 8. *See infra* § VII.C.2.c.

Recognizing that the relative movement was undesirable, a person of skill would have modified the tabs and channels already provided by Ogden so that more of the tabs engage with a snap to provide more stability between the headgear connector and the mask frame. Ex. 1206 ¶ 111. A person of skill would have recognized that the tabs provide more predictable assembly and disassembly forces than an annular snap-fit without the tabs. *Id.* ¶¶ 112–113. Further, by creating a snap-fit using a plurality of tabs, the snap characteristics can be more easily adjusted by changing individual tab geometry or mating surface geometry. *Id.* ¶ 114. Multiple snaping tabs also provide additional securement features if one tab fails. *Id.*

h. Dependent Claim 11

Claim 11 depends from Claim 1 and includes "wherein the central bore is located on a main body of the mask frame."

The bore of the Ogden mask frame 3 is located on the main body, as shown below in Figure 8. Ex. 1202 at col. 2:50–54.



i. Dependent Claim 12

Claim 12 depends from Claim 1 and includes "comprising a vent assembly for gas washout."

Ogden does not expressly disclose a vent assembly, but such vents were commonly used in CPAP masks. Ex. 1206 ¶¶ 116–119. For example, Gunaratnam discloses a mask assembly with an air vent assembly 940, as shown below in Figure 15. Ex. 1203 at col. 6:25–30.

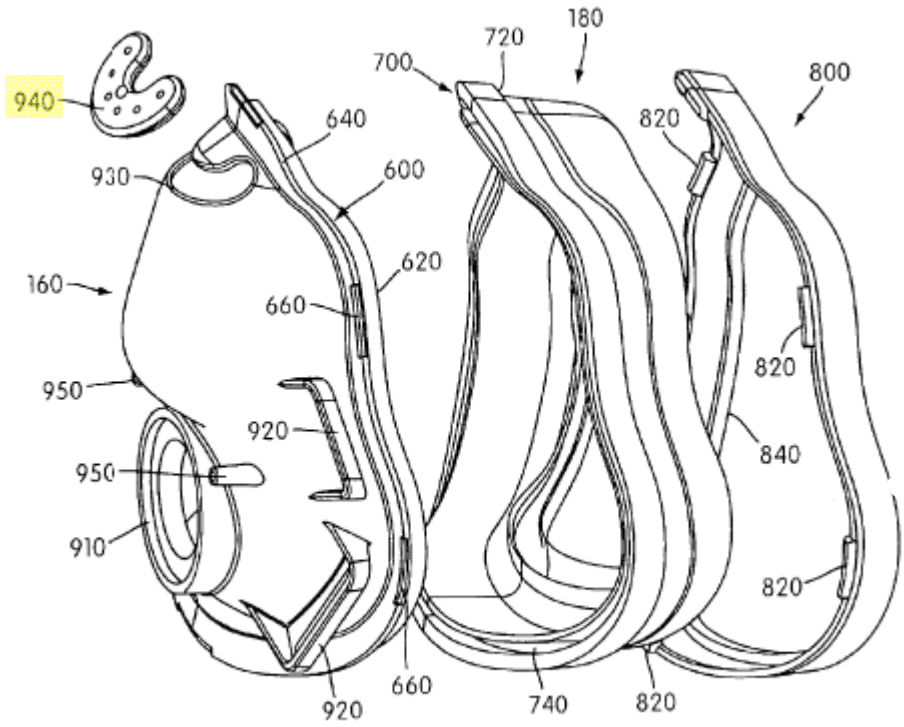


FIG. 15

A person of skill in the art would have recognized the need for a vent assembly and would have provided one on the mask of Ogden, as taught by

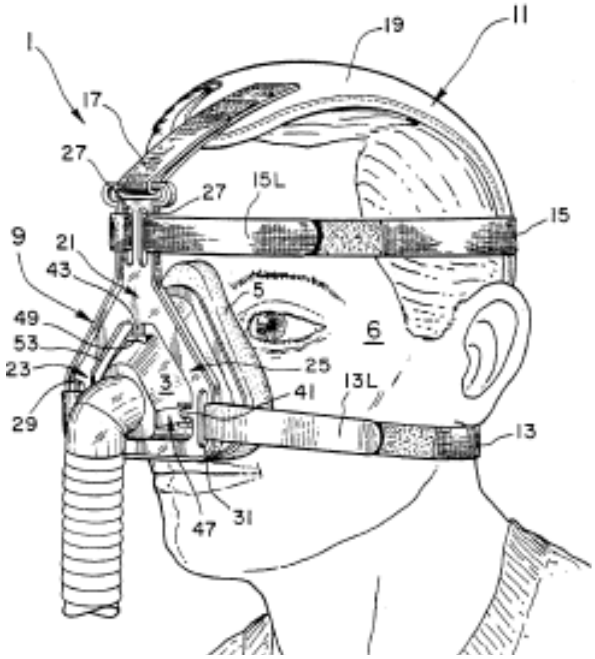
Gunaratnam. Ex. 1206 ¶¶ 118, 120. Such vent assemblies were frequently included in mask assemblies to release gases exhaled by the user. *Id.* ¶¶ 118–120.

j. Dependent Claim 13

Claim 13 depends from Claim 1 and includes "wherein the forehead support is T-shaped."

As shown in Figure 1 below, the upper support of Ogden is T-shaped with a narrower lower portion and a wider upper portion. Ex. 1206 ¶ 122.

Fig. 1



To the extent Ogden is somehow insufficient for this feature, T-shaped forehead supports were commonly used prior to the ’196 Patent, as shown below in Figures 5c and 5d of Gunaratnam. Ex. 1203 at col. 4:46–48; Ex. 1206 ¶¶ 123–126. For the reasons provided above with respect to Claim 1, a person of skill would have modified the Ogden mask to include the features of the Gunaratnam forehead support. *See supra* § VII.B.4.a.v. Further, a person of skill would have known to include a T-shaped forehead support to provide greater contact area for added stability and comfort, without obstructing the user’s field-of-view. Ex. 1206 ¶ 127.

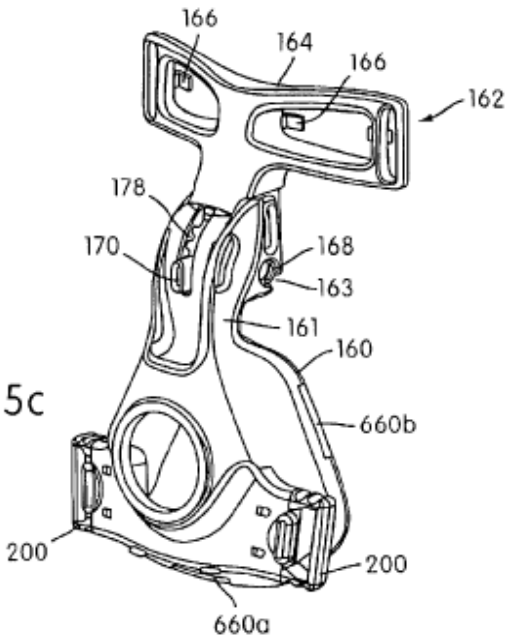


FIG. 5c

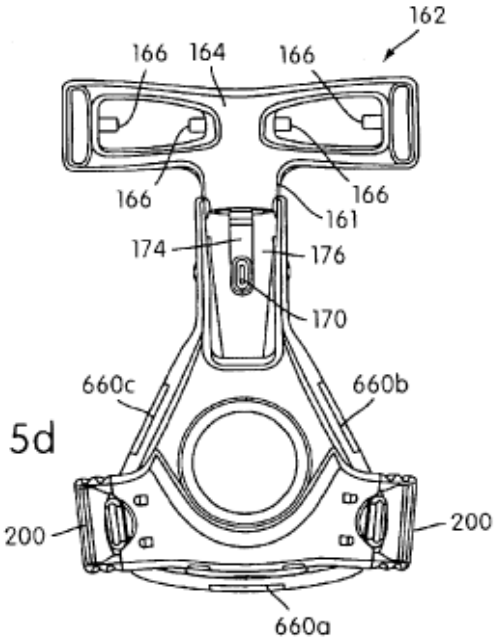


FIG. 5d

k. Dependent Claim 14

Claim 14 depends from Claim 1 and includes "wherein the sealing cushion cannot be easily detached from the mask frame."

Ogden discloses a sealing cushion that is glued or press-fit about the rear perimeter of the mask frame. Ex. 1202 at col. 2:54–57. A person of skill would have understood that a cushion that is glued to the frame is permanently attached. Ex. 1206 ¶ 129.

l. Dependent Claim 15

Claim 15 depends from Claim 14 and includes "wherein the sealing cushion and the mask frame are permanently attached."

As discussed above, Ogden discloses a cushion permanently attached to the mask frame. *See supra* § VII.B.4.k.; Ex. 1206 ¶ 131

m. Dependent Claim 16

Claim 16 depends from Claim 1 and includes "wherein said headgear connector is constructed of a similar material as the frame."

Ogden discloses that the headgear connector and frame are both made from rigid plastics. Ex. 1202 at cols. 2:50–54, 3:25–26.

n. Dependent Claim 17

Claim 17 depends from Claim 16 and includes "wherein said headgear connector and said mask frame are constructed of a substantially rigid, non-malleable plastic material."

Ogden discloses that the headgear connector and frame are both made from rigid plastics. Ex. 1202 at cols. 2:50–54, 3:25–26; Ex. 1206 ¶ 133.

o. Dependent Claim 18

Claim 18 depends from Claim 17 and includes "wherein said headgear connector and said mask frame are constructed of polycarbonate."

Ogden does not expressly disclose that the frame and headgear connector are made from polycarbonate, but this material was extremely common and typically used for CPAP components. Ex. 1206 ¶¶ 135–136. For example, Gunaratnam discloses that its mask components are constructed of polycarbonate. Ex. 1203 at cols. 4:22–26, 5:34–35.

A person of skill would have selected polycarbonate as suitable for the intended purpose of the rigid frame/headgear connector. Ex. 1206 ¶ 136; s*ee also* M.P.E.P. 2144.07 ("Art Recognized Suitability for an Intended Purpose."). It was well-known to construct the headgear connector and the frame from polycarbonate to provide strength, rigidity, and toughness to support the headgear. Ex. 1206 ¶ 136. Additionally, polycarbonate CPAP components can be cleaned, disinfected, and/or sterilized by most commonly used methods. *Id.*

p. Independent Claim 19

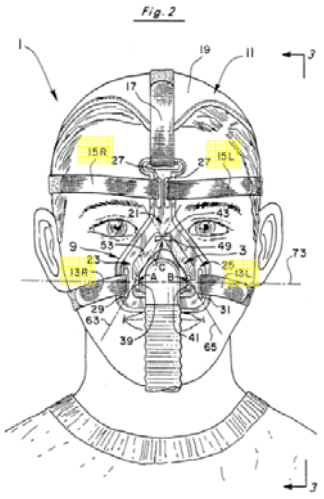
Independent Claim 19 includes the following limitations:

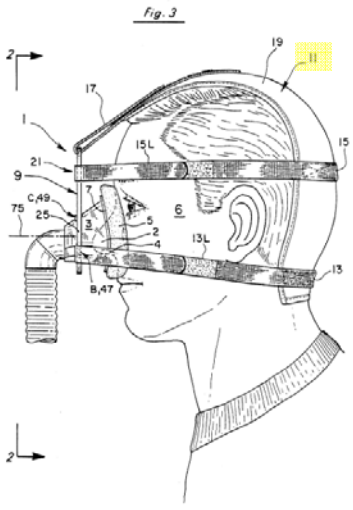
i. Preamble: "A mask system for delivering breathable gas to a patient at positive pressure to treat sleep disordered breathing, the mask system comprising:"

Ogden discloses masks that fit over at least a patient's nose and deliver breathable gas from a continuous positive airway pressure device to treat sleep-disordered breathing. Ex. 1202 at cols. 1:9–12, 5:41–44.

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

The Ogden headgear includes a pair of upper side straps 15L, 15R, a pair of lower side straps 13L, 13R, and a rear portion 19, as shown below in Figures 2 and 3. Ex. 1202 at cols. 2:62—3:2.





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

As explained above, the combination of Ogden and Gunaratnam teaches lower headgear clip anchors adapted to receive lower headgear clips. *See supra* § VII.B.4.a.iv. The lower headgear clips of Gunaratnam are adapted to receive lower headgear straps. Ex. 1203 at col. 4:32–34.

iv. "a mask according to claim 1."

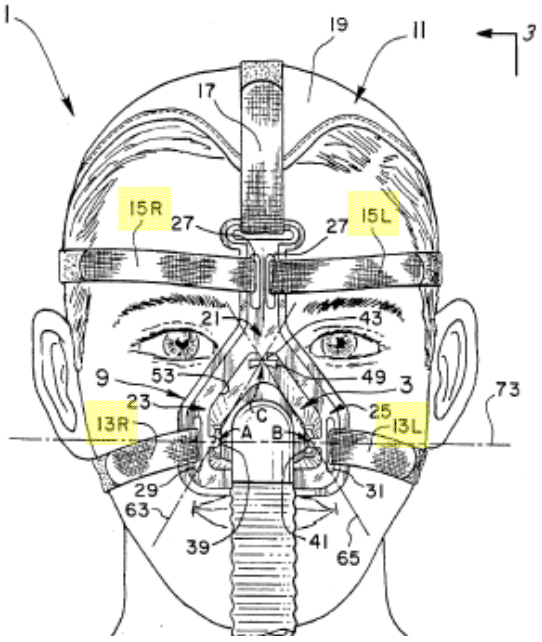
The combination of Ogden, Gunaratnam, and Amarasinghe discloses all of the features of Claim 1, as discussed above. *See supra* § VII.B.4.a.

q. Dependent Claim 20

Claim 20 depends from Claim 19 and includes "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."

Ogden discloses a headgear assembly with a pair of upper side straps 15L, 15R that extend above the patient's ears and a pair of lower side straps 13L, 13R that extend below the patient's ears, as shown below in Figure 2. Ex. 1202 at col. 2:62–66.

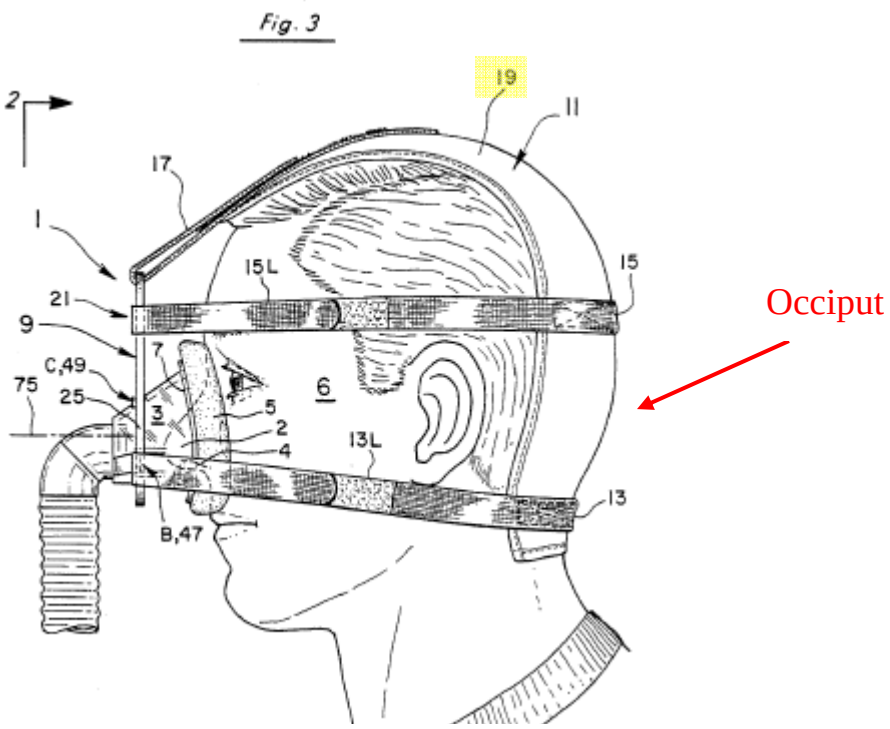
Fig. 2



r. Dependent Claim 21

Claim 21 depends from Claim 20 and includes "wherein the rear portion of the headgear is adapted to cup the occiput of the patient's head."

The Ogden headgear assembly includes a rear portion 19 that cups the occiput of the patient's head (or the back of the skull), as shown below in Figure 3. Ex. 1202 at cols. 2:66—3:1, 3:64–67.



s. Dependent Claim 22

Claim 22 depends from Claim 1 and includes "wherein said forehead support is adjustable."

Ogden does not expressly disclose an adjustable forehead support, but such supports were well-known and common in CPAP masks. Ex. 1206 ¶¶ 144–146. For example, the forehead support 162 of Gunaratnam (shown below) is an "adjustable forehead support." Ex. 1203 at col. 4:49–52.

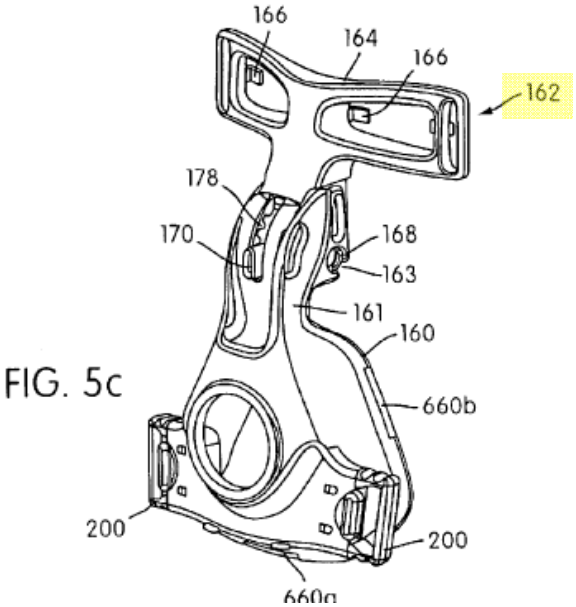


FIG. 5c

A person of skill would have been motivated to include the features of the Gunaratnam forehead support for at least the reasons provided above. *See supra* § VII.B.4.a.v. In particular, a person of skill would have been motivated to include an adjustable forehead support to enable the forehead support to be positioned in a

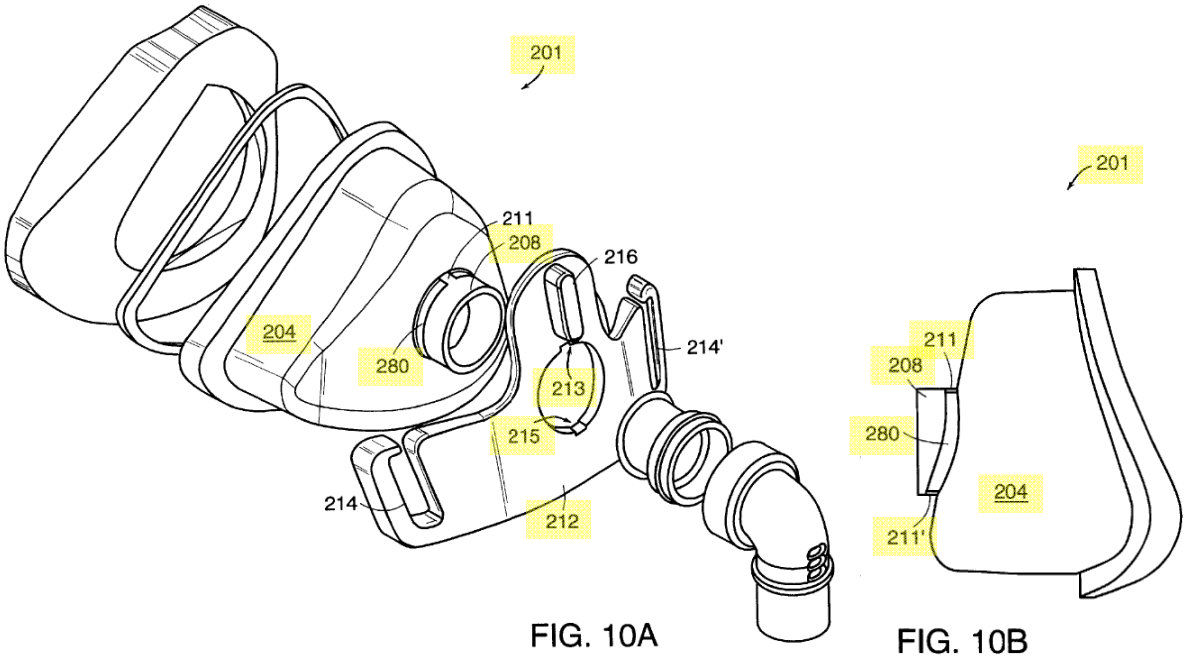
number of positions to accommodate patients having a wide scope of facial geometries. *See* Ex. 1203 at cols. 4:65—5:2; Ex. 1206 ¶ 146.

C. Ground 2: Claims 4, 5, and 8 would have been obvious over Ogden in view of Gunaratnam, Amarasinghe, and Lovell

1. Overview of Lovell (Ex. 1205)

Lovell was submitted during the prosecution of the '196 Patent, but was not cited by the Examiner. Ex. 1201 at 5.

Lovell discloses CPAP masks with a seal attached to a perimeter of a shell to form a breathing chamber. Ex. 1205 at Abstract, col. 2:56–58.



As shown above in Figures 10A–10B of Lovell, the mask 201 has a retainer 212 that is contoured to match the surface of the shell 204 and is coupled to an inlet 208 on the front face of the shell 204. *Id.* at col. 9:43–46. The shell 204 has depressed annular regions 280 (extending between tabs 211, 211') on the inlet

208 that mate with the tabs (extending between slots 213, 215) formed in the headgear connector 212. *Id.* at col. 9:57–66.

2. Limitations of Claims 4, 5, and 8

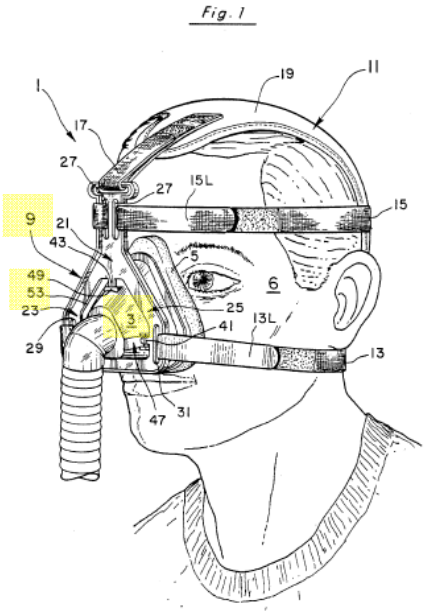
A person of skill in the art at the time of the purported invention would have been motivated to combine the teachings of Ogden, Gunaratnam, and Amarasinghe for at least the reasons provided above. *See supra* § VII.B. Because Lovell discloses a CPAP patient interface with similar structural features, its features would have been readily compatible with and easily incorporated into the Ogden mask with a reasonable expectation of success. Ex. 1206 ¶ 152. Combining these familiar CPAP mask features according to known methods would have done no more than yield predictable results. *See id.*; *see also KSR*, 550 U.S. at 416.

a. Dependent Claim 4

Claim 4 depends from Claim 3 and includes "wherein at least a portion of said headgear connector is shaped to conform to a portion of said mask frame."

The Ogden headgear connector 9 has an aperture 53 that is dimensioned to receive the top ridge of the shell 3 and extends around the shell 3. Ex. 1202 at col. 3:39–42; Ex. 1206 ¶ 154. However, to the extent Ogden provides insufficient teachings for this feature, headgear connectors shaped to conform to the mask frame were well-known prior to the '196 Patent. Ex. 1206 ¶¶ 155–157. For example, Lovell expressly discloses a headgear connector 212 that is contoured to match the external curvature of the frame 204. Ex. 1205 at col. 9:43–59.

Ogden



Lovell

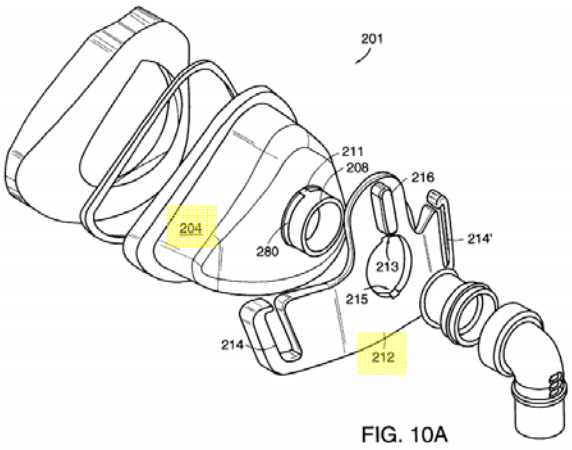


FIG. 10A

A person of skill in the art at the time of the invention would have been motivated to shape the Ogden headgear connector to conform to a portion of the mask frame, as taught by Lovell, to provide stability and reduce the likelihood of the mask coming into contact with other objects (*e.g.*, pillows or bedding). Ex. 1206 ¶ 158. Further, a person of skill would have recognized that positioning the headgear connector structure closer to the frame decreases the profile of the mask to make the mask more visually appealing and improve the user's field-of-view. *Id.* Shaping the headgear connector to conform to the mask frame, for example by shaping side portions of Ogden headgear connector toward the frame and and cushion, would have been easily achieved by modifying the mold and with a reasonable expectation of success. *Id.* ¶ 159.

b. Dependent Claim 5

Claim 5 depends from Claim 4 and includes "wherein the mask frame includes a peripheral edge to engage the headgear connector."

The Ogden mask frame 3 includes an outer surface with three channels 45, 47, and 49 that receive detents 39, 41, and 43 of the headgear connector 9. Ex. 1202 at col. 3:10–30.

To the extent Ogden does not disclose a frame with a peripheral edge that engages the headgear connector, such arrangements were disclosed in prior art

CPAP masks and would have been well-known to a person of skill. Ex. 1206 ¶¶ 162–164.

For example, the mask frame 204 of Lovell includes interfacing structures (depressed annular region 280) along the peripheral edge of the mask frame that engage the headgear connector 212, as shown below in Figure 10A. Ex. 1205 at col. 9:59–64. The headgear connector to frame connection in Lovell is similar to that shown in the '196 Patent. Ex. 1206 ¶¶ 162–163. As shown below in Figure 2A, the '196 Patent discloses the central bore 224 including a flange or interfacing structure 225 (shaded red) along its peripheral edge that is adapted to removably connect to the headgear connector. Ex. 1201 at col. 6:28–32.

Prior Art Lovell (reversed)	**'196 Patent**

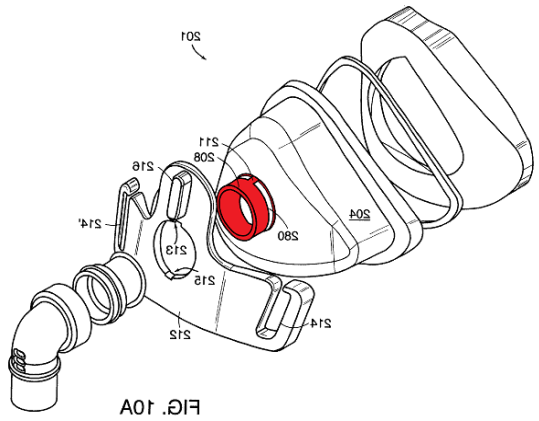
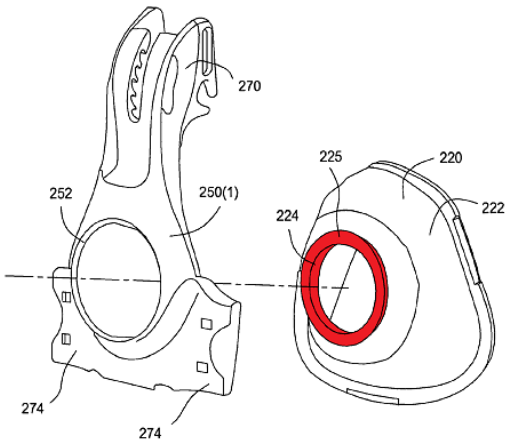

	

FIG. 10A	FIG. 2A

A person of skill in the art would have been motivated to modify Ogden to include the peripheral edge and attachment features of Lovell. Ex. 1206 ¶¶ 165–166. For example, a person of skill would have been motivated to modify Ogden to include an outwardly projecting inlet at its peripheral edge and to connect the headgear connector at the inlet, as disclosed by Lovell. *Id*. ¶ 165.

A person of skill in the art at the time of the invention would have recognized that the modified connection would allow the headgear connector to connect to the mask frame near the elbow connection. *Id.* ¶ 166. Such an arrangement would enable additional design features that better secure and seal the elbow to the mask frame. *Id.* Further, a person of skill would have recognized that such an attachment would require matching the edges of the headgear connector to the mask frame and consequently provide assurance to the user that the headgear connector and mask frame are fully attached and engaged correctly. *Id.*

c. Dependent Claim 8

Claim 8 depends from Claim 7 and includes "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."

Ogden discloses that "previous mask assemblies of similar construction to the present invention fixedly mounted the rigid plate 9' to their shell 3'." Ex. 1202

at col. 3:57–59. Thus, although Ogden discloses embodiments in which the headgear connector pivots relative to the mask frame, it also acknowledges that it was well-known to attach the mask frame and headgear connector in a non-movable manner. Ex. 1206 ¶ 169.

The mask assemblies of Lovell have headgear connectors that are not movable relative to the mask frame. *Id.* ¶¶ 170, 172. Lovell discloses that "the retainer 212 is properly retained by the cooperation of the tabs 211, 211' (not shown), the slots 213, 215, and the depressed annular region 280 when fully seated against the shell 204." Ex. 1205 at col. 9:59–64.

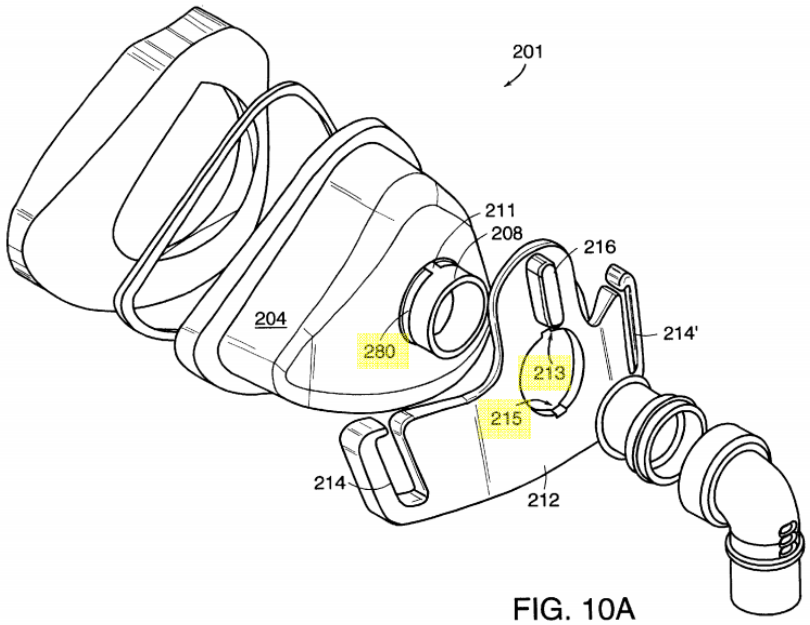


FIG. 10A

A person of skill at the time of the purported invention would have been motivated to modify the headgear connector and mask frame attachment of Ogden

to have no relative movement. Ex. 1206 ¶¶ 169–181. Such a person would have known that, in Ogden, the headgear connector moves relative to the mask frame, so it is not possible to control the pressure along the perimeter of the mask. Ex. 1206 ¶ 173. A person of 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. *Id*. Because users have unique and differing facial geometries, 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. *Id*.

In view of advances in cushion design (*e.g.*, Lovell and Gunaratnam) and manufacturing technology in the time period between Ogden and the'196 Patent, a person of skill would have understood that any supposed benefit of relative movement between the headgear connector and the frame could be achieved in a much simpler and effective way (improved cushions). *Id.* ¶¶ 175–179. Recognizing that the relative movement was undesirable, a person of skill would have modified Ogden to include a more reliable cushion/seal and a non-movable headgear connector to provide stability and improve the seal. *Id.* ¶¶ 173–181. Further, a person of skill would have recognized that a mask with a non-movable

headgear connector and compliant seal would distribute contact pressure and would allow the user to comfortably lie in almost any position and to shift positions without disturbing the sealing engagement, as taught by Lovell. *See* Ex. 1205 at col. 2:42–46; Ex. 1206 ¶ 176.

A person of skill would have recognized that the motivating benefits of modifying the frame of Ogden to be not movable relative to the headgear connector, as taught by Lovell, outweighed any lost benefit of the movable headgear connector of Ogden. Ex. 1206 ¶ 179; *see also* Ex. 1208 at 269; M.P.E.P. 2144.04(II)(a) ("Omission of an Element and Its Function is Obvious if the Function of the Element is Not Desired."); *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.").

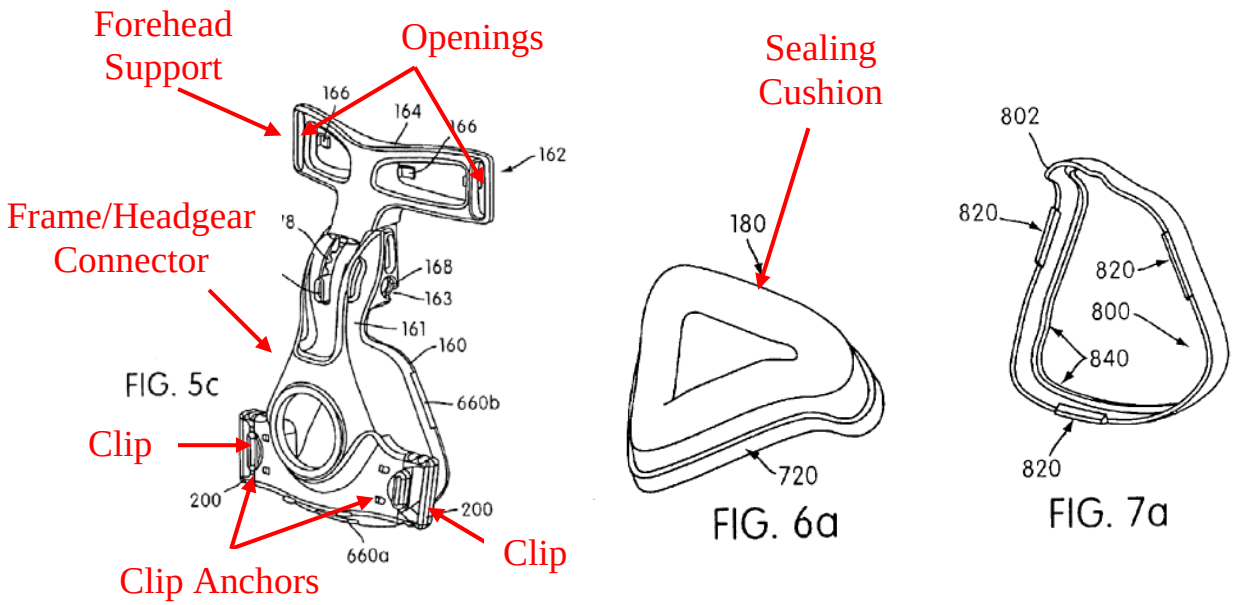
D. Ground 3: Claims 1–22 would have been obvious over Gunaratnam in view of Lovell and Amarasinghe

1. Limitations of Claims 1–22

As explained in detail below, Gunaratnam describes a mask assembly having nearly all of the limitations of independent Claim 1.

With respect to Claim 1, Gunaratnam teaches masks for delivering breathable gas to a patient at positive pressure to treat sleep disordered breathing, the mask comprising: a mask frame (frame 160); a sealing cushion (cushion 180) provided to the mask frame and adapted to form a seal with the patient's face; and a headgear connector (integral with frame 160), said headgear connector including a pair of lower headgear clip anchors (strap connection points 630) adapted to be engaged with respective ones of a pair of lower headgear clips (connectors 200), said headgear connector including a forehead support (forehead support 162) 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. *See* Ex. 1203 cols. 1:21—39, 3:30–32, 4:32–34, 4:46–48, 5:14–24, 5:29–47, Figs. 5a–7e.

Many of these claimed features are identified in the annotated versions of Gunaratnam Figures 5c, 6a, and 7a provided below.



Any 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. Ex. 1206 ¶¶ 182–273. Because Gunaratnam, Lovell, and Amarasinghe all teach structurally similar CPAP masks for the treatment of sleep-disordered breathing, their features would have been easily incorporated into the mask of Gunaratnam with a reasonable expectation of success. Ex. 1206 ¶ 184. Combining these familiar CPAP mask features according to known methods would

have done no more than yield predictable results. *See id.*; *see also KSR*, 550 U.S. at 416.

a. Independent Claim 1

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

Gunaratnam discloses nasal and full-face masks "for delivery of breathable gases to a patient for the treatment of sleep disordered breathing (SDB)." Ex. 1203 at col. 1:21–25.

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

As shown below in Figure 5c, Gunaratnam discloses a mask frame 160 that both forms part of the interior of the breathing chamber and includes headgear anchors. Ex. 1203 at col. 4:22–24.

Prior Art Gunaratnam

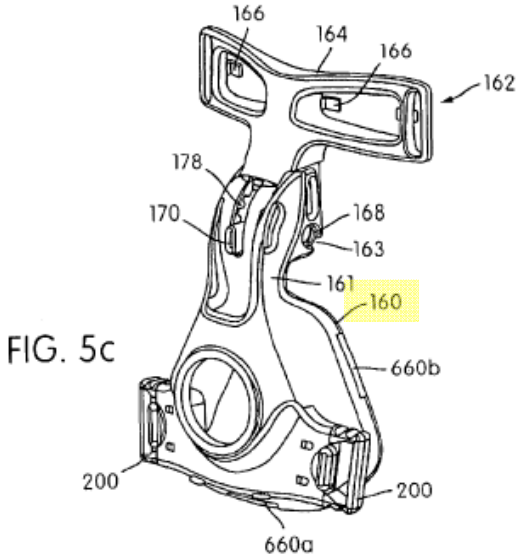


FIG. 5c

However, mask arrangements with a separate mask frame that defines the interior of the breathing cavity and has no built-in headgear anchors were well-known and disclosed in the prior art. Ex. 1206 ¶¶ 188–189.

For example, Lovell discloses a frame 204 (shaded red) having no headgear attachment points. The frame 204 defines the interior of the breathing cavity and has a central bore 208, as shown below in Figure 10A. Ex. 1205 at col. 9:44–46.

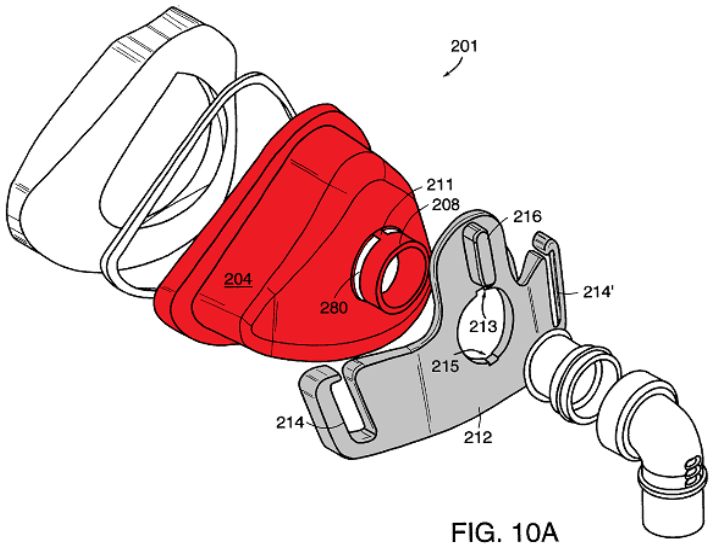
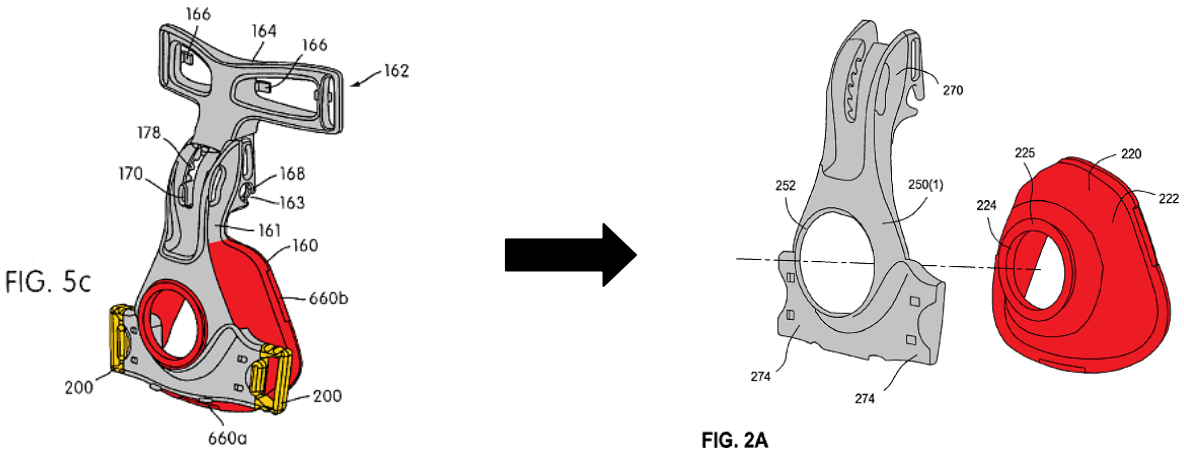


FIG. 10A

In view of Lovell and other prior art mask assemblies having a separate headgear connector and mask frame, a person of skill in the art would have been motivated to divide the Gunaratnam frame 160 into a separate headgear connector (shaded gray) and mask frame (shaded red), as depicted below. Ex. 1206 ¶ 190. The result would be the mask assembly of the '196 Patent, as demonstrated in the figures below. *Id.*

Prior Art Gunaratnam **'196 Patent**



A person of skill would have made this modification to provide a breathing chamber, the interior of which is only defined by the frame and cushion. *Id.* ¶¶ 191–193. As 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. *Id.* ¶ 191. Thus, the breathing chamber could be removed for cleaning or replacement, separately and apart from

the headgear connector and the headgear. *Id.* ¶ 192. Because the headgear would not have to be removed, the headgear connector and the headgear could be reattached without requiring strap adjustment. *Id.* ¶ 193.

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

Gunaratnam discloses a sealing cushion 180 provided to the mask frame that seals against the patient's face, as shown below in Figure 6A. Ex. 1203 at cols. 1:33–39, 5:14–24.

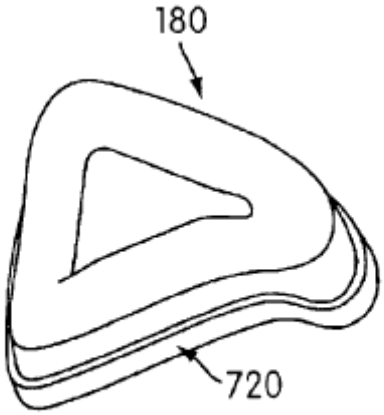
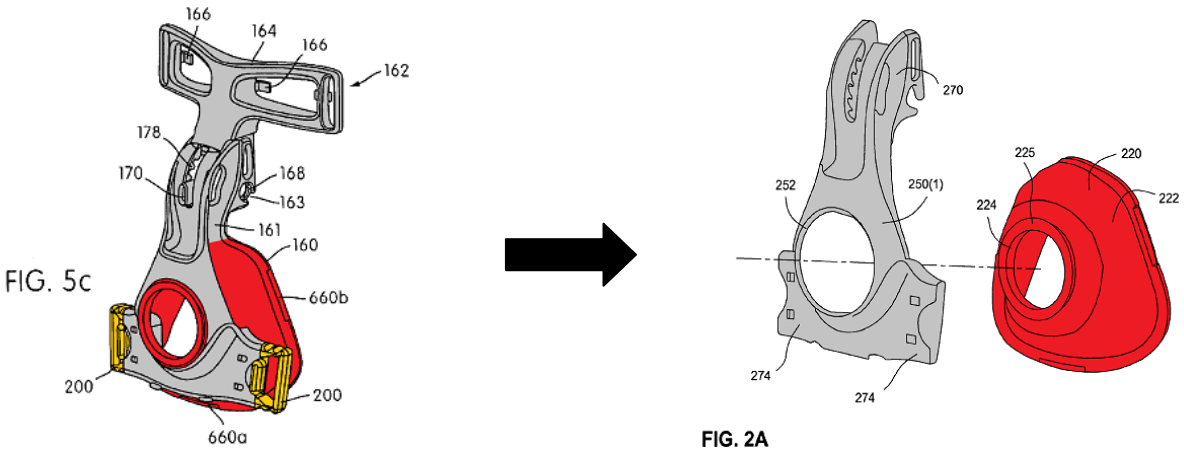


FIG. 6a

iv. "a headgear connector adapted to engage the mask frame,"

As discussed above, the Gunaratnam mask assembly, as modified in view of Lovell, would have the claimed headgear connector (shaded gray) and mask frame (shaded red). *See supra* § VII.D.1.a.ii. These components would engage at the inlet, as taught by Lovell and similar to the connection shown below in Figure 2A of the '196 Patent. Ex. 1206 ¶ 195.

Prior Art Gunaratnam **'196 Patent**



It was common knowledge to provide a separate headgear connector and to connect the mask components at the inlet. *Id.* ¶ 196. For example, Lovell discloses a headgear connector (shaded gray) that engages the frame (shaded red) at the inlet 208. Ex. 1205 at col. 9:57–64.

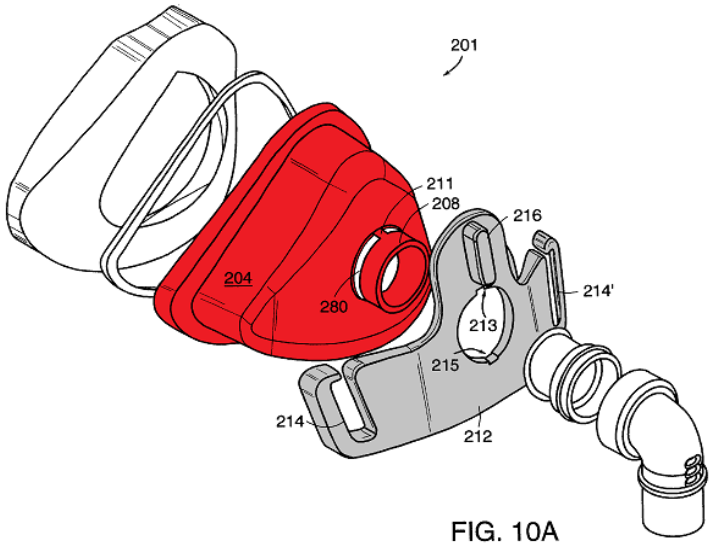


FIG. 10A

A person of 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. Ex. 1206 ¶ 197. Further, a 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.*

v. "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,"

As modified, the separated headgear connector of Gunaratnam (shaded gray) would retain its lower headgear clip anchors that receive lower headgear clips (shaded yellow), as shown below in Figure 5c. Ex. 1203 at col. 4:32–34.

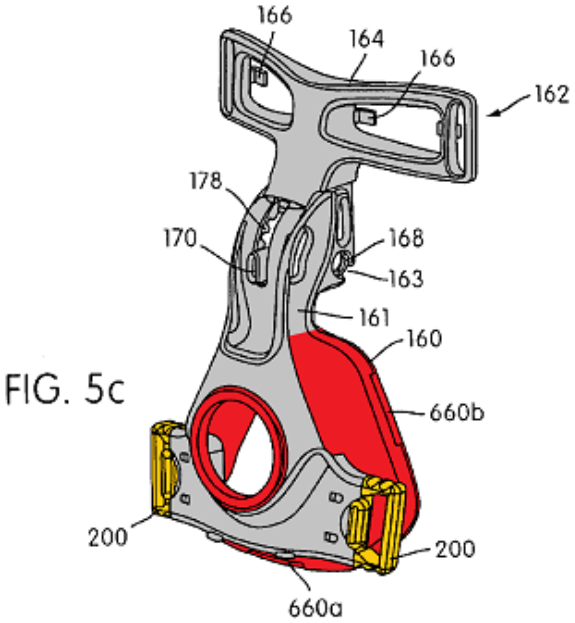


FIG. 5c

vi. "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"

As modified, the separated headgear connector of Gunaratnam (shaded gray) would retain its forehead support 162 that is connected to the remainder of the headgear connector 160 by an upper support member 161, shown in Figure 5c (below, left), similar to the forehead support 272 shown in Figure 2B of '196 Patent (below, right). Ex. 1203 at col. 4:46–59; Ex. 1206 ¶ 199. Gunaratnam discloses that "forehead supports include loops through which straps can pass." *Id.* at col. 1:45–48.

Prior Art Gunaratnam

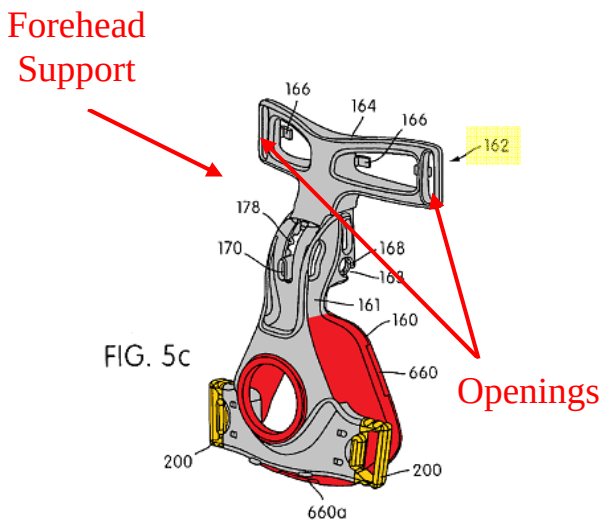


FIG. 5c

'196 Patent

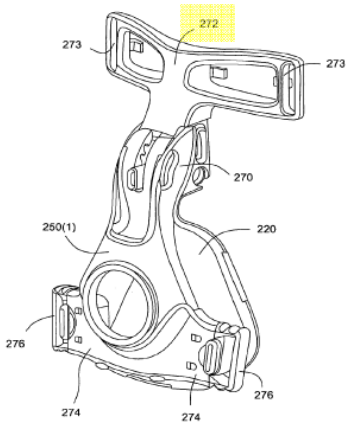


FIG. 2B

vii. "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."

(a) "removably connect"

As explained above, as modified in view of Lovell, the headgear connector of Gunaratnam would removably engage the mask frame at the inlet. *See supra* § VII.D.1.a.iv.

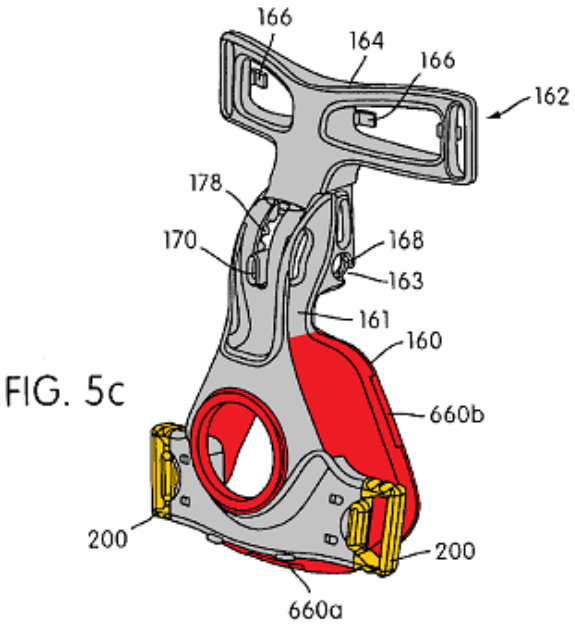


FIG. 5c

A person of skill would have incorporated the removable connection disclosed by Lovell into the Gunaratnam mask assembly. Ex. 1206 ¶ 203. In

Lovell, the headgear connector (shaded gray) has an opening with tabs (extending between slots 213, 215) that removably attach to the depressed annular regions 280 of the mask frame (shaded red), as shown below in Figure 10A. Ex. 1205 at col. 9:57–64; Ex. 1206 ¶ 203.

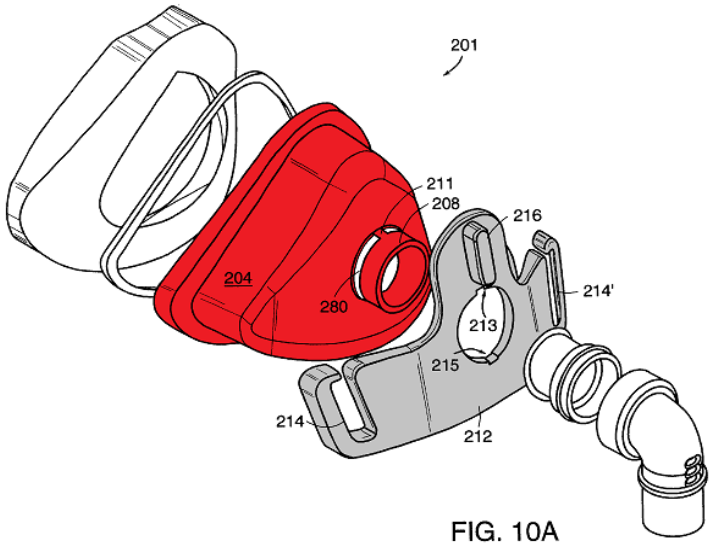


FIG. 10A

A person of skill would have recognized that removable connections between the headgear connector and the mask frame are desirable for cleaning or replacing mask components. *See* Ex. 1203 at col. 5:34–43; Ex. 1206 ¶ 204.

(b) "each headgear connector being different in at least one aspect"

Gunaratnam does not expressly disclose a mask frame that is adapted to connect to more than one headgear connector, where the headgear connectors are different in at least one aspect. However, such mask arrangements in which the frame is adapted to connect to different headgear connectors were well-known and disclosed in the prior art. Ex. 1206 ¶¶ 205–214.

For example, Amarasinghe discloses a mask frame 13 that is adapted to removably connect to multiple headgear connectors 12 (shaded red) that have different head strap attachment points 15, as shown below in Figure 2. Ex. 1204 ¶¶ 29, 33.

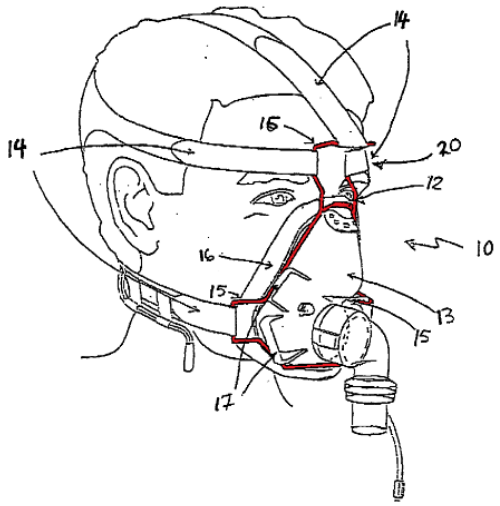


Fig. 2

Amarasinghe discloses headgear connectors "each with a different number of headgear attachment points or at least having a set number of headgear attachment points positioned in a variety of configurations with respect to the mask shell in order that a suitable choice may be made." *Id.* ¶ 33. Thus, the patient could choose a preferred headgear connector 12 from the various different headgear connectors for use with the same mask frame 13. Ex. 1206 ¶ 206. Sullivan-I is another prior art ResMed mask system that included this concept of providing multiple different headgear connectors that can be used with the same cushion. Ex. 1216 at 4, 6.

Although the mask frame 13 of Amarasinghe includes headgear attachment points, those attachment points are not used or necessary. Ex. 1206 ¶ 207. Therefore, a person of skill would have understood that this same concept of multiple different headgear connectors could also be used with frames that do not have headgear anchors, such as the mask assembly of Gunaratnam modified in view of Lovell, without diminishing the benefits and functionality of the mask system. *Id.*

A person of 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. *See* Ex. 1204 ¶¶ 29, 33; Ex. 1206 ¶ 215. Further, a person of skill would have understood that patients have different head shapes and different preferences for headgear arrangements. Ex. 1206 ¶¶ 215–216. For example, as shown below, Lovell recognizes that different headgear connector configurations may be desirable. *See* Ex. 1205 at cols. 6:2–13, 9:36–42; Ex. 1206 ¶ 213. With multiple different headgear connector options, the patient could choose his/her preferred arrangement and use it with the same mask frame, without having to puchase several different entire mask assemblies. Ex. 1206 ¶ 217.

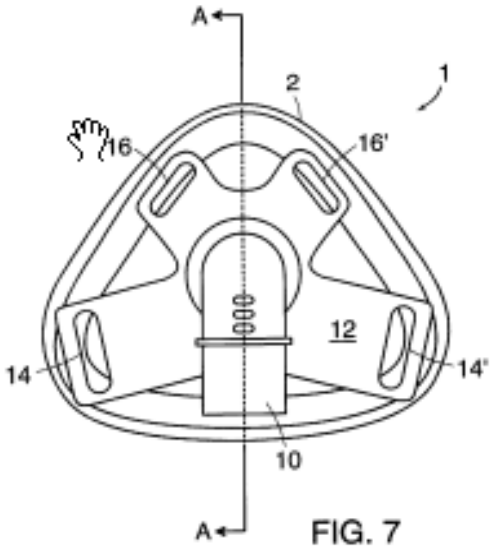


FIG. 7

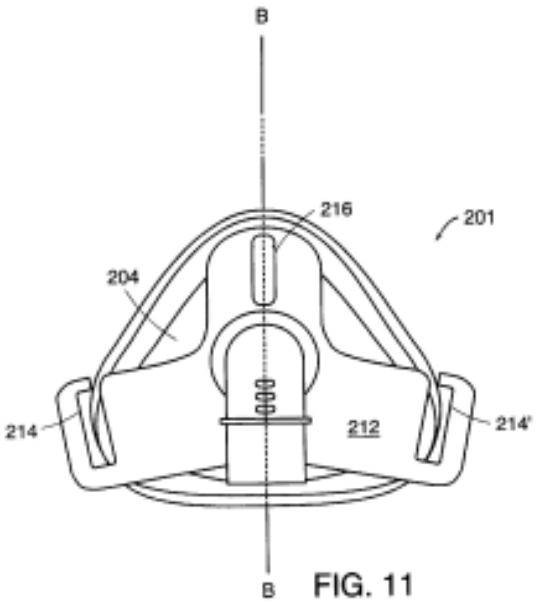


FIG. 11

The headgear connector would have been easily modified and reproduced into different versions with a reasonable expectation of success. *Id*. ¶ 218.

Providing 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.*

b. Dependent Claim 2

Claim 2 depends from Claim 1 and includes "wherein the mask frame and the sealing cushion comprise a full-face mask."

Gunarantam expressly discloses both nasal and full-face masks and its disclosed features apply to both nasal and full-face masks. Ex. 1203 at cols. 1:21–25, 6:3–13.

c. Dependent Claim 3

Claim 3 depends from Claim 2 and includes "wherein the sealing cushion is secured to the mask frame."

As explained above, the combination of Gunaratnam and Lovell teaches the claimed mask frame. *See supra* § VII.D.1.a.ii. 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. *See* Ex. 1203 at cols. 5:14–18, 5:29–46; Ex. 1206 ¶ 220. Gunaratnam and Lovell also disclose that it was known to glue or bond the cushion and frame together. Ex. 1203 at col. 1:49–50; Ex. 1206 ¶ 220.

d. Dependent Claim 4

Claim 4 depends from Claim 3 and includes "wherein at least a portion of said headgear connector is shaped to conform to a portion of said mask frame."

As modified, the Gunaratnam headgear connector would be shaped to conform to an outer surface of the frame. Ex. 1206 ¶ 223. It was common knowledge to contour the headgear connector to match the external curvature of the frame, as disclosed by Lovell. Ex. 1205 at col. 9:44–46; Ex. 1206 ¶¶ 223–224.

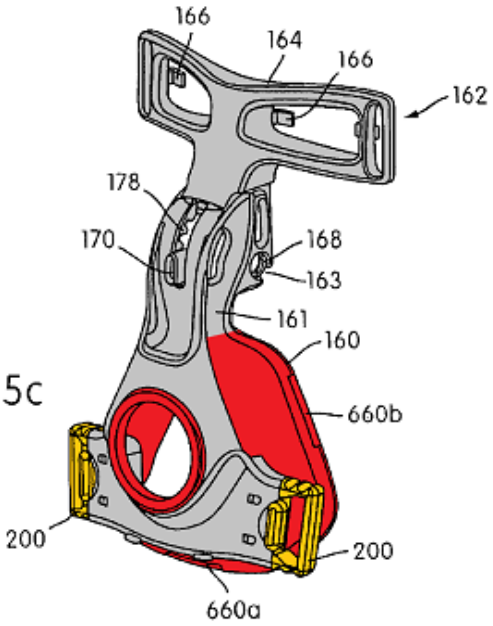


FIG. 5c

A person of skill in the art at the time of the invention would have been motivated to provide a headgear connector that conforms to a portion of the frame, as taught by Lovell, to provide stability and reduce the likelihood of the mask coming into contact with other objects (*e.g.*, pillows or bedding). Ex. 1206 ¶ 225. Further, a person of skill would have recognized that positioning the headgear connector structure closer to the frame decreases the profile of the mask to make the mask more visually appealing and improve the user's field-of-view. *Id.*

e. Dependent Claim 5

Claim 5 depends from Claim 4 and includes "wherein the mask frame includes a peripheral edge to engage the headgear connector."

As explained above, as modified in view of Lovell, the modified mask frame of Gunaratnam (shaded red) would include an inlet at the peripheral edge of the mask frame that engages the headgear connector (shaded gray), as taught by Lovell. *See supra* § VII.D.1.a.iv. As shown on the next page, this connection would be similar to that shown in the '196 Patent. Ex. 1206 ¶ 227. The '196 Patent discloses the frame (shaded red) including a flange or interfacing structure 225 along its peripheral edge that is adapted to removably connect to the headgear connector (shaded gray). Ex. 1201 at col. 6:28–32.

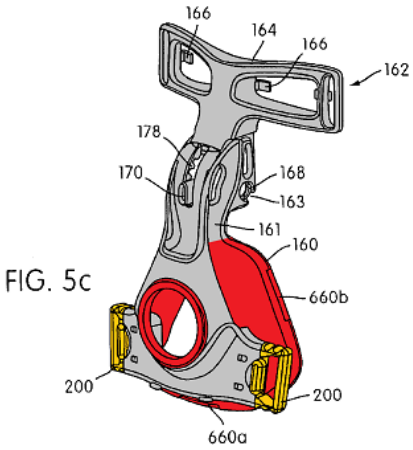


FIG. 5c

Gunaratnam

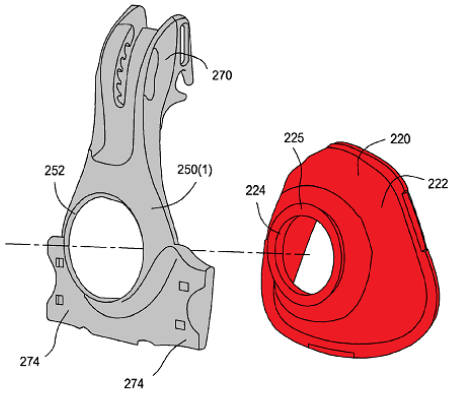


FIG. 2A

'196 Patent

This type of connection was common knowledge to one skilled in the art. Ex. 1206 ¶ 228–229. For example, Lovell discloses interfacing structures at the peripheral edge of the mask frame (shaded red) that engages the headgear connector (shaded gray), as shown below in Figure 10A. Ex. 1205 at col. 9:59–64.

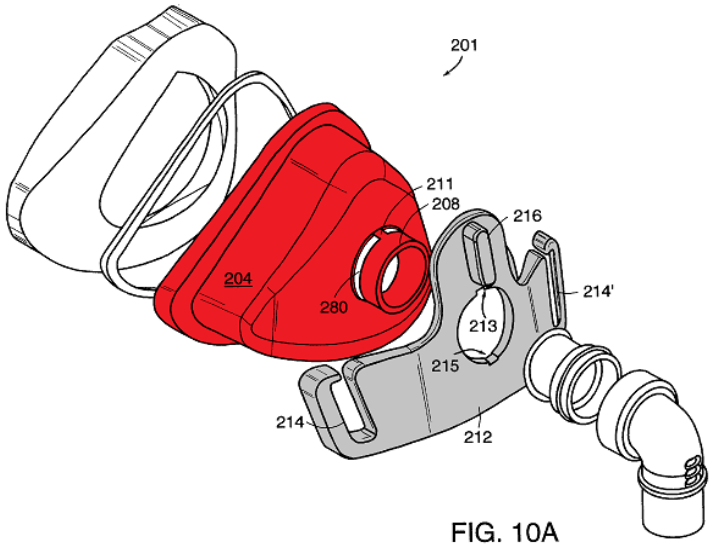


FIG. 10A

Joining 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.* ¶ 230. Further, a person of skill in the art would have recognized that the modified connection near the elbow connection would enable additional design features that better secure and seal the elbow to the mask frame. *Id.* ¶ 231.

f. Dependent Claim 6

Claim 6 depends from Claim 1 and includes "comprising an elbow assembly, said elbow assembly being adapted to be connected to an air delivery tube."

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. Ex. 1203 at col. 4:22–26. However, such elbow assemblies were common in prior art CPAP masks. Ex. 1206 ¶ 234. For example, as shown below, Lovell discloses a conduit elbow adapted to connect to the inlet 208. Ex. 1205 at cols. 7:29–32, 9:34–36.

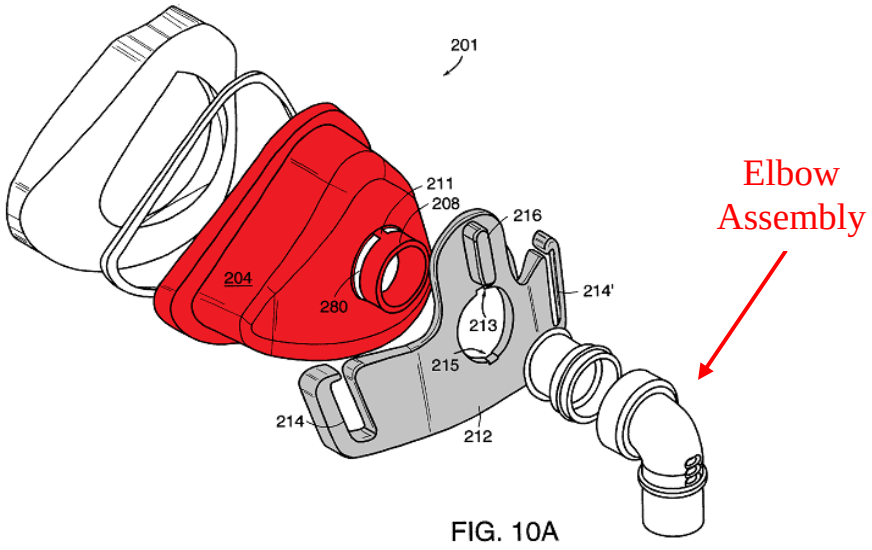


FIG. 10A

It 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. Ex. 1206 ¶ 235.

g. Dependent Claim 7

Claim 7 depends from Claim 1 and includes "wherein the headgear connector is removably attachable to the mask frame."

As explained above, in modifying the Gunaratnam mask frame in view of Lovell, a person of skill would have adopted the removable connection disclosed by Lovell. *See supra* § VII.D.1.a.vii.(a).

h. Dependent Claim 8

Claim 8 depends from Claim 7 and includes "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."

As explained above, in modifying the Gunaratnam mask assembly in view of Lovell, a person of skill would have adopted the removable connection disclosed by Lovell. *See supra* § VII.D.1.a.vii.(a). The removable connection of Lovell is a snap-fit arrangement between the frame and the headgear connector that prevents relative movement between those components. Ex. 1205 at col. 9:57–66;

Ex. 1206 ¶ 238. Thus, the modified mask assembly would include a headgear connector that is not movable relative to the mask frame. Ex. 1206 ¶ 238.

i. Dependent Claim 9

Claim 9 depends from Claim 7 and includes "wherein the headgear connector and the mask frame are adapted to be engaged by a snap-fit."

As explained above, the modified Gunaratnam mask assembly would have adopted the removable snap-fit connection disclosed by Lovell. *See supra* § VII.D.1.a.vii.(a)

Snap-fit connections between CPAP components were common prior to the '196 Patent. Ex. 1206 ¶¶ 241–242. For example, as shown below, Lovell discloses a snap-fit connection in which two tabs (extending between slots 213, 215) formed in the headgear connector 212 engage the cylindrical inlet 208 with an interference fit and then are received into the depressed annular regions 280 on the inlet 208. Ex. 1205 at col. 9:59–64; Ex. 1206 ¶ 241.

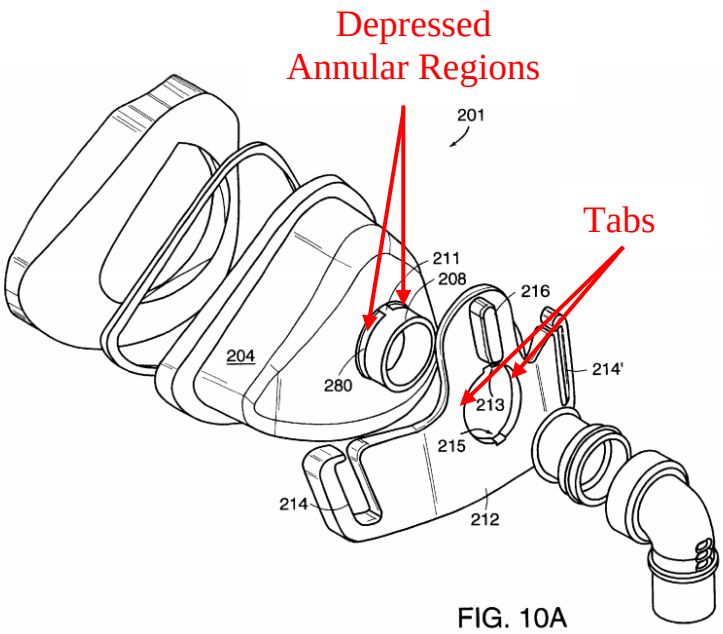


FIG. 10A

A person of skill in the art would have known that snap-fit connections are desirable because such connections typically only require simple linear movement of the parts towards one another. *Id.* ¶ 243. A person of skill also would have recognized that snap-fit arrangements ensure that the headgear connector and the cushion module are securely attached. *Id.* Further, a person of skill would have

recognized that snap assemblies like that of Lovell are reversible, so the cushion module could be removed or replaced for cleaning. *Id.*

j. Dependent Claim 10

Claim 10 depends from Claim 7 and includes "wherein the headgear connector comprises a plurality of tabs to attach the mask frame with a snap-fit."

As explained above, in modifying the Gunaratnam mask assembly in view of Lovell, a person of skill would have adopted the removable snap-fit connection disclosed by Lovell. *See supra* §§ VII.D.1.a.vii.(a), VII.D.1. i. Lovell discloses a headgear connector 212 including tabs (extending between slots 213, 215) that form a snap-fit with the depressed annular regions 280 on the frame 204. Ex. 1205 at col. 9:59–64.

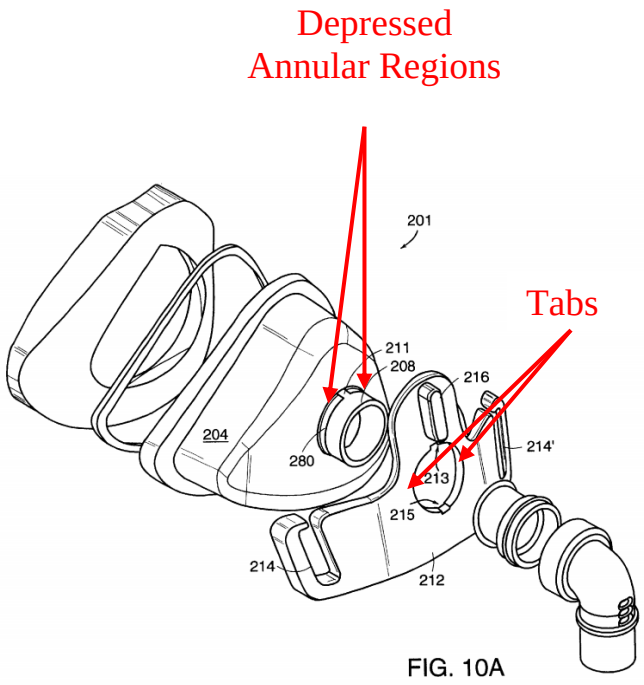


FIG. 10A

A person of skill in the art would have been motivated to provide a snap-fit connection to ensure secure attachment for at least the reasons provided above. *See supra* § VII.D.1.i. A person of skill would have known to use a plurality of tabs, particularly in annular snap-fit arrangements, to provide more predictable assembly and disassembly forces compared to annular snap-fit connections without tabs. Ex. 1206 ¶¶ 247–248. Further, by creating a snap-fit using a plurality of tabs, the snap characteristics could be more easily adjusted by changing individual tab geometry or mating surface geometry. *Id.* ¶ 249. Multiple snap-fit tabs also provide additional securement features if one tab fails. *Id.*

k. Dependent Claim 11

Claim 11 depends from Claim 1 and includes "wherein the central bore is located on a main body of the mask frame."

As explained above, the combination of Gunaratnam and Lovell teaches the claimed mask frame. *See supra* § VII.D.1.a.ii. As modified, the separated frame (shaded red) would include a central bore on the main body of the mask frame, as was common in the prior art. Ex. 1206 ¶¶ 253–255.

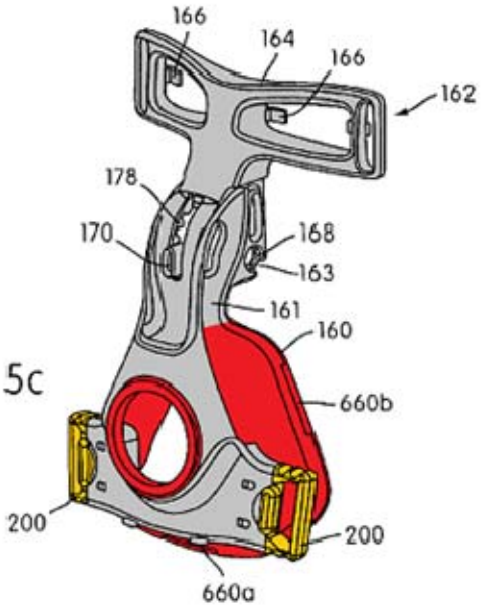


FIG. 5c

l. Dependent Claim 12

Claim 12 depends from Claim 1 and includes "comprising a vent assembly for gas washout."

The embodiment shown in Figure 5c of Gunaratnam does not include a vent assembly, but other embodiments, such as Figure 15 (below), disclose an air vent assembly 940 for gas washout. Ex. 1203 at col. 6:25–30. Such vent assemblies were frequently included in mask assemblies to release gases exhaled by the user. Ex. 1206 ¶ 44.

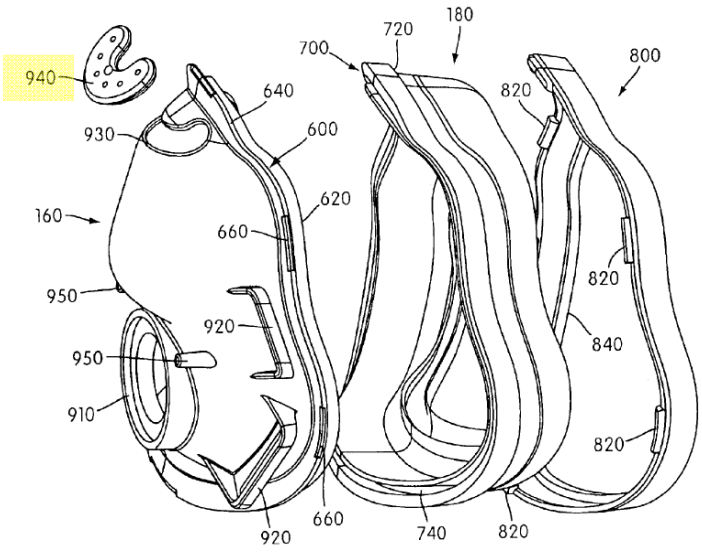


FIG. 15

m. Dependent Claim 13

Claim 13 depends from Claim 1 and includes "wherein the forehead support is T-shaped."

The forehead support 162 of Gunaratnam is T-shaped, as shown below in Figure 5c. Ex. 1203 at col. 4:46–48.

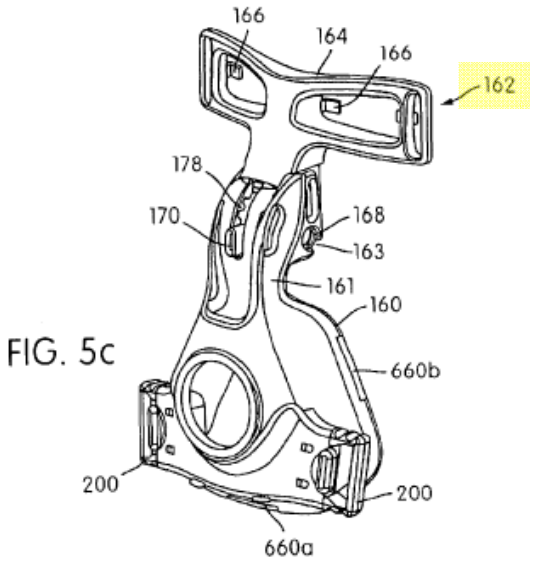


FIG. 5c

n. Dependent Claim 14

Claim 14 depends from Claim 1 and includes "wherein the sealing cushion cannot be easily detached from the mask frame."

Gunaratnam discloses that it was known to glue the mask frame to the cushion. Ex. 1203 at col. 1:54. Lovell also discloses that the cushion 2 is affixed to the frame 4 by bonding. Ex. 1205 at col. 4:34–36; *see also id.* at cols. 2:62–64, 4:14–16.

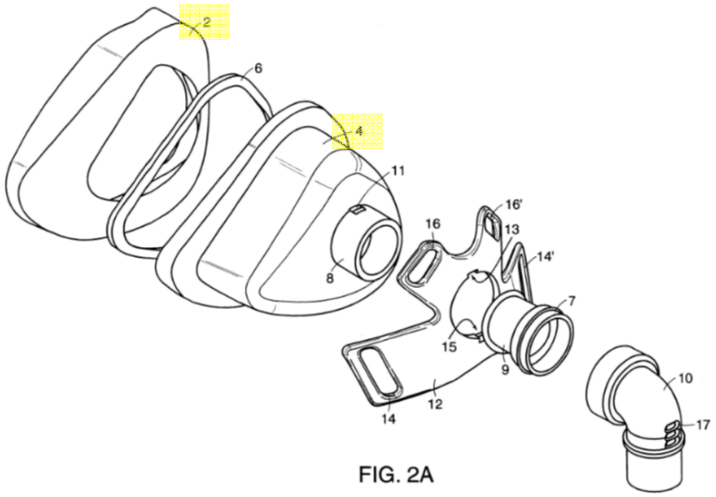


FIG. 2A

Although Gunarantnam teaches a removable cushion, a person of skill in the art at the time of the invention would have been motivated to permanently attach the cushion to the frame in order to prevent leakage at the interface between the cushion and the frame. *See* Ex. 1205 at col. 4:55–58; Ex. 1206 ¶ 260. Because the entire breathing chamber, including the modified frame and the cushion, would be

removable from the headgear connector, a person of skill would have understood the Gunaratnam clip 800 was no longer necessary to separately remove the cushion and would have not included that feature. *Id.* ¶ 261.

o. Dependent Claim 15

Claim 15 depends from Claim 14 and includes "wherein the sealing cushion and the mask frame are permanently attached."

As discussed above, Gunaratnam and Lovell disclose a cushion permanently attached to the mask frame. *See supra* § VII.D.1.n.; Ex. 1206 ¶ 263.

p. Dependent Claim 16

Claim 16 depends from Claim 1 and includes "wherein said headgear connector is constructed of a similar material as the frame."

Gunaratnam discloses a polycarbonate frame 160. Ex. 1203 at col. 4:22–26. When dividing the Gunaratnam frame into a separate headgear connector and mask frame (*see supra* § VII.D.1.a.ii.), both components would still be constructed from the same polycarbonate material. Ex. 1206 ¶ 265.

q. Dependent Claim 17

Claim 17 depends from Claim 16 and includes "wherein said headgear connector and said mask frame are constructed of a substantially rigid, non-malleable plastic material."

As explained above, when dividing the Gunaratnam frame into a separate headgear connector and mask frame, both components would still be constructed from the same polycarbonate material. *See supra* § VII.D.1.p. Polycarbonate is a substantially rigid, non-malleable plastic material. Ex. 1206 ¶ 268.

r. Dependent Claim 18

Claim 18 depends from Claim 17 and includes "wherein said headgear connector and said mask frame are constructed of polycarbonate."

As explained above, when dividing the Gunaratnam frame into a separate headgear connector and mask frame, both components would still be constructed from the same polycarbonate material. *See supra* § VII.D.1.p.; Ex. 1206 ¶ 270.

s. Independent Claim 19

Independent Claim 19 includes the following limitations:

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

Gunaratnam discloses nasal and full-face masks "for the delivery of breathable gases to a patient for the treatment of sleep disordered breathing (SDB)." Ex. 1203 at col. 1:21–25.

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

Gunaratnam provides an example of headgear from ResMed's Mirage® Mask in Figure 1(below).

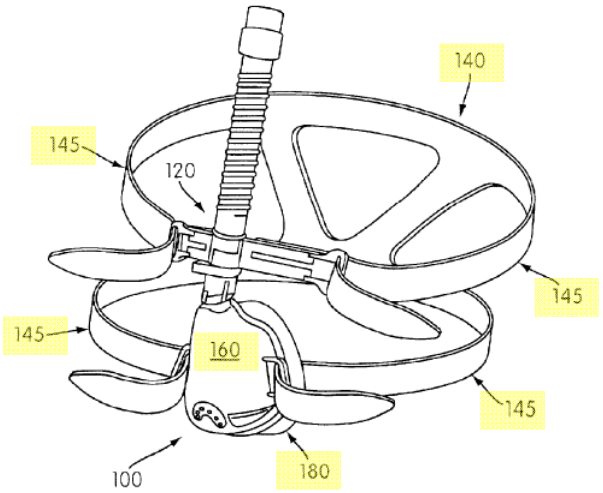


FIG. 1
PRIOR ART

The headgear 140 includes a pair of upper side straps 145, a pair of lower side straps 145, and a rear portion. Ex. 1203 at col. 1:40–45. A person of skill in the art would have understood that this type of headgear with upper and lower straps would have been used to connect to the upper and lower headgear strap connection points of the Gunaratnam masks. Ex. 1206 ¶¶ 272–273.

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

As modified, the separated headgear connector of Gunaratnam (shaded gray) would still include lower headgear clip anchors that receive lower headgear clips (shaded yellow) adapted to receive a pair of lower side straps. Ex. 1203 at col. 4:32–34.

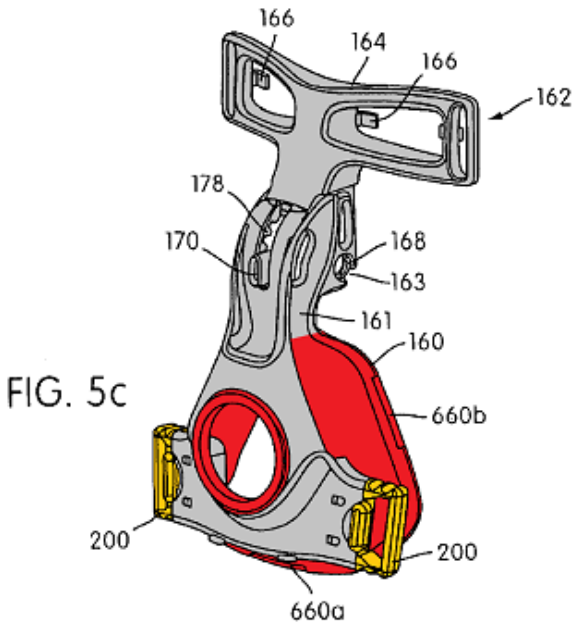


FIG. 5c

iv. "a mask according to claim 1."

As discussed above with respect to Claim 1, the combination of Gunaratnam, Lovell, and Amarasinghe teaches the mask assembly of Claim 1. *See supra* § VII.D.1.

t. Dependent Claim 20

Claim 20 depends from Claim 19 and includes "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."

Gunaratnam discloses headgear 140 that includes a pair of upper side straps 145 arranged to extend above the patient's ears and a pair of lower side straps 145 arranged to extend below the ears. Ex. 1203 at col. 1:40–45.

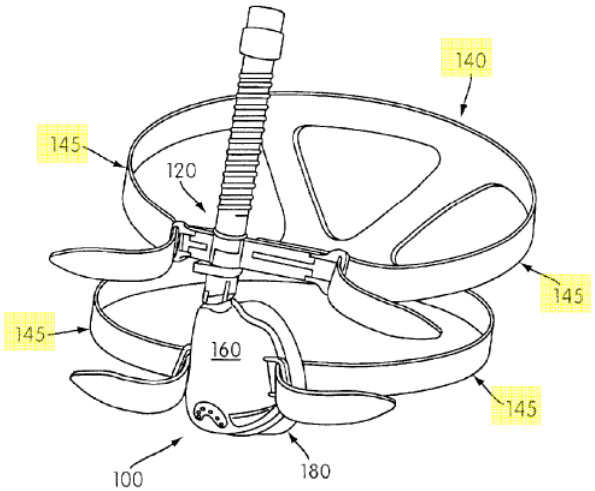


FIG. 1
PRIOR ART

u. Dependent Claim 21

Claim 21 depends from Claim 20 and includes "wherein the rear portion of the headgear is adapted to cup the occiput of the patient's head."

Gunaratnam discloses headgear 140 that includes "a rear portion which engages the region near the occiput of the patient." Ex. 1203 at col. 1:40–45.

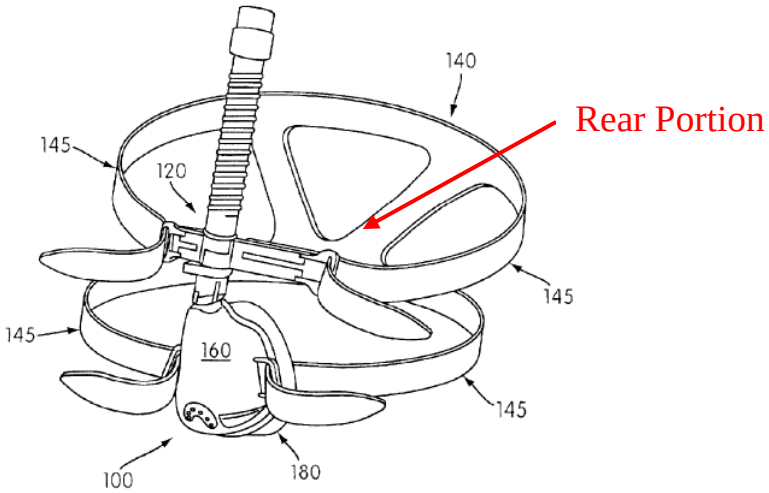


FIG. 1
PRIOR ART

v. Dependent Claim 22

Claim 22 depends from Claim 1 and includes "wherein said forehead support is adjustable."

Gunaratnam discloses that its forehead support 162 is adjustable. Ex. 1203 at col. 4:46–48.

VIII. SECONDARY CONSIDERATIONS

Although secondary considerations should be taken into account, they do not control the obviousness conclusion. *Newell Cos., Inc. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988). Where a strong *prima facie* obviousness showing exists, as here, the Federal Circuit has repeatedly held that even relevant secondary considerations supported by substantial evidence may not dislodge the primary conclusion of obviousness. *See, e.g.*, *Leapfrog Enters. Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007). Further, a showing of secondary considerations requires a nexus between the evidence of the secondary consideration and a novel feature of the claims of the ’196 Patent. *See, e.g.*, *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010).

Patent Owner has not presented any evidence of secondary considerations in any of the instituted reviews of the ’196 Patent. Further, Petitioner does not believe that any potential evidence of secondary considerations could outweigh the strong *prima facie* case of obviousness. In the event that the Patent Owner puts forth any allegations regarding secondary considerations, Petitioner will address those allegations in due course.

Respectfully submitted,
KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: July 14, 2017

By: */ Benjamin J. Everton /*

Brenton R. Babcock (Reg. No. 39,592)
Benjamin J. Everton (Reg. No. 60,659)
Email: BoxFPH533-3@Knobbe.com
Customer No. 20,995
Attorneys for Petitioner
Fisher & Paykel Healthcare Limited
(949) 760-0404

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

Pursuant to 37 C.F.R. § 42.24(d), Counsel for Petitioner Fisher & Paykel Healthcare hereby certify that this petition requesting *inter partes* review complies with the type-volume limitation of 37 C.F.R. § 42.24(a)(1)(i). According to Microsoft Office Word 2010's word count, this petition contains approximately 13,829 words, including any statement of material facts to be admitted or denied in support of the petition, and excluding the table of contents, table of authorities, mandatory notices under § 42.8, certificate of service or word count, or appendix of exhibits or claim listing.

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: July 14, 2017

By: */ Benjamin J. Everton /*

Brenton R. Babcock (Reg. No. 39,592)
Benjamin J. Everton (Reg. No. 60,659)
Email: BoxFPH533-3@Knobbe.com
Customer No. 20,995
Attorneys for Petitioner
Fisher & Paykel Healthcare Limited
(949) 760-0404

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT 8,960,196** and **Fisher & Paykel Healthcare Exhibits 1201–1230** are being served on July 14, 2017, via Federal Express overnight mail on counsel of record for U.S. Patent No. 8,960,196, as addressed below:

Correspondence Address of Record for U.S. Patent No. 8,960,196 at the U.S. Patent and Trademark Office:

Nixon & Vanderhye, PC
901 North Glebe Road, 11th Floor
Arlington, VA 22203

Dated: July 14, 2017

/ Benjamin J. Everton /
Brenton R. Babcock (Reg. No. 39,592)
Benjamin J. Everton (Reg. No. 60,659)
Customer No. 20,995
Attorneys for Petitioner
Fisher & Paykel Healthcare Limited