Filed: January 9, 2017

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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. IPR2017-00634
U.S. Patent No. 8,944,061

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,944,061

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OTHER AUTHORITIES

EXHIBIT LIST

Exhibit No.	Description
1101	U.S. Patent No. 8,944,061
1102	U.S. Patent No. 6,631,718 ("Lovell")
1103	U.S. Patent No. 6,796,308 ("Gunaratnam")
1104	U.S. Publication No. 2003/0029454 ("Gelinas")
1105	Declaration of Jason Eaton, P.E.
1106	Curriculum Vitae of Jason Eaton, P.E.
1107	Excerpts of the File History of U.S. Patent No. 8,944,061
1108	PCT Publication No. WO 2004/041342 (Berthon-Jones)
1109	U.S. Patent No. 5,662,101 ("Ogden")
1110	Malloy, Robert A., Plastic Part Design for Injection Molding: An Introduction, pp. 336-345 (Hanser Gardner Publications, Inc. 1994) ("Malloy")
1111	U.S. Patent No. 6,412,488 ("Barnett")
1112	U.S. Publication No. 2004/0118406 ("Lithgow")
1113	U.S. Publication No. 2002/0020416 ("Namey")
1114	U.S. Publication No. 2005/0155604 ("Ging")
1115	Complaint for Patent Infringement, *ResMed Inc. v. Fisher & Paykel Healthcare Corp. Ltd., et al.*, Case No. 3:16-cv-02072-JAH-MDD (S.D. Cal.)

Exhibit No.	Description
1116	Answer of ResMed Corp. to Complaint for Patent Infringement and Counterclaims, *Fisher &Paykel Healthcare Ltd. v. ResMed Corp.*, Case No. 3:16-cv-02068-GPC-WVG (S.D. Cal.)

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 17, 18, 20–23, 26–30, 32, 33, 35–38, 41–46, 48–50, and 81–91 ("Challenged Claims") of U.S. Patent No. 8,944,061 ("the '061 Patent") (Ex. 1101), which is purportedly owned by ResMed Limited ("Patent Owner" or "ResMed").

I. INTRODUCTION

For decades, face masks have been used to facilitate breathing by delivering gas to the wearer or protecting the wearer from inhaling harmful particles or gases. Such face masks can be used to deliver pressurized gas to keep patient airways open and treat sleeping disorders, such as sleep apnea, in a medical treatment called continuous positive airway pressure ("CPAP"). CPAP masks cover the patient's nose and/or mouth, and are usually supported on the patient's head by headgear.

The Challenged Claims of the ’061 Patent include a CPAP mask having a first frame 414 associated with a cushion 416, and a second frame 412 that attaches to the first frame 414 and headgear, among other features. The second frame 412 includes a first, annular opening 448 adapted to engage an elbow (not shown), and a second opening (unlabeled) between the first annular opening 448 and an upper support member 444.

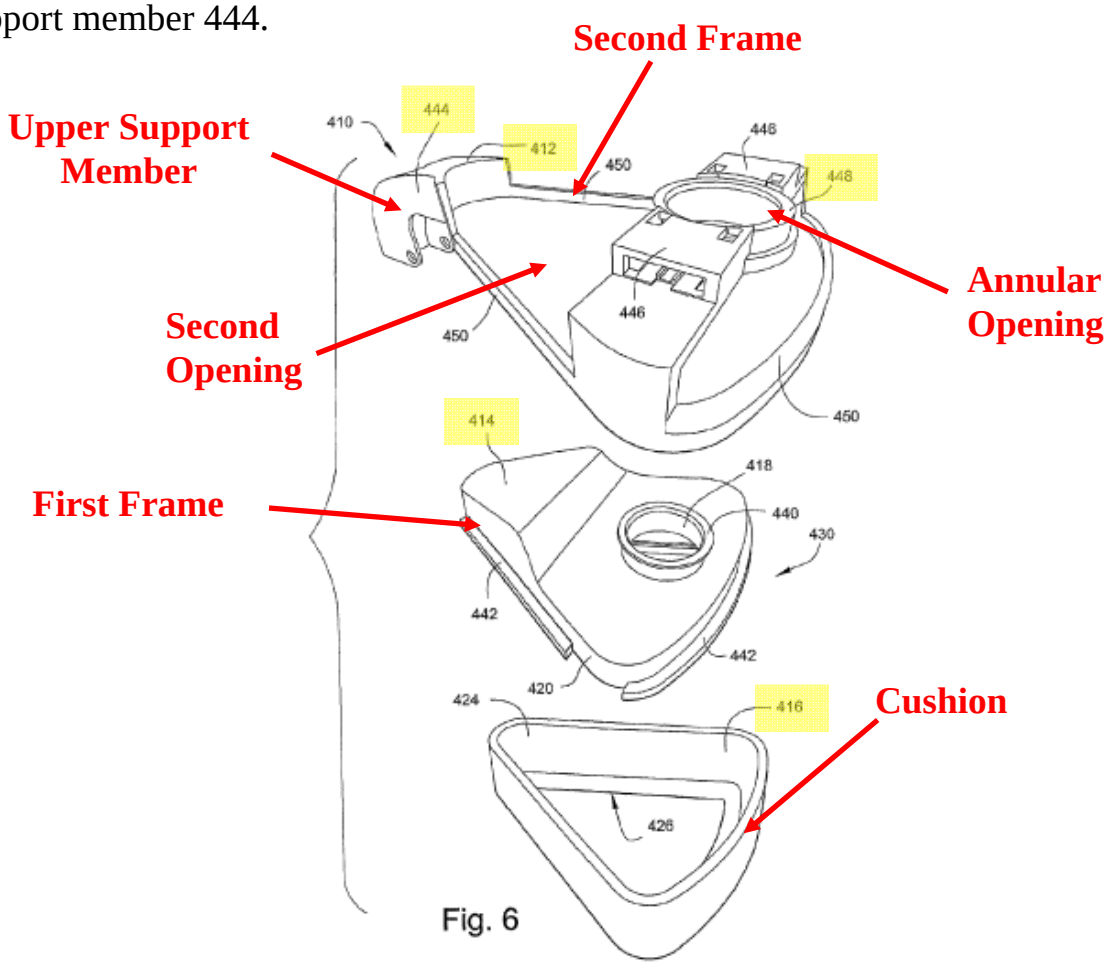
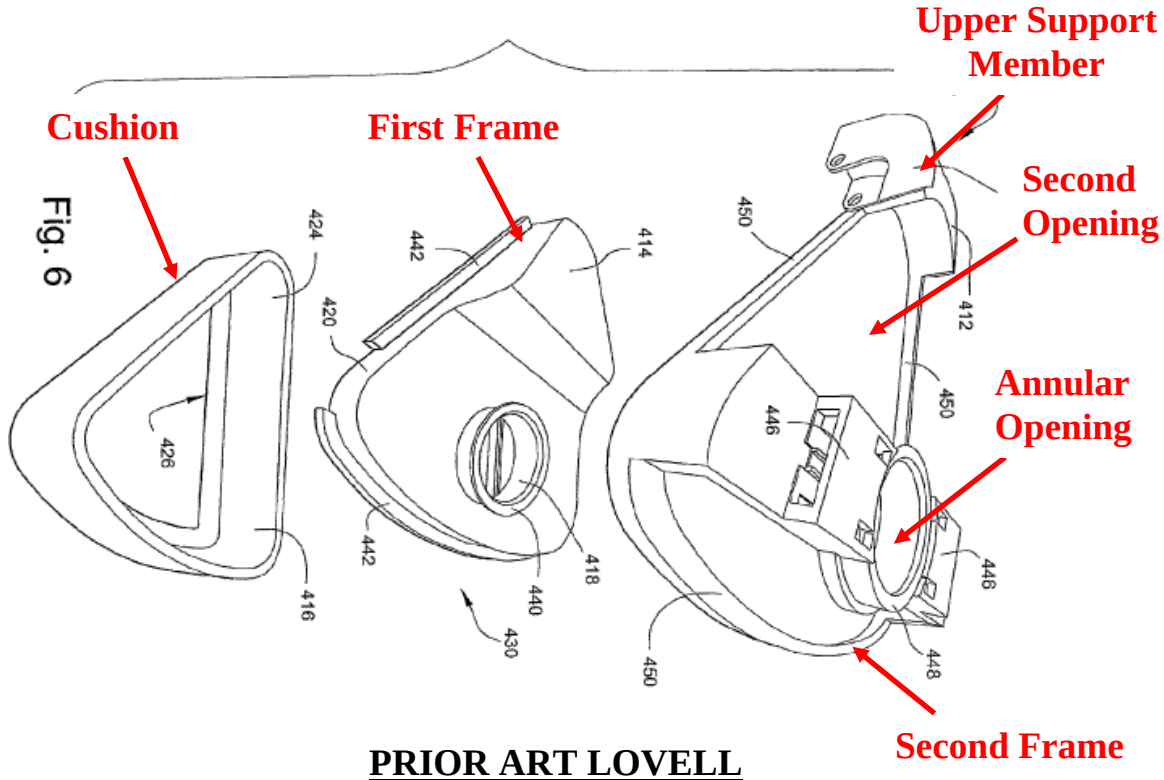


Fig. 6

However, as shown on the next page, many of the claimed features were well-known and included in the prior art (*e.g.*, Lovell) before the earliest priority date of the ’061 Patent. Ex. 1105 ¶ 56.

'061 PATENT (ROTATED)



PRIOR ART LOVELL

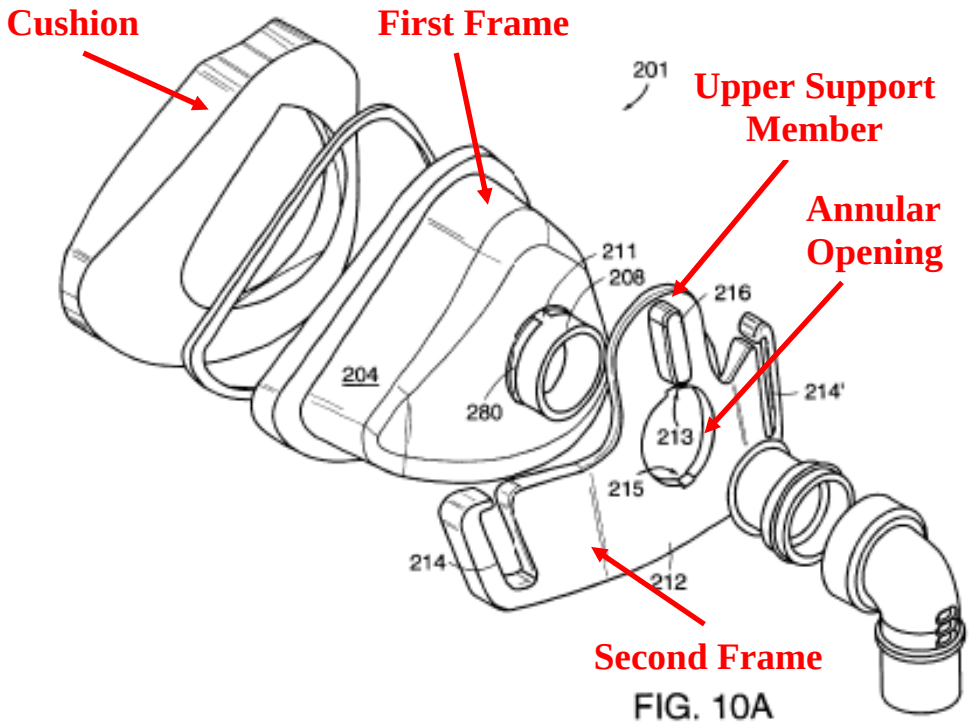


FIG. 10A

Lovell discloses a second frame with open spaces that allow access to the first frame, but it does not disclose a second opening positioned between the annular opening and the upper support member. However, such arrangements were well-known and taught in the prior art. *See infra* § VII(B)(4)(f); Ex. 1105 ¶¶ 92–98. For example, Gelinas discloses a two-frame arrangement in which the second frame includes a first, annular opening and a second opening between the first opening and an upper support member, as shown below in Figure 7. *See* Ex. 1104 ¶¶ 26, 32.

PRIOR ART GELINAS

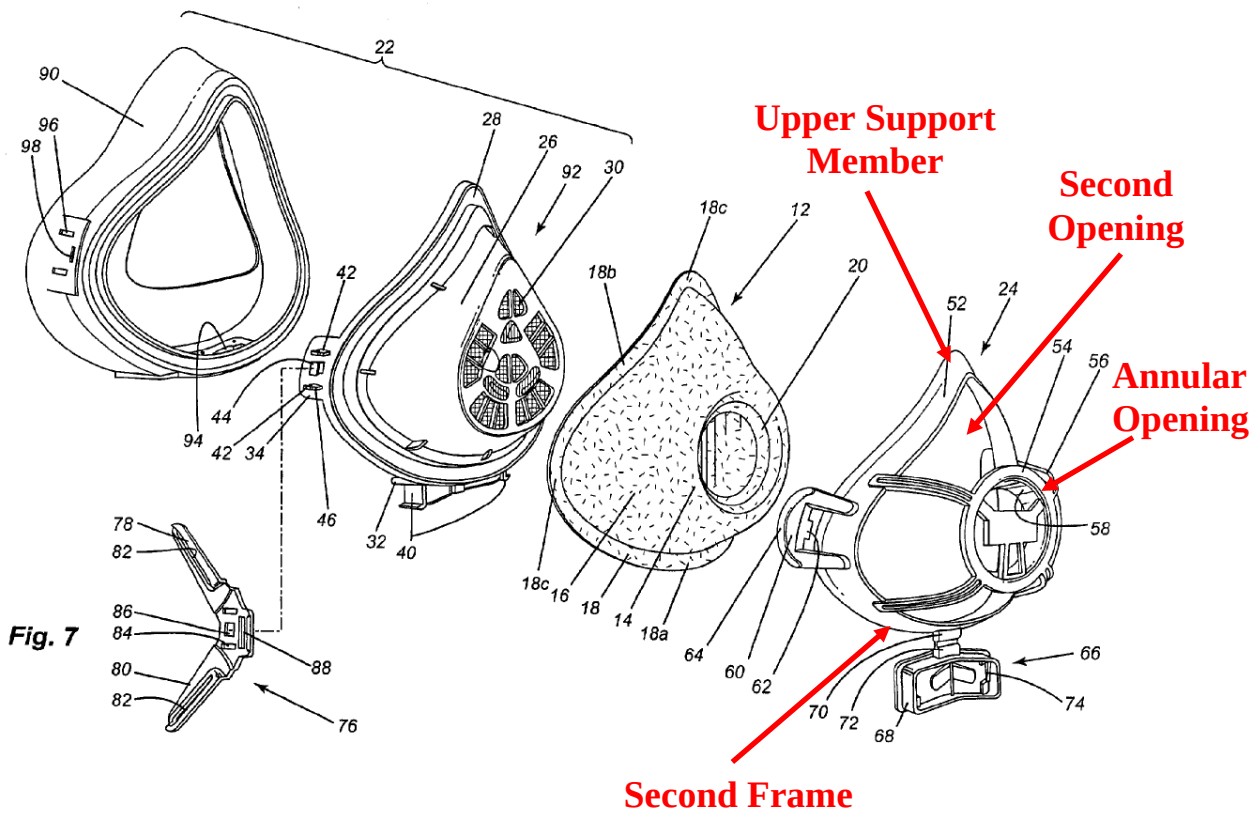


Fig. 7

As explained in more detail below, a person of skill in the art would have been motivated to modify the second frame of Lovell to include a second opening, as taught by Gelinas. Ex. 1105 ¶¶ 92–98; *see infra* §§ VII(B)(4)(f), (4)(h), (4)(i).

Any additional differences between the Challenged Claims and Lovell were minor, well-known features, and their combination in the claims provided no unexpected results or benefits. *See infra* §§ VII(B)(4)(a)–(k); Ex. 1105 ¶¶ 41–127. The Challenged Claims consist of long lists of simple and well-known mechanical mask features, and a person of skill in the art would have had a reasonable expectation of success in combining the features of Lovell with those of the other prior art respiratory masks to arrive at the claimed assemblies.

II. THIS PETITION IS NOT REDUNDANT UNDER 35 U.S.C. § 325(d)

This petition is not redundant with Petitioner's other co-pending IPR petitions challenging the '061 Patent. These petitions include different grounds challenging different claims and involving different prior art.

For example, the present petition requests review of Claims 17, 18, 20–23, 26–30, 32, 33, 35–38, 41–46, 48–50, and 81–91 over Lovell in view of other patent prior art. Petitioner has concurrently filed a second IPR petition challenging Claims 51–80 in view of the same prior art. Although these two petitions rely on the same prior art, these petitions are not redundant because there are no overlapping claims.

Petitioner has concurrently filed a third IPR petition challenging Claims 17, 18, 20–23, 26–30, 32, 33, 35–38, 41–46, and 48–91 of the ’061 Patent in view of different prior art, specifically WO 2004/041342 (Berthon-Jones). As mentioned above, the claims of the ’061 Patent include numerous extensive lists of well-known features. Lovell and Berthon-Jones disclose different subsets of these common features. For example, Lovell discloses a second frame with an annular opening that interlocks with the first frame at the inlet opening of the first frame. Berthon-Jones discloses a full-face mask assembly and a second frame with an opening at least partially defined by two elongate frame members. Although Lovell and Berthon-Jones both describe CPAP masks, they have different structural designs that result in different obviousness analyses.

In addition, the prior art combinations of the first two petitions are different from the combinations of the third petition, as are the reasons why a person of skill would combine those references. Accordingly, while Petitioner’s obviousness analysis in these petitions is compelling, those analyses differ in the references, the nature of the combinations, and the reasons for the combinations. Likewise, ResMed’s defense of its patent will likely focus on different structural features, which Petitioner cannot fully anticipate.

Also, the present Petition and the second petition rely on prior art reference U.S. Publication No. 2003/0029454 (Gelinas) which relates to a respirator

breathing mask and not specifically to a CPAP mask. ResMed may argue that Gelinas is not analogous art and therefore cannot be considered as part of the obviousness analyses. Although such an argument is without merit, as discussed below, the third petition does not rely on Gelinas and provides alternative obviousness grounds in the event the Board determines that Gelinas is somehow not analogous art. Thus, the petitions rely on different prior art references for one of the main features of the Challenged Claims and provide alternative grounds subject to different arguments by ResMed. *See ABS Global Inc. v. XY, LLC*, IPR2014-01161, Paper No. 9 (Decision on Institution of Inter Partes Review) at 19 (PTAB January 13, 2015).

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))

Fisher & Paykel Healthcare Limited is the real party-in-interest. Petitioner Fisher & Paykel 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)

On August 16, 2016, ResMed filed a complaint in the Southern District of California alleging infringement of the ’061 Patent. Ex. 1115. ResMed voluntarily dismissed this complaint on August 18, 2016.

ResMed and Fisher & Paykel are currently involved in pending litigation in the Southern District of California involving the '061 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 '061 Patent in its counterclaims on September 7, 2016. Ex. 1116.

Fisher & Paykel has concurrently filed two other petitions for *inter partes* review of the '061 Patent that would affect, or be affected by, a decision in this proceeding.

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 Street, 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 Street, 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: BoxFPH538-2@knobbe.com.

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

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

Petitioner hereby certifies that the '061 Patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting *inter partes* review challenging the patent claims on the grounds identified herein.

B. Claims and Statutory Grounds (37 C.F.R. § 42.104(b)(1) & (b)(2))

1. Prior Art

Petitioner respectfully requests *inter partes* review of the Challenged Claims (Claims 17, 18, 20–23, 26–30, 32, 33, 35–38, 41–46, 48–50, and 81–91) of the '061 Patent, filed on March 15, 2013, which is a continuation of U.S. Application No. 11/989,137, filed as PCT Application No. PCT/AU2006/000035 on January 12, 2006, which claims priority to Provisional Application Nos. 60/726,265 and 60/734,746 filed on October 14, 2005 and November 9, 2005, respectively. Ex. 1101 at 1. The earliest possible priority date of the '061 Patent is **October 14, 2005**.

The Challenged Claims would have been obvious in view of the following prior art references:

- U.S. Patent No. 6,631,718 to Lovell ("Lovell") (Ex. 1102) issued on October 14, 2003. Ex. 1102 at 1. Because Lovell issued more than one year before the earliest possible priority date of the '061 Patent, it is prior art under 35 U.S.C. § 102(b).[1]
- U.S. Patent No. 6,796,308 to Gunaratnam *et al*. ("Gunaratnam") (Ex. 1103) issued on September 28, 2004. Ex. 1103 at 1. Because Gunaratnam issued more than one year before the earliest possible priority date of the '061 Patent, it is prior art under 35 U.S.C. § 102(b).
- U.S. Publication No. 2003/0029454 to Gelinas *et al*. ("Gelinas") (Ex. 1104) published on February 13, 2003. Ex. 1104 at 1. Because Gelinas published more than one year before the earliest filing date of the '061 Patent, it is prior art under 35 U.S.C. § 102(b).

2. Ground

The Challenged Claims (Claims 17, 18, 20–23, 26–30, 32, 33, 35–38, 41–46, 48–50, and 81–91) would have obvious over Lovell in view of Gunaratnam and Gelinas under 35 U.S.C. § 103.

[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 '061 Patent.

C. Claim Construction

Solely for the purpose of this review, Petitioner construes the Challenged Claims of the '061 Patent such that the claims are given their broadest reasonable interpretation in light of the specification of the '061 Patent.[2] 37 C.F.R. § 42.100(b); *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278–79 (Fed. Cir. 2015), *aff'd*, 136 S. Ct. 2131 (2016). In that light, Petitioner provides the following analyses for the construction of two limitations of the Challenged Claims, which is consistent with the plain and ordinary meaning of the claim terms in light of the '061 Patent's specification.

[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 and/or claim interpretation may apply.

1. "annular connection adapted to engage an elbow" and "inlet elbow engages the second frame"

Independent Claim 17 includes a second frame comprising an "annular connection adapted to engage an elbow of an inlet conduit." Dependent Claims 50 and 91 include the inlet elbow or elbow "engages the second frame."

The term "engage" in these phrases should be construed in a way that would not require direct contact or coupling between the second frame and the elbow. Ex. 1105 ¶¶ 32–36, 81–85. In the context of the relevant embodiments shown in Figures 3, 4, and 6–8, the '061 Patent uses the term "engage" to describe arrangements in which the annular connection on the second frame would not directly contact the elbow. *Id.* ¶¶ 32–36, 83–85.

With respect to Figures 3–4, the '061 Patent describes the second frame 212 as including "an annular elbow connection seal 248 adapted to engage an inlet conduit, *e.g.*, elbow." Ex. 1101 at col. 7:11–17. The specification describes the second embodiment shown in Figures 6–8 in the same way. *Id.* at col. 8:27–34. Yet, as shown below, the figures for these embodiments show that, when assembled, the annular connection 248/448 of the second frame 212/412 (unshaded) is partially covered by the annular wall 240/440 of the first frame 214/414 (shaded in blue), such that the annular wall 240/440 is positioned between the annular connection 248/448 and any elbow that would be coupled thereto.

Ex. 1105 ¶¶ 33–35, 83–85.

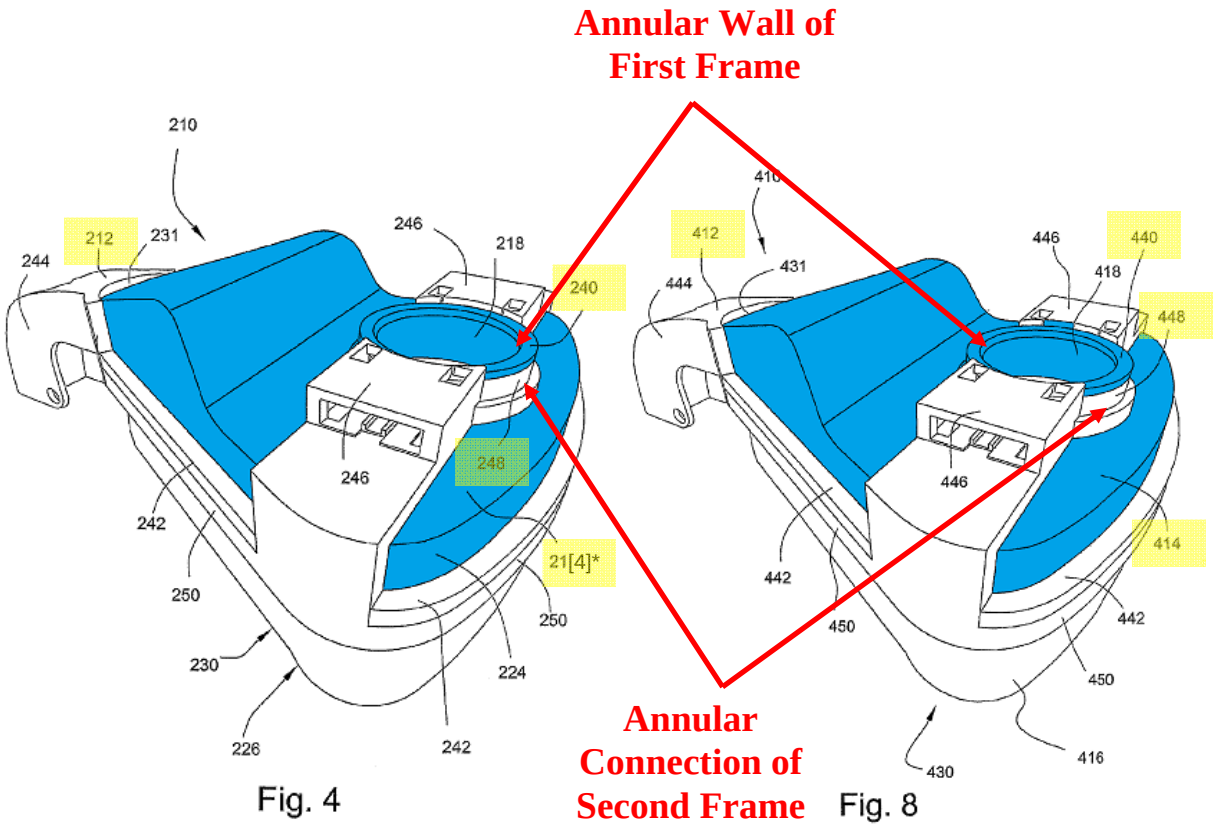


Fig. 4 Fig. 8

*Apparently mislabeled as "218"

Although the '061 Patent does not show an elbow in any of its figures, a person of skill in the art would have understood that such an elbow would contact the annular wall 240/440 of the first frame 214/414 and not the annular connection 248/448 of the second frame 212/412. *Id.* ¶¶ 35–36, 83–85.

The '061 Patent provides no teachings of how the annular connection 248/448 of the second frame 212/412 could directly contact or couple with the elbow when the mask is assembled. *Id.* ¶ 35. Nor does it describe any second frame with an annular connection that directly contacts the elbow. *Id.*. Thus, when the specification uses the term "engage," in this context, it does not require

that the second frame and the elbow directly contact one another. *Id.* ¶¶ 35–36.

Based on the claim language and the teachings of the specification, a proper construction of the term "engage," in the context of Claims 17, 50, and 91, would include arrangements that support in an operable position relative to, either directly or in cooperation with other components. *Id.* ¶¶ 32–36.

2. "annular opening and the elbow are sealingly connected"

Dependent Claims 46 and 48 recite "the annular opening and the elbow are sealingly connected." The term "sealingly connected" with respect to these claims should not be construed to require direct coupling or sealing between the elbow and the annular opening of the second frame. Ex. 1105 ¶¶ 37–39.

As described above with respect to the term "engage," the relevant embodiments of the '061 Patent show an annular opening 248/448 on the second frame 212/412 that would not directly contact or seal with the elbow. *See supra* § IV(C)(1). Although the specification describes that the second frame 212/412 includes an annular opening 248/448 adapted to engage an elbow (Ex. 1101 at cols. 7:11–17, 8:27–34), the specification also teaches that the annular opening 248/448 of the second frame 212/412 interlocks with the annular wall 240/440 of the first frame 214/414. *Id.* at col. 7:23–25, 8:38–46. As shown in the corresponding figures below, the annular wall 240/440 on the first frame 214/414 (shaded in blue) extends through the annular opening 248/448 of the second frame 212/412

(unshaded), and thus would be positioned between the annular opening 248/448 and any elbow that would be coupled thereto. Ex. 1105 ¶¶ 37–39.

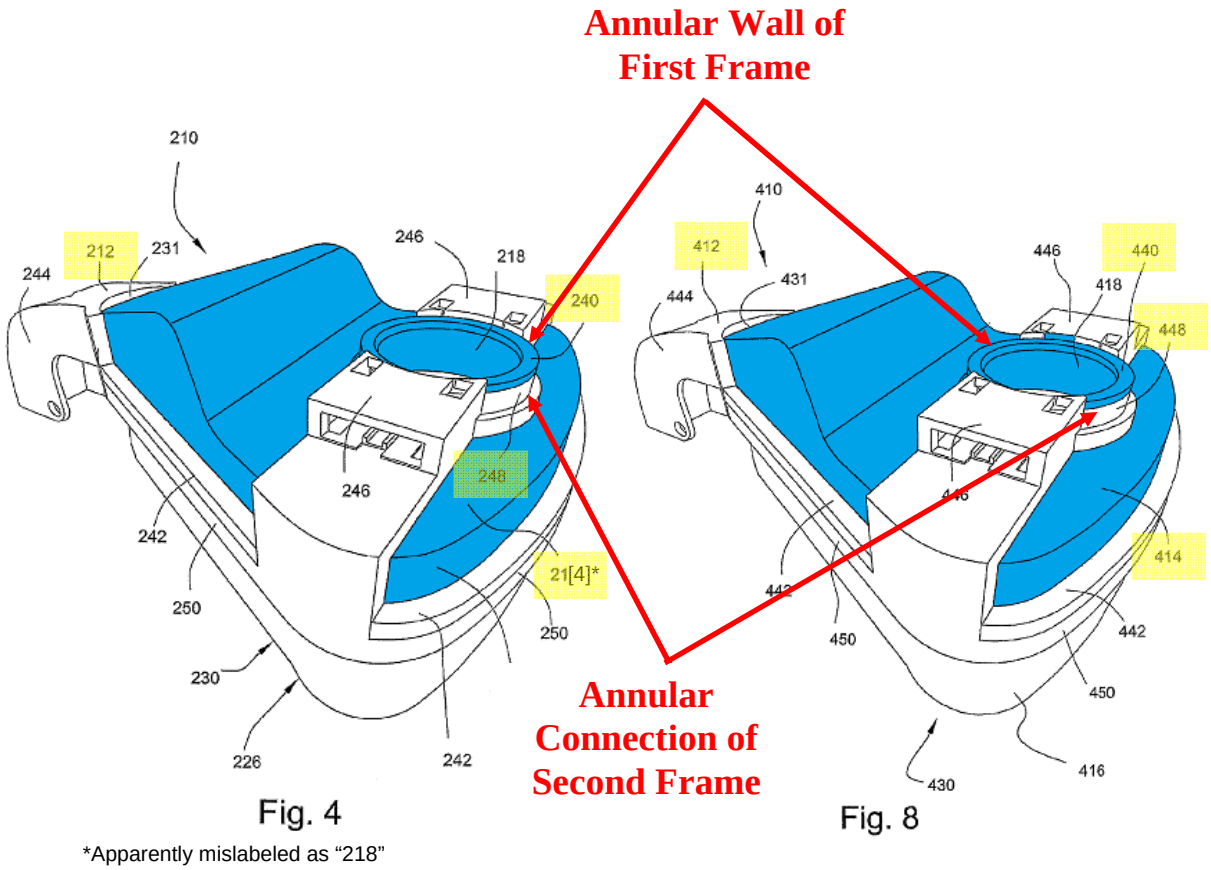


Fig. 4

*Apparently mislabeled as "218"

Fig. 8

Based on the figures and description, a person of skill would have understood that an elbow would contact and form a seal with the annular wall 240/440 of the first frame 214/414 when the mask is assembled, not with the second frame 212/412. *Id.* ¶¶ 37–39. Although element 248/448 is described as an "annular elbow connection seal," the figures show there would be no direct connecting or sealing between the annular opening 248/448 of the second frame 212/412 and the elbow. *Id.* Thus, a person of skill in the art would have understood that the term "sealingly connected," in this context, does not require that the elbow directly connect or seal with the annular opening 248/448 of the

second frame 212/412. *Id*.

Based on the claim language and description in the specification, a proper construction of "sealingly connected," in the context of Claims 46 and 48, would include arrangements that are directly or indirectly coupled to allow a seal between the interior of the elbow and the breathing chamber. *Id.*

V. THE '061 PATENT

A. Example Embodiments

The '061 Patent discloses CPAP full-face mask assemblies for treating sleep disordered breathing. Ex. 1101 at Abstract.

The Challenged Claims of the '061 Patent are relevant to only two of the disclosed mask embodiments. Ex. 1105 ¶ 28. In particular, the Challenged Claims are directed to the mask embodiments that include a first frame and cushion constrained by a second frame (or skeleton frame), where the second frame receives the straps of a headgear assembly. Ex. 1101 at 2:34–42. The purpose of the second frame is to "maintain the cushion to the frame." *Id.*

In the first relevant embodiment, the '061 Patent discloses a mask assembly 210 with a cushion/frame sub-assembly 230 that engages a second frame 212 (or skeleton frame), as shown in Figure 3 below. *Id.* at col. 6:56–58.

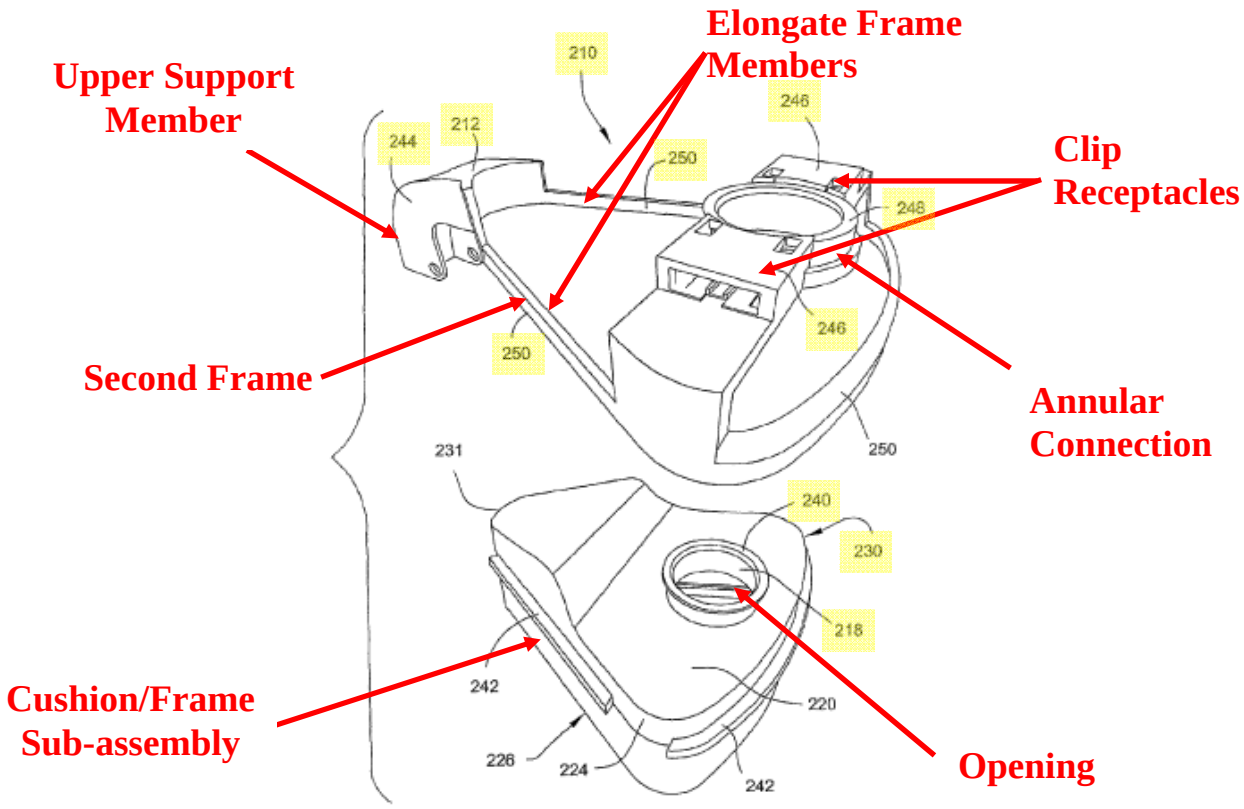


Fig. 3

The cushion/frame sub-assembly 230 has an opening 218 for communicating with an elbow (not shown), and an annular wall 240 surrounding the opening 218. *Id.* at col. 6:53–68. The second frame 212 includes an annular elbow connection 248 adapted to engage the elbow. *Id.* at col. 7:11–16. The second frame 212 also includes lower headgear clip receptacles 246 and an upper support member 244 that supports a forehead support (not shown). *Id.* The upper support member 244 and clip receptacles 246 are interconnected by elongate frame members 250. *Id.* at

col. 7:16–18.

As shown in Figure 4 below, when the mask is assembled, the second frame 212 (shaded in red) interlocks or frictionally engages the cushion/frame assembly 230. *Id.* at col. 7:24–27.

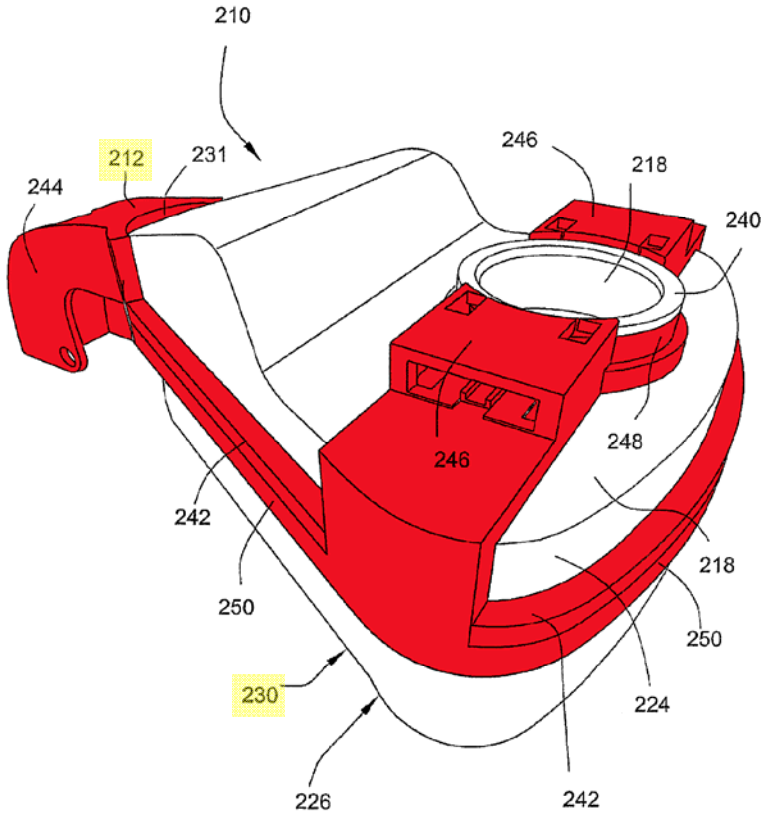
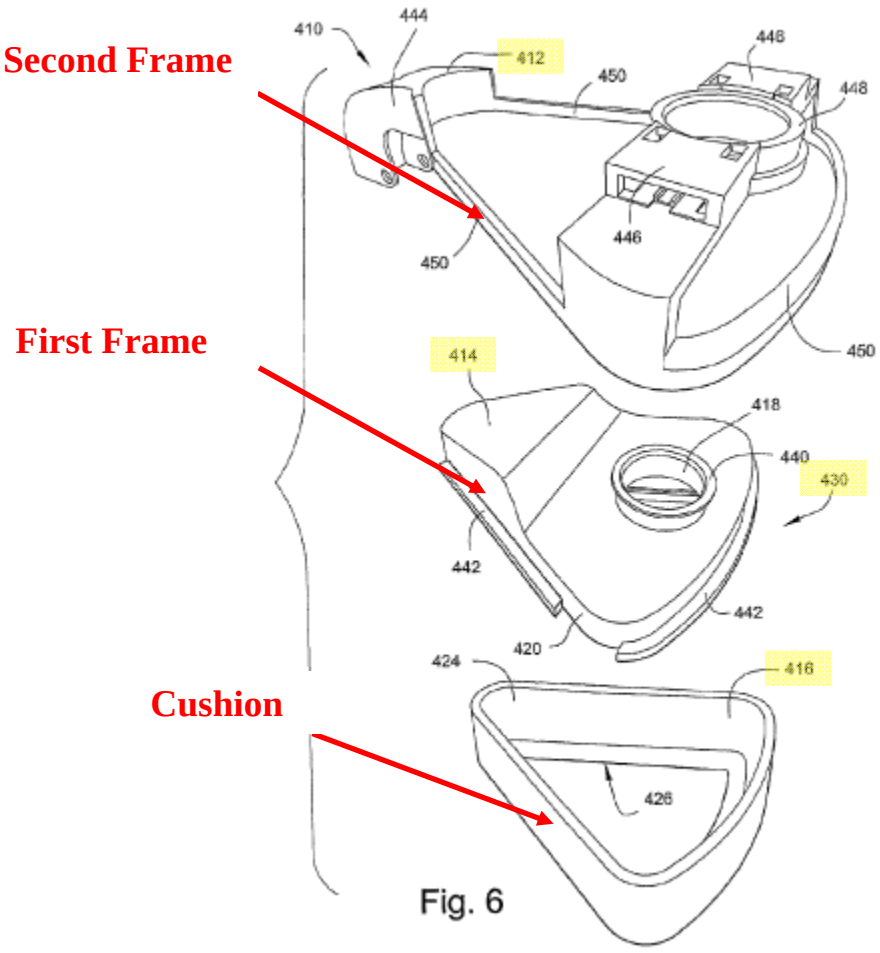


Fig. 4

The second embodiment, shown in Figures 6–8, is very similar to the first embodiment, except that the first frame 414 and the cushion 416 are separately formed and then interlocked to provide a cushion/frame sub-assembly 430. *Id.* at col. 8:1–3; Ex. 1105 ¶¶ 28–30. As shown in Figure 6 below, the second frame 412 engages the cushion/frame sub-assembly 430 in the same way as the first embodiment. Ex. 1101 at col. 8:38–48.



B. Summary of the Prosecution History of the ’061 Patent

The ’061 Patent issued from U.S. Patent Application No. 13/834,189, filed on March 15, 2013. Ex. 1101 at 1.

On February 26, 2014, the Examiner rejected all of the pending claims based on ResMed’s own U.S. Publication No. 2002/0108613, which later issued as the Gunaratnam patent (Ex. 1103). Ex. 1107 at 219–226. In the Office Action, the Examiner pointed out that Gunaratnam “discloses a full-face mask assembly comprising a frame 800, a cushion 180 provided to the frame, the cushion adapted to seal around the patient’s nose and mouth, and a skeleton frame 160 to maintain the cushion to the frame, the skeleton frame including lower headgear clip receptacles 920 adapted to be engaged with clips provided on the straps of a headgear assembly, and an annular elbow connection seal 910 adapted to engage an inlet conduit (fig. 8; page 3, paragraph 0050).” *Id.* at 222.

In response to the Examiner’s rejections, the Applicant canceled all of the pending claims and added 31 entirely new claims. *Id.* at 280–289. The Examiner issued a Notice of Allowance on September 9, 2014, allowing all but one of the pending claims. *Id.* at 297–301. On October 16, 2014, the Applicant filed an amendment with a request for continued examination. *Id.* at 373–393. In this amendment, the Applicant amended two of the pending claims “to correct typographical errors” and added new Claims 71–130. *Id.* at 373–392. On

December 12, 2014, the Examiner issued another Notice of Allowance, allowing all of the pending claims. *Id.* at 399–403.

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 ’061 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. 1105 ¶¶ 24–26.

VII. THE CHALLENGED CLAIMS OF THE ’061 PATENT ARE UNPATENTABLE

This Petition explains in detail why the Challenged Claims are unpatentable. The Petition is supported by the declaration of Jason Eaton, P.E. Ex. 1105. Mr. Eaton is Principal Mechanical Engineer at MSA Safety and has extensive industry experience in CPAP mask systems and design. *Id*. ¶¶ 2–8. His declaration explains the basis for his conclusions that the Challenged Claims would have been obvious. *Id.* ¶¶ 41–129.

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 Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966)).

B. Claims 17, 18, 20–23, 26–30, 32, 33, 35–38, 41–46, 48–50, and 81–91 Would Have Been Obvious Over Lovell in View of Gunaratnam and Gelinas

1. Overview of Lovell (Ex. 1102)

The Lovell reference was submitted during the prosecution of the '061 Patent, along with over one thousand other prior art references submitted by the applicant. *See* Ex. 1101 at 1–12. However, Lovell was not cited by the Examiner during the prosecution.

Lovell describes CPAP masks that provide pressurized air or therapeutic gas to a patient suffering from an airflow limitation or other respiratory ailment. Ex. 1102 at col. 1:5–8, 4:11–19. In one embodiment, a nasal mask 1 includes a seal 2 affixed to a shell 4. *Id.* at col. 4:34–36. The shell 4 can be manufactured from a compliant polymer, and the seal 2 can include silicone. *Id*. at cols. 4:34–42,

7:51–55. The shell 4 and seal 2 form a chamber that receives the patient's nose in use. *Id.* at col. 4:47–50.

As shown in Figure 2A below, the mask 1 includes an inlet 8 to which a swivel connector 9 or other conduit is coupled. *Id.* at col. 5:9–14. Retainer 12 is disposed about the inlet 8 and couples to the shell 4 to retain the mask on the patient. *Id.* at col. 5:62–63. Retainer 12 is contoured to match the external curvature of the shell 4 and includes four connection points 14, 14', 16, 16' that receive headgear straps. *Id.* at col. 5:65—6:13.

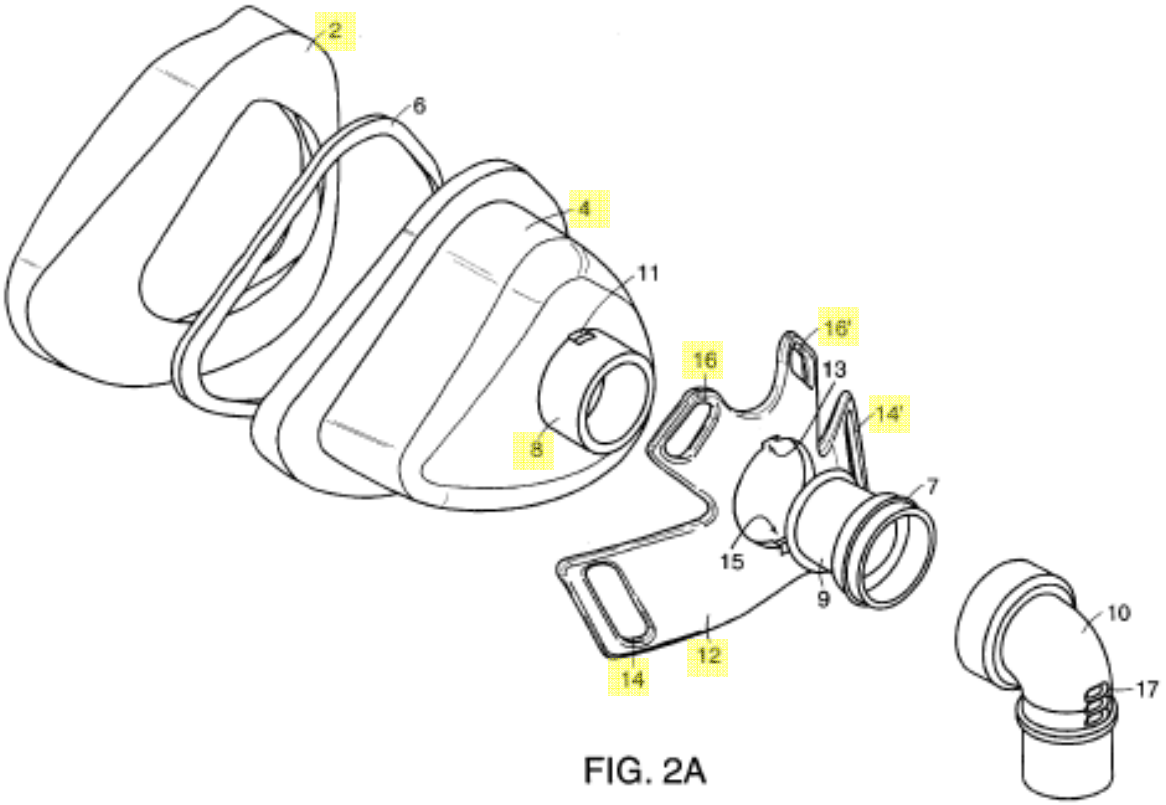


FIG. 2A

Lovell discloses a second embodiment of a nasal mask with many of the features of the nasal mask shown in Figure 2A (shown on previous page), but it includes a different retainer 212, as shown in Figure 10A below. *Id.* at col. 9:34–42.

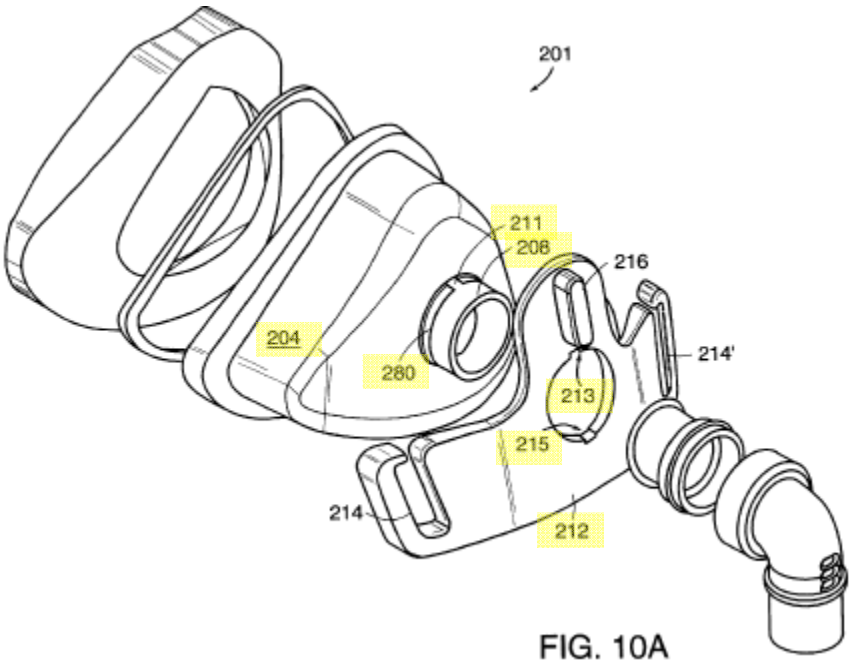


FIG. 10A

Retainer 212 includes two slots 213, 215 that mate with two tabs 211, 211' (211' not shown above) on the inlet 208 of the shell 204. *Id.* at col. 9:46–48. A depressed annular region 280 on the inlet 208 mates with the edges of an aperture passing through the retainer 212. *Id.* at col. 9:57–59. The retainer aperture and the inlet 208 are generally sized in an interference fit so that, when the retainer 212 is fully seated against the shell 204, the retainer 212 is properly retained by the cooperation of the tabs 211, 211', the slots 213, 215, and the depressed annular region 280. *Id.* at col. 9:59–64. The retainer 212 also has three headgear

connection points: two lower points 214, 214' and one upper point 216. *Id.* at col. 9:49–51.

2. Overview of Gunaratnam (Ex. 1103)

The Gunaratnam reference was submitted during the prosecution of the '061 Patent. *See* Ex. 1101 at 1–12. Gunaratnam is a ResMed patent and its corresponding publication was cited by the Examiner during the prosecution of the '061 Patent as an anticipatory reference. *Id.* The claims rejected over Gunaratnam were canceled on May 27, 2014. Ex. 1107 at 280–289.

Gunaratnam discloses nasal and full-face CPAP masks "for the treatment of sleep disordered breathing." Ex. 1103 at col. 1:21–25. The mask assemblies described in Gunaratnam include a rigid mask frame 160 and a soft cushion 180 that form a cavity that overlies the nose and/or mouth of a patient. *Id.* at cols. 1:32–39, 4:20–30.

As shown below, the frame 160 includes a gas inlet aperture 610 for connection to a gas delivery conduit (not shown) of a patient gas delivery system. *Id.* at col. 4:22–25. The frame 160 also includes strap connection points 630 on opposite sides of inlet aperture 610 for connecting headgear, and an upper support extension 161 that supports a forehead contacting portion 162. *Id.* at cols. 4:31–34, 4:46–58.

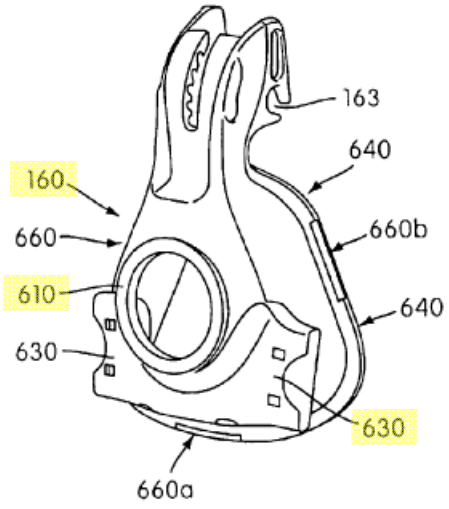


FIG. 5a

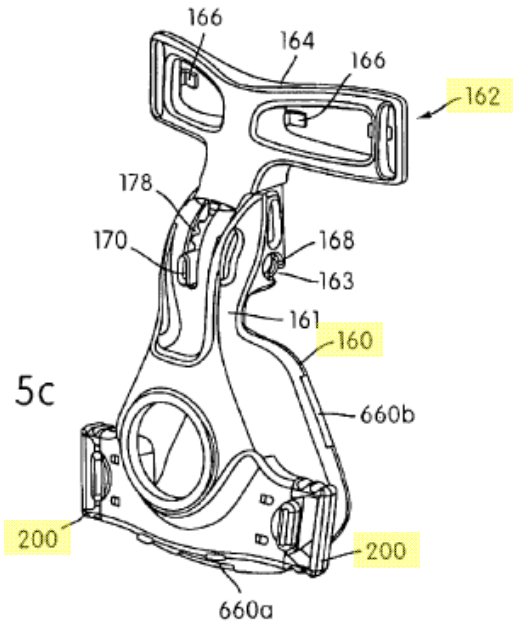


FIG. 5c

Although the Gunaratnam embodiment illustrated above is a nasal mask, features of the mask frame and cushion are similarly applicable to a full-face mask. *Id*. at col. 6:30–34. For example, Figure 15 (below) illustrates a frame 160 that is adapted to cover both the mouth and nose. *Id*. at col. 6:25–26. A second aperture 930 is located in the upper portion of the mask frame 160, above the inlet aperture 910. *Id.* at col. 6:27–29.

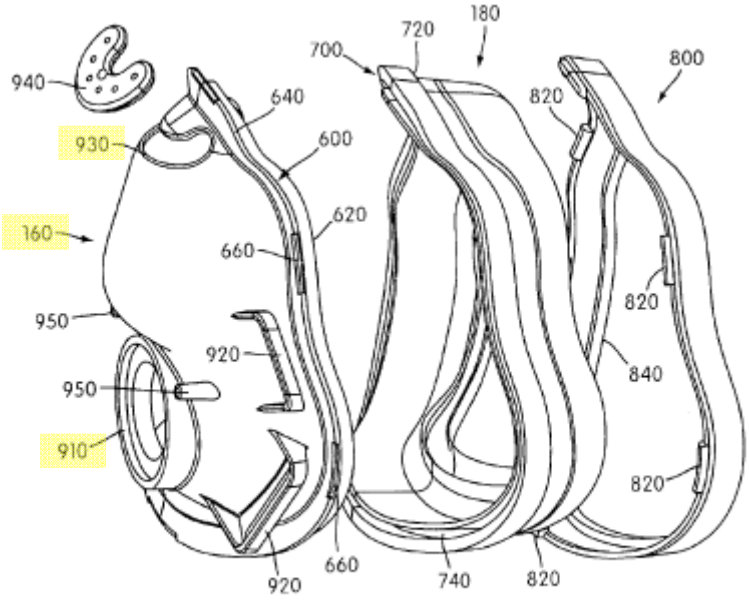


FIG. 15

3. Overview of Gelinas (Ex. 1104)

The Gelinas reference was submitted during the prosecution of the ’061 Patent, but was not cited by the Examiner. *See* Ex. 1101 at 1–12.

Gelinas discloses a respirator mask that provides a seal against a user’s face and covers the user’s mouth and nose. Ex. 1104 at Abstract. As shown in Figure 7 below, Gelinas discloses a respirator mask 10 with two main components: a

facepiece 22 and cover 24. *Id.* ¶ 26. The facepiece 22 is a sub-assembly that includes a semi-rigid/plastic frame 92 and a soft, flexible face-contacting part 90. *Id.* Cover 24 is a frame made of a rigid or semi-rigid plastic and can be detachably mated with the facepiece 22. *Id.* ¶ 31. The cover 24 includes a peripheral portion 52 and a ring 54 connected by four branches 56. *Id.* ¶ 32.

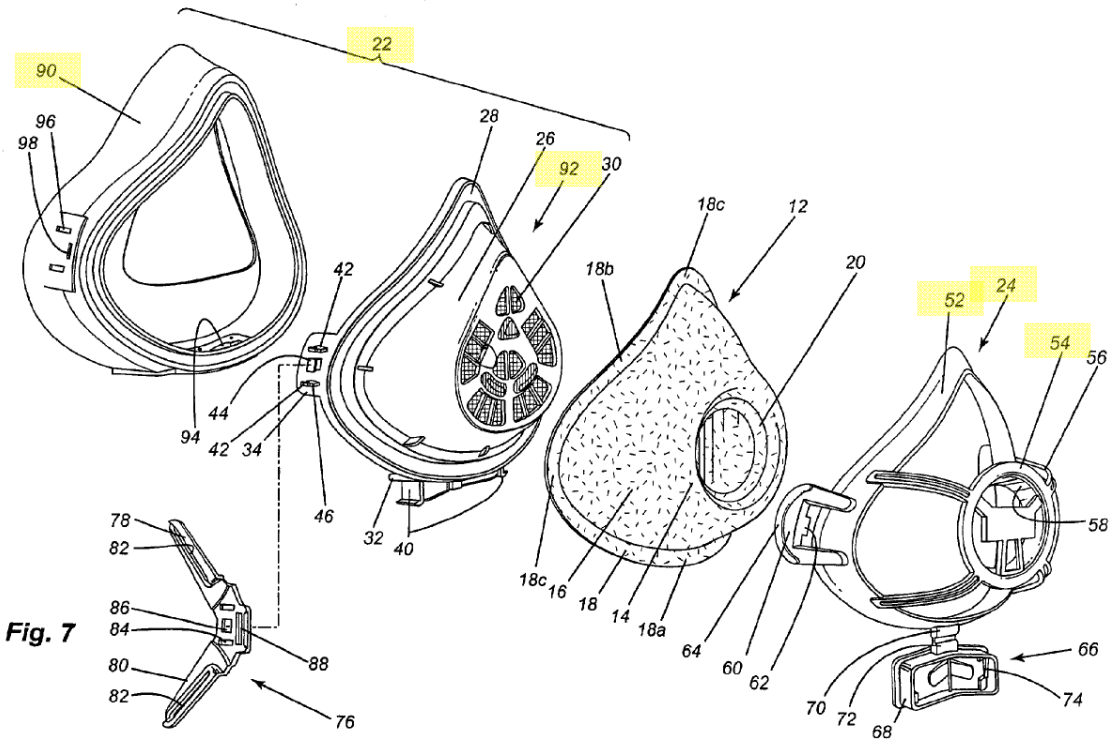


Fig. 7

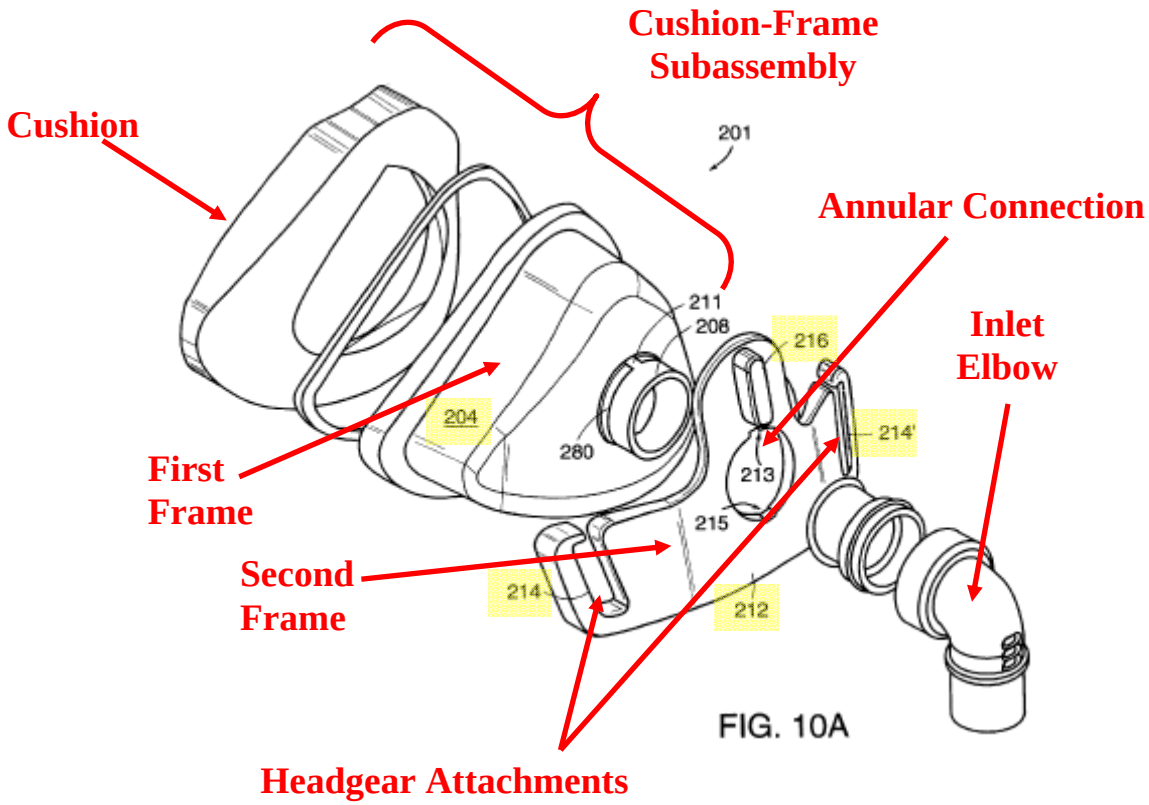
4. Potential Differences and Reasons to Combine the Prior Art

As detailed in the claim charts below, Lovell discloses nearly all of the limitations of the Challenged Claims of the '061 Patent. *See infra* §§ VII(B)(4)(a)–(k).

With respect to independent Claim 17, Lovell teaches a CPAP mask assembly having a first frame (shell 204) made of first material (*e.g.*,

Pellethane™); and a cushion (unlabeled) connected to the first frame, the cushion being adapted to form a seal around a patient's nose and being made from a second material (*e.g.*, silicone gel) that is more flexible than the first material. Ex. 1102 at cols. 4:34–58, 7:45–58. Lovell teaches a second frame (retainer 212) adapted to constrain the first frame, the second frame comprising an upper support member (216), two lower headgear attachments (214, 214'), and an annular connection (aperture in retainer 212). *Id.* at cols. 6:2–10, 9:43–48.

Many of these claimed features are identified in the annotated version of Figure 10A of Lovell below. Ex. 1105 ¶ 56.



As detailed below, any differences between Lovell and the Challenged Claims were minor, well-known at the time of the invention, and taught by Gunaratnam and Gelinas. Ex. 1105 ¶¶ 57–59.

Because Lovell and Gunaratnam both teach CPAP masks with similar frame structures, the features taught in Gunaratnam would have been readily compatible with and easily incorporated into the mask of Lovell with a reasonable expectation of success. *Id.* ¶ 59. Moreover, a person of skill also would have looked at prior art respirator masks, such as Gelinas, when designing a CPAP mask. *Id.* ¶¶ 58–59. Gelinas is from the same field of endeavor, namely facial breathing masks, and was submitted as relevant prior art during the prosecution of the '061 Patent. *See* Ex. 1101 at 1–12. Even if it were determined that Gelinas is not from the same field of endeavor, the second frame 24 disclosed in Gelinas is pertinent to the same problem of providing access to an underlying frame in a two-frame arrangement, as explained further below. *See infra* § VII(B)(4)(f); Ex. 1105 ¶ 58; *see also In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004). As such, a person of skill would have understood that the features of Gelinas would have been readily compatible with and easily combined with the features of Lovell and Gunaratnam with a reasonable expectation of success. Ex. 1105 ¶ 59.

Based on the teachings in the prior art and the knowledge of one skilled in the art, a person of skill would have been motivated to combine the teachings of

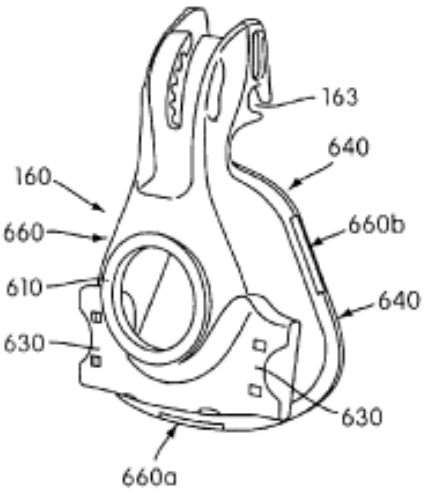
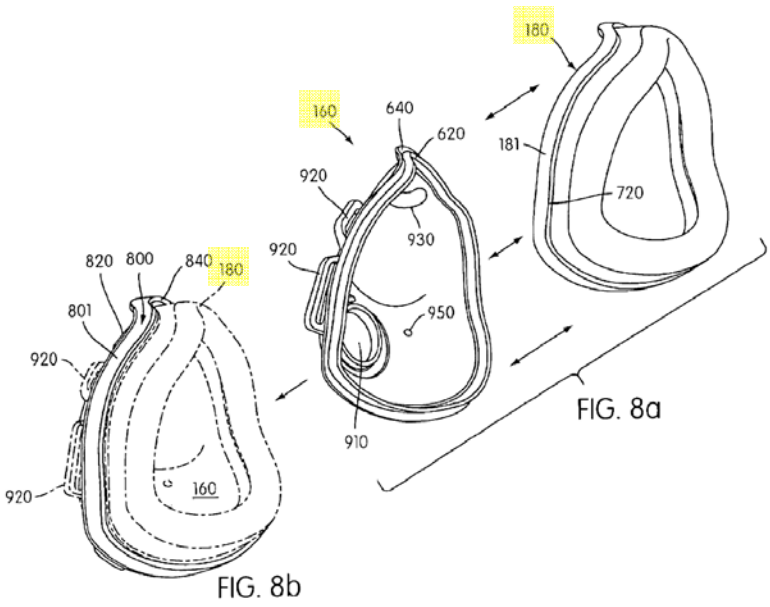
Lovell with those of Gunaratnam and Gelinas. *Id*. ¶ 58; *see also KSR*, 550, U.S. at 419. Such modifications would have been mere combinations of familiar elements according to known methods that do no more than yield predictable results. Ex. 1105 ¶ 59; *see KSR*, 550, U.S. at 416.

a. seal around a patient's nose and mouth

Independent Claims 17, 32 and 81 of the '061 Patent include "the cushion being adapted to form a seal around a patient's nose and mouth." Dependent Claims 20, 35, 48, 85, and 89 include the first frame or the cushion is "contoured to fit over a patient's nose and mouth." Dependent Claims 23, 38, and 48 include the first frame and the cushion together form a "breathing chamber around the patient's nose and mouth."

Lovell discloses nasal mask assemblies having a cushion-frame sub-assembly that forms a seal and chamber around a patient's nose (Ex. 1102 at col. 4:55–58), but does not expressly disclose a full-face cushion-frame sub-assembly that seals around the nose and mouth. However, full-face masks were well-known in CPAP applications during the relevant time period, and a person of skill would have recognized that nasal mask features were generally compatible with full-face masks. Ex. 1105 ¶¶ 61–64. For example, Gunaratnam describes a CPAP nasal mask frame in Figure 5a (below, left) and discloses that the "invention is also suitable for a full-face mask system." Ex. 1103 at col. 6:3–7. Figures 8a and 8b

(below, right) of Gunaratnam show a full-face frame 160 and cushion 180 that seals around the patient's nose and mouth regions. *Id.*

 FIG. 5a	 FIG. 8a FIG. 8b
Nasal Mask Frame	**Full-Face Mask Assembly**

As shown in Figure 1 (below), Gelinas also describes a cushion that "defines a continuous seal for sealingly engaging the face of the wearer and covering the mouth and nose of the wearer." Ex. 1104 ¶ 27.

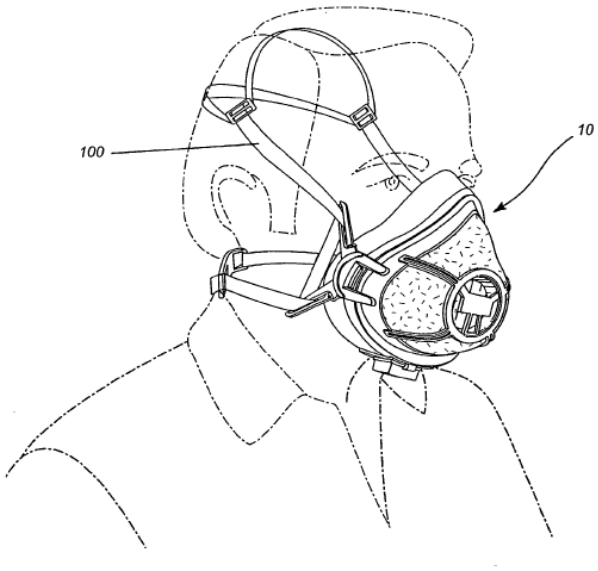


Fig. 1

A person of skill in the art at the time of the invention would have recognized that patients who breathe through their mouth during sleep may require a full-face mask. Ex. 1105 ¶ 64. A person of skill would have recognized that it was common to use arrangements and features from nasal masks in the designs of full-face masks (*see* Ex. 1103 at col. 6:3–7) and would have been motivated to modify the mask assembly of Lovell to be a full-face mask that seals around the patient's nose and mouth. Ex. 1105 ¶ 64; *see also KSR*, 550 U.S. at 419.

b. cushion material more flexible than frame material

Independent Claims 17, 32, and 81 include "a first frame made of a first material, . . . the cushion . . . being made from a second material that is more flexible than the first material."

Lovell discloses a cushion formed from a film and filled with soft material such as silicone gel. Ex. 1102 at cols. 2:59–64, 7:45–58. The first frame 204 of Lovell is formed by molding a compliant polymer such as Pellethane. *Id*. at col. 4:40–44. A person of skill in the art would have understood that the silicone cushion material is softer and more flexible than the molded polymer first frame. Ex. 1105 ¶ 66.

However, to the extent the disclosure of Lovell is somehow insufficient for this feature, mask assemblies with frames and more flexible cushions were common at the time of the invention. *Id*. ¶ 67. For example, Gunaratnam discloses that the frame 160 is constructed of rigid polycarbonate and the cushion is formed of soft silicone. Ex. 1103 at cols. 4:22–23, 5:22–24.

A person of skill in the art would have known to construct a cushion-frame sub-assembly in which the cushion is made of a material that is more flexible than the frame material so that the cushion is comfortable and effectively seals against the patient's face. Ex. 1105 ¶ 68. Such a person would have also known to make the frame from a material more rigid than the cushion to provide a solid mounting

base for the cushion-frame subassembly, provide secure attachment to the second frame, and prevent movement of the cushion-frame subassembly. *Id*. ¶¶ 66–68.

c. "forehead support"

Independent Claims 17 and 32 of the '061 Patent include a second frame having an "upper support member" that "supports a forehead support" (Claim 17) or is adapted to "assist with forehead support" (Claim 32).

Although Lovell discloses a second frame 212 with an upper support member 216 that supports upper headgear straps (Ex. 1102 at col. 10:1–12), Lovell does not expressly disclose an upper support member that directly supports or contacts the user's forehead.

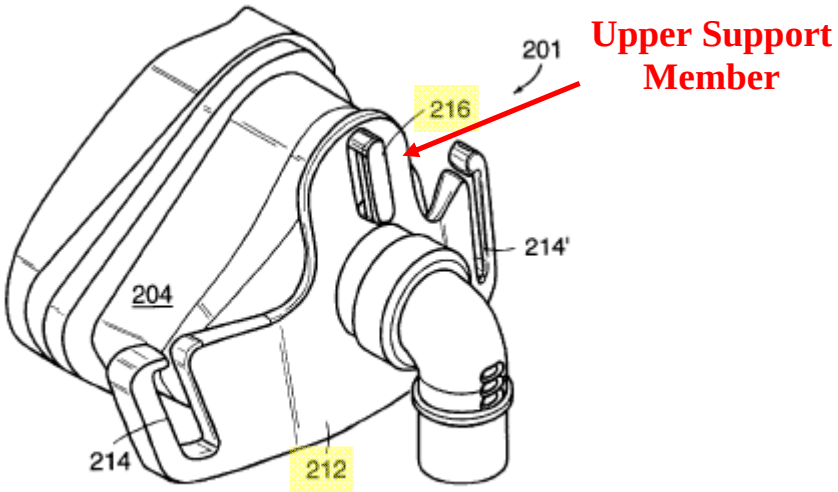
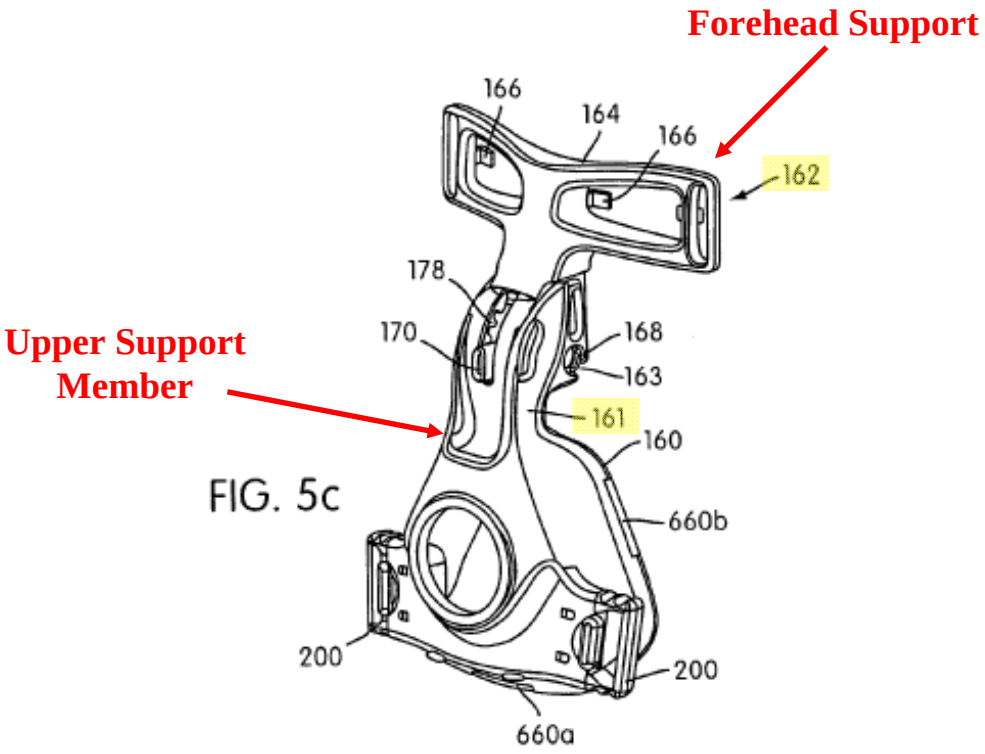


FIG. 9

However, such forehead supports were common in CPAP masks and were often used to provide additional support for the upper portion of the mask. Ex. 1105 ¶¶ 71–74. For example, Gunaratnam describes a frame with an upper

support member 161 that supports a forehead support 162, and the forehead support 162 provides direct support to the forehead, as shown below in Figure 5c. Ex. 1103 at col. 4:47–52; Ex. 1105 ¶ 72.



A person of skill in the art at the time of the invention would have recognized the benefits of incorporating the forehead support of Gunaratnam into the second frame 212 of Lovell, particularly in a full-face version of the mask of Lovell. Ex. 1105 ¶ 75; *supra* § VII(B)(4)(a). A person of skill would have been motivated to include a forehead support that contacts the wearer's face to provide additional support in the forehead area and to keep the mask positioned properly on the face. Ex. 1105 ¶ 75.

d. "clip attachments"

Independent Claims 17 and 32 include a second frame with "two lower headgear clip attachments engaged with clips provided to straps of a headgear assembly." Dependent Claims 28, 43, 48, 87 and 89 include "two lower headgear clip attachments are adjacent to and on opposite lateral sides of the annular connection [of the second frame]."

Lovell discloses a second frame 212 with two lower headgear attachment points 214, 214'. Ex. 1102 at col. 9:49–53. Lovell also discloses that these attachment points 214, 214' could have slots or notches configured for quick attachment/detachment of the straps of a headgear assembly, without having to release the features that provide for strap length adjustment. *Id.* at col. 10:41–44.

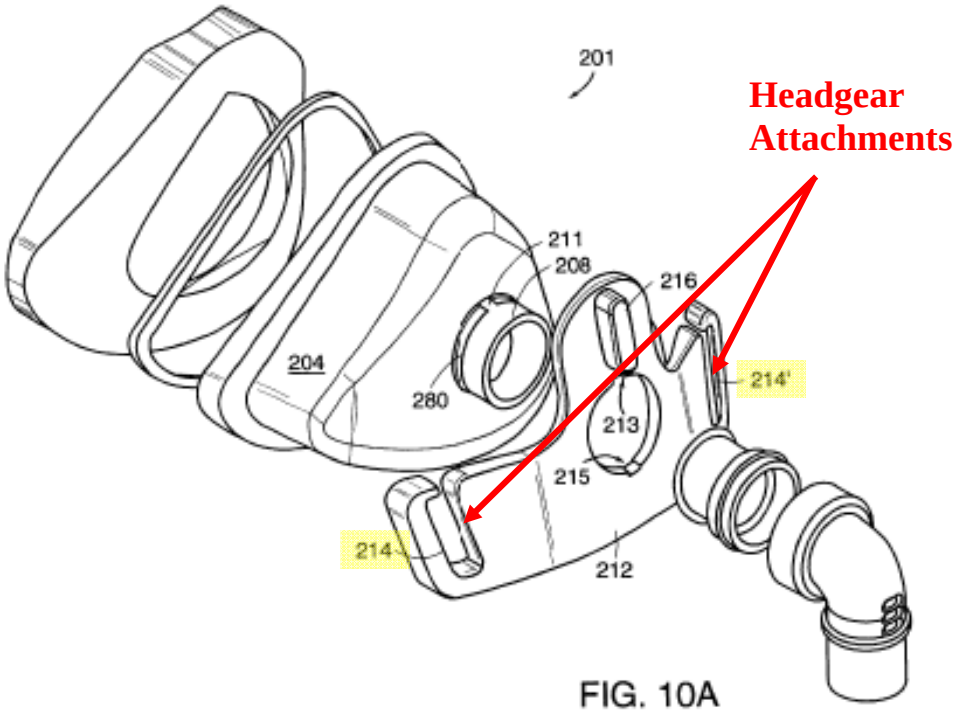


FIG. 10A

Providing quick attachment/detachment of the headgear straps from the mask assembly without re-adjustment was one of the main aspects of the mask assemblies disclosed in Lovell. *Id.* at col. 10:41–44; Ex. 1105 ¶¶ 77–78. Lovell also recognizes that alternate attachment structures such as "snaps, hook and eye closures, hook and loop fasteners, or the like, may be employed." Ex. 1102 at col. 6:10–19.

To the extent Lovell somehow provides insufficient teachings for this feature, such headgear clip attachments were well-known in the field of CPAP masks. Ex. 1105 ¶ 79. For example, Gunaratnam discloses an outer frame that includes two lower headgear clip attachments 630 that receive clips 200, as shown below in Figures 5a and 5c. Ex. 1103 at col. 4:31–34.

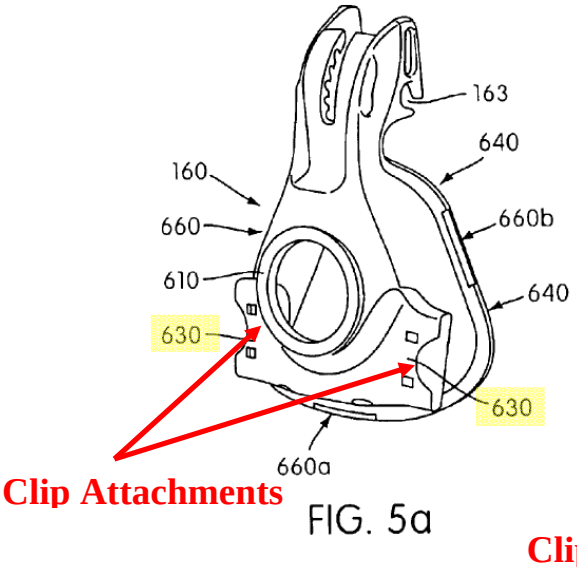


FIG. 5a

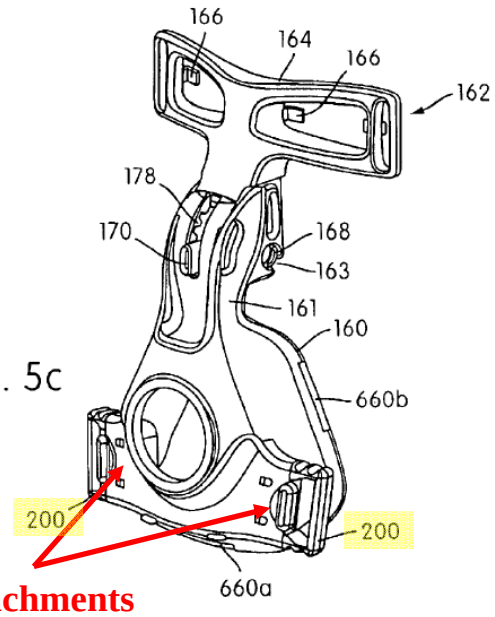


FIG. 5c

A person of skill in the art at the time of the invention would have been motivated to provide these well-known clip attachments to allow patients to more easily attach and detach the headgear. Ex. 1105 ¶ 80. Clip attachments allow for one-time adjustment of the headgear straps and easy attachment and detachment of the mask from the face. *Id.* Such a modification would have been a simple substitution of one known element for another that does no more than yield predictable results. *Id.*; *see KSR*, 550, U.S. at 416.

e. "annular connection adapted to engage an elbow" or "elbow engages the second frame"

Independent Claim 17 of the '061 Patent requires a second frame that includes an "annular connection adapted to engage an elbow of an inlet conduit." Dependent Claims 50 and 91 include a mask assembly in which the "elbow engages the second frame."

As explained above, a proper interpretation of the term "engage" in the context of these claims would include arrangements that support in an operable position relative to, either directly or in cooperation with, other components. *See supra* § IV(C)(1). Under such a proper construction, Lovell describes a second frame 212 with an annular connection that supports the elbow in an operable position to allow air flow into the cushion-frame sub-assembly. Ex. 1105 ¶¶ 82–85.

As shown on the next page, similar to the relevant embodiments of the '061 Patent, Lovell shows an inlet 208 on the first frame 204 that extends through an annular connection (surrounding the unnumbered opening) on the second frame 212, such that the elbow of the inlet conduit directly contacts the inlet 208 on the first frame 204. Ex. 1102 at col. 9:43–48; Ex. 1105 ¶ 85. Thus, Lovell teaches an annular connection on the second frame adapted to engage an elbow. Ex. 1105 ¶ 85.

’061 PATENT

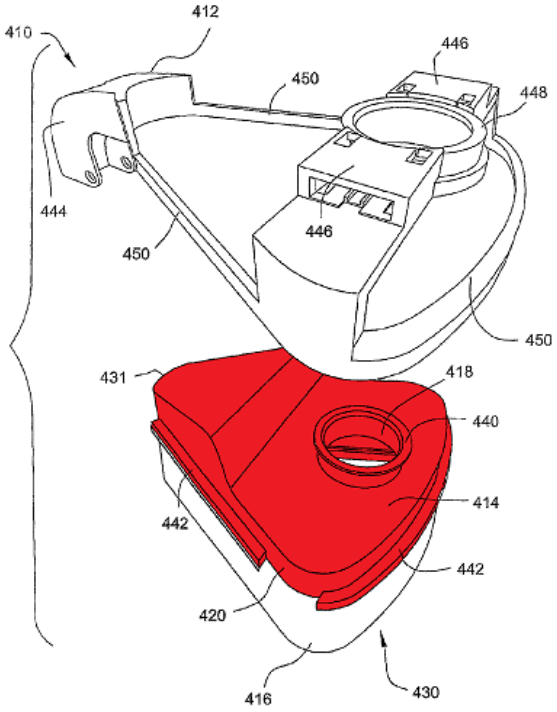


Fig. 7

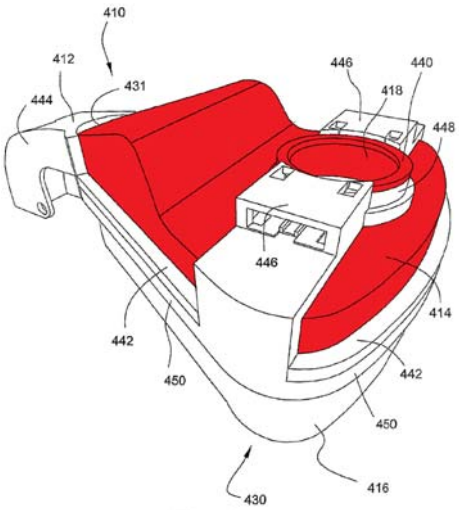


Fig. 8

PRIOR ART LOVELL

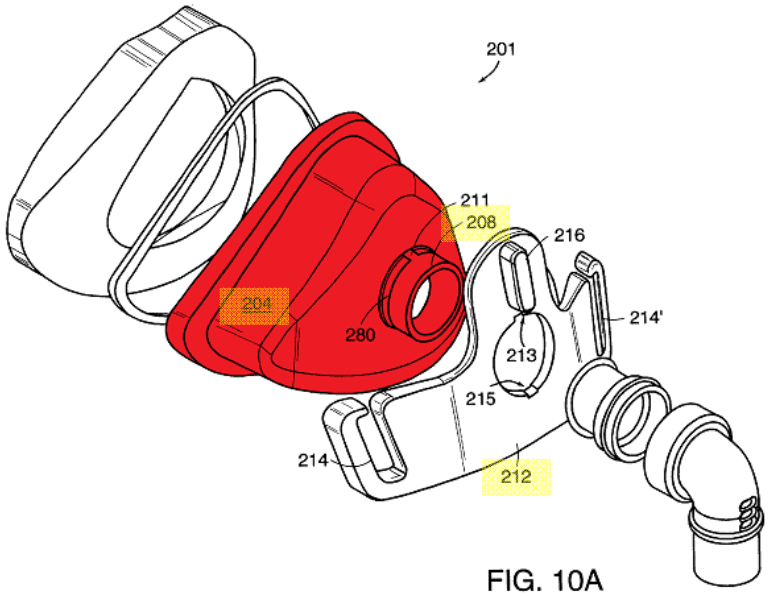


FIG. 10A

However, if these limitations are interpreted to somehow require that the annular connection of the second frame directly contact the elbow, such arrangements were also well-known in the field of CPAP masks. Ex. 1105 ¶¶ 86–89. For example, Gunaratnam discloses that "[t]he frame 160 . . . incorporates a gas inlet aperture (610) for connection to a gas delivery conduit (not shown) of a patient gas delivery system, as shown below in Figure 5a." Ex. 1103 at col. 4:22–25.

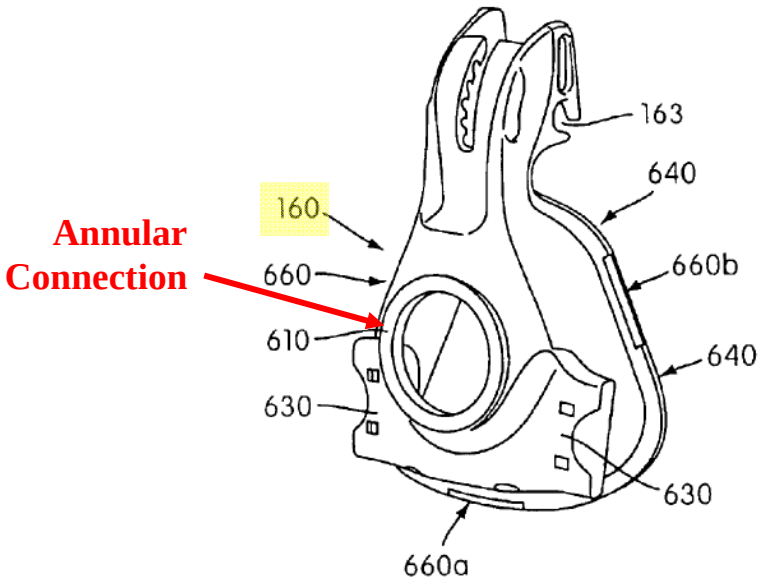


FIG. 5a

A person of skill in the art at the time of the invention would have viewed Lovell and Gunaratnam as teaching two design choices for establishing a seal between an interior of an elbow and a breathing chamber, each having its own advantages. Ex. 1105 ¶ 88. A person of skill would have understood that Lovell utilizes a direct connection between the elbow and the cushion-frame sub-

assembly, which requires only a single seal. *Id.*

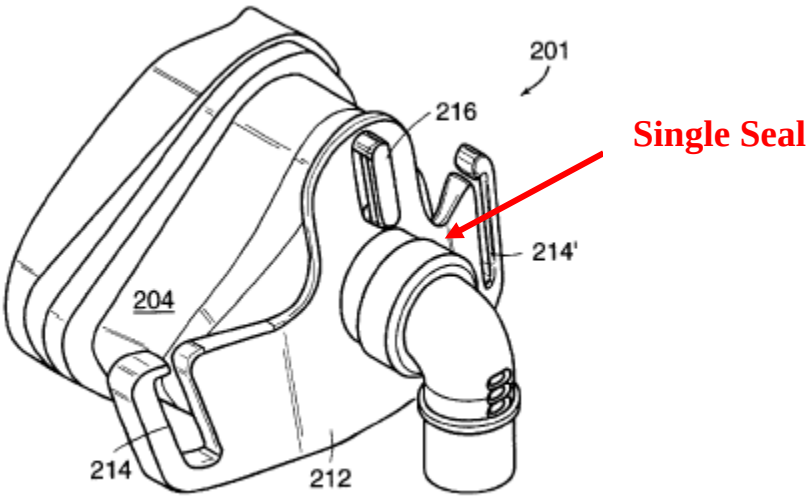


FIG. 9

Gunaratnam teaches separate sealed connections between: 1) the second frame and the elbow and 2) the second frame and the cushion-frame sub-assembly. *Id.* ¶¶ 89–90.

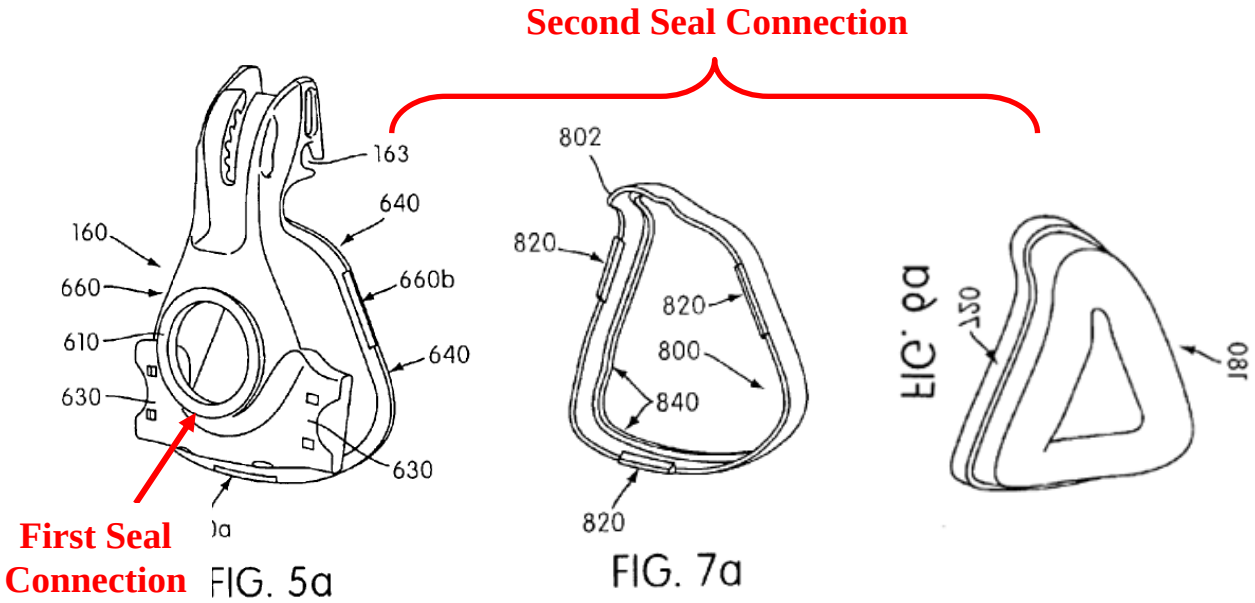


FIG. 5a FIG. 7a

Although Gunaratnam requires two separate seals, directly attaching the elbow to the second frame would make it easier for a patient to detach the cushion

subassembly or elbow without affecting the engagement of other mask components. *Id.* ¶ 90. A person of skill would have recognized that the ability to remove the cushion sub-assembly on its own permits the elbow to be permanently or semi-permanently coupled to the second frame. *Id*. Such an arrangement makes removal and/or replacement of the cushion sub-assembly a simpler process for end users. *Id*. ¶¶ 90–91. A person of skill in the art would have selected this two-seal arrangement as one of a finite number of predictable solutions for providing a connection between the interior of the elbow and the breathing chamber. *Id.* ¶ 91; *see also KSR*, 550, U.S. at 421.

f. separate opening

Independent Claim 17 includes "an opening located between the annular connection and the upper support member, the opening providing access to the first frame." Independent Claims 32 and 81 include "a separate opening located between the annular opening and the upper support member, the separate opening providing access to the first frame while the mask assembly is fully assembled."

Lovell discloses a second frame 212 with an annular opening and open spaces that allow access to the first frame 204 (Ex. 1102 at cols. 9:43–48, 10:1–12), but Lovell does not expressly disclose an opening or separate opening between the annular opening and the upper support member.

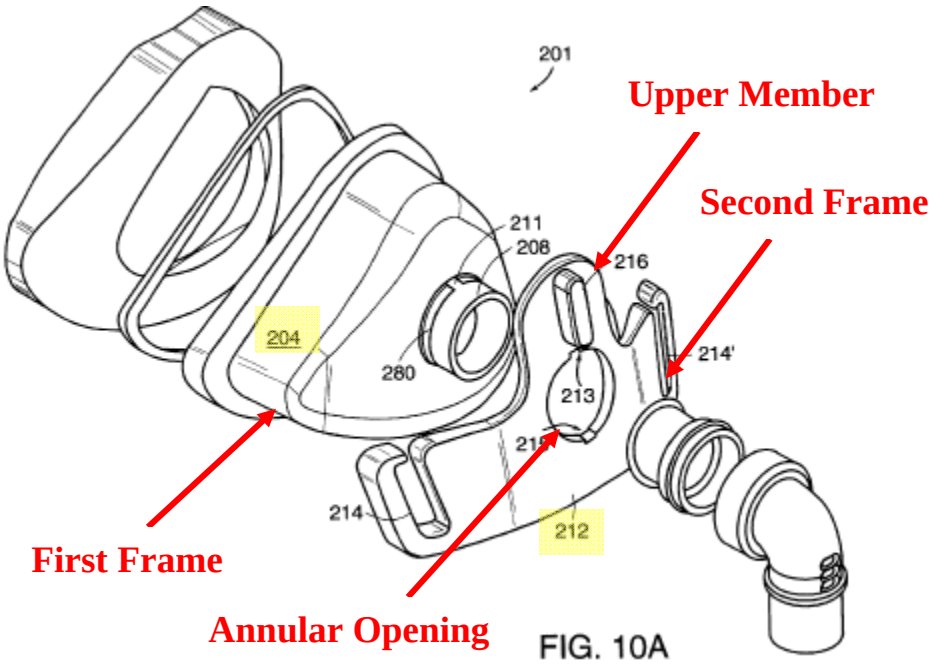
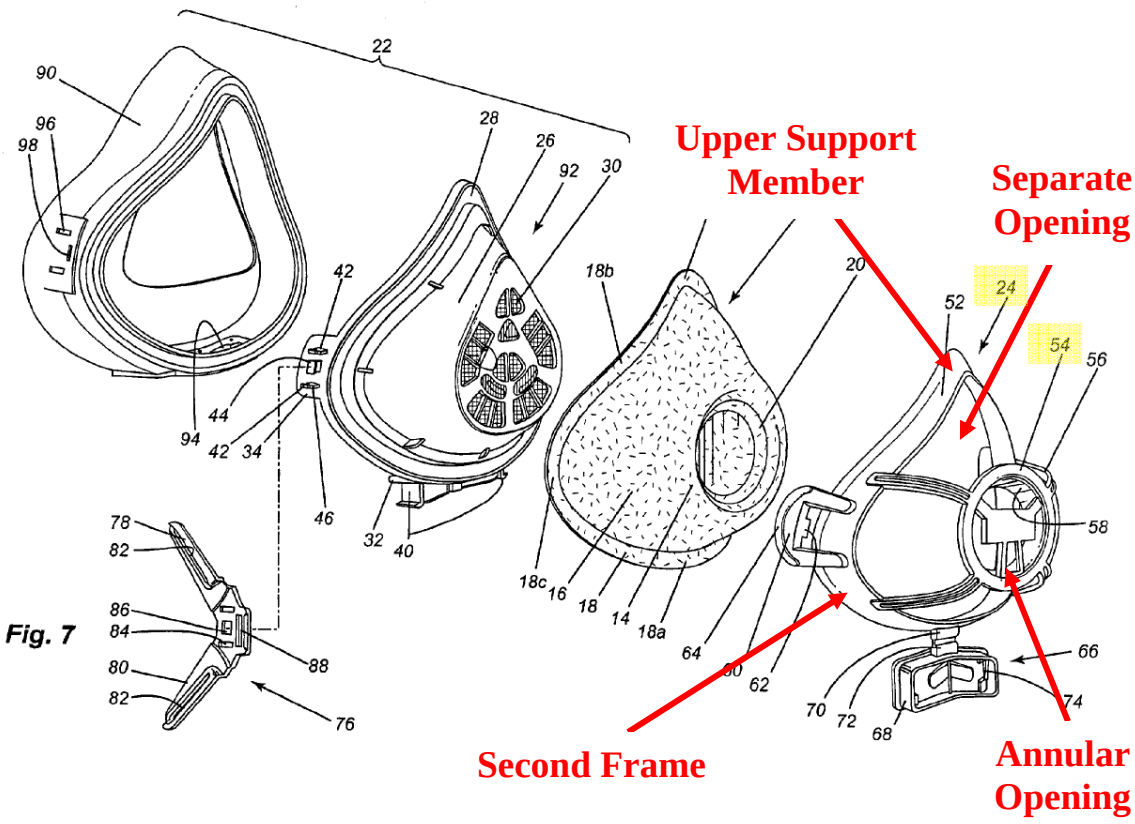


FIG. 10A

However, such separate openings in the second frame were well-known and disclosed in the prior art. Ex. 1105 ¶¶ 93–98. For example, as shown below in annotated Figure 7 (below), Gelinas discloses a second frame 24 with a separate opening between an annular opening 54 and an upper support member of the second frame 24. Ex. 1104 ¶¶ 26–32.



As shown in Figure 1 of Gelinas (below), when assembled, the first frame is accessible through the separate opening in the second frame 24. *See* Ex. 1104 at Fig. 1; Ex. 1105 ¶ 94.

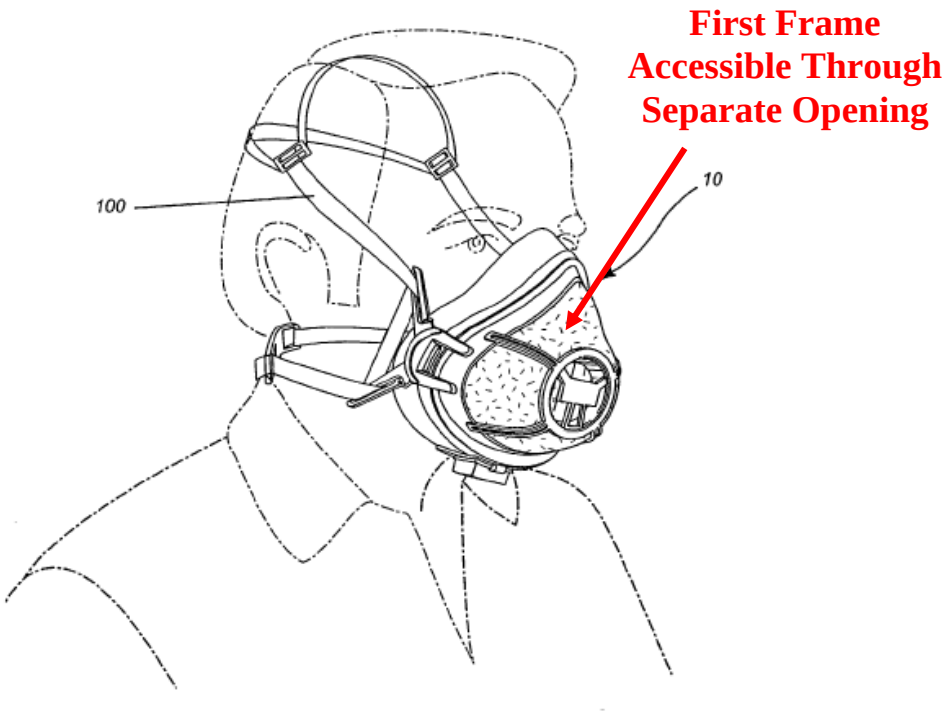


Fig. 1

A person of skill in the art would have been motivated to modify the nasal mask of Lovell to be a full-face mask for at least the reasons provided above. *See supra* § VII(B)(4)(a). In making such a modification, a person of skill would have recognized that the full-face mask would require a gas washout vent to enable CO_2 washout and vent the breathing chamber upon overpressurization. *See* Ex. 1102 at col. 5:36–41; Ex. 1105 ¶¶ 96–97. Although Lovell discloses a vent on the elbow (Ex. 1102 at col. 5:36–41), it was common and well-known in the industry to place

such a vent on the first frame and in direct contact with the breathing chamber to minimize deadspace. Ex. 1105 ¶¶ 96–97. In particular, Gunaratnam teaches providing the vent at the well-known position in the nasal bridge region of the mask assembly. *See supra* § VII(B)(2).

A person of skill in the art would have recognized that providing a vent on the first frame of a two-frame mask system would require access to the vent through the second frame. Ex. 1105 ¶ 98. As such, a person of skill would have been motivated to modify the second frame to include a separate opening between the annular elbow connection and the upper support member of the second frame, as taught by Gelinas, to provide access to a vent in the nasal bridge region of the first frame. *Id.*

Additionally, a person of skill in the art would have recognized that providing a second frame with a separate opening as in Gelinas would facilitate a more secure connection between the periphery of the second frame (surrounding the second opening) and the first frame, while also minimizing the amount of material in the second frame. *Id.*

g. "first frame and the cushion are integrally molded"

Dependent Claims 18, 33, 48, 84 and 89 include "the first frame and the cushion are integrally molded in one piece to provide a cushion-frame sub-assembly."

Lovell discloses that the chamber for receiving the patient's nose is substantially leakage-free due to the "bond or interface" between the cushion and the first frame. Ex. 1102 at col. 4:34–58.

However, to the extent Lovell somehow provides insufficient disclosure for this feature, it was well-known at the time of the invention to integrally mold the cushion with the first frame. Ex. 1105 ¶ 100.

For example, Gelinas discloses that the cushion 90 can be secured to first frame 92 by "different means such as mechanical securing means, chemical affixing means or through-molding processes." Ex. 1104 ¶ 26.

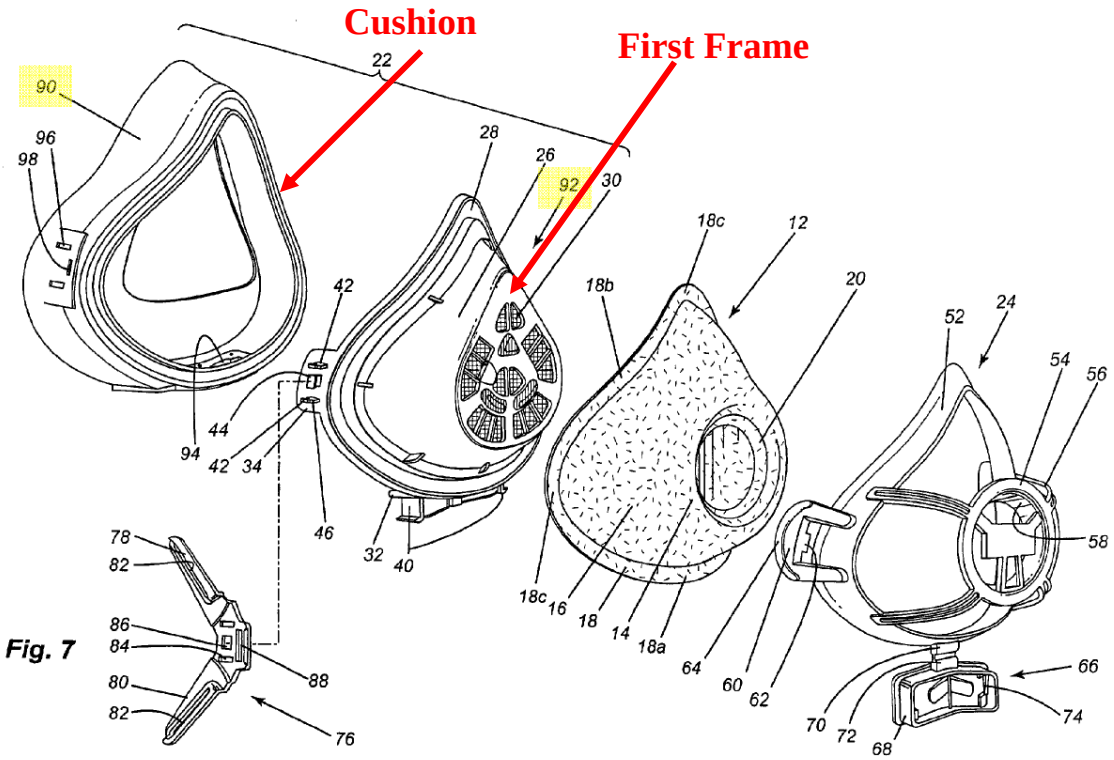


Fig. 7

A person of skill in the art would have been motivated to integrally mold the cushion to the first frame to provide an airtight seal between the seal and the

cushion and prevent undesired removal of the cushion from the frame. Ex. 1105 ¶ 101.

h. "connecting members" or "frame members"

Dependent Claims 26, 41, and 48 include "two connecting members that connect a lower portion of the second frame to the upper support member" and the opening or separate opening is located "between the two connecting members." Dependent Claims 82 and 89 include "two elongate frame members connecting the upper member and lower member and at least partially bounding the separate opening." Dependent Claims 83 and 89 include "the elongate frame members include contact points with the first frame to prevent rotation of the first frame with respect to the second frame."

The second frame 212 of Lovell includes open spaces that allow access to the first frame 204, but it does not expressly disclose the connecting members or elongate frame members. However, as discussed above and shown in Figure 7 below, Gelinas describes a second frame 24 with a separate opening between an annular opening 54 and an upper member of the frame 24. *See supra* § VII(B)(4)(f).

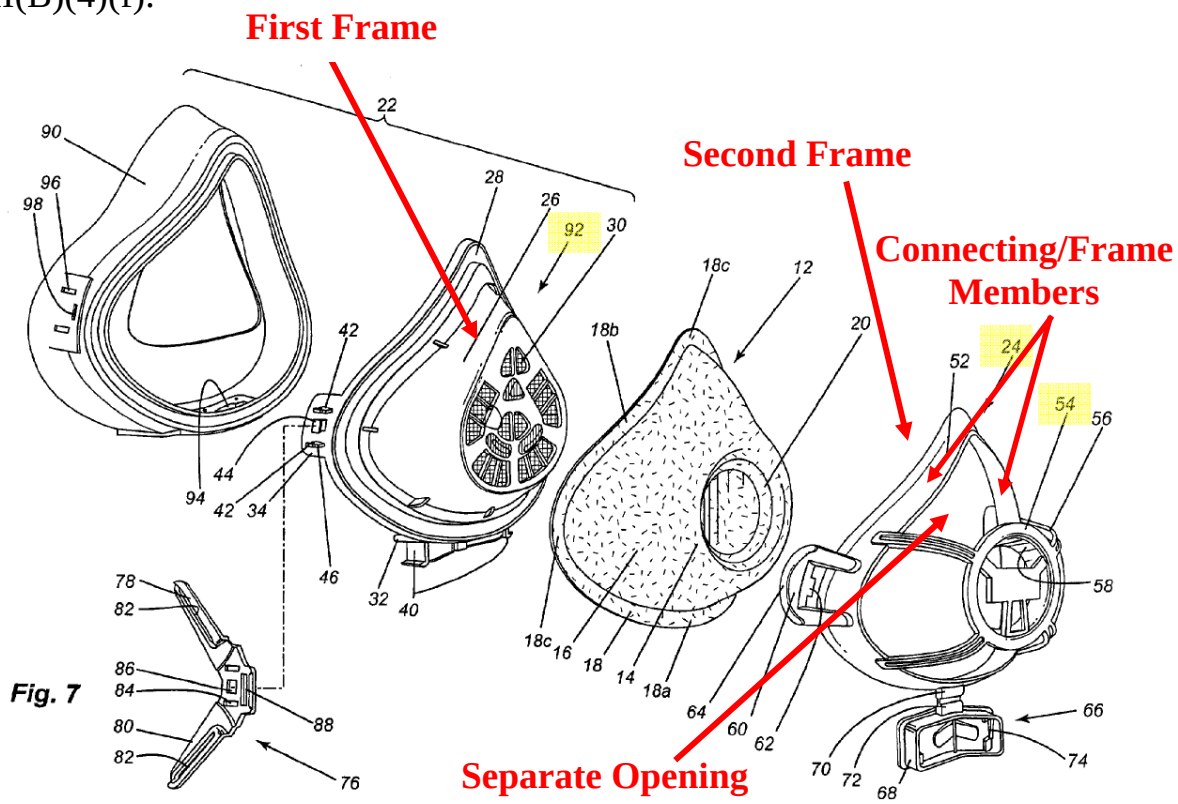


Fig. 7

As shown above, the separate opening is bounded by two elongate frame members (or connecting members) connecting an upper member and a lower member/portion of the second frame 24. Ex. 1104 ¶¶ 26, 32; Ex. 1105 ¶¶ 103–105. As shown below in Figure 2 of Gelinas, the frame members 52 contact the first frame 92 and prevent rotation of the first frame 92 with respect to the second frame 24. Ex. 1105 ¶ 104.

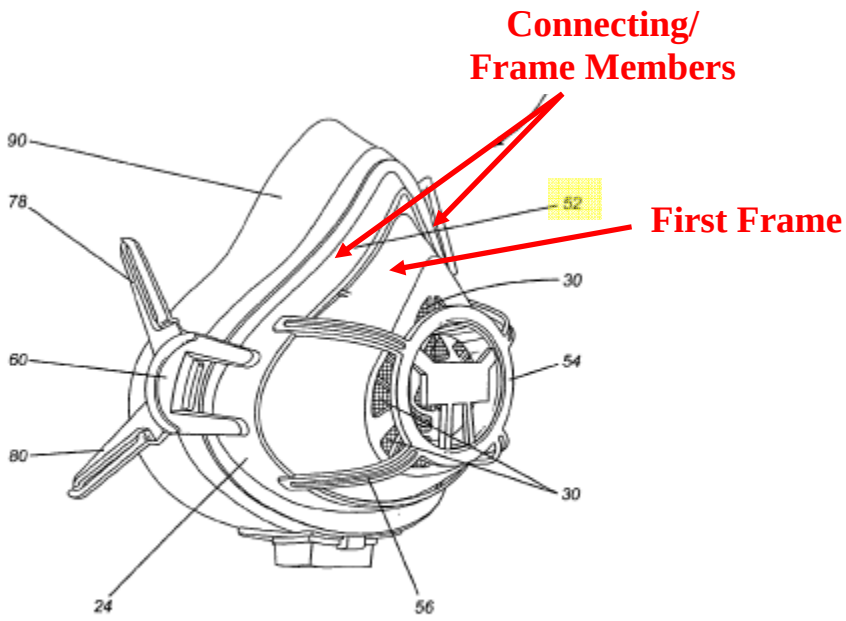


Fig. 2

A person of skill in the art at the time of the invention would have been motivated to incorporate the separate opening of Gelinas between the annular opening and an upper member of the second frame for at least the reasons provided above. *See supra* § VII(B)(4)(f). A person of skill would have known to incorporate such connecting/frame members on the second frame to support the

upper portion of the second frame above the separate opening. Ex. 1105 ¶ 106. Connecting/frame members would allow for an opening and provide engagement features for the upper portion of the second frame, without the need for additional members or structures on the second frame. *Id*.

i. "opening is substantially triangular"

Dependent Claims 27, 42, 49, 86, and 90 include the opening or separate opening is "substantially triangular."

As discussed above, the combination of Lovell, Gunaratnam, and Gelinas teaches a separate opening. *See supra* § VII(B)(4)(f). As shown below in Figure 7 of Gelinas, the separate opening between the annular opening and the upper portion of the frame 24 is triangular in shape. Ex. 1105 ¶¶ 108–109. Gelinas discloses that the flange portion 18 on filter 12 defines a "generally triangular figure," and the connecting/frame members 52 defining the separate opening follow this same triangular figure. *See* Ex. 1104 ¶ 25, Figure 7; Ex. 1105 ¶¶ 108–109.

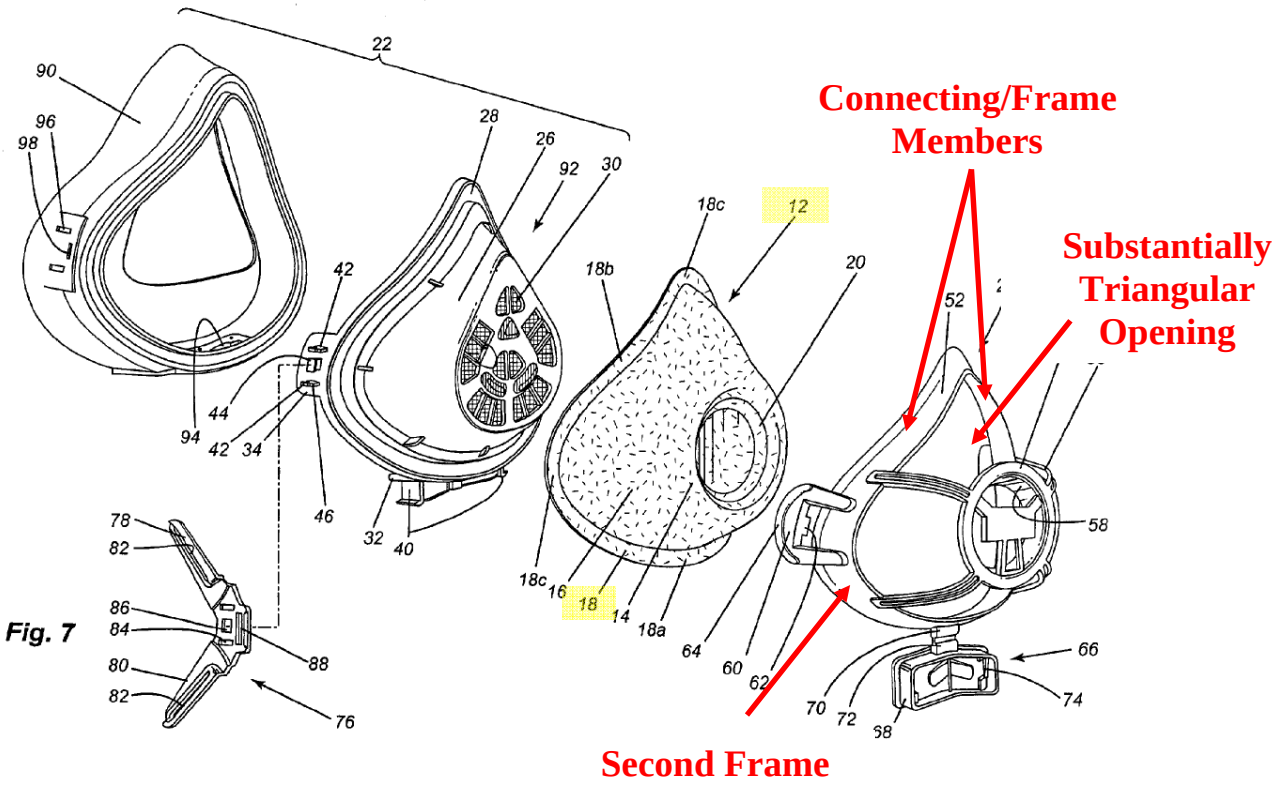


Fig. 7

A person of skill in the art would have recognized that full-face masks were generally triangular in shape to follow the contour of the user's nose and mouth, and thus would have been motivated to provide connecting members that follow the triangular shape of the mask assembly and define a triangular opening. Ex. 1105 ¶¶ 109–111. The triangular opening would have been the result of minimalistic design approach of a second frame that would reduce materials used and allow for easier manufacturing. *Id*.

j. "annular opening and the elbow are sealingly connected"

Dependent Claims 46 and 48 include "the annular opening and the elbow are sealingly connected."

As explained above, a proper construction of the term "sealingly connected" in the context of these claims would include arrangements in which the elbow is directly or indirectly coupled to the second frame to allow a seal between the interior of the elbow and the breathing chamber. *See supra* § IV(C)(2).

Under such a proper construction, Lovell describes a mask assembly with an inlet elbow that is sealingly connected to the second frame (see Figure 10A below). Ex. 1105 ¶¶ 113–114; *see supra* §§ IV(C)(2), VII(B)(4)(e). The elbow is indirectly coupled to the second frame 212 to provide a seal between the interior of the elbow and the breathing chamber defined by the first frame 204. Ex. 1105 ¶ 114.

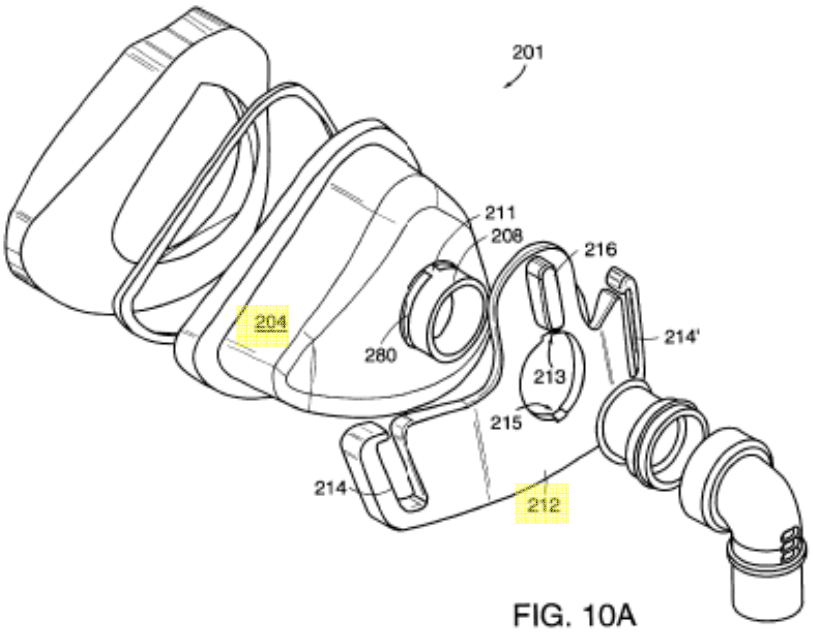


FIG. 10A

To the extent the second frame or its annular connection is somehow required to directly contact and seal with the elbow, such configurations were also well-known. *Id.* ¶¶ 115–116. As shown below in Figure 5a below, Gunaratnam discloses an outer frame with a gas inlet aperture 610 for direct sealing connection to an elbow or conduit. Ex. 1103 at col. 4:22–25.

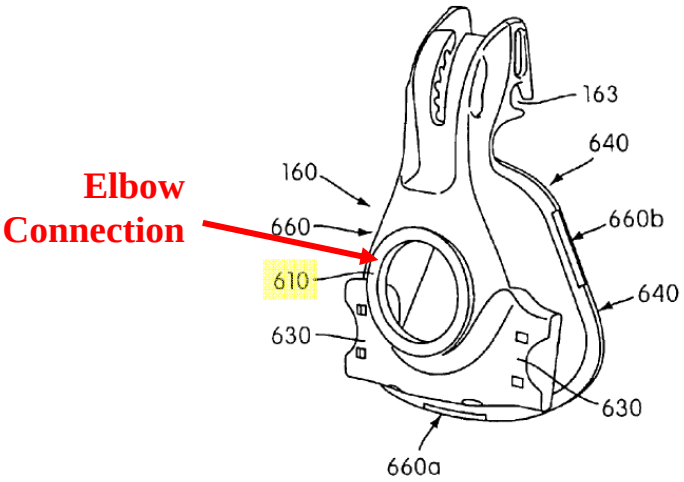


FIG. 5a

A person of skill in the art would have known to sealingly connect the inlet elbow directly with the annular opening of the second frame. Ex. 1105 ¶¶ 117–119. As discussed above, a person of skill would have recognized two viable design options for establishing a sealed connection between the elbow and the breathing chamber of the cushion-frame subassembly: (1) a direct connection between the elbow and the cushion sub-assembly, and (2) a direct connection between the elbow and the second frame with a second connection between the first and second frames. *See supra* § VII(B)(4)(e); Ex. 1105 ¶¶ 117–119.

The first option, as taught by the '061 Patent and Lovell, requires only one sealing connection and has its own advantages. Ex. 1105 ¶ 117.

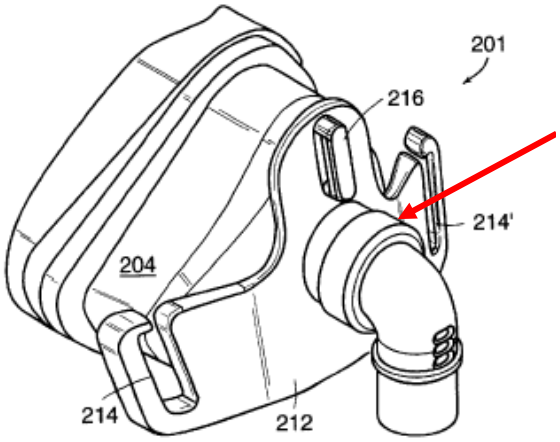


FIG. 9

The second option (*e.g.*, Gunaratnam) requires two separate seals. *Id.* ¶ 118. But a person of skill would have recognized that directly attaching the elbow to the second frame would make it easier for a patient to detach the elbow without affecting the engagement of other mask components. *Id.* ¶ 119.

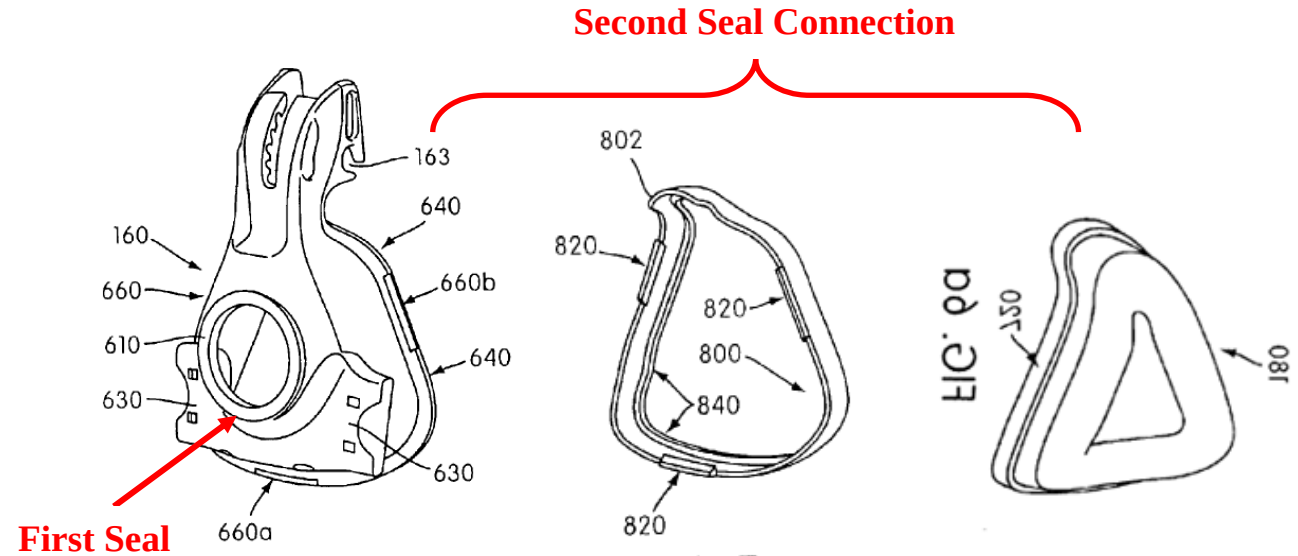


FIG. 5a

FIG. 7a

A person of skill in the art would have selected the second arrangement as one of a finite number of predictable solutions for providing a connection between the interior of the elbow and the breathing chamber. *Id.* ¶ 119; *see also KSR*, 550, U.S. at 421.

k. "snap fit"

Independent Claim 81 includes "wherein the first frame and the second frame snap-fit together."

Lovell discloses a snap-fit connection between the first and second frames. Specifically, Lovell discloses a depressed annular regions 280 (shaded in blue) on the inlet 208 of the first frame 204 that mate with the retaining portions (highlighted in blue) of an annular opening (unlabeled) passing through the second frame 212. Ex. 1102 at col. 9:46–64.

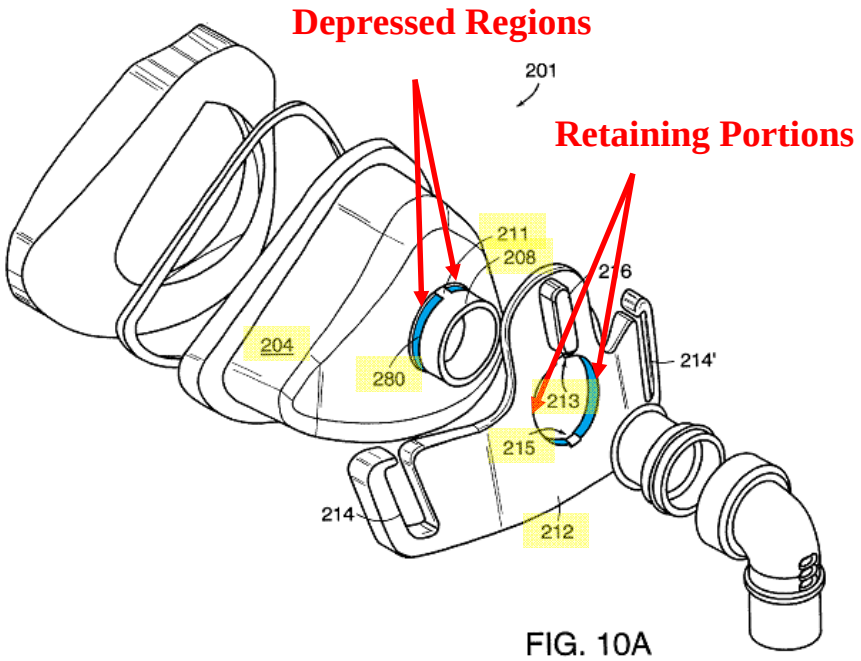


FIG. 10A

The annular opening on the second frame 212 and the inlet 208 are generally sized to form an interference fit so that, when the second frame 212 is fully seated against the first frame, the second frame 212 is properly retained by the cooperation of the tabs 211, 211', the slots 213, 215, and the depressed annular region 280. *Id.*

A person of ordinary skill would have understood that this connection, with the retaining portions on the second frame 212 engaging the inlet 208 with an interference fit and then releasing into the depressed annular regions 280 on the first frame 204, is a snap-fit according to the broadest reasonable interpretation. Ex. 1105 ¶¶ 121–122.

To the extent Lovell somehow provides insufficient teachings for a snap-fit, such snap-fit engagements were common in CPAP masks assemblies. *Id.* ¶¶ 121–126. For example, as shown in Figs. 5c and 7a of Gunaratnam (below), the second frame 160 includes recesses 660a, 660b, and 660c (not shown) to retain the tabs 820 of the first frame 800 in a snap-fit arrangement. Ex. 1103 at col. 5:34–38.

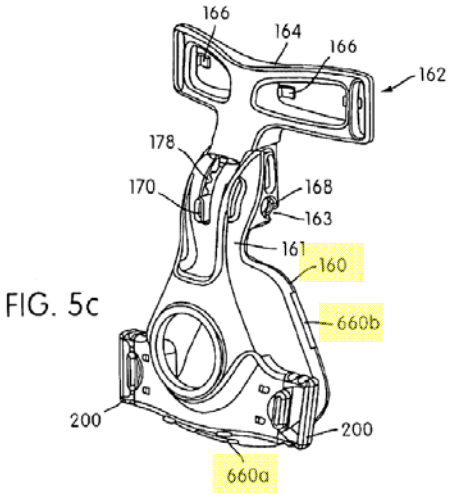


FIG. 5c

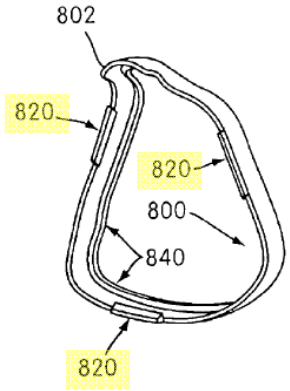
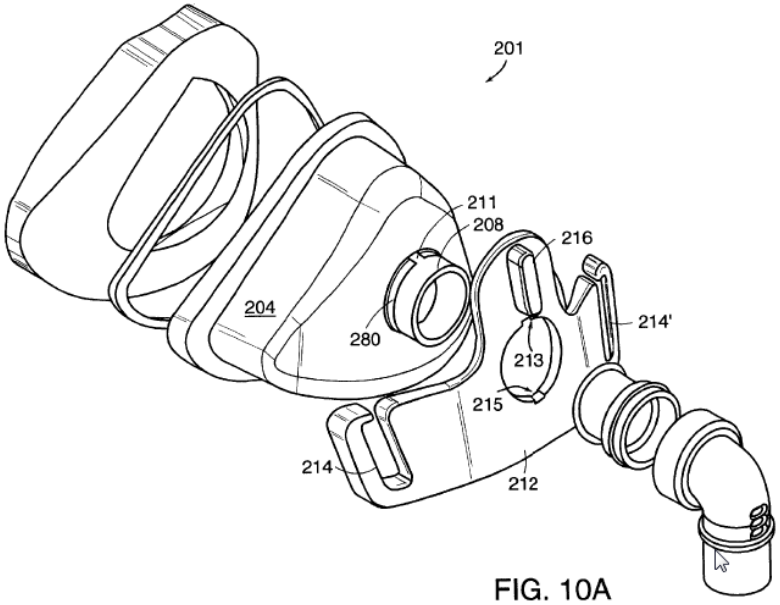


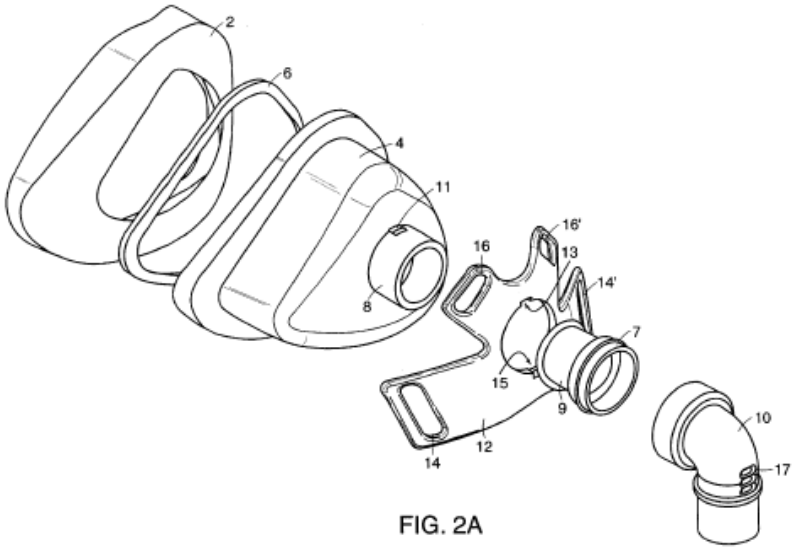
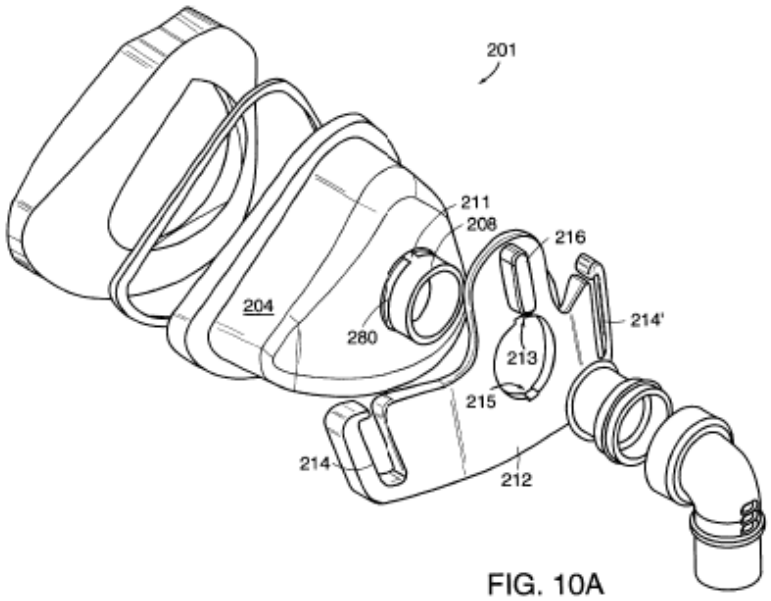
FIG. 7a

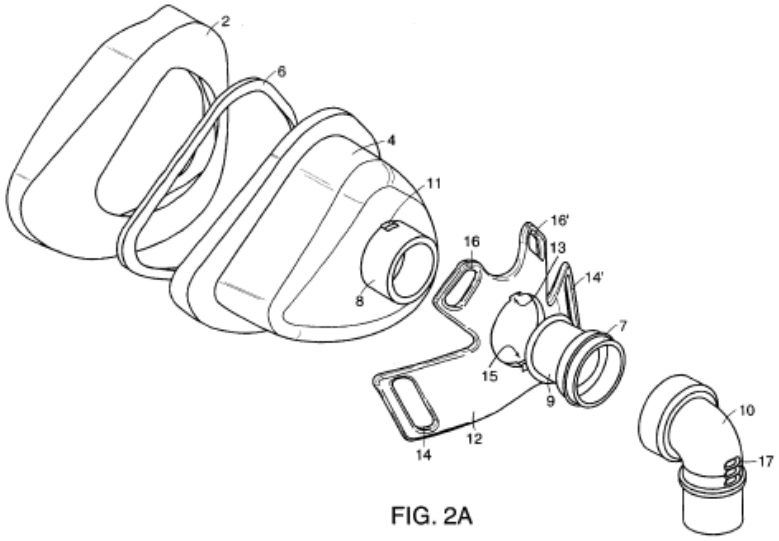
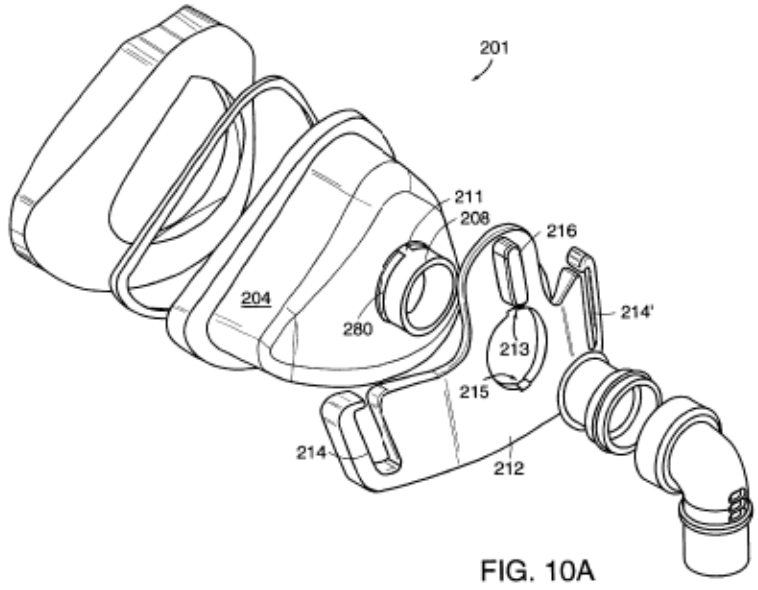
A person of skill would have been motivated to use such a snap-fit engagement to attach the first and second frames to ensure that the mask components are fully attached and aligned correctly. Ex. 1105 ¶ 127. A person of skill would have recognized that a snap-fit arrangement would be advantageous because the snap-fit provides consistent fit and function, regardless of surface condition or contaminants, which could adversely affect retention. *Id.* A person of skill would have also recognized that such a snap-fit arrangement provides repeated assembly/disassembly from the engaged position without destroying parts. *Id.*

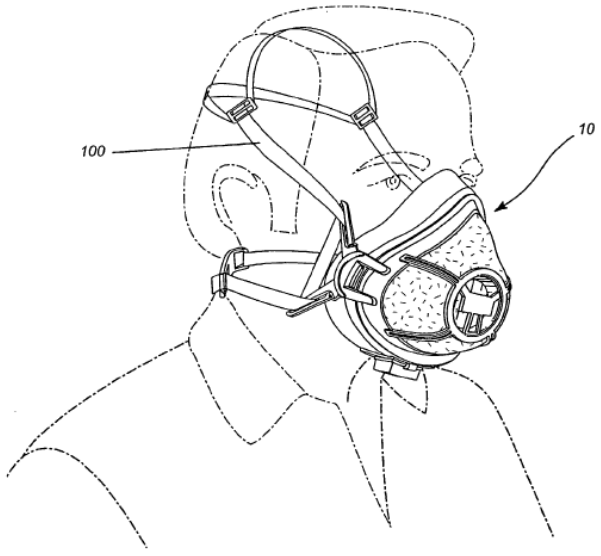
VIII. CLAIM CHARTS

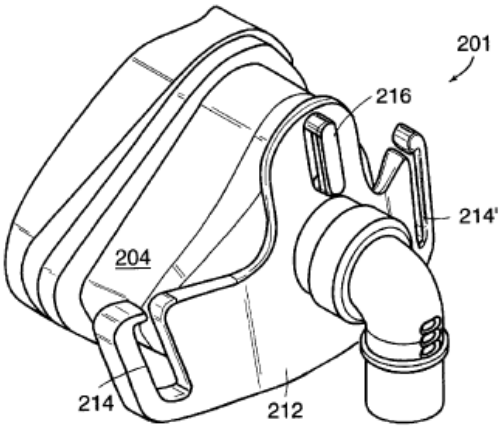
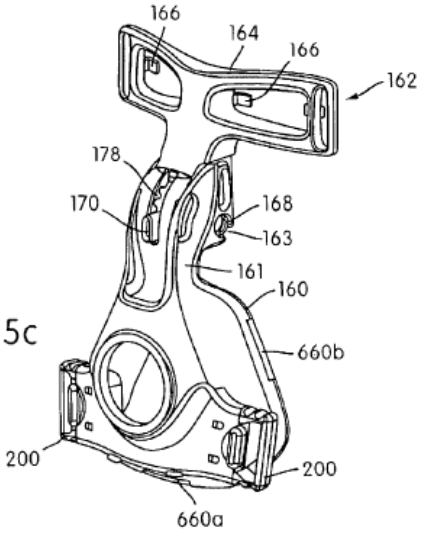
The following claim charts contain specific citations to the teachings of Lovell, Gunaratnam and/or Gelinas that disclose all of the limitations in the Challenged Claims. More detailed claim charts are included in the accompanying Declaration of Mr. Jason Eaton, P.E. Ex. 1105 ¶ 128.

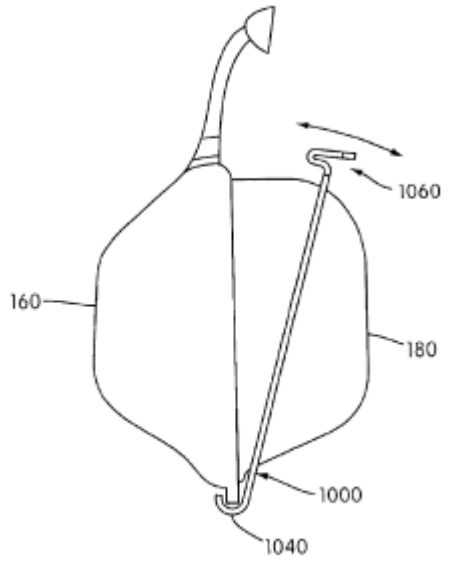
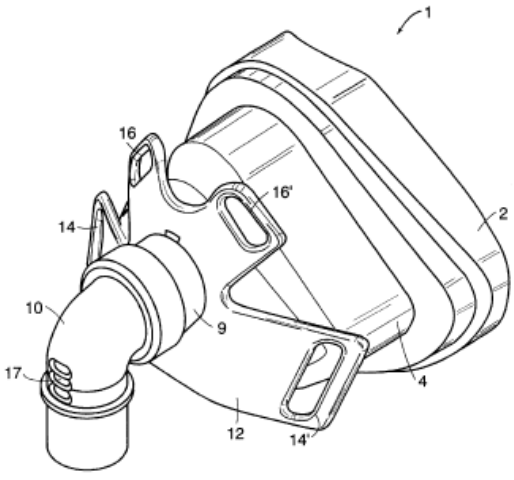
Claim	Prior Art
17. A mask assembly for treatment of sleep disorder breathing by delivering a flow of pressurized gas to a patient, the mask assembly comprising:	**Lovell**: "The present invention provides a comfortable, reliably sealing nasal mask for delivering a breathable gas to a user. . . . Nasal masks according to the invention . . . are useful for treating respiratory ailments in a recumbent or sleeping user." Ex. 1102 at col. 4:11–19.  FIG. 10A

[A] a first frame made of first material;	**Lovell**: "[S]hell 4, typically is manufactured from a flexible material by a molding process using a compliant polymer. For example, but without limitation, one compliant material is Pellethane™." Ex. 1102 at col. 4:40–44.  FIG. 2A Nasal mask 201, shown in Figs. 9–11, has many of the features of the nasal mask 1 shown in Figs. 1–8. *Id.* at col. 9:34–36.  FIG. 10A

[B] a cushion connected to the first frame, the cushion being adapted to form a seal around a patient's nose and mouth and being made from a second material that is more flexible than the first material; and	**Lovell**: "[N]asal mask 1 according to the invention includes a seal 2 affixed to a shell 4, for example by bonding." Ex. 1102 at cols. 4:34–36. "[T]he seal 2 is a bladder that is formed from a film 60, 64 and that is filled with a soft material 62. . . . [C]ertain types of silicone gel meet this durometer value" *Id.* at col. 7:45–58. "The chamber 80 is substantially leakage-free due to the . . . the conformance of the seal 2 against a user's skin." *Id*. at col. 4:55–58.  FIG. 2A Nasal mask 201, shown in Figs. 9–11, has many of the features of the nasal mask 1 shown in Figs. 1–8. *Id.* at col. 9:34–36.  FIG. 10A

	Gunaratnam: "The invention is also suitable for a full-face mask system. FIGS. 8a–15 show several exploded views of a Mirage® full-face mask which includes an embodiment of the invention, including a mask frame (160), cushion (180) and clip (800)." Ex. 1103 at col. 6:3–7, Figure 8. "The frame (160) is adapted to cover both the mouth and nose region of the patient's face . . . ." *Id.* at col. 6:25–26. "[F]rame (160) is constructed as a substantially rigid shell of polycarbonate or similar transparent plastics material . . . ." *Id*. at col. 4:22–24. "The cushion is formed of soft material such as silicone, and projects rearwardly of the mask frame so as to space the rigid frame away from the patient's face." *Id*. at col. 5:22–24. **Gelinas:** "[F]irst part 90 defines a continuous seal for sealingly engaging the face of the wearer and covering the mouth and nose of the wearer." Ex. 1104 ¶ 27.  *Fig. 1*

[C] a second frame adapted to constrain the first frame, the second frame comprising an upper support member that supports a forehead support,	**Lovell**: "The retainer 212 is disposed about the inlet 208 to facilitate retention of the mask 201 on a user." Ex. 1102 at col. 9:43–44. "[U]pper connection point 216 in concert with an upper retention strap provides additional retention force on the upper portion of the nasal mask 201, proximate a user's eyes, to ensure sealing along the bridge of the nose and prevent annoying air leaks." *Id.* at col. 10:7–11.  FIG. 9 **Gunaratnam**: "FIGS. 5c-5f also show an adjustable forehead support (162) connected to the frame (160). The adjustable forehead support (162) includes a bridge portion (164) adapted to locate . . . pads (not shown) adapted to contact the forehead of the patient." Ex. 1103 at col. 4:47–52.  FIG. 5c

	See also frame 160 of Fig. 16a of Gunaratnam.  FIG. 16a
[D] two lower headgear clip attachments engaged with clips provided to straps of a headgear assembly,	**Lovell**: "[F]our connection points disposed remotely from the inlet 8, two lower connection points 14, 14' and two upper connection points 16, 16' . . . and all connection points 14, 14', 16, 16' are disposed symmetrically about a vertical centerline A—A of the mask 1." Ex. 1102 at col. 6:2–10. "[C]onnection points 14, 14', 16, 16' form slots which allow for connection of the retainer 12 with straps of a headgear apparatus." *Id*. at col. 6:10–19.  FIG. 1 "The retainer 212 has three connection points disposed remotely from the inlet 208, two lower connection

points 214, 214' and one upper connection point 216." *Id.* at col. 9:49–53. "Further, once the straps are adjusted a first time, they need not be adjusted again, merely being slipped out of the lower connection points 214, 214' by the notches." *Id*. at col. 10:41–44. Lovell also recognizes that alternate attachment structures such as "snaps, hook and eye closures, hook and loop fasteners, or the like, may be employed." *Id*. at col. 6:10–19.

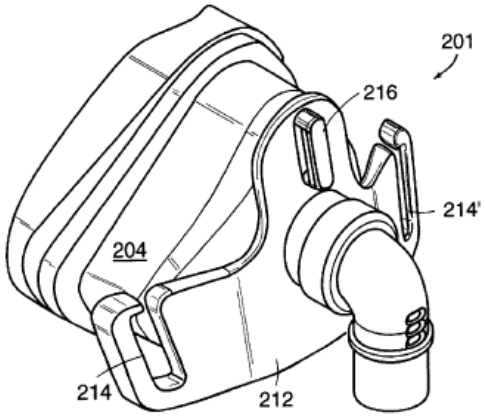


FIG. 9

Gunaratnam: "On the front surface of the frame, are strap connection points (630) for connection of the mask to patient headgear. Connectors (200) are shown in FIGS. 5c-5f." Ex. 1103 at col. 4:31–34.

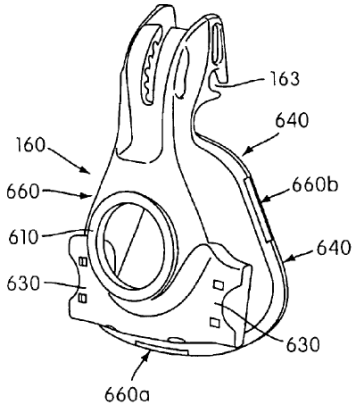


FIG. 5a

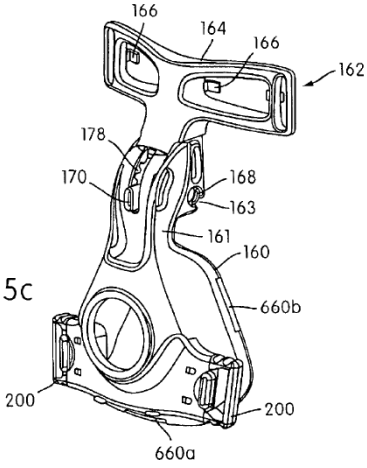
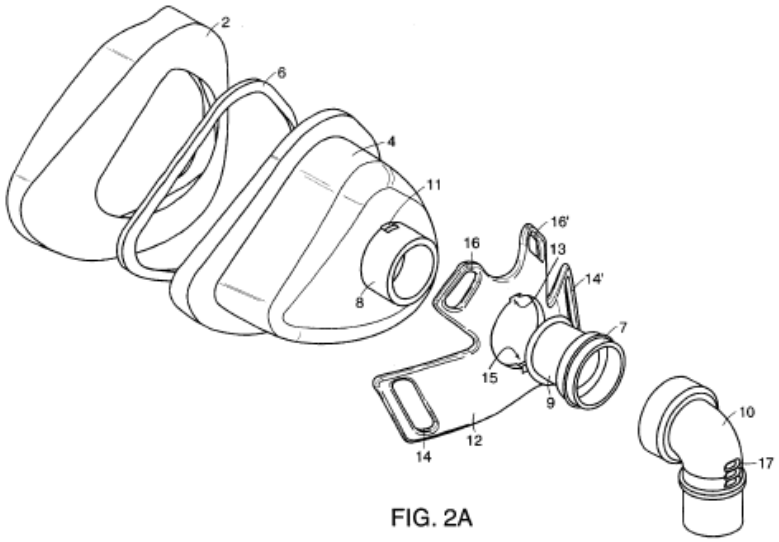
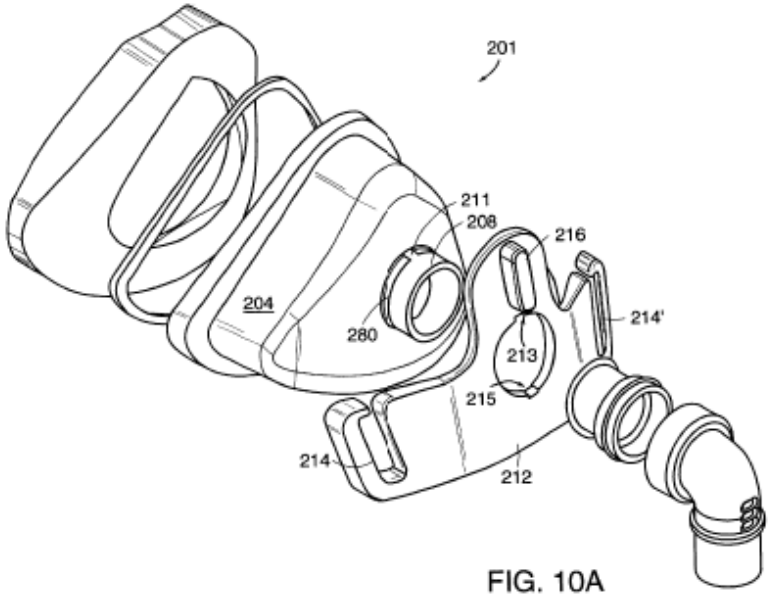
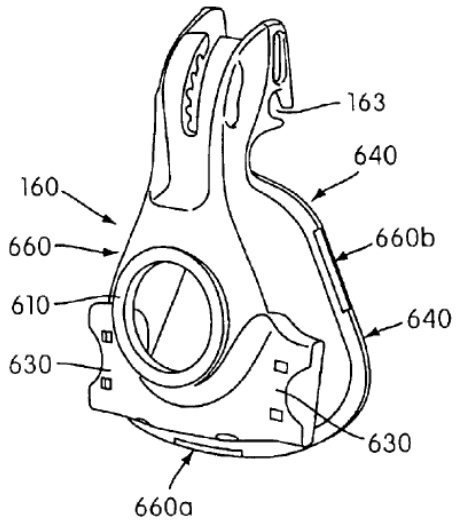
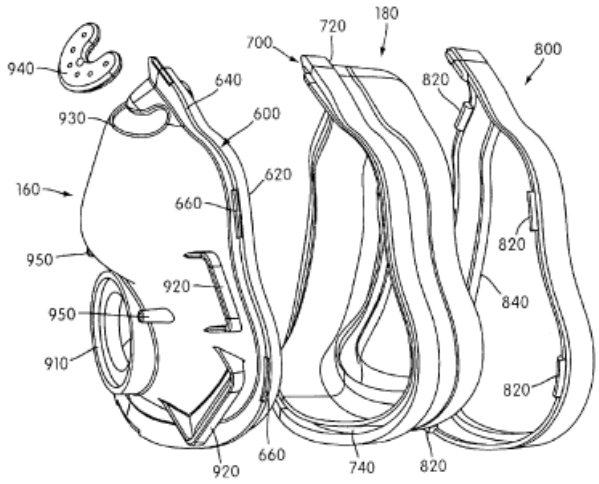
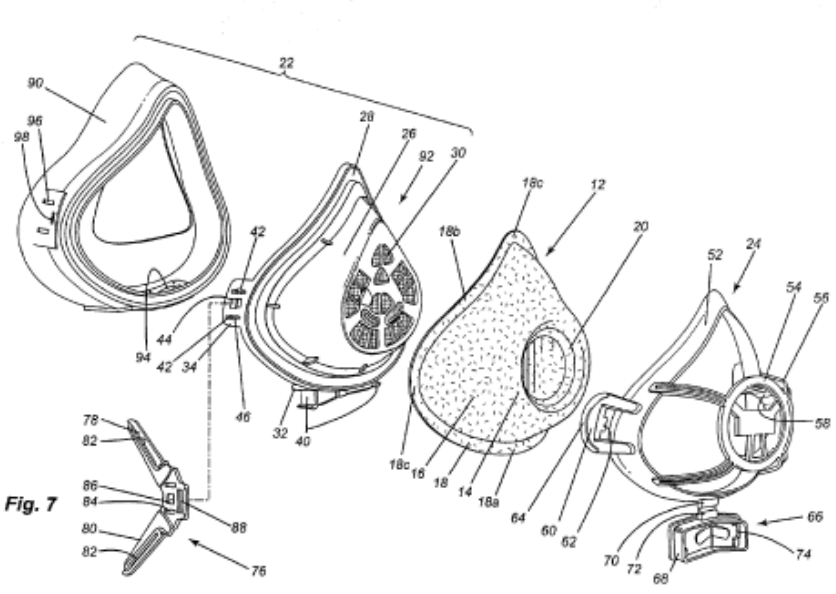


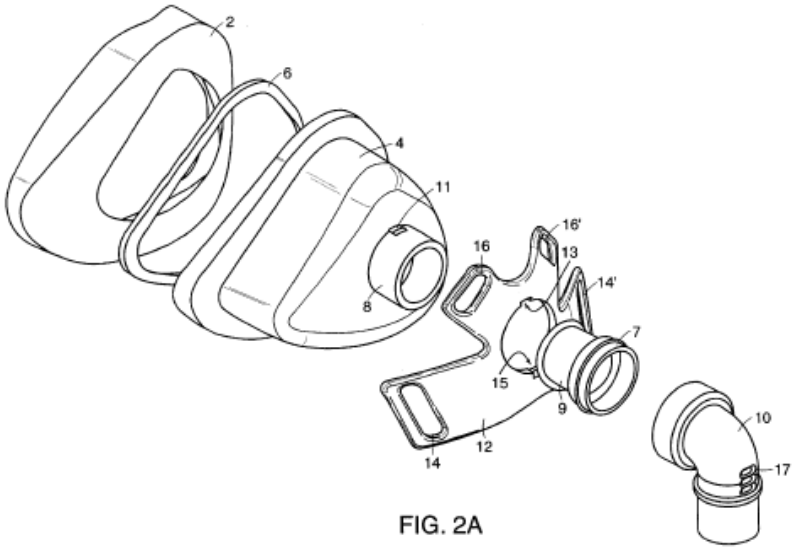
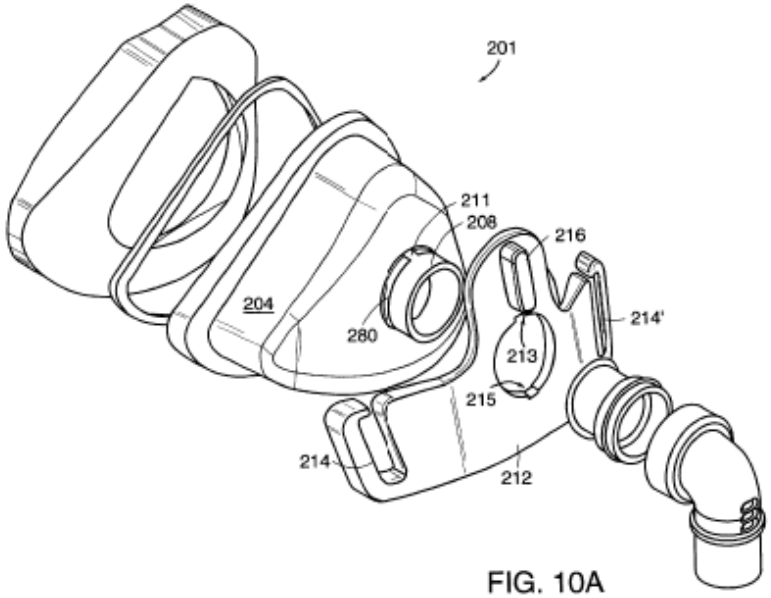
FIG. 5c

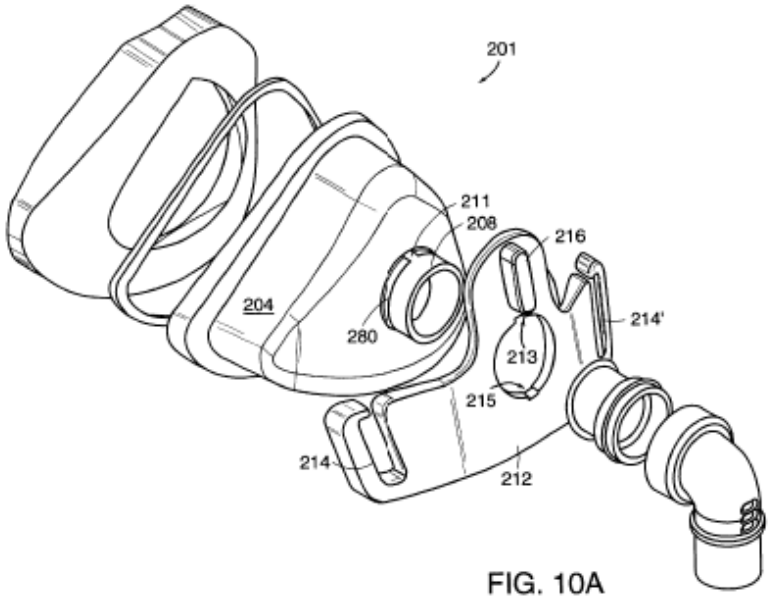
[E] an annular connection adapted to engage an elbow of an inlet conduit and	**Lovell**: "The nasal mask 1 also forms an inlet 8 with which a swivel connector 9 or other connector for a conduit mates." Ex. 1102 at col. 5:9–10.  FIG. 2A Nasal mask 201, shown in Figs. 9–11, has many of the features of the nasal mask 1 shown in Figs. 1–8. *Id.* at col. 9:34–36. "[R]etainer 212 is disposed about the inlet 208 to facilitate retention of the mask 201 on a user. The retainer 212 is contoured such that it approximately matches the external curvature of the contoured shell 204." *Id.* at col. 9:43–48.  FIG. 10A

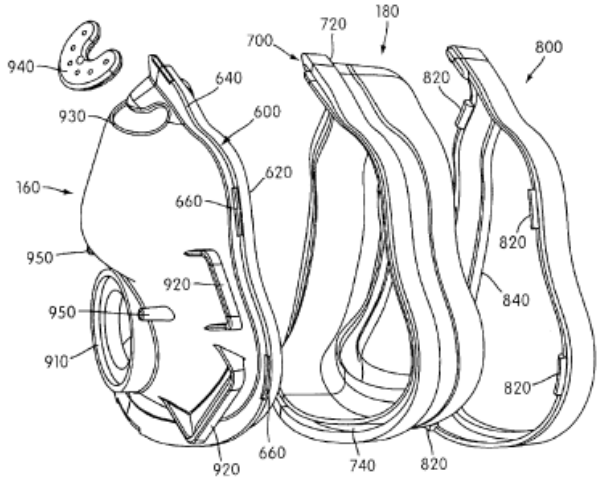
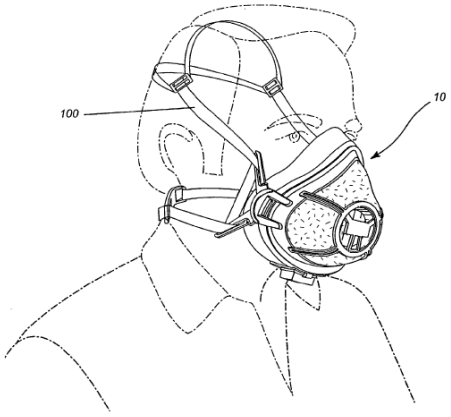
	Gunaratnam: "The frame 160 . . . incorporates a gas inlet aperture (610) for connection to a gas delivery conduit (not shown) of a patient gas delivery system." Ex. 1103 at col. 4:22–26.  FIG. 5a

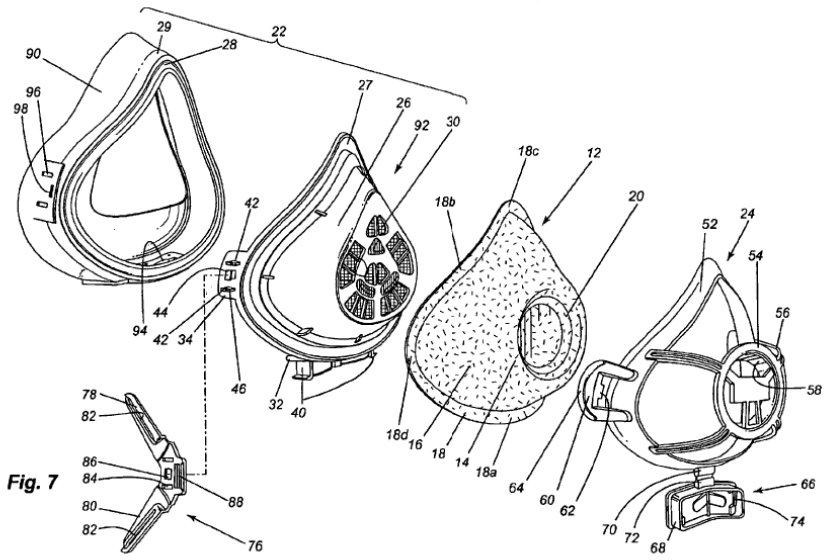
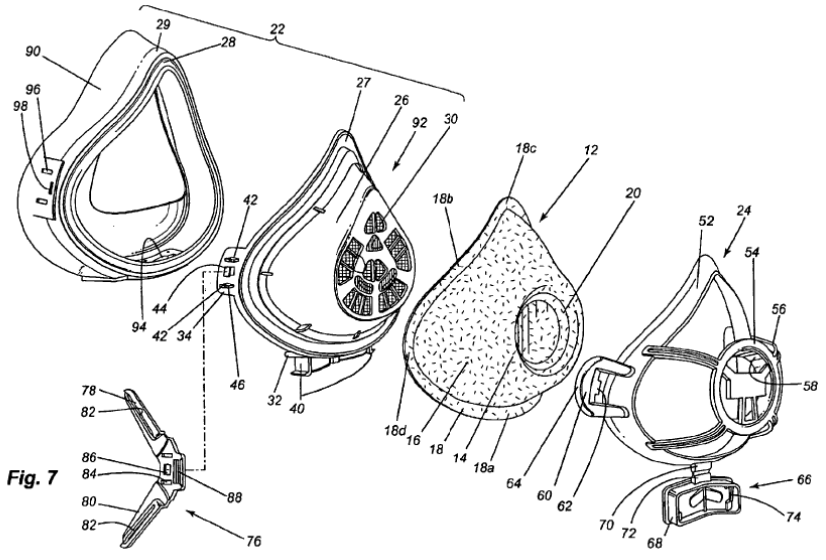
[F] an opening located between the annular connection and the upper support member, the opening providing access to the first frame.	**Gunaratnam**: "The frame (160) is adapted to cover both the mouth and nose region of the patient's face, and includes, a gas inlet aperture (910), connection points (920) for headgear straps, an aperture (930) for receiving an air vent (940) (FIG. 15) and ports (950)." Ex. 1103 at col. 6:25–29, Figures 8a and 15.  FIG. 15 **Gelinas**: "Cover 24 comprises a peripheral portion 52 and a ring 54, peripheral portion 52 and ring 54 being connected together by four branches 56. Peripheral portion 52 has a continuous surface 53 that surrounds the mouth and nose of the wearer. Ring 54 comprises an annular band 58 that extends inwardly therefrom." Ex. 1104 ¶ 32.  Fig. 7

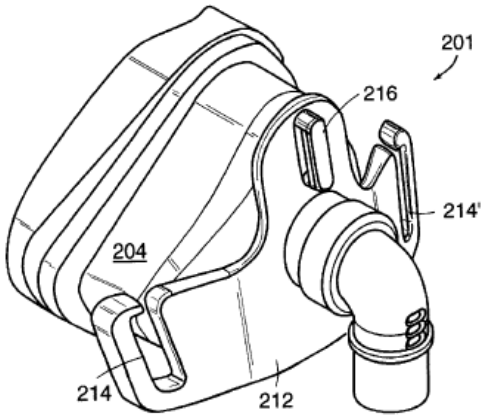
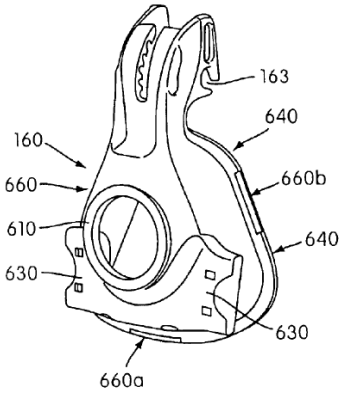
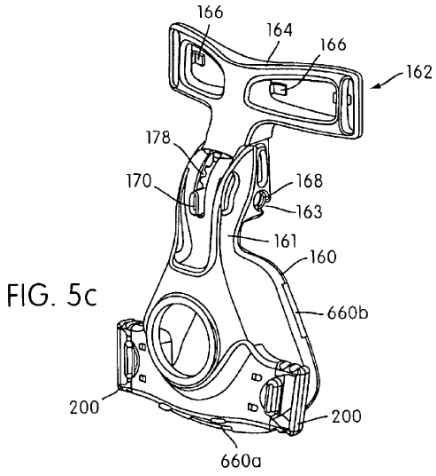
18. The mask assembly according to claim 17, wherein the first frame and the cushion are integrally molded in one piece to provide a cushion-frame sub-assembly.	**Lovell**: "[O]ne embodiment of a nasal mask 1 according to the invention includes a seal 2 affixed to a shell 4, for example by bonding." Ex. 1102 at cols. 4:34–36. "The chamber 80 is substantially leakage-free due to the bond or interface between the seal 2 and the shell 4." *Id*. at col. 4:55–58. **Gelinas:** "[F]irst part 90 can be secured to second part 92 by different means such as mechanical securing means, chemical affixing means or through-molding processes." Ex. 1104 ¶ 26.
20. The mask assembly according to claim 17, wherein the first frame is contoured to fit over the patient's nose and mouth.	**Lovell**: "[S]hell 4 has a generally triangular shape that is convex and is contoured such that a chamber 80 is formed by the sides of the shell 4 for receiving therein a patient's nose." Ex. 1102 at col. 4:47–49. **Gunaratnam**: "The frame may be constructed from a material such as polycarbonate, forming a cavity which overlies the patient's nose and/or mouth." Ex. 1103 at col. 1:34–36. "The invention is also suitable for a full-face mask system. FIGS. 8a-15 show several exploded views of a Mirage® full-face mask which includes an embodiment of the invention." *Id*. at col. 6:3–6. **Gelinas:** "[F]irst part 90 defines a continuous seal for sealingly engaging the face of the wearer and covering the mouth and nose of the wearer." Ex. 1104 ¶ 27.

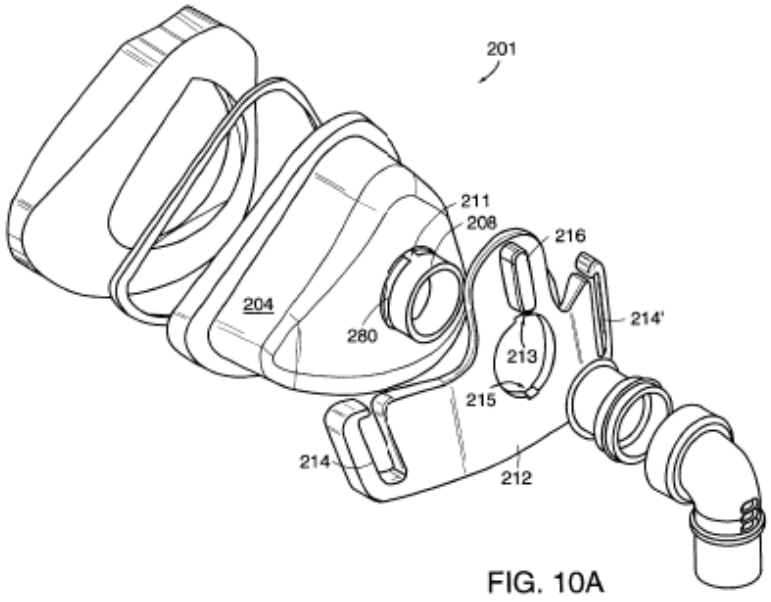
21. The mask assembly according to claim 17, wherein the first frame comprises an opening that provides a flow path adapted to communicate with the inlet conduit.	**Lovell**: "The nasal mask 1 also forms an inlet 8 with which a swivel connector 9 or other connector for a conduit mates." Ex. 1102 at col. 5:9–10.  FIG. 2A Nasal mask 201, shown in Figs. 9–11, has many of the features of the nasal mask 1 shown in Figs. 1–8. *Id.* at col. 9:34–36.  FIG. 10A

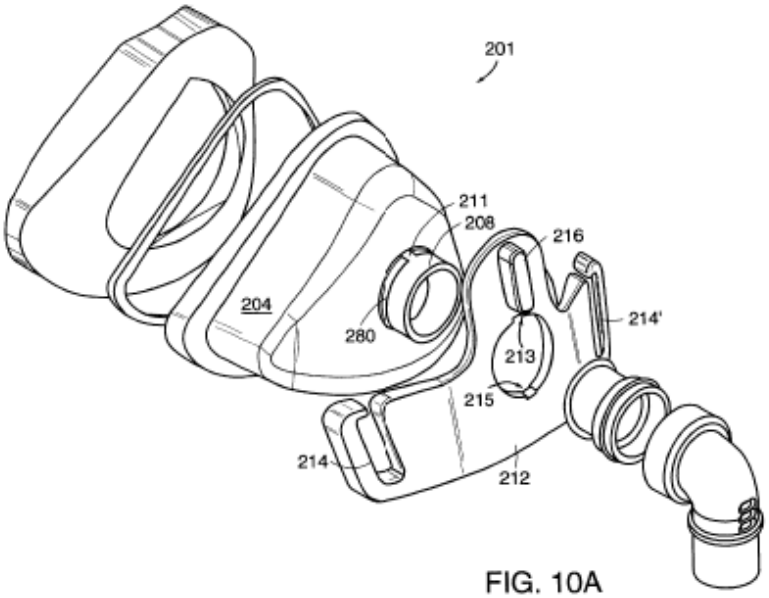
22. The mask assembly according to claim 17, wherein the second frame includes contact points to prevent rotation of the first frame with respect to the second frame.	**Lovell**: "Two tabs 211, 211' included on the inlet 208 mate with two slots 213, 215 formed in the retainer 212 in a particular angular orientation." Ex. 1102 at col. 9:46–48.  FIG. 10A

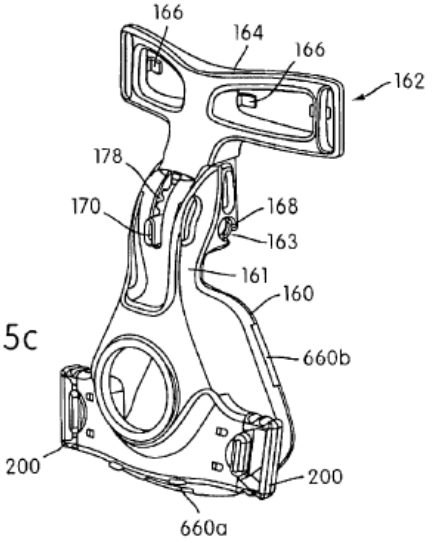
23. The mask assembly according to claim 17, wherein the first frame and the cushion together form a breathing chamber around the patient's nose and mouth.	**Lovell**: "The shell 4 has a generally triangular shape that is convex and is contoured such that a chamber 80 is formed by the sides of the shell 4 for receiving therein a patient's nose . . . ." Ex. 1102 at col. 4:47–49. **Gunaratnam**: "The frame may be constructed from a material such as polycarbonate, forming a cavity which overlies the patient's nose and/or mouth." Ex. 1103 at col. 1:34–37. "The invention is also suitable for a full-face mask system. FIGS. 8a-15 show several exploded views of a Mirage® full-face mask which includes an embodiment of the invention." *Id*. at col. 6:3–6.  FIG. 15 **Gelinas:** "[F]irst part 90 defines a continuous seal for sealingly engaging the face of the wearer and covering the mouth and nose of the wearer." Ex. 1104 ¶ 27.  Fig. 1

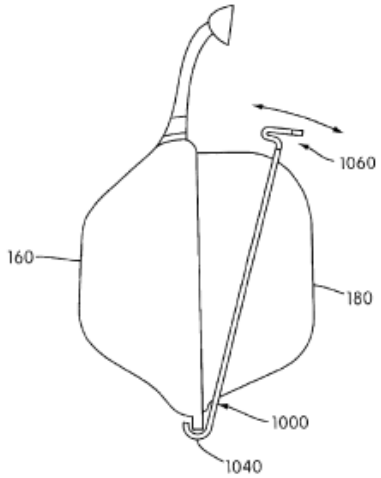
26. The mask assembly according to claim 17, wherein the second frame comprises two connecting members that connect a lower portion of the second frame to the upper support member and the opening is located between the two connecting members.	**Gelinas**: "Cover 24 comprises a peripheral portion 52 and a ring 54, peripheral portion 52 and ring 54 being connected together by four branches 56. Peripheral portion 52 has a continuous surface 53 that surrounds the mouth and nose of the wearer. Ring 54 comprises an annular band 58 that extends inwardly therefrom." Ex. 1104 ¶ 32.  Fig. 7
27. The mask assembly according to claim 17, wherein the opening is substantially triangular.	**Gelinas**: "Flange portion 18 defines a generally triangular figure." *See* Ex. 1104 ¶ 25, Figure 7.  Fig. 7

28. The mask assembly according to claim 17, wherein the two lower headgear clip attachments are adjacent to and on opposite lateral sides of the annular connection.	**Lovell**: "The retainer 212 has three connection points disposed remotely from the inlet 208, two lower connection points 214, 214' and one upper connection point 216." Ex. 1102 at col. 9:49–53. "Further, once the straps are adjusted a first time, they need not be adjusted again, merely being slipped out of the lower connection points 214, 214' by the notches." *Id*. at col. 10:41–44. Lovell also recognizes that alternate attachment structures such as "snaps, hook and eye closures, hook and loop fasteners, or the like, may be employed." *Id*. at col. 6:10–19.  FIG. 9 **Gunaratnam:** "On the front surface of the frame, are strap connection points (630) for connection of the mask to patient headgear." Ex. 1103 at col. 4:32–34, Figures 5a and 5c.  FIG. 5a  FIG. 5c

29. The mask assembly according to claim 17, wherein the first frame is releasably secured to the second frame by way of an interlocking and/or frictional fit.	**Lovell**: "The retainer aperture and the inlet 208 are generally sized in an interference fit so that the retainer 212 is properly retained by the cooperation of the tabs 211, 211', the slots 213, 215, and the depressed annular region 280 when fully seated against the shell 204." Ex. 1102 at col. 9:59–64.  FIG. 10A **Gunaratnam**: "To disengage, for example for cleaning of the mask assembly or replacement of the cushion, the detents may be forced outwardly against their natural resilience to release from the recesses (660) and ride over the outer edge of flange (640)" Ex. 1103 at col. 5:38–42.

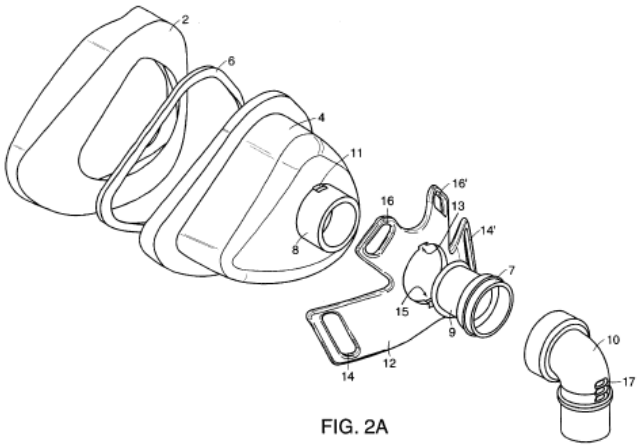
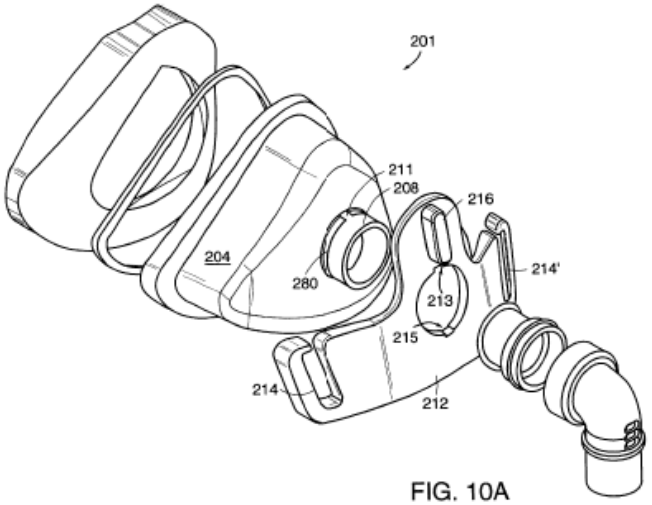
30. The mask assembly according to claim 17, wherein the first frame and the second frame have complementary shapes.	**Lovell**: "[R]etainer 212 is contoured such that it approximately matches the external curvature of the contoured shell 204." Ex. 1102 at col. 9:44–46. "[A] depressed annular region 280 on the inlet 208 mates with the edges of an aperture passing through the retainer 212. The retainer aperture and the inlet 208 are generally sized in an interference fit so that the retainer 212 is properly retained by the cooperation of the tabs 211, 211', the slots 213, 215, and the depressed annular region 280 when fully seated against the shell 204." *Id.* at col. 9:46–64.  FIG. 10A
32. A mask assembly for treatment of sleep disorder breathing by delivering a flow of pressurized gas to a patient, the mask assembly comprising:	*See supra* Claim 17[Preamble].
a first frame made of first material;	*See supra* Claim 17[A].
a cushion connected to the first frame, the cushion being adapted to form a seal around a	*See supra* Claim 17[B].

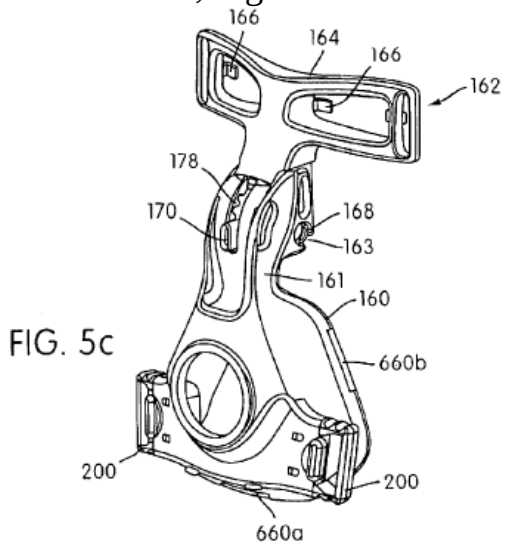
patient's nose and mouth and being made from a second material that is more flexible than the first material,	
the first frame and the cushion together forming a breathing chamber; and	*See supra* Claim 23.
a second frame adapted to constrain the first frame, the second frame comprising an upper support member adapted to assist with forehead support,	*See supra* Claim 17[C]. **Lovell**: "The retainer 212 is disposed about the inlet 208 to facilitate retention of the mask 201 on a user." Ex. 1102 at col. 9:43–44. "The upper connection point 216 in concert with an upper retention strap provides additional retention force on the upper portion of the nasal mask 201." *Id*. at col. 10:7–11. **Gunaratnam**: "FIGS. 5c-5f also show an adjustable forehead support (162) connected to the frame (160). The adjustable forehead support (162) includes a bridge portion (164) adapted to locate . . . pads (not shown) adapted to contact the forehead of the patient." Ex. 1103 at col. 4:47–52.  FIG. 5c

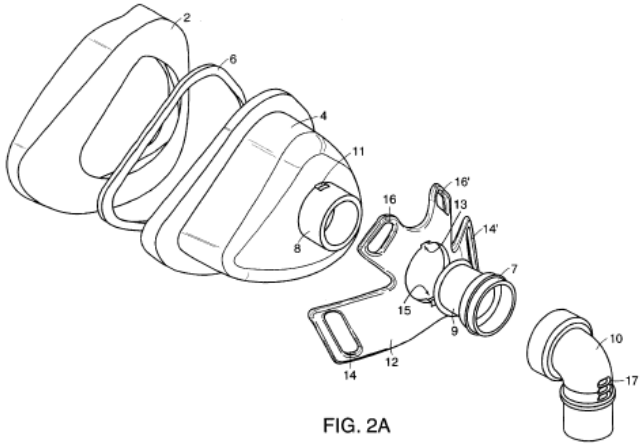
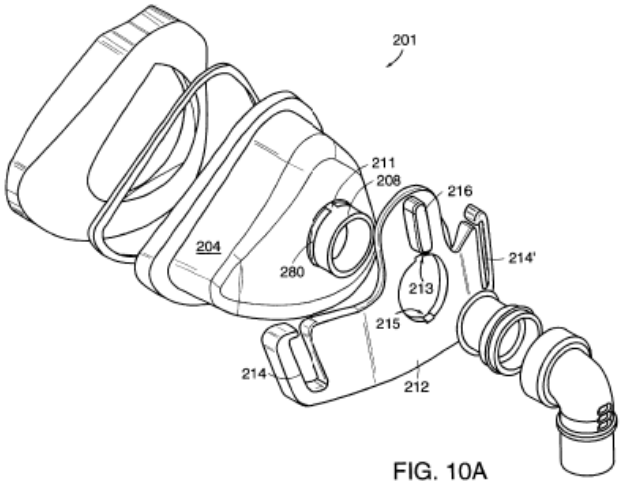
	See also frame 160 of Fig. 16a of Gunaratnam.  FIG. 16a
two lower headgear clip attachments engaged with clips provided to straps of a headgear assembly,	*See supra* Claim 17[D].
an annular opening adapted to allow an elbow to provide pressurized gas to the patient, and	*See supra* Claim 17[E]. **Lovell**: "[N]asal masks useful for providing pressurized air or therapeutic gas to a patient suffering from an airflow limitation or other respiratory ailment." Ex. 1102 at col. 1:5–8.
a separate opening located between the annular opening and the upper support member, the separate opening providing access to the first frame while the mask assembly is fully assembled.	*See supra* Claim 17[F].
33. The mask assembly according to claim 32, wherein the first frame and the	*See supra* Claim 18.

cushion are integrally molded in one piece to provide a cushion-frame sub-assembly.	
35. The mask assembly according to claim 32, wherein the first frame is contoured to fit over the patient's nose and mouth.	*See supra* Claim 20.
36. The mask assembly according to claim 32, wherein the first frame comprises a frame-opening that provides a flow path adapted to communicate with the elbow.	*See supra* Claim 21.
37. The mask assembly according to claim 32, wherein the second frame includes contact points contacting the first frame to prevent rotation of the first frame with respect to the second frame.	*See supra* Claim 22.
38. The mask assembly according to claim 32, wherein the first frame and the cushion together form the breathing chamber around the patient's nose and mouth.	*See supra* Claim 23.

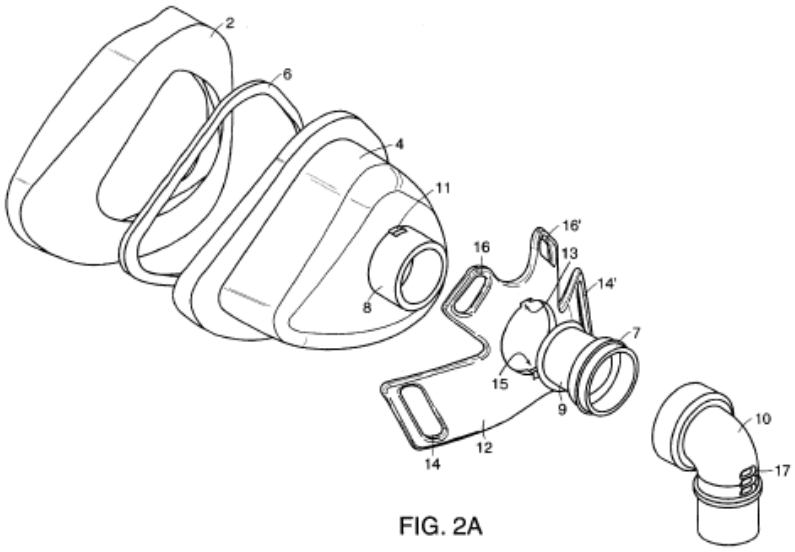
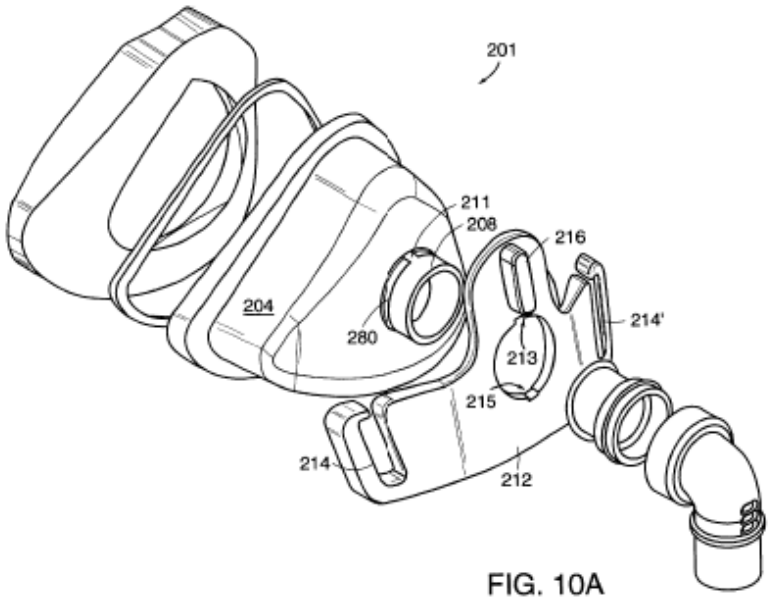
41. The mask assembly according to claim 32, wherein the second frame comprises two connecting members that connect a lower portion of the second frame to the upper support member, and the separate opening is located between the two connecting members.	*See supra* Claim 26.
42. The mask assembly according to claim 32, wherein the separate opening is substantially triangular.	*See supra* Claim 27
43. The mask assembly according to claim 32, wherein the two lower headgear clip attachments are adjacent to and on opposite lateral sides of the annular opening.	*See supra* Claim 28
44. The mask assembly according to claim 32, wherein the first frame is releasably secured to the second frame by way of an interlocking and/or frictional fit.	*See supra* Claim 29

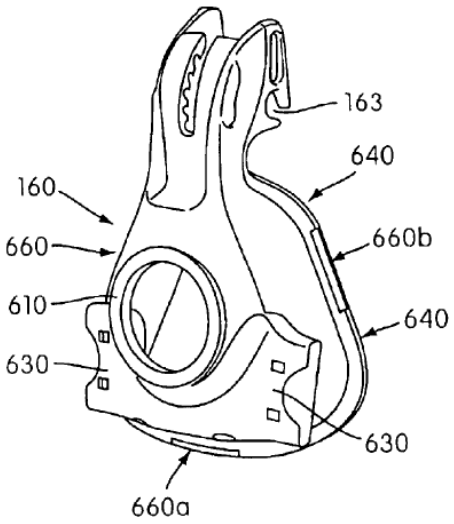
45. The mask assembly according to claim 32, wherein the first frame and the second frame have complementary shapes.	*See supra* Claim 30
46. The mask assembly according to claim 32, wherein the annular opening and the elbow are sealingly connected.	**Lovell**: "The nasal mask 1 also forms an inlet 8 with which a swivel connector 9 or other connector for a conduit mates." Ex. 1102 at col. 5:9–10.  FIG. 2A Nasal mask 201, shown in Figs. 9–11, has many of the features of the nasal mask 1 shown in Figs. 1–8. *Id.* at col. 9:34–36. "[R]etainer 212 is disposed about the inlet 208 to facilitate retention of the mask 201 on a user. The retainer 212 is contoured such that it approximately matches the external curvature of the contoured shell 204." *Id.* at col. 9:43–48.  FIG. 10A

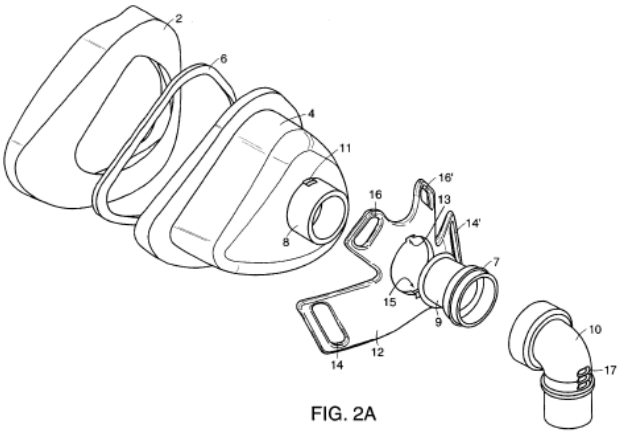
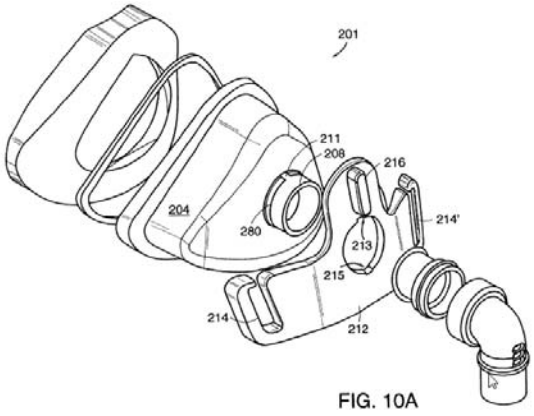
	Gunaratnam: "The frame 160 . . . incorporates a gas inlet aperture (610) for connection to a gas delivery conduit (not shown) of a patient gas delivery system." Ex. 1103 at col. 4:22–26, Figures 5a–5f.  FIG. 5c
48. The mask assembly according to claim 32, wherein the first frame and the cushion are integrally molded in one piece to provide a cushion-frame sub-assembly,	*See supra* Claim 18
the cushion is contoured to fit the patient's nose and mouth,	*See supra* Claim 20
the first frame comprises a frame-opening that allows for a flow path to communicate the elbow with an interior of the first frame,	*See supra* Claim 21.

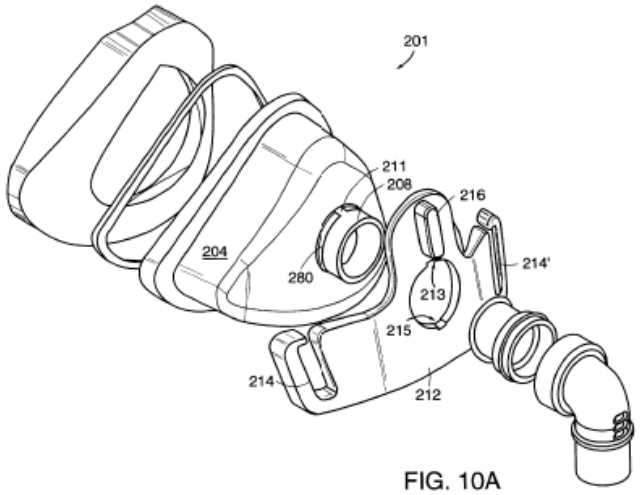
the second frame includes contact points that prevent rotation of the first frame with respect to the second frame,	*See supra* Claim 22.
the first frame and the cushion together form the breathing chamber around the patient's nose and mouth,	*See supra* Claim 23
the cushion comprises a face contacting portion that contacts a patient's face,	**Lovell**: "The chamber 80 is substantially leakage-free due to . . . the conformance of the seal 2 against a user's skin." Ex. 1102 at col. 4:55–58.  FIG. 2A Nasal mask 201, shown in Figs. 9–11, has many of the features of the nasal mask 1 shown in Figs. 1–8. *Id.* at col. 9:34–36.  FIG. 10A

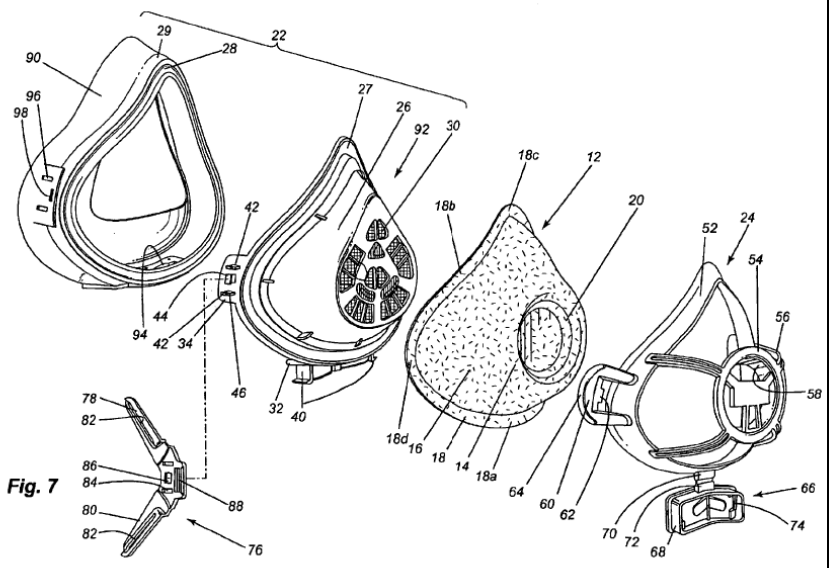
the second frame comprises two connecting members that connect a lower portion of the second frame to the upper support member and the separate opening is located between the two connecting members,	*See supra* Claim 26
the two lower headgear clip attachments are adjacent to and on opposite lateral sides of the annular opening,	*See supra* Claim 28.
the annular opening and the elbow are sealingly connected, and	*See supra* Claim 46.
the first frame is releasably secured to the second frame by way of an interlocking and/or frictional fit.	*See supra* Claim 29.
49. The mask assembly according to claim 48, wherein the separate opening is substantially triangular and the first frame and the second frame have complementary shapes.	*See supra* Claims 27 and 30.

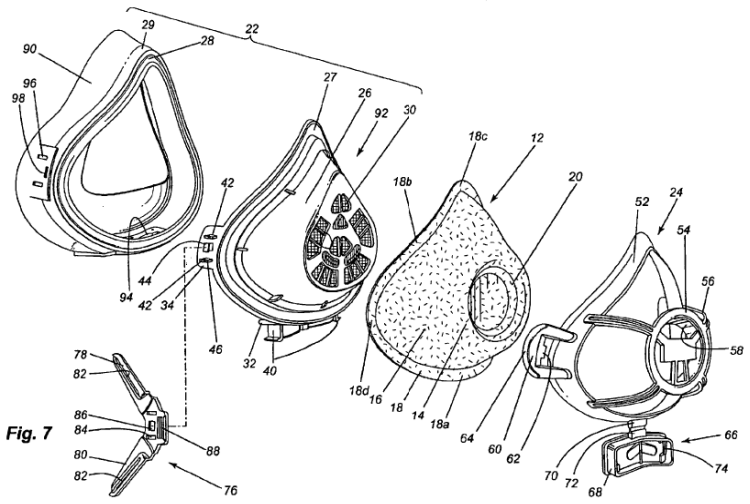
50. The mask assembly according to claim 48, wherein the elbow engages the second frame.	**Lovell**: "The nasal mask 1 also forms an inlet 8 with which a swivel connector 9 or other connector for a conduit mates." Ex. 1102 at col. 5:9–10.  FIG. 2A "[R]etainer 212 is disposed about the inlet 208 to facilitate retention of the mask 201 on a user." *Id.* at col. 9:43–48.  FIG. 10A

	Gunaratnam: "The frame 160 . . . incorporates a gas inlet aperture (610) for connection to a gas delivery conduit (not shown) of a patient gas delivery system." Ex. 1103 at col. 4:22–26.  FIG. 5a
81. A mask assembly for treatment of sleep disorder breathing by delivering a flow of pressurized gas to a patient, the mask assembly comprising:	*See supra* Claim 17[Preamble].
a first frame made of first material;	*See supra* Claim 17[A].
a cushion connected to the first frame, the cushion being adapted to form a seal around a patient's nose and mouth and being made from a second material that is more flexible than the first material,	*See supra* Claim 17[B].
the first frame and the cushion together forming a breathing	*See supra* Claim 23.

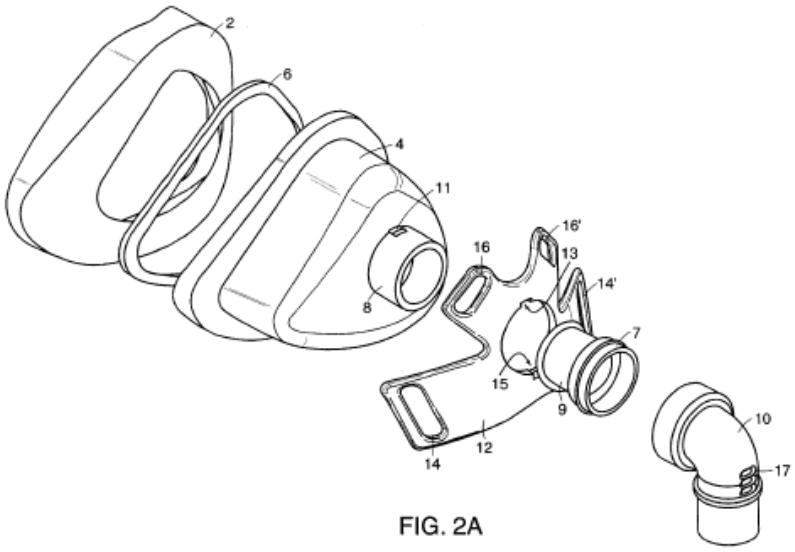
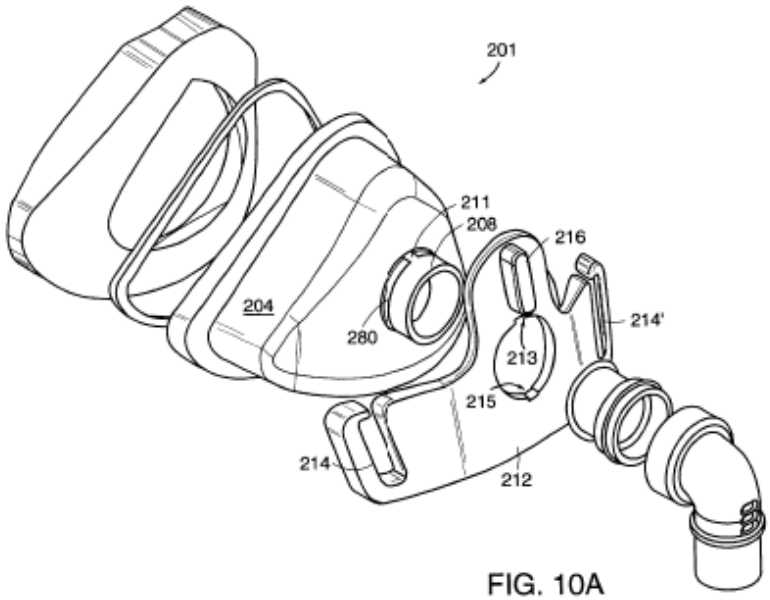
chamber; and	
a second frame adapted to constrain the first frame, the second frame comprising an upper member,	*See supra* Claim 17[C].
a lower member with an annular opening adapted to allow an inlet conduit to provide pressurized gas to the patient, and	**Lovell**: "The nasal mask 1 also forms an inlet 8 with which a swivel connector 9 or other connector for a conduit mates." Ex. 1102 at col. 5:9–10. "Conduit elbow 10, connected to the inlet 8, allows for gas from a breathable gas source to flow through the conduit elbow 10, past the apertures 17, and into the cavity 80 formed by the nasal mask 1." *Id*. at col. 7:28–31.  FIG. 2A Nasal mask 201, shown in Figs. 9–11, has many of the features of the nasal mask 1 shown in Figs. 1–8. *Id.* at col. 9:34–36. "[R]etainer 212 is disposed about the inlet 208 to facilitate retention of the mask 201 on a user." *Id.* at col. 9:43–48.  FIG. 10A

a separate opening located between the annular opening and the upper member, the separate opening providing access to the first frame when the mask assembly is fully assembled,	*See supra* Claim 17[F].
wherein the first frame and the second frame snap-fit together.	**Lovell**: "[A] depressed annular region 280 on the inlet 208 mates with the edges of an aperture passing through the retainer 212. The retainer aperture and the inlet 208 are generally sized in an interference fit so that the retainer 212 is properly retained by the cooperation of the tabs 211, 211', the slots 213, 215, and the depressed annular region 280 when fully seated against the shell 204." Ex. 1102 at col. 9:46–64.  FIG. 10A **Gunaratnam: "**In the illustrated embodiment the clip (800) includes three securing tabs (820) such that inwards projections on the detents are formed as resilient detents which extend past the outer edge of flange (640) to be retained in recesses (660) on the front of the flange (640)." Ex. 1103 at col. 5:34–38.

82. The mask assembly according to claim 81, further comprising two elongate frame members connecting the upper member and lower member and at least partially bounding the separate opening.	**Gelinas**: "Cover 24 comprises a peripheral portion 52 and a ring 54, peripheral portion 52 and ring 54 being connected together by four branches 56. Peripheral portion 52 has a continuous surface 53 that surrounds the mouth and nose of the wearer. Ring 54 comprises an annular band 58 that extends inwardly therefrom." Ex. 1104 ¶ 32.  Fig. 7

83. The mask assembly according to claim 82, wherein the elongate frame members include contact points with the first frame to prevent rotation of the first frame with respect to the second frame.	**Gelinas**: "Cover 24 comprises a peripheral portion 52 and a ring 54, peripheral portion 52 and ring 54 being connected together by four branches 56. Peripheral portion 52 has a continuous surface 53 that surrounds the mouth and nose of the wearer. Ring 54 comprises an annular band 58 that extends inwardly therefrom." Ex. 1104 ¶ 32. "Cover 24 further comprises two C-shaped latches 60 extending from peripheral portion 52, each C-shaped latch 60 comprises a protuberance 62 and a finger responsive portion 64. Cover 24 also comprises a securing member 66 having a generally rectangular section 68 secured to peripheral portion 52 by a connector 70 having a groove 72. Section 68 comprises two internal notches 74." *Id*.  Fig. 7
84. The mask assembly according to claim 81, wherein the first frame and the cushion are integrally molded in one piece to provide a cushion-frame sub-assembly.	*See supra* Claim 18.

85. The mask assembly according to claim 81, wherein the first frame is contoured to fit over the patient's nose and mouth.	*See supra* Claim 20.
86. The mask assembly according to claim 81, wherein the separate opening is substantially triangular.	*See supra* Claim 27.
87. The mask assembly according to claim 81, further comprising two headgear clip attachments adjacent to and on opposite lateral sides of the annular opening.	*See supra* Claim 28.

88. The mask assembly according to claim 81, wherein the inlet conduit comprises an inlet elbow.	**Lovell**: "A conduit elbow 10 fits onto the swivel connector 9 at a sealing flange 7 on the swivel connector 9." Ex. 1102 at col. 5:14–16.  FIG. 2A Nasal mask 201, shown in Figs. 9–11, has many of the features of the nasal mask 1 shown in Figs. 1–8. *Id.* at col. 9:34–36.  FIG. 10A

89. The mask assembly according to claim 81, further comprising two headgear clip attachments adjacent to and on opposite lateral sides of the annular opening; and	*See supra* Claim 28.
two elongate frame members connecting the upper member and lower member and at least partially bounding the separate opening, wherein	*See supra* Claim 82.
the elongate frame members include contact points with the first frame to prevent rotation of the first frame with respect to the second frame,	*See supra* Claim 83.
the first frame and the cushion are integrally molded in one piece to provide a cushion-frame sub-assembly,	*See supra* Claim 18.
the first frame is contoured to fit over the patient's nose and mouth, and	*See supra* Claim 20.
the inlet conduit comprises an inlet elbow.	*See supra* Claim 88.

90. The mask assembly according to claim 89, wherein the separate opening is substantially triangular.	*See supra* Claim 27.
91. The mask assembly according to claim 89, wherein the inlet elbow engages the second frame.	*See supra* Claim 50.

IX. SECONDARY CONSIDERATIONS, EVEN IF CONSIDERED, FAIL TO OVERCOME THE *PRIMA FACIE* EVIDENCE OF OBVIOUSNESS

Although secondary considerations should be taken into account, they do not control the obviousness conclusion. *Newell Cos. 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). For example, evidence of commercial sales as a secondary consideration of non-obviousness generally would not be sufficient to overcome the strong *prima facie* showing of obviousness. Also, ResMed must show a nexus between any secondary considerations and the claims of the '061 Patent. *See, e.g., Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010)

("Our case law clearly establishes that the patentee must establish a nexus between the evidence of commercial success and the patented invention.").

Petitioner is not aware of any secondary considerations that would be relevant to the obviousness inquiries presented here. Further, Petitioner does not believe that any potential 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 of non-obviousness, Petitioner will address those allegations in due course.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: January 9, 2017

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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 13,008 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.

Dated: January 9, 2017 By: /Brenton R. Babcock/
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CERTIFICATE OF SERVICE

I hereby certify that true and correct copies of the foregoing **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT 8,944,061** and **Fisher & Paykel Exhibits 1101-1116** are being served on January 9, 2017, via FedEx Priority Overnight service on counsel of record for U.S. Patent 8,944,061 patent owner **RESMED LIMITED** at the address below:

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