

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

**DECLARATION OF JASON EATON, P.E., IN SUPPORT OF
PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,944,061**

TABLE OF CONTENTS

	Page No.
I. BACKGROUND AND QUALIFICATIONS	1
II. INFORMATION AND MATERIALS CONSIDERED	4
III. LEGAL STANDARDS FOR OBVIOUSNESS.....	6
IV. LEVEL OF ORDINARY SKILL IN THE ART	9
V. BACKGROUND OF THE '061 PATENT	10
VI. CLAIM CONSTRUCTION	15
VII. SUMMARY OF OPINIONS	22
VIII. CHALLENGED CLAIMS WOULD HAVE BEEN OBVIOUS TO A PERSON OF SKILL IN THE ART	22
A. Lovell (U.S. Patent No. 6,631,718).....	22
B. Gunaratnam (U.S. Patent No. 6,796,308)	26
C. Gelinas (U.S. Publication No. 2003/0029454)	29
D. Potential Differences Between the Prior Art and the Challenged Claims	32
1. Seal around nose and mouth (full-face mask)	35
2. Cushion material more flexible than frame material	38
3. Upper support member supporting a forehead support.....	41
4. Clip attachments.....	45
5. Annular connection adapted to engage an elbow	49
6. Separate opening	59
7. First frame and the cushion are integrally molded	63
8. Connecting members	64

TABLE OF CONTENTS
(continued)

	Page No.
9. Opening is substantially triangular	69
10. Annular opening and elbow are sealingly connected	72
11. Snap-fit.....	78
IX. CLAIM CHARTS.....	85
X. CONCLUSION.....	131

I, Jason Eaton, P.E. declare and state as follows:

I. BACKGROUND AND QUALIFICATIONS

1. I have been retained by Knobbe, Martens, Olson & Bear, LLP, counsel for Fisher & Paykel Healthcare Limited (“Fisher & Paykel”). I have been asked by counsel to review relevant materials and render my expert opinion in connection with technical matters related to Fisher & Paykel’s petition for *inter partes* review of U.S. Pat. 8,944,061 (“the ’061 Patent”). I have been asked to provide opinions regarding the patentability of Claims 17, 18, 20–23, 26–30, 32, 33, 35–38, 41–46, 48–50, and 81–91 (collectively, the “Challenged Claims”) of the ’061 Patent.

2. My current curriculum vitae (Ex. 1106) includes a listing of my patents, and work in research and product development engineering. The following paragraphs briefly summarize my relevant experience.

3. I hold a B.S. in Mechanical Engineering from West Virginia University, and am licensed in the state of Pennsylvania as a Professional Engineer (#PE073173).

4. I am presently a Principal Mechanical Engineer at MSA Safety. As a Principal Mechanical Engineer, I am responsible for technical design and engineering in development of new products, specifically for components of

Supplied Air Respirators used in firefighting applications. As such, I have deep experience in product development, conceptual design, design for manufacturability, design for human comfort and ergonomics, and manufacturing processes for a broad variety of material types and designs.

5. Prior to my current position at MSA Safety, I was employed with Philips Respironics as a Senior Mechanical Engineer. While at Philips, I worked in two primary business units. The first was the Patient Interface business, where I was responsible for New Product Development Engineering of patient interfaces, or masks, used in CPAP therapy for sleep-disordered breathing. I was specifically the lead mechanical engineer for the design and commercial release of the ComfortGel nasal mask, sold by Philips/Respironics, beginning in 2003 and discontinued in 2010. This product was the basis for a platform of products, including the ComfortGel Full, ComfortSelect, and ComfortGel Blue. I was also the lead mechanical design engineer on a project to design an interface based on U.S. Patent 8,118,027, and had significant engineering input to a number of other projects. Based on my recognized experience and expertise, I continued providing engineering support, concept development, and peer review to the Philips/Respironics Patient Interface group from fall of 2004 until at least 2010. I also worked in Philips Respironics Children's Medical Ventures business unit, in which I was responsible for leading new product development engineering design

Declaration of Jason Eaton, P.E., in support of
IPR Petition – U.S. Patent No. 8,944,061

of a patient interface mask for a CPAP and respiratory support system designed to aid premature and medically fragile infants.

6. I have conducted research and product development projects involving a variety of different design configurations of CPAP patient interfaces. As such, I am well-versed in the product requirements, performance requirements, and manufacturing processes used in the design of patient interfaces. Based on my experience, I am an expert in the field of CPAP interface design and mask assemblies.

7. I am also familiar with the historical development of patient interface masks for positive airway pressure therapy since the early 2000s and am a named inventor on 10 issued patents, 8 of which relate directly to the field of patient interface masks for positive airway pressure therapy.

8. I have used my education and my years of experience working in the field of patient interface masks for positive airway pressure therapy, and my understanding of the knowledge, creativity, and experience of a person of skill in the art in forming the opinions expressed in this declaration.

9. I am being compensated for my time in connection with this proceeding at my customary rate of \$150 per hour. My compensation is not dependent on the outcome of this proceeding. I have no personal or financial stake

or interest in the outcome of this proceeding. I am not an employee, consultant, or contractor of Fisher & Paykel or ResMed.

10. Between now and such time that I may be asked to testify, I expect to continue my review, evaluation, and analysis of evidence presented before and/or at the hearing. I expect to review the declarations and other evidence submitted by ResMed's experts. I reserve the right to amend or supplement this declaration, as appropriate, after considering the opinions set forth by Patent Owner's experts. In the event that additional relevant information becomes available to me, I also reserve the right to review and consider that information in further developing or refining my opinions.

II. INFORMATION AND MATERIALS CONSIDERED

11. In order to render my opinions in this matter, I have reviewed the specification and claims of the '061 Patent (Ex. 1101). I have been informed that the '061 Patent was filed on March 15, 2013 and issued on February 3, 2015. I also understand that the '061 Patent 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 U.S. Provisional Application Nos. 60/726,265 and 60/734,746 filed on October 14, 2005 and November 9, 2005, respectively.

12. I have also reviewed the following materials:

- U.S. Patent No. 6,631,718 ("Lovell"), Ex. 1102;

Declaration of Jason Eaton, P.E., in support of
IPR Petition – U.S. Patent No. 8,944,061

- U.S. Patent No. 6,796,308 (“Gunaratnam”), Ex. 1103;
- U.S. Publication No. 2003/0029454 (“Gelinas”), Ex. 1104;
- Excerpts of the File History of US. Patent 8,944,061, Ex. 1107;
- PCT Publication No. WO 2004/041342 (“Berthon-Jones”),
Ex. 1108;
- U.S. Patent No. 5,662, (“Ogden”), Ex. 1109;
- The book Plastic Part Design for Injection Molding, Robert A.
Malloy (1994) (“Malloy”), Ex. 1110;
- U.S. Patent No. 6,412,488 (“Barnett”), Ex. 1111;
- U.S. Publication No. 2004/0118406 (“Lithgow”), Ex. 1112
- U.S. Publication No. 2002/0020416 to Namey (“Namey”),
Ex. 1113; and
- U.S. Publication No. 2005/0155604 to Ging et al. (“Ging”),
Ex. 1114.

13. The above referenced materials are in addition to any other materials referenced directly or indirectly in this declaration. I expect to review additional materials that might be provided by the parties as this proceeding progresses.

III. LEGAL STANDARDS FOR OBVIOUSNESS

14. I have been asked to provide my opinion as to whether the Challenged Claims of the '061 Patent would have been obvious to a person of ordinary skill in the art at the time of the alleged invention, in view of the prior art.

15. I am an engineer by training and profession. The opinions I am expressing in this report involve the application of my engineering knowledge and experience to the evaluation of certain prior art with respect to the '061 Patent.

16. Although I have technical expertise, I am not an expert in patent law. Therefore, I have requested that the attorneys from Knobbe, Martens, Olson & Bear provide me with guidance as to the applicable patent law in this matter. The paragraphs below express my understanding of how I must apply current principles related to patent validity to my analysis.

17. I have been informed and understand that a patent claim can be found to be unpatentable if the claim would have been obvious in view of the prior art. I understand that this determination is made from the perspective of a person having ordinary skill in the art who is presumed to be aware of all prior art.

18. I have been informed that 35 U.S.C. §103 governs the determination of obviousness. According to 35 U.S.C. §103:

“A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102, 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.”

19. I have been informed that the factors to be considered in an obviousness inquiry include: the scope and content of the prior art; the differences between the prior art and the claimed invention; the level of ordinary skill in the pertinent art; and any evidence of “objective indicia of nonobviousness.” Those objective indicia include considerations such as whether a product covered by the claims is commercially successful and whether there was a long-felt but unmet need in the field for the claimed invention, among other things.

20. In determining the scope and content of the prior art, it is my understanding that a reference is considered appropriate prior art if it falls within the field of the inventor’s endeavor. In addition, a reference is prior art if it is reasonably pertinent to the particular problem with which the inventor was involved. A reference is reasonably pertinent if it logically would have commended itself to an inventor’s attention in considering his problem. If a reference relates to the same problem as the claimed invention, that supports use of the reference as prior art in an obviousness analysis.

21. To assess the differences between prior art and the claimed subject matter, it is my understanding that the law requires the claimed invention to be considered as a whole. This “as a whole” assessment requires showing that one of ordinary skill in the art at the time of invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would have selected the elements from the prior art and combined them in the claimed manner.

22. It is my further understanding that the law recognizes several rationales for combining references or modifying a reference to show obviousness of the claimed subject matter. Some of these rationales include: combining prior art elements according to known methods to yield predictable results; simple substitution of one known element for another to obtain predictable results; a predictable use of prior art elements according to their established functions; applying a known technique to a known device (method or product) ready for improvement to yield predictable results; choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; and some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

23. I also understand that an obviousness analysis must consider whether there are additional factors that would indicate that the invention was non-obvious.

These factors include whether there was: (i) a long-felt need in the industry; (ii) any unexpected results; (iii) skepticism of the invention; (iv) commercial success; (v) praise by others for the invention; and (vi) copying by other companies. I also understand that evidence of these additional factors is generally not sufficient to overcome a strong showing of obviousness. I am not aware of any evidence that would suggest that any of the Challenged Claims of the '061 Patent would have been non-obvious. However, even if such evidence exists, I do not believe it would overcome the strong evidence showing that these claims would have been obvious.

IV. LEVEL OF ORDINARY SKILL IN THE ART

24. I have been informed that for purposes of assessing the obviousness of patent claims, the level of skill possessed by the hypothetical person of ordinary skill in the art is informed by several factors. These factors include the type of problems encountered in the relevant art, the prior art solutions to those problems, the rapidity with which innovations are made in the relevant art, the sophistication of the relevant technology, and the educational level of active workers in the field.

25. The relevant field for the '061 Patent includes breathing apparatuses and interface masks. I consider myself to be an expert in the relevant field.

26. In my opinion, a person having ordinary skill in the art at the relevant time period, which I understand to be around the time of U.S. Provisional

Application Nos. 60/726,265 and 60/734,746 filed on October 14, 2005 and November 9, 2005, respectively, 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. This education and industry background provides the necessary training and understanding of the mask assemblies described in the '061 Patent. Thus, based on my experience in the field of patient interface masks, the person of skill would have the education and experience described above. All of my opinions and analysis set forth herein is provided from the perspective of the person of ordinary skill in the art.

V. BACKGROUND OF THE '061 PATENT

27. The '061 Patent describes a full-face mask assembly for treating a breathing-related sleep disorder, and the mask assembly includes a first frame (or inner frame 414) associated with a mask seal which forms a seal over the nose and mouth of a patient and a second frame (or skeleton frame 212/412) configured to support headgear.¹ The second frame is a skeleton frame that helps to “maintain the cushion to the frame,” and hold the cushion sub-assembly in place on a

¹ Ex. 1101 at Abstract.

patient.² The '061 Patent claims to address the following problems in mask assemblies: “difficulty with alignment and assembly,” “difficulty with adhesive,” “points of ingress that cannot be easily cleaned,” and “interference methods that can be difficult to use on large frames, e.g. full-face mask, and can have misalignment issues.”³

28. The '061 Patent describes only two embodiments of a mask assembly with a first frame and second frame. In one embodiment, “a frame and a cushion are integrally molded in one-piece to provide a cushion-frame sub-assembly.”⁴ The cushion-frame sub-assembly 230 has an annular opening 218 for receiving pressurized air from an inlet conduit.⁵ An annular wall 240 surrounds the opening 218 and extends towards the inlet conduit. I have provided Figure 3 of the '061 Patent below, which shows the cushion-frame sub-assembly 230 and a second frame 212 that engages and constrains the sub-assembly 230.⁶ The second frame 212 has an upper support member 244 that extends upward and supports a forehead

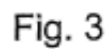
² *Id.* at col. 2:35–36.

³ *Id.* at col. 1:52–64.

⁴ *Id.* at col. 6:59–63.

⁵ *Id.* at col. 6:53–66, Figure 3.

⁶ *Id.* at col. 6:56–58.



⁷ *Id.* at col. 7:11–16.

- 12 -

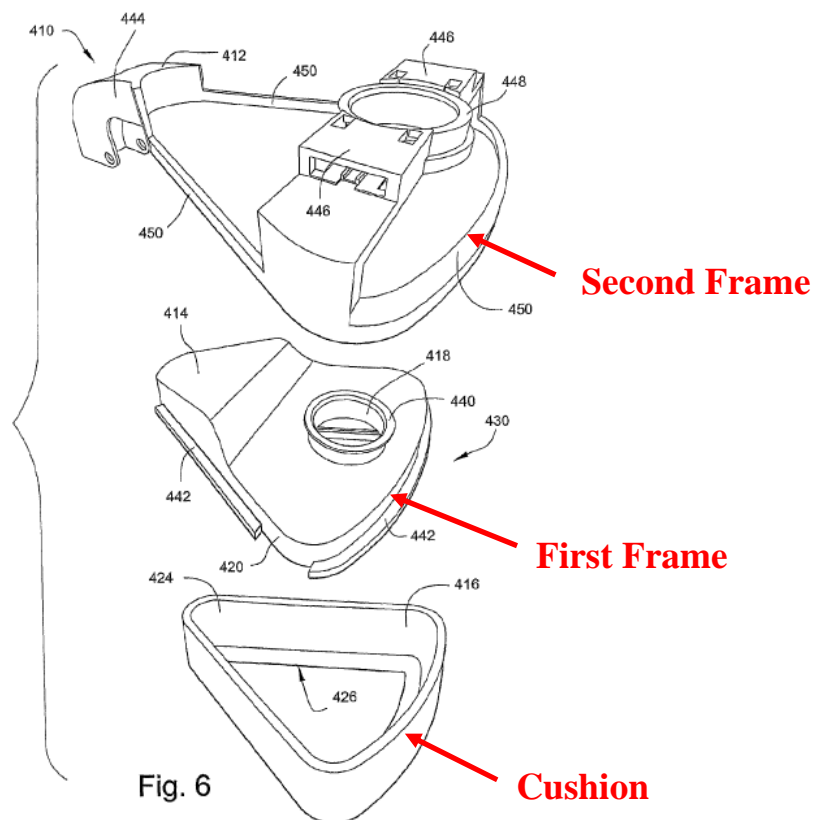


30. In the other two-frame mask embodiment, the '061 Patent describes a mask assembly that is very similar to the embodiment of Figures 3–4. However, as can be seen in Figures 6–8, the first frame 414 and cushion 416 are first formed

⁹ *Id.* at col. 7:24–27.

¹⁰ *Id.* at col. 7:26–30.

separately and then interlocked to provide a cushion-frame sub-assembly 430.¹¹ The first frame 414 can be made of a rigid material such as polycarbonate.¹² Figure 6, which I have provided below, illustrates the second frame 412 configured to engage the cushion-frame sub-assembly in the same way as the previous embodiment. The second frame 412 adds rigidity to the mask assembly and also provides attachment points for a headgear assembly.¹³



¹¹ *Id.* at col. 8:1–3.

¹² *Id.* at col. 8:21–22.

¹³ *Id.* at col. 8:38–48.

VI. CLAIM CONSTRUCTION

31. I understand that the first step in analyzing the patentability of a patent claim begins with an analysis of the wording of the claim itself, also referred to as “claim construction.” I understand that the proper standard for claim construction in an IPR proceeding is the broadest reasonable interpretation in light of the specification to one having ordinary skill in the art. Although not material to my other conclusions herein, I have provided below my opinions regarding the proper construction of certain claim terms, based on broadest reasonable interpretation in light of the specification of the ’061 Patent to a person having ordinary skill in the art in 2004–2005.

32. “annular connection adapted to engage an elbow,” “inlet elbow engages the second frame”: These phrases are found in Claim 17, 50 or 91. According to the specification, the term “engage” in this context does not require direct contact or coupling with the elbow. The specification uses the term “engage” broadly across several different arrangements. The ’061 Patent describes some embodiments, not having a two-frame arrangement, in which an annular opening or seal 2048 is “adapted to engage an inlet conduit, e.g., elbow.”¹⁴ In

¹⁴ Ex. 1101 at col. 16:25–26.

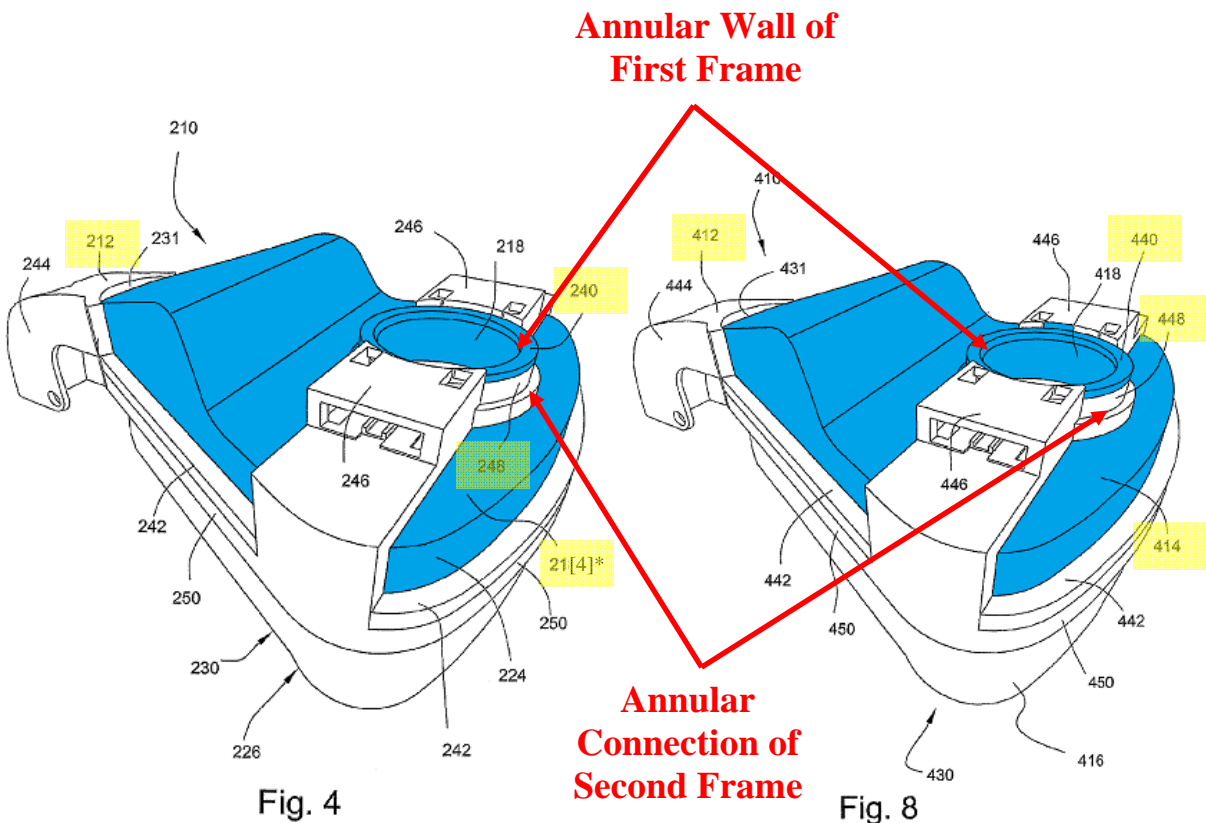
these embodiments, the annular seal 2048 engages the inlet conduit by directly contacting and sealing against it.

33. However, in the embodiments having a first frame and a second frame, the annular connection would not directly contact the elbow. For example, the specification states that, regarding the embodiment shown in Figures 3–4, the “[second] frame 212 includes . . . an annular elbow connection seal 248 adapted to engage an inlet conduit, e.g., elbow.”¹⁵ Also, for the mask assembly shown in Figures 6–8, the specification states “the [second] frame 412 includes . . . an annular elbow connection seal 448 adapted to engage an inlet conduit, e.g., elbow.”¹⁶

¹⁵ *Id.* at col. 7:11–17.

¹⁶ *Id.* at col. 8:27–34.

34. Although element 248/448 is described as an “annular elbow connection seal,” the figures for these embodiments show that the annular wall 240/440 of the first frame 214/414 (shaded in blue) prevents an elbow from directly engaging annular connection 248/448 of the second frame 212/412 (see Figures 4 and 8 below), and there is no disclosure explaining how the annular connection 248/448 could directly contact or couple with the inlet conduit or elbow when the mask is assembled.



*Apparently mislabeled as “218”

35. The '061 Patent does not show an inlet conduit or elbow in any of its figures, but a person of skill in the art would understand that such an inlet conduit

or elbow would not directly contact the annular connection 248/448 and instead would likely be received into and contact the annular wall 240/440 of the first frame 214/414. As shown in the figures, including Figures 4 and 8 provided above, the annular wall 240/440 on the first frame 214/414 extends through the annular connection 248/448 and would contact or directly receive the conduit or elbow when the mask is assembled. Although this is not described in the embodiments presented in the '061 Patent, the annular connection 248/448 of the second frame 212/412 may function in cooperation with the annular wall 240/440 of the first frame 414 to support the inlet conduit or elbow without directly contacting elbow.

36. Based on the claim language and description in the specification, it is my opinion that a person of ordinary skill in the art reading the '061 Patent would understand “engage,” in the context of Claims 17, 50, and 91, to include supporting in an operable position relative to, either directly or in cooperation with other components.

37. “Annular opening and the elbow are sealingly connected”: This phrase is found in Claims 46 and 48. According to the specification of the ’061 Patent, the phrase “sealingly connected” in this context does not require direct coupling or sealing between the elbow and the annular opening of the second frame. As described above, the two-frame embodiments have an annular opening that would not directly connect with or seal with the elbow.¹⁷ The specification states that, regarding the embodiment shown in Figures 3–4, the “[second] frame 212 includes . . . an annular elbow connection seal 248 adapted to engage an inlet conduit, e.g., elbow.”¹⁸ But the specification also says that “the annular elbow connection seal 248 interlocks with the annular wall 240 of the cushion-frame sub-assembly 230.”¹⁹ Also, for the mask assembly shown in Figures 6–8, the specification states “the [second] frame 412 includes . . . an annular elbow connection seal 448 adapted to engage an inlet conduit, e.g., elbow.”²⁰ The corresponding figures (see Figures 4 and 8 below) show that the annular wall 240/440 on the first frame 414 extends through the annular connection 248/448

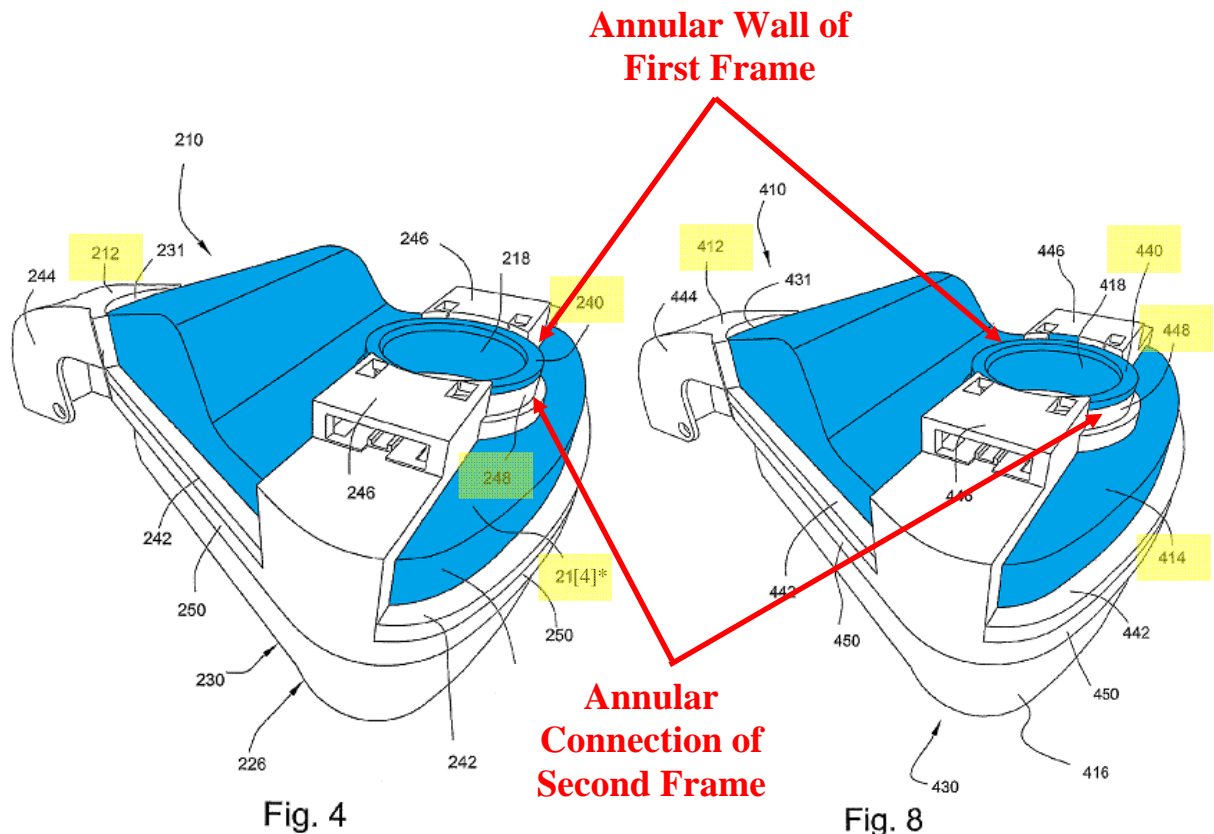
¹⁷ See *supra* ¶¶ 32–36.

¹⁸ Ex. 1101 at col. 7:11–17.

¹⁹ *Id.* at col. 7:23–25.

²⁰ *Id.* at col. 8:27–34.

and would connect and seal with the inlet conduit or elbow when the masks are assembled.



*Apparently mislabeled as “218”

38. Although element 248/448 is described as an “annular elbow connection seal,” as shown above, the figures suggest that there would not have been direct connecting or sealing between the annular opening of the second frame and the inlet conduit or elbow, and there is no disclosure describing a second frame with an annular opening that directly connects or seals with the inlet conduit or elbow. The '061 Patent does not show an inlet conduit or elbow in any of its figures, but a person of skill in the art would understand that such an inlet conduit or elbow would not directly connect or seal with the illustrated annular opening

and instead would likely be received into and seal with the annular wall 240/440 of the first frame 214/414, as shown in Figures 4 and 8 above.

39. Based on the claim language and description in the specification, it is my opinion that a person of ordinary skill in the art reading the '061 Patent would understand “sealingly connected,” in the context of Claims 46 and 48, to include being directly or indirectly coupled to allow a seal between the interior of the elbow and the breathing chamber.

VII. SUMMARY OF OPINIONS

40. It is my opinion that Claims 17, 18, 20–23, 26–30, 32, 33, 35–38, 41–46, 48–50, and 81–91 of the '061 Patent are obvious over Lovell (Ex. 1102) in view of Gunaratnam (Ex. 1103) and Gelinas (Ex. 1104).

VIII. CHALLENGED CLAIMS WOULD HAVE BEEN OBVIOUS TO A PERSON OF SKILL IN THE ART

41. Lovell in view of Gunaratnam and Gelinas would have rendered obvious Claims 17, 18, 20–23, 26–30, 32, 33, 35–38, 41–46, 48–50, and 81–91 for the reasons I explain below.

A. Lovell (U.S. Patent No. 6,631,718)

42. Lovell describes mask assemblies with a two-frame arrangement that provides pressurized air or therapeutic gas to a patient suffering from an airflow limitation or other respiratory ailment.²¹

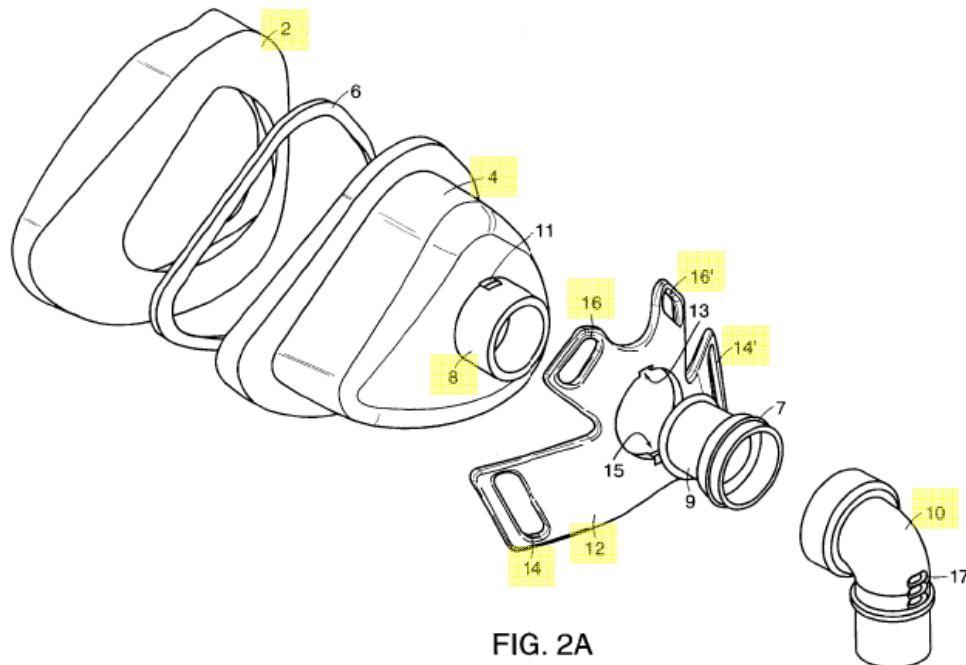
43. A first mask assembly includes a nasal mask 1 with a seal 2 attached to a shell 4 and the seal 2 is made of a flexible material such as a compliant polymer or a silicone gel.²² The sub-assembly of the shell 4 and seal 2 forms a chamber 80 that surrounds the patient's nose in use.²³ As illustrated in Figure 2A

²¹ Ex. 1102 at cols. 1:5–8, 4:11–19.

²² *Id.* at cols. 4:34–42, 7:51–55.

²³ *Id.* at col. 4:47–50.

below, the nasal mask 1 includes an inlet 8 to which a swivel connector 9 or other conduit can be coupled.²⁴ Lovell describes the conduit as including a conduit elbow 10 that is configured to swivel about the centerline of the inlet 8.²⁵



44. The mask assemblies of Lovell also include a retainer 12. The retainer 12 is positioned adjacent the inlet 8 and couples to the shell/seal sub-assembly to constrain the sub-assembly on the patient.²⁶ The retainer 12 is contoured and shaped to match the external curvature of the shell 4 and also

²⁴ *Id.* at col. 5:9–14.

²⁵ *Id.* at col. 5:20–24.

²⁶ *Id.* at col. 5:62–63.

includes four connection points 14, 14', 16, 16' that receive headgear straps.²⁷

Lovell describes connection points 14, 14', 16, 16' on the retainer 212 that can include slots, notches, or other mechanical features for attaching headgear straps, such as snaps, hook and eye closures, hook and loop fasteners, or similar structures.²⁸

45. In a second mask assembly, Lovell describes 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 212.²⁹ The retainer 212 attaches to the shell/seal sub-assembly at the inlet 208 and constrains the mask on the patient.³⁰ The shell 204 has a depressed annular region 280 on the inlet 208 that mates with the edges of an aperture passing through the retainer 212.³¹ The retainer aperture and the inlet 208 are generally sized and shaped to provide an interference fit so that the retainer 212 is properly retained when the tabs 211, 211', the slots 213, 215, and the depressed annular region 280 cooperate and the retainer 212 is fully seated

²⁷ *Id.* at col. 5:65—6:13.

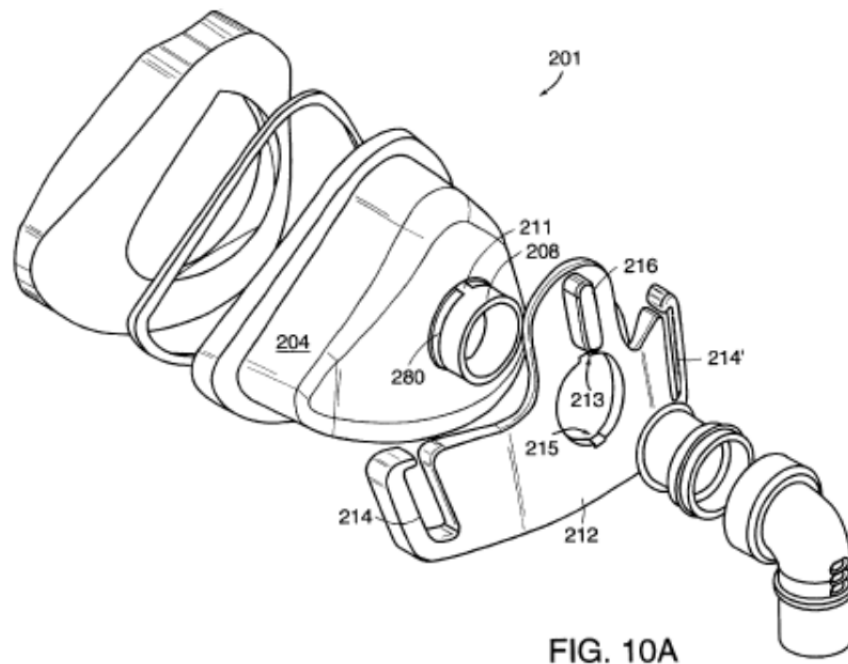
²⁸ *Id.* at col. 6:10–19.

²⁹ *Id.* at col. 9:34–42.

³⁰ *Id.* at col. 9:43–44.

³¹ *Id.* at col. 9:57–59.

against the shell 204.³² A releasable snap-fit is then formed as portions of the annular opening of the retainer 212 release into the depressed annular region 280 in the shell 204. The retainer 212 can be constructed from a polycarbonate material.³³



46. As illustrated in Figure 10A above, the retainer 212 has three headgear connection points: two lower points 214, 214', and one upper point 216.³⁴ The upper connection portion 216 receives an upper headgear strap and provides additional retention force on the upper portion of the nasal mask 201.³⁵ This upper

³² *Id.* at col. 9:59–64.

³³ *Id.* at col. 9:66–67.

³⁴ *Id.* at col. 9:49–51.

³⁵ *Id.* at col. 10:7–10.

retention strap is configured and oriented in a manner that does not block the vision of a patient but is proximate the user's eyes.³⁶

B. Gunaratnam (U.S. Patent No. 6,796,308)

47. Gunaratnam describes mask assemblies that include a rigid mask frame 160 and a soft seal or cushion 180 that together form a cavity that overlies the nose and/or mouth of a patient.³⁷ The Gunaratnam specification makes clear that the described arrangements could be applied to both full-face and nasal masks.³⁸

48. In one embodiment, Gunaratnam describes a frame 160 with a gas inlet aperture 610 that can be connected to a gas delivery conduit of a patient gas delivery system.³⁹ The front of the frame 160 includes strap connection points 630 for connection of the mask to headgear straps.⁴⁰ As illustrated in Figures 5a and 5c below, Gunaratnam describes a mask frame 160 with lower clip attachments 630

³⁶ *Id.* at col. 10:14–16.

³⁷ Ex. 1103 at cols. 1:33–39, 6:3–7.

³⁸ *Id.* at col. 1:21–25.

³⁹ *Id.* at col. 4:22–25.

⁴⁰ *Id.* at col. 4:31–34.

on opposite sides of the inlet aperture 610.⁴¹ The described mask frame 160 also includes an upper support member 161 that supports a forehead contacting portion 162.⁴²

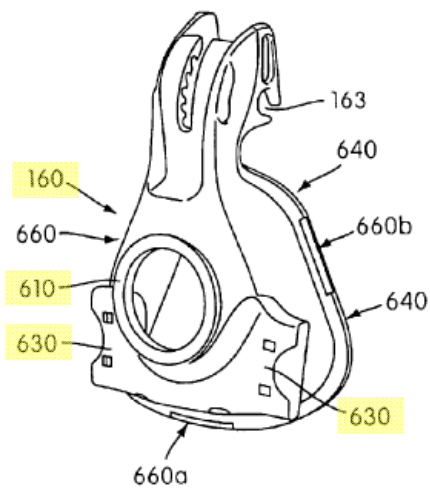


FIG. 5a

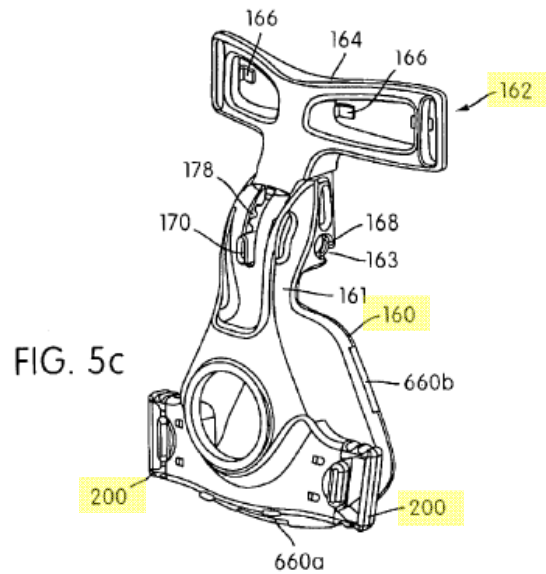
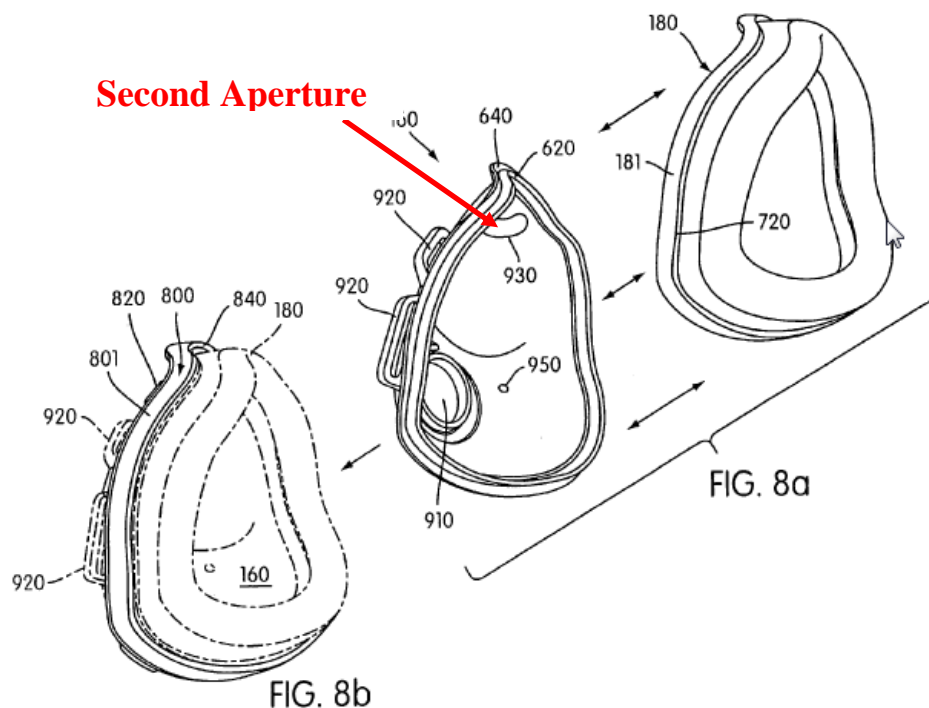


FIG. 5c

⁴¹ *Id.* at col. 4:31–34, Figure 5a and 5c.

⁴² *Id.* at col. 4:46–59, Figures 5c–5f.

49. 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.⁴³ For example, Figure 15 (below) illustrates a frame 160 that is adapted to cover both the mouth and nose.⁴⁴ A second aperture 930 is located in the upper portion of the mask frame 160, above the inlet aperture 910.⁴⁵



⁴³ *Id.* at col. 6:30–34.

⁴⁴ *Id.* at col. 6:25–26.

⁴⁵ *Id.* at col. 6:27–29.

means or through-molding processes.⁴⁹ The cover 24 is made of a rigid or semi-rigid plastic and can be secured to the facepiece 22.⁵⁰ The cover 24 has a concave shape that is complementary to the shape of the second part 92.⁵¹ The cover 24 is detachably mated with the facepiece 22 to define a void area therebetween.⁵²

52. As illustrated in Figure 7 above, Gelinas describes a cover 24 that includes a peripheral portion 52 and a ring 54.⁵³ The peripheral portion 52 and the ring 54 are connected by four branches 56.⁵⁴ The cover 24 includes an upper portion at the top of the peripheral portion 52 and a lower portion that is connected to the ring 54.⁵⁵ The peripheral portion 52 includes an elongated portion on each side of the cover 24 that extends from the lower portion of the cover 24 to the upper portion of the cover 24.⁵⁶ Gelinas states that the cover 24 could have many

⁴⁹ *Id.*

⁵⁰ *Id.* ¶ 31.

⁵¹ *Id.*

⁵² *Id.*

⁵³ *Id.* ¶ 32.

⁵⁴ *Id.*

⁵⁵ *Id.* at Figure 7.

⁵⁶ *Id.* at Figure 7.

configurations, “so long as air is able to pass through cover 24 and reach facepiece 22.”⁵⁷ Therefore, Gelinas teaches construction of a second frame (cover 26) with openings that provide access to the cushion-frame sub-assembly.

53. Gelinas describes a strap 100 for holding the respirator mask over the head of the wearer.⁵⁸ Gelinas further describes v-shaped members 76 that comprise branches 78 and 80 having apertures 82, which allows insertion of strap 100.⁵⁹ V-shaped members 76 are configured to receive features on second part 92, as well as features on cover 24.⁶⁰ The cover 24 has c-shaped latch features 60 with protuberance 62 and finger responsive portion 64 that engage the headgear connector members 76. Gelinas also teaches alternatively that the headgear strap 100 can be attached to cover 24 by way of apertures similar to 82 on branches 78 and 80.⁶¹ One skilled in the art would recognize that this would allow removal of the cushion-frame sub-assembly from the second frame and headgear.

⁵⁷ *Id.* ¶ 33.

⁵⁸ *Id.* ¶ 37.

⁵⁹ *Id.* ¶¶ 34, 37.

⁶⁰ *Id.* ¶ 34.

⁶¹ *Id.* ¶ 38.

D. Potential Differences Between the Prior Art and the Challenged Claims

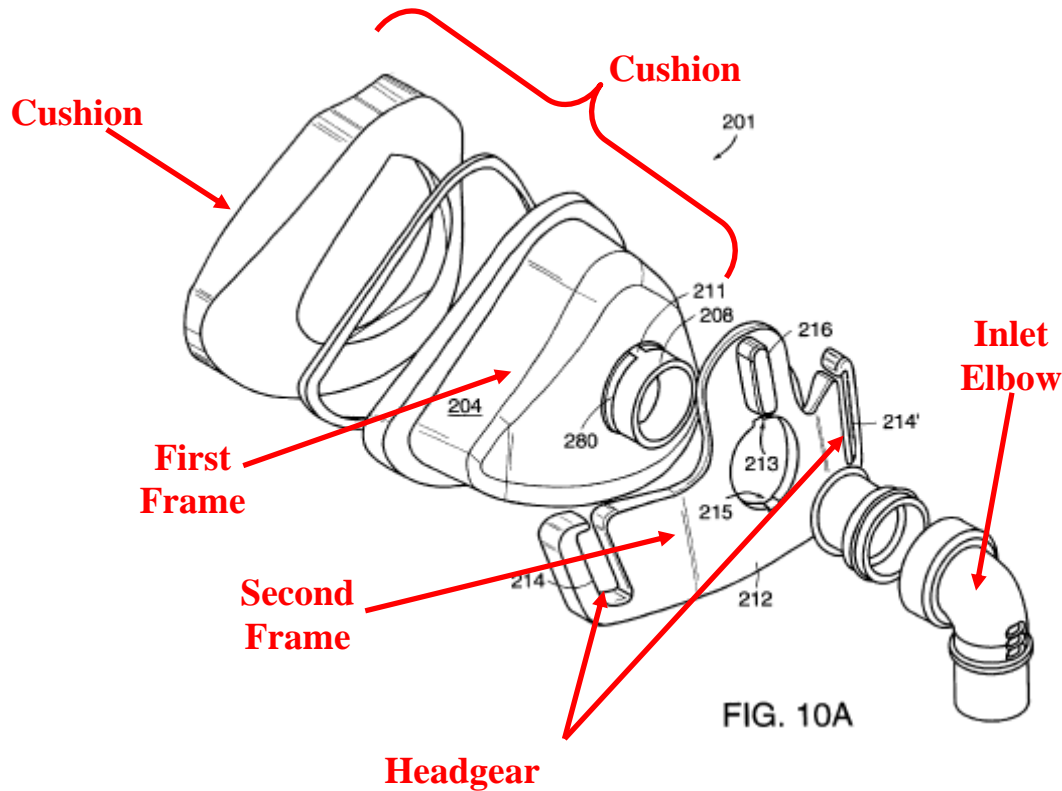
54. As shown in the Claim Charts I provide below, Lovell expressly discloses nearly all of the limitations of the Challenged Claims.

55. With respect to independent Claim 17, Lovell teaches a CPAP mask assembly having a first frame (shell 204) made of first material (*e.g.*, PellethaneTM); a cushion (seal 2) 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.⁶² 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).⁶³

⁶² Ex. 1102 at cols. 4:34–58, 7:45–58.

⁶³ *Id.* at cols. 6:2–10, 9:43–48, Figs. 2A and 10A.

56. Many of these claimed features are identified in the annotated version of Fig. 10A below:



57. Any differences between the Challenged Claims and Lovell were minor, well-known at the time of the invention, and included in the prior art, for example, by the disclosure of Gunaratnam and Gelinas, as explained below.

58. A person of skill in the art would have known and been motivated to combine the teachings of Lovell, Gunaratnam, and Gelinas at the time of the supposed '061 Patent invention. Lovell and Gunaratnam are from the same field of CPAP breathing masks, and teach the use of masks for treatment of sleep disordered breathing. Further, the respirator mask described in Gelinas is from the

same field of endeavor as CPAP masks, as taught by Lovell and Gunaratnam. Similar to Lovell, Gelinas teaches the separation of a mask assembly into a cushion-frame sub-assembly (facepiece 22) and a removable second frame (cover 24). Gelinas is pertinent to the same problem of providing access to an underlying frame in a two-frame arrangement. A person of ordinary skill in the art would have been aware of and looked to respirator masks, such as Gelinas, as well as existing CPAP mask designs when contemplating design features.

59. Since the mask assemblies of Lovell, Gunaratnam, and Gelinas have similar frame structures and share similar construction, the features of Lovell, Gunaratnam, and Gelinas would have been compatible and a person of skill in the art would have expected to have success in combining and interchanging the features and overall arrangements of these designs. Combining these familiar features according to known methods would have done no more than yield predictable results.

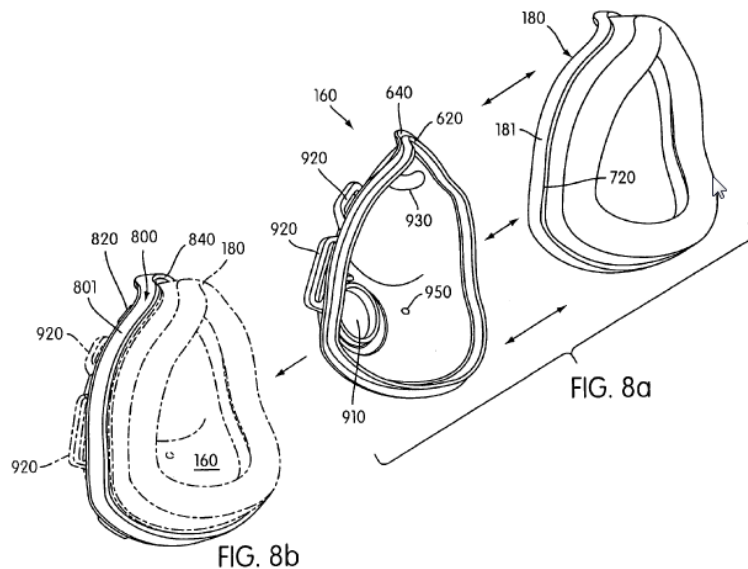
1. Seal around nose and mouth (full-face mask)

60. 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.”

61. Lovell discloses nasal masks with a cushion that forms a seal around the nose,⁶⁴ but does not specifically describe a full-face cushion that seals around a patient’s nose and mouth. However, full-face masks were common during the relevant time period for CPAP masks. It was also well-known to use the features of a nasal mask in designing a full-face mask.

⁶⁴ Ex. 1102 at col. 4:7–9.

62. For example, Gunaratnam describes a “nasal mask frame including a rim portion according to an embodiment of the invention.”⁶⁵ Later Gunaratnam states that the “invention is also suitable for a full-face mask system,” as shown in Figures 8a and 8b below.⁶⁶ In the full-face version, Gunaratnam discloses a frame 160 and a cushion 180 that seals around the patient’s nose and mouth regions.⁶⁷



63. This is consistent with the general knowledge of a person of ordinary skill in the art prior to the '061 Patent, specifically that design arrangements and features from nasal mask designs were readily adaptable to full-face masks. For

⁶⁵ Ex. 1103 at col. 4:20–22.

⁶⁶ *Id.* at col. 6:3–6.

⁶⁷ *Id.* at col. 6:3–15, Figures 8a and 8b.

example, 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.”⁶⁸ As another example, Ogden discloses that the features of a “nasal mask covering the nose 2 and nares 4 . . . [are] equally applicable to full face masks covering the patient’s nose and mouth.”⁶⁹ Barnett also discloses a nasal mask assembly and discloses that “[n]on-invasive ventilation and pressure support therapies involve the placement of a patient interface device, which is typically a nasal/oral mask, on the face of patient.”⁷⁰

64. A person of skill in the art would have known that patients who may breathe through their mouth during sleep require a full-face mask. Based on the teachings of prior art respiratory masks (*e.g.*, Gunaratnam, Gelinas, Ogden, and Barnett), a person of skill in the art would have known that the nasal seal of Lovell could be adapted to seal around both the mouth and nose. Many features of full-face and nasal masks were interchangeable, and a person of skill in the art would have had a reasonable expectation of success in modifying the mask assemblies of Lovell to be full-face mask assemblies.

⁶⁸ Ex. 1104 ¶ 27.

⁶⁹ Ex. 1109 at col. 2:46–50.

⁷⁰ Ex. 1111 at col. 1:26–29.

2. Cushion material more flexible than frame material

65. 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.”

66. Lovell discloses that the cushion 2 is formed from a film 60, 64 and filled with soft material 62 such as silicone gel.⁷¹ The first frame 4/204 of Lovell is formed by molding a compliant polymer such as Pellethane.⁷² A person of skill in the art would have understood that silicone cushion 2 is softer and more flexible than the molded polymer first frame 4/204 that supports the cushion and securely attaches to the second frame 12/212.

67. However, to the extent the disclosure of Lovell is somehow insufficient for this limitation, flexible cushions with more rigid frames were common in CPAP masks at the time of the invention. For example, Gunaratnam discloses that frame 160 is constructed of rigid polycarbonate and the cushion is formed of soft silicone.⁷³ As another example, Ogden discloses that the rigid, cup-shaped shell 3 is made of hard plastic and the seal 5 is made of a soft pliable

⁷¹ Ex. 1102 at col. 7:45–58.

⁷² *Id.* at col. 4:40–44.

⁷³ Ex. 1103 at cols. 4:22–23, 5:22–24.

material such as elastomer, urethane foam, or rubber.”⁷⁴ Namey discloses a frame 38 that supports a cushion 40 and is formed from a material that is more rigid than the cushion, “such as rigid or semi-rigid plastic.”⁷⁵ Ging is another prior art reference that teaches a “rigid shell” attached to a “soft face-contacting cushion.”⁷⁶

68. A person of skill in the art would have known to construct a cushion-frame sub-assembly using a cushion material that is more flexible than a first frame material so that the cushion is comfortable and effectively seals against the patient’s face. However, the internal positive air pressure in the mask assembly will cause a flexible cushion to deform under pressure, thus leading to undesired displacement of the mask assembly and its seal. This would be especially problematic with a flow generator designed to provide more than a single level of pressure, as the displacement of the mask would be dynamic based on breathing and delivered pressure over time. One skilled in the art would have known that a first frame constructed of a more rigid material would be a suitable and predictable solution for resisting such displacement so the sealing surface of the cushion

⁷⁴ Ex. 1109 at col. 2:50–57.

⁷⁵ Ex. 1113 ¶ 21.

⁷⁶ Ex. 1114 ¶¶ 5, 110.

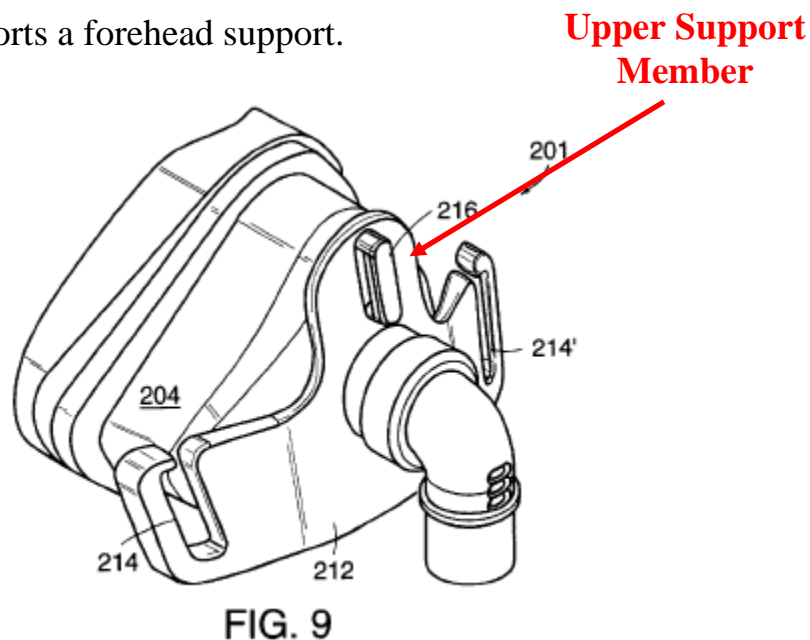
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IPR Petition – U.S. Patent No. 8,944,061

remains in intimate contact with the patient's face. Additionally, a person of skill would have known to make the first frame from a less flexible material than the cushion to provide a solid mounting base and an effective attachment structure for the second frame. During transport, the use of a less flexible frame would also prevent the mask assemblies from deforming when packaged with multiple components.

3. Upper support member supporting a forehead support

69. Independent Claims 17 and 32 of the '061 Patent require that the second frame have an “upper support member” that “supports a forehead support” (Claim 17) or assists with “forehead support” (Claim 32).

70. Lovell discloses a second frame with an upper support member that supports upper head gear straps,⁷⁷ but does not expressly disclose that the upper support member supports a forehead support.

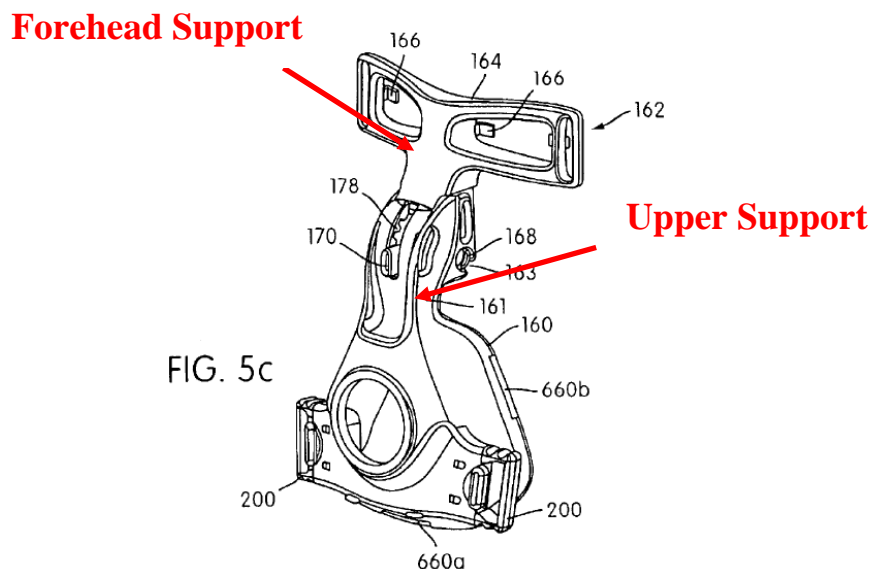


71. The relevant embodiments of the '061 Patent do not show or describe any particular forehead support. But to the extent Lovell provides insufficient teachings for the upper support member supporting a forehead support, such upper

⁷⁷ Ex. 1102 at col. 10:7–11, Figure 9.

support members and forehead supports were common knowledge and taught by the prior art.

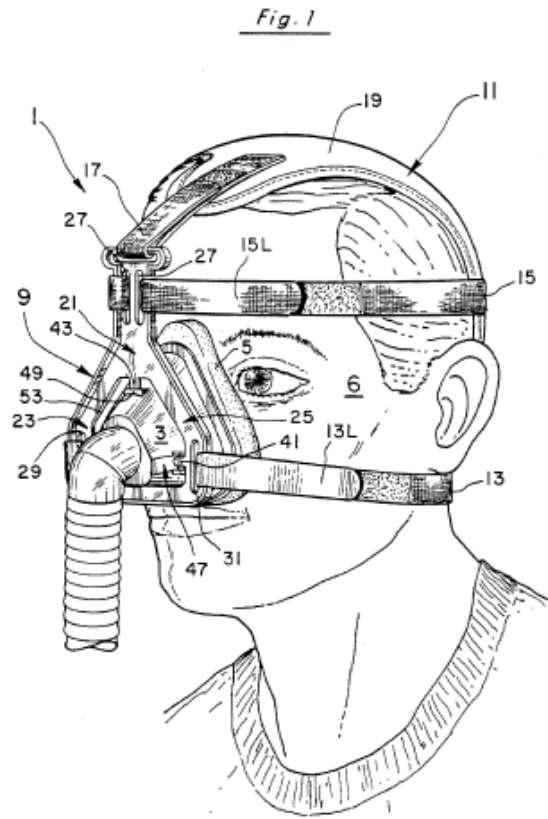
72. This is illustrated by Gunaratnam which describes an outer frame with an upper support portion that receives and supports a forehead support adapted to contact the forehead of a patient. As shown in Figure 5c (below), Gunaratnam describes a frame with an upper support member 161 adapted to receive a forehead support 162 that is positioned adjacent to or contacting the forehead.⁷⁸ Gunaratnam discloses “[t]he adjustable forehead support (162) includes a bridge portion (164) adapted to locate at least one and preferably two spaced apart pads (not shown) adapted to contact the forehead of the patient.”⁷⁹



⁷⁸ Ex. 1103 at Figures 5c–5f.

⁷⁹ *Id.* at col. 4:47–52.

73. Ogden also discloses “[t]he upper side straps in this last regard could be the two straps 15R and 15L as illustrated or one continuous strap passing through loops 27 and anchoring the top portion 21 of the rigid plate 9 (see FIGS. 1-3).”⁸⁰ The top portion 21 provides a forehead support.



⁸⁰ Ex. 1109 at col. 3:7–10, Fig. 1.

74. Lithgow also discloses a frame 12 having an upper support member that supports a forehead support 16, as shown in annotated Figure 1B below.⁸¹

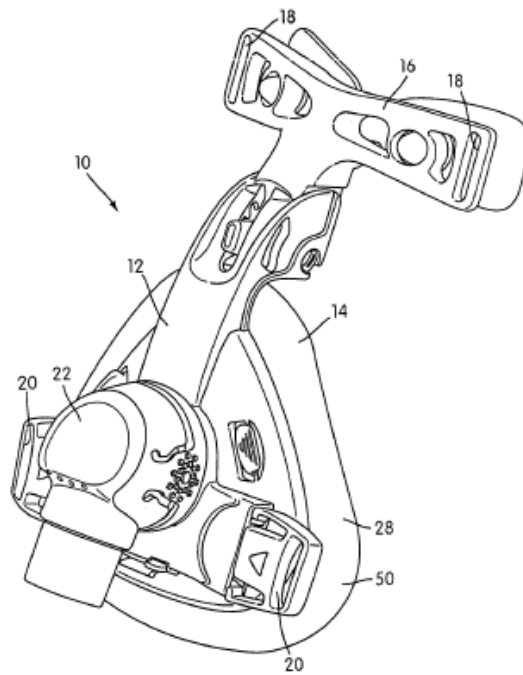


FIG. 1B

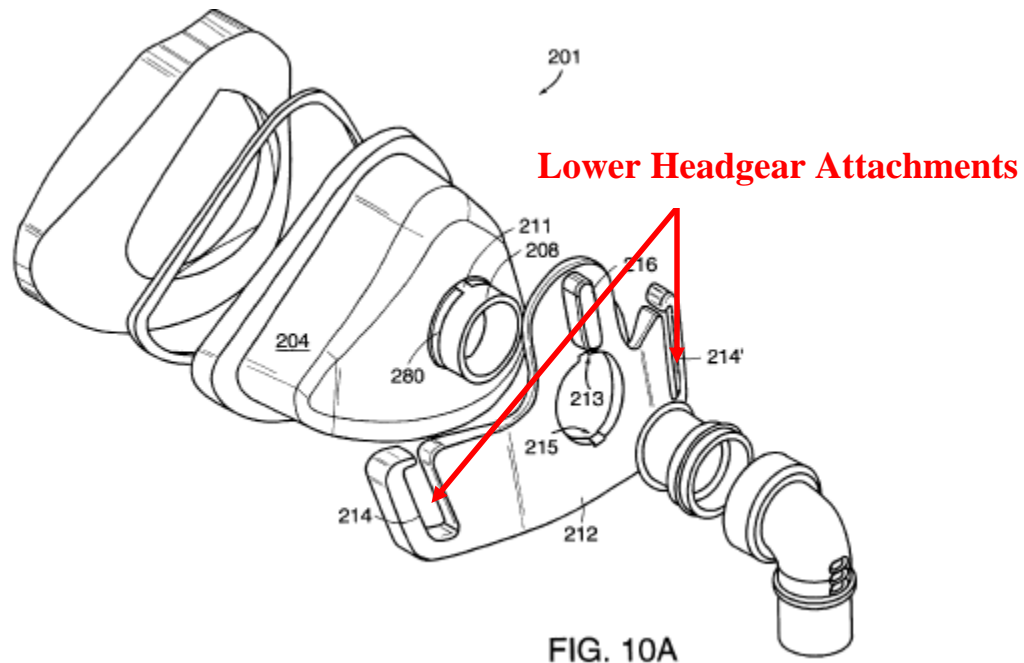
⁸¹ Ex. 1112 ¶ 111.

75. A person of skill in the art would have known to incorporate this well-known forehead support feature in the second frame of Lovell, for example, including in a full-face version of the mask of Lovell. The forehead support would provide additional support to the mask when it is attached to a patient's face and would assist in keeping the mask in its desired position on the face. Such additional support from the forehead support would help prevent movement of the mask relative to the patient's face, especially when the patient moves during sleep.

4. Clip attachments

76. Independent Claims 17 and 32 of the '061 Patent require that the second frame includes "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."

77. Lovell discloses a second frame with two lower headgear attachment points.⁸² Lovell illustrates slots or notches in these headgear attachment points, configured for quick attachment/detachment of the straps of a headgear assembly, without the need for releasing the features that provide for strap length adjustment.⁸³ “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.”⁸⁴



⁸² Ex. 1102 at col. 9:49–53.

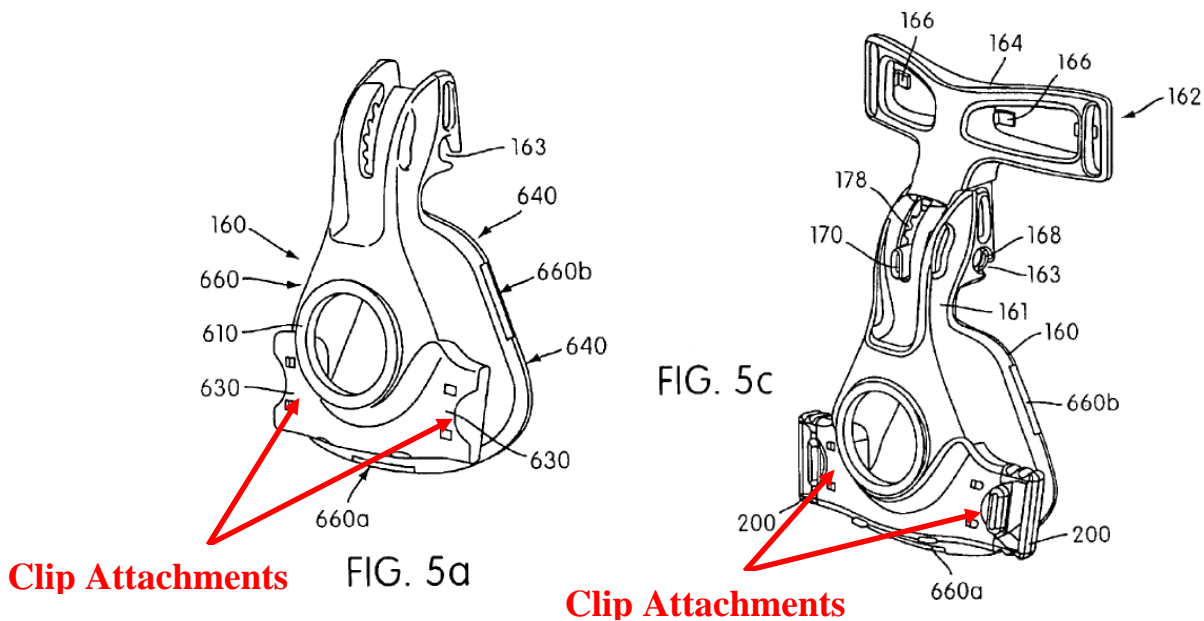
⁸³ *Id.* at col. 10:41–44, Figure 9.

⁸⁴ *Id.*

78. The ability to quickly attach/detach the headgear straps from the mask assembly without re-adjustment was one of the main focuses of the disclosed Lovell arrangement. This is consistent with adding a rigid or semi-rigid clip component to the headgear strap which could also provide ease of use and/or alignment of the connection point. Although such clip components are not specifically illustrated in Lovell, Lovell recognizes that alternate attachment structures such as “snaps, hook and eye closures, hook and loop fasteners, or the like, may be employed.”⁸⁵

⁸⁵ *Id.* at col. 6:10–19.

79. To the extent the teachings of Lovell are insufficient for this limitation, such clip attachments were common knowledge prior to the '061 Patent among skilled artisans and taught by the prior art. For example, Gunaratnam illustrates an outer frame with two lower headgear clip attachments 630, just like those that are described in the '061 Patent.⁸⁶ The clip attachments 630 described in Gunaratnam are adapted to receive clip portions on the straps of a headgear assembly.⁸⁷



80. A person of skill in the art would have known to incorporate these commonly known clip attachment features on the second frame of Lovell. A

⁸⁶ Ex. 1103 at col. 4:31–34.

⁸⁷ *Id.*

skilled artisan would have recognized that clip attachments on the second frame would allow patients to more easily attach and detach the headgear for cleaning, without requiring a user to lose the adjusted position.⁸⁸ Such clip attachments allow for one-time adjustment of the headgear straps and easy attachment and detachment of the mask from the face. With clip attachments, the user does not have to stretch the straps over the head with the mask pulled tightly toward the face when fitting the mask. Substituting the headgear attachments in Lovell with clips would have been a simple substitution of one known element for another that does no more than yield predictable results.

5. Annular connection adapted to engage an elbow

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

82. Lovell clearly describes a mask assembly with an inlet elbow that couples to an annular connection on the mask frame assembly,⁸⁹ but it may not

⁸⁸ *Id.* at col. 4:31–33, Figs. 5a-5f.

⁸⁹ Ex. 1102 at Figure 10A, col. 9:43–48.

specifically describe the inlet conduit or elbow directly contacting the second frame.

83. In the context of the '061 Patent, the phrases, “annular connection adapted to engage an elbow” and “inlet elbow engages the second frame,” would not require that the annular opening of the second frame directly contact the elbow, as I have discussed above.⁹⁰ Therefore, Lovell describes a second frame 212 with an annular connection that engages the elbow in an operable position relative to the first frame 204 to allow air to flow into the cushion-frame sub-assembly. In fact, Lovell and the '061 Patent describe very similar connections between the annular opening of the second frame and the elbow.

84. The '061 Patent describes “an annular elbow connection seal 248 adapted to engage an inlet conduit, e.g., elbow” and illustrates this as a structure in which the annular wall 440 on the first frame 414 extends through the annular connection 448 of the second frame 412 and contacts or directly receives the elbow when the masks are assembled.⁹¹ As shown below, the '061 Patent shows that the annular wall 440 of the first frame 414 protrudes to the outer side of the second

⁹⁰ See *supra* ¶¶ 32–36.

⁹¹ Ex. 1101 at cols. 7:11–17, 8:27–34, Figures 3–4.

frame 412 where an elbow would be coupled.⁹² Although the '061 Patent does not illustrate the elbow, a person of skill would understand that such an elbow would be received by the annular wall 440 of the first frame 414 and not the annular connection 448 of the second frame 412.

⁹² *Id.* at Figures 4 and 8.

'061 PATENT

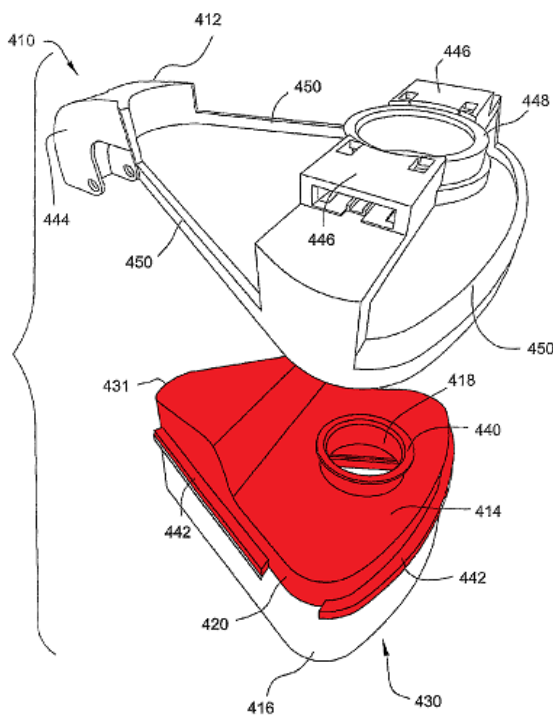


Fig. 7

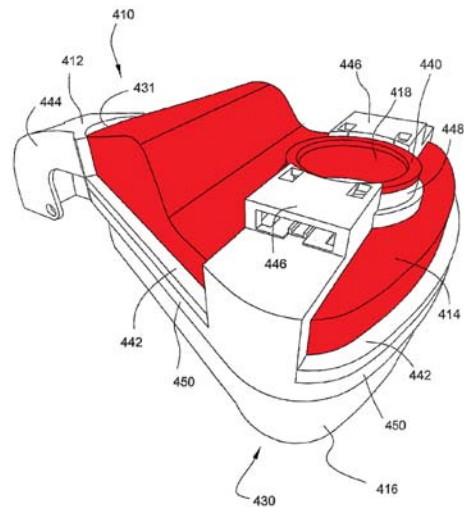


Fig. 8

PRIOR ART LOVELL

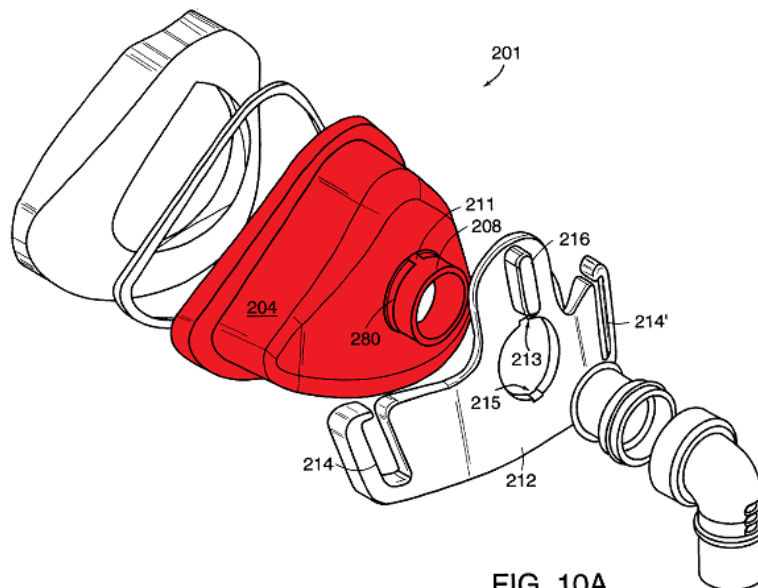


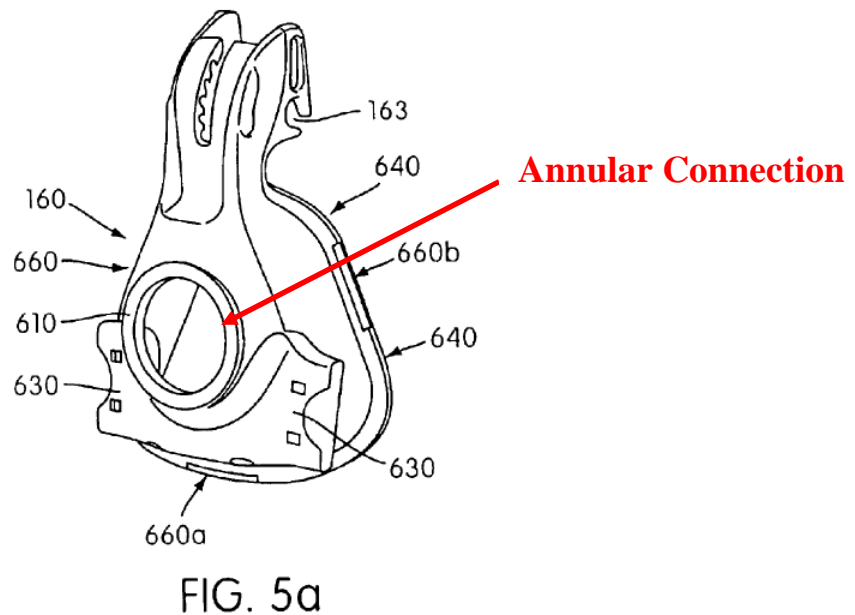
FIG. 10A

85. This is very similar to the arrangement of Lovell (shown above) in which a second frame 212 includes an annular connection (surrounding the unnumbered opening) adapted to interconnect with the inlet 208 at the junction between the first frame 204 and the elbow.⁹³ Like the '061 Patent, it is the inlet 208 on the first frame 204 that extends through and outside of the annular connection of the second frame 212 to directly contact and seal with the elbow.⁹⁴ Thus, under the proper construction, Lovell discloses an “annular connection adapted to engage an elbow” and an “inlet elbow engages the second frame.”

⁹³ Ex. 1102 at Figure 10A, col. 9:43–48.

⁹⁴ *Id.* at col. 5:9–16, Figures 2A and 10A.

86. To the extent the second frame or its annular connection is required to directly contact the elbow, such configurations were also well-known. For example, Gunaratnam discloses an outer frame with an annular connection 610/910 for direct contact and connection to a gas delivery conduit.⁹⁵



⁹⁵ Ex. 1103 at col. 4:20–26, Figures 5a–5f.

87. As another example, Barnett discloses an elbow 36 that is directly attached to the second frame 34 (see Fig. 1A below).⁹⁶

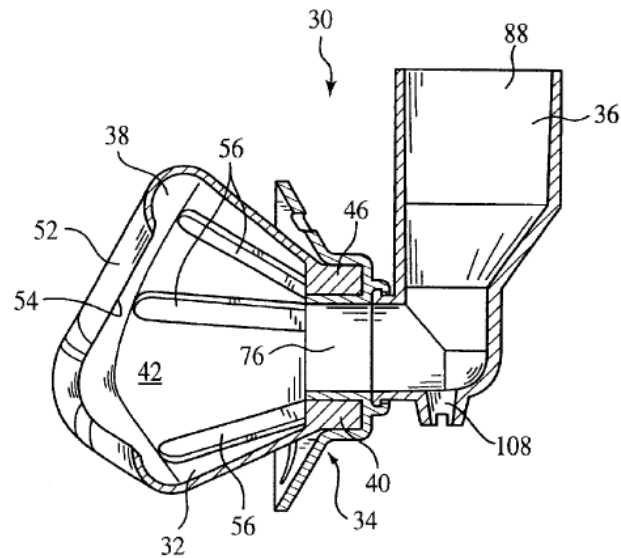
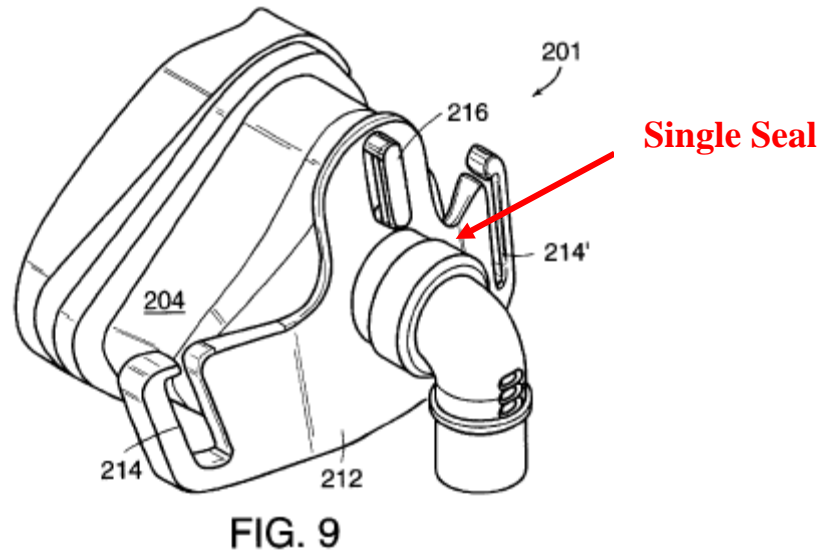


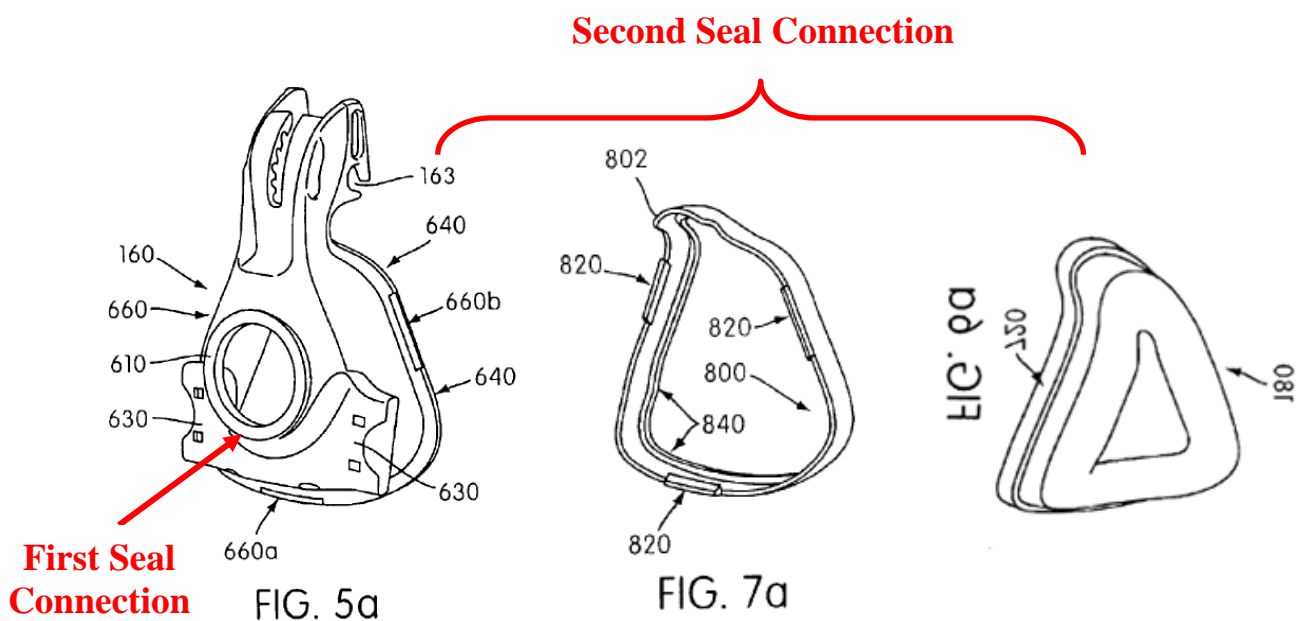
FIG. 1A

⁹⁶ Ex. 1111 at cols. 3:52–57, 9:13–65.

88. Lovell and Gunaratnam represent two design choices for establishing a seal between an interior of an elbow and a breathing chamber. Each option has advantages. Lovell provides a direct connection between the elbow and the cushion-frame sub-assembly, which forms a single seal.



89. Gunaratnam separately connects the elbow and the cushion-frame sub-assembly to the second frame, which requires a seal from the elbow to the second frame and another seal from the second frame to the cushion-frame sub-assembly, but allows separate removal of the elbow and the cushion-frame sub-assembly from the second frame.



90. The ability to remove the cushion sub-assembly on its own permits, if desired, the elbow to be permanently or semi-permanently coupled to the second frame. Such an arrangement makes removal and/or replacement of the cushion sub-assembly a simpler process for end users for routine maintenance such as cleaning the cushion-frame subassembly components.

91. A person of skill in the art at the time of the invention would have been motivated to directly attach the elbow to the second frame to make it easier for a patient to detach the elbow without affecting the engagement of other mask components. This type of arrangement is just one of a finite number of predictable solutions for providing a connection between the elbow and the interior of the breathing chamber. A person of skill in the art would have understood that attaching the elbow to the skeleton frame would allow for more flexibility in the design of the elbow as compared to attaching the elbow to a component of the breathing chamber because the breathing chamber requires an air tight seal.

6. Separate opening

92. Independent Claim 17 includes “an opening located between the annular connection and the upper support member.” Independent Claims 32 and 81 include “a separate opening located between the annular opening and the upper support member.”

93. As I have explained above, Lovell discloses a two-frame arrangement having an annular opening on the second frame, wherein the second frame has open spaces that provide access to the first frame.⁹⁷ Lovell does not expressly disclose a separate opening between the annular opening and an upper portion of the second frame. However, second frames having such a separate opening to allow access to the first frame were well-known to a person of skill in the art.

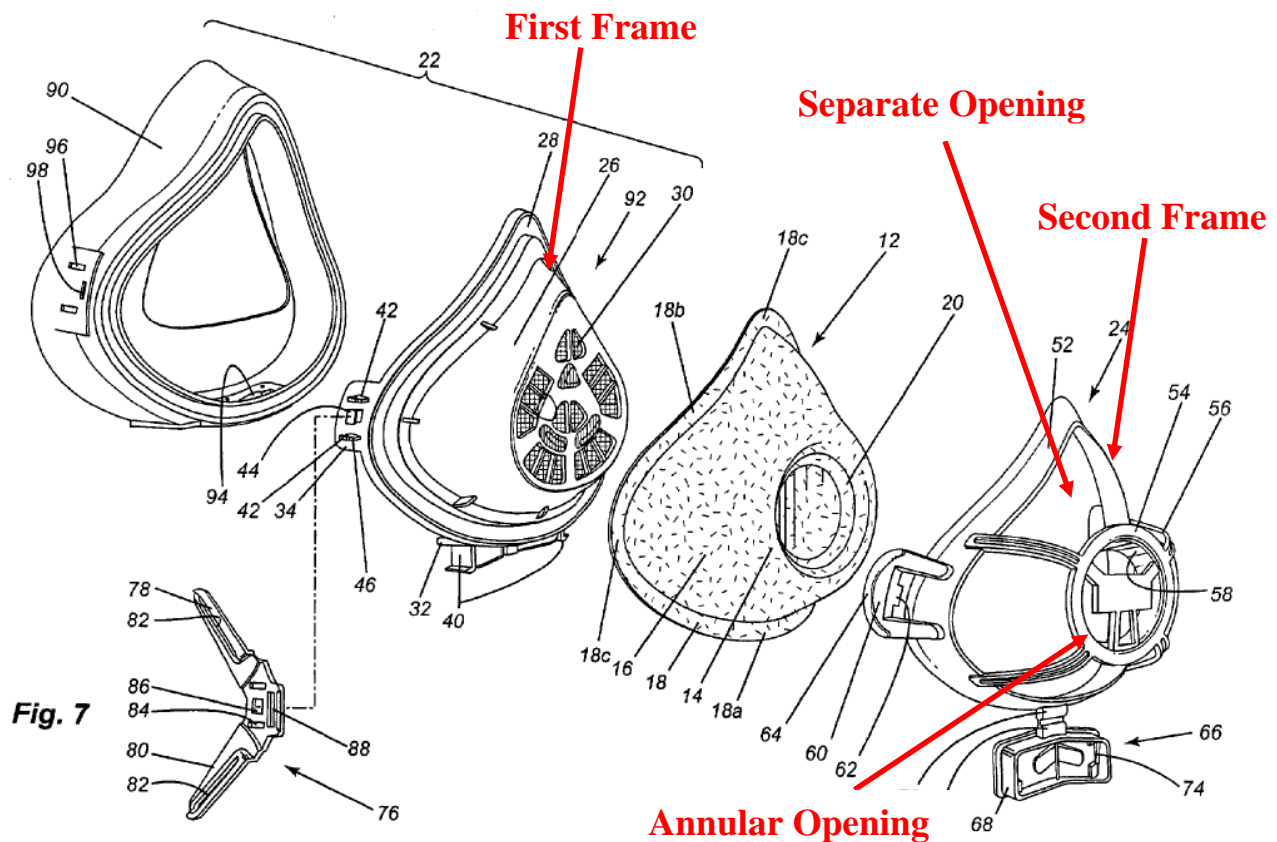
94. For example, Gelinas describes a two-frame mask assembly with a first frame 92 and a second frame 24.⁹⁸ The second frame 24 defines an opening between an annular opening 54 and an upper portion of the second frame 24.⁹⁹ The second frame 24 has two connecting members 52 that connect an upper portion and

⁹⁷ See *supra* ¶¶ 82–85.

⁹⁸ Ex. 1104 ¶¶ 26, 31.

⁹⁹ *Id.* ¶¶ 26–32, Figure 7.

a lower portion of the second frame 24.¹⁰⁰ The separate opening provides access to the first frame 92 and its vents 30. When assembled, the first frame 26 is accessible through the separate opening in the second frame 24.



¹⁰⁰ *Id.* ¶ 32.

95. As shown in Figure 51 below, Berthon-Jones also describes a CPAP mask assembly with separate openings in the mask frame.¹⁰¹

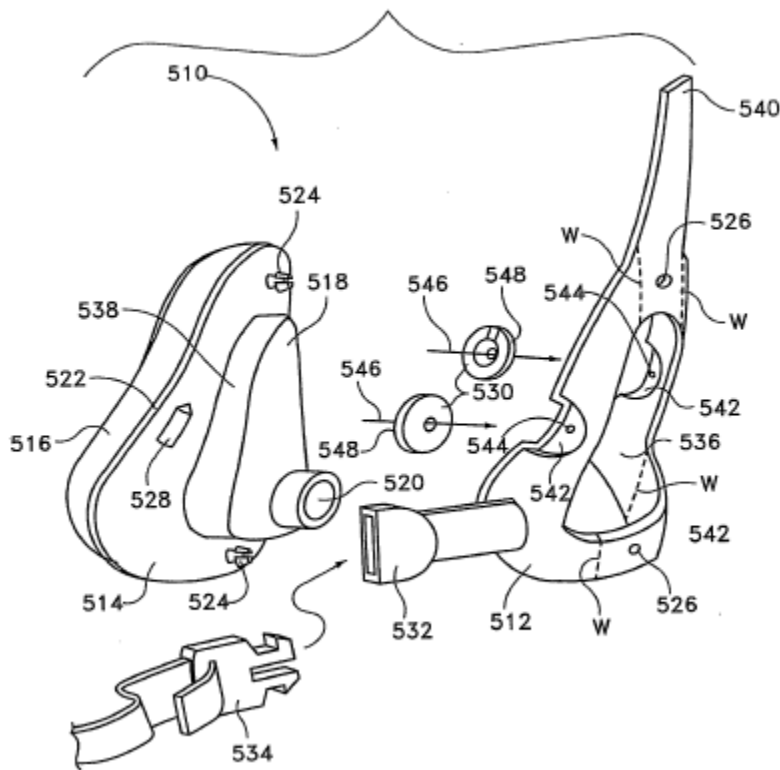


Fig.51

96. As explained above, a person of skill in the art would have known to modify the nasal mask of Lovell to be a full-face mask.¹⁰² A person of skill also would have recognized that the full-face mask would require a gas washout vent to enable CO₂ washout and vent the breathing chamber upon overpressurization.¹⁰³ It

¹⁰¹ Ex. 1108 ¶¶ 183–184.

¹⁰² See *supra* ¶¶ 60–64.

¹⁰³ See Ex. 1102 at col. 5:36–41.

was common in the industry to place such a vent on the first frame, particularly in the nasal-bridge region, and taught by the prior art. For example, Gunaratnam shows that it was common to provide a vent in the nasal bridge region of the mask assembly.¹⁰⁴

97. Although Lovell discloses a vent on the elbow, a person of skill in the art would have been motivated to modify a full-face version of the mask of Lovell to include a vent on the nasal bridge region of the first frame and in contact with the breathing chamber, as taught by Gunaratnam. It was well-known to place the vent on the first frame adjacent the nasal region so as to be closer to the patient's nose and to minimize dead space. Positioning the vent or opening opposite the inlet relative to the nose would permit air to flow from the inlet, by the patient's nose, and exit the vent to flush exhaled air effectively and minimize re-breathing of exhaled air.

98. 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 vents through the second frame, and thus would have been motivated to modify the second frame to include a separate opening between the annular elbow connection and the upper portion of the second frame. Additionally, a person of skill in the art

¹⁰⁴ Ex. 1103 at col. 6:25–29, Figures 8a and 15.

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. A skilled artisan would have reasonably expected success in modifying the mask system of Lovell to include these features. The combination of these features would be nothing more than a combination of elements that were well-known in the art and which produce results that would have been predictable to one of ordinary skill in the art.

7. First frame and the cushion are integrally molded

99. 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.”

100. Lovell discloses that the breathing chamber is substantially leakage-free due to the bond or interface between the cushion 2 and the frame.¹⁰⁵ To the extent Lovell’s disclosure is insufficient for this limitation, a person of ordinary skill would have known to integrally mold the cushion with the first frame. For example, Gelinas discloses that the cushion 90 can be secured to first frame (second part 92) by “different means such as mechanical securing means, chemical

¹⁰⁵ Ex. 1102 at col. 4:34–58.

affixing means or through-molding processes.”¹⁰⁶ Namey also discloses molding a frame 38 to a cushion 40 to form a secure, airtight bond between the frame and the cushion.¹⁰⁷

101. A person of skill in the art would have recognized that an integrally molded cushion-frame sub-assembly would simplify manufacturing by joining CPAP components without additional structures or materials (e.g., adhesives). This would also eliminate hand assembly of the cushion-frame sub-assembly. Integrally molding the cushion and the first frame would have also provided an airtight seal and would have prevented undesired removal of the cushion from the first frame.¹⁰⁸

8. Connecting members

102. 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 is located between the two connecting members.” Dependent Claims 82 and 89 includes “two elongate frame members connecting the upper member and the lower member and at least partially bounding the separate opening.”

¹⁰⁶ Ex. 1104 ¶ 26.

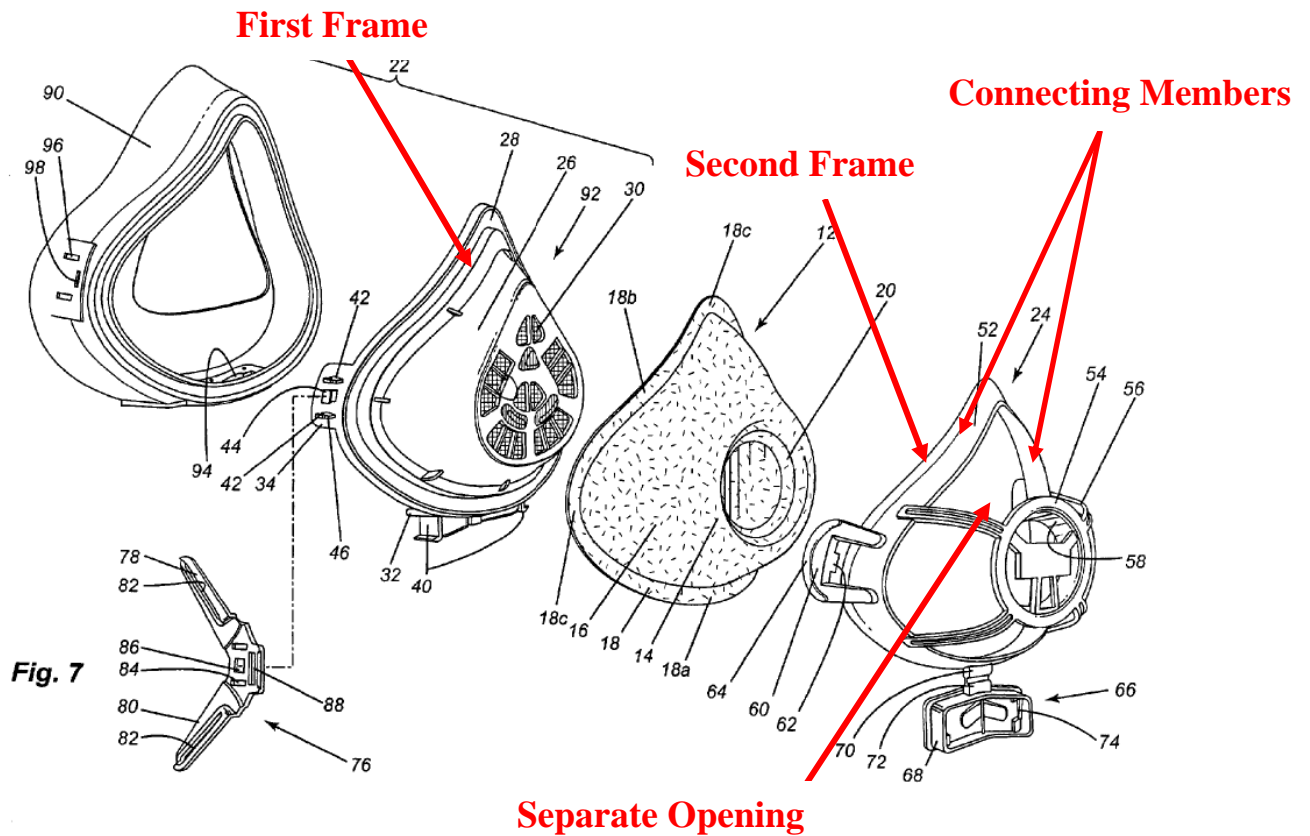
¹⁰⁷ Ex. 1113 ¶ 28, Fig. 4b.

¹⁰⁸ *See id.*

Declaration of Jason Eaton, P.E., in support of
IPR Petition – U.S. Patent No. 8,944,061

Dependent Claims 83 and 89 further includes “the elongate frame members include contact points with the first frame to prevent rotation of the first frame with respect to the second frame.”

103. Lovell does not expressly disclose connecting members on the second frame, but such connecting members were common knowledge to those skilled in the art and taught in the prior art. For example, the second frame 24 of Gelinas defines an opening between an annular opening 54 and an upper portion of the second frame 24 to provide access to the first frame 92.¹⁰⁹ The second frame 24 has two connecting members 52 that connect an upper portion and a lower portion of the second frame.¹¹⁰



¹⁰⁹ Ex. 1104 ¶¶ 26, 32, Figure 7.

¹¹⁰ *Id.*

104. As shown below in Figure 2 of Gelinas, the connecting members 92 contact the periphery of the first frame 92 and prevent rotation of the first frame with respect to the second frame.

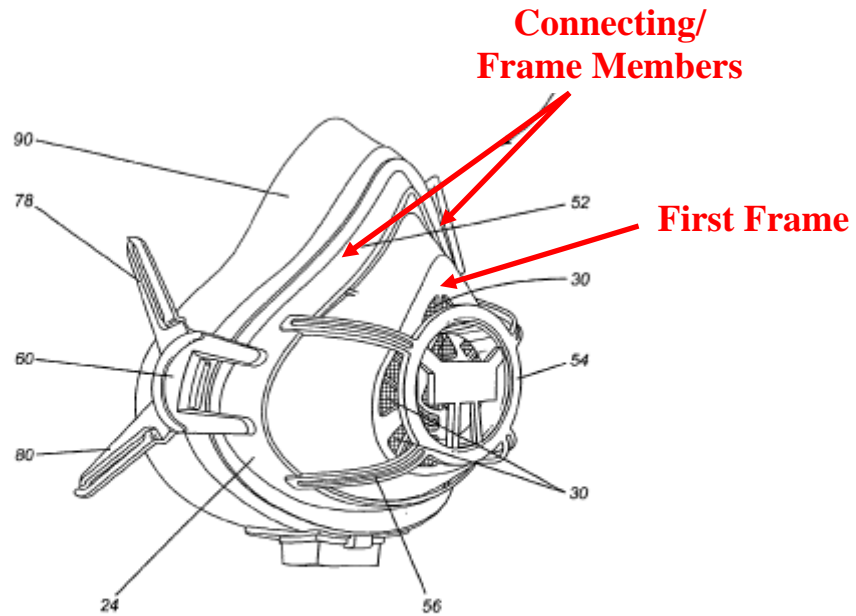


Fig. 2

105. Such features were commonly used in CPAP masks. As shown in Figure 51 (below), Berthon-Jones also describes a CPAP mask assembly with frame having two connecting members that connect a lower portion of the frame to an upper portion of the frame and an opening located between the two connecting members.¹¹¹

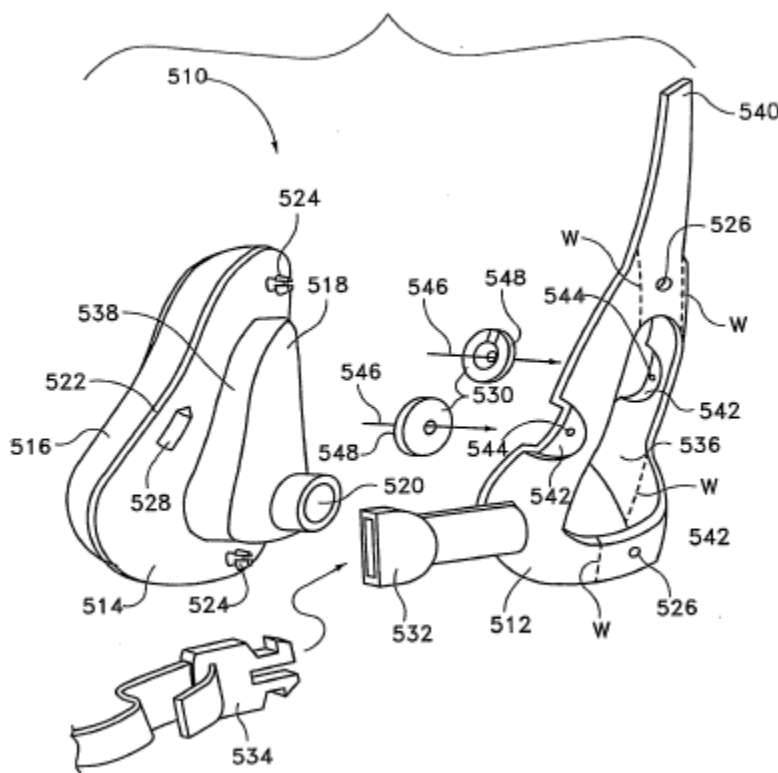


Fig.51

106. For at least the reasons provided above, a skilled artisan would have been motivated to incorporate the second opening of Gelinas between the annular opening and an upper portion of the second frame of Lovell to provide access to a

¹¹¹ Ex. 1108 ¶¶ 183–184.

vent assembly.¹¹² A skilled artisan would have also known to incorporate connecting members on the second frame to support the upper portion of the second frame above the second opening. Such integral connecting members would define 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.

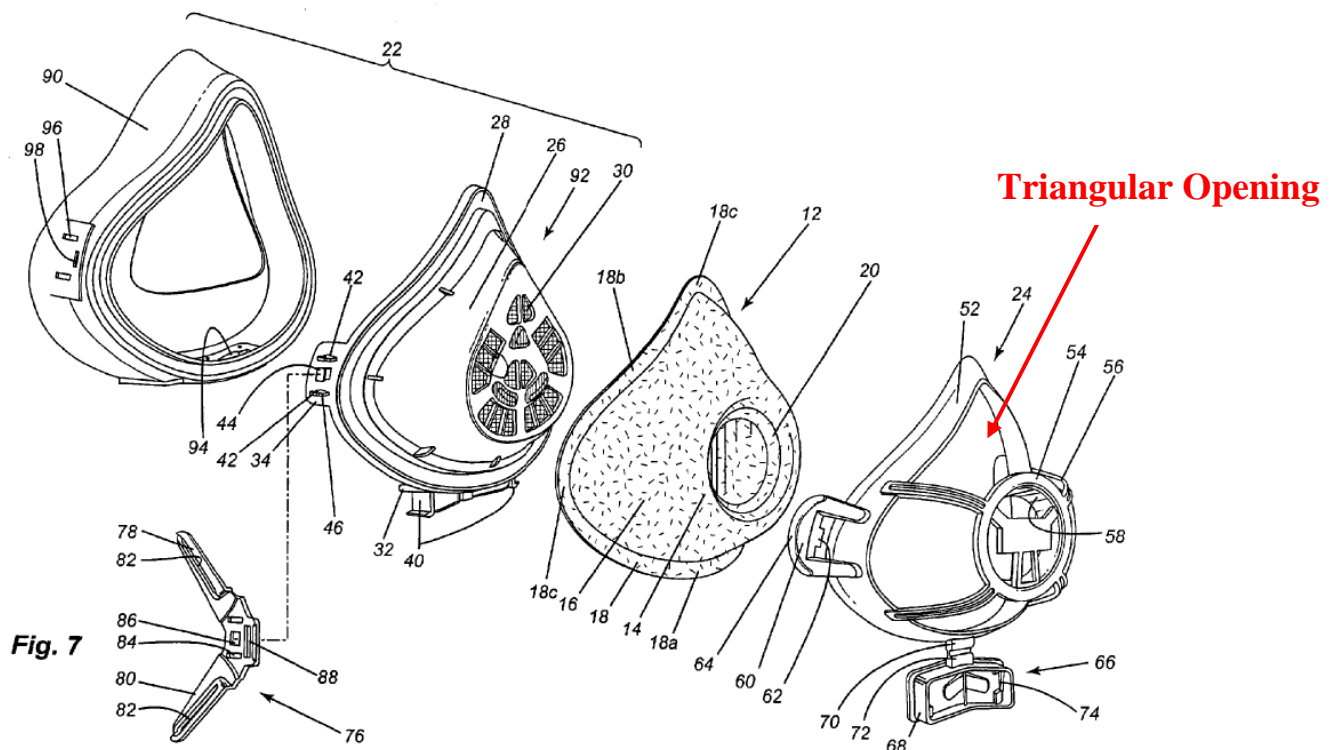
9. Opening is substantially triangular

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

108. Although Lovell does not expressly disclose a second opening that is substantially triangular, such triangular openings were common knowledge to those skilled in the art and taught by the prior art.

¹¹² See *supra* ¶¶ 92–98.

109. For example, in Gelinas, the second opening between the frame members is triangular in shape. Specifically, Gelinas discloses that “[f]lange portion 18 defines a generally triangular figure” and the upper frame members 52 follow this same triangular figure.¹¹³



¹¹³ Ex. 1104 ¶ 25, Figure 7.

110. Such triangular openings were common in full-face CPAP masks. For example, Figure 51 of Berthon-Jones (below) illustrates a mask chassis 512 having a substantially triangular shape and a central aperture 536 with a substantially triangular shape.¹¹⁴

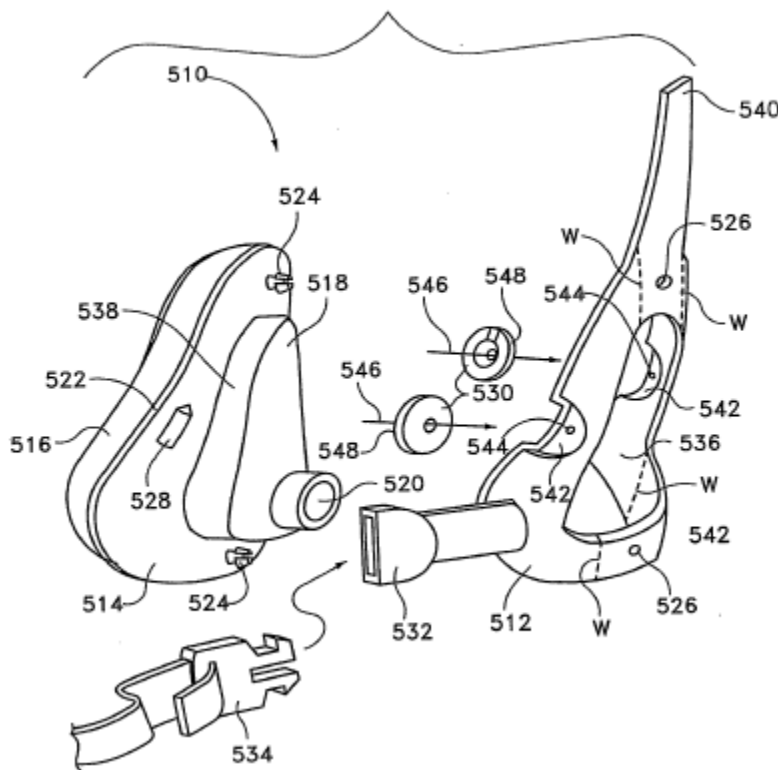


Fig.51

111. As discussed above, a person of skill in the art would have been motivated to modify the second frame to include a second opening.¹¹⁵ A person of ordinary skill in the art would have known that most full-face masks have a

¹¹⁴ Ex. 1108 ¶¶ 183–184.

¹¹⁵ See *supra* ¶¶ 92–98.

generally triangular shape (*see e.g.*, Fig. 51 of Berthon Jones on previous page) and would have been motivated to make the second opening triangular so that the frame members would follow the outer shape of the mask assembly. Moreover, a person of skill in the art would have recognized that simple connecting members that follow the shape of a generally triangular mask frame would define a triangular opening. Such a triangular opening would be the result of minimalistic design approach that would reduce materials used and allow for easier manufacturing.

10. Annular opening and elbow are sealingly connected

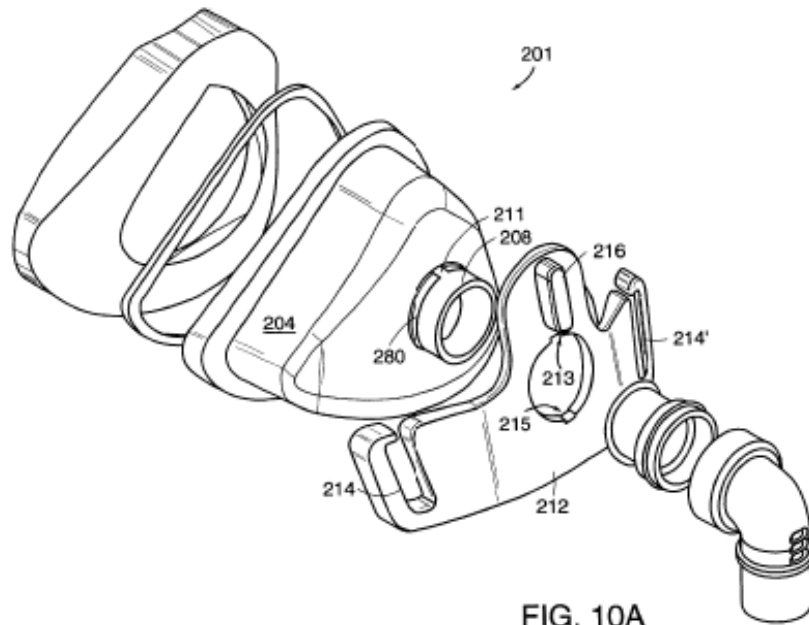
112. Dependent Claims 46 and 48 of the '061 Patent require a mask assembly in which the “annular opening and the elbow are sealingly connected.”

113. As explained above, in the context of the '061 Patent, 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.¹¹⁶

114. Lovell describes a mask assembly with an inlet elbow that couples and seals to the second frame 212 (see Figure 10A below). The elbow is indirectly

¹¹⁶ *See supra* ¶¶ 37–39.

coupled to the second frame 212 to allow a seal between the interior of the elbow
and the breathing chamber defined by the first frame 204.



115. To the extent the second frame or its annular connection is required to directly contact and seal with the elbow, such configurations were well-known. As I explained above, Gunaratnam discloses an outer frame with a gas inlet aperture 610/910 for direct sealing connection to an elbow of a gas delivery conduit.¹¹⁷ Gunaratnam states, “The frame 160 . . . incorporates a gas inlet aperture (610) for connection to a gas delivery conduit (not shown) of a patient gas delivery system.”¹¹⁸ A person of skill in the art would have known to modify the mask assembly of Lovell in view of Gunaratnam to arrive at an arrangement in which the elbow directly seals with the second frame, as one design option.

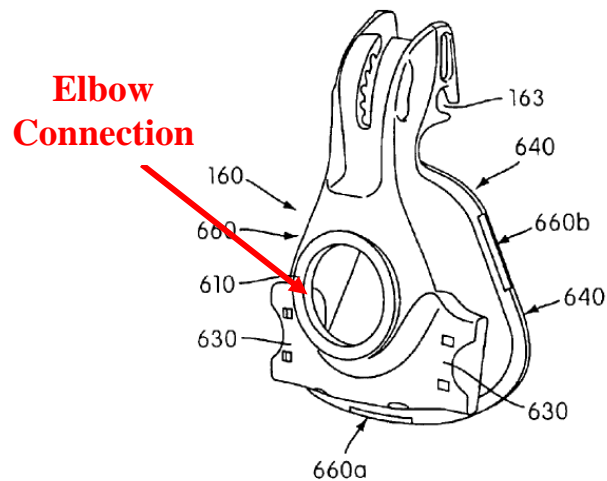


FIG. 5a

¹¹⁷ See *supra* ¶ 86.

¹¹⁸ Ex. 1103 at col. 4:20–26, Figures 5a–5f.

116. As another example of a direct connection between the second frame and the elbow, Barnett discloses an elbow 36 that is directly mounted and sealed to the outer frame 34 (see Fig. 1A below).¹¹⁹

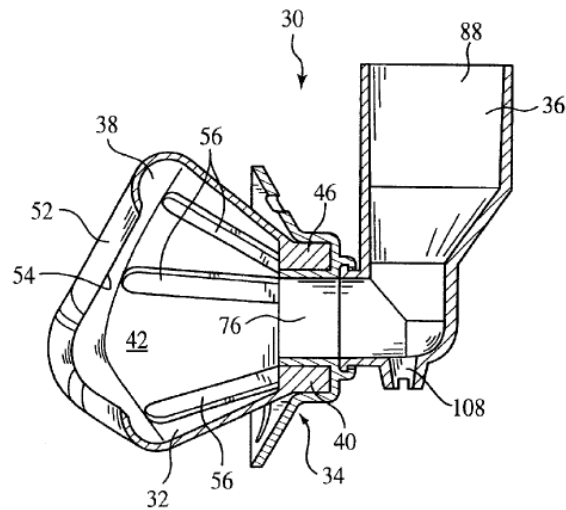
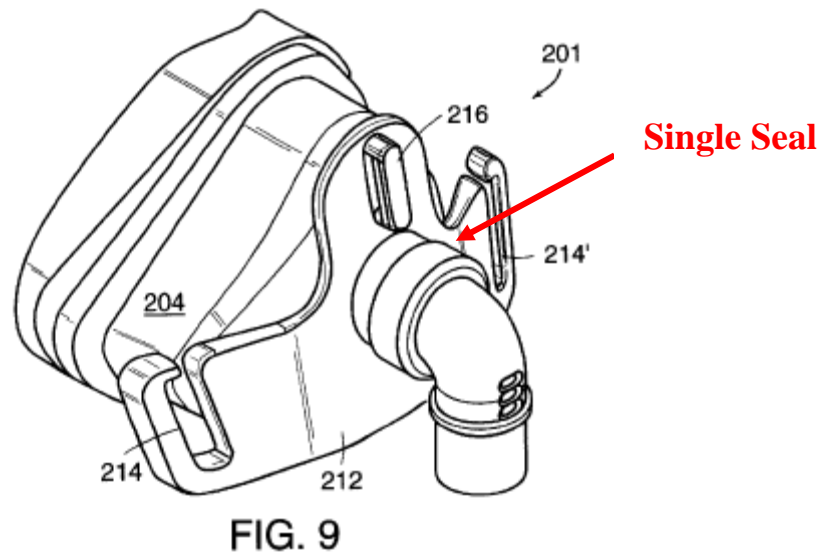


FIG. 1A

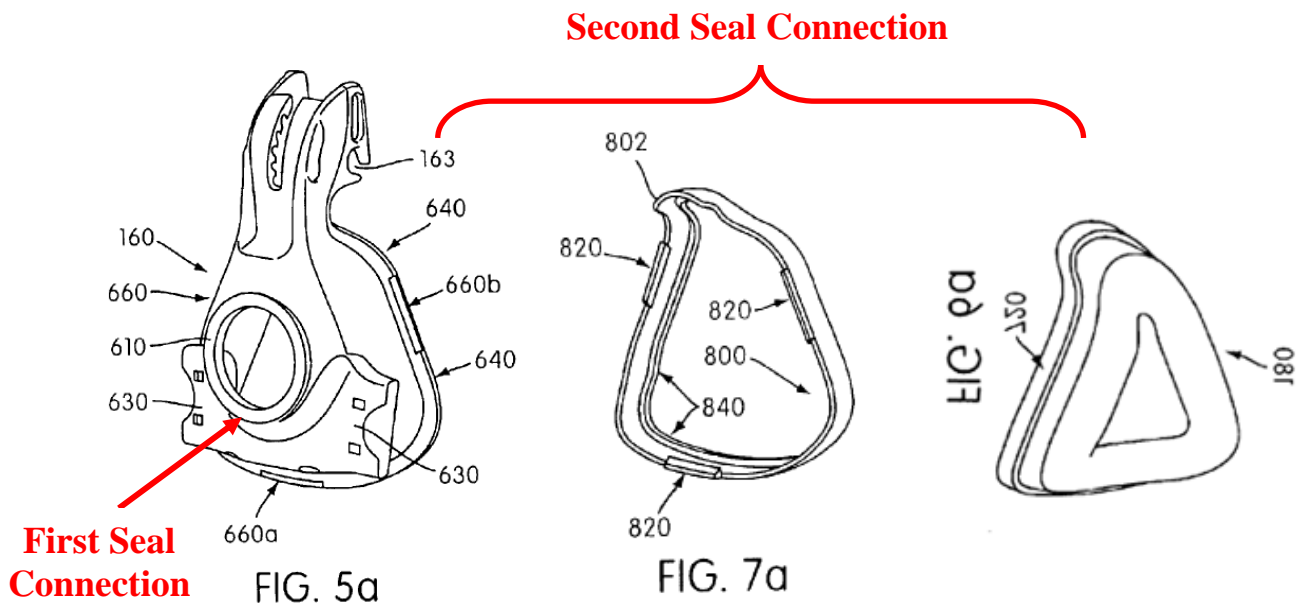
¹¹⁹ Ex. 1111 at col. 3:52–57, , 9:13–65.

117. As I have mentioned above, Lovell and Gunaratnam represent two well-known design choices for establishing a seal between an interior of an elbow and a breathing chamber of a mask.¹²⁰ Each option has advantages. Lovell utilizes a direct connection between the elbow and the cushion-frame sub-assembly.



¹²⁰ See *supra* ¶¶ 88–91.

118. Gunaratnam separately connects the elbow and the cushion sub-assembly to the second or outer frame, which allows separate removal of the elbow and the cushion sub-assembly from the outer frame.



119. A person of skill in the art at the time of the invention would have been motivated to directly attach the elbow to the second frame to make it easier for a patient to detach the elbow without affecting the engagement of other mask components. Such a configuration would have been one of a finite number of predictable solutions for providing a connection between the interior of the elbow and the breathing chamber. A person of skill would have recognized that this arrangement would be advantageous to the patient who wished to temporarily disconnect from the flow generator without removing the mask and headgear, for example. Additionally, a person of skill in the art would have understood that attaching the elbow to the second frame would allow for more flexibility in the design of the elbow as compared to attaching the elbow to a component of the breathing chamber because the breathing chamber requires an air tight seal.

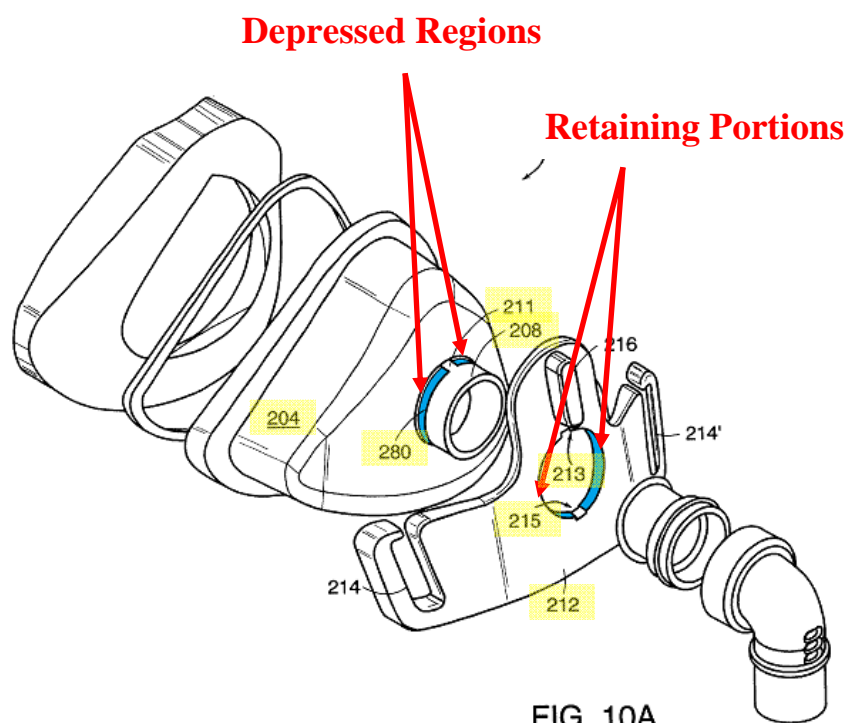
11. Snap-fit

120. Independent Claim 81 includes “wherein the first frame and the second frame snap-fit together.”

121. As described above, Lovell discloses a snap-fit connection between the first frame and the second frame.¹²¹ Specifically, Lovell describes a connection in which portions of the second frame (retainer 212) engage the inlet structure 208

¹²¹ See *supra* ¶ 45.

on the first frame (shell 204) with an interference fit and then release into the depressed annular region 280 to form a snap-fit.¹²² A skilled artisan would have also known that snap-fit engagements were common in CPAP masks assemblies and would have been motivated to use such an engagement to attach the first frame and second frame.



122. The interference fit of Lovell, which provides retention between the mask frame and headgear connector, constitutes a removable snap-fit attachment. The book *Plastic Part Design for Injection Molding*, Robert A. Malloy (1994) describes “snap joint assemblies” as assemblies in which “a protruding feature on

¹²² Ex. 1102 at col. 9:46–64, Figure 10A.

one component, such as a hook or beam, is deflected briefly during the product assembly operation due to an interference, after which the protruding part recovers elastically, and catches in an undercut or indentation on the mating component.”¹²³

A person of skill in the art would have understood “snap-fit,” according to its ordinary meaning, to include an assembly operation that includes interference, deflection, and then elastic recovery of one or more of the parts to a position that provides engagement between the parts.

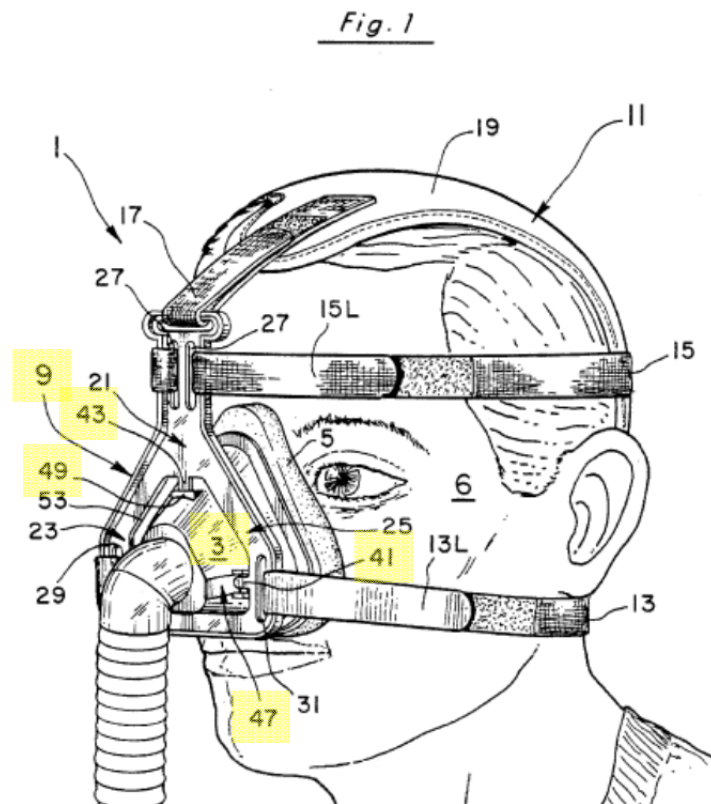
123. To the extent Lovell somehow provides insufficient teachings for a snap-fit, such snap-fit connections in CPAP masks were well-known at the time of the invention and would have been part of the general knowledge of a person of skill in the art. For example, Barnett teaches a tongue and groove snap-fit connection can be provided on main body portion 46 of the cushion module and the retaining portion 76, in addition to or in place of the friction engagement.¹²⁴

124. As another example, Ogden discloses a CPAP mask with a frame module 9 that attaches to the main body 3 of a cushion module by interaction of three detents 39, 41, and 43 received into channels 45, 47, and 49, as shown in

¹²³ Ex. 1110 at 342.

¹²⁴ Ex. 1111 at col. 7:28–33.

Figure 1 below.¹²⁵ Ogden teaches that at least the detent 43 and channel 49 at the top of the frame 3 are dimensioned to snap together to hold or maintain the frame module 9 on the main body 3.¹²⁶



125. Ging is another prior art reference that teaches a snap-fit connection between the cushion-frame subassembly and the second frame, as shown in annotated Figures 27a, 27d, and 27e below.¹²⁷ In Ging, the retention lip 44 is inserted with interference and deflection, and then recovers elastically to a position

¹²⁵ Ex. 1109 at col. 5:14–30.

¹²⁶ *Id.* at col. 5:14–19.

within undercut 33 to provide engagement between the cushion-frame subassembly
40 and the second frame.¹²⁸

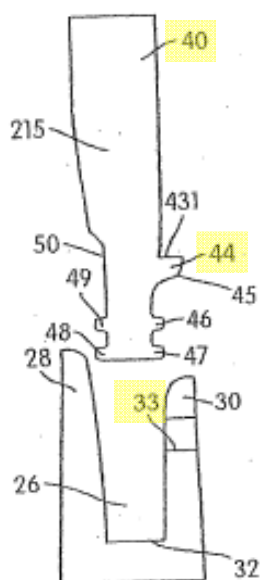


FIG. 27a

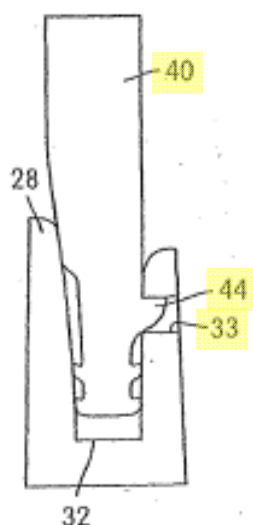


FIG. 27d

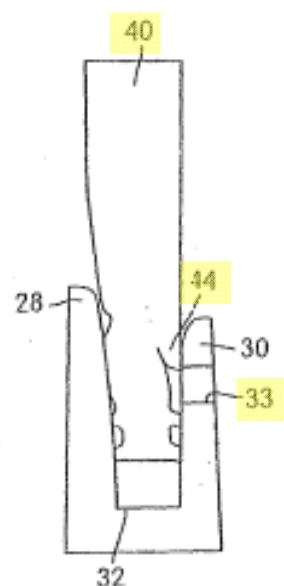
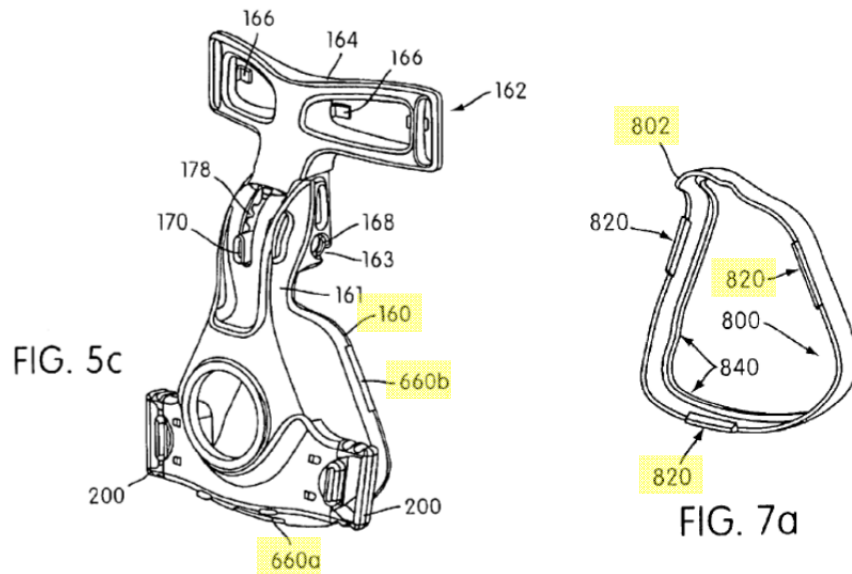


FIG. 27e

¹²⁷ See Ex. 1114 ¶¶ 201, 208, Figs. 27a–27e.

¹²⁸ *Id.*

126. Gunaratnam also discloses a snap-fit with securing tabs 820 that secure the first and second frames and allow for disengagement of these pieces.¹²⁹



127. A person of skill in the art would have been motivated to provide such a snap-fit between the first frame and the second frame. It was well-known to provide a snap-fit connection between a second frame and the cushion-frame sub-assembly to ensure that the components are fully attached and engaged correctly. The snap-fit connection also provides the user with a tactile cue when aligning and assembling the cushion. Additionally, one skilled in the art would have recognized that such 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. A person of skill would

¹²⁹ Ex. 1103 at col. 5:34–43, Figs. 5a and 7a.

Declaration of Jason Eaton, P.E., in support of
IPR Petition – U.S. Patent No. 8,944,061

have also recognized that such a snap-fit arrangement provides repeated assembly/disassembly from the engaged position without destroying parts.

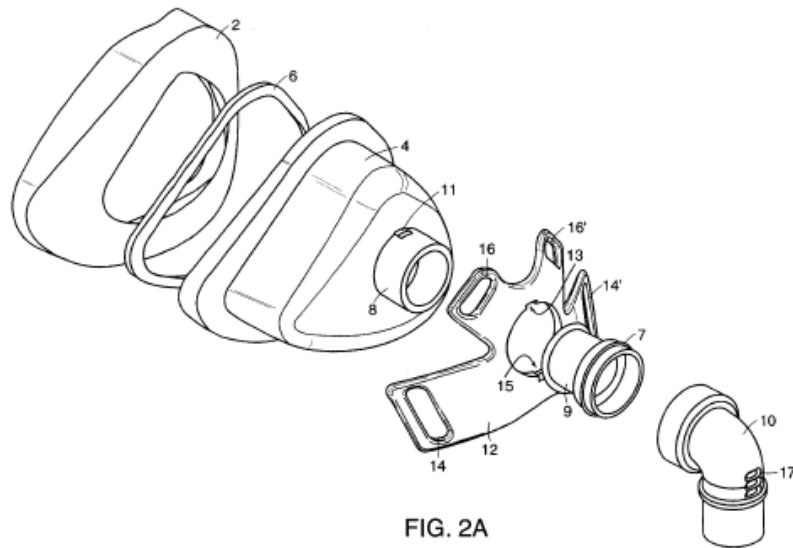
IX. CLAIM CHARTS

128. The claim charts below summarize the disclosure in Lovell, Gunaratnam, Gelinas, Berthon-Jones, Ogden, Barnett, Matula, Namey, Ging, and/or Lithgow that a person of ordinary skill would understand to teach each limitation of Claims 17, 18, 20–23, 26–30, 32, 33, 35–38, 41–46, 48–50, and 81–91 of the '061 Patent.

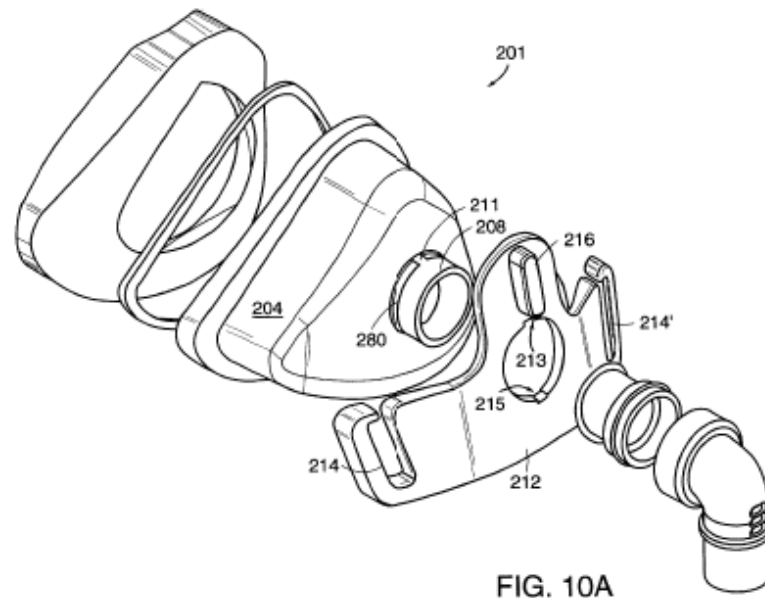
Claims	Prior Art
<p>17. A mask assembly for treatment of sleep disorder breathing by delivering a flow of pressurized gas to a patient, the mask assembly comprising:</p>	<p>Lovell discloses “nasal masks useful for providing pressurized air or therapeutic gas to a patient suffering from an airflow limitation or other respiratory ailment.” Ex. 1102 at col. 1:5–8. Lovell further recognizes that “[n]asal masks are often employed in the treatment of sleep apnea syndrome, characterized by intermittent upper airway obstruction during sleep.” <i>Id.</i> at col. 1:22–25.</p> <div data-bbox="578 1056 1265 1589" data-label="Image"> <p style="text-align: center;">FIG. 10A</p> </div> <p>“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.” <i>Id.</i> at col. 4:11–19.</p>

[A] a first frame
made of first
material;

Lovell discloses that “shell 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.



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.



[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 discloses that “nasal mask 1 according to the invention includes a seal 2 affixed to a shell 4, for example by bonding.” Ex. 1102 at col. 4:34–36. The cushion 2 is made from a second material (*e.g.*, silicone gel) that is less rigid than the first material (*e.g.*, PellethaneTM). *Id.* at cols. 4:40–44, 7:45–58. The cushion 2 forms a seal around a patient's nose. *Id.* at col. 4:55–58. The first frame 4/204 and the cushion 2 of Lovell together form a breathing chamber. *Id.* at col. 4:47–58. “The chamber 80 is substantially leakage-free due to the bond or interface between the seal 2 and the shell 4, and the conformance of the seal 2 against a user's skin.” *Id.* at col. 4:55–58.

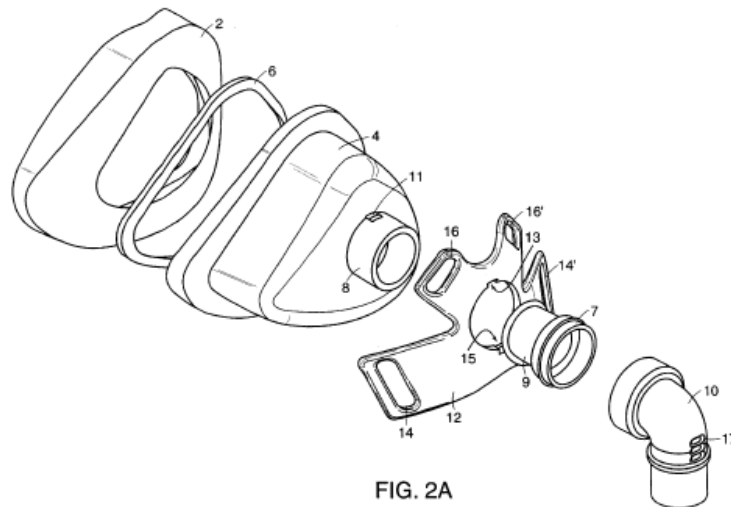


FIG. 2A

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.

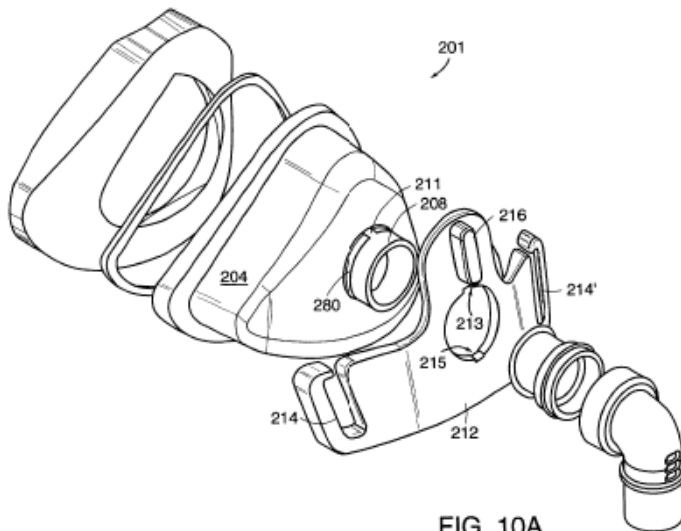
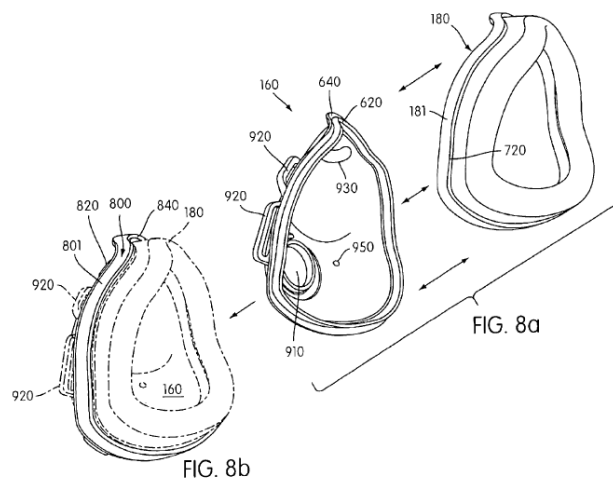


FIG. 10A

Although Lovell discloses a nasal mask, the need for similarly-configured full face masks was well-known before 2005. For example, **Gunaratnam** discloses a “nasal mask frame including a rim portion according to an embodiment of the invention is shown in FIG. 5a.” Ex. 1103 at col. 4:20–21. Later in its disclosure, Gunaratnam discloses that the “invention is also suitable for a full-face mask system,” as shown in Figures 8a and 8b. *Id.* at col. 6:3–5. In the full-face version, Gunaratnam discloses a frame 160 and a cushion 180 that seals around the patient’s nose and mouth regions. *Id.* at col. 6:3–10.



Gelinas discloses that “first 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.

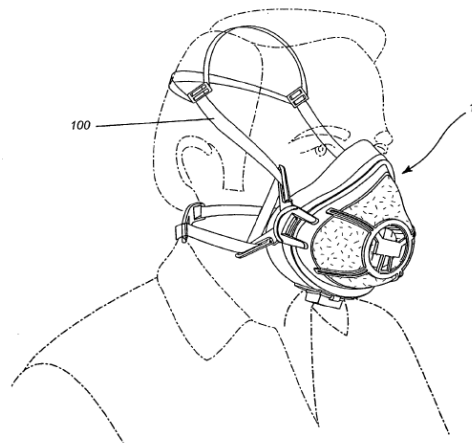


Fig. 1

	<p>Barnett discloses a nasal mask assembly, but further explains that full-face masks were well-known. “Non-invasive ventilation and pressure support therapies involve the placement of a patient interface device, which is typically a nasal/oral mask, on the face of patient to interface the ventilator or pressure support device with the airway of the patient so that a flow of breathing gas can be delivered from the pressure/flow generating device to the airway of the patient.” Ex. 1111 at col. 1:26–32.</p> <p>Ogden also describes the interchangeability of nasal mask and full-face mask features. “Referring to FIGS. 1-3, the facial mask assembly 1 of the present invention is illustrated as a nasal mask covering the nose 2 and nares 4 (see FIG. 3) of the patient 6 but the invention is equally applicable to full face masks covering the patient's nose and mouth.” Ex. 1109 at col. 2:46–50.</p>
<p>[C] a second frame adapted to constrain the first frame, the second frame comprising an upper support member that supports a forehead support,</p>	<p>Lovell discloses a second frame 212 that comprises an upper member 216 that supports an upper strap. Ex. 1102 at col. 10:7–16. “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, proximate a user’s eyes, to ensure sealing along the bridge of the nose and prevent annoying air leaks which would impinge upon the user’s eyes.” <i>Id.</i> at col. 10:7–11. “The upper retention strap is configured and oriented so as not to block the vision of a user.” <i>Id.</i> at col. 10:14–16.</p> <div data-bbox="641 1268 1297 1824" data-label="Image"> </div> <p style="text-align: center;">FIG. 9</p>

To the extent the “forehead support” is limited to a structural support that is positioned in contact with the forehead of the patient, such supports were a well-known solution for the need to provide additional support for the upper portion of the mask and the similar problems noted in Lovell.

For example, **Gunaratnam** addresses the need for additional upper mask support by providing a support structure that is adjacent to or contacting the forehead of the patient. As shown in the figures below, Gunaratnam discloses “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. 4:46–59, Figures 5c–5f.

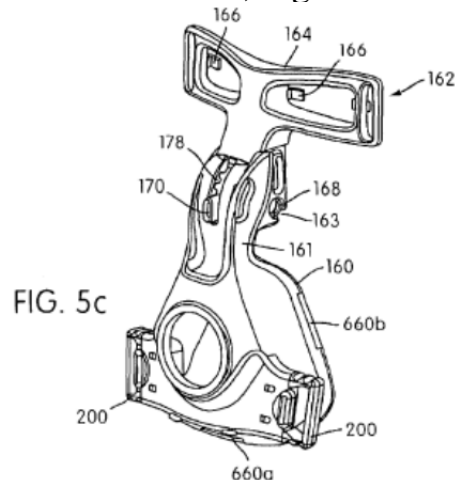
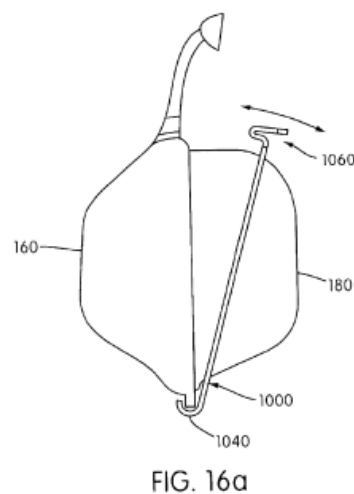


Fig. 16a of Gunaratnam also illustrates a forehead support.



Lithgow discloses that “the headgear assembly may include a pair of upper and lower straps with the upper straps removably connected to clip structure 18 provided on the forehead support 16 and the lower straps removably connected to clip structures 20 provided on the frame 12.” Ex. 1112 ¶ 111.

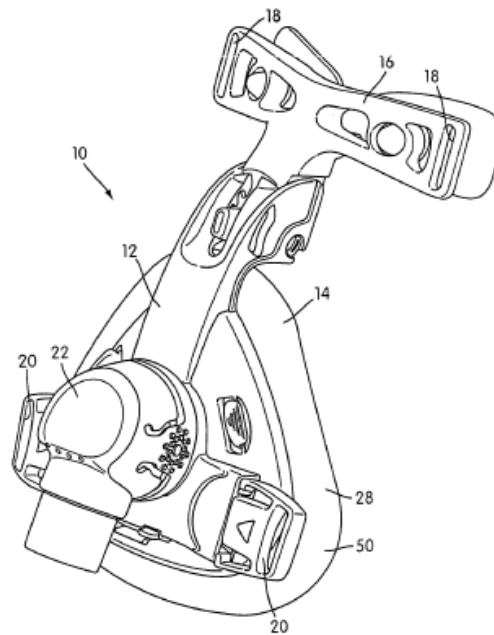
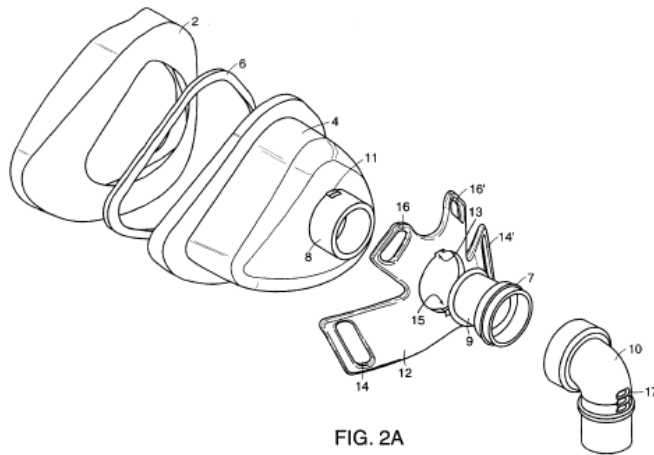


FIG. 1B

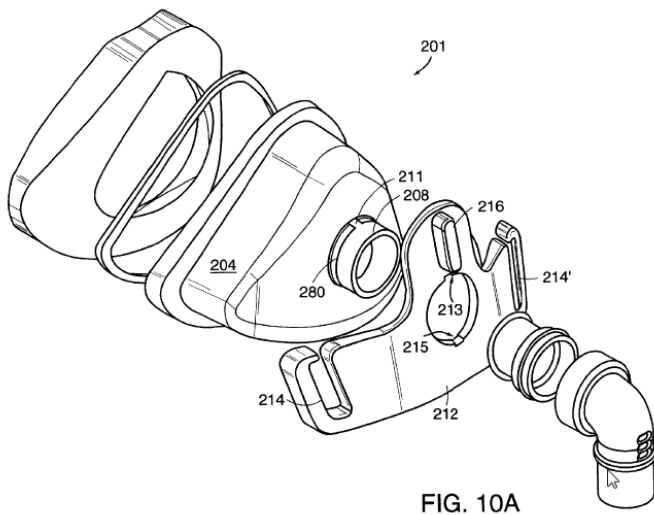
Ging discloses that “[a] mask assembly typically includes a rigid shell, a soft face-contacting cushion, a forehead support and headgear for securing the mask to the head.” Ex. 1114 ¶ 5.

[D] two lower headgear clip attachments engaged with clips provided to straps of a headgear assembly,

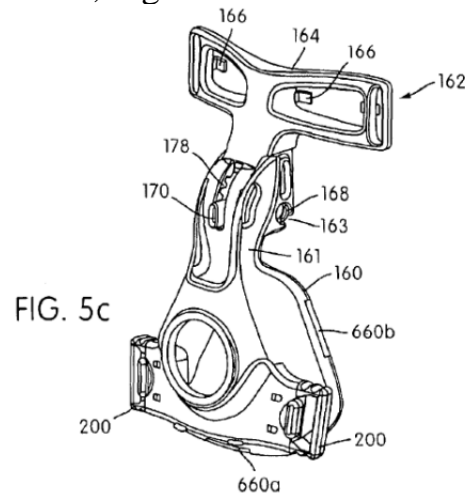
Lovell discloses that the frame has “four connection points disposed remotely from the inlet 8, two lower connection points 14, 14’ and two upper connection points 16, 16’ . . . the upper connection points 16, 16’ are above the lower connection points 14, 14’ and all connection points 14, 14’, 16, 16’ are disposed symmetrically about a vertical centerline A—A of the mask 1.” Ex. 1102 at col 6:2–10. Lovell further discloses that the “connection points 14, 14’, 16, 16’ form slots which allow for connection of the retainer 12 with straps of a headgear apparatus . . . For example, snaps, hook and eye closures, hook and loop fasteners, or the like, may be employed.” *Id.* at col. 6:10–19.



In another embodiment, Lovell discloses that “[t]he connection points 214, 214’, 216 form slots which allow for connection of the retainer 212 with straps of a headgear apparatus.” *Id.* at col. 10:1–3.



Gunaratnam discloses, “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; Figures 5a–5f.



Berthon-Jones discloses, “The mask chassis 512 provides connecting receptacles 532 for corresponding ends of the mask headgear 534. In mask chassis 512, two connecting receptacles 532 are provided, one at each of the left and right edges of the mask chassis 512. However, any number of connecting receptacles 532 may be provided, disposed about the mask chassis 512 as required, depending on the number and position of the headgear straps or strap ends. In FIGURE 51, the connecting receptacles 532 and mask headgear 534 are illustrated as having releasable snap-fit connections.” Ex. 1108 at ¶ 183.

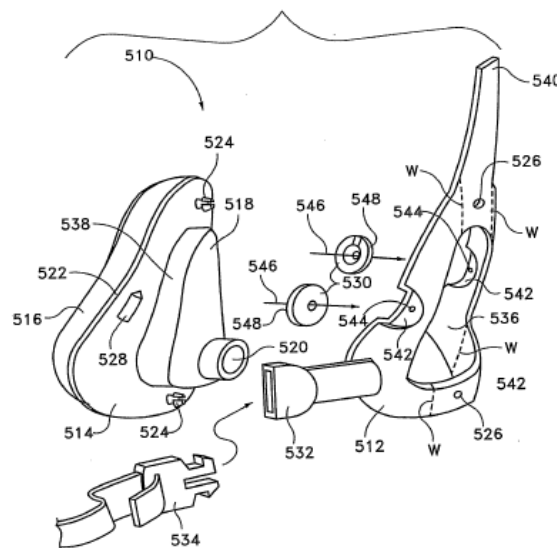


Fig.51

[E] an annular connection adapted to engage an elbow of an inlet conduit and

Lovell discloses, “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.

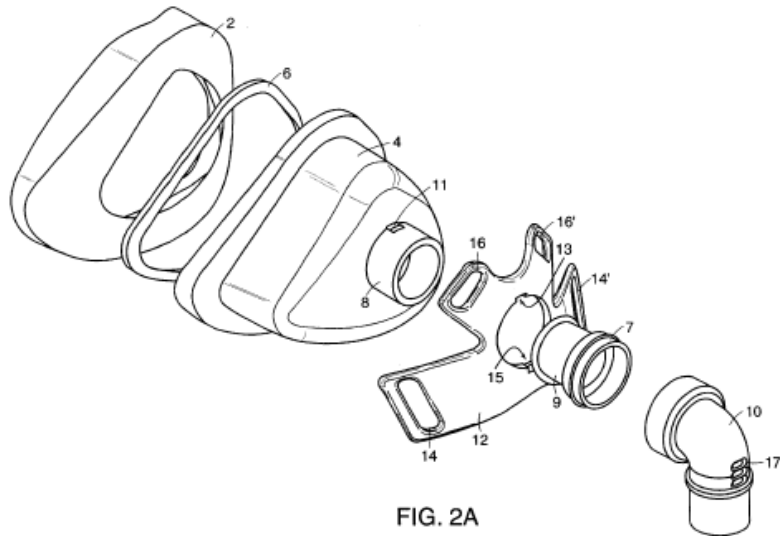


FIG. 2A

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.

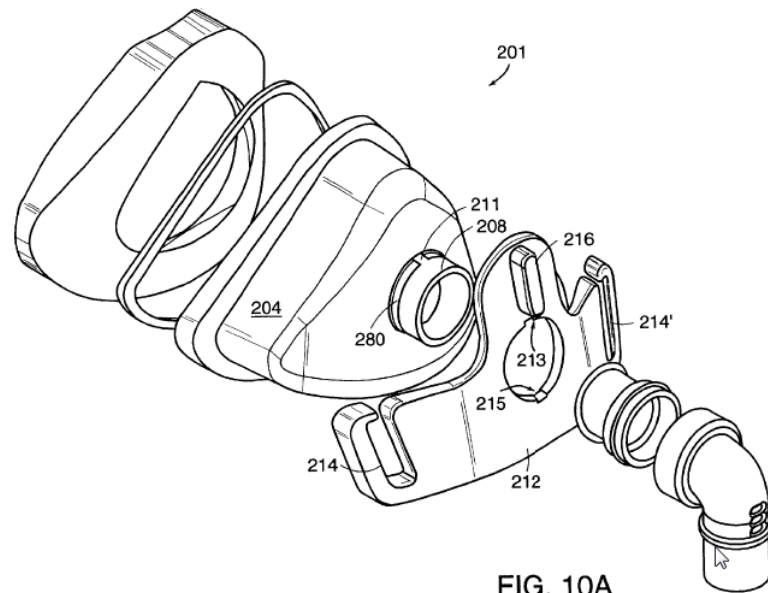
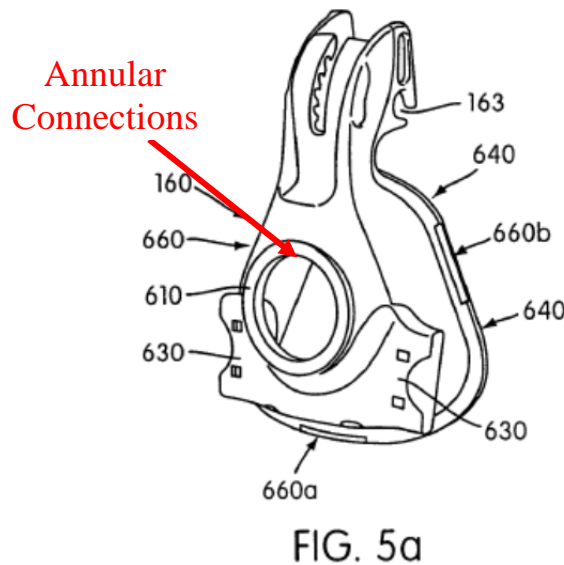


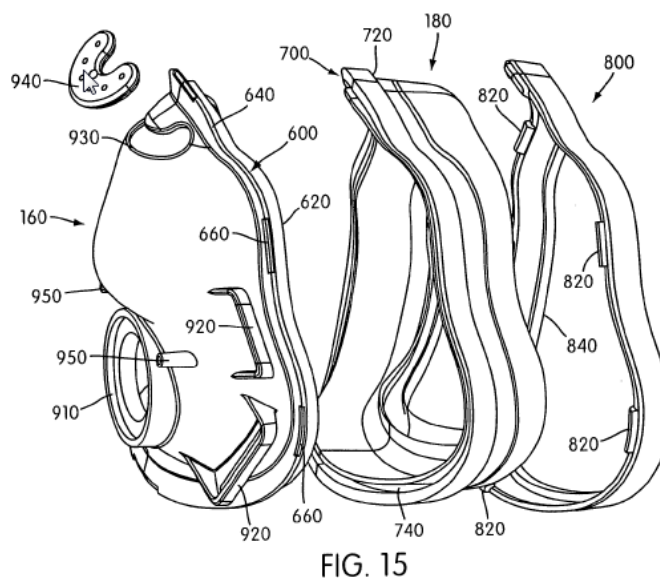
FIG. 10A

Gunaratnam 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.” Ex. 1103 at col. 4:20–26, Figures 5a–5f.

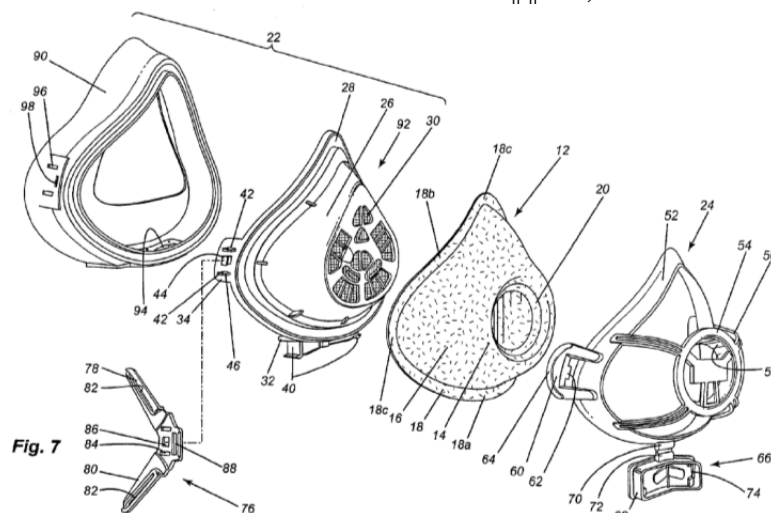


[F] an opening located between the annular connection and the upper support member, the opening providing access to the first frame.

Gunaratnam describes placement of “an aperture (930) for receiving an air vent (940) (FIG. 15) and ports (950)” at the nasal region of the frame 160. Ex. 1103 at col. 6:25–29, Figures 8a and 15.



Gelinas discloses, “Cover 24 has a cup shape that is complementary to cup shaped portion 26. Cover 24 is detachably mated with facepiece 22 to define with facepiece 22 a void area therebetween that is also cup-shaped and suitable to receive filter 12. Cover 24 is movable from a first position, in which the void area is opened allowing the installation or removal of filter 12, to a second position, in which cover 24 mates with facepiece 22 and filter 12 is received in the void area.” Ex. 1104 ¶ 31. The cover 24 (or second frame) that has two elongate frame members and defines an opening between a central ring 54 and the elongate frame members of the cover 24. *See id.* ¶¶ 26, 32.



When assembled, the first frame 92 and filter 12 protrude through the open triangular space defined by frame members 52.

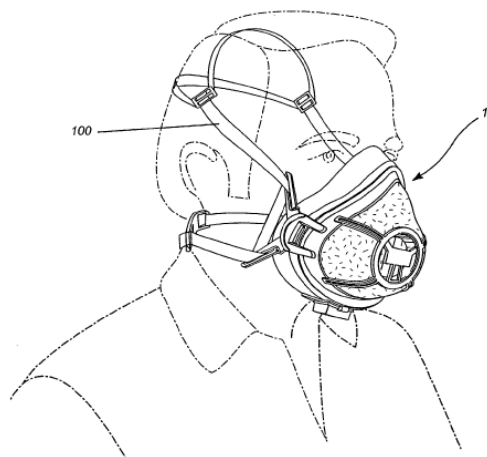


Fig. 1

Berthon-Jones: “At the top and bottom of the secondary frame portion on its patient-outward surface are connecting members 524 that are adapted to be inserted into corresponding receiving holes 526 in the mask chassis” Ex. 1108 ¶ 182. “The mask chassis 512 includes a central aperture 536 that is constructed and sized to receive the raised, central portion 518 of the cushion/secondary frame 514.” *Id.* ¶ 184.

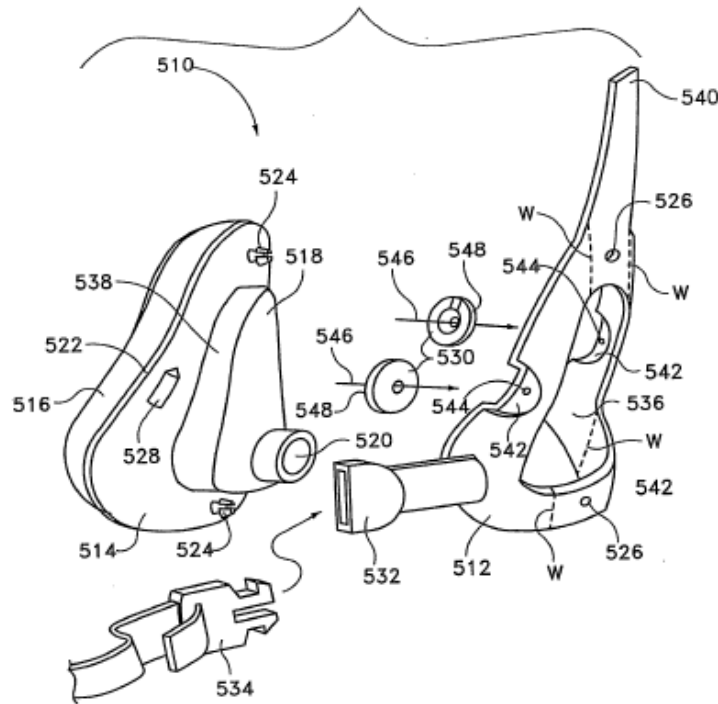
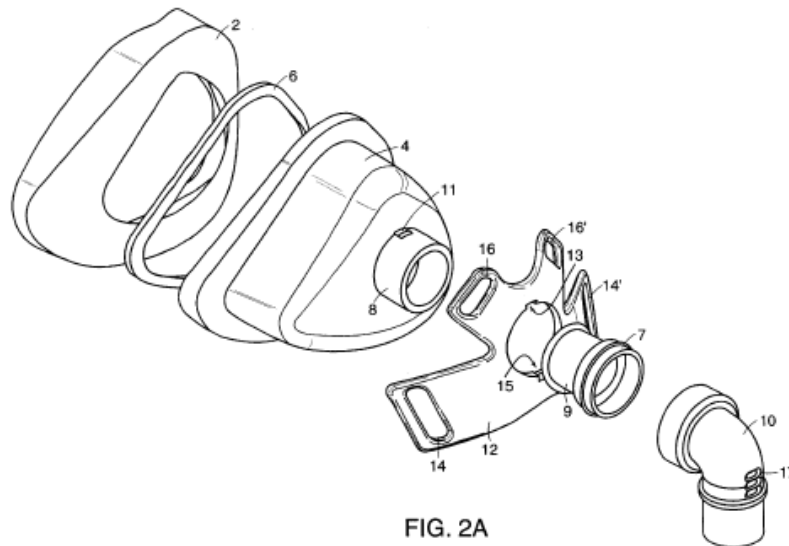


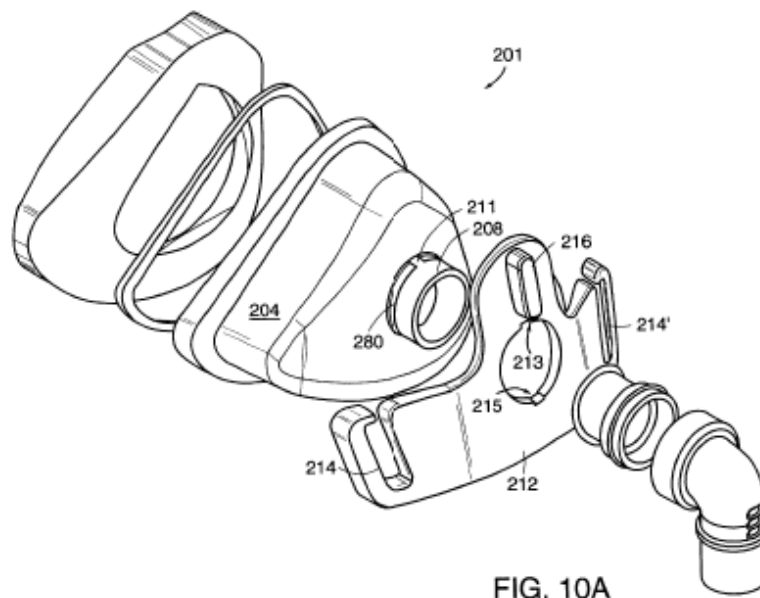
Fig.51

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 discloses that “one 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.

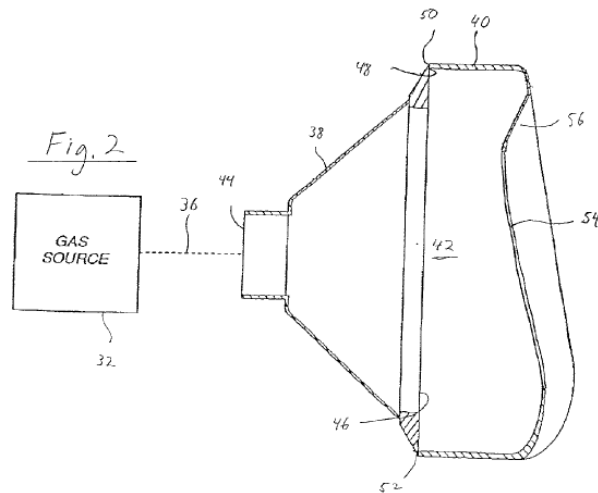


Nasal mask 201 shown in Figs. 9–11, has many of the features of the nasal mask 1 shown in Figs. 1–8. *Id.* at col. 9:34–36.



Gelinas discloses that “first 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.

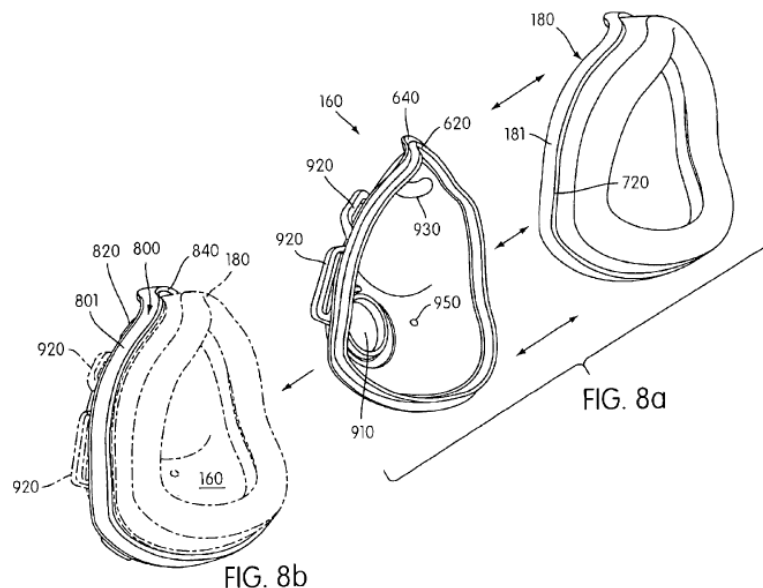
Namey discloses, “The hard plastic of mask body 38 begins cooling and curing immediately after injection of molten plastic ceases. Preferably, the molding of mask seal member 40 to mask body 38 is performed while the mask body is still curing and cooling so that the material defining mask seal member 40, such as silicone, molecularly bonds with the as-yet uncured material of mask body 38, thereby forming a secure, airtight bond between the mask body and the mask seal member at joint 52.” Ex. 1113 ¶ 28.



Berthon-Jones: “[The cushion portion 516] may be molded to (i.e., fused to) the secondary frame portion 18, fixed using adhesives, or secured with appropriate connecting structures.” Ex. 1108 ¶ 181.

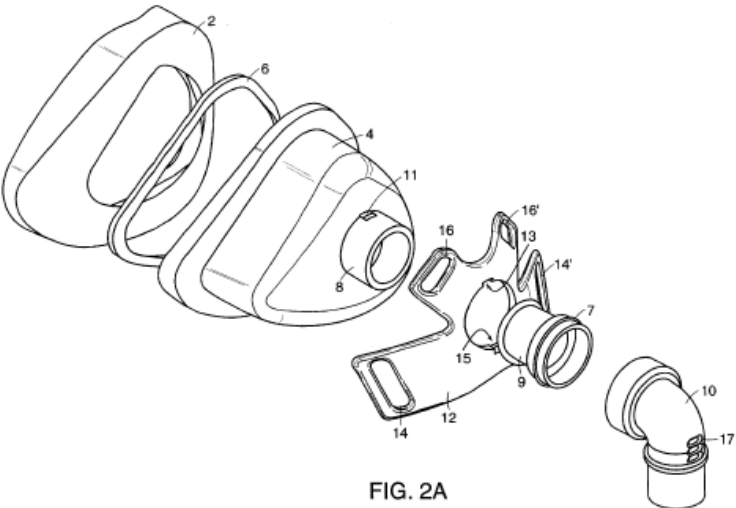
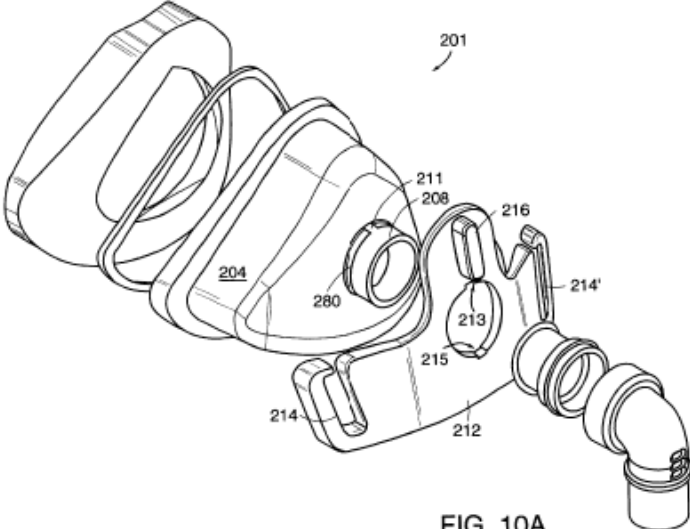
20. The mask assembly according to claim 17, wherein the first frame is contoured to fit over the patient's nose and mouth.

Although Lovell discloses a nasal mask, the need for similarly-configured full face masks was well-known before 2005. For example, **Gunaratnam** discloses a “nasal mask frame including a rim portion according to an embodiment of the invention is shown in FIG. 5a.” Ex. 1103 at col. 4:20–21. Later in its disclosure, Gunaratnam discloses that the “invention is also suitable for a full-face mask system,” as shown in Figures 8a and 8b. Ex. 1103 at col. 6:3–5. In the full-face version, Gunaratnam discloses a frame 160 and a cushion 180 that seals around the patient's nose and mouth regions. Ex. 1103 at col. 6:3–10.



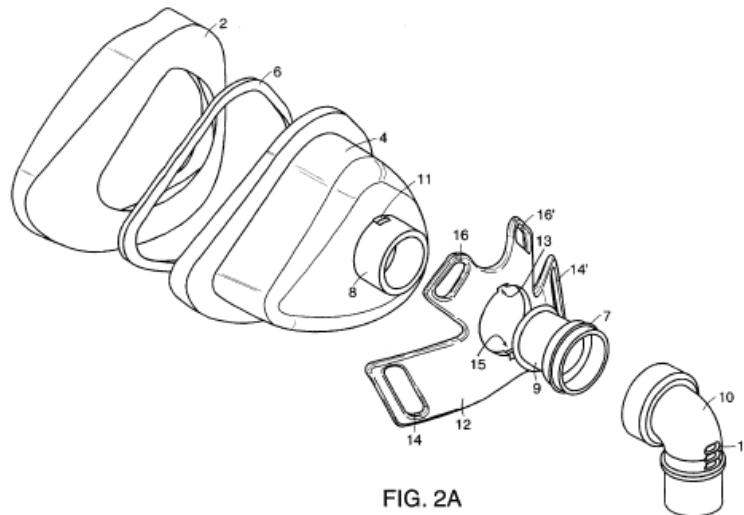
Gelinas discloses a first frame 92 with a first part 90 that “surrounds the nose and mouth of the wearer . . . [and] defines a continuous seal for sealingly engaging the face of the wearer and covering the mouth and nose of the wearer.” Ex. 1104 ¶ 27.

Barnett discloses a nasal mask assembly, but further explains that full-face masks were well-known. “Non-invasive ventilation and pressure support therapies involve the placement of a patient interface device, which is typically a nasal/oral mask, on the face of patient to interface the ventilator or pressure support device with the airway of the patient so that a flow of breathing gas can be delivered from the pressure/flow generating device to the

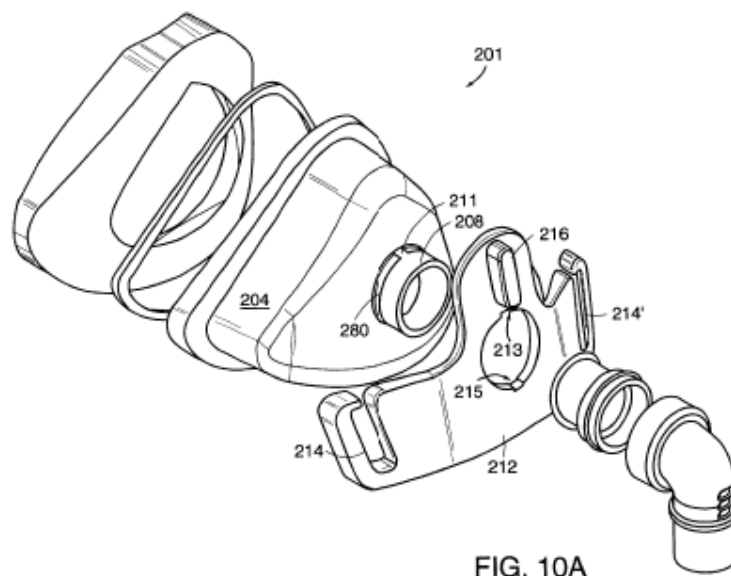
	<p>airway of the patient.” Ex. 1111 at col. 1:26–32.</p> <p>Ogden also describes the interchangeability of nasal mask and full-face mask features. “Referring to FIGS. 1-3, the facial mask assembly 1 of the present invention is illustrated as a nasal mask covering the nose 2 and nares 4 (see FIG. 3) of the patient 6 but the invention is equally applicable to full face masks covering the patient's nose and mouth.” Ex. 1109 at col. 2:46–50.</p>
<p>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.</p>	<p>Lovell discloses, “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.</p>  <p>FIG. 2A</p> <p>Nasal mask 201 shown in Figs. 9–11, has many of the features of the nasal mask 1 shown in Figs. 1–8. <i>Id.</i> at col. 9:34–36.</p>  <p>FIG. 10A</p>

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 discloses “[t]wo tabs 11, 11’ included on the inlet 8 mate with two slots 13, 15 formed in the retainer 12 in a particular angular orientation. Ex. 1102 at col. 5:66—6:2.

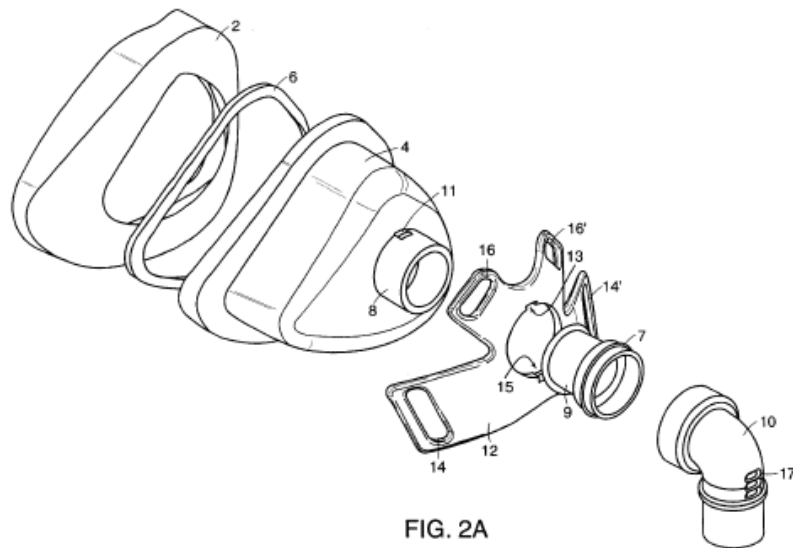


In a second embodiment, Lovell teaches a second frame 212 that removably interlocks with the cushion/frame sub-assembly by interlocking with the first frame 204 via tabs 211, 211’ and slots 213, 215. *Id.* at col. 9:46–48. Lovell discloses “[t]he retainer aperture and the inlet 208 are generally sized 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. 9:59–64.

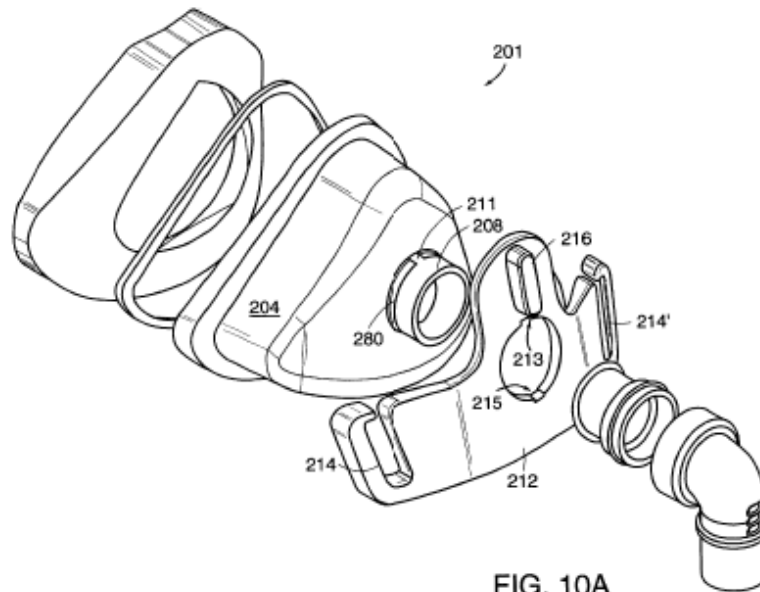


23. The mask assembly according to claim 17, wherein the first frame and the cushion together form a breathing chamber around the patient's nose and mouth.

Lovell discloses, “The chamber 80 is substantially leakage-free due to the bond or interface between the seal 2 and the shell 4, and the conformance of the seal 2 against a user's skin.” Ex. 1102 at col. 4:55–58.

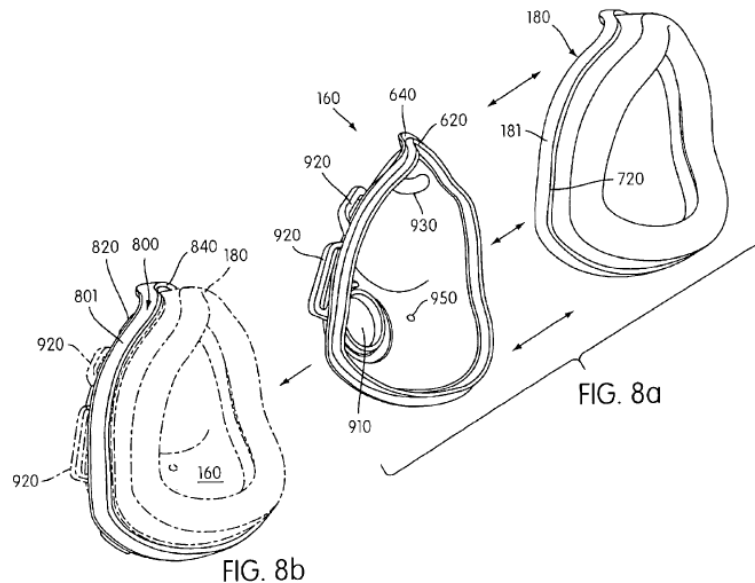


Nasal mask 201 shown in Figs. 9–11, has many of the features of the nasal mask 1 shown in Figs. 1–8. *Id.* at col. 9:34–36.



Although Lovell discloses a nasal mask, the need for similarly-configured full face masks was well-known before 2005. For example, **Gunaratnam** discloses a “nasal mask frame including a rim portion according to an embodiment of the invention is shown in FIG. 5a.” Ex. 1103 at col. 4:20–21. Later in its

disclosure, Gunaratnam discloses that the “invention is also suitable for a full-face mask system,” as shown in Figure 8a and 8b. Ex. 1103 at col. 6:3–5. In the full-face version, Gunaratnam discloses a frame 160 and a cushion 180 that seals around the patient’s nose and mouth regions. Ex. 1103 at col. 6:3–10.



Gelinas discloses a first frame 92 with a first part 90 that “surrounds the nose and mouth of the wearer . . . [and] defines a continuous seal for sealingly engaging the face of the wearer and covering the mouth and nose of the wearer.” Ex. 1104 ¶ 27.

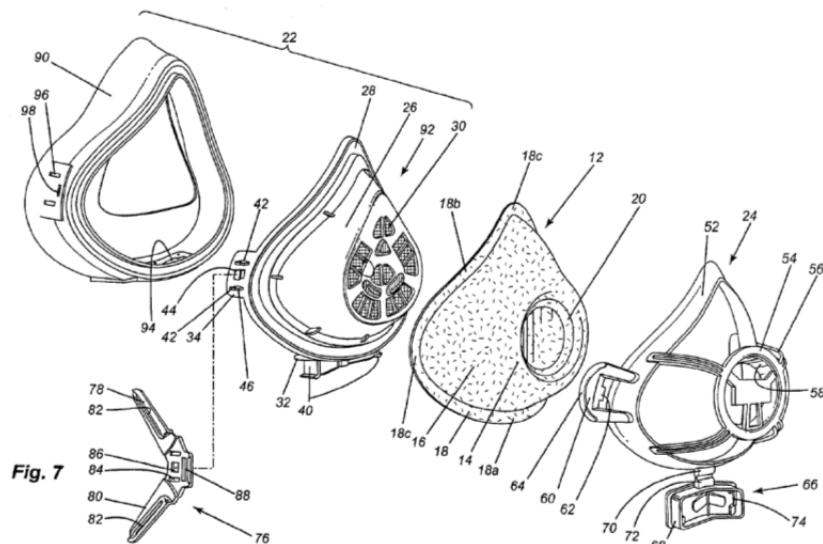
Barnett discloses a nasal mask assembly, but further explains that full-face masks were well-known. “Non-invasive ventilation and pressure support therapies involve the placement of a patient interface device, which is typically a nasal/oral mask, on the face of patient to interface the ventilator or pressure support device with the airway of the patient so that a flow of breathing gas can be delivered from the pressure/flow generating device to the airway of the patient.” Ex. 1111 at col. 1:26–32.

Ogden also describes the interchangeability of nasal mask and full-face mask features. “Referring to FIGS. 1-3, the facial mask assembly 1 of the present invention is illustrated as a nasal mask covering the nose 2 and nares 4 (see FIG. 3) of the patient 6 but

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.

the invention is equally applicable to full face masks covering the patient's nose and mouth.” Ex. 1109 at col. 2:46–50.

Gelinas discloses a frame 24 that has two elongate frame members and defines an opening between a central ring 54 and the elongate frame members of the frame 24. *See* Ex. 1104 ¶¶ 26, 32.



Berthon-Jones: “The mask chassis 512 includes a central aperture 536 that is constructed and sized to receive the raised, central portion 518 of the cushion/secondary frame 514 . . . Adjacent to the central aperture 536 on the left and right sides of the mask chassis 512 are adjustment wheel retaining portions 542.” Ex. 1108 ¶ 184, Fig. 51.

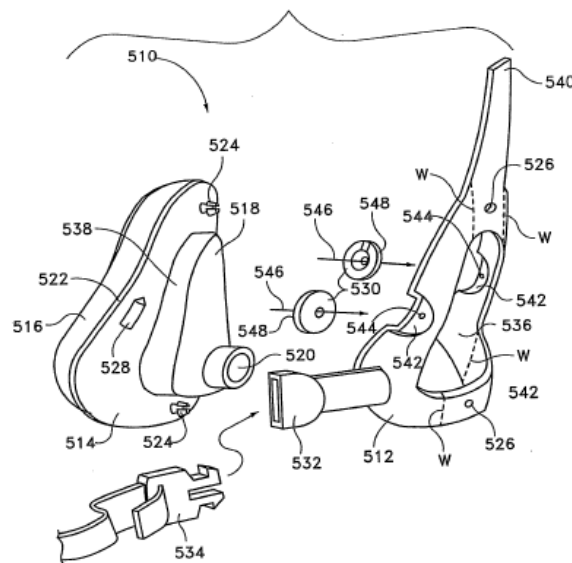
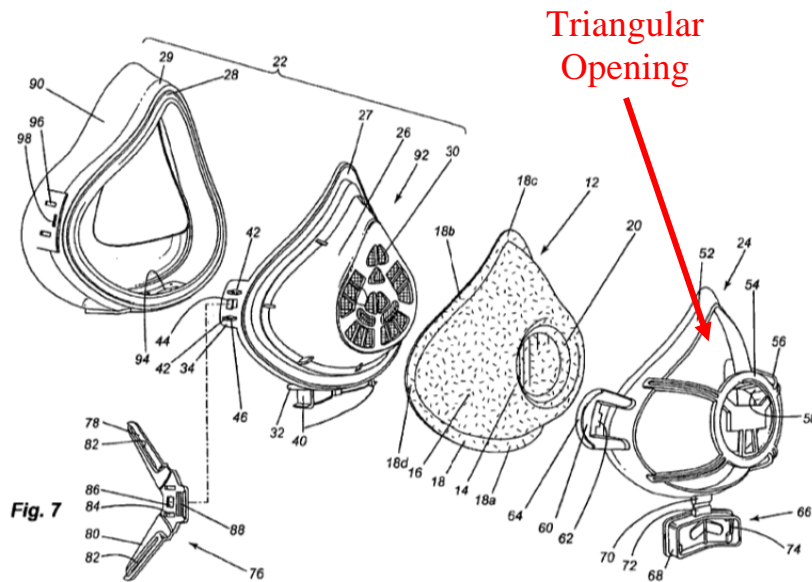


Fig.51

27. The mask assembly according to claim 17, wherein the opening is substantially triangular.

Gelinas discloses an opening defined between peripheral frame 52, upper two branches 56 and upper portion of ring 54 that is substantially triangular. *See* Ex. 1104 ¶¶ 31, 32. Gelinas states that “[f]lange portion 18 defines a generally triangular figure.” *Id.* ¶ 25.



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 discloses that the frame has “four connection points disposed remotely from the inlet 8, two lower connection points 14, 14’ and two upper connection points 16, 16’ . . . the upper connection points 16, 16’ are above the lower connection points 14, 14’ 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. Lovell further discloses that the “connection points 14, 14’, 16, 16’ form slots which allow for connection of the retainer 12 with straps of a headgear apparatus . . . For example, snaps, hook and eye closures, hook and loop fasteners, or the like, may be employed.” *Id.* at col. 6:10–19.

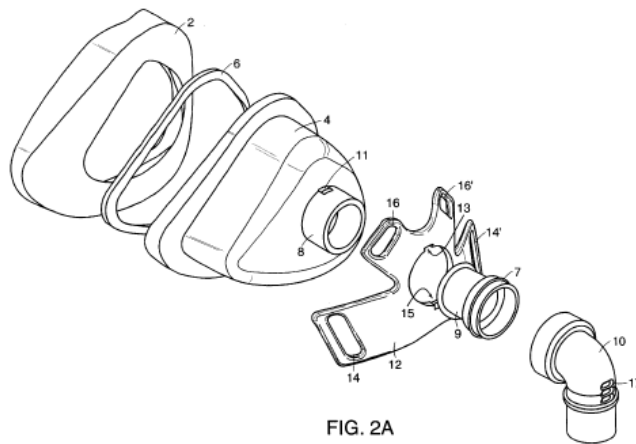


FIG. 2A

In another embodiment, Lovell discloses that “[t]he connection points 214, 214’, 216 form slots which allow for connection of the retainer 212 with straps of a headgear apparatus.” *Id.* at col. 10:1–3.

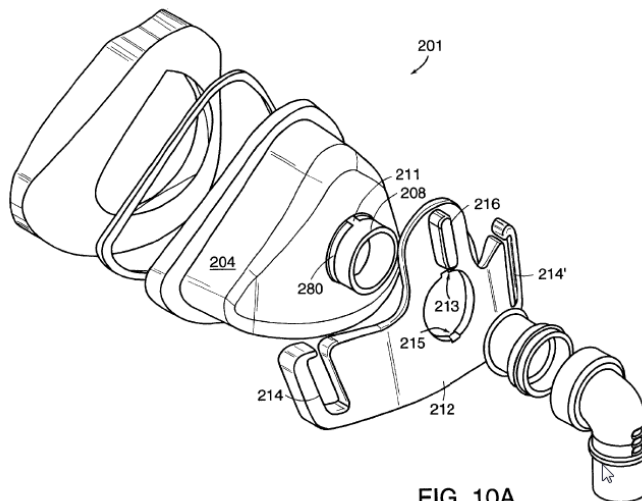
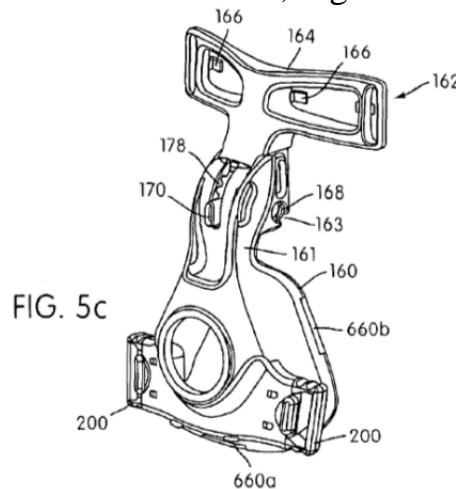


FIG. 10A

Gunaratnam discloses lower headgear clip attachments 630 that are adjacent to and on opposite lateral sides of the annular connection. Ex. 1103 at col. 4:31–34; Figures 5a–5f.



Berthon-Jones: “The mask chassis 512 provides connecting receptacles 532 for corresponding ends of the mask headgear 534. In mask chassis 512, two connecting receptacles 532 are provided, one at each of the left and right edges of the mask chassis 512. However, any number of connecting receptacles 532 may be provided, disposed about the mask chassis 512 as required, depending on the number and position of the headgear straps or strap ends. In FIGURE 51, the connecting receptacles 532 and mask headgear 534 are illustrated as having releasable snap-fit connections.” Ex. 1108 at ¶ 183.

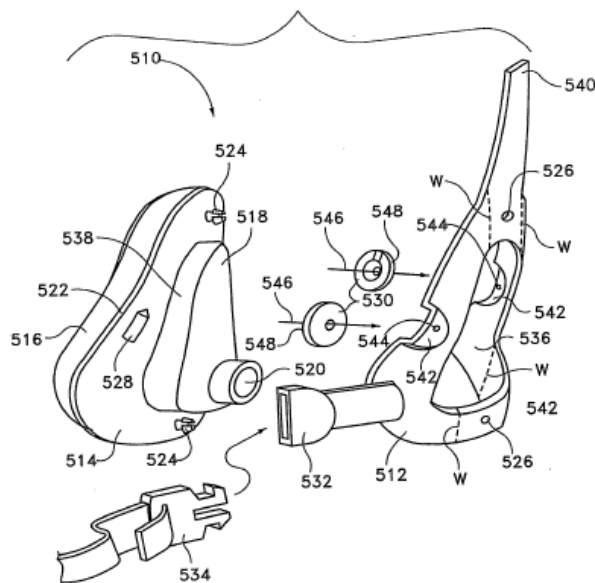
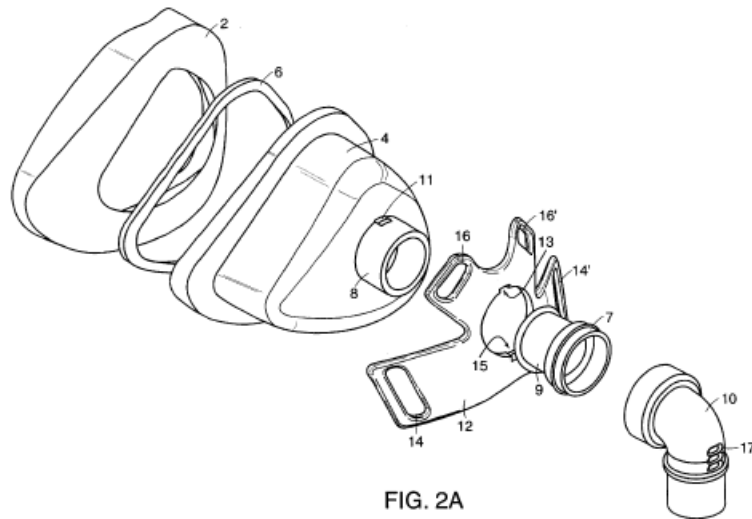


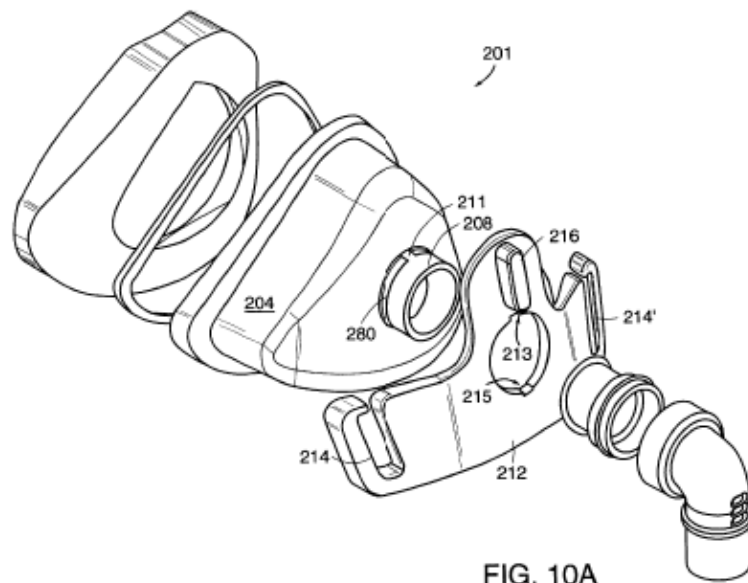
Fig.51

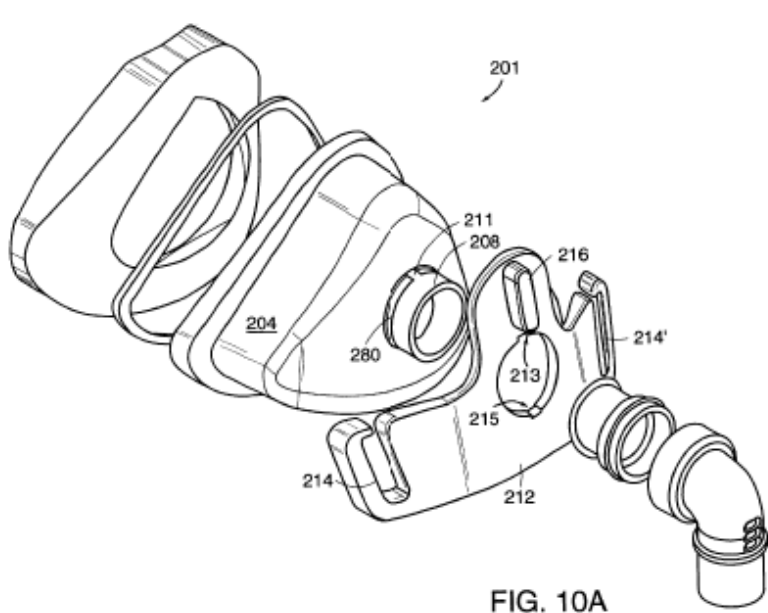
29. The mask assembly according to claim 17, wherein the first frame is releasably secured to the second frame by way of an interlocking and/or frictional fit.

Lovell discloses “[t]wo tabs 11, 11’ included on the inlet 8 mate with two slots 13, 15 formed in the retainer 12 in a particular angular orientation. Ex. 1102 at col. 5:66—6:2.



In a second embodiment, Lovell teaches a second frame 212 that removably interlocks with the cushion/frame sub-assembly by interlocking with the first frame 204 via tabs 211, 211’ and slots 213, 215. *Id.* at col. 9:46–48. Lovell discloses “[t]he 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. 9:59–64.



	<p>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.</p> <p>Berthon-Jones: “The mask assembly 510 has two major portions, a semi-rigid mask chassis 512 and a cushion/secondary frame 514. The two portions 512, 514 are separable, but may be releasably or fixedly connected, as described above.” Ex. 1108 ¶ 177.</p>
<p>30. The mask assembly according to claim 17, wherein the first frame and the second frame have complementary shapes.</p>	<p>Lovell discloses that the “retainer 212 is contoured such that it approximately matches the external curvature of the contoured shell 204.” Ex. 1102 at col. 9:44–46.</p>  <p>FIG. 10A</p>
<p>32. A mask assembly for treatment of sleep disorder breathing by delivering a flow of pressurized gas to a patient, the</p>	<p><i>See supra</i> Claim 17[Preamble].</p>

Declaration of Jason Eaton, P.E., in support of
IPR Petition – U.S. Patent No. 8,944,061

mask assembly comprising:	
a first frame made of first material;	<i>See supra</i> 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,	<i>See supra</i> Claim 17[B].
the first frame and the cushion together forming a breathing chamber; and	<i>See supra</i> 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,	<i>See supra</i> Claim 17[C].
two lower headgear clip attachments	<i>See supra</i> Claim 17[D].

Declaration of Jason Eaton, P.E., in support of
IPR Petition – U.S. Patent No. 8,944,061

engaged with clips provided to straps of a headgear assembly,	
an annular opening adapted to allow an elbow to provide pressurized gas to the patient, and	<p><i>See supra</i> Claim 17[E].</p> <p>Lovell discloses “nasal 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.</p>
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.	<p><i>See supra</i> Claim 17[F].</p>

Declaration of Jason Eaton, P.E., in support of
IPR Petition – U.S. Patent No. 8,944,061

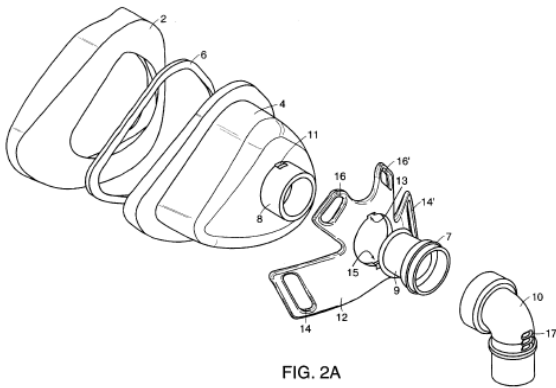
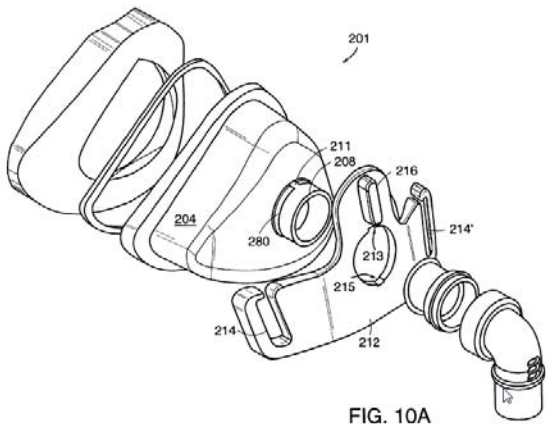
33. The mask assembly according to claim 32, wherein the first frame and the cushion are integrally molded in one piece to provide a cushion-frame sub-assembly.	<i>See supra</i> Claim 18.
35. The mask assembly according to claim 32, wherein the first frame is contoured to fit over the patient's nose and mouth.	<i>See supra</i> 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.	<i>See supra</i> Claim 21.
37. The mask assembly according to claim 32,	<i>See supra</i> Claim 22.

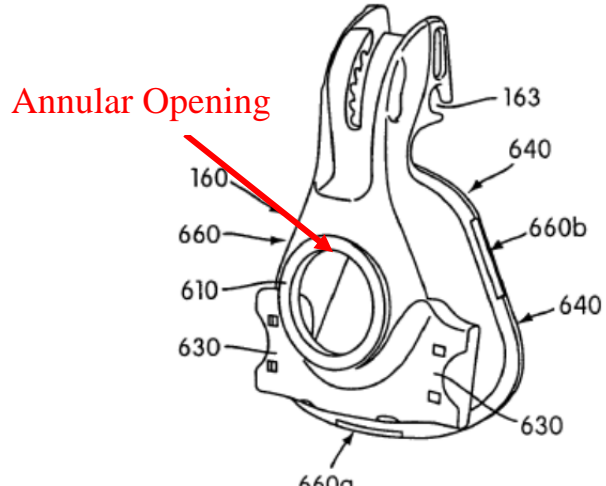
Declaration of Jason Eaton, P.E., in support of
IPR Petition – U.S. Patent No. 8,944,061

wherein the second frame includes contact points contacting the first frame to prevent rotation of the first frame with respect to the second frame.	
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.	<i>See supra</i> 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	<i>See supra</i> Claim 26.

Declaration of Jason Eaton, P.E., in support of
IPR Petition – U.S. Patent No. 8,944,061

opening is located between the two connecting members.	
42. The mask assembly according to claim 32, wherein the separate opening is substantially triangular.	<i>See supra</i> 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.	<i>See supra</i> 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.	<i>See supra</i> Claim 29.

<p>45. The mask assembly according to claim 32, wherein the first frame and the second frame have complementary shapes.</p>	<p><i>See supra</i> Claim 30.</p>
<p>46. The mask assembly according to claim 32, wherein the annular opening and the elbow are sealingly connected.</p>	<p>Lovell discloses, “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.</p>  <p>FIG. 2A</p> <p>Nasal mask 201 shown in Figs. 9–11, has many of the features of the nasal mask 1 shown in Figs. 1–8. <i>Id.</i> 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.” <i>Id.</i> at col. 9:43–48.</p>  <p>FIG. 10A</p>

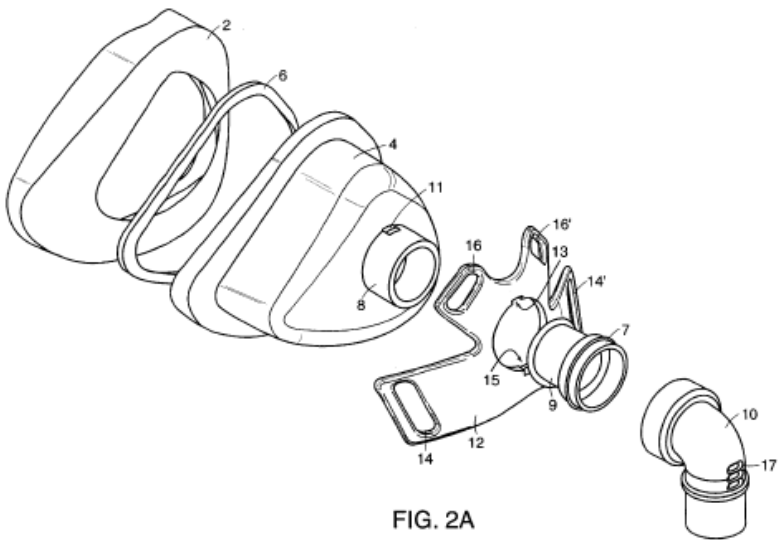
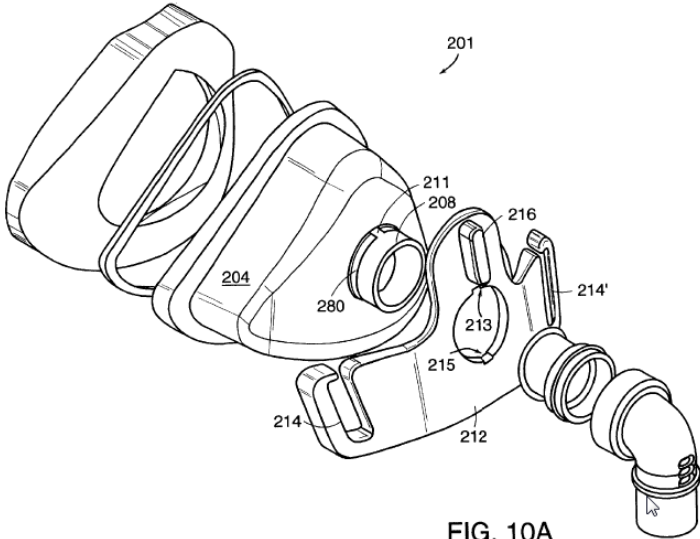
	<p>Gunaratnam discloses an outer frame with a gas inlet aperture 610/910 for direct connection to an elbow of a gas delivery conduit. Ex. 1103 at col. 4:20–26, Figures 5a–5f. Gunaratnam discloses that “[t]he frame 160 . . . incorporates a gas inlet aperture (610) for connection to a gas delivery conduit (not shown) of a patient gas delivery system.” <i>Id.</i></p>  <p>FIG. 5a</p>
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,	<i>See supra</i> Claim 18.
the cushion is contoured to fit the patient's nose and mouth,	<i>See supra</i> Claim 20.
the first frame	<i>See supra</i> Claim 21.

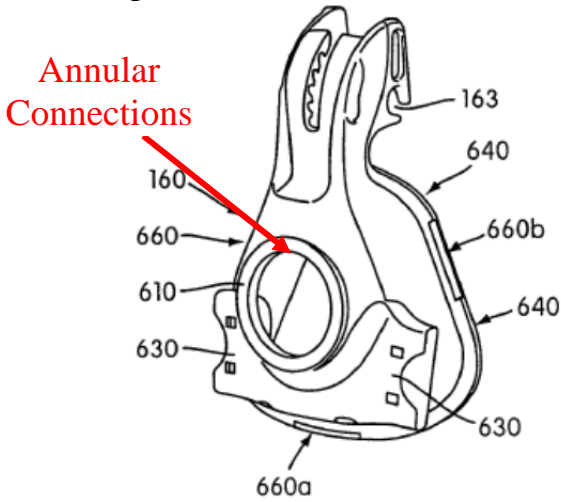
Declaration of Jason Eaton, P.E., in support of
IPR Petition – U.S. Patent No. 8,944,061

comprises a frame-opening that allows for a flow path to communicate the elbow with an interior of the first frame,	
the second frame includes contact points that prevent rotation of the first frame with respect to the second frame,	<i>See supra</i> Claim 22.
the first frame and the cushion together form the breathing chamber around the patient's nose and mouth,	<i>See supra</i> Claim 23.
the cushion comprises a face contacting portion that contacts a patient's face,	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, 7:45–58. “The chamber 80 is substantially leakage-free due to the bond or interface between the seal 2 and the shell 4, and the conformance of the seal 2 against a user’s skin.” <i>Id.</i> at col. 4:55–58.
the second frame comprises two connecting members that connect a lower portion of the second frame to the upper support member and the separate	<i>See supra</i> Claim 26.

Declaration of Jason Eaton, P.E., in support of
IPR Petition – U.S. Patent No. 8,944,061

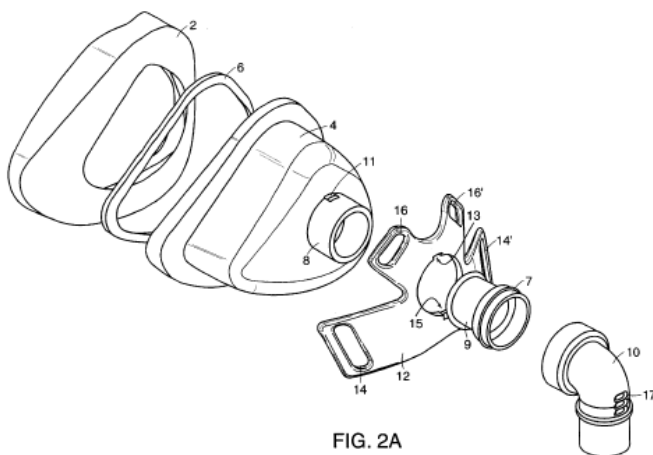
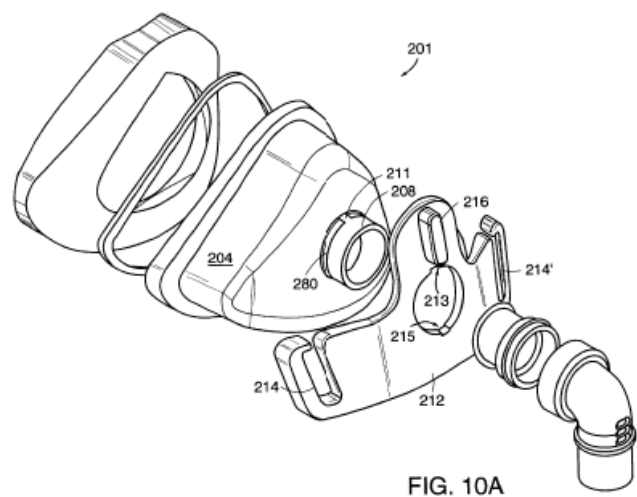
opening is located between the two connecting members,	
the two lower headgear clip attachments are adjacent to and on opposite lateral sides of the annular opening,	<i>See supra</i> Claim 28.
the annular opening and the elbow are sealingly connected, and	<i>See supra</i> Claim 46.
the first frame is releasably secured to the second frame by way of an interlocking and/or frictional fit.	<i>See supra</i> 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	<i>See supra</i> Claims 27 and 30.

<p>shapes.</p> <p>50. The mask assembly according to claim 48, wherein the elbow engages the second frame.</p>	<p>Lovell discloses, “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.</p>  <p>FIG. 2A</p> <p>Nasal mask 201 shown in Figs. 9–11, has many of the features of the nasal mask 1 shown in Figs. 1–8. <i>Id.</i> 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.” <i>Id.</i> at col. 9:43–48.</p>  <p>FIG. 10A</p> <p>Gunaratnam discloses that “[t]he frame 160 . . . incorporates a gas inlet aperture (610) for connection to a gas delivery conduit</p>
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	<p>(not shown) of a patient gas delivery system.” Ex. 1103 at col. 4:20–26, Figures 5a–5f.</p>  <p>FIG. 5a</p>
81. A mask assembly for treatment of sleep disorder breathing by delivering a flow of pressurized gas to a patient, the mask assembly comprising:	<i>See supra</i> Claim 17[Preamble].
a first frame made of first material;	<i>See supra</i> 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	<i>See supra</i> Claim 17[B].

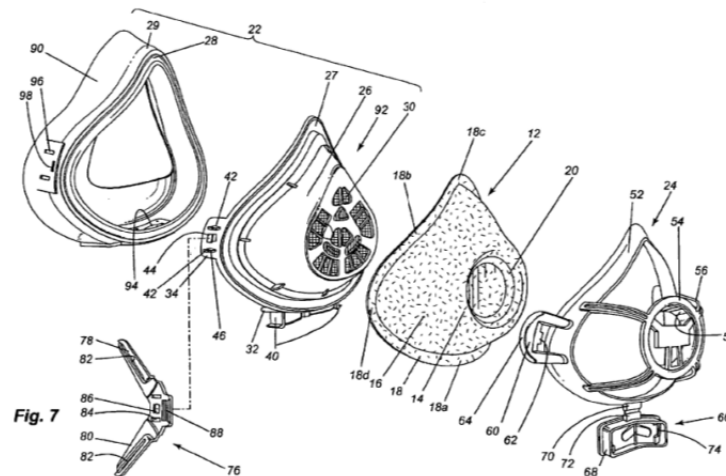
Declaration of Jason Eaton, P.E., in support of
IPR Petition – U.S. Patent No. 8,944,061

from a second material that is more flexible than the first material,	
the first frame and the cushion together forming a breathing chamber; and	<i>See supra</i> Claim 23.
a second frame adapted to constrain the first frame, the second frame comprising an upper member,	<i>See supra</i> Claim 17[C].
a lower member with an annular opening adapted to allow an inlet conduit to provide pressurized gas to the patient, and	<i>See supra</i> Claim 17[E]. Lovell discloses “nasal 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 member, the separate opening providing access to the first frame when the mask	<i>See supra</i> Claim 17[F].

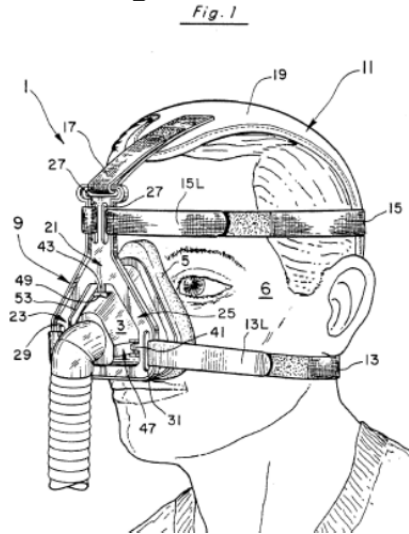
<p>assembly is fully assembled,</p>	
<p>wherein the first frame and the second frame snap-fit together.</p>	<p>Lovell discloses “[t]wo tabs 11, 11’ included on the inlet 8 mate with two slots 13, 15 formed in the retainer 12 in a particular angular orientation. Ex. 1102 at col. 5:66—6:2.</p>  <p>FIG. 2A</p> <p>In a second embodiment, Lovell teaches a second frame 212 that removably interlocks with the cushion/frame sub-assembly by interlocking with the first frame 204 via tabs 211, 211’ and slots 213, 215. <i>Id.</i> at col. 9:46–48. Lovell discloses “[t]he 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.” <i>Id.</i> at col. 9:59–64.</p>  <p>FIG. 10A</p>

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.

Gelinas: “As shown in FIG. 6, bottom wall 32 comprises openings 38 through which the breath of the wearer can be exhaled and two spaced apart L-shaped protuberances 40.” Ex. 1104 at col. 3:67—4:4. “Section 68 comprises two internal notches 74.” *Id.* at col. 4:44. “Cover 24 is hingedly attached to body 22 when each L-shaped protuberance 40 is clipped within internal notch 74.” *Id.* at col. 5:9–11. “Securing member 66 can be replaced by other securing means for securing cover 24 to facepiece 22. For example, a hinge-like connector, a strap, a hook and eye, or a press-stud can be used.” *Id.* at col. 4:51–55.



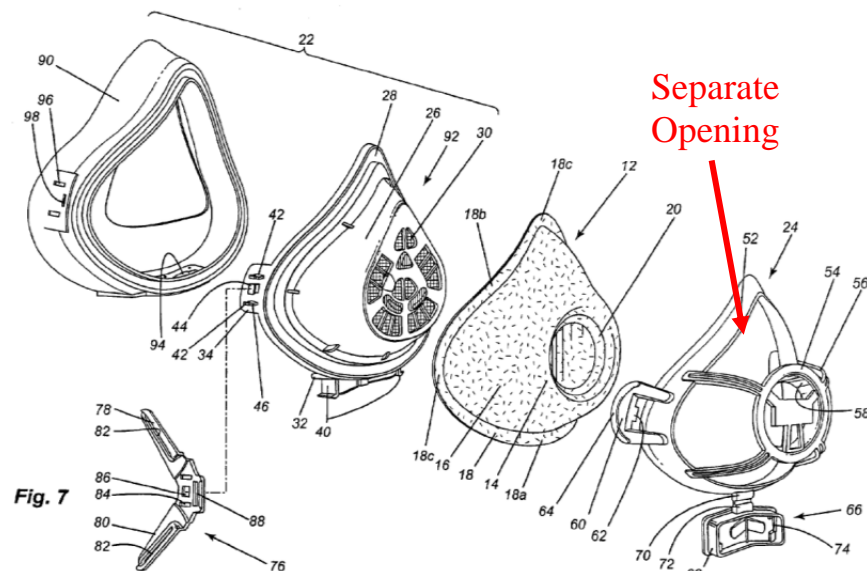
Ogden: “Further, although the detent-channel 43, 49 at the top of the shell 3 at the third location C is preferably dimensioned to snap together to hold or maintain the rigid plate 9 on the rigid shell 3, this detent-channel 43, 49 is still preferably a loose fit.”
Ex. 1109 at col. 5:14–19, Fig. 1.



In **Ging**, the retention lip 44 is inserted with interference and deflection, and then recovers elastically to a position within undercut 33 to provide engagement between the cushion module 40 and the frame module. Ex. 1114 ¶ 201, Figs. 27d–27e.

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 discloses a frame 24 that has two elongate frame members and defines an opening between a central ring 54 and the elongate frame members of the frame 24. *See* Ex. 1104 ¶¶ 26, 32.



Berthon-Jones: “The mask chassis 512 includes a central aperture 536 that is constructed and sized to receive the raised, central portion 518 of the cushion/secondary frame 514 . . . Adjacent to the central aperture 536 on the left and right sides of the mask chassis 512 are adjustment wheel retaining portions 542.” Ex. 1108 ¶ 184, Fig. 51.

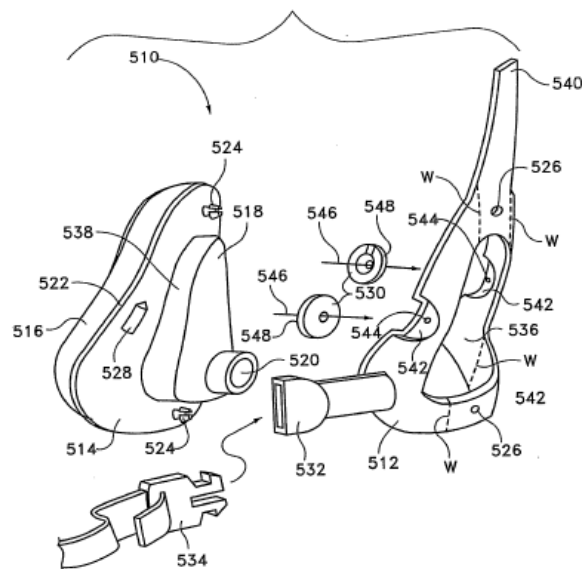
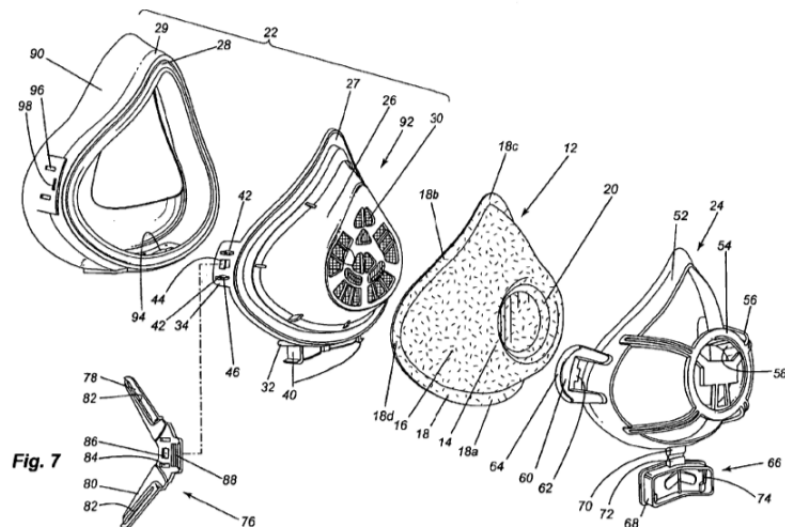


Fig.51

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 discloses, “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. The upper portions of elongate frame members 52 contact the first frame 92 along their length and prevent rotation of the first frame 92 with respect to the second frame 24. Also, the elongate members 52 include other features that contact the first frame 92 and prevent relative rotation. “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.* ¶ 32.



84. The mask assembly according to claim 81, wherein the first frame and the cushion are

See supra Claim 18.

Declaration of Jason Eaton, P.E., in support of
IPR Petition – U.S. Patent No. 8,944,061

integrally molded in one piece to provide a cushion-frame sub-assembly.	
85. The mask assembly according to claim 81, wherein the first frame is contoured to fit over the patient's nose and mouth.	<i>See supra</i> Claim 20.
86. The mask assembly according to claim 81, wherein the separate opening is substantially triangular.	<i>See supra</i> 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.	<i>See supra</i> Claim 28.

Declaration of Jason Eaton, P.E., in support of
IPR Petition – U.S. Patent No. 8,944,061

88. The mask assembly according to claim 81, wherein the inlet conduit comprises an inlet elbow.	Lovell discloses an inlet conduit that comprises an elbow 10 (referring to number in first embodiment). Ex. 1102 at col. 5:14–16, Figure 2A. Lovell discloses “[a] conduit elbow 10 fits onto the swivel connector 9 at a sealing flange 7 on the swivel connector 9.” <i>Id.</i> at col. 5:14–16, Figure 2A.
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	<i>See supra</i> Claim 28.
two elongate frame members connecting the upper member and lower member and at least partially bounding the separate opening, wherein	<i>See supra</i> Claim 82.
the elongate frame members include contact points with the first frame to prevent rotation of the first	<i>See supra</i> Claim 83.

Declaration of Jason Eaton, P.E., in support of
IPR Petition – U.S. Patent No. 8,944,061

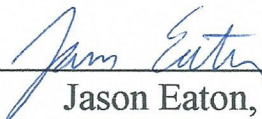
frame with respect to the second frame,	
the first frame and the cushion are integrally molded in one piece to provide a cushion-frame sub-assembly,	<i>See supra</i> Claim 18.
the first frame is contoured to fit over the patient's nose and mouth, and	<i>See supra</i> Claim 20.
the inlet conduit comprises an inlet elbow.	<i>See supra</i> Claim 88.
90. The mask assembly according to claim 89, wherein the separate opening is substantially triangular.	<i>See supra</i> Claim 27.
91. The mask assembly according to claim 89, wherein the inlet elbow engages the second frame.	<i>See supra</i> Claim 50.

X. CONCLUSION

129. For these reasons, Claims 17, 18, 20–23, 26–30, 32, 33, 35–38, 41–46, 48–50, and 81–91 of the '061 Patent would have been obvious.

130. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Executed on January 9, 2017 at Hunker, Pennsylvania.

By: 
Jason Eaton, P.E.

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