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. IPR2017-01658
U.S. Patent No. 9,119,931

DECLARATION OF JASON EATON, P.E., IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT 9,119,931

TABLE OF CONTENTS

Page No.

TABLE OF CONTENTS
(*continued*)

Page No.

TABLE OF CONTENTS
(*continued*)

Page No.

TABLE OF CONTENTS
(*continued*)

Page No.

TABLE OF CONTENTS
(*continued*)

Page No.

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. No. 9,119,931 ("the '931 Patent"). I have been asked to provide opinions regarding the patentability of Claims 1, 4–8, 10–22, 25, 26, 28–32, 46, 51, 53–56, and 65 (collectively, the "Challenged Claims") of the '931 Patent.

2. My current curriculum vitae is included as Exhibit 1403, which lists 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 No. 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

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 ResMed'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 '931 Patent (Ex. 1401). I have been informed that the '931 Patent was filed on July 31, 2014 and issued on September 1, 2015. I also understand that the '931 Patent is a continuation of U.S. Patent Application No. 13/964,280, filed on August 12, 2013, which is a continuation of U.S. Patent Application No. 13/745,077, filed on January 18, 2013 (now U.S. Patent No. 8,528,561), which is a continuation of U.S. Patent Application No. 12/736,024, filed on February 27, 2009 (now U.S. Patent No. 8,550,084). The '931 patent also claims priority to provisional U.S. Patent Application

No. 61/064,406, filed on March 4, 2008, provisional U.S. Patent Application No. 61/071,893, filed on May 23, 2008, and provisional U.S. Patent Application No. 61/136,617, filed on September 19, 2008.

12. I have also reviewed the following materials:

- U.S. Provisional Application No. 61/064,406, Ex. 1406
- U.S. Provisional Application No. 61/071,893, Ex. 1407
- U.S. Provisional Application No. 61/136,617, Ex. 1408
- Excerpts from the File History of U.S. Patent No. 9,119,931, Ex. 1409
- PCT Publication No. WO 2007/048174 (Ng), Ex. 1410
- U.S. Publication No. 2005/0011524 (Thomlinson), Ex. 1411
- U.S. Publication No. 2007/0044804 (Matula-II), Ex. 1412
- U.S. Patent No. 6,796,308 (Gunaratnam-I), Ex. 1413
- U.S. Patent No. 6,412,488 (Barnett), Ex. 1414
- PCT Publication No. WO 2007/045008 (Worboys), Ex. 1415
- Affidavit of Christopher Butler, Ultra Mirage Brochure (Ultra Mirage), dated September 6, 2016, Ex. 1416
- Affidavit of Christopher Butler, FlexiFit Instructions (FlexiFit), dated September 6, 2016, Ex. 1417
- Declaration of Fiona Cresswell, dated September 21, 2016, Ex. 1418

- U.S. Publication No. 2004/0182398 (Sprinkle), Ex. 1419
- PCT Publication No. WO 2007/041751 (D'Souza), Ex. 1420
- PCT Publication No. WO 2006/000046 (Hitchcock), Ex. 1421
- U.S. Patent No. 5,662,101 (Ogden), Ex. 1422
- PCT Publication No. WO 2007/147088 (Matula-I), Ex. 1423
- U.S. Patent No. 7,827,990 (Melidis), Ex. 1424
- PCT Publication No. WO 2005/123166 (Frater), Ex. 1425
- U.S. Patent No. 6,631,718 (Lovell), Ex. 1426
- U.S. Patent No. 6,851,425 (Jaffre), Ex. 1427
- U.S. Publication No. 2004/0067333 (Amarasinghe), Ex. 1428
- U.S. Publication No. 2004/0226566 (Gunaratnam-II), Ex. 1429
- U.S. Publication No. 2006/0060200 (Ho), Ex. 1430
- U.S. Publication No. 2005/0155604 (Ging), Ex. 1431
- PCT Publication No. WO/2005/021075 (McAuley), Ex. 1432
- U.S. Publication No. 2004/0118406 (Lithgow), Ex. 1433
- U.S. Publication No. 2006/0042629 (Geist), Ex. 1434
- U.S. Patent No. 5,921,239 (McCall), Ex. 1435
- U.S. Patent No. 6,435,181 (Jones, Jr.), Ex. 1436
- U.S. Publication No. 2006/0201514 (Jones), Ex. 1437

- PCT Publication No. WO 2004/041342 (Berthon-Jones), Ex. 1438
- U.S. Publication No. 2006/0124131 (Chandran), Ex. 1439
- PCT Publication No. WO 2006/074515 (Hitchcock-II), Ex. 1440
- U.S. Patent No. 5,657,752 (Landis), Ex. 1441
- PCT Publication No. WO2005051468 (Darkin), Ex. 1442
- Malloy, Robert A., Plastic Part Design for Injection Molding: An Introduction, pp. 336–345 (Hanser Gardner Publications, Inc. 1994) (Malloy), Ex. 1443
- U.S. Patent No. 6,581,594 (Drew), Ex. 1444
- U.S. Patent No. 6,561,190 (Kwok), Ex. 1445
- PCT Publication No. WO 00/50122 (Fecteau), Ex. 1446
- Excerpt from Webster's II New College Dictionary, Ex. 1447
- Excerpt from Oxford American College Dictionary, Ex. 1448

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. RELEVANT LEGAL STANDARDS

14. I have been asked to provide my opinion as to whether Claims 1, 4–8, 10–22, 25, 26, 28–32, 46, 51, 53–56, and 65 of the '931 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 '931 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 of this title, 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 the 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 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 further understand that for evidence of any of these factors to be given weight in the obviousness analysis, there must be a nexus or connection between the asserted additional factor and the merits of the claimed invention. Where an asserted additional factor actually results from something other than what is both claimed and novel in the claim, there is no nexus to the merits of the claimed invention. I am not aware of any evidence regarding these potential additional factors that would suggest that Claims 1, 4–8, 10–22, 25, 26, 28–32, 46, 51, 53–56, and 65 of the ’931 Patent would have been non-obvious.

IV. PERSON 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 ’931 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 the earliest priority application, U.S. Provisional Application No. 61/064,406, filed on March 4, 2008, 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 ’931 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 set forth herein are provided from the perspective of a person having ordinary skill in the art.

V. BACKGROUND OF THE '931 PATENT

27. The '931 Patent describes a mask system intended for use in positive pressure therapy for users with Obstructive Sleep Apnea (OSA) or another respiratory disorder.[1] The mask system includes a frame, a cushion provided to the frame and designed to form a seal with the patient's face, a shroud provided to the frame and designed to attach to headgear, and an elbow provided to the mask and designed to connect to an air delivery tube that delivers breathable gas to the patient.[2] Headgear is removably attached to the shroud to maintain the mask system in a desired position on the patient's face.[3]

[1] Ex. 1401 at col. 6:20–28.

[2] *Id.* at col. 6:18–23.

[3] *Id.* at col. 6:23–25.

28. I have provided an annotated version of Figure 1B from the '931 Patent below to show these various features of the mask assembly.

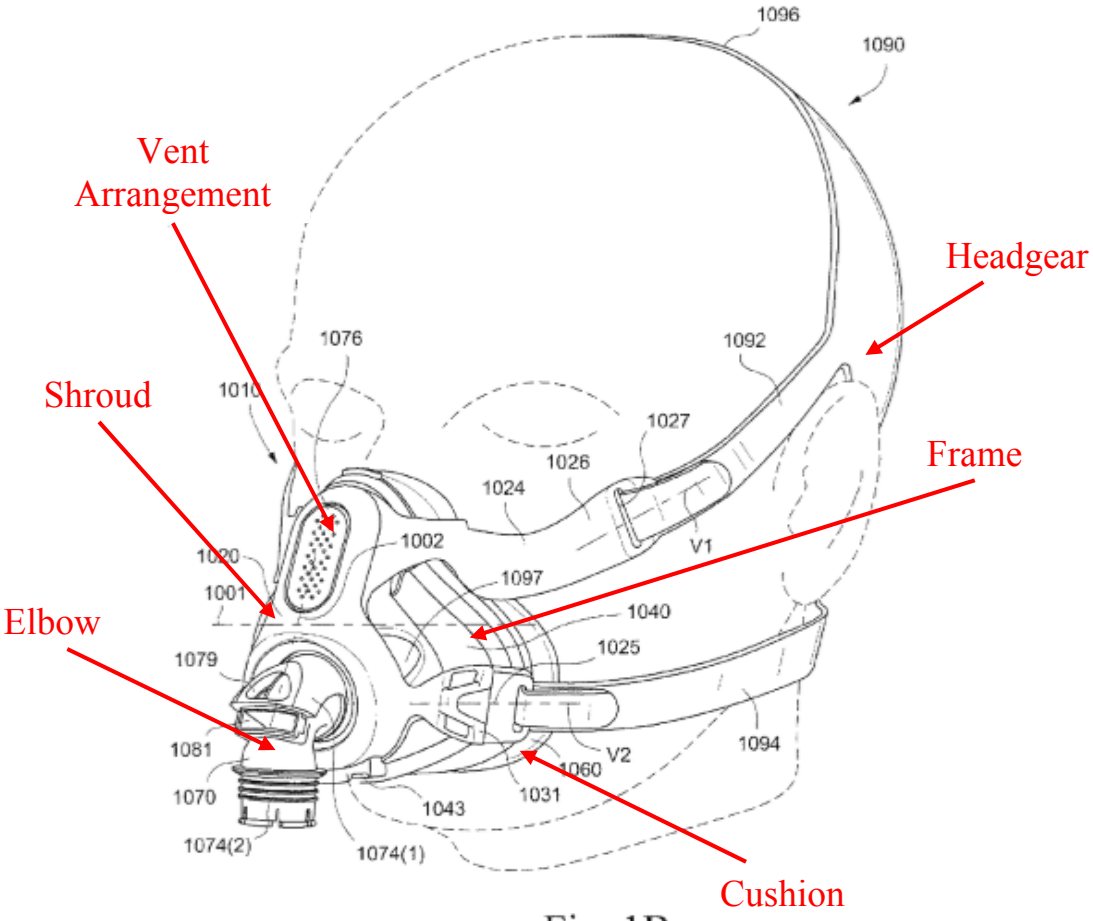


Fig. 1B

29. The frame of the mask system is structured to keep the cushion, shroud, and elbow in an operative position with respect to the patient's face.[4] The frame defines a breathing chamber or cavity designed to receive the patient's nose

[4] *Id.* at col. 6:51–54.

and mouth and to provide air communication to the patient.[5] The frame includes an opening to receive or communicate with the elbow, and a vent arrangement for gas washout.[6]

30. The shroud is connected to the frame and is structured to attach headgear to the mask system.[7] Upper headgear connectors extend from each side of the top end of the shroud, and lower headgear connectors extend from each side of the lower end of the shroud.[8] The shroud includes an opening or vent receiving hole to accommodate the vent arrangement, and an elbow hole to accommodate the elbow.[9]

31. Regarding the vent arrangement, the earliest-filed provisional application from which the '931 Patent claims priority benefit, U.S. Provisional Application No. 61/064,406, filed on March 4, 2008 (Ex. 1406), describes a vent on the elbow or the silicone seal, not on the frame. Also, I could not identify any disclosure of a protruding vent arrangement in any of the Provisional

[5] *Id.* at col. 6:60–62.

[6] *Id.* at col. 6:62–66.

[7] *Id.* at col. 7:9–11.

[8] *Id.* at col. 7:28–30.

[9] *Id.* at col. 7:21–25.

Applications.[10] Further, the first and second provisional applications do not disclose a shroud module including a retaining portion extending rearward from the front opening.[11]

32. As shown below, the headgear has upper straps 1092 that are designed to adjust the position of the mask in a similar way that an adjustable forehead support would alter the position of the mask system, i.e., by moving the top of the mask system closer or further away from the patient's nasal bridge.[12] The lower straps 1094 are designed to remain under the patient's ear to avoid, for example, the strap rubbing or irritating the patient's ear in use.[13]

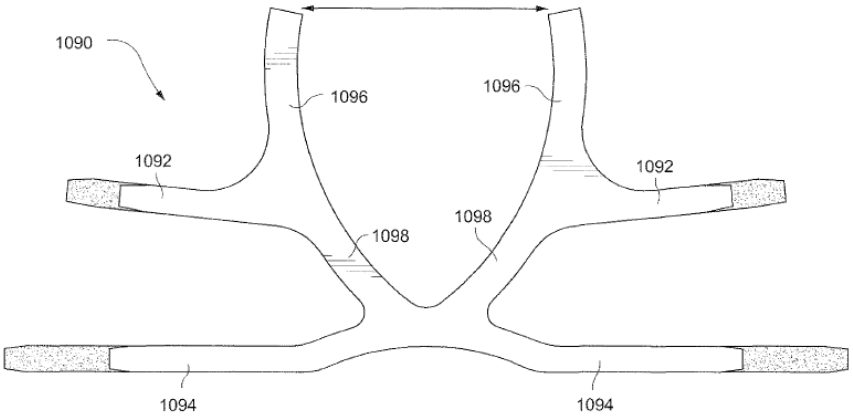


Fig. 9

[10] Ex. 1406; Ex. 1407; Ex. 1408

[11] Ex. 1406; Ex. 1407.

[12] Ex. 1401 at col. 10:63–67.

[13] *Id.* at col. 9:53–59.

33. The cushion or seal is structured to interface with the frame and form a seal with the patient's nose and mouth in use, and is designed to be more compliant or flexible (e.g., particularly in the nasal bridge region) to accommodate more movement, especially if the mask does not have a forehead support.[14] A nasal bridge section may be provided in a nasal bridge region of the cushion and/or frame, including a bellows structure that provides a higher degree of flexibility or increased movement.[15]

34. The mask system includes an elbow that connects to an air delivery tube and is rotatably attached to the frame in use.[16] The elbow can include a slot to receive an anti-asphyxia valve (AAV), and a port that is selectively closed by a flap portion of the AAV (depending on the presence of pressurized gas).[17]

35. The mask system also provides a modular design that allows different styles and/or sizes of the frame (also referred to as a frame module), shroud (also referred to as a shroud module), cushion (also referred to as a cushion module), and/or elbow (also referred to as an elbow module) to be interchanged or mixed

[14] *Id.* at col. 12:24–34.

[15] *Id.* at col. 14:23–27.

[16] *Id.* at cols. 15:56–57, 16:19–20.

[17] *Id*. at col. 16:42–45.

and matched with one another to provide a more customized mask system for the patient, and allow selected modules to be easily replaced.[18]

[18] *Id*. at col. 17:19–27.

VI. CLAIM CONSTRUCTION

36. 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." As the basis for my opinions and conclusions herein, claim terms are presumed to take on their ordinary and customary meaning, based on the broadest reasonable interpretation in light of the specification of the '931 Patent to a person having ordinary skill in the art in the 2008 time frame.

A. "protruding vent arrangement"

37. Claims 1, 46, and 51 recite "the frame includes a protruding vent arrangement having a plurality of holes." Claim 65 recites, "the frame includes a protruding vent arrangement having a plurality of gas washout holes." I understand that the Board previously determined that the broadest reasonable interpretation consistent with the specification for this protruding vent feature is "a discrete vent structure that extends above the surrounding surface of the frame and contains a plurality of vent holes."[19] My analysis provided in this Declaration is based on this interpretation of a protruding vent arrangement.

[19] Ex. 1409 at 391–393, 417–419.

B. "accommodate"

38. Claims 1, 46, and 51 recite "the shroud module includes a first opening to accommodate said protruding vent arrangement." Claim 65 recites "the shroud module includes an upper opening to accommodate said protruding vent arrangement."

39. Based on the claim language, description in the specification, and dictionary definitions, it is my opinion that a person of ordinary skill in the art reading the '931 Patent would understand "accommodate," in the context of Claims 1, 46, and 51, to mean to provide enough space for something.

40. The claims themselves do not provide any further description or explanation of accommodation made by the opening. The specification of the '931 Patent refers briefly to this feature and states, "[t]he top end includes an opening or vent receiving hole 1021 to accommodate the vent arrangement 1076 that protrudes from the frame 1040, and the bottom end includes an opening or elbow hole 1032 to accommodate the elbow 1070 and elbow opening into the frame 1040 (e.g., shroud provides no contact with elbow when assembled)."[20] This description refers to Figure 3 (provided below) and suggests that, similar to the elbow hole 1032, the upper opening provides sufficient space for the protruding

[20] Ex. 1401 at col. 7:21–27.

vent and does not have to contact the vent arrangement when assembled. A person of skill would have understood this description to suggest that the openings are not constrained by the shape or size of the elbow or vent arrangement and can be larger than the vent arrangement and elbow.

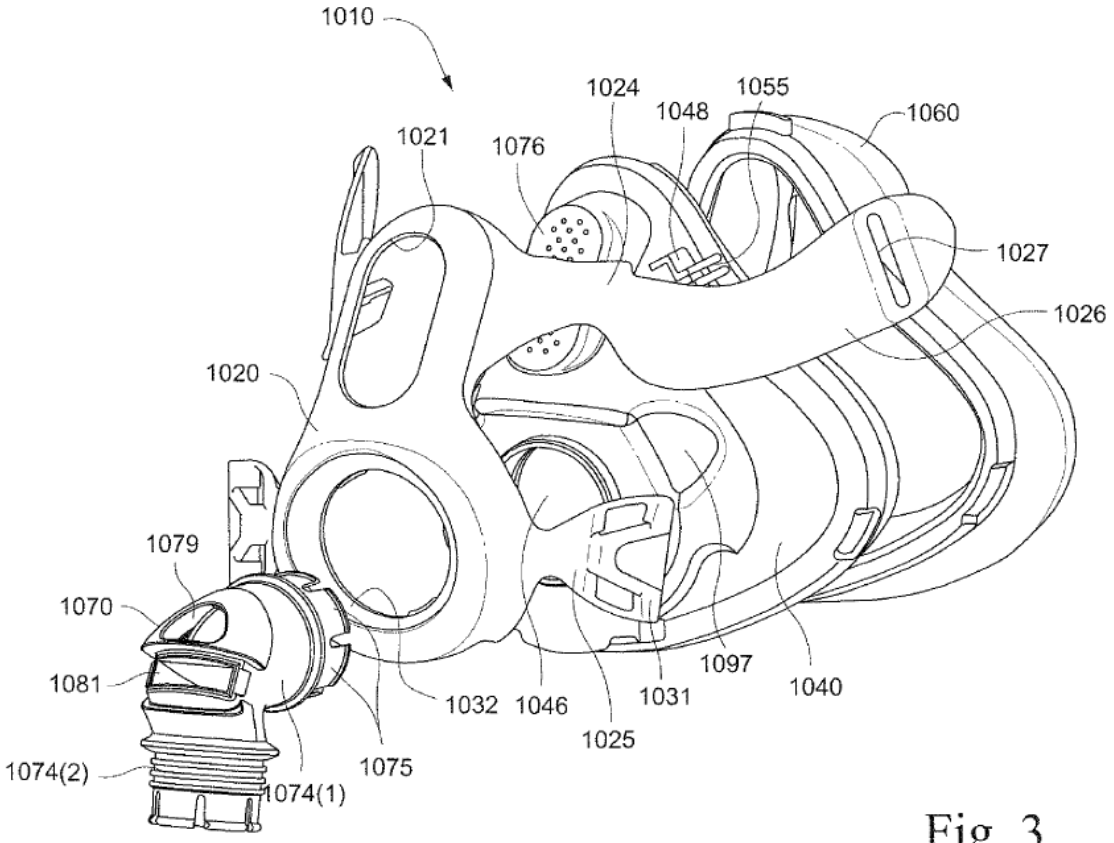


Fig. 3

41. This is consistent with what a person of skill would understand to be the ordinary meaning of the term "accommodate." In fact, the dictionary definitions indicate that an opening "accommodates" when there is "enough space

for" or "allow[s] for" another object.[21] Other dictionaries provide similar definitions, such as provide "sufficient space for."[22]

VII. SUMMARY OF OPINIONS

42. It is my opinion that Claims 1, 6, 11, 16, 31, and 32 would have been obvious over Ng in view of Thomlinson.

43. It is my opinion that Claims 4, 5, 10, and 26 would have been obvious over Ng in view of Thomlinson and Matula-II.

44. It is my opinion that Claims 7, 8, and 18 would have been obvious over Ng in view of Thomlinson and Gunaratnam-I.

45. It is my opinion that Claims 12 and 14 would have been obvious over Ng in view of Thomlinson and Barnett.

46. It is my opinion that Claims 13 and 15 would have been obvious over Ng in view of Thomlinson, Barnett, and Worboys.

47. It is my opinion that Claims 17 would have been obvious over Ng in view of Thomlinson and Ultra Mirage.

48. It is my opinion that Claims 19, 21, and 25 would have been obvious over Ng in view of Thomlinson and FlexiFit.

[21] Ex. 1447 at 7.

[22] Ex. 1448 at 7.

49. It is my opinion that Claim 20 would have been obvious over Ng in view of Thomlinson, FlexiFit, and Sprinkle.

50. It is my opinion that Claim 22 would have been obvious over Ng in view of Thomlinson, FlexiFit, and Matula-II.

51. It is my opinion that Claims 28–30 would have been obvious over Ng in view of Thomlinson, Matula-II, Gunaratnam-I, and Barnett.

52. It is my opinion that Claims 46, 51, and 53–56 would have been obvious over Ng in view of Thomlinson, Barnett, FlexiFit, Matula-II, Worboys, and Sprinkle.

53. It is my opinion that Claim 65 would have been obvious over Ng in view of Thomlinson, Barnett, and Matula-II.

VIII. CLAIMS 1, 4–8, 10–22, 25, 26, 28–32, 46, 51, 53–56, AND 65 OF THE '931 PATENT WOULD HAVE BEEN OBVIOUS TO A PERSON OF ORDINARY SKILL IN THE ART

A. Claims 1, 6, 11, 16, 31, and 32 would have been obvious over Ng in view of Thomlinson

1. Ng (WO 2007/048174)

54. Ng describes mask systems intended for use in positive pressure therapy for users with sleep-disordered breathing that includes a frame that can be used with different styles or types of cushion assemblies.[23]

[23] Ex. 1410 ¶ 2.

55. I have provided an annotated version of Figure 1 from Ng below to show these various features of the mask system.

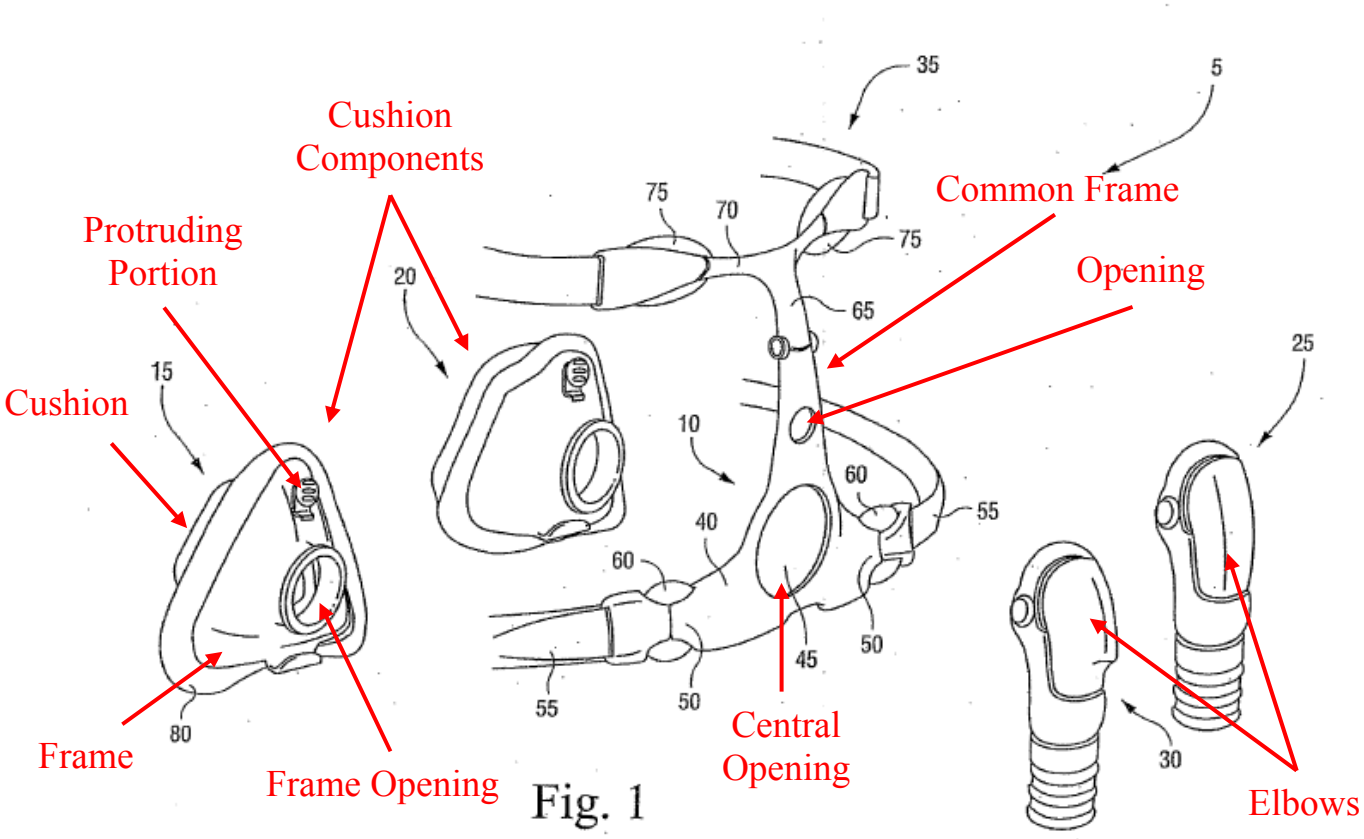


Fig. 1

56. The common frame 10 includes a main body 40 defining a central opening 45.[24] The common frame 10 includes a second opening positioned above the central opening 45.[25] Each of the cushion components 15, 20 includes a protruding portion that is exposed through the second opening towards a front side

[24] *Id.* ¶ 30.

[25] *See id.* at Fig. 1.

of the common frame 10 when the cushion component 15, 20 is attached to the common frame 10.[26]

57. The common frame 10 is configured to removably couple to one of the interchangeable cushion components 15, 20 and to one of the elbow components 25, 30.[27] Each of the cushion components 15, 20 differs in at least one aspect such that one may be more optimal or preferable for some users, while another may be more suitable for other users.[28] Each of the cushion components 15, 20 includes a frame and a cushion structured to engage a patient's face, the frame and the cushion defining a mask interior breathing chamber.[29]

58. Each of the two cushion components 15, 20 includes a frame opening bounded by a collar and is structured to align with the central opening 45 provided to the common frame 10.[30] The common frame 10 is configured for use with each

[26] *See id.*

[27] *Id*. ¶ 31.

[28] *Id*.

[29] *See id.* at Fig. 1.

[30] *See id.*

of the elbow components 25, 30.[31] The elbow components 25, 30 can include gas washout vents that are configured for predetermined washout rates and noise.[32]

59. The main body 40 includes at least two lateral arms 50, each of which can be coupled to a headgear strap 55 of headgear.[33] The common frame 10 may also include a forehead support 65 that has a bridge 70 provided with forehead pads 75 to rest against the user's forehead in use.[34] The bridge 70 includes a pair of connectors each structured to connect to a headgear strap of the headgear.[35]

[31] *Id.* ¶ 32.

[32] *Id.*

[33] *Id.* ¶ 30.

[34] *Id.*

[35] *See id.*

2. Thomlinson (U.S. Publication No. 2005/0011524)

60. Thomlinson discloses patient interface devices intended to deliver positive airway pressure for users with sleep apnea—including OSA—that include different strap systems and varied exhalation port configurations.[36]

61. As shown below in Figure 1, nasal interface body 2 includes one or more locking tabs 38 on distal portion 16.[37] The locking tabs 38 can be used to releasably engage a strap attachment plate 92 separately shown in Figure 28A below.[38]

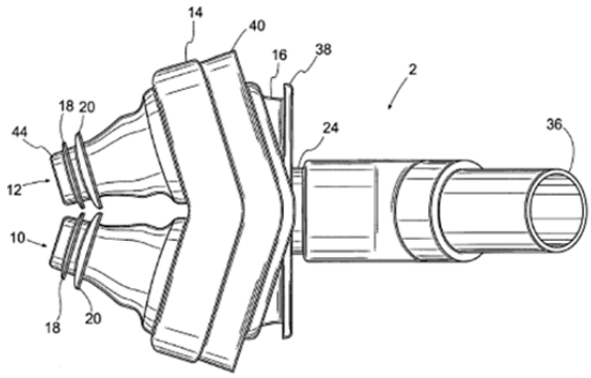


Fig. 1

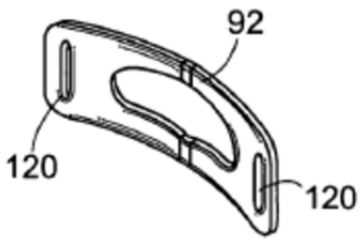


Fig. 28A

62. Strap attachment plate 92 includes one or more strap connections 120 for receiving a strap system.[39] Strap attachment plate 92 can facilitate the use of a

[36] Ex. 1411 ¶ 188.

[37] *Id.* ¶ 203.

[38] *Id.*

[39] *Id.* ¶ 306.

strap system because it may increase the ease at which a strap can be connected to or removed from the nasal interface.[40] Strap attachment plate 92—and any attached straps—can also be easily added or removed from the system because the strap attachment plate is not integral to the nasal interface.[41] The strap system can be fastened and unfastened using alternative methods to Velcro®—such as snaps, buckles, buttons, and ties.[42]

63. Figure 3 below illustrates another view of the nasal interface body 2, which shows one or more protruding exhalation ports 22 integrated with the locking tabs.[43]

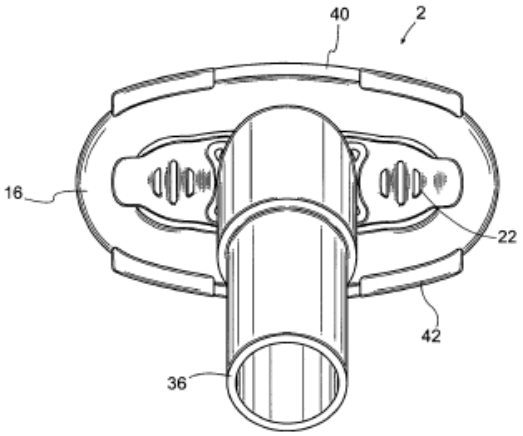


Fig. 3

[40] *Id.* ¶ 307.

[41] *Id.*

[42] *Id.* ¶ 312.

[43] *Id.* ¶ 204.

64. In another embodiment, a protruding exhalation port 22 is positioned between two inlets, as shown below in Figure 8.[44]

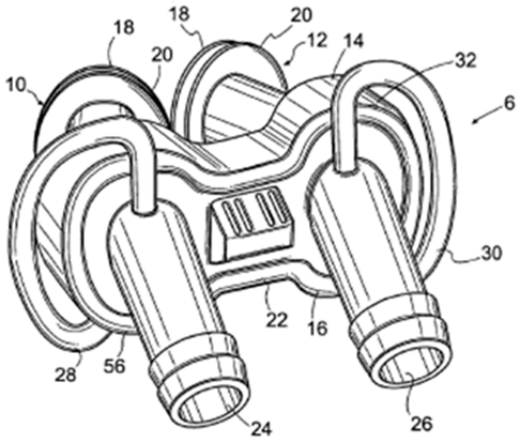


Fig. 8

3. Potential Differences from the Prior Art and Reasons to Combine

65. As detailed in the Claim Chart I provide below, Ng discloses nearly all of the features claimed in Claims 1, 6, 11, 16, 31, and 32. Any minor differences were well-known in the art at the time of the invention.

66. With respect to Claim 1, Ng teaches a mask system, comprising: (i) a shroud module (common frame 10); wherein the shroud module includes headgear connectors (press-fit connector 60) adapted to removably attach to respective headgear straps of headgear (headgear straps 55); and (ii) a cushion module (cushion components 15, 20), comprising: a rigid or semi-rigid frame defining a breathing chamber; and a cushion to form a seal with the patient's face in a nasal

[44] *Id.* ¶ 209.

bridge region, a cheek region and a lower lip/chin region of the patient's face, wherein the cushion is constructed of a first, relatively soft, elastomeric material and the frame is constructed of a second material that is more rigid than the cushion.[45] The shroud module and the cushion module are configured to be removably and non-rotatably coupleable to one another (at central opening 45 and second opening above the central opening).[46] The frame includes a protruding arrangement, and the shroud module includes a first opening (opening above central opening 45) to accommodate said protruding arrangement.[47] Further, the shroud module includes a second opening (central opening 45) positioned to align with a frame opening leading to the breathing chamber.[48]

[45] *See* 1410 ¶¶ 3, 29–31.

[46] *See id.* at Fig. 1.

[47] *See id.*

[48] *See id.*

67. I have identified many of these claimed features in the annotated version of Figure 1 of Ng provided below.

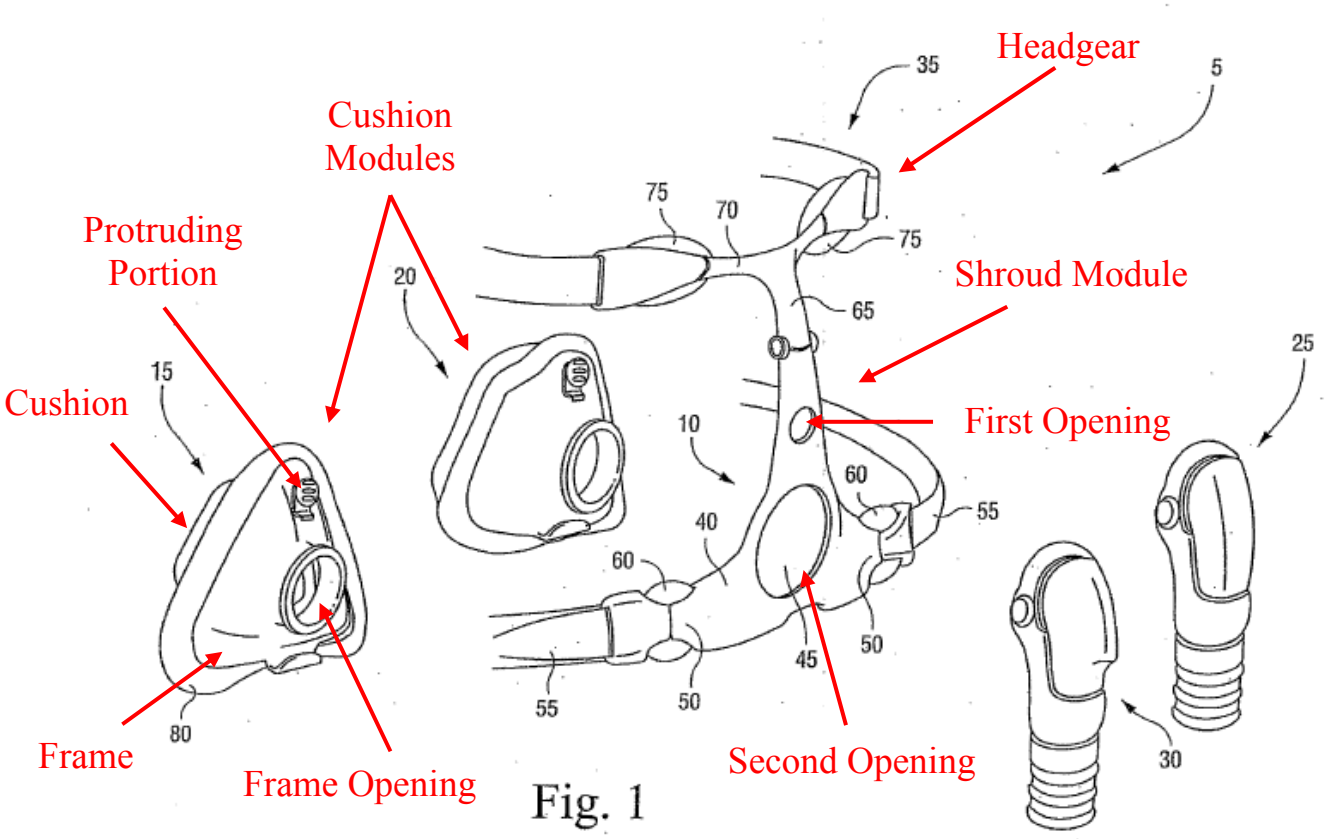


Fig. 1

68. With respect to Claim 1, Ng does not expressly disclose removable headgear straps or a protruding vent arrangement. However, as I explain below, these features were well-known prior to the '931 Patent and taught by several prior art references, including Thomlinson.[49] Moreover, as detailed below, any additional differences between the Challenged Claims and the teachings of Ng

[49] *See infra* ¶¶ 70–75, 82–97.

were similarly well-known and disclosed in the prior art, including in ResMed's own prior art publications.

69. Because Ng and Thomlinson both describe patient interface assemblies for delivering positive airway pressure for the treatment of sleep-disordered breathing,[50] the features of Thomlinson would have been readily compatible with and easily incorporated into the Ng mask with a reasonable expectation of success. Although Thomlinson discloses an interface with a pair of nasal prongs, a person of skill would have understood that the teachings of Thomlinson are equally applicable to other types of interfaces (e.g., nasal or full-face cushions). In fact, Ng discloses that its cushion components could be "full-face, nasal, nasal prongs, nose tip, and/or a combination of any of the above."[51] Some users prefer nasal prongs to provide breathable gas directly to the nares. Thomlinson discloses various types of nasal prongs interfaces, but these interfaces include many features that are generic to CPAP patient interfaces, including masks. In fact, many features are common with and interchangeable among all CPAP patient interfaces. These include, for example, the elbow connection, exhaust vents on the frame or elbow, tubing that attaches to the elbow, etc. Combining

[50] Ex. 1410 ¶ 2; Ex. 1411 ¶ 2.

[51] *See id.* at Abstract.

these familiar CPAP features according to known methods would have done no more than yield predictable results.

a. "headgear connectors adapted to removably attach to respective headgear straps of headgear" (Claim 1)

70. Claim 1 recites "wherein the shroud module includes headgear connectors adapted to removably attach to respective headgear straps of headgear."

71. As shown below, Ng discloses a shroud module 10 including at least two lateral arms 50 attached to respective headgear straps 55 using press-fit headgear connectors 60.[52] A person of skill would understand that these press-fit connectors 60 are headgear clips adapted to removably attach to headgear straps.

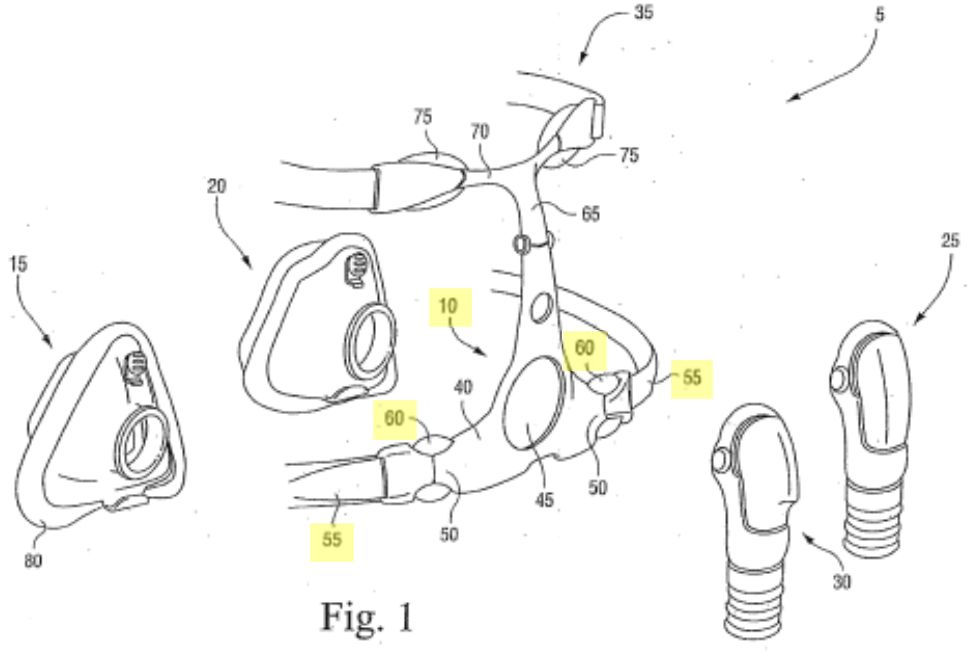
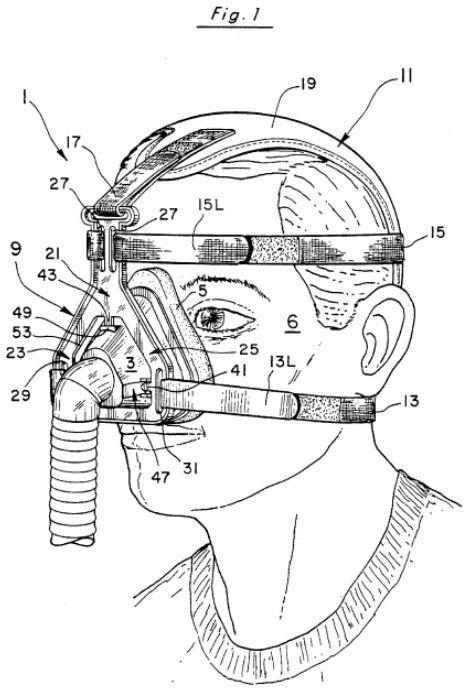


Fig. 1

[52] Ex. 1410 ¶ 30.

72. To the extent the press-fit connectors provide insufficient teachings for the removability of the headgear straps, removable headgear straps were well-known and commonly used prior to the '931 Patent. For example, Thomlinson discloses a strap system that "can be fastened/unfastened using alternative methods to Velcro, such as snaps, buckles, buttons and ties."[53]

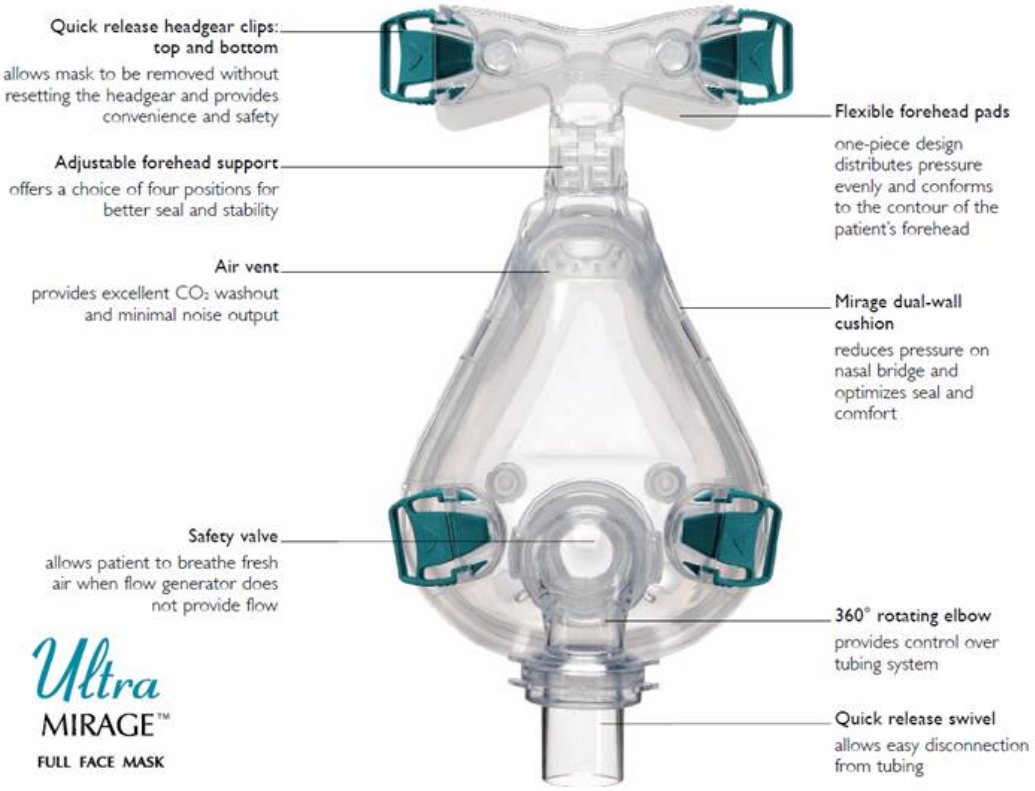
73. Removability is one of the main purposes for using Velcro® on straps. As shown in Figure 1 of Ogden below, it was common and well-known in the industry that headgear straps are typically removable from the headgear connectors on the shroud using hook and loop material (e.g., Velcro®).[54]



[53] Ex. 1411 ¶ 312.

[54] Ex. 1422 at col. 2:62—3:17.

74. Another method to provide removable straps is using headgear clips. For example, Ultra Mirage discloses "[q]uick release headgear clips: top and bottom allows mask to be removed without resetting the headgear and provides convenience and safety."[55]



75. A person of skill in the art at the time of the invention would have been motivated to provide headgear connectors adapted to removably attach to headgear straps to enable quick and easy mask fitting.[56] Such headgear connectors

[55] Ex. 1416 at 6.

[56] *See* Ex. 1417 at 10 ("FITTING YOUR MASK").

also facilitate removal of the headgear for cleaning or replacing the mask.[57] It was common knowledge that cleaning masks with fixed headgear straps is more difficult and may structurally or functionally impair the headgear.[58] Further, releasable mechanisms, such as clips, provide a convenient way to separate the headgear at night time or in an emergency.[59] Removable headgear also allows the mask to be removed without resetting the headgear, or even without removing the headgear from the user's head.[60]

b. "the frame is constructed of a second material that is more rigid than the cushion" (Claim 1)

76. Claim 1 recites "wherein the cushion is constructed of a first, relatively soft, elastomeric material and the frame is constructed of a second material that is more rigid than the cushion."

77. Ng discloses that mask assemblies "typically included a soft-face contacting portion, such as a cushion, and a rigid shell or frame."[61] It was common

[57] Ex. 1434 ¶¶ 7–8

[58] *Id.*

[59] *See id.*; Ex. 1428 ¶ 14.

[60] *See* Ex. 1416 at 6; Ex. 1434 ¶ 8.

[61] Ex. 1410 ¶ 3.

for CPAP masks to include cushions constructed from silicone, which is an elastomeric material. A person of skill would have recognized that silicone cushions were and still are desirable because they provide a compliant and comfortable seal against the user's face.[62] Silicone is also biocompatible and easy to clean.[63] Moreover, silicones are readily moldable into complex contours, including undercut surfaces, and in a broad range of wall thicknesses, which make them very versatile materials for interface design.

78. Further, a person of skill would have recognized that the Ng cushion module 15, 20 includes a frame constructed of a material that is more rigid than the cushion material. Ng discloses that cushion module 15 may be an Activa™ component.[64] The Activa™ component is described in U.S. Application No. 10/655,622, published as U.S. Publication No. 2004/0118406 (Lithgow).[65] Lithgow discloses a silicone cushion 26 and a frame 24 having a "stiffer grade material."[66]

[62] *See* Ex. 1413 at col. 1:36–39.

[63] Ex. 1438 ¶ 244.

[64] Ex. 1410 ¶ 31.

[65] *Id.* ¶ 60.

[66] Ex. 1433 ¶ 139.

79. A person of skill would have understood that, prior to the '931 Patent, rigid frames were commonly used in CPAP masks to provide support for the soft cushion.[67] Polycarbonate is one example of a material that is commonly used in prior art mask frames that is more rigid than typical cushion materials.

80. Further, a person of skill would have recognized that a frame constructed of a more rigid material than the cushion would facilitate engagement with the shroud module.[68] A more rigid frame would provide dimensionally stable features to form reliable and consistent snap fits with components such as the shroud.[69] The more rigid frame would also prevent deformation of the cushion, which creates wrinkles or unwanted folds in the sealing surfaces of the cushion. Further, the use of more rigid frame materials would allow snap fits to mate with an audible and/or tactile click to assure the user of proper assembly. To the extent the elbow contacts the frame, constructing the frame from a dimensionally stable, rigid material would provide reduced friction between the elbow and frame, allowing the elbow to swivel more freely and consistently.[70]

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[67] Ex. 1432 at 6:21–24.

[68] *See* Ex. 1433 ¶ 139.

[69] *See infra* ¶¶ 116–125, 130–135.

[70] *See infra* ¶¶ 172–177.

81. Further below, I provide other examples in the prior art of silicone cushions and polycarbonate frames with respect to Claim 18 and reasons for using those specific materials.[71]

[71] *See infra* ¶¶ 153–158.

c. "protruding vent arrangement" (Claim 1)

82. Claim 1 recites "wherein the frame includes a protruding vent arrangement having a plurality of holes, wherein the shroud module includes a first opening to accommodate said protruding vent arrangement."

83. As shown below, Ng discloses a shroud module 10 with a first opening that accommodates a protruding portion on the frame.[72]

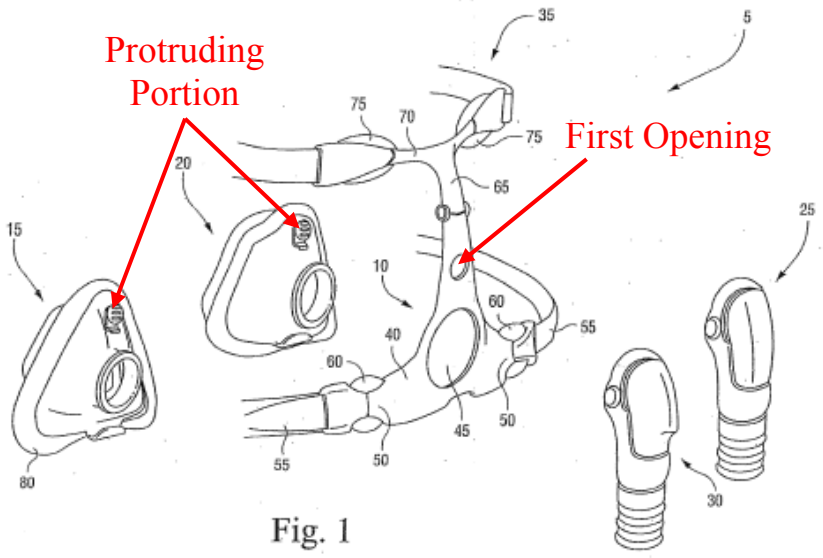


Fig. 1

84. As explained above, the phrase "a first opening to accommodate said protruding vent arrangement" includes a first opening that provides enough space for the protruding vent arrangement.[73] Because the protruding portion on the

[72] *See* Ex. 1410 at Fig. 1.

[73] *See supra* ¶¶ 38–41.

frame is a clip structure, the first opening would provide enough space for the protruding clip to serve its intended purpose.

85. With respect to Figure 1, Ng discloses that the elbow module 25, 30 may include a gas washout vent,[74] but other embodiments in Ng include a gas washout vent on the cushion module.[75] Prior to the '931 Patent, vents in the nasal bridge region of the frame were well-known in the prior art, especially on full-face masks. Because of the large amount of dead space in a full-face mask, a person of skill at the time of the purported invention would have been motivated to move the gas washout vent from the elbow module 25, 30 to the cushion module 15, 20. It was well-known to place the vent in the nasal bridge region, e.g., at a position above the frame opening, to minimize noise output by generally directing air away from the user, bedding, etc., regardless of elbow position. Positioning the vent in the nasal bridge region would also prevent blockage of the vent holes and would be less susceptible to undesirable draft on the patient or sleeping partner. This position allows the exhaust air to be directed away from the patient's face and body and also not towards a sleeping partner. Additionally, it was well-known to place the vent in the nasal bridge region to promote greater air movement and

[74] Ex. 1410 ¶ 32.

[75] *Id.* ¶ 43.

reduce dead space, which is the volume "downstream" from the vent that cannot be efficiently purged of exhaled air. Positioning the vent opposite the inlet relative to the nose was also desirable so that air from the inlet would flow by the patient's nose and exit the vent to flush exhaled air effectively.

86. The protruding portion on the cushion module 15, 20 of Ng is a discrete structure that extends above the surrounding surface of the frame. The protruding portion does not include a plurality of vent holes, but it does include an integral clip and the integration of clips and protruding vent arrangements was known in CPAP interfaces prior to the '931 Patent. For example, Thomlinson discloses a frame 16 having two protruding vent arrangements, each of which has a plurality of vent holes 22 and functions as a clip.[76] The Thomlinson shroud module 92 has an opening that accommodates the protruding vent arrangements, as shown below in Figure 28A.

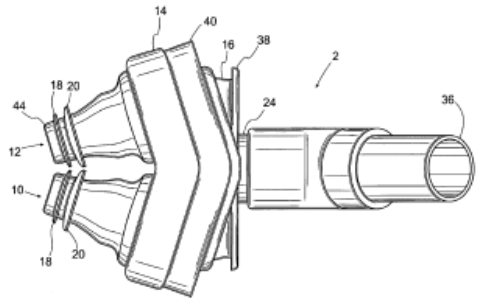


Fig. 1

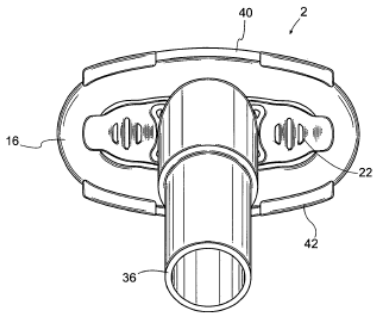


Fig. 3

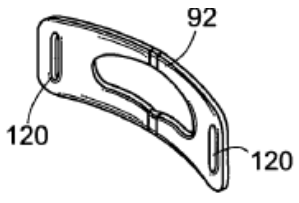


Fig. 28A

[76] Ex. 1411 ¶ 203.

87. A person of skill at the time of the purported invention would have been motivated to provide a protruding vent arrangement, like that disclosed by Thomlinson, in place of the protruding clip in the nasal bridge region of the Ng mask. As modified, the protruding vent arrangement would provide a discrete structure that extends above the surrounding surface of the frame and includes a plurality of vent holes. The first opening of the Ng shroud module would accommodate the protruding vent arrangement so that the arrangement extends through the opening to secure the cushion module to the shroud module and allow unimpeded flow of air from the vent holes.

88. Although Thomlinson discloses a nasal prong interface, a person of skill would have understood that the vent structure is generic to the various types of CPAP interfaces, including full-face masks. A person of skill would have recognized that replacing the Ng protruding clip with a protruding vent arrangement, as taught by Thomlinson, would preserve the clip functionality of the Ng protrusion and provide an exhaust vent in the nasal bridge region of the Ng frame. Further, as described above, it was well-known to place the vent in the nasal bridge region to promote greater air movement and reduce dead space, which

is the volume "downstream" from the vent that cannot be efficiently purged of exhaled air.[77]

89. Alternatively, if a person of skill did not want to integrate the clipping function with the protruding vent arrangement, Thomlinson also discloses a discrete protruding vent arrangement with a plurality of holes and without any clipping function, as shown below in Figure 8.[78]

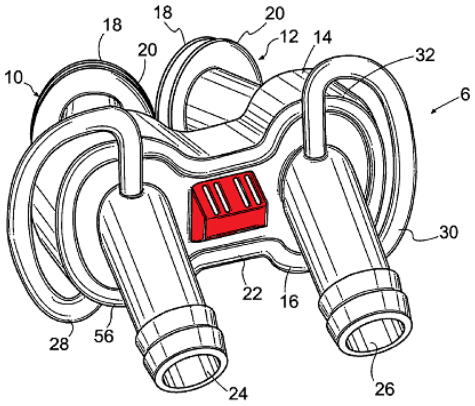


Fig. 8

90. In this alternative arrangement, a person of skill would have provided an additional opening on the Ng shroud between the first and second openings to accommodate the protruding vent structure in the nasal bridge region. Otherwise, the shroud would block the vent and cause excessive noise as a result of interference with the vented air.

[77] *See supra* ¶ 85.

[78] *See* Ex. 1411 ¶ 209, Fig. 8.

91. A person of skill in the art would have been familiar with discrete vent arrangements that extend above the surrounding surface of the frame as such arrangements were commonly included on CPAP mask frames, as disclosed in numerous prior art references in addition to the Thomlinson reference. For example, as shown below in Figure 8 of Hitchcock, the discrete vent structure (shaded red) extends above the surrounding surface of the frame.[79]

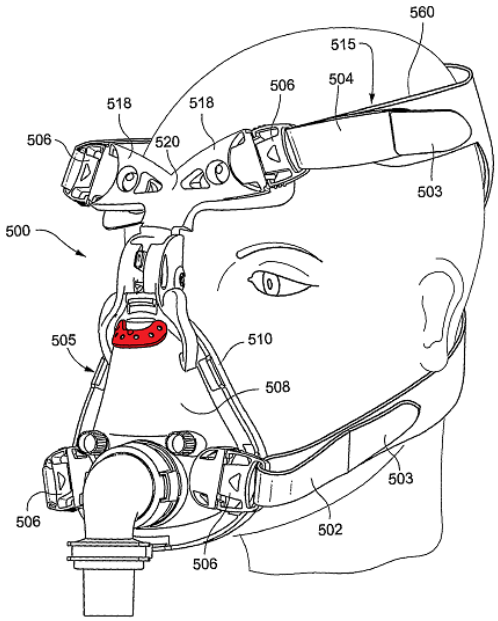


Fig. 8

[79] *See* Ex. 1421 at Fig. 8.

92. As another example, Jones, Jr. discloses a protruding vent arrangement 11 (shaded red) that extends above the surrounding surface of the mask body 12.[80] A circular opening 19 is formed in the mask body 12 for receiving the exhaust port member 11.[81] A plurality of vent holes 22 extend through the protruding vent arrangement 11 at a predetermined angle relative to the axis of rotation 20.[82]

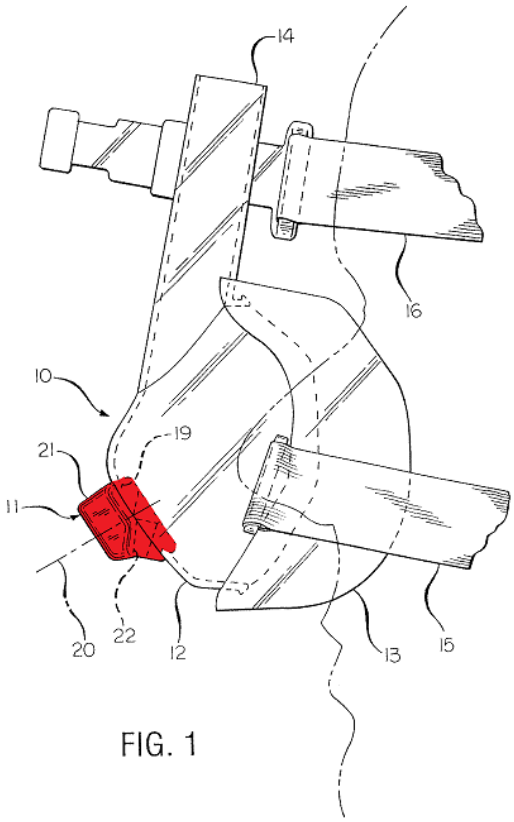


FIG. 1

[80] Ex. 1436 at col. 3:3–8.

[81] *Id.*

[82] *Id.* at col. 3:23–25.

93. As another example, Jones discloses a frame 130 with a protruding vent arrangement 30.10 (shaded red) having a plurality of vent holes 30.9.[83] The protruding vent arrangement 30.10 is a thicker wall section formed integrally on the frame 130.[84] The protruding vent arrangement 30.10 forms a channel for receiving the headgear connector 40.[85]

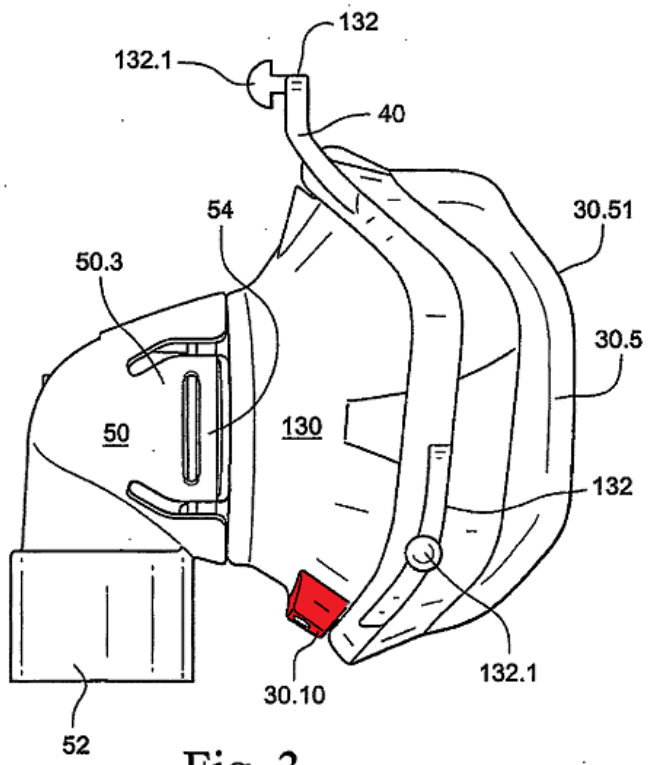


Fig. 3

[83] Ex. 1437 ¶ 226.

[84] *Id.*

[85] *Id.*

94. A person of skill would have been motivated to provide a protruding vent arrangement on the D'Souza frame for CO_2 washout.[86] For example, Geist discloses a mask assembly with a shroud module and cushion module in which the vent is positioned on the frame of the cushion module to provide CO_2 washout.[87] In particular, a person of skill would have been motivated to incorporate a protruding vent arrangement that extends above a surrounding surface of the frame to better control the direction of exhaust air and to direct the exhaust air away from the user.[88] With protruding vent arrangements, there can be a thicker wall which allows for more design flexibility with the shape and orientation of the vent holes.[89] A person of skill would have recognized that the orientation of the vent holes can minimize interference between the vented air and the surrounding structures, which also minimizes turbulence and noise.[90] Further, a protruding vent arrangement also allows for a vent design having longer holes with tapered diameters to minimize the noise output.

[86] *See* Ex. 1416 at 6.

[87] Ex. 1434 ¶ 40.

[88] *See* Ex. 1436 at 3:33–38; Ex. 1437 ¶ 226.

[89] *See* Ex. 1436 at 3:23–42; Ex. 1411 at Fig. 8.

[90] *See* Ex. 1436 at 3:28–30.

95. Further, as demonstrated in the prior art, it was common knowledge to one skilled in the art to include a protruding vent arrangement that also serves as an engagement feature for the shroud module.[91] Based on this common knowledge, a person of skill would have replaced the protruding clip structure of Ng with a protruding vent arrangement, as disclosed by Thomlinson and explained above.[92]

96. In instances where the protruding vent arrangement is made from a separate part and joined or assembled to the frame, greater flexibility is afforded in manufacturing techniques. The separate vent permits geometries that would otherwise be difficult or impossible to form directly on a frame molded by traditional techniques, e.g., to be readily formed in a mold without undercuts or hidden surfaces. Forming the vent in a separate insert instead of directly in the mask shell can reduce noise by damping vibrations caused by air passage through the orifices.[93] Further, separable vent arrangements would have been desirable for interchangeable vent arrangements.[94] A first vent may be desirable for generally low pressure treatment, but a second vent may be desirable for higher treatment

[91] *See* Ex. 1437 ¶ 226.

[92] *See supra* ¶¶ 84–88.

[93] *See* Ex. 1445 at cols. 2:28–31, 4:13–20.

[94] *See* Ex. 1442 ¶ 89.

pressures.[95] Separable vent arrangements also would have been desirable for "single use" vents that are replaced after each use.[96]

97. Protruding vent arrangements made from a separate part were common in the prior art. As discussed above, Jones, Jr. discloses a separate protruding vent arrangement.[97] As another example, Gunaratnam-I includes a separate air vent arrangement 940, as shown below.[98]

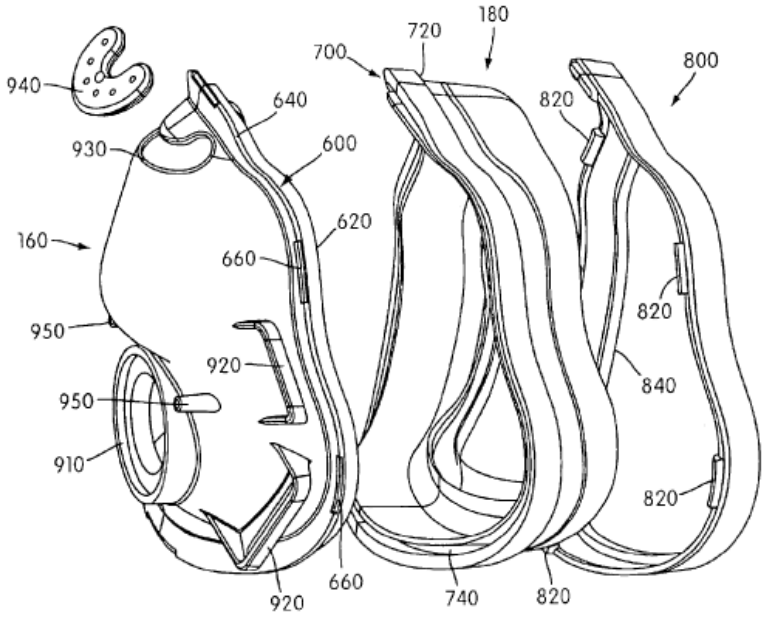


FIG. 15

[95] *See id.*

[96] *See id.* ¶ 90.

[97] *See supra* ¶ 92.

[98] Ex. 1413 at col. 6:25–29.

d. "air delivery tube" (Claim 11)

98. Claim 11 depends from Claim 1 and includes "further comprising an elbow module adapted to be connected to an air delivery tube that delivers breathable gas to the patient."

99. Ng discloses mask assemblies for use with flow generators and adapted to engage an elbow and an air delivery tube, as shown in Figure 1.[99] Such tubes were common in these CPAP systems and a person of skill in the art would have understood that an air delivery tube connects the elbow to the flow generator. For example, Thomlinson specifically describes air delivery tubing 90 connected to the elbow.[100]

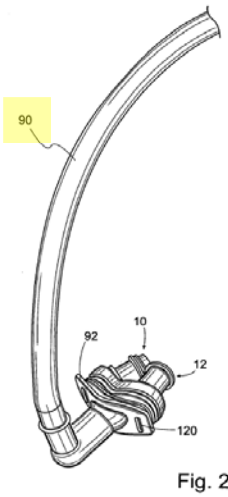


Fig. 29

[99] Ex. 1410 ¶ 3, Fig. 1.

[100] Ex. 1411 ¶ 316.

100. It was well-known at the time of the invention to use tubing, as taught by Thomlinson, to connect an elbow or inlet conduit to a flow generator. The Ng mask would have been readily compatible with commercially available and standardized tubing conduits commonly used to deliver positive airway pressure breathing air to mask assemblies. Tubing was a necessary component of the system which involves a stationary flow generator providing positive pressure flow to a patient-worn mask assembly.

B. Claims 4, 5, 10, and 26 would have been obvious over Ng in view of Thomlinson and Matula-II

1. Matula-II (U.S. Publication No. 2007/0044804)

101. Matula-II generally describes a CPAP interface that includes a faceplate 36 coupled to a seal member 38.[101]

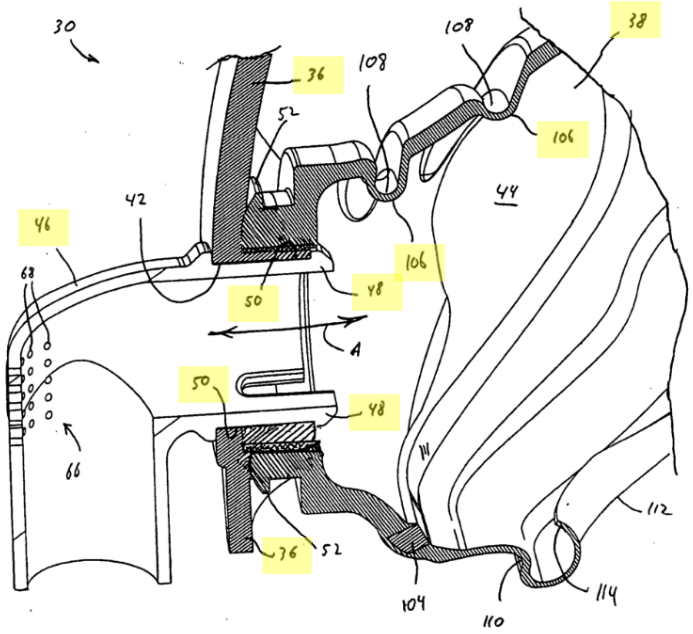


Fig. 4

102. As shown above, coupling member 46 includes a pair of prongs 48 that create a channel 50 to receive the wall of the faceplate 36 and the end of the seal member 38.[102] Matula-II also describes a seal member 38 that includes

[101] Ex. 1412 ¶¶ 52–53.

[102] *Id.* ¶ 53.

multiple folds 106 at an upper portion of the seal member "so that the seal member has the desired degree of flexibility."[103]

2. Potential Differences from the Prior Art and Reasons to Combine

103. A person of skill in the art would have been motivated to combine Ng, Thomlinson, and Matula-II for at least the reasons provided above.[104] Similar to Ng and Thomlinson, Matula-II discloses a CPAP interfaces for treatment of sleeping disorders.[105] The teachings of Matula-II would have been readily compatible with and easily incorporated into the Ng mask with a reasonable expectation of success because each feature would function for its intended purpose and provide its known benefit, as taught in the prior art. Combining the features of Ng, Thomlinson, and Matula-II would have been a mere combination of familiar patient interface features that would have yielded only predictable results.

a. "one or more folds" (Claim 4)

104. Claim 4 depends from Claim 1 and includes "wherein a nasal bridge portion of the cushion includes one or more folds to provide in use a higher level of adaptability or flexibility to the nasal bridge region of the cushion module

[103] *Id.* ¶ 66.

[104] *See supra* ¶¶ 68–100.

[105] *See* Ex. 1412 ¶¶ 3, 5.

relative to another region of the cushion module; and further wherein each of said one or more folds comprises adjacent first side walls interconnected by a second side wall."

105. As shown below, Ng discloses a gusset portion 80 in cushion module 15.[106] And in other embodiments, Ng discloses a fold in the nasal bridge region of the cushion, as shown in Figure 24. Ng does not specify a higher level of adaptability or flexibility in the nasal bridge region of the cushion module relative to another region of the cushion module; however, these fold configurations providing higher flexibility in the nasal bridge region were well-known prior to the '931 Patent and were taught by the prior art.

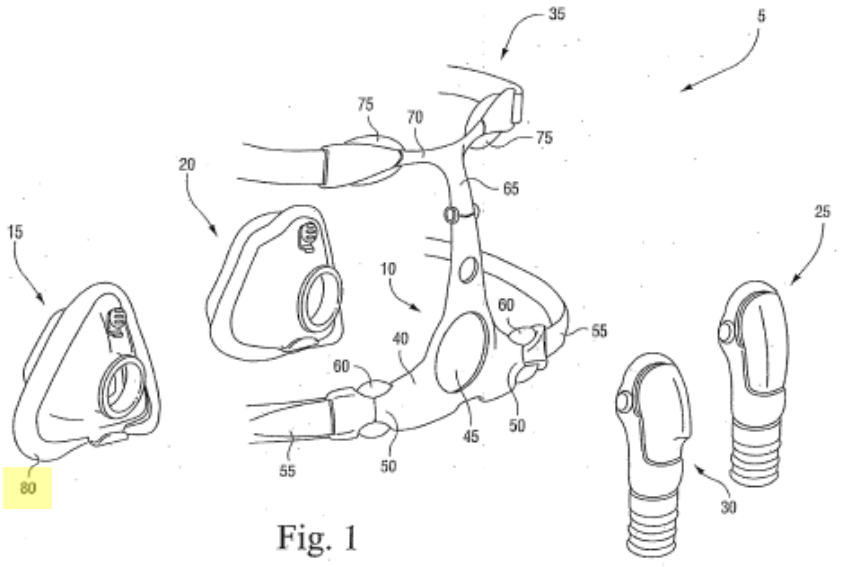
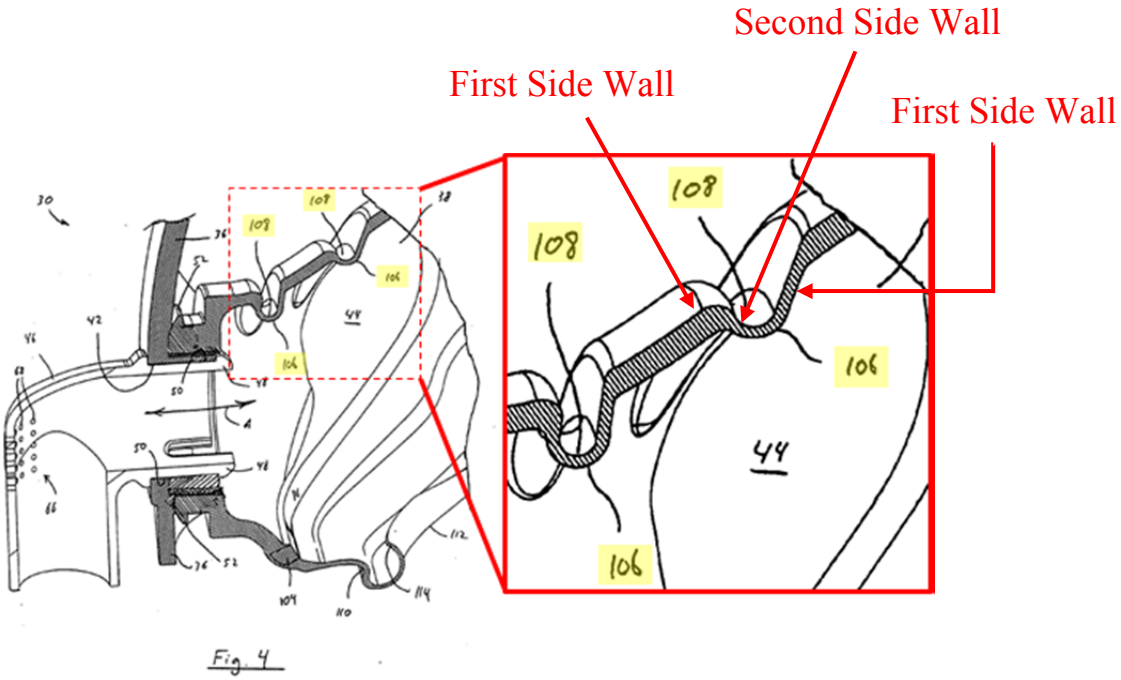


Fig. 1

[106] Ex. 1410 ¶ 31.

106. For example, Matula-II discloses folds 106 (also referred to as pleats or gusset) positioned only in the nasal bridge portion of the cushion 38, which provides "the desired degree of flexibility."[107] These folds provide a higher level of adaptability or flexibility to the nasal bridge region of the cushion module relative to another region of the cushion module. As shown below, the Matula-II fold 106 has first side walls interconnected by a second side wall.



[107] Ex. 1412 ¶ 66.

107. The Matula-II fold is similar to the fold structure shown in the '931 Patent, in which each fold has adjacent first side walls 52(1) interconnected by a second side wall 52(2), as shown below in Figure 32–3.[108]

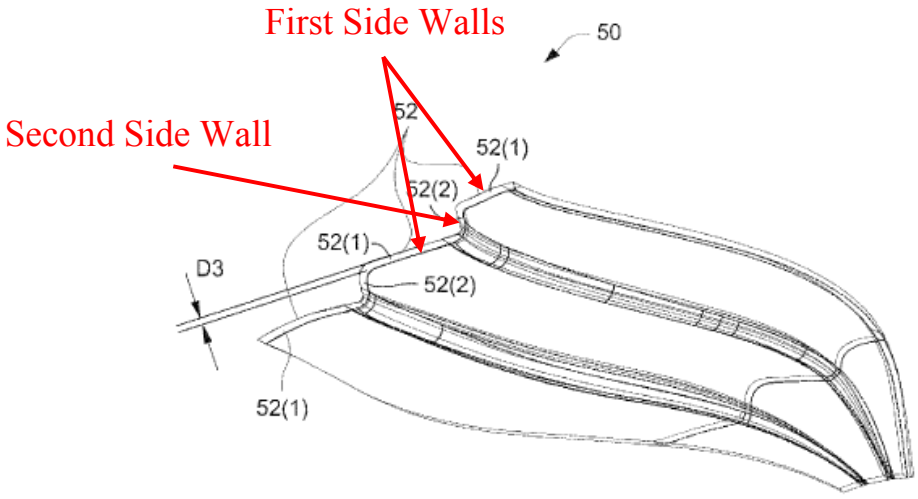


Fig. 32-3

108. As further evidence that the use of such folds was common and well-known, Melidis describes cushions having a similarly constructed fold 9 in the nasal bridge region. Figure 2 (on the next page) shows a side view of a cushion 3 with a fold 9 that has adjacent first side walls interconnected by a second side wall.[109] The fold 9 has the greatest indentation depth t in the region of the end which is towards the bridge of the nose.[110] Figure 10 (on the next page) shows a cross-section view of a portion of a cushion with a plurality of fold

[108] Ex. 1401 at col. 14:40–42, Fig. 32–3.

indentations 39, 40. These fold arrangements provide a higher degree of flexibility in the nasal bridge region.[111]

Fig.10

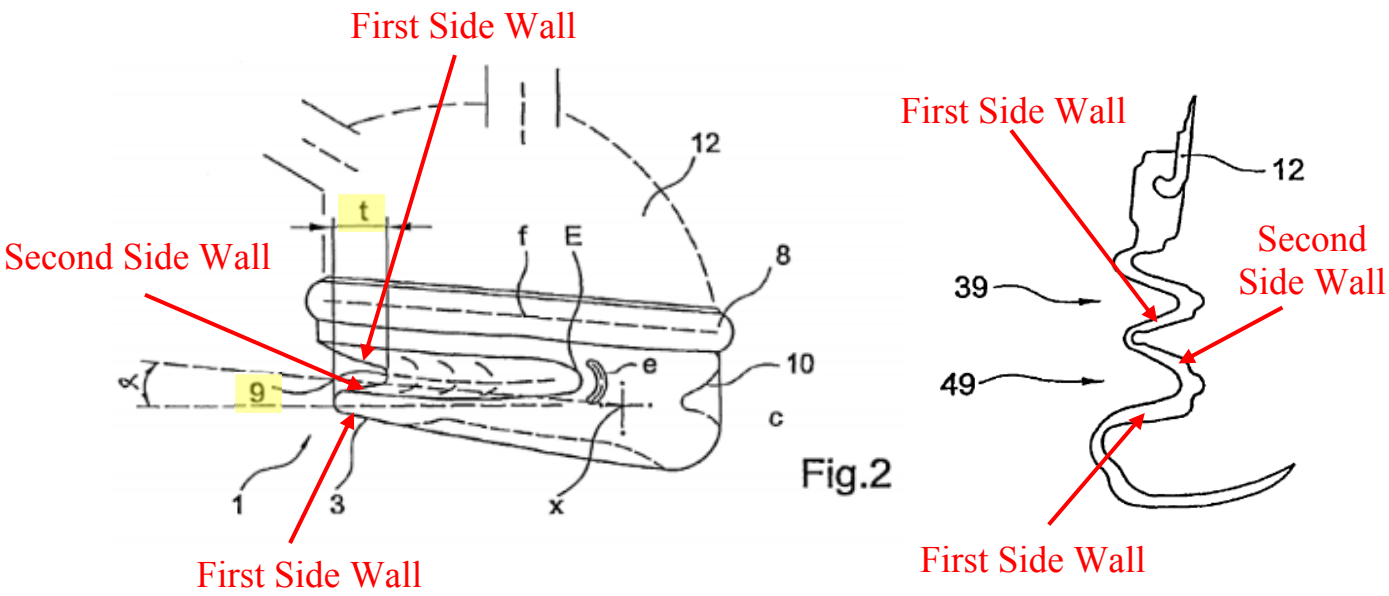


Fig.2

[109] Ex. 1424 at 5:55–57.

[110] *Id.* at 8:18–20.

[111] *Id.* at 8:38–42.

109. As another example, Frater also discloses one or more folds in the nasal bridge region.[112]

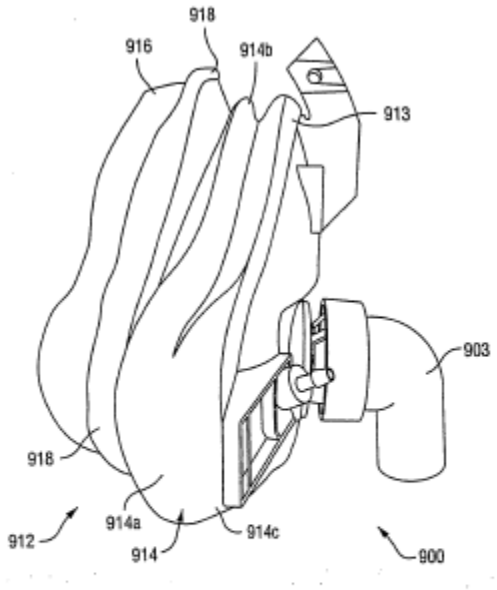


Fig. 51

[112] Ex. 1425 ¶ 164.

110. A person of skill in the art would have been motivated to incorporate the Matula-II fold configuration in the nasal bridge region of the Ng mask to increase patient comfort and optimize the distribution of sealing force against the user's face.[113] It was well-known in the industry that decreasing pressure on the nasal bridge was needed due to the thinness of the soft tissue in this area over the bony structure of the nose.[114] Localized high pressure spots are uncomfortable and can disrupt the sleep cycle. In fact, too much pressure in the nasal bridge area can cut off blood flow which leads to pressure ulcers. Ng recognizes that it is desirable for the nasal bridge region to be more flexible to provide a better fit.[115]

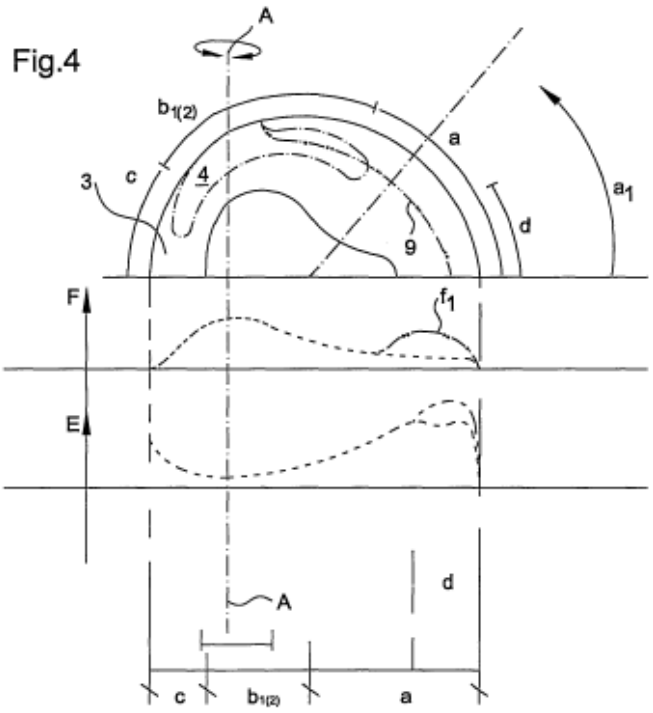
111. To address these concerns, a person of skill would have provided more flexibility in the nasal bridge region than other regions of the mask. One skilled in the art would have recognized that there is an inverse relationship between the level of flexibility and the amount of pressure force transmitted to the wearer's face. This is demonstrated in Figure 4 of Melidis (below), which shows a simplified view of the cushion and diagrams of the load-bearing capability and

[113] *See* Ex. 1424 at col. 1:30–61; Ex. 1412 ¶ 3; Ex. 1425 ¶ 163.

[114] *See* Ex. 1433 ¶ 130.

[115] Ex. 1410 ¶ 59.

flexibility in each region of the cushion.[116] These graphs show that the highest level of flexibility E in the nasal bridge region *a* and the lowest level of pressure force F transmitted in that same region.[117] A person of skill would have recognized that this flexibility/load-bearing profile was desirable in view of the delicate nasal bridge region that the other areas of the face (e.g., cheeks *b*) would be better suited to support higher load areas or pressures to maintain the position of the mask, and thus require less flexibility in those regions.[118]



[116] Ex. 1424 at col. 8:53–55.

[117] *Id.* at col. 8:53—9:2.

[118] *Id.* at col. 2:42–47.

b. "collar surrounding said frame opening" (Claim 5)

112. Claim 5 depends from Claim 1 and includes "wherein the frame includes a collar surrounding said frame opening."

113. As shown below, Ng discloses a collar surrounding the frame opening.[119]

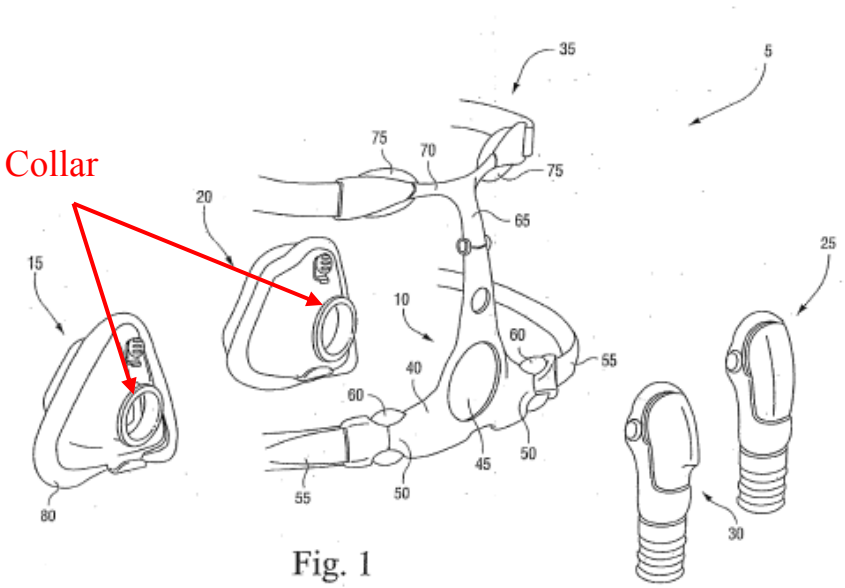


Fig. 1

[119] *See* Ex. 1410 at Fig. 1.

114. A person of skill would have recognized that a collar surrounding the frame opening facilitate a stables mechanical coupling with the shroud module.[120] As shown in Figures 4 and 5 below, Matula-II also discloses a cushion module having a collar 52 surrounding the opening.[121]

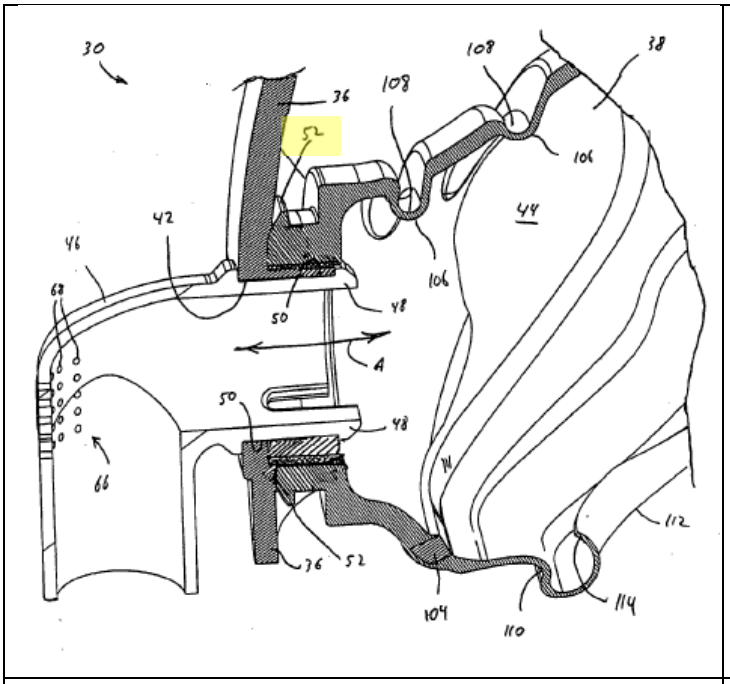


Figure 4

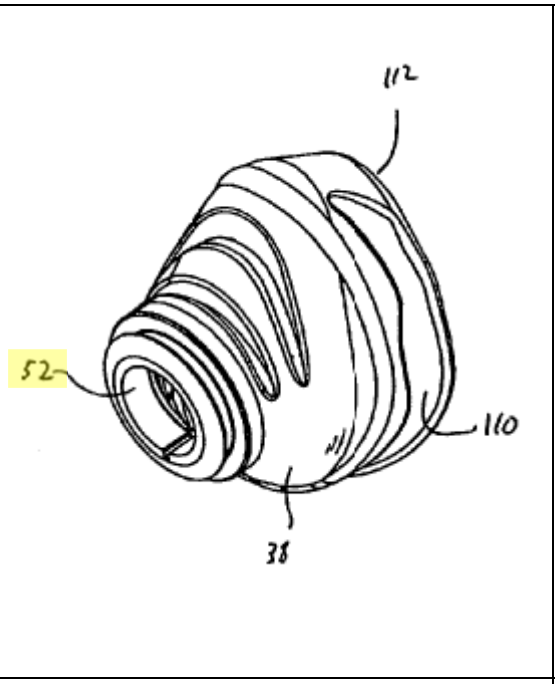


Figure 5 (PARTIAL)

c. "plurality of snap fingers" (Claim 5)

115. Claim 5 further includes "wherein the shroud includes a retaining portion with a plurality [of] snap fingers structured to engage the collar with a snap-fit."

[120] Ex. 1412 ¶ 53.

[121] *See id.*

116. Ng does not disclose a plurality of snap fingers, but snap fingers were well-known and commonly used in CPAP masks prior to the '931 Patent. For example, as shown in Figures 4 and 5 below, Matula-II shows a plurality of snap fingers 48 structured to mechanically couple the seal member to the faceplate.[122] Because the faceplate 36 of Matula-II is semi-rigid, the snap-fingers 48 deflect radially inward and elastically recover to mechanically couple the seal member 38 to the faceplate 36 with a snap-fit.[123]

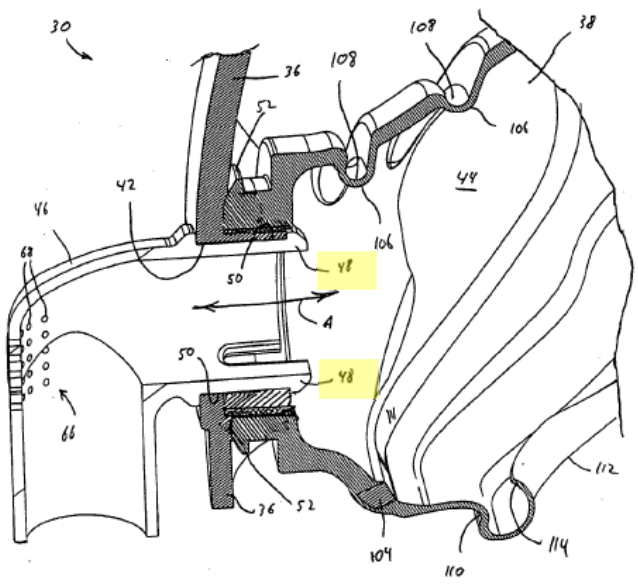


Figure 4

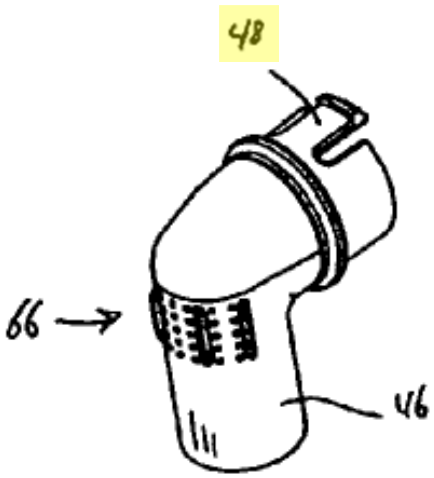


Figure 5 (partial)

[122] Ex. 1412 ¶ 53, Fig. 4.

[123] *Id.*

117. A person of skill in the art desiring to couple the shroud module to the cushion module in Ng would have recognized that the components could and would be joined together with an annular snap-fit. When joining the components with an annular snap-fit, a person of skill would have been motivated to modify Ng to include a plurality of snap fingers sized to engage the Ng collar, as taught by Matula-II, that extend rearward from the second opening 45 of the shroud module 10. As modified, the snap fingers would extend rearward into the frame opening to engage the inside diameter or underside surface of the Ng collar with a snap-fit similar to the Matula-II snap-fit arrangement.[124] Alternatively, the snap fingers would extend rearward from the second opening 45 of the shroud module 10 and engage the outer periphery of the collar.

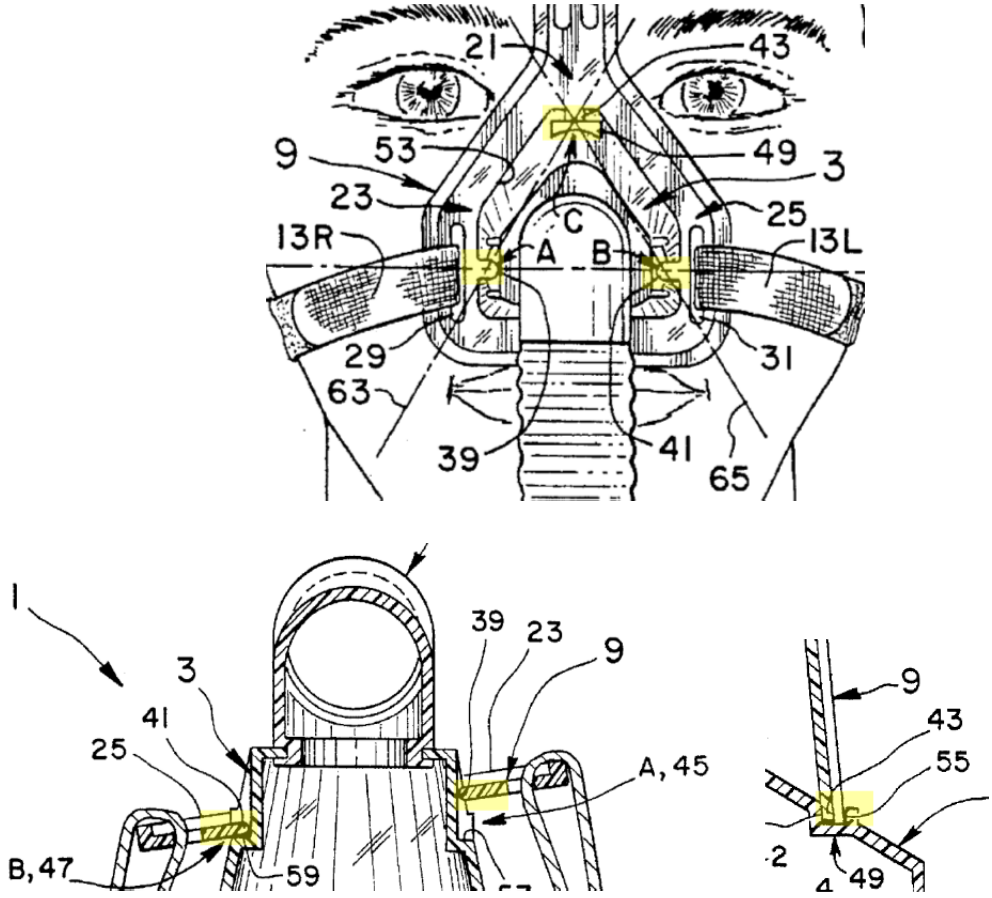
[124] *See id.*

118. Although the snap fingers of Matula-II are on the elbow, incorporating snap fingers into the Ng shroud module would have been a mere combination of known features to obtain predictable results. Further, incorporating snap fingers onto the Ng shroud module would provide a secure connection between the shroud module 10 and the cushion module 15, 20. Since the Ng frame has a collar, it would have been simple to provide snap fingers on the shroud module to engage the collar, without requiring any complex tooling or design. A person of skill would have recognized that positioning the snap fingers on the shroud module, instead of the elbow module, was desirable, so the cushion module could be disconnected from the shroud module without also disconnecting the elbow module.

119. The book *Plastic Part Design for Injection Molding*, Robert A. Malloy (1994), also confirms that snap fingers were commonly used in annular snap-fit arrangements and were part of the common knowledge of a person of skill in the art.[125] As further evidence that snap fingers on shroud modules are common knowledge to one skilled in the art, Ogden discloses that the rigid shroud 9 is snap-

[125] Ex. 1443 at 345.

fit to rigid shell 3 by fingers 39, 41, 43 interlocking into channels 45, 47, 49, as shown in the partial views of Figures 2, 7, and 8 of Ogden below.[126]



120. The Ogden detent or snap finger 43 and the channel 49 are "dimensioned to snap together to hold or maintain the rigid plate 9 on the rigid shell 3."[127] The removable snap-fit interlock results from moving the shroud module and the cushion module towards one another along a longitudinal axis.

[126] Ex. 1422 at col. 4:20–23.

[127] *Id*. at col. 5:14–18.

121. Lovell provides another example of snap fingers in an annular connection. As shown below in Figure 10A of Lovell, the snap fingers (edges of aperture between slots 213, 215) that on the shroud module 212 engage the depressed annular regions 280 between the tabs 211 on the frame 204.[128] The interference fit, elastic recovery, and engagement between the Lovell snap fingers and the depressed annular regions 280 provides retention between the mask frame and shroud module and constitutes a removable snap-fit attachment.

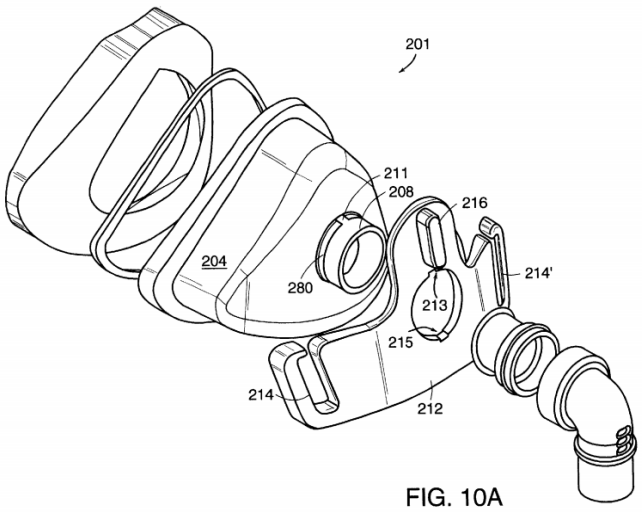


FIG. 10A

122. A person of skill would have been motivated to provide a snap-fit arrangement to ensure that the shroud module and the cushion module are fully attached. Further, it was well-known prior to the '931 Patent that snap-fit connections were desirable because such connections could be configured to simply require moving one component towards the other component along an

[128] Ex. 1426 at col. 9:59–64.

axis.[129] A person of skill also would have recognized that snap assemblies would be configured to be reversible,[130] so the cushion module could be removed or replaced for cleaning.

123. A person of skill in the art would have understood that snap-fingers were a common design configuration for annular snap-fit arrangements. Annular snap-fit arrangements can have high installation and removal forces. These forces are highly dependent on the degree of interference between the two parts. As the degree of interference changes, the installation and removal forces can change dramatically. Thus, tolerances become critical in annular snap-fit arrangements. A person of skill would have known to use segmenting to divide a continuous annular snap into snap fingers to allow for more generous manufacturing tolerances and more predictable installation and removal forces.[131]

124. The snap fingers facilitate deflection of the interlocking features during assembly to the shroud, and then elastically recover to an assembled and interlocked position. This increased ease of deflection reduces forces required for engagement of the parts, making it easier to join the shroud to the cushion module.

[129] *See* Ex. 1443 at 342.

[130] *See id.*

[131] *See id.* at 345.

Although there are various methods of connecting annular parts, a person of skill would have selected snap fingers to provide more predictable assembly and disassembly forces. Thus, a person of skill in the art at the time of the invention would have been motivated to modify Ng to include a plurality of snap fingers on the shroud module to facilitate the engagement of the shroud and cushion module.

125. When Ng is modified to include the plurality of snap-fingers, the upper clip on the Ng frame may be unnecessary. Nevertheless, a person of skill still would have included the protruding vent arrangement for at least the reasons I provide above.[132] Further, a person of skill would have included the protruding vent arrangement to prevent rotation between the shroud module and the cushion module.

d. "an annular or part annular cushion retaining portion" (Claim 10)

126. Claim 10 depends from Claim 1 and includes "wherein the shroud module includes an annular or part annular cushion retaining portion structured to retain the cushion module."

[132] *See supra* ¶¶ 82–97.

127. As shown below, Ng discloses a shroud module 10, including an annular opening 45, that retains the cushion module 15, 20.[133]

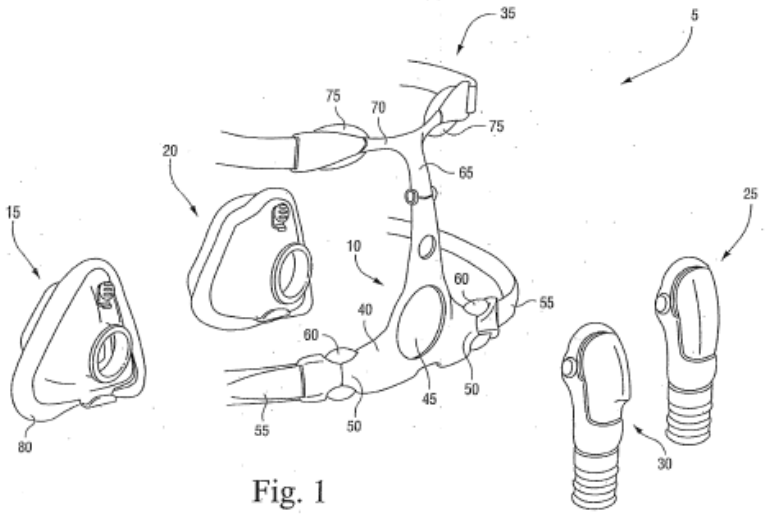


Fig. 1

128. As explained above, a person of skill would have been motivated to modify Ng to include a plurality of snap fingers extending rearward from the second opening 45.[134] A person of skill would have recognized that the plurality of snap fingers would provide an annular or part annular cushion retaining portion structured to retain the cushion module.

[133] Ex. 1410 ¶¶ 29–31.

[134] *See supra* ¶¶ 115–125.

e. "snap-fit arrangement" (Claim 26)

129. Claim 26 depends from Claim 1 and includes "wherein the mask system further comprises a snap-fit arrangement to removably snap-fit attach the shroud module and the cushion module to one another by moving the shroud module and the cushion module towards one another along the longitudinal axis."

130. Ng discloses a removable snap-fit arrangement between the shroud module 10 and the cushion module 15, 20. Ng discloses a shroud module 10 configured to selectively couple to an interchangeable cushion module 15, 20.[135] A person of skill would have understood that the protruding clip portion on the cushion module 15, 20 interlocks with the corresponding opening on the shroud module 10.

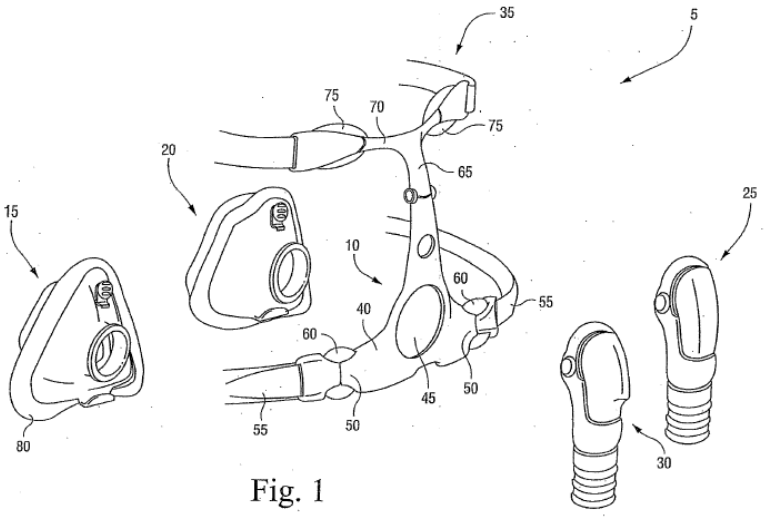


Fig. 1

[135] Ex. 1410 ¶ 31.

131. This interlocking part of Ng, with the parts undergoing some type of interference, deflection, and elastic recovery to achieve the interlocked assembly, would have been understood to result in a snap-fit. The book *Plastic Part Design for Injection Molding*, Robert A. Malloy (1994) describes "snap joint assemblies" as assemblies in which "a protruding feature on one component, such as a hook or beam, is deflected briefly during the product assembly operation due to an interference, after which the protruding part recovers elastically, and catches in an undercut or indentation on the mating component."[136] This type of removable snap-fit would have been familiar to a person of skill in the art and was common in CPAP mask components.

132. To the extent the teachings of Ng are insufficient for this feature, snap-fit arrangements between cushion modules and shroud modules were well-known prior to the '931 Patent. A person of skill would have been motivated to modify the shroud module of Ng to include a plurality of snap fingers for at least the reasons explained above.[137]

133. Ng, as modified in view of Matula-II, provides a snap-fit arrangement in which the snap fingers elastically deform to removably couple the cushion

[136] Ex. 1443 at 342.

[137] *See supra* ¶¶ 115–125.

module 15, 20 to the shroud module 10 by moving the cushion module 15, 20 and the shroud module 10 towards one another along the longitudinal axis. As modified, the snap fingers would extend rearward into the frame opening to engage the Ng collar with a snap-fit, as taught by Matula-II.[138] Alternatively, the snap fingers would extend rearward from the second opening 45 of the shroud module 10 and engage the outer periphery of the collar.[139]

134. The features of Ng that couple the shroud to the frame require a specific and possibly non-intuitive engagement of the parts, where a user has to hook the lower hook of the frame onto the shroud, then rotate the frame upward about the hook to engage the protruding clip portion. If a user failed to hook the lower hook, for example, they might be able to engage the upper clip, but with the frame in an improper, but engaged, position. In view of this, a person of skill would have been motivated to include snap fingers at the shroud opening and remove the lower hook, which would provide a snap-fit attachment by moving the shroud module and the cushion module towards one another along the longitudinal axis. Mating features that simply require moving the two parts along one axis where annular features of complementary shape engage provide the simplest and

[138] *See* Ex. 1412 ¶ 53.

[139] *See* Ex. 1415 ¶ 179.

most intuitive means of engagement. Further, this modification would simplify the design of the Ng cushion module.

135. As discussed above, a person of skill would have been motivated to provide a snap-fit arrangement to ensure that the shroud module and the cushion module are fully attached. Further, it was well-known prior to the '931 Patent that snap-fit connections were desirable because such connections could be configured to simply require moving one component towards the other component along a longitudinal axis.[140] Mating features that simply require moving the two parts along one axis and include annular features of complementary shape provide the simplest and most intuitive means of engagement. A person of skill also would have recognized that snap assemblies can be configured to be reversible,[141] so the cushion module could be removed or replaced for cleaning.

[140] *See* Ex. 1443 at 342.

[141] *See id.*

C. Claims 7, 8, and 18 would have been obvious over Ng in view of Thomlinson and Gunaratnam-I

1. Gunaratnam-I (U.S. Patent No. 6,796,308)

136. Gunaratnam-I describes respiratory masks designed to deliver breathable gas to a patient with sleep disordered breathing.[142] The mask assembly includes a mask frame 160 (shown below), cushion 180, and clip 800.[143] The mask frame 160 is a substantially rigid shell made of polycarbonate.[144]

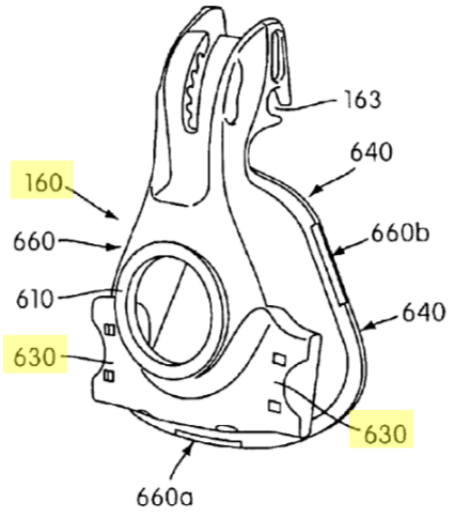


FIG. 5a

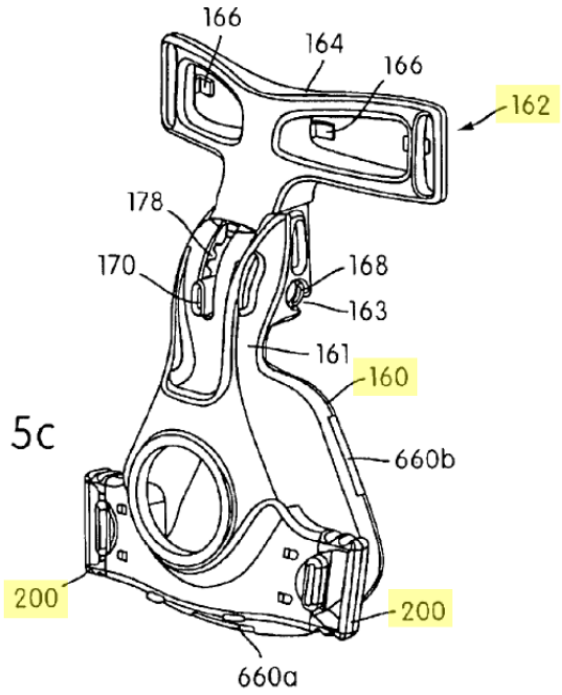


FIG. 5c

[142] Ex. 1413 at col. 1:21–25.

[143] *Id.* at col. 6:3–7.

[144] *Id.* at col. 4:22–26.

137. As shown in Figures 5a and 5c of Gunaratnam-I (above), Gunaratnam-I discloses headgear connectors 160/162 with strap connection points 630, which connect the mask to headgear and a forehead support 162.[145] The strap connection points 630 can connect to the headgear via connectors 200.[146]

2. Potential Differences from the Prior Art and Reasons to Combine

138. A person of skill in the art would have been motivated to combine Ng, Thomlinson, and Gunaratnam-I for at least the reasons provided above.[147] Similar to Ng and Thomlinson, Gunaratnam-I discloses a patient interface for the delivery of breathable gases to a patient for the treatment of sleep disordered breathing.[148] A person of ordinary skill in the art would have been aware of and looked to known CPAP interfaces when contemplating design features. Combining the features of Ng, Thomlinson, and Gunaratnam-I would have been a mere combination of familiar interface features that would have yielded only predictable results.

[145] *Id.* at col. 4:32–48.

[146] *Id.* at col. 4:32–34.

[147] *See supra* ¶¶ 68–100.

[148] Ex. 1413 at col. 1:21–25.

a. "each upper headgear connector includes a slot" (Claim 7)

139. Claim 7 depends from Claim 6 and includes "wherein each upper headgear connector includes a slot adapted to receive a respective headgear strap in use."

140. Ng discloses upper headgear connectors, and a person of skill would understand that the headgear connectors include slots that receive the headgear straps. Upper headgear connector slots were well-known and commonly used prior to the '931 Patent. For example, as shown in Figure 28A below, Thomlinson discloses headgear connector slots 120.[149]

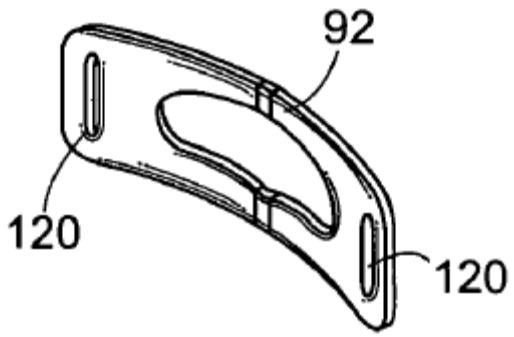


Fig. 28A

[149] Ex. 1411 ¶ 306.

141. Slots to receive upper headgear straps were commonly used at the time of the invention. As shown below, FlexiFit, Gunaratnam-I, and Lithgow each disclose mask systems with upper headgear connectors including slots.[150]

FlexiFit **Gunaratnam-I** **Lithgow**

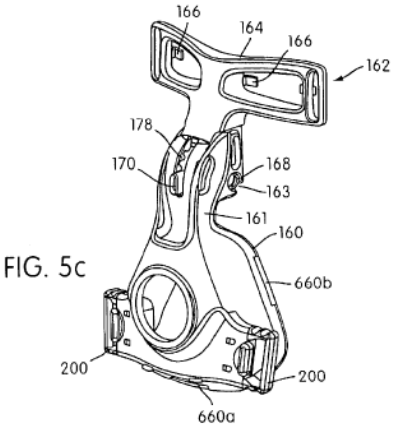


FIG. 5c

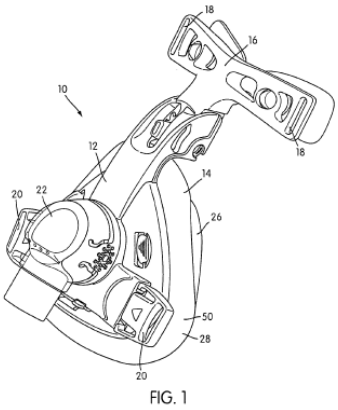


FIG. 1

142. A person of skill in the art at the time of the invention would have known to modify the mask assembly of Ng to include upper headgear connectors with slots, as taught by Thomlinson and Gunaratnam-I, in order to facilitate donning/doffing the mask (see FlexiFit image above) while maintaining simplicity in design and manufacturing.[151] Using slots instead of clips would reduce part count and simplify the molding of headgear attachment features. The advantage of a removable clip is reduced at the upper headgear connection as this part of the

[150] *See* Ex. 1413 at Fig. 5c; Ex. 1417 at 10 ("ASSEMBLING THE MASK"); Ex. 1433 at Fig. 1.

[151] Ex. 1426 at col. 7:6–13.

headgear assembly is only drawn into tension as the mask reaches its wearing position, as addressed in more detail below.[152]

143. Headgear slots also allow for easy adjustment of strap length. In use, the user can easily loop an end of the strap through the headgear slot and fold the strap over on itself to engage a remainder of the strap, e.g., using Velcro®.[153]

[152] *See infra* ¶¶ 211–215.

[153] *Id.*

b. "each lower headgear connector is adapted to be removably interlocked with a headgear clip" (Claim 8)

144. Claim 8 depends from Claim 7 and includes "wherein each lower headgear connector is adapted to be removably interlocked with a headgear clip associated with a respective headgear strap."

145. As shown below, Ng discloses lower headgear connectors connected to headgear straps using press-fit connectors 60.[154] A person of skill would understand that these press-fit connectors 60 are headgear clips.

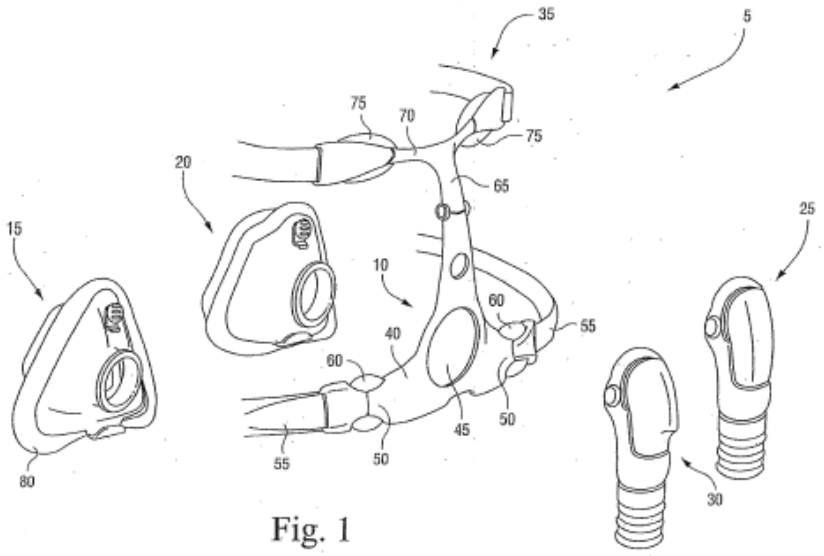


Fig. 1

146. To the extent these press-fit connectors somehow provide insufficient teachings for lower headgear connectors adapted to be removably interlocked with

[154] Ex. 1410 ¶ 30.

headgear clips, such headgear connectors were well-known and commonly used in CPAP masks prior to the '931 Patent.

147. As discussed above, Gunaratnam-I discloses upper headgear slots.[155] Gunaratnam-I also discloses lower headgear clips 200 that are received into headgear clip anchors 630 on the headgear connector 160, as shown in Figures 5a and 5c below.

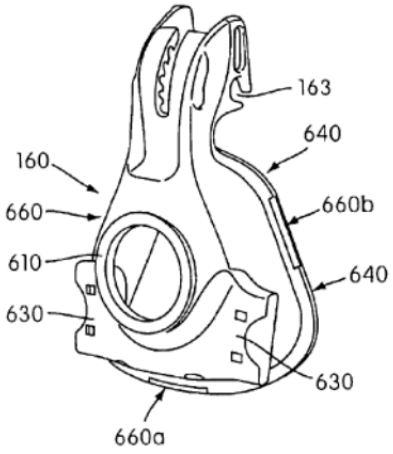


FIG. 5a

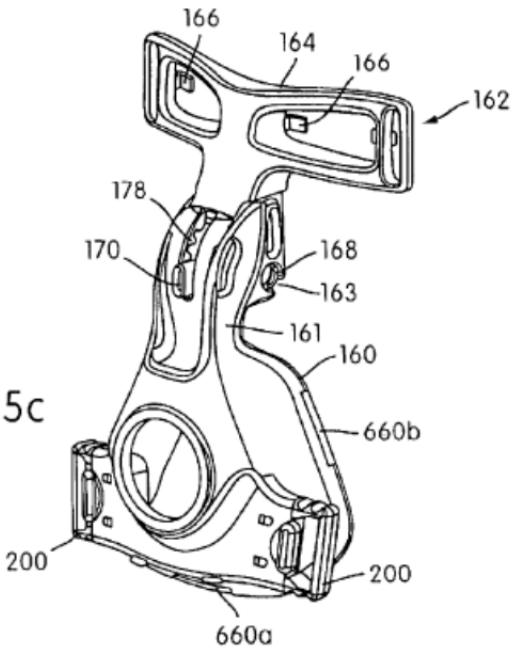


FIG. 5c

148. Gunaratnam-I discloses that "[o]n 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."[156] A skilled artisan would have

[155] *See supra* ¶¶ 136–137, 141–143.

[156] Ex. 1413 at col. 4:32–34.

understood that headgear clips are one of a finite number of predictable options that could be used to attach headgear to the Ng shroud module. Typical ways to connect the headgear to the shroud included slots, headgear clips, or hooks.

149. As shown below, Lithgow also discloses the combination of upper headgear slots and lower headgear clips.[157]

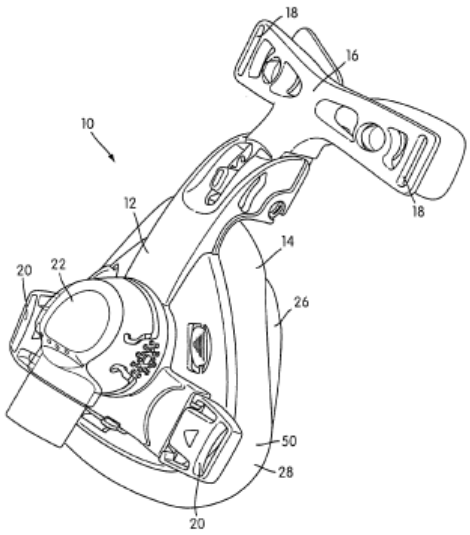


FIG. 1

150. A person of skill in the art would have recognized that releasable clip attachments as headgear connectors would allow for quick and easy release and re-attachment of headgear to the mask assembly without requiring adjustment.[158]

[157] Ex. 1433 ¶ 111.

[158] *See* Ex. 1416 at 6.

Further, quick release mechanisms, such as clips, provide a convenient way to separate the headgear and remove the mask in an emergency.[159]

151. Unlike the upper straps, the lower headgear straps undergo significant tension when the headgear is pulled over a user's head, making it difficult to position the lower headgear straps. Lower headgear clips improve ease of donning/doffing because a user would not have to force the lower headgear straps over his/her head or overcome strap tension while holding the mask away from the face and sliding it down from the top of the head. This advantage would have been minimal at the top headgear connection because those straps are only brought into tension as they near the worn position. Thus, as an alternative design option, a skilled artisan would have known to provide slots at the upper headgear connectors, instead of clips.

152. Although clip attachments have their own advantages, such as quick release, a person of skill in the art would have also recognized simple slots on the frame as a design option with its own advantages. For example, by providing releasable clip attachments only at the lower headgear connector and using a simple slot at the upper headgear connector, the mask would have fewer parts and the manufacturing would be simplified. Such a configuration of clip attachments

[159] *See* Ex. 1428 ¶ 14.

at lower headgear connectors and slots at upper headgear connectors was a well-known option at the time of the invention.

c. "the shroud module and the frame comprise polycarbonate and the cushion comprises silicone"

153. Claim 18 depends from Claim 1 and includes "wherein the shroud module and the frame comprise polycarbonate and the cushion comprises silicone."

154. As explained above, Ng discloses a rigid frame and a soft cushion.[160] Ng also discloses a polycarbonate frame.[161] Ng does not expressly disclose a polycarbonate shroud module or a silicone cushion; however, as outlined in the Claim Chart I provide below,[162] it was well-known in the industry at the time of the invention to construct CPAP components, including the shroud, from polycarbonate. At the "protruding vent" limitation in the Claim Chart, I have provided numerous examples of prior art interfaces that included discrete protruding vent arrangements on the frame, which confirms that a person of skill in

[160] *See supra* ¶¶ 76–81.

[161] Ex. 1410 ¶ 66.

[162] *See infra* ¶ 257.

the art would have been well aware of this common feature and its use on all types of patient interfaces.

155. For example, Gunaratnam-I discloses that the cushion can be constructed from silicone, and the other components (e.g., the frame and shroud module) can be constructed from polycarbonate.[163]

156. As another example, Lovell discloses a CPAP mask assembly including a polycarbonate shroud 12.[164]

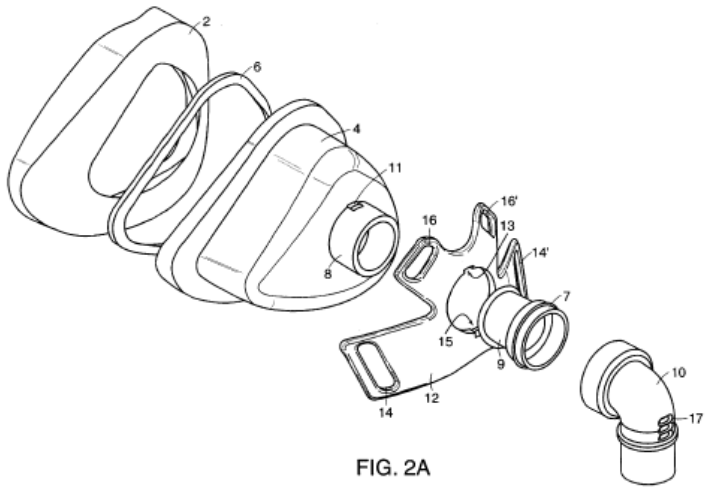


FIG. 2A

157. A person of skill would have recognized that silicone cushions were and still are desirable because they provide a compliant and comfortable seal against the user's face.[165] Silicone is also biocompatible and easy to clean.[166]

[163] Ex. 1413 at cols. 1:34–39, 5:33–34.

[164] Ex. 1426 at cols. 6:13–14, 7:46–53.

[165] *See* Ex. 1413 at col. 1:36–39.

Moreover, silicones are readily moldable into complex contours, including undercut surfaces, and in a broad range of wall thicknesses, which make them very versatile materials for interface design.

158. Further, it was well-known at the time of the invention to use polycarbonate for constructing CPAP mask components because polycarbonate satisfies the various purposes for the shroud and the frame. For example, polycarbonate can provide a high degree of transparency, which makes a mask less visually obtrusive to the patient and allows for visual inspection for contamination.[167] Polycarbonate is also a relatively good insulator and provides good mechanical properties of strength, rigidity, and toughness.[168] Polycarbonate grades are available that comply with the biocompatibility testing standards with which masks for sleep disordered breathing must comply. Further, polycarbonate can be cleaned, disinfected, and/or sterilized by most commonly used methods without significant degradation of material properties. Thus, one skilled in the art would have known that polycarbonate would be a desirable plastic material to construct the frame and shroud.

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[166] Ex. 1438 ¶ 244.

[167] *See* Ex. 1432 at 6:21–24; Ex. 1413 at col. 4:22–26.

[168] *See* Ex. 1432 at 6:21–24; Ex. 1433 ¶ 139; Ex. 1413 at col. 4:22–26.

D. Claims 12 and 14 would have been obvious over Ng in view of Thomlinson and Barnett

1. Barnett (U.S. Patent No. 6,412,488)

159. Barnett discloses nasal CPAP mask assemblies having a seal member 32 that defines a breathing cavity and a collar 34 that includes multiple headgear attachment points.[169] A conduit coupling member or elbow 36 is rotatably mounted to the collar 34 and freely rotates 360 degrees about a central axis of collar 34.[170]

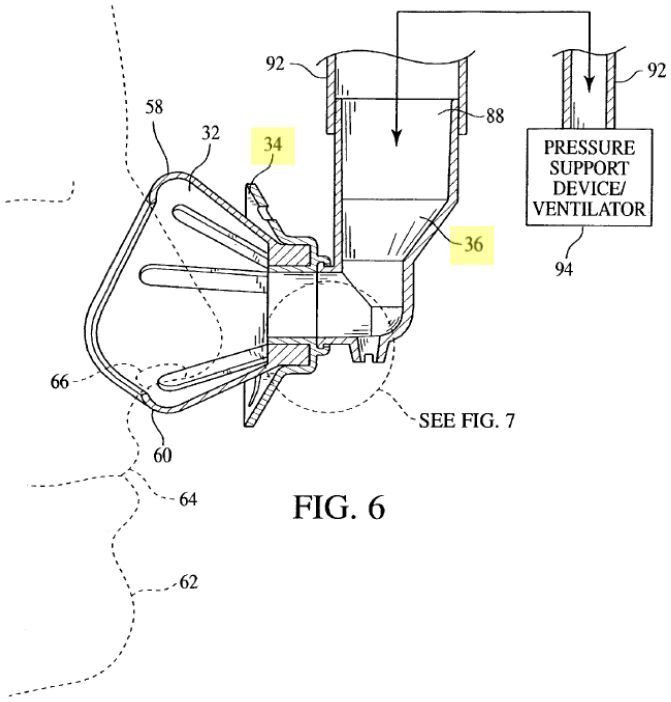

FIG. 6

[169] Ex. 1414 at Abstract, col. 1:7–32.

[170] *Id*. at col. 3:52–56.

160. In addition, Barnett discloses seal members 32, 32' that differ in the "contour of the first end portion, size, and shape" to accommodate different patient populations, such as adults and children.[171] Seal member 32 is designed to fit the face of relatively large adult patients, whereas seal member 32' is designed to fit the face of small adults and children.[172] "[S]eal member 32' includes a neck portion 46 that is substantially the same size and configuration as neck portion 46 in seal member 32 so that seal members 32 and 32' can be used in conjunction with a commonly sized collar 34 and conduit coupling member 36."[173]

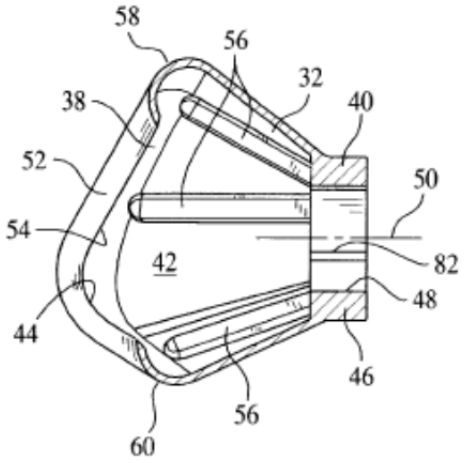

FIG. 2A

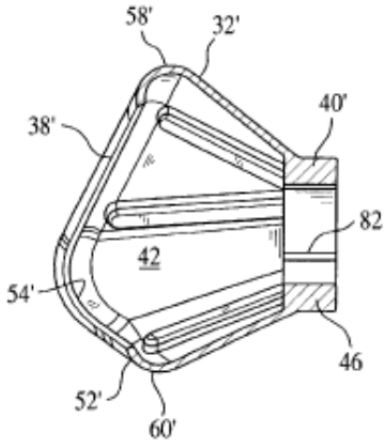

FIG. 3B

[171] *Id*. at cols. 6:1–9, 5:52–67.

[172] *Id.*

[173] *Id.* at col. 6:9–14.

2. Potential Differences from the Prior Art and Reasons to Combine

161. A person of skill in the art would have been motivated to combine Ng, Thomlinson, and Barnett for at least the reasons provided above.[174] Similar to Ng and Thomlinson, Barnett discloses a patient interface assembly for treatment of sleep-disordered breathing.[175] A person of ordinary skill in the art would have been aware of and looked to known CPAP patient interfaces when contemplating design features.

162. Ng does not expressly disclose each of the claimed elbow module features in Claims 12 and 14, but Barnett discloses these features. Because each of the patient interface assemblies described in Ng, Thomlinson, and Barnett includes an elbow module, a person of skill in the art would have recognized that the elbow module features of Barnett would have been readily compatible with Ng and Thomlinson, and easily combinable with a reasonable expectation of success. Each feature would function for its intended purpose and provide its known benefit, as taught in the prior art. Combining the features of Ng, Thomlinson, and Barnett would have been a mere combination of familiar patient interface features that would have yielded only predictable results.

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[174] *See supra* ¶¶ 68–100.

[175] Ex. 1414 at col. 3:34–43.

a. "elbow module is provided to the shroud module" (Claim 12)

163. Claim 12 depends from Claim 11 and includes "wherein the elbow module is provided to the shroud module."

164. Ng discloses that the shroud module 10 is configured to be selectively coupled to one of the elbow modules 25, 30.[176] However, Ng does not explain how these parts are coupled beyond what is shown in Figure 1 below.

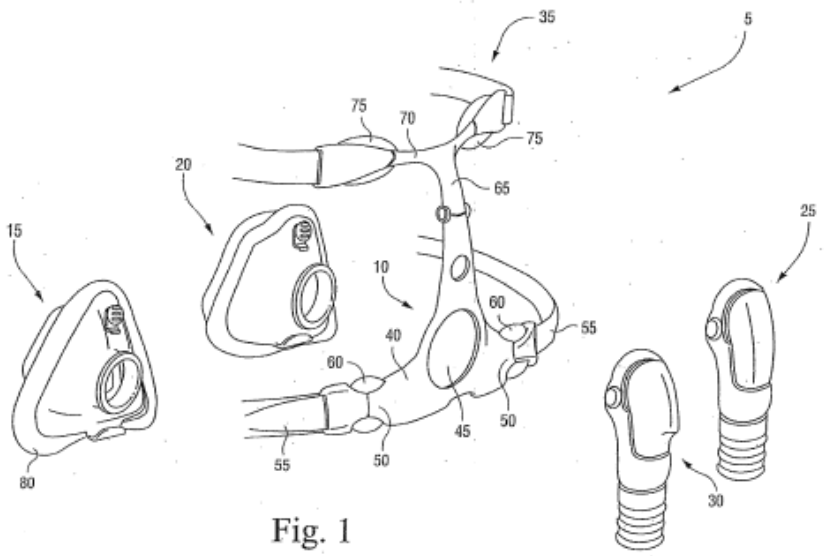


Fig. 1

165. To the extent the shroud module is required to directly contact the elbow, there are many well-known options for providing the elbow module directly to the shroud module. For example, Barnett discloses an elbow module 36 that is

[176] Ex. 1410 ¶ 31.

directly mounted to the shroud 34.[177] As shown below, it was common to provide a flange 100 on the front side of the shroud module 34 to accommodate the elbow.[178]

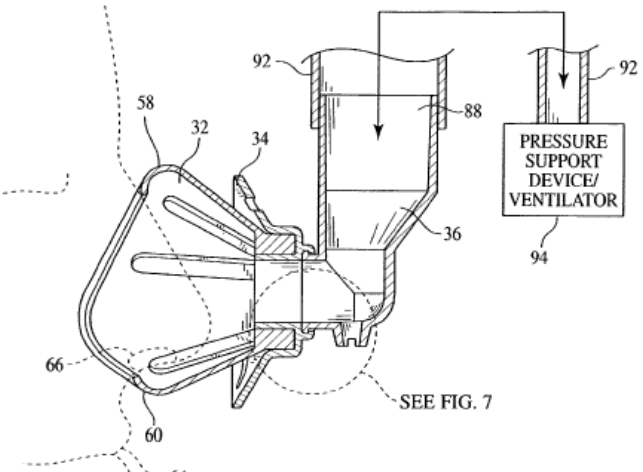


FIG. 6

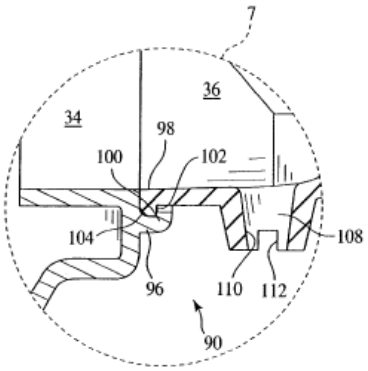


FIG. 7

[177] Ex. 1414 at col. 3:52–57.

[178] *Id.* at col. 9:32–40.

166. As shown in the annotated drawing below, a person of skill would have been motivated to directly attach the elbow to the shroud module, e.g., by providing features on the front side of the Ng shroud module. One of the finite number of ways to do this is to provide a flange on the front side of the shroud module, as shown below.

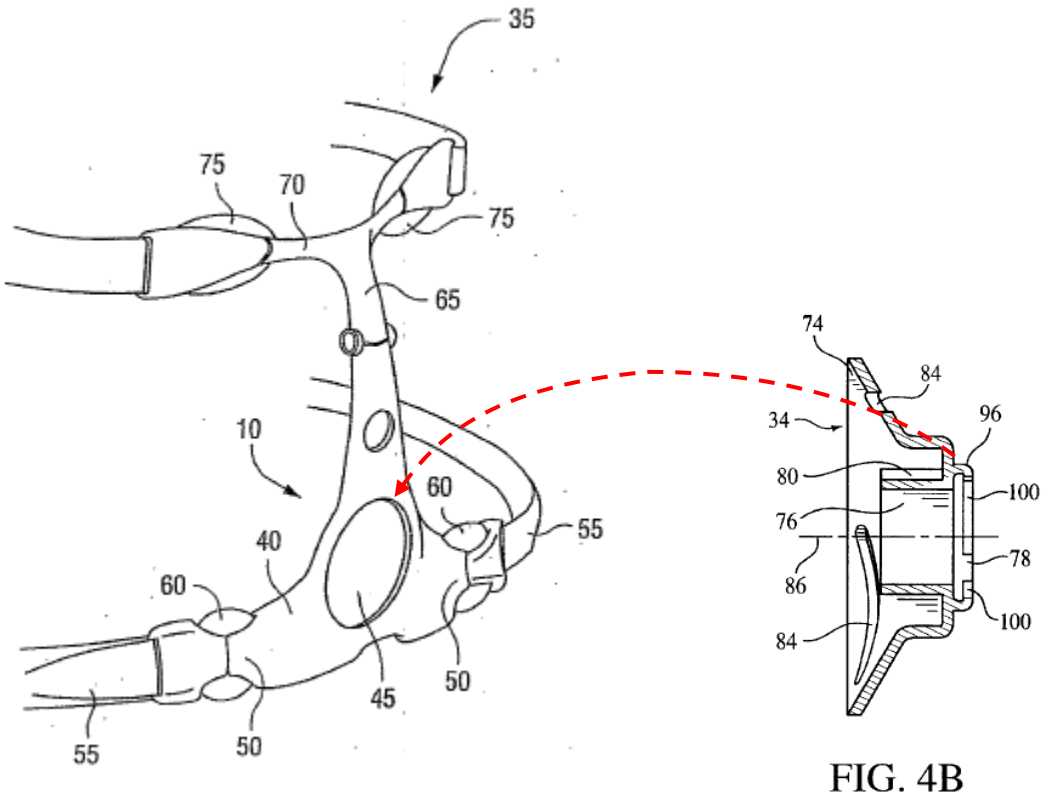


FIG. 4B

167. Gunaratnam-I also discloses a frame 160 with an annular connection 610/910 for direct contact and connection to an elbow.[179]

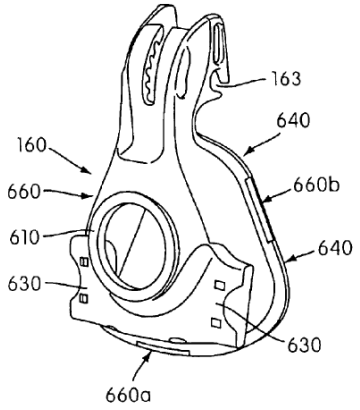


FIG. 5a

168. As another example, Matula-I discloses an elbow 1270 that directly engages rim 1252 of the shroud module 1246 using claims 1272.[180]

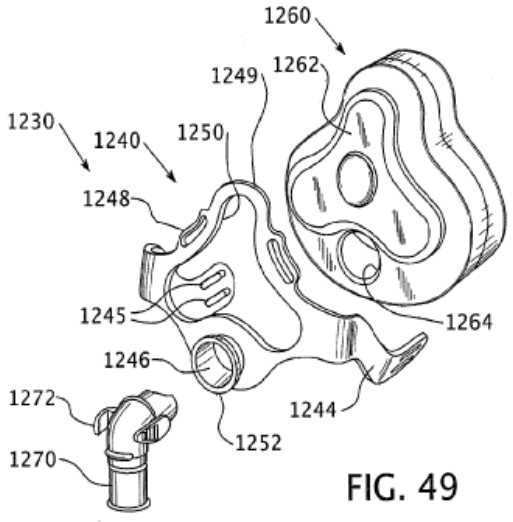


FIG. 49

[179] Ex. 1413 at col. 4:20–26.

[180] Ex. 1423 ¶ 105.

169. Ng and Barnett represent two design choices for establishing a connection between the breathing chamber and the elbow module. Each option has advantages. Ng provides a direct connection between the elbow and the cushion module, which forms a single seal. Barnett separately connects the elbow and the cushion module to the shroud module, which requires a seal from the elbow to the shroud module and another seal from the shroud module to the cushion-module, but allows separate removal of the elbow and the cushion-module from the second frame. Although Barnett describes this two-seal design, other designs exist in which the elbow could be directly provided to the shroud module and still provide a single seal with the cushion module.

170. A person of skill in the art at the time of the invention would have been motivated to directly attach the elbow to the shroud module, as taught in Barnett, in order to make it easier for a patient to detach the elbow from the shroud without affecting the engagement of other mask components. A person of skill in the art would have understood that attaching the elbow to the shroud would allow for more flexibility in the design of the elbow as compared to attaching the elbow to a component of the breathing chamber. This is because the breathing chamber requires an air tight seal, and as such, the retaining features between the elbow and the chamber would need to be formed in a way that preserves the airtight breathing chamber. By attaching the elbow to the shroud, this requirement of airtight

retaining features between the elbow and the frame is avoided. Features that are not required to be airtight can be readily molded onto the shroud. Further, a person of skill would have considered the elbow connection of Barnett to be desirable because it still allows for 360 degree rotation, as I explain in the next section.[181]

171. In the case where the elbow seals to the frame, while being retained in position by features on the shroud, tolerances that provide for sealing between the elbow and frame can be controlled on cylindrical features which constrain movement of the elbow relative to the frame to rotation and translation about one axis only. The shroud module need only constrain motion about one axis of translation, which can allow for generous manufacturing tolerances on the retaining features between the shroud and the elbow.

b. "the elbow module and the shroud module are directly connected with a mechanical interlock while allowing 360 degree rotation of the elbow module" (Claim 14)

172. Claim 14 depends from Claim 11 and includes "wherein the elbow module and the shroud module are directly connected with a mechanical interlock while allowing 360 degree rotation of the elbow module."

[181] *See infra* ¶¶ 172–177.

173. Ng discloses an elbow module, but does not expressly disclose that the elbow module and the shroud module are directly connected with a mechanical interlock while allowing 360 degree rotation of the elbow. However, as explained above with respect to Claim 12, it was a well-known option to directly connect the elbow module to the shroud module with a mechanical interlock.[182]

174. Further, it was well-known at the time of the invention to connect a 360 degree rotating elbow directly to the shroud. For example, as shown in Figures 1A and 1B below, Barnett discloses an elbow 36 that is mounted to the shroud 34 and freely rotates over a range of 360 degrees in direction A.[183]

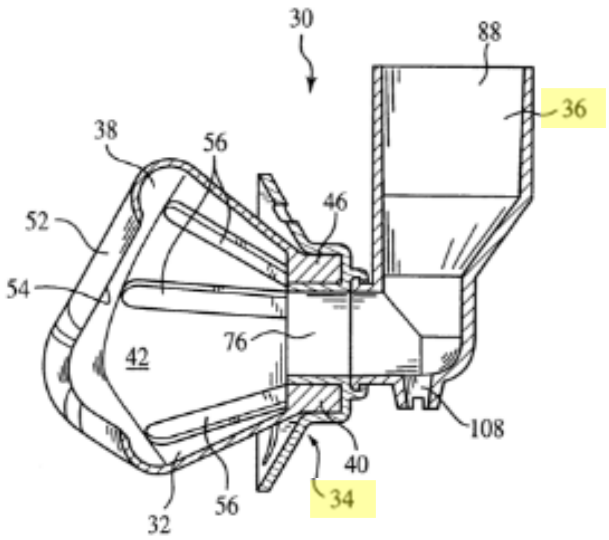


FIG. 1A

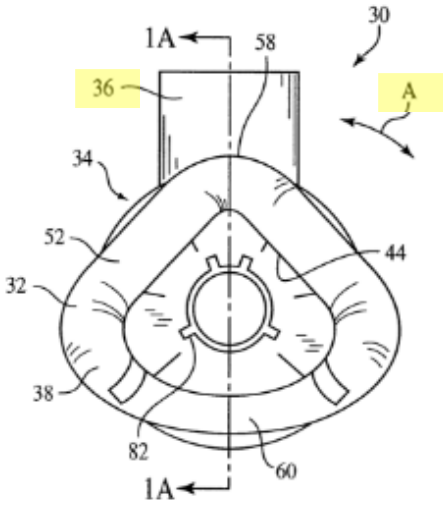
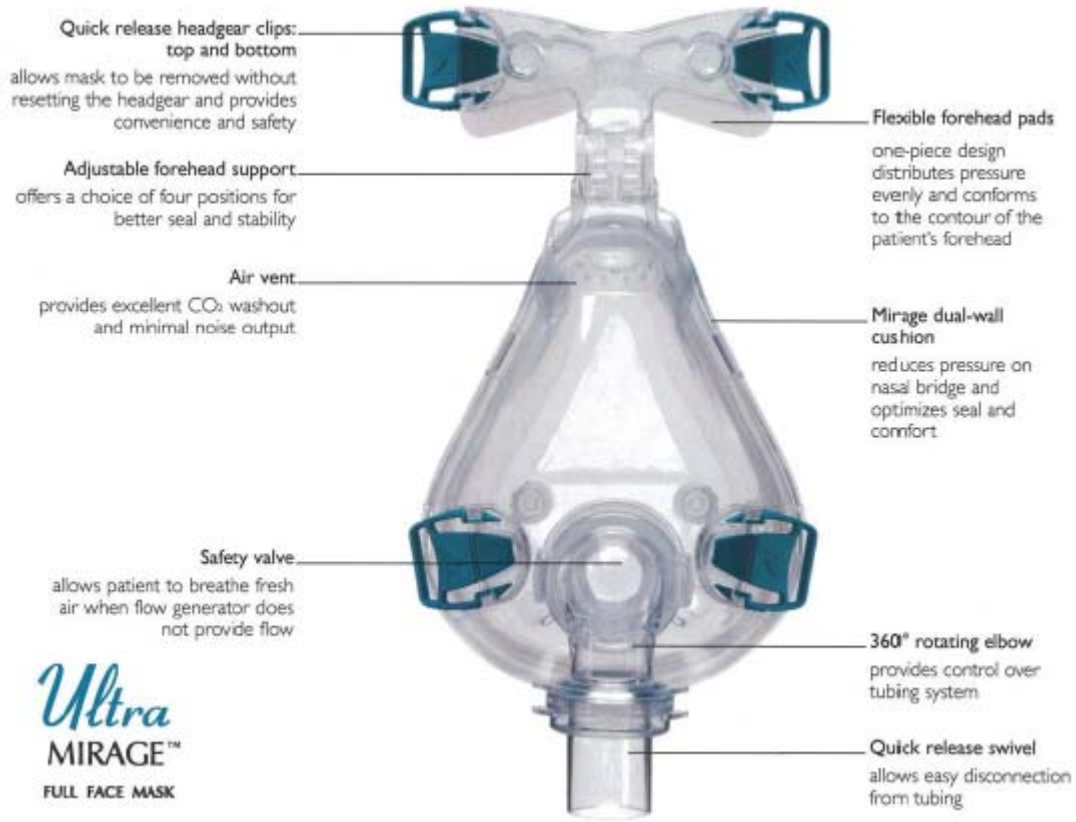


FIG. 1B

[182] *See supra* ¶¶ 163–171.

[183] Ex. 1414 at col. 3:52–57.

175. Ultra Mirage also discloses a 360˚ rotating elbow to provide control over the tubing system.[184]



176. A person of skill in the art would have understood that the 360 degree rotatable elbow shown in Barnett would have been readily compatible with the Ng mask. Figure 1 of Ng does not have any structures that would prevent its mask from providing a 360 degree rotatable elbow.

177. A person of skill would have been motivated to make the elbow rotatable over a 360 degree range to provide control over the tubing system.[185] It

[184] Ex. 1416 at 6.

was common and well-known that an elbow that is rotatable over a 360 degree range would allow the wearer to position the tubing in a range of positions that provide the most convenient, comfortable, and low force mask connection. Such elbow rotation was very common in masks for positive airway pressure therapy at the time of the invention and would have been well-known to one skilled in the art.

[185] *See id.*

E. Claims 13 and 15 would have been obvious over Ng in view of Thomlinson, Barnett, and Worboys

1. Worboys (WO 2007/045008)

178. Worboys discloses a respiratory mask elbow assembly 5 made from a relatively rigid material, such as polycarbonate or other plastic.[186] The elbow assembly 5 includes an anti-asphyxia valve (AAV) assembly 15.[187] As shown in Figures 1 and 2 below, the AAV assembly 15 includes a flap portion 45 that can be moved either to direct ambient air to the elbow assembly 5 or to allow pressurized gas to pass through.[188]

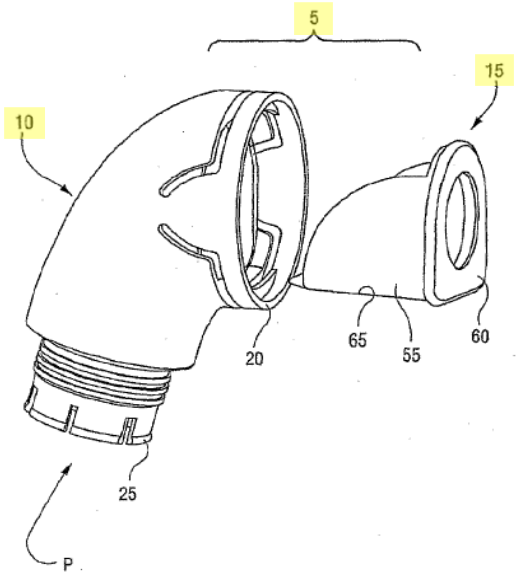


Fig. 1

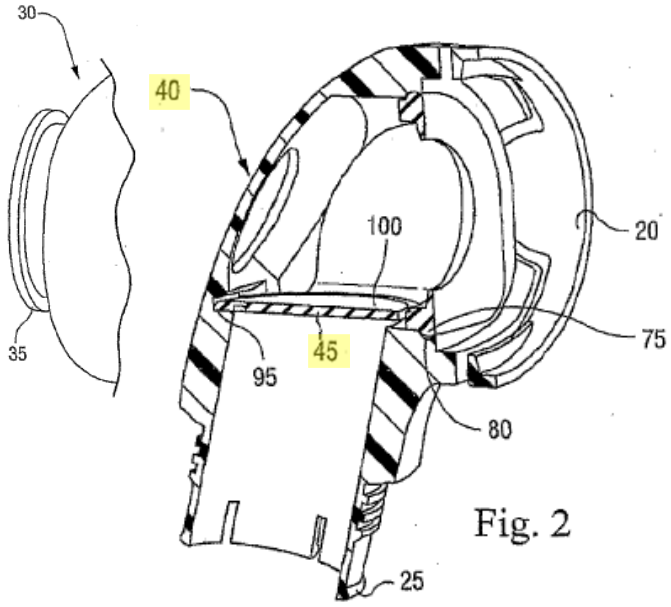


Fig. 2

[186] Ex. 1415 ¶ 105.

[187] *Id.* at Abstract.

[188] *Id.*

2. Potential Differences from the Prior Art and Reasons to Combine

179. A person of skill in the art would have been motivated to combine Ng, Thomlinson, and Worboys for at least the reasons provided above.[189] Similar to Ng and Thomlinson, Worboys discloses a patient interface assembly for treatment of sleep-disordered breathing.[190] A person of ordinary skill in the art would have been aware of and looked to known CPAP patient interfaces when contemplating design features.

180. Ng does not disclose each of the claimed elbow module features in Claims 13 and 15, but Worboys discloses these features. Because each of the patient interfaces described in Ng, Thomlinson, and Worboys includes an elbow module, a person of skill in the art would have recognized that the elbow module features of Worboys would have been readily compatible with Ng and Thomlinson, and easily combinable with a reasonable expectation of success. Each feature would function for its intended purpose and provide its known benefit, as taught in the prior art. Combining the features of Ng, Thomlinson, and Worboys would have been a mere combination of familiar patient interface features that would have yielded only predictable results.

[189] *See supra* ¶¶ 68–100.

[190] Ex. 1415 ¶ 2.

a. "elbow module comprises polycarbonate" (Claim 13)

181. Claim 13 depends from Claim 11 and includes "wherein the elbow module comprises polycarbonate."

182. Ng does not expressly disclose a polycarbonate elbow. However, it was well-known in the industry at the time of the invention to construct CPAP components, including the elbow, from polycarbonate. For example, Worboys discloses a polycarbonate elbow.[191] Lovell also discloses that elbows can be manufactured from polycarbonate.[192]

183. A person of skill would have selected polycarbonate based on its well-known suitability for elbows in CPAP mask systems. Polycarbonate provides a high degree of transparency, which makes a mask less visually obtrusive to the patient and allows for visual inspection for condensation or contamination.[193] Polycarbonate also provides good mechanical properties of strength, rigidity, and toughness.[194] Polycarbonate grades are available that comply with biocompatibility testing standards to which masks for sleep disordered breathing

[191] Ex. 1415 ¶ 105.

[192] Ex. 1426 at col. 5:33–35.

[193] *See* Ex. 1432 at 6:21–24.

[194] *See id.*; Ex. 1415 ¶ 105.

must comply. Further, polycarbonate can be cleaned, disinfected, and/or sterilized by most commonly used methods without significant degradation of material properties. Thus, one skilled in the art would have been motivated to use polycarbonate for the elbow or any other rigid components of the mask assembly.

b. "anti-asphyxia valve" (Claim 15)

184. Claim 15 depends from Claim 11 and includes "wherein the elbow module includes an anti-asphyxia valve and wherein the anti-asphyxia valve includes a flap portion adapted to selectively close a port provided in the elbow module."

185. Ng does not disclose an anti-asphyxia valve, but this feature was common and well-known in the industry before the '931 Patent, and a person of skill would have known to include one in the elbow. For example, Worboys discloses an AAV assembly in the elbow module. As shown in Figures 1 and 2 of Worboys below, Worboys discloses an AAV assembly 15 located in the elbow 10 that includes a flap portion 45 that will selectively remain in the "rest" position to allow the patient to breathe in ambient air through the port 40.[195]

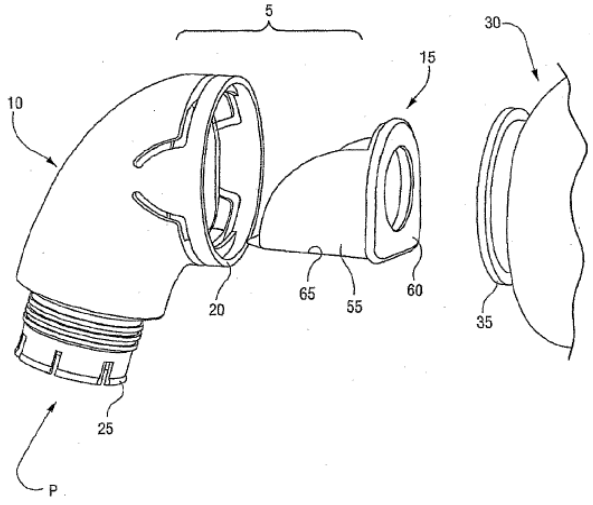


Fig. 1

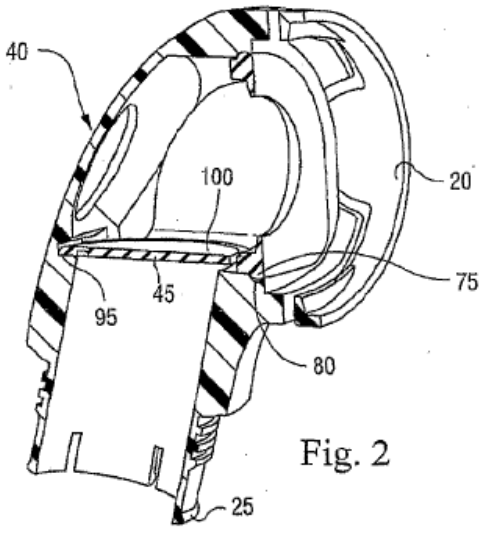


Fig. 2

[195] Ex. 1415 ¶ 106.

186. Other prior art publications also show that AAVs were a common feature of respiratory mask assemblies. For example, Jaffre discloses that it was common practice to include a valve in the patient circuit that automatically allows the patient to access the ambient atmosphere if the pressure support system fails.[196] As shown in Figures 8 and 9 on the next page, the elbow in Jaffre has a flap portion 68 that selectively closes port 88.[197]

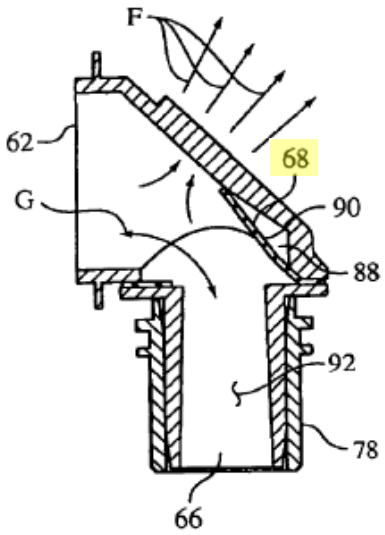


FIG. 8

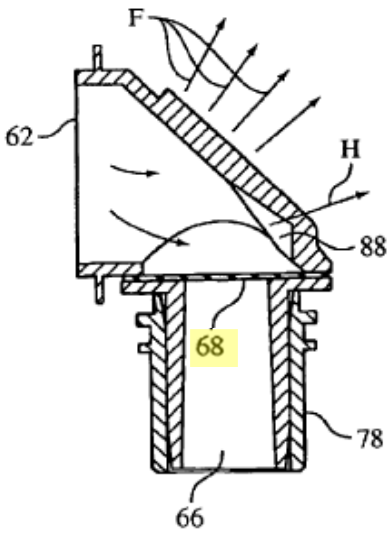


FIG. 9

[196] Ex. 1427 at col. 10:4–8.

[197] *Id.* at col. 10:14–28.

187. A person of skill in the art at the time of the invention would have known to provide the AAV of Worboys to the Ng elbow so that patients could breathe fresh air when the flow generator does not provide flow. This feature would prevent a patient from asphyxiating. Worboys teaches that there may be a clinical requirement to provide an AAV as a safety device.[198] Worboys discloses:

> If the flow generator's operation is interrupted as a result of power outage or other mechanical/electrical failure, there may be a significant build up of carbon dioxide in the mask as the patient's exhaled air is not washed out of outlet vents that are usually provided to the mask assembly. This may represent a health risk to the patient.[199]

188. A person of skill in the art would have understood that an AAV using a flap would have been advantageous because the relatively low mass and high surface area of the flap would allow it to be readily moved between its operating positions based on the presence or absence of pressurized flow from the flow generator, regardless of the orientation of the elbow relative to gravity. The inclusion of such an AAV is nothing more than a combination of well-known elements that produces results that would have been predictable to one of ordinary skill in the art.

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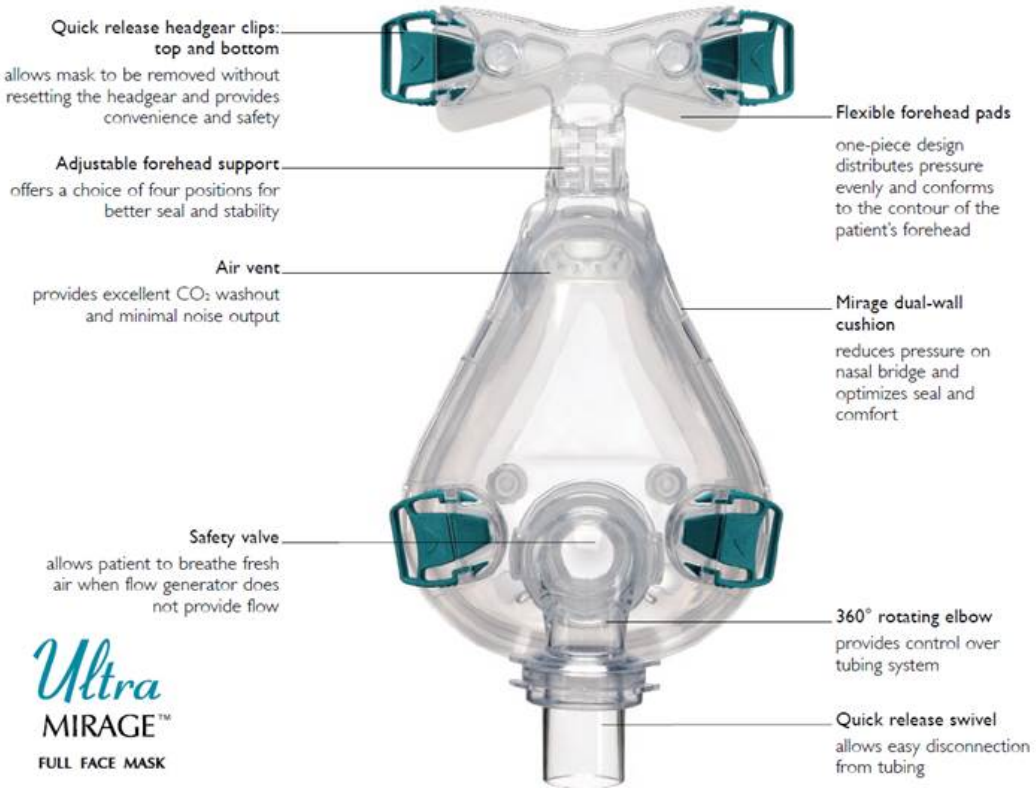
[198] Ex. 1415 ¶ 4.

[199] *Id.* ¶ 8.

F. Claims 17 would have been obvious over Ng in view of Thomlinson and Ultra Mirage

1. Ultra Mirage (Affidavit of Christopher Butler, Ultra Mirage Brochure)

189. The Ultra Mirage brochure from 2006 discloses a mask assembly for use by CPAP and bilevel therapy users.[200] The mask covers both the nose and mouth to provide effective therapy in the presence of mouth breathing.



[200] Ex. 1416 at 6.

190. The Ultra Mirage mask assembly includes an air vent positioned on the mask frame, which provides "excellent CO_2 washout and minimal noise output."[201] The mask assembly claims superior airflow characteristics to minimize CO_2 rebreathing.[202]

191. The Ultra Mirage Full Face Mask assembly includes an inlet in the form of an elbow, which rotates 360 degrees with respect to the mask frame.[203] A quick release swivel provides rotation of the air delivery conduit relative to the inlet elbow. The inlet elbow also includes a safety valve, which allows the patient to breathe fresh air when the flow generator does not provide flow. Quick release headgear clips are provided on the adjustable forehead support and the lower region of the mask frame, which allow the mask to be removed without resetting the headgear and provide convenience and safety.[204]

192. A person having ordinary skill in the art would have continuously educated him or herself on the features of CPAP masks available on the market and would have looked at the CPAP mask designs of well-known companies,

[201] *Id*.

[202] *Id*. at 7.

[203] *Id*. at 6.

[204] *Id*.

including Fisher & Paykel, ResMed, and Respironics. Each of these companies maintains a website publicizing their products that include hyperlinks to download brochures, manuals, instructions for use, and/or other product information regarding the features and functions of their products. I personally have visited the websites of Fisher & Paykel, ResMed, and Respironics to review and understand the features of their CPAP mask designs. Engineers in the industry and others having ordinary skill in the art at the time of the supposed invention would have been familiar with these websites and would have visited them often to stay informed regarding the available CPAP masks available and their different design features.

193. During the 2006–2007 timeframe, a person of ordinary skill in the art would have been familiar with the CPAP masks made by Fisher & Paykel, ResMed, and/or Respironics. Such a person would have also located information relating to these masks through searches conducted on a search engine such as www.google.com, or by navigating directly to the websites of Fisher & Paykel, ResMed, and Respironics. A person of skill would have clicked through the hyperlinks to locate the product webpages publicizing the particular CPAP products made by Fisher & Paykel, ResMed, and/or Respironics. Finally, a person of skill would have followed the hyperlinks on the product webpages to locate and

download brochures, manuals, instructions for use, and/or other product information regarding the product featured on the webpage.

194. The Wayback Machine (Internet Archive) shows that the public had access to a ResMed webpage publicizing the Ultra Mirage ™ by at least September 1, 2006.[205] The public, including those of ordinary skill in the art, would have been able to locate and download the ResMed Ultra Mirage™ brochure and components card by following the hyperlinks labeled "Brochure" and "Components" on the Ultra Mirage™ webpage.[206]

195. The Wayback Machine also shows that the public had access to a Fisher & Paykel webpage publicizing the FlexiFit by at least October 16, 2006.[207]

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[205] *See*, e.g., http://web.archive.org/web/20060827111931/http://resmed.com.au/portal/site/ResMedAU/?vgnCId=ea4b4ace9397df00VgnVCMServerc60210acRCRD&vgnChId=c0488e6cd9edcf00VgnVCMServerc50210ac____&vgnFormat=Clinician&epi_menuItemID=eff0b226993fb131e6bdaac46c2001ca&vgnReset=1&vgnPNum=null.

[206] *See id.*

[207] *See*, e.g., https://web.archive.org/web/20061016042115/http:/www.fphcare.com/osa/flexiFit431.asp.

The public, including those of ordinary skill in the art, would have been able to locate and download the Fisher & Paykel FlexiFit™ manual and user instructions by following the hyperlinks under "FlexFit™ 431 User Instructions" and "FlexFit™ 431 Product Brochure" on the FlexiFit™ webpage.[208]

196. These websites show that a person of skill in the art would have had access to at least the Ultra Mirage Brochure (Ex. 1416) and FlexiFit Instructions (Ex. 1417) well before the March 4, 2008 priority date of the '931 Patent.

2. Potential Differences from the Prior Art and Reasons to Combine

197. A person of skill in the art would have been motivated to combine Ng, Thomlinson, and Ultra Mirage for at least the reasons provided above.[209] Similar to Ng and Thomlinson, Ultra Mirage discloses a CPAP patient interface.[210] A person of ordinary skill in the art would have been aware of and looked to known CPAP masks and patient interfaces when contemplating design features. Combining the features of Ng, Thomlinson, and Ultra Mirage would have been a mere combination of familiar patient interface features that would have yielded only predictable results.

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[208] *See id.*

[209] *See supra* ¶¶ 68–100.

[210] Ex. 1416 at 6.

a. "a small cushion module, a medium cushion module and a large cushion module" (Claim 17)

198. Claim 17 depends from Claim 1 and includes "a small cushion module, a medium cushion module and a large cushion module, wherein each of said small cushion module, said medium cushion module and said large cushion module is removably coupleable to the same shroud module."

199. Ng discloses different cushion modules 15, 20 that are removably coupled to the same shroud module.[211] The cushion modules 15, 20 "differ in at least one respect such that one may be more optimal or preferable for use with one user, while another may be more suitable or preferably for use with another user."[212] Ng does not expressly disclose a small cushion module, a medium cushion module, and a large cushion module, but it was common and well-known that cushions used in CPAP mask assemblies were provided in a range of sizes to accommodate a diverse patient population. For example, Ultra Mirage describes mask product sizes for small, medium, and large masks.[213]

[211] Ex. 1410 ¶ 31.

[212] *Id.*

[213] Ex. 1416 at 7.

200. Usage of different sized cushion modules was common in the industry prior to the '931 Patent. For example, Ging discloses providing different sized cushions, preferably one to three sizes, which provide a good fit in a wide range of patients without having an excessive inventory.[214] As shown below, Barnett also describes different sized cushion modules 32, 32' to accommodate different sized people or populations.[215] The different cushions 32, 32' are meant to be used with the same shroud 34 and elbow 36.[216]

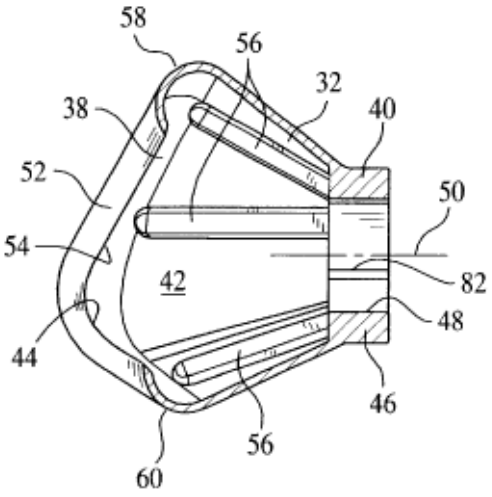


FIG. 2A

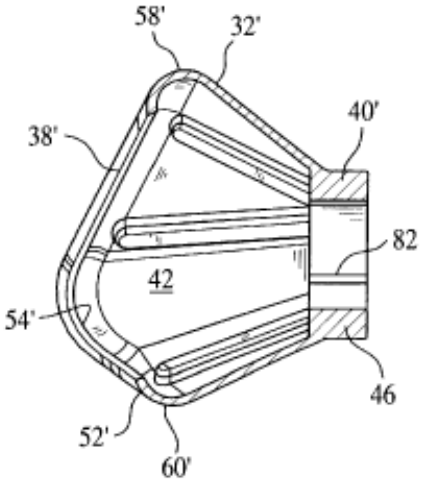


FIG. 3B

201. As further evidence that different sized cushion modules were commonly applied to the same shroud module, Ho discloses that "any interface

[214] Ex. 1431 ¶¶ 184, 193.

[215] Ex. 1414 at cols. 6:1–4, 5:52–67.

[216] *Id.* at col. 6:1–14.

suitable for sealing against the user can be used in the mask assembly of [Ho]."[217] Different sized cushions or nasal prongs can be supported by the same support body.[218] Specifically, Ho states, "While the present invention has been described above as having a cushion that encapsulates the nasal region, it is to be understood that the present invention contemplates using other types of devices in conjunction with support body 36. For example, larger cushions that encapsulate the nose and mouth can be attached to the support body."[219]

202. A person of skill in the art would have recognized advantages of providing different sized, interchangeable cushions for different sized patient populations. Different sized cushion modules that fit a common shroud module would reduce the number of components required (as compared to distinct shroud sizes to match distinct cushion module sizes). In particular, a person of skill would have provided a range of sizes which could include small, medium, and large-sized interchangeable cushion modules to the same shroud module to accommodate a

[217] Ex. 1430 ¶ 36.

[218] *Id.*

[219] *Id.*

range of facial shapes without having to carry excessive inventory.[220] If leaks persist, the user can easily change to an alternate mask size.[221]

203. Reducing the number of components would also reduce mold tooling cost and manufacturing costs. Additionally, packaging multiple cushion sizes in a kit would enable users to quickly and efficiently find an appropriate mask fit.

[220] *See* Ex. 1431 ¶¶ 8, 20, 193.

[221] *See* Ex. 1417 at 10 ("FITTING YOUR MASK").

G. Claims 19, 21, and 25 would have been obvious over Ng in view of Thomlinson and FlexiFit

1. FlexiFit (FlexiFit Instructions)

204. The FlexiFit Instructions describe a FlexiFit HC 431 Full Face Mask that is intended for use by individuals requiring CPAP or bilevel ventilator treatment. The instructions for "FITTING YOUR MASK" describe a mask with a headgear assembly that includes top horizontal straps, lower horizontal straps, and top crown straps.[222] Users are instructed to gently adjust the top horizontal straps, then the lower horizontal straps, then the top crown straps.[223] Proper adjustment of the straps ensures the top of the seal remains stable on the bridge of the nose, and the bottom of the seal remains fixed under the chin.[224] If leaks occur around the upper half of the mask, the user is instructed to gently tighten the top horizontal straps.[225] If leaks occur around the lower half of the mask, the user is instructed to gently tighten the lower horizontal straps.[226] The four straps of the headgear are to

[222] Ex. 1417 at 10 ("FITTING YOUR MASK").

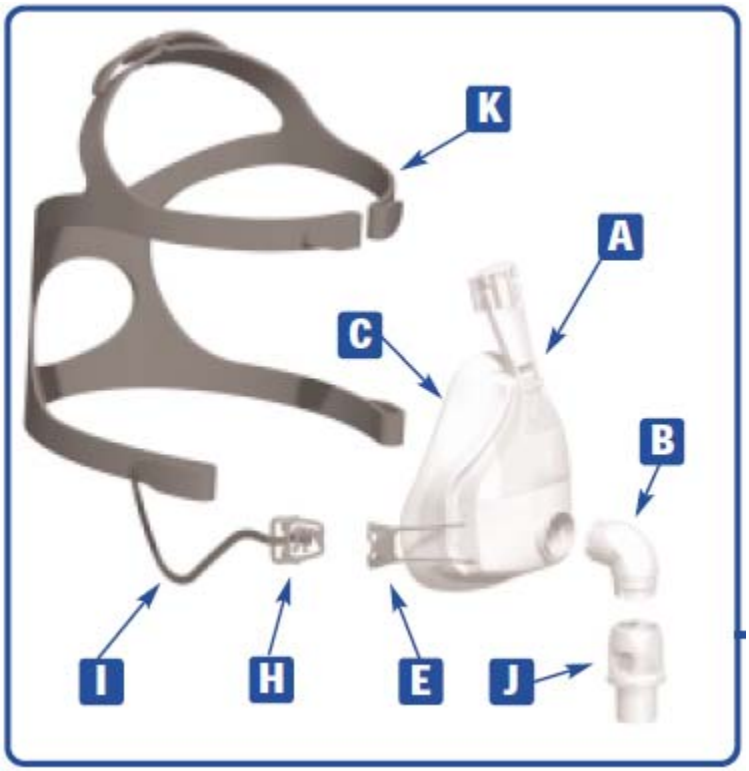
[223] *Id*.

[224] *Id*.

[225] *Id*.

[226] *Id*.

be attached to the corresponding slots in the mask base and the Glider™ strap (E).[227] This can be done without undoing the Velcro® tabs by sliding the Headgear into the slots.[228]



[227] *Id*. at 10 ("ASSEMBLING YOUR MASK").

[228] *Id*.

205. As shown in Figures 3–5 of FlexiFit below, the top horizonal straps attach to corresponding slots in the mask base (A) by sliding Velcro® tabs into the slots, and a lower horizontal strap attaches to the mask base (A) using headgear clip (H).[229] The top and lower horizontal straps can be re-adjusted to prevent leaks.[230]

2. Potential Differences from the Prior Art and Reasons to Combine

206. Claim 19 depends from independent Claim 1 and includes additional headgear features that are discussed below. Claims 20, 21, and 25 depend from Claim 19 and include additional features that are commonly included in respiratory mask assemblies.

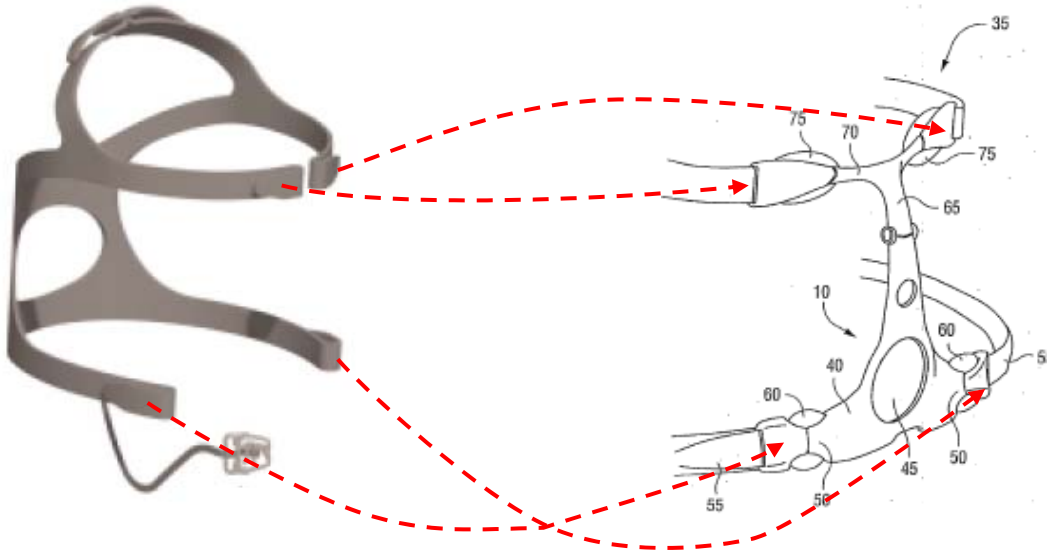
207. Ng does not expressly disclose each of these headgear features; however, the claimed headgear features was well-known in the CPAP industry

[229] *Id*.

[230] *Id*. at 10 ("FITTING YOUR MASK").

prior to the '931 Patent. In fact, as detailed below, the combination of claimed headgear features was embodied in the FlexiFit HC 431 headgear.[231] FlexiFit discloses headgear with upper and lower straps, which would have been compatible with the upper and lower headgear connectors of the Ng shroud, as shown in the annotated drawings on the next page. Thus, the teachings of FlexiFit would have been readily compatible with and easily incorporated into the Ng mask assembly. The FlexiFit headgear configuration represents a typical headgear design at the time of the supposed invention and it was one of a finite number of predictable ways to structure the headgear. Combining the features of Ng, Thomlinson, and FlexiFit would have been a mere combination of familiar mask features that would have yielded only predictable results.

FlexiFit (partial) **Ng (partial)**



[231] *See infra* ¶¶ 208–230.

a. "a pair of upper straps and pair of lower straps" (Claim 19)

208. Claim 19 depends from Claim 1 and includes "the headgear includes a pair of upper straps and pair of lower straps, with the upper straps being removably attached to respective ones of the headgear connectors and the lower straps being connected to respective ones of the headgear connectors."

209. As shown below, Ng discloses a shroud module 10 including at least two lateral arms 50 attached to respective headgear straps 55 using press-fit headgear connectors 60.[232]

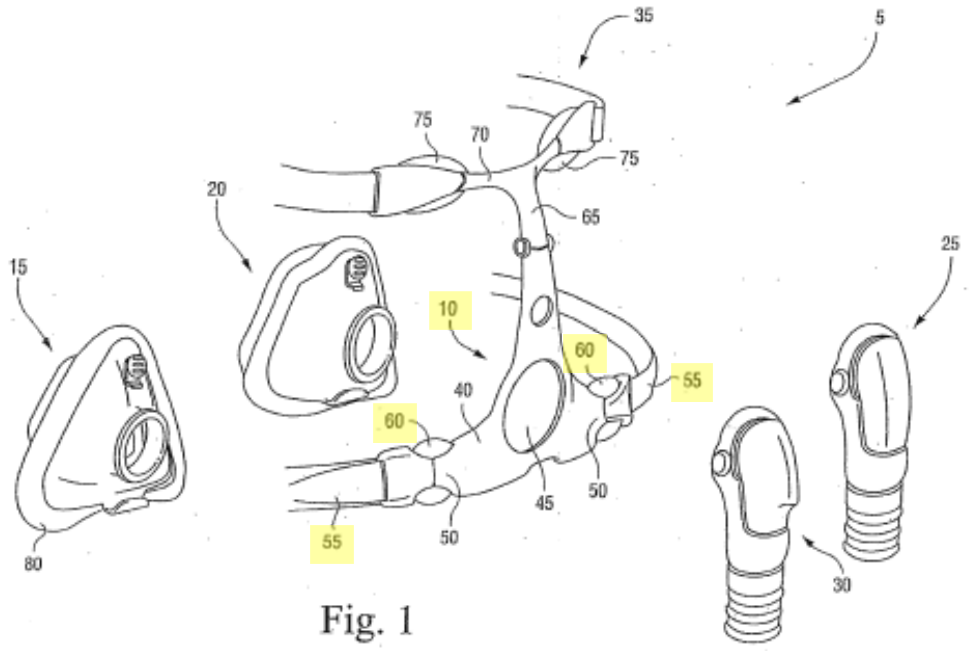


Fig. 1

[232] Ex. 1410 ¶ 30.

210. As explained above, a person of skill in the art would have understood that the Ng mask includes headgear removably attached to headgear connectors.[233] To the extent Ng is somehow deficient, the combination of Ng and Thomlinson teaches removably attachable upper and lower headgear straps.[234] FlexiFit also discloses removably attachable upper and lower headgear straps.[235]

b. "a free end of each of the upper straps and the lower straps includes a hook tab" (Claim 19)

211. Claim 19 depends from Claim 1 and includes "a free end of each of the upper straps and the lower straps includes a hook tab structured to engage a remainder of the respective upper strap and respective lower strap to secure the upper and lower straps in place in a length adjustable manner."

212. Ng discloses that each headgear strap includes hook and loop fastening elements.[236] To the extent there is insufficient teaching that the hook tabs are positioned at the free ends of the straps, such positioning would have been a matter of simple design preference to a person of skill in the art.

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[233] *See supra* ¶ 71.

[234] *See supra* ¶¶ 72–73.

[235] Ex. 1417 at 10 ("ASSEMBLING YOUR MASK").

[236] Ex. 1410 ¶ 67.

213. For example, as shown below, FlexiFit teaches hook and loop material or Velcro® tabs at the end of each strap.[237]

[237] *See* Ex. 1417 at 10 ("ASSEMBLING YOUR MASK").

214. As further evidence that positioning Velcro® at free ends of headgear straps was common practice, Amarasinghe discloses, "At the end of each strap is secured a piece of hook material, which, in use, passes through a headgear attachment point and fastens on corresponding loop material on the strap."[238] Figure 1 of Ogden also discloses hook and loop material at the free end of each of the upper and lower headgear straps.[239] Representative images of Amarasinghe and Ogden are shown below.

Amarasinghe

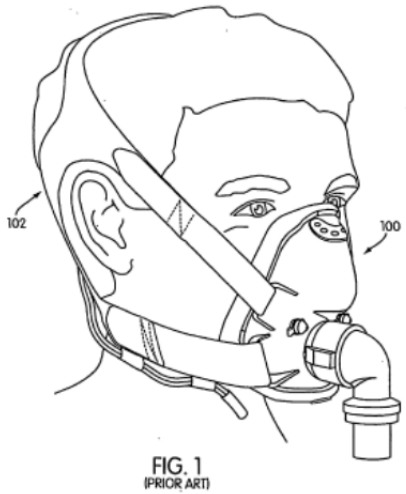
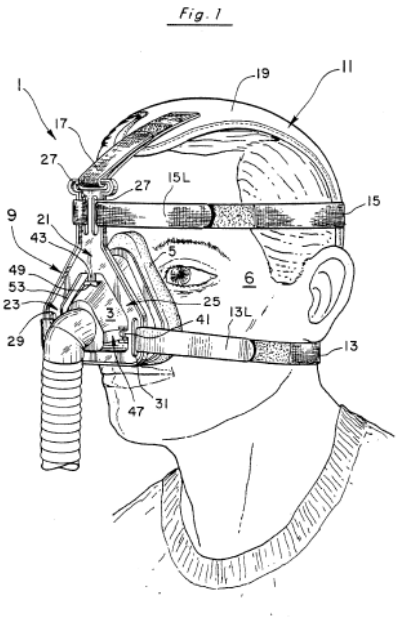


FIG. 1
(PRIOR ART)

Ogden



[238] Ex. 1428 ¶ 12.

[239] Ex. 1422 at col. 3:10–20.

215. A person of skill would have been motivated to position to Velcro® at free ends of headgear straps prevent loose ends and facilitate headgear removal. Further, a person of skill would have recognized that positioning hooks at an end of the strap and loops along a length of the strap would provide a wide range of adjustment and maintain the straps in the adjusted position.[240] Properly adjusted headgear straps ensure proper contact between the mask and the user's face.[241]

[240] *See* Ex. 1426 at col. 7:6–13.

[241] *See id.* at col. 7:19–22.

c. "a pair of top straps and a pair of rear straps" (Claim 19)

216. Claim 19 further includes "the upper straps split to form a pair of top straps and a pair of rear straps."

217. Ng does not expressly disclose that the upper straps in Figure 1 split to form a pair of top straps and a pair of rear straps. However, other embodiments of Ng, including that shown in Figure 16 below, include straps splitting to form a pair of top straps and a pair of rear straps. Although Figure 16 of Ng does not include both upper and lower headgear straps, FlexiFit specifically discloses upper straps that split into top straps and rear straps.[242]

Ng **FlexiFit**

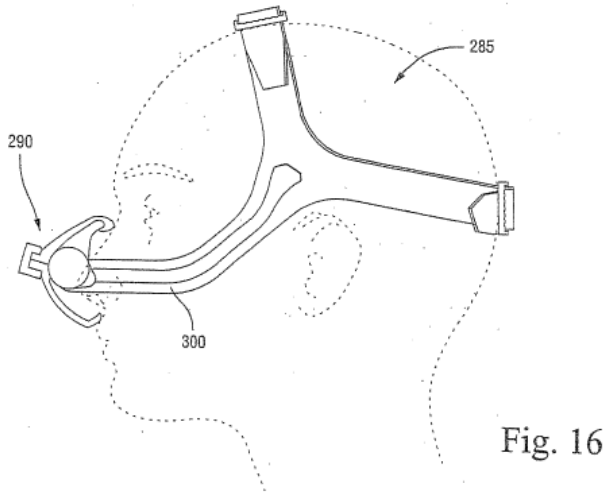


Fig. 16

218. It was common in the industry to provide straps that split into top straps and rear straps. For example, Figure 135 of Gunaratnam-II (below, left)

[242] Ex. 1417 at 10.

discloses side straps splitting to form top straps and rear straps. Figure 1 of Amarasinghe (below, right) also discloses a pair of upper straps that split to form top straps that pass over the top of the patient's head and the rear straps pass behind the patient's head.

Gunaratnam-II

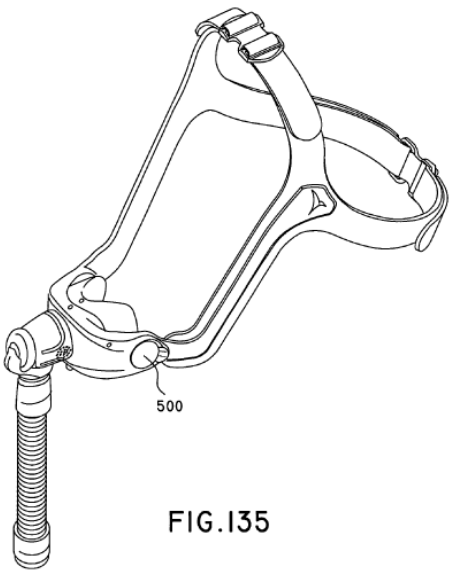


FIG.135

Amarasinghe

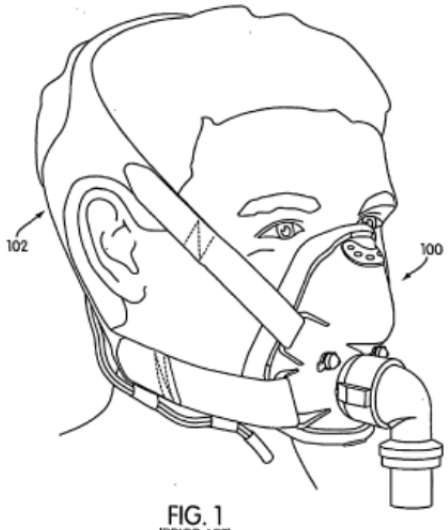


FIG. 1
(PRIOR ART)

219. A person of skill in the art would have replaced the upper straps in Figure 1 of Ng with the strap configuration shown in Figure 16 of Ng to better support and secure the upper portion of the mask and stabilize the upper straps. An upper strap crossing the occiput of the patient's head may be unstable depending on the location of the strap, the patient's head shape, and the patient's hairstyle. By using a top strap, downward motion of the top strap is limited, and the upper strap is stabilized on the patient's head.

d. "buckle" (Claim 19)

220. Claim 19 further includes "the top straps being connected together by a buckle and configured to pass over the top of the patient's head in use."

221. Ng does not expressly disclose top straps being connected together by a buckle in the embodiment shown in Figure 1. However, other embodiments of Ng, including that shown in Figure 16 below, include top straps connected together by a buckle at the top of the patient's head. As shown below, FlexiFit also discloses top crown straps connected together by a buckle at the top of the patient's head.[243]

Ng

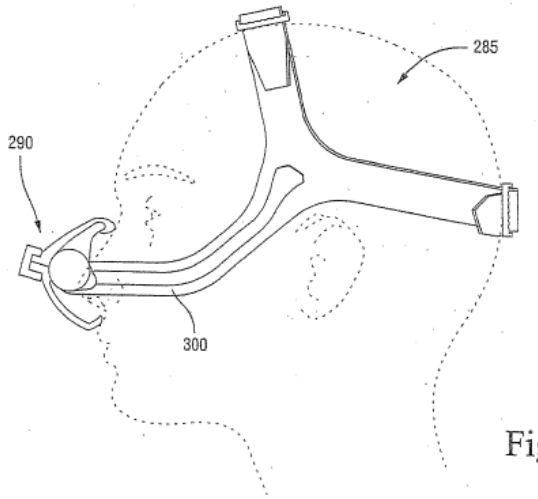
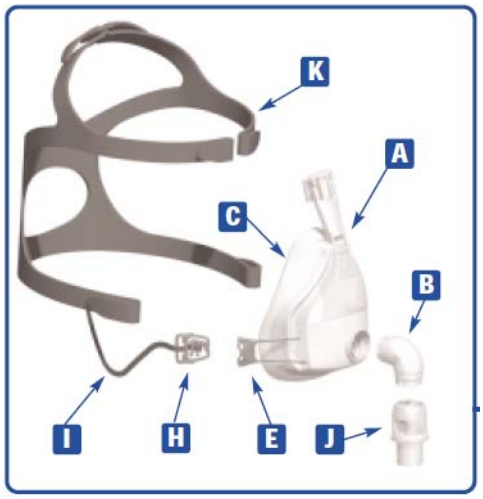


Fig. 16

FlexiFit



[243] *See* Ex. 1417 at 10 ("FITTING YOUR MASK").

222. As further evidence that this feature was common in the industry, Figure 135 of Gunaratnam-II (below) discloses top straps connected together by a buckle.

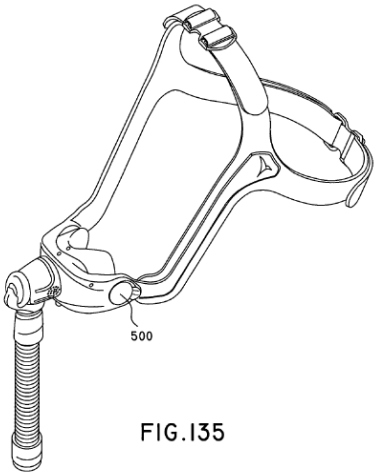


FIG.135

223. A person of skill in the art would have known to join the top straps using a buckle to facilitate adjustments for a better fit and to maintain the straps in a desired position.[244] Positioning a buckle at the top of the head would prevent pressure from the buckle from causing discomfort to the user, as the top of the head is not generally a supporting surface for the head during sleep. Thus, this area of the head would be free from loads that might press the buckle uncomfortably against the user's head. Use of a buckle also allows the headgear straps to be cut from a flat sheet of material, yet conform to the generally rounded shape of a patient's head. This enables manufacturing efficiencies, as the upper

[244] *See* Ex. 1431 ¶ 149.

strap and top strap may be cut from a single sheet of material, which avoids sewing or other fabric joining operations.

e. "a free end of each of the top straps has a hook tab" (Claim 19)

224. Claim 19 further includes "and a free end of each of the top straps has a hook tab threaded through the buckle to engage a remainder of the respective top strap to secure the top straps in place relative to the buckle in a length adjustable manner."

225. As explained above, it was common practice to provide a hook tab on a free end of each strap.[245] A person of skill also would have been motivated to provide hook tabs on the free end of each top strap in order to facilitate adjustment and removal of the headgear straps.

f. "the rear straps and the top straps form a closed loop" (Claim 21)

226. Claim 21 depends from Claim 19 and includes "wherein the rear straps and the top straps form a closed loop to encircle a rear portion of the patient's head when in use."

[245] *See supra* ¶¶ 212–215.

227. As explained above, a person of skill would have been motivated to modify the headgear in Figure 1 of Ng to include upper straps that split to form a pair of top straps and a pair of rear straps.[246] It was common in CPAP headgear to provide rear straps and top straps that form a closed loop encircling a rear portion of the patient's head.

228. For example, as shown below in Figure 16 of Ng, the top straps and the rear straps form a closed loop. As another example, FlexiFit discloses the rear straps and the upper straps forming a closed loop.[247]

Ng

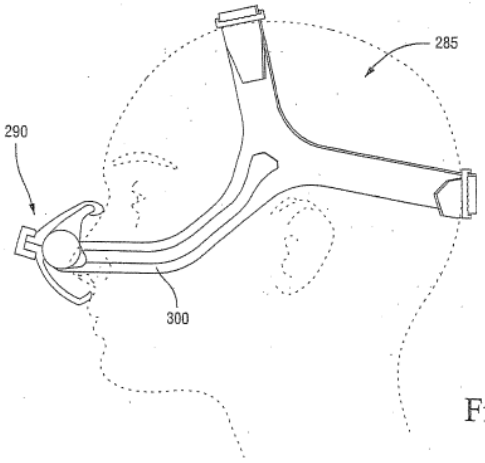
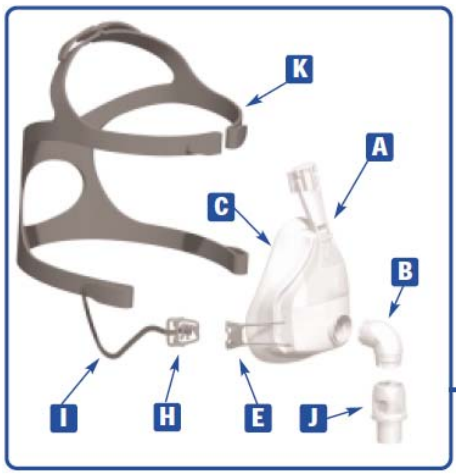


Fig. 16

FlexiFit



[246] *See supra* ¶¶ 217–219.

[247] Ex. 1417 at 10.

229. As shown below, Gunaratnam-II also discloses the rear straps and the upper straps forming a closed loop.

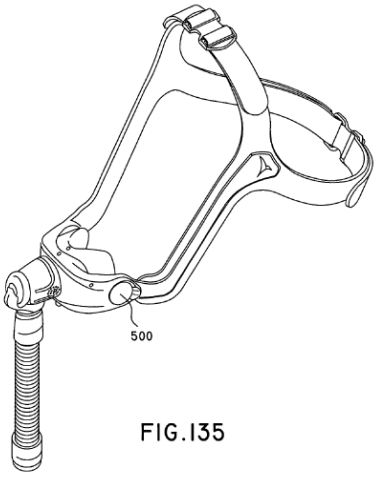


FIG.135

230. A person of skill at the time of the invention would have been motivated to provide a headgear configuration with a rear loop, as taught by FlexiFit, to stabilize the upper and lower straps, while minimizing the total amount of material required for the headgear. An upper strap crossing the occiput of the patient's head may be unstable depending on the location of the strap, the patient's head shape, and the patient's hairstyle. By using the closed loop configuration, the upper strap is stabilized on the patient's head.

H. Claim 20 would have been obvious over Ng in view of Thomlinson, FlexiFit, and Sprinkle

1. Sprinkle (U.S. Publication No. 2004/0182398)

231. As shown in Figure 2 (below), Sprinkle describes a mask 10 having headgear 80.[248] The straps 162, 164 of the headgear 80 provide substantial cushion between the user's forehead and the upper headgear connectors in the forehead support assembly 30.[249]

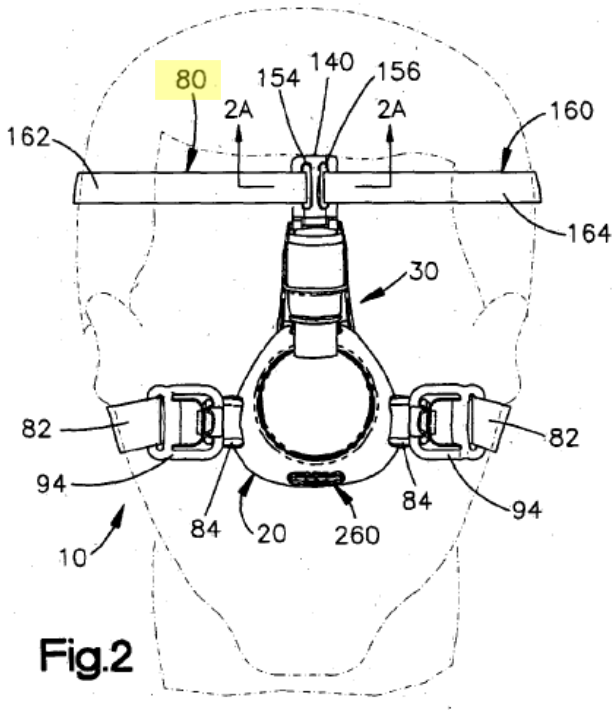


Fig.2

[248] Ex. 1419 ¶ 72.

[249] *Id.* ¶ 74.

2. Potential Differences from the Prior Art and Reasons to Combine

232. A person of skill in the art would have been motivated to combine Ng, Thomlinson, FlexiFit, and Sprinkle for at least the reasons provided above.[250] Similar to Ng, Thomlinson, FlexiFit, and Sprinkle discloses a CPAP patient interface.[251] A person of ordinary skill in the art would have been aware of and looked to known CPAP patient interfaces when contemplating design features. Combining the features of Ng, Thomlinson, FlexiFit, and Sprinkle would have been a mere combination of familiar patient interface features that would have yielded only predictable results.

[250] *See supra* ¶¶ 68–100, 207–230.

[251] Ex. 1419 at 72.

a. "the upper straps provide padding" (Claim 20)

233. Claim 20 depends from Claim 19 and includes "wherein the upper straps provide padding to the respective headgear connectors of the shroud module on the patient's face during use."

234. Ng does not expressly disclose that its headgear straps provide padding, but the use of padded straps was common in prior art CPAP masks. For example, Sprinkle illustrates upper headgear straps similar to those of FlexiFit and explains that it provides padding to the face of the user, as shown in Figures 1–2A below.[252]

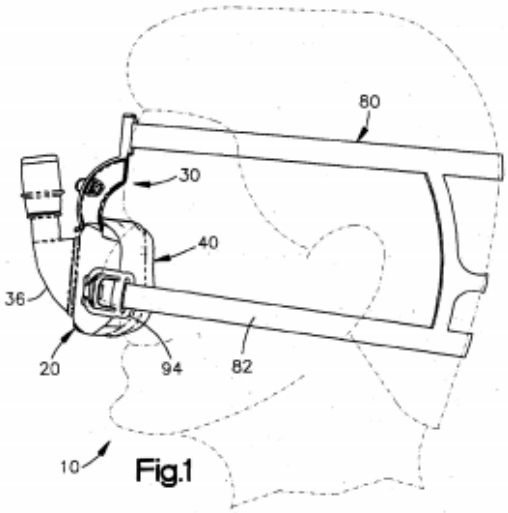


Fig.1

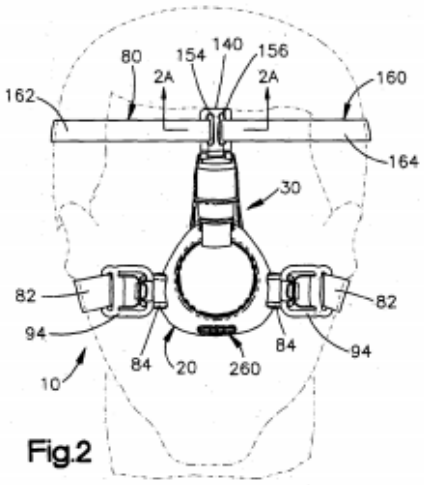


Fig.2

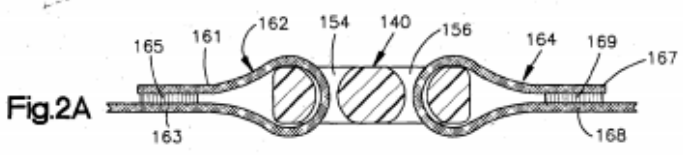


Fig.2A

[252] Ex. 1419 ¶ 74.

235. A person of skill in the art would have known to use the upper headgear straps to provide padding to the patient-facing side of upper headgear connectors for a comfortable fit. A skilled artisan would have understood that using the headgear strap to provide padding would reduce the number of components and the complexity of mask assembly by eliminating separate cushion members or cushioning pieces.

I. Claim 22 would have been obvious over Ng in view of Thomlinson, FlexiFit, and Matula-II

1. Potential Differences from the Prior Art and Reasons to Combine

236. Dependent Claim 22 depends from Claim 19 and includes features that are substantially similar to those discussed above with respect to at least Claim 26.[253] The only difference is that the front opening in Claim 22 is the second opening in Claim 26.

237. Claim 22 recites "wherein the mask system further comprises a snap-fit arrangement to removably snap-fit attach the shroud module and the cushion module to one another by moving the shroud module and the cushion module towards one another along the longitudinal axis." As I explained above, Ng

[253] *See supra* ¶¶ 129–135.

discloses the claimed snap-fit arrangement.[254] However, to the extent the teachings of Ng are insufficient for this feature, Ng as modified in view of Matula-II provides the claimed snap-fit arrangement.[255]

238. For at least the reasons provided above, a person of skill in the art at the time of the purported invention would have been motivated to combine the teachings of Ng, Thomlinson, FlexiFit, and Matula-II to arrive at the claimed features of Claim 22.[256] None of these common features produced unexpected results and their combination does no more than yield predictable results.

J. Claims 28–30 would have been obvious over Ng in view of Thomlinson, Matula-II, Gunaratnam-I, and Barnett

1. Potential Differences from the Prior Art and Reasons to Combine

239. Dependent Claims 28–30 depend directly or indirectly from Claim 1 and includes features that are substantially similar to those discussed above with respect to at least Claims 5–8, 11, 14, 18, and 25.[257] There are a couple differences between Claims 28–30 and claim limitations I discussed above, but these

[254] *See supra* ¶¶ 130–131.

[255] *See supra* ¶¶ 132–135.

[256] *See supra* ¶¶ 68–100, 103–135, 206–230.

[257] *See supra* ¶¶ 98–100, 112–125, 139–158, 172–177.

differences do not affect my analysis. Claim 28 recites "at least one snap finger," but Claim 5 recites "a plurality of snap fingers." Also, Claim 28 recites "the elbow module is rotatably attached to the shroud module," but Claim 14 recites "the elbow module and the shroud module are directly connected with a mechanical interlock."

240. As detailed in the Claim Chart I provide below, Ng discloses nearly all of the features of Claims 28–30.[258] Any differences between Claims 28–30 and Ng were well-known in the industry at the time of the invention and taught by Thomlinson, Matula-II, Gunaratnam-I, and/or Barnett.[259]

241. For at least the reasons provided above, a person of skill in the art at the time of the purported invention would have been motivated to combine the teachings of Ng, Thomlinson, Matula-II, Gunaratnam-I, and Barnett to arrive at the claimed features of Claims 28–30.[260] None of these common features produced unexpected results and their combination does no more than yield predictable results.

[258] *See infra* ¶¶ 257.

[259] *See supra* ¶¶ 98–100, 112–125, 139–158, 172–177.

[260] *See supra* ¶¶ 68–100, 103–135, 138–158, 161–177.

242. In particular, a person of skill would have been motivated to combine the teachings of Ng and Thomlinson to arrive at the claimed headgear connectors, which are also embodied in Gunaratnam-I.[261] Further, a person of skill would have modified the Ng shroud module in view of the teachings of Matula-II to include rearward extending snap-fingers to engage the cushion module and in view of the teachings of Barnett to directly engage the shroud module and the elbow module to accommodate the elbow module.[262] A person of skill would have recognized that the inclusion of each of the features in Claims 28–30 would have been desirable so the individual components (e.g., the headgear, cushion module, and/or shroud) could be easily removed without disassembling the entire system.

[261] *See supra* ¶¶ 70–75, 139–152.

[262] *See supra* ¶¶ 115–135, 163–177.

K. Claims 46, 51, and 53–56 would have been obvious over Ng in view of Thomlinson, Barnett, FlexiFit, Matula-II, Worboys, and Sprinkle

1. Potential Differences from the Prior Art and Reasons to Combine

243. Claims 46, 51, and 53–56 include long lists of well-known features that are included in other claims. As detailed in the Claim Chart I provide below, Ng discloses nearly all of the limitations of Claims 46, 51, and 53–56. In fact, Claim 51 includes a long list of features identically recited in at least Claims 43 and 46. Any differences between Ng and Claims 46, 51, and 53–56 were well-known in the industry at the time of the invention and taught by Thomlinson, Barnett, FlexiFit, Matula-II, Worboys, and/or Sprinkle.

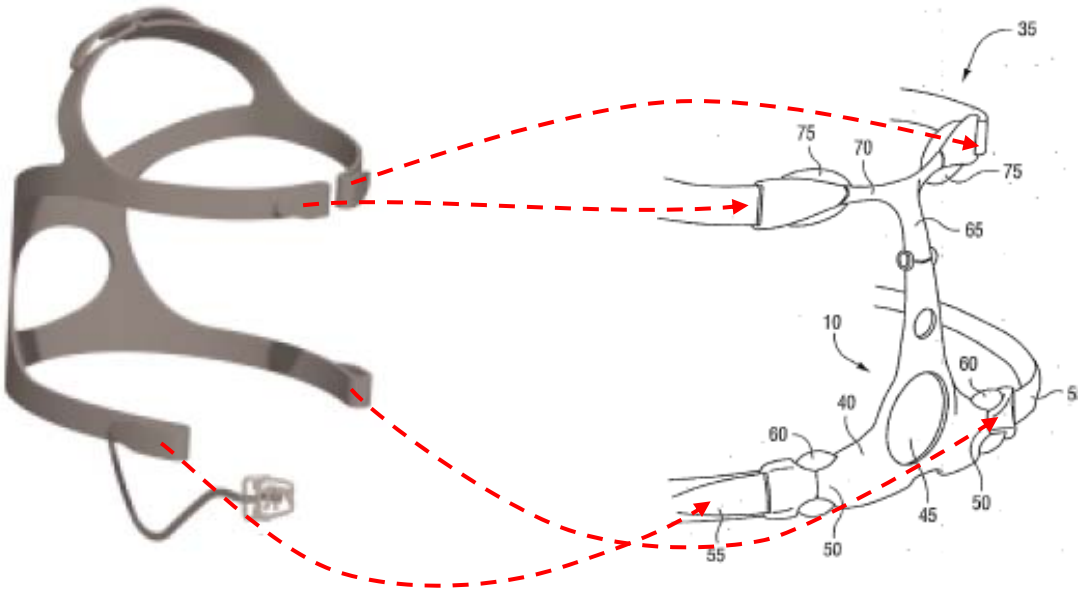
244. As I discussed above, a person of skill would have been motivated to modify Ng in view of Thomlinson to arrive at the claimed protruding vent configuration.[263]

245. Although the combination of Ng and Thomlinson also teaches all of the claimed headgear features, the claimed headgear configuration is entirely embodied in the FlexiFit headgear.[264] As shown below, because the Ng mask assembly has pairs of upper and lower headgear connectors, the FlexiFit headgear

[263] *See supra* ¶¶ 83–97.

would have been compatible with the Ng mask assembly. Further, as discussed above, Sprinkle discloses upper straps that provide padding.[265]

FlexiFit (partial) **Ng (partial)**



246. As explained above, prior to the '931 Patent, it was well-known to include snap-fingers to form snap-fit arrangements between CPAP components.[266] A person of skill would have been motivated to modify Ng in view of the teachings

[264] *See supra* ¶¶ 204–230.

[265] *See supra* ¶¶ 233–235.

[266] *See supra* ¶¶ 116–135.

of Matula-II to include rearward extending snap-fingers on the shroud to engage the cushion module.[267]

247. Ng discloses that its shroud module is configured to be selectively coupled to one of the elbow modules,[268] but does not describe the particulars of this connection. However, as explained above, it was a well-known option to directly engage the elbow module and the shroud module in a manner that the second opening of the shroud module would accommodate the elbow module.[269]

248. I have discussed nearly all of these potential differences above with respect to Claims 1, 5–7, 10–12, 14, 15, 19–22, 25, 26, and 32.[270] The only feature not described above is the swivel feature in Claim 43 from which Claim 46 depends. I discuss this feature further below.[271]

249. For at least the reasons provided above, a person of skill would have been motivated to combine the teachings of Ng, Thomlinson, Barnett, FlexiFit,

[267] *See supra* ¶¶ 115–135.

[268] Ex. 1410 ¶ 31.

[269] *See supra* ¶¶ 164–177.

[270] *See supra* ¶¶ 70–100, 112–135, 139–143, 163–177, 179–188, 206–230, 232–238.

[271] *See infra* ¶¶ 250–254.

Matula-II, Worboys, and/or Sprinkle to arrive at the combinations of features in Claims 46, 51, and 53–56. None of these common features produced unexpected results and their combination as part of a long list of well-known features does no more than yield predictable results.

a. "the elbow including a swivel" (Claim 43)

250. Claim 46 depends from Claim 43, and Claim 43 includes "the elbow including a swivel adapted to connect to an air delivery tube." Ng does not expressly disclose an elbow including a swivel, but such a feature was common and well-known in the industry at the time of the invention.

251. For example, Worboys discloses that the second portion 25 of the elbow "typically will be provided with a swivel joint which in turn is connected to an air delivery tube in communication with a flow generator."[272]

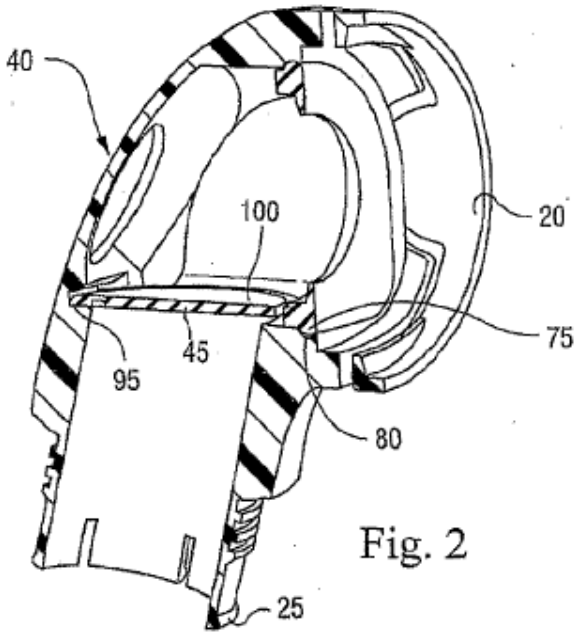
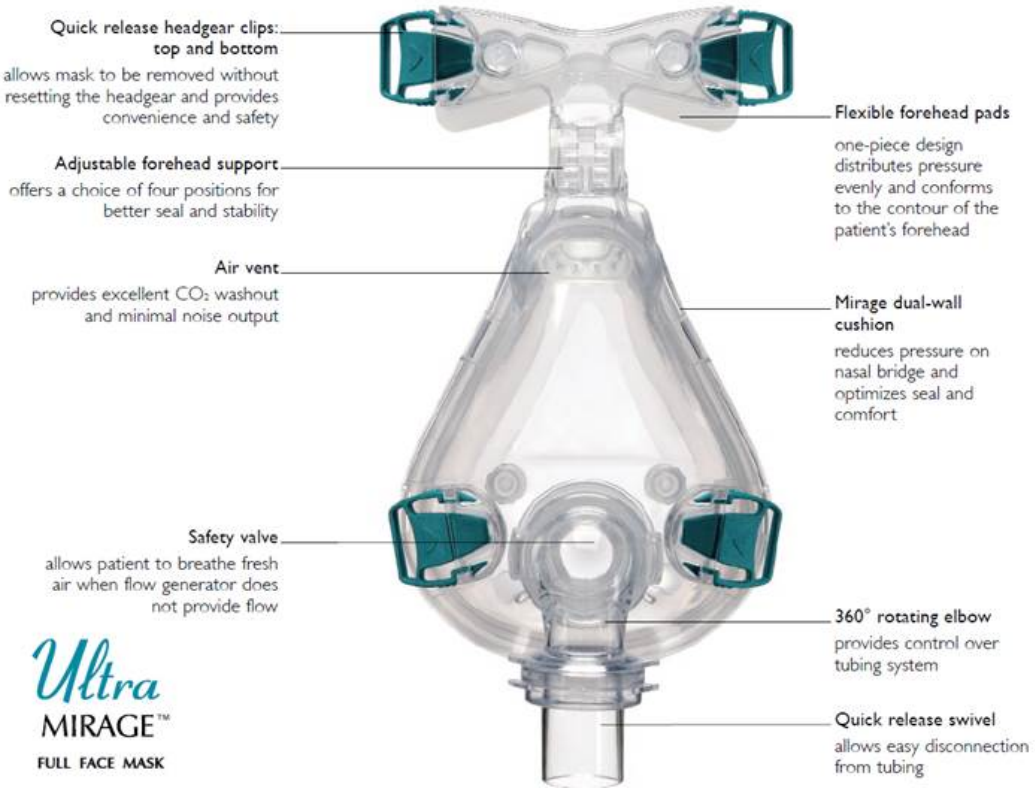


Fig. 2

[272] Ex. 1415 ¶ 105.

252. As shown below, Ultra Mirage also discloses a quick release swivel between the elbow and the air delivery tubing.[273]



[273] Ex. 1416 at 6.

253. As another example, Ging discloses a swivel connector member 300 between the elbow and the delivery tube 310.[274]

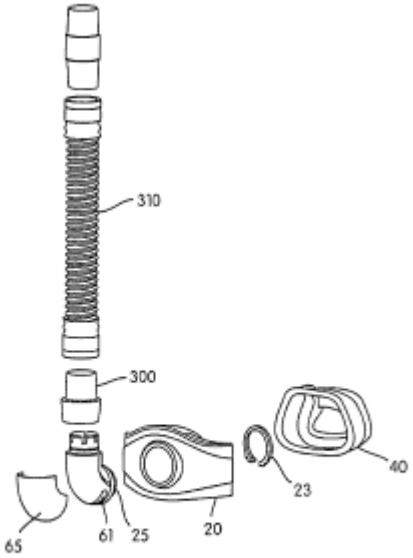


FIG. 6b

254. It was well-known at the time of the invention to provide an elbow with a swivel joint to facilitate easy disconnection of the air delivery tube.[275] A person of skill would have recognized that the swivel joint allows the air delivery tubing to move relative to the mask assembly in response to movement between the wearer and the air delivery tubing, which helps reduce loads applied by the tubing to the mask assembly, and thus prevent leaks between mask assembly and

[274] Ex. 1431 ¶ 153.

[275] *See* Ex. 1416 at 6.

the wearer.[276] Swivel connectors provide an additional degree of freedom of movement without increasing the undesirable torque.[277] This additional degree of movement also helps prevent the air delivery tubing from twisting.[278] Adding the swivel feature to the Ng mask assembly would have done no more than yield predictable results.

L. Claim 65 would have been obvious over Ng in view of Thomlinson, Barnett, and Matula-II

1. Potential Differences from the Prior Art and Reasons to Combine

255. As detailed in the Claim Chart I provide below, Ng discloses nearly all of the features in Claim 57. Any differences between Claim 57 and Ng are discussed above with respect to Claims 1, 6, 11, 14, 19, 22, 26, 43, and 46.[279] Claim 65 depends from Claim 57 and includes the protruding vent arrangement recited in Claim 1. The protruding vent arrangement in Claim 65 is discussed above with respect to Claim 1.[280]

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[276] *See* Ex. 1422 at col. 5:56–61.

[277] *See* Ex. 1431 ¶ 114.

[278] *See* Ex. 1435 at col. 1:38–41.

[279] *See supra* ¶¶ 70–100, 129–135, 172–177, 208–225, 236–238, 243–254.

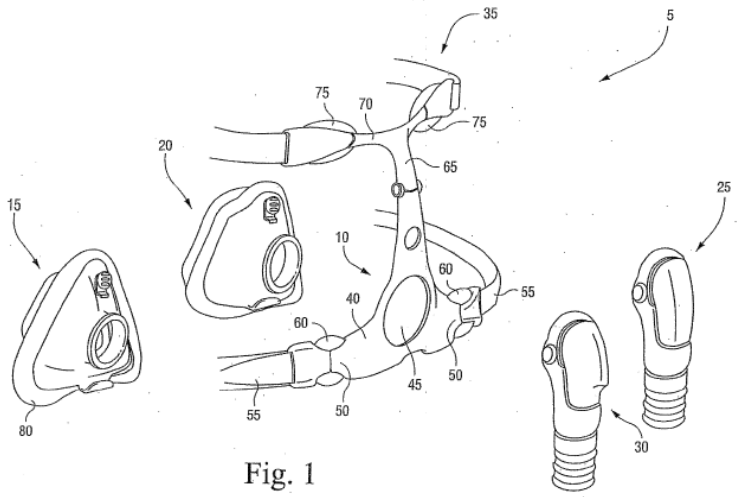
[280] *See supra* ¶¶ 82–97.

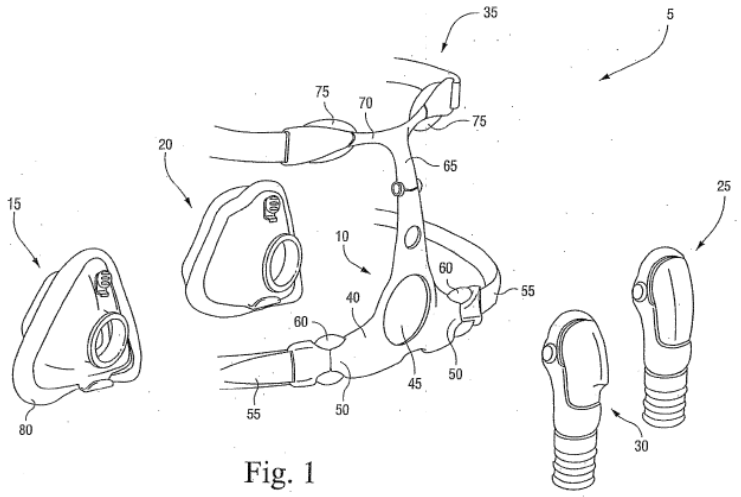
256. For at least the reasons provided above, a person of skill in the art at the time of the purported invention would have been motivated to combine the teachings of Ng, Thomlinson, Barnett, and Matula-II to arrive at the claimed features of Claim 65.[281] Each of these references discloses a CPAP patient interface for treatment of sleep-disordered breathing. A person of skill would have expected success in combining the various features disclosed in the references because each feature would function for its intended purpose and provide its known benefit, as taught in the prior art. The combination of these features would have done no more than yield predictable results.

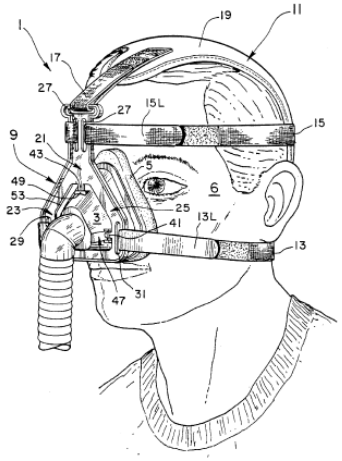
[281] *See supra* ¶¶ 68–135, 161–177.

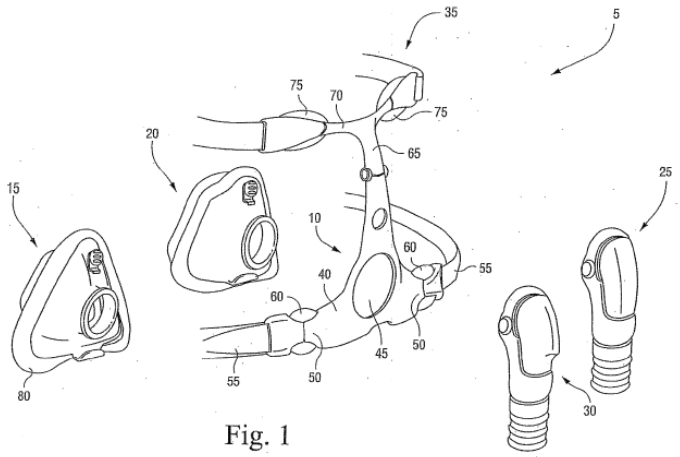
IX. CLAIM CHARTS

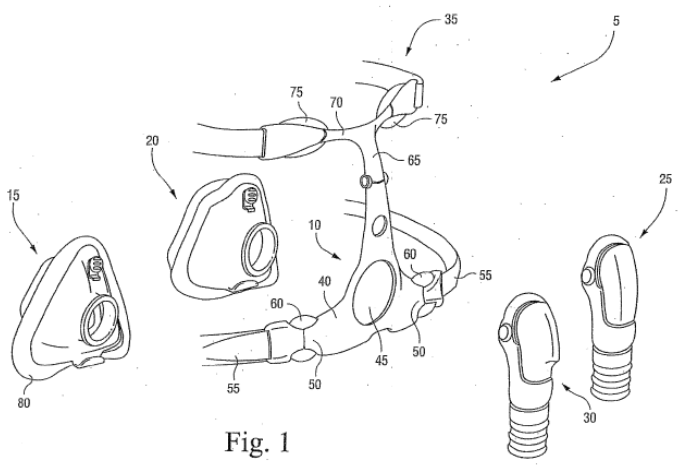
257. The Claim Chart below summarizes the disclosure in the prior art that a person of ordinary skill would have understood to teach each limitation of Claims 1, 4–8, 10–22, 25, 26, 28–32, 46, 51, 53–56, and 65 of the '931 Patent.

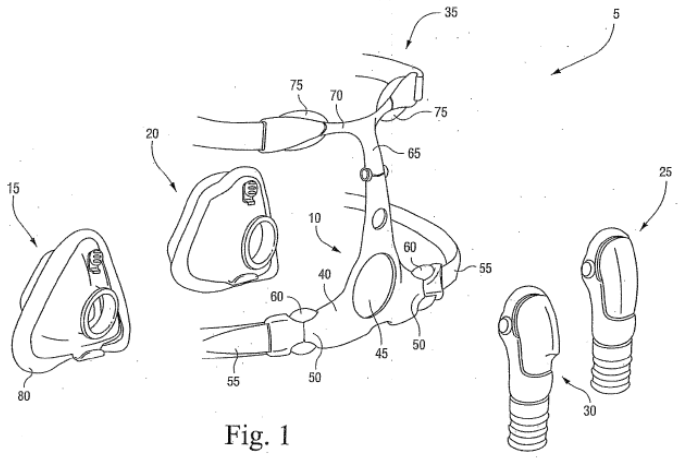
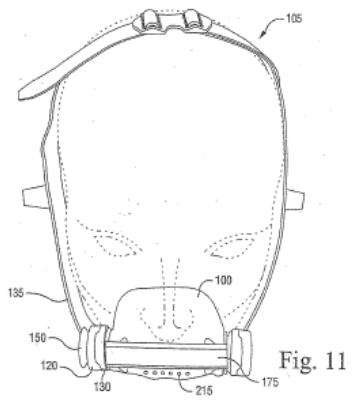
'931 Patent	Prior Art
1. A mask system, comprising:	**Ng:** "Fig. 1 illustrates an interchangeable mask system 5 according to an embodiment of the present invention." Ex. 1410 ¶ 29.  Fig. 1

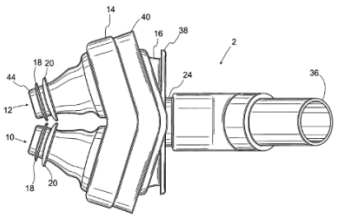
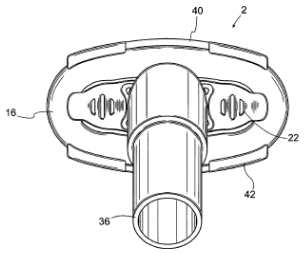
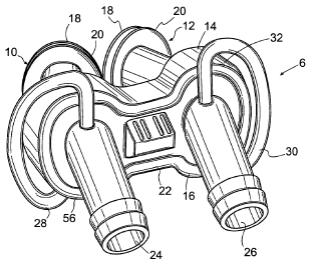
’931 Patent	Prior Art
(i) a shroud module; wherein the shroud module includes headgear connectors adapted to removably attach to respective headgear straps of headgear; and	**Ng:** “The common frame 10 has a main body 40 defining a central opening 45. Main body 40 includes at least two lateral arms 50, each of which can be coupled to a headgear strap 55 of headgear. The straps may be connected to the frame using a press-fit connector 60, as is known in the art.” Ex. 1410 ¶ 30.  Fig. 1 **Thomlinson:** “Strap attachment plate 92 can facilitate the use of a strap system 102 by increasing the ease at which a strap can be connected to or removed from the nasal interface. Because the strap attachment plate is not integral to the nasal interface, the strap attachment plate, and any attached straps, can be more easily added or removed from the system.” Ex. 1411 ¶ 307. “A strap system can be fasted/unfastened using alternative methods to Velcro, such as snaps, buckles, buttons and ties.” Ex. 1411 ¶ 312. **Ultra Mirage:** “Quick release headgear clips: top and bottom allows mask to be removed without resetting the headgear and provides convenience and safety.” Ex. 1416 at 6.

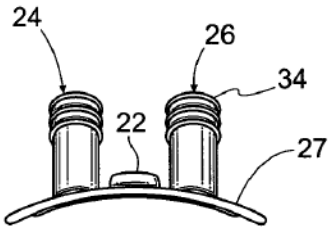
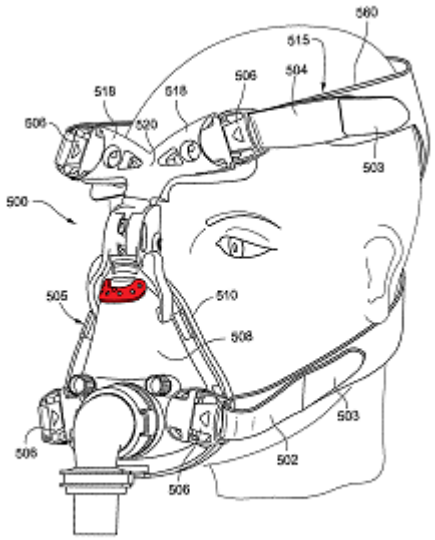
’931 Patent	Prior Art
	Ogden: “[E]ach side strap 13R and 13L is preferably attached to a respective side portion 23, 25 of the rigid plate 9 on respective sides of the patient's nose 2. This can be done in any number of well-known, adjustable manners including . . . hook and loop materials on the straps themselves. . . . The remaining straps 15R, 15L, and 17 are also individually attachable in this manner.” Ex. 1422 at col. 3:10–20. Fig. 1 
(ii) a cushion module, comprising: a rigid or semi-rigid frame defining a breathing chamber; and a cushion to form a seal with the patient's face in a nasal bridge region, a cheek region and a lower lip/chin region of the patient's face,	**Ng:** “Common frame 10 is configured to be selectively coupled to one of cushion components 15, 20 and to one of elbow components 25, 30. Cushion components 15, 20 differ in at least one respect such that one may be more optimal or preferable for use with one user, while another may be more suitable or preferably for use with another user. For example, cushion component 15 may be an Activa™ component, while cushion component 20 may be an UltraMirage™ Series II cushion component, both available from ResMed. These cushion components can be significantly different from one another, e.g., the Activa™ includes a gusset portion 80 and a cushion clip assembly (not shown) which is not incorporated in the UltraMirage™ cushion design.” Ex. 1410 ¶ 31.

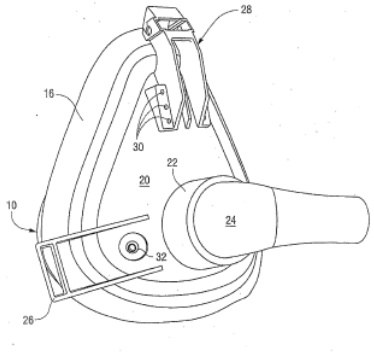
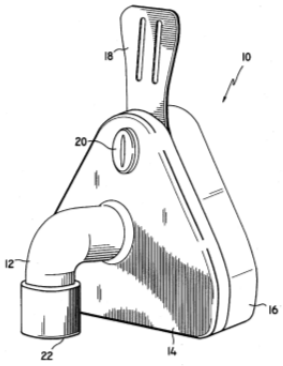
’931 Patent	Prior Art
	“Interfaces, such as a nasal mask assembly, for use with blowers and flow generators in treatment of sleep disordered breathing (SDB) typically include a soft-face contacting portion, such as a cushion, and a rigid shell or frame.” *Id*. ¶ 3. “[A] supplemental cushion component in the form of a nasal cushion or a full-face cushion, wherein the cushion component and the supplemental cushion component cooperatively seal with the user’s face in use.” *Id*. ¶ 13. “A system of breathing arrangements for delivering breathable gas to a patient, comprising at least first and second cushion components (15, 20), e.g., full-face, nasal, nasal prongs, nose tip, and/or a combination of any of the above, including a nasal or full-face cushion and nasal prongs/nozzles combination, etc., that are different from one another in at least one aspect, and a common frame assembly (10) configured to support each of the first and second cushion components (15, 20). Various embodiments are directed to a full-face or nasal mask used with a frame having lateral connector portions having a stiffening member.” *Id*. at Abstract.  Fig. 1

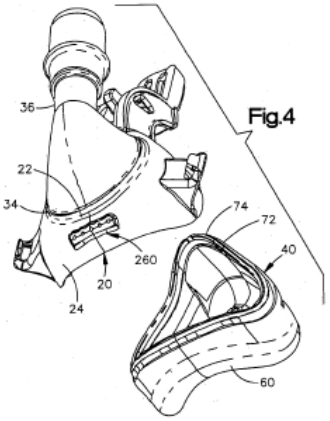
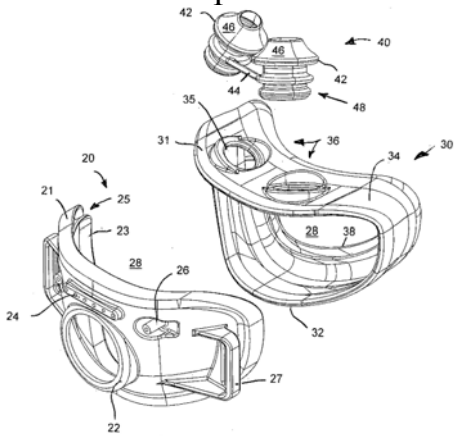
’931 Patent	Prior Art
wherein the cushion is constructed of a first, relatively soft, elastomeric material and the frame is constructed of a second material that is more rigid than the cushion,	**Ng:** “Interfaces, such as a nasal mask assembly, for use with blowers and flow generators in treatment of sleep disordered breathing (SDB) typically include a soft-face contacting portion, such as a cushion, and a rigid shell or frame.” Ex. 1410 ¶ 3. **Lithgow:** “The cushion 14 is constructed from a soft, flexible skin-compatible material such as silicone. The cushion 14 may be formed, for example, in a one shot injection molding process as is known in the art. However, the cushion 14 may be formed with any suitable material and may be formed by any suitable process. For example, while face contacting portion 26 of cushion 14 may have a softer grade material, the gusset portion may have a harder grade material to provide stiffness as a spring element. The non-face contacting portion 24 may have a stiffer grade material so a direct assembly to frame without a cushion clip may be possible.” Ex. 1433 ¶ 139.
[A] wherein the shroud module and the cushion module are configured to be removably and non-rotatably coupleable to one another; and	**Ng:** “Common frame 10 is configured to be selectively coupled to one of cushion components 15, 20 and to one of elbow components 25, 30.” Ex. 1410 ¶ 31.  Fig. 1

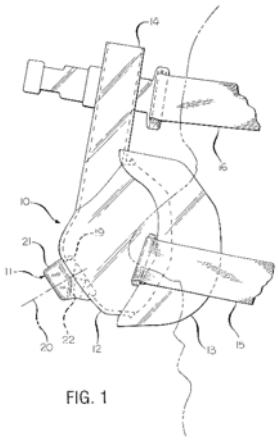
’931 Patent	Prior Art
	A person of skill would have understood that the shroud module 10 and cushion module 15, 20 are non-rotatably coupleable because the cushion module attaches to the shroud at two points (annular opening 45 and the clip located above the annular opening). This arrangement would have prevented relative rotation between the two parts.
[B] wherein the frame includes a protruding vent arrangement having a plurality of holes, wherein the shroud module includes a first opening to accommodate said protruding vent arrangement, and	**Ng:** “Common frame 10 is configured to be selectively coupled to one of cushion components 15, 20 and to one of elbow components 25, 30.” Ex. 1410 ¶ 31.  Fig. 1 “As shown in Figs. 3, 7-8, and 11, the mask assembly includes a gas washout vent 215. The vent 215 could be on the frame and/or the cushion component.” *Id.* ¶ 43.  Fig. 11

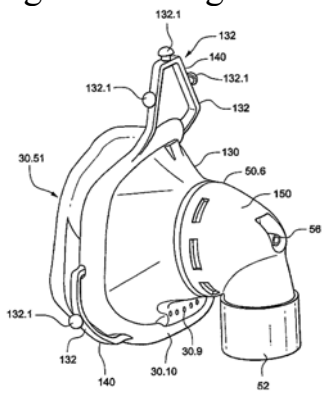
’931 Patent	Prior Art
	Thomlinson: “A nasal interface body 2 according to the present invention can also include one or more locking tabs 38 on the distal portion 16. The locking tabs 38 can be used to releasably engage a strap attachment plate 92, as depicted in FIG. 37 and described further below.” Ex. 1411 ¶ 203.  Fig. 1 “Further, and as shown in FIG. 3, one embodiment of a nasal interface can also include one or more exhalation ports 22, which are described in more detail below.” *Id.* ¶ 204.  Fig. 3 “As shown in FIG. 8, nasal interface body 6 can also include first inlet 24 and a second inlet 26, as well as exhalation port 22. In one embodiment, exhalation port 22 is positioned between inlet 24 and second inlet 26.” *Id*. ¶ 209.  Fig. 8

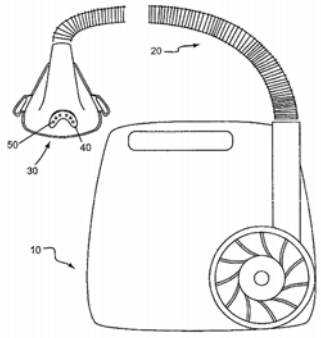
’931 Patent	Prior Art
	“As shown in the figures and in particular FIGS. 3, 14A, 15D, 15F, 16C and 16F, distal portion 16 can also include one or more exhalation ports 22, described further below.” *Id*. ¶ 247.  Fig. 14A **Hitchcock:** *See* Ex. 1421 at Fig. 8.  Fig. 8

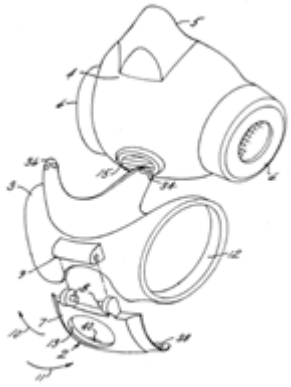
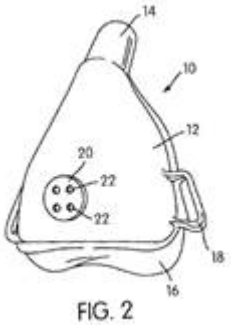
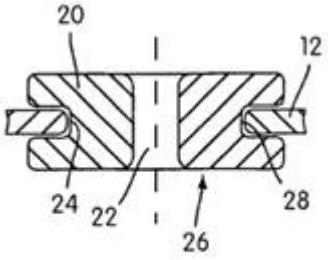
’931 Patent	Prior Art
	Hitchcock-II: “A number of vents 30 may be provided so as to allow gas exhaled by the patient to vent to atmosphere.” Ex. 1440 ¶ 42.  Fig. 1-2 **Landis:** “[T]he aperture in mask frame 14 to receive variable orifice member 20 is configured as a cylindrical wall projecting outward from the mask frame to engage a variable orifice member cap, as described in greater detail below.” Ex. 1441 at col. 5:35–38.  FIG. 1 “In one construction, variable orifice vent aperture member 20 is configured as a cap to mount onto and engage projecting walls of a cylindrical opening in the mask frame or other associated structure (not shown).” *Id.* at col. 6:19–23.

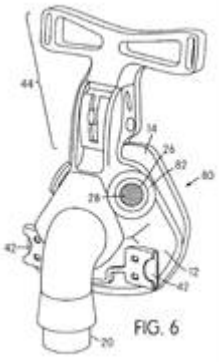
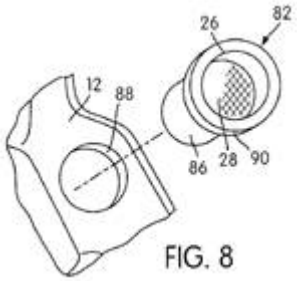
’931 Patent	Prior Art
	Sprinkle: “FIGS. 4 and 23 illustrate an exhalation vent portion 260 of the mask 10. The vent portion 260 includes a thickened wall area 262 in the lower part of the side wall 24 of the shell 20. Five circular exhalation openings 264 are formed at equally spaced intervals in the thickened area 262. The exhalation openings 264 extend from the exterior of the mask 10 to the central chamber 32 of the shell 20. The exhalation openings 264 enable exhaled air to flow out of the mask 10.” Ex. 1419 ¶ 99.  **Chandran:** “The ventilation interface 20 is configured with at least one exhalation port 24.” Ex. 1439 ¶ 60.  *Id.* at Fig. 2.

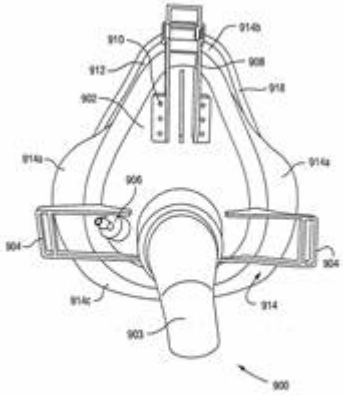
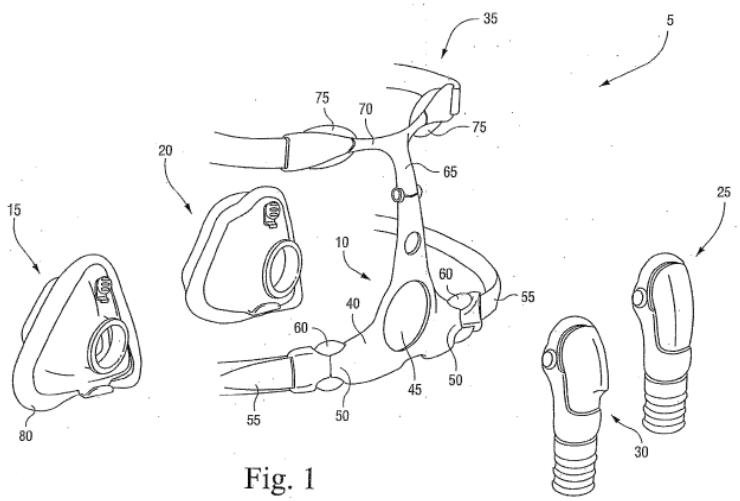
’931 Patent	Prior Art
	Jones, Jr.: “[T]he exhaust port member 11 is shown as having a generally circular perimeter 17 with a recessed or reduced diameter annular groove 18 formed in the perimeter 17, as shown in FIG. 4. A circular opening 19 is formed in the mask body 12 for receiving the exhaust port member 11.” Ex. 1436 at col. 3:3–15. “At least one and preferably two vent ports 22 extend through the exhaust port member 11 at a predetermined angle relative to the axis of rotation 20.” *Id.* at col. 3:23–25.  FIG. 1

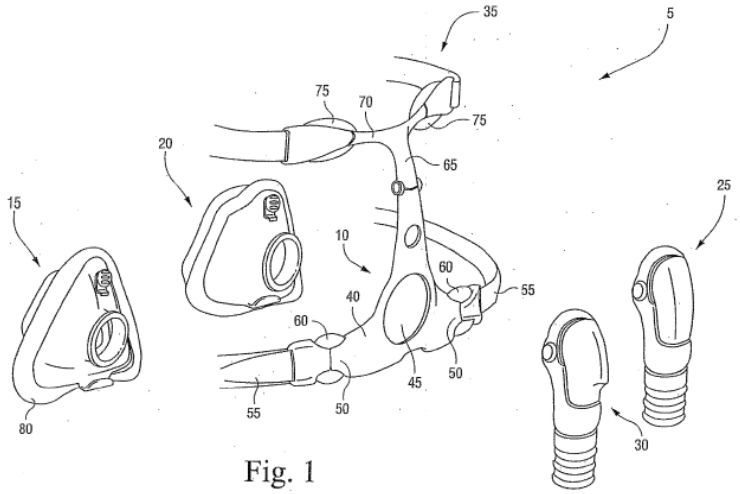
’931 Patent	Prior Art
	Jones: “[T]he lip region 30.8 has a series of four vent orifices 30.9 passing therethrough” Ex. 1437 ¶ 221.  *Id.* at Fig. 10. “The shell/cushion 130 includes a series of vents or vent orifices 30.9, which in a preferred form comprises four orifices. The vent orifices 30.9 are formed through a thicker wall section 30.10 formed integrally on the shell/cushion 30. The wall section 30.10 is shown in FIG. 3. The wall section 30.10 has two functions. The first is to form a front flange which with the rear flange 36 in the lip region 30.8 forms the lower channel 140.4. The second function is that the wall section 30.10 allows the vent orifices 30.9 to be positioned at an angle with respect to the elbow.” *Id.* ¶ 226.

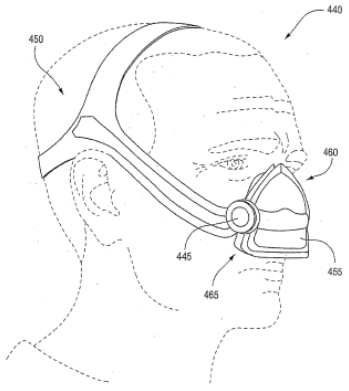
’931 Patent	Prior Art
	Darkin: “The patient interface 30 includes a vent 40. The vent 40 includes one or more holes, e.g., six holes 50.” Ex. 1442 ¶ 55.  Fig. 1 “Another advantage of the invention is to provide different vents for different pressure ranges. For example, at low pressures, it may be appropriate to have a vent with large holes in order to provide sufficient vent flow. The same vent at higher pressures would have unnecessarily high vent flow which leads to increased noise. Hence in accordance with an embodiment of the invention, when a patient is using a generally low pressure treatment, they can utilize a first vent, but when treatment pressures are higher they can use a second vent.” *Id.* ¶ 89. “Another advantage of the invention is that it provides a quick and simple system of replacing disposable vents. For example, certain styles of vents may clog easily and be designed for a single night's use. In accordance with an embodiment of the invention a vent assembly can comprise a set of "single use" vents. After a first night's use, the patient can switch to the second vent. After a second night's use, the patient can switch to a third vent, and so on.” *Id.* ¶ 90.

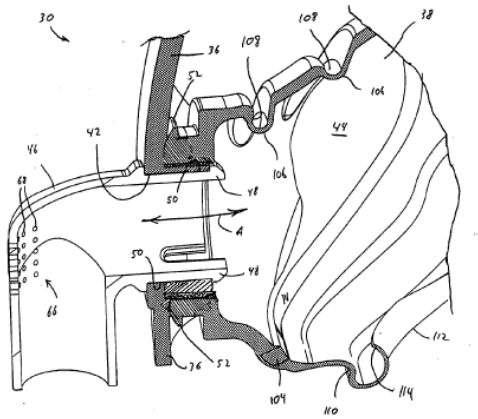
’931 Patent	Prior Art
	Fecteau: “[A] respirator 1 incorporates a quick release mechanism 2 into a facepiece support system, or yoke, 3.” Ex. 1446 at 4:24–25. “[Q]uick release mechanism 2 consists of an over center cam latch 7 pivotly attached to yoke 3 via hinge pins 8 disposed within hinge 9 and further includes relief cut 13 to accommodate exhale valve 15 while in the latched position.” *Id.* at 4:29–32.  FIG. 2 **Kwok:** “The mask includes a Silastic™ insert 20 through which is provided an orifice 22 for gas washout.” Ex. 1445 at col. 3:43–44. “[T]he insert 20 has an external groove or recess 24 which engages the rim 28 of a corresponding shaped opening 26 in the mask shell 12 to retain the insert 20 in place.” *Id.* at col. 3:57–60. “In the embodiment shown in FIGS. 2 to 5 and 7 the insert 20 includes more than one orifice 22.” *Id.* at col. 3:61–62.  FIG. 2  FIG. 8

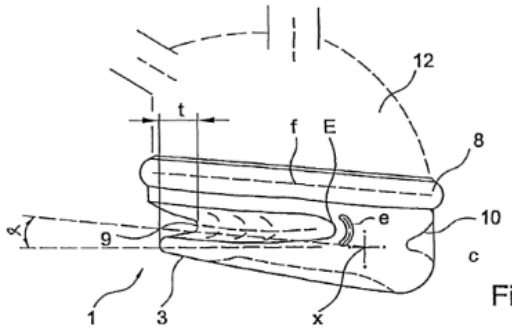
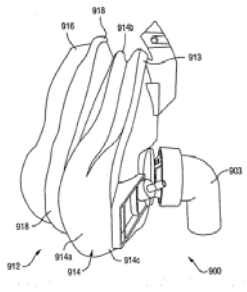
’931 Patent	Prior Art
	Drew: “The mask 10 includes a gas washout vent constituted by an opening 26 in the shell 12 across which extends a thin air permeable membrane 28.” Ex. 1444 at col. 4:32–34. “FIG. 6 shows a nasal respiratory mask 80.” *Id.* at col. 5:31. “In the mask 40 of FIG. 2, the [gas washout] vent is provided in the gas inlet 20, whereas in the mask 80 the vent is provided in the shell 12. More particularly, the mask 80 includes two cylindrical inserts 82 which have an inner opening 26 across which extends the thin air permeable material 28.” *Id.* at col. 5:35–40. “[T]he insert 82 [] comprises a cylindrical portion 86 sized to be a snug fit into a circular orifice 88 provided in the mask shell 12.” *Id.* at col. 6:2–4.  FIG. 6  FIG. 8

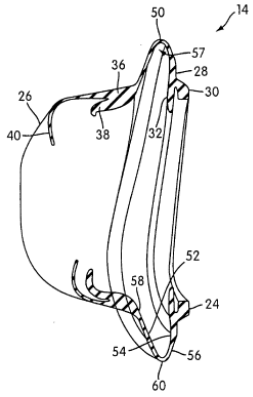
’931 Patent	Prior Art
	Frater: “Shell 902 may also be provided with one or more vents 910.” Ex. 1425 ¶ 163.  Fig. 50
[C] further wherein the shroud module includes a second opening positioned to align with a frame opening of the frame leading to the breathing chamber.	**Ng:** “The common frame 10 has a main body 40 defining a central opening 45.” Ex. 1410 ¶ 30.  Fig. 1

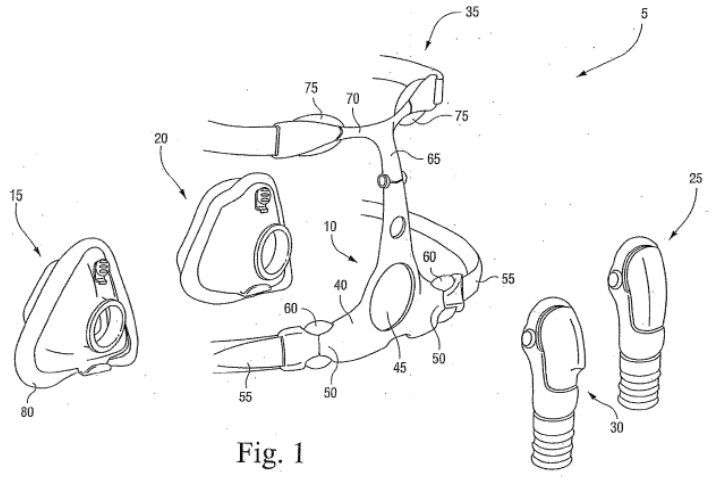
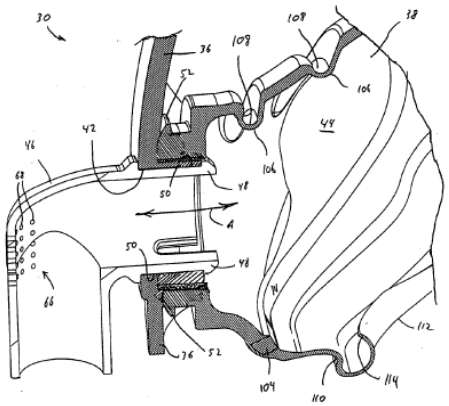
’931 Patent	Prior Art
4. The mask system of claim 1, wherein a nasal bridge portion of the cushion includes one or more folds to provide in use a higher level of adaptability or flexibility to the nasal bridge region of the cushion module relative to another region of the cushion module; and further wherein each of said one or more folds comprises adjacent first side walls interconnected by a second side wall.	**Ng:** “For example, cushion component 15 may be an Activa™ component, while cushion component 20 may be an UltraMirage™ Series II cushion component, both available from ResMed. These cushion components can be significantly different from one another, e.g., the Activa™ includes a gusset portion 80 and a cushion clip assembly (not shown) which is not incorporated in the UltraMirage™ cushion design.” Ex. 1410 ¶ 31.  Fig. 1 “The upper part 460 of the cushion may include a thin membrane (the lower cushion may be like a double wall Vista™ cushion). This has the advantage of reduced weight and subjectively feels light to wear. It may also allow deflection around contours of nose as it will be more flexible than a conventional thick cushion.” *Id.* ¶ 59.

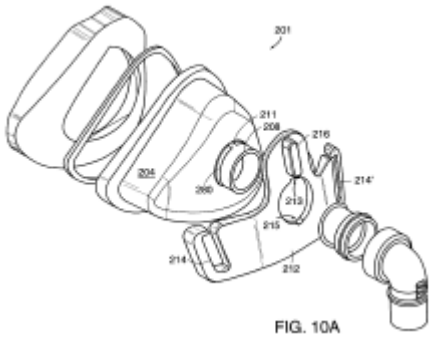
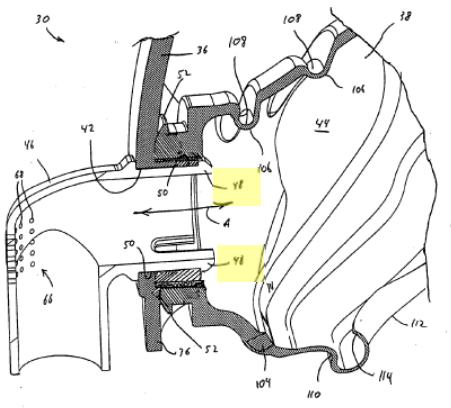
’931 Patent	Prior Art
	“In an alternative, the upper part 460 of the cushion shown in Fig. 24 includes a bellows type arrangement around the cushion which may be inflated to help pressure and fit, like the ResMed Activa™ mask, described in U.S. Patent No. 4,772,760 and U.S. application no. 10/655,622, filed September 5, 2003, each incorporated herein by reference in its entirety.” *Id*. ¶ 60.  Fig. 24

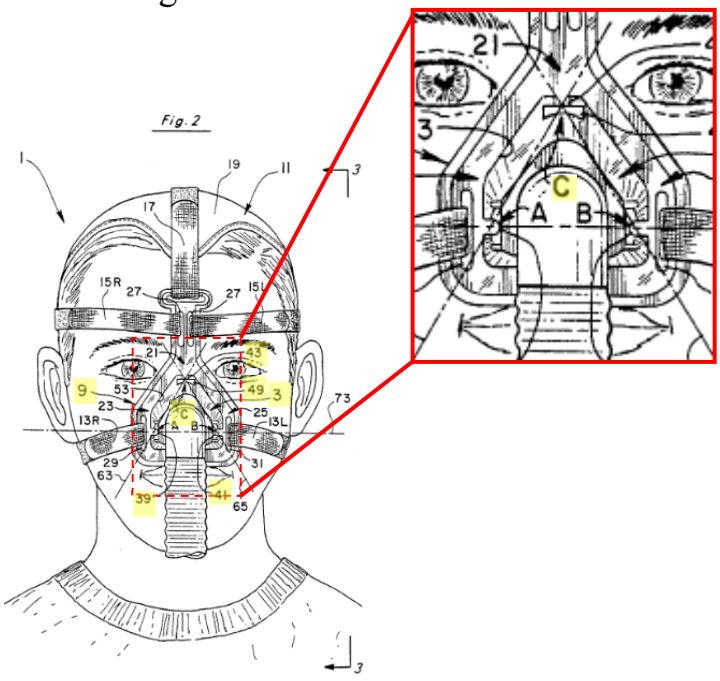
’931 Patent	Prior Art
	Matula-II: “[S]eal member 38 includes at least one pleat 106 (which can also be referred to as a fold or gusset) provided at a portion of the seal member so that the seal member has the desired degree of flexibility. In this case, pleats 106 are provided at and upper portion of the seal member so that this portion of the seal member can expand and contract with adjustment of the adjustment mechanism.” Ex. 1412 ¶ 66. “Pleats 106 are oriented such that the pleat protrudes into chamber 44 with a channel 108 defined on the exterior surface of the seal member.” *Id*.  Fig. 4

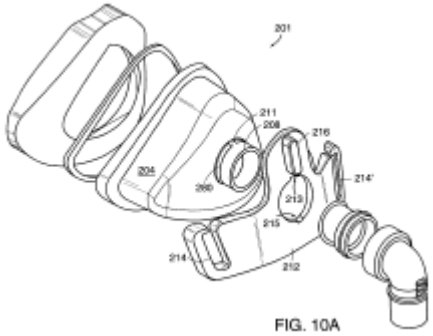
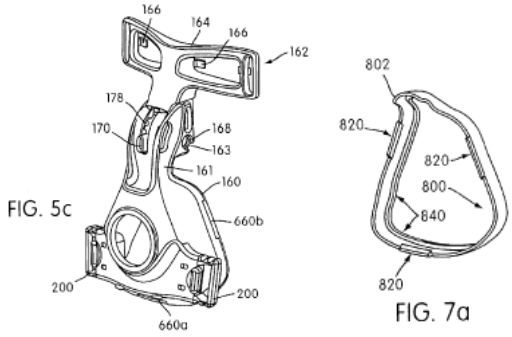
’931 Patent	Prior Art
	Melidis: “[S]ealing lip is elastically yieldingly arranged in such a way that in the region of the bridge of the nose there is a higher degree of flexibility than in the region of the nostrils and/or the upper lip.” Ex. 1424 at col. 1:40–43. “This embodiment also has a local folding bellows structure 9. . . . . [I]ndentation depth t in the region of the end towards the bridge of the nose is larger than in the other regions.” *Id.* at col. 8:30–35; *see also id.* at col. 8:18–20, 8:56–59.  Fig.2 **Frater:** “As described above in relation to Fig. 29, for example, these portions of the gusset have various profiles in order to tailor the amount of force which is applied to the particular region of the patient's face, depending on the sensitivity of the patient's face as well as the required sealing forces thereof. Fig. 51 is a side profile view of the mask assembly 900.” Ex. 1425 ¶¶ 163–164.  Fig. 51

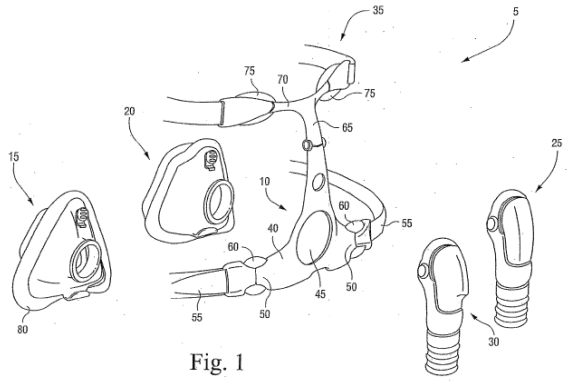
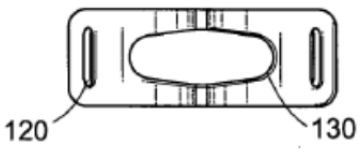
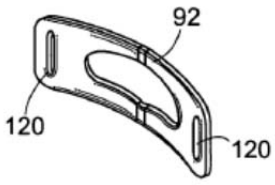
’931 Patent	Prior Art
	Lithgow: “The contact force applied to the contact line on the patient’s face can be further tailored by adjusting a thickness of the arcuate wall 56 of the gusset portion, as shown in FIGS. 6, 6C, and 13A-C. The arcuate wall 56 acts as a spring structure to provide a component of the contact force on the patient’s face through the membrane 40.” Ex. 1433 ¶ 133. “The gusset portion 50 can be provided in only selected regions of the face, and not others. It need not be provided along the entire perimeter of the cushion. For example, the gusset portion 50 could be provided along only the lip portion.” *Id.* ¶ 130.  FIG. 6C

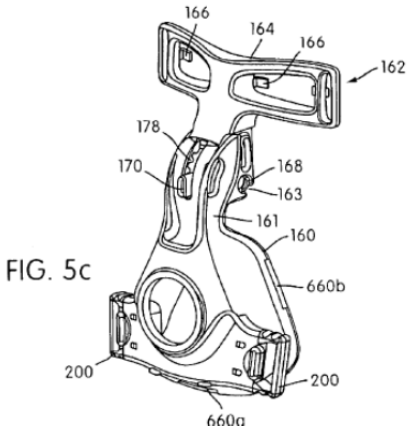
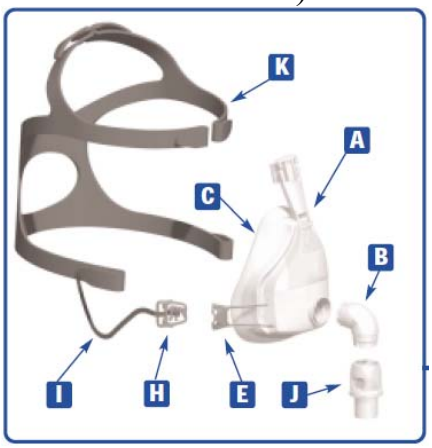
’931 Patent	Prior Art
5. The mask system of claim 1, **[A]** wherein the frame includes a collar surrounding said frame opening, and	**Ng**: The cushion frame includes an annular collar around the opening. *See* Ex. 1410 at Fig. 1.  Fig. 1 **Matula-II:** “[T]he end of seal member 38 is joined to a ring 52 that is more rigid than the end of the seal member to provide a strong, stable mechanical coupling of the seal member to the faceplate.” Ex. 1412 ¶ 53.  Fig. 4

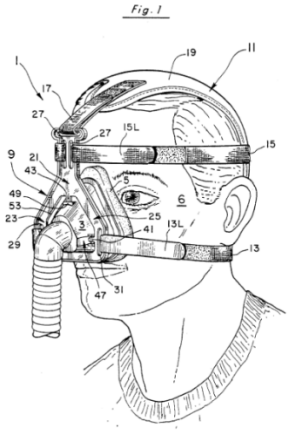
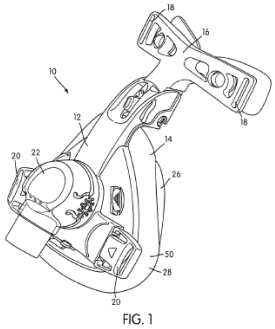
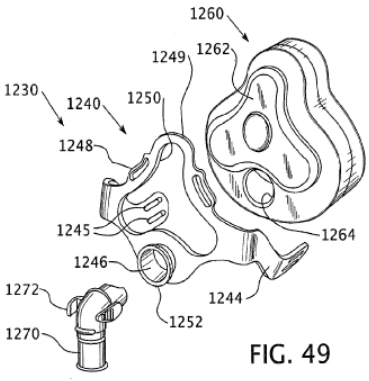
’931 Patent	Prior Art
	Lovell: “The retainer aperture and the inlet 208 are generally sized in an interference fit so that the retainer 212 is properly retained by the cooperation of the tabs 211, 211', the slots 213, 215, and the depressed annular region 280 when fully seated against the shell 204.” Ex. 1426 at col. 9:59-64; *see also id.* at col. 9:43-48.  FIG. 10A
[B] wherein the shroud includes a retaining portion with a plurality snap fingers structured to engage the collar with a snap-fit.	**Matula-II:** “Coupling member 46 includes a pair of prongs 48 that define a channel 50 to receive the wall of the faceplate and the end of seal member 38.” Ex. 1412 ¶ 53. A person of skill in the art would have understood that the “prongs” of Matula-II could also be referred to as “snap fingers.”  Fig. 4

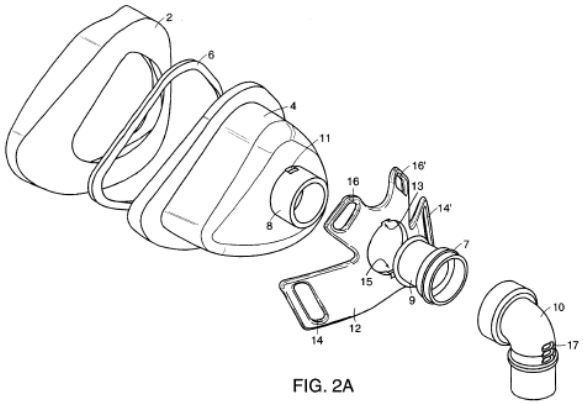
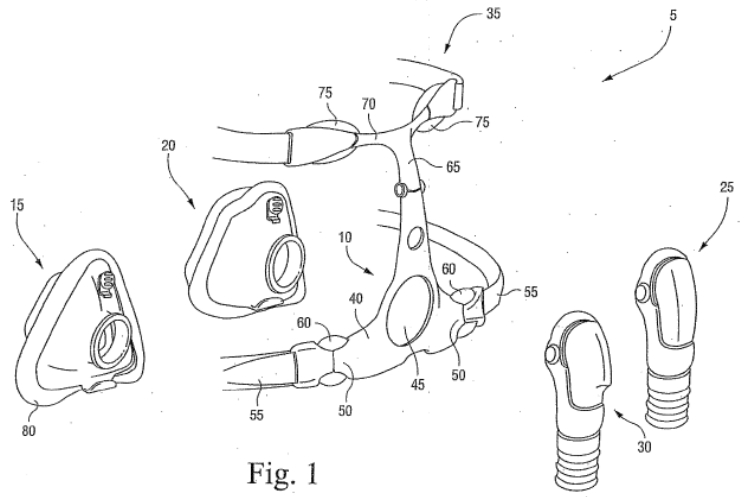
’931 Patent	Prior Art
	Ogden: “[R]igid plate 9 is preferably mounted to the rigid shell 3 at first, second, and third locations A, B, and C. . . . Further, although the detent-channel 43, 49 at the top of the shell 3 at the third location C is preferably dimensioned to snap together to hold or maintain the rigid plate 9 on the rigid shell 3.” Ex. 1422 at col. 4:59—5:19. 

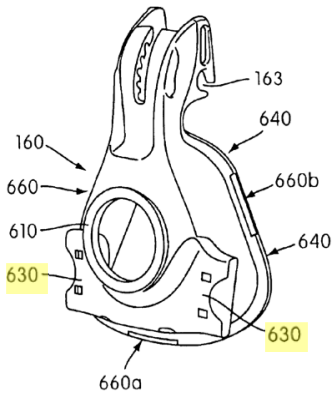
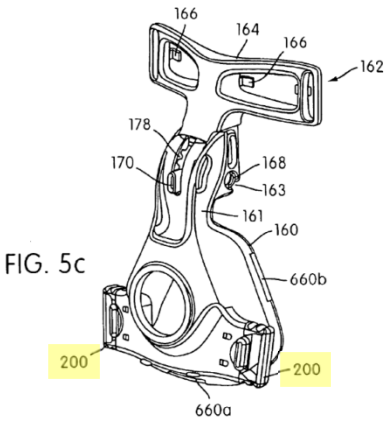
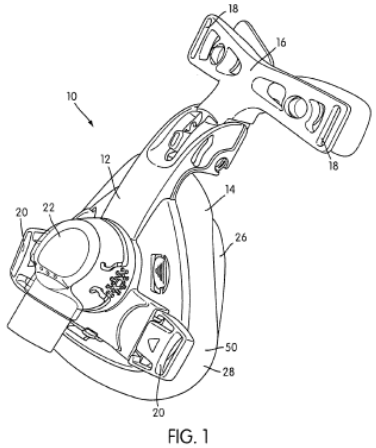
’931 Patent	Prior Art
	Lovell: “The retainer 212 is disposed about the inlet 208 to facilitate retention of the mask 201 on a user. . . . Two tabs 211, 211' included on the inlet 208 mate with two slots 213, 215 formed in the retainer 212 in a particular angular orientation. . . . The retainer aperture and the inlet 208 are generally sized in an interference fit so that the retainer 212 is properly retained by the cooperation of the tabs 211, 211', the slots 213, 215, and the depressed annular region 280 when fully seated against the shell 204.” Ex. 1426 at col. 9:43–48, 9:59–64.  FIG. 10A **Gunaratnam-I:** “[T]he 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). 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. 1413 at col. 5:34–43.  FIG. 5c FIG. 7a

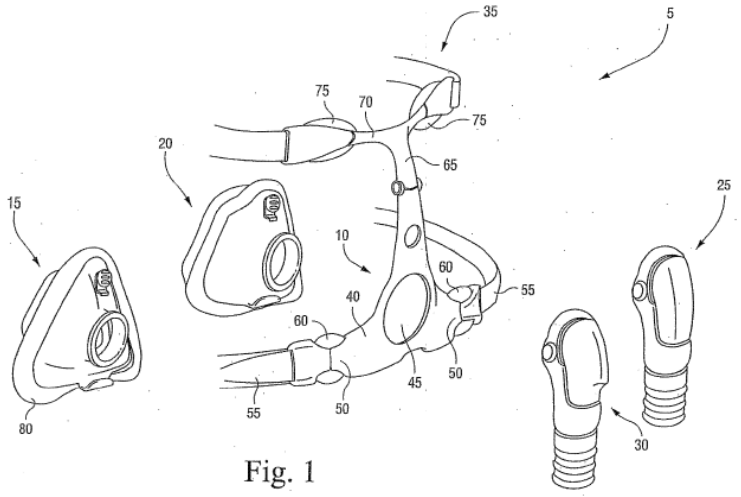
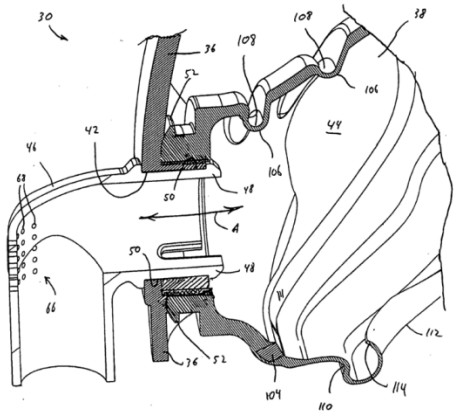
’931 Patent	Prior Art
6. The mask system of claim 1, wherein the shroud module includes upper and lower headgear connectors on each side of the shroud module.	**Ng:** “The common frame 10 has a main body 40 defining a central opening 45. Main body 40 includes at least two lateral arms 50, each of which can be coupled to a headgear strap 55 of headgear. The straps may be connected to the frame using a press-fit connector 60, as is known in the art. Common frame 10 may also include a forehead support 65 that has a bridge 70 provided with forehead pads 75 to rest against the user’s forehead in use.” Ex. 1410 ¶ 30.  Fig. 1
7. The mask system of claim 6, wherein each upper headgear connector includes a slot adapted to receive a respective headgear strap in use.	**Thomlinson:** “As shown in FIG. 28B, strap attachment plate 92 . . . includes one or more strap connections 120 for receiving a strap system 102.” Ex. 1411 ¶ 306.  Fig. 28D  Fig. 28A

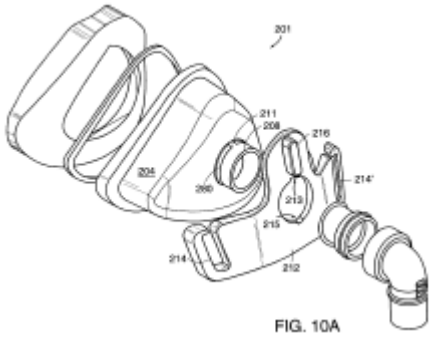
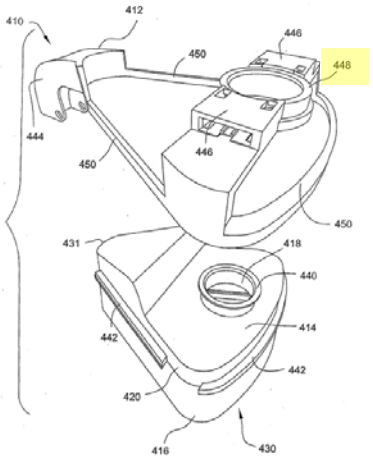
’931 Patent	Prior Art
	Gunaratnam-I: “As compared to FIGS. 5a-5b, FIGS. 5c-5f also show an adjustable forehead support (162) connected to the frame (160).” Ex. 1413 at col. 4:46–48.  FIG. 5c **FlexiFit:** “[A]ttach the four straps in to the corresponding slots in the Mask Base.” Ex. 1417 at 10 (“ASSEMBLING YOUR MASK”). 

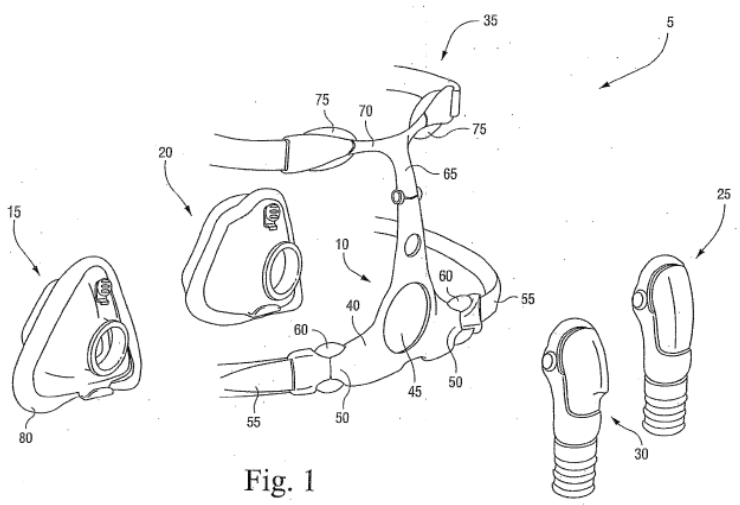
’931 Patent	Prior Art
	Ogden: “The upper side straps in this last regard could be the two straps 15R and 15L as illustrated or one continuous strap passing through loops 27 and anchoring the top portion 21 of the rigid plate 9 (see FIGS. 1-3).” Ex. 1422 at col. 3:7–10.  **Lithgow:** *See* Ex. 1433 at Fig. 1.  **Matula-I:** “[A]ttachment elements 1248 are provided in the form of slots provided . . . [o]n a central portion 1249 of the body member.” Ex. 1423 ¶ 103. 

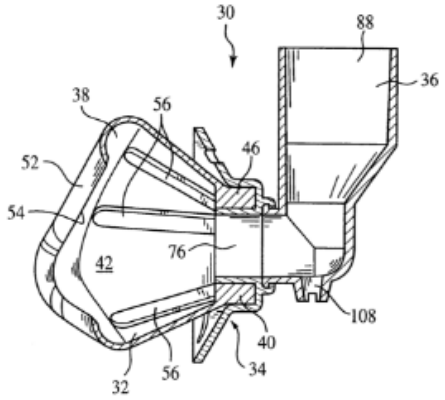
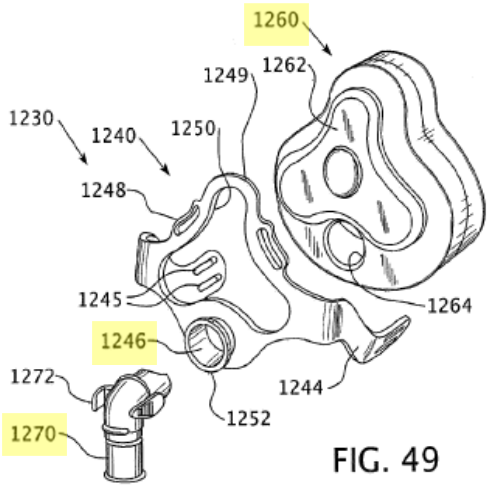
’931 Patent	Prior Art
	Lovell: “These connection points 14, 14', 16, 16' form slots which allow for connection of the retainer 12 with straps of a headgear apparatus, as shown in FIG. 3.” Ex. 1426 at col. 6:10–13.  FIG. 2A
8. The mask system of claim 7, wherein each lower headgear connector is adapted to be removably interlocked with a headgear clip associated with a respective headgear strap.	**Ng:** “Main body 40 includes at least two lateral arms 50, each of which can be coupled to a headgear strap 55 of headgear. The straps may be connected to the frame using a press-fit connector 60, as is known in the art.” Ex. 1410 ¶ 30.  Fig. 1

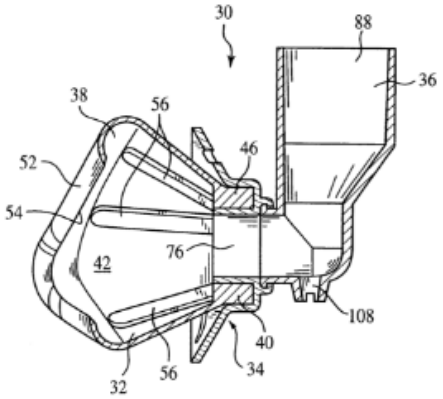
’931 Patent	Prior Art
	Gunaratnam-I: “On the front surface of the frame, are strap connection points (630) for connection of the mask to patient headgear. Connectors (200) are shown in FIGS. 5c-5f.” Ex. 1413 at col. 4:31–33.  FIG. 5a  FIG. 5c **Ultra Mirage:** “Quick release headgear clips: top and bottom.” Ex. 1416 at 6. **Lithgow:** “For example, the headgear assembly may include a pair of upper and lower straps with the upper straps removably connected to clip structures 18 provided on the forehead support 16 and the lower straps removably connected to clip structures 20 provided on the frame 12.” Ex. 1433 ¶ 111.  FIG. 1

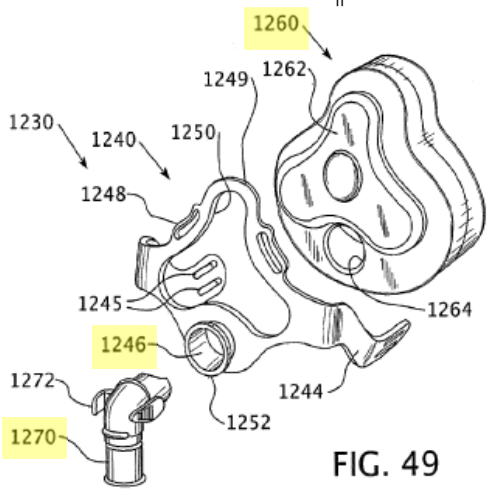
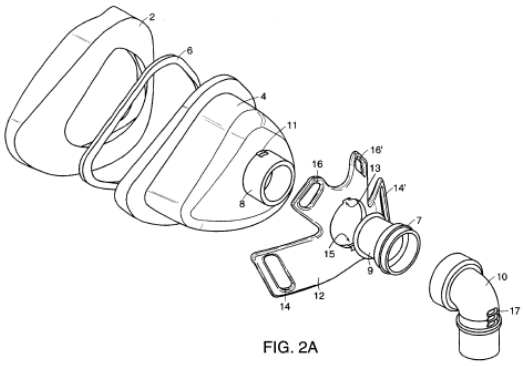
’931 Patent	Prior Art
10. The mask system of claim 1, wherein the shroud module includes an annular or part annular cushion retaining portion structured to retain the cushion module.	**Ng:** “Common frame 10 is configured to be selectively coupled to one of cushion components 15, 20 and to one of elbow components 25, 30.” Ex. 1410 ¶ 31. “The common frame 10 has a main body 40 defining a central opening 45.” *Id*. ¶ 30.  Fig. 1 **Matula-II:** *See* Ex. 1412 at Fig. 4.  Fig. 4

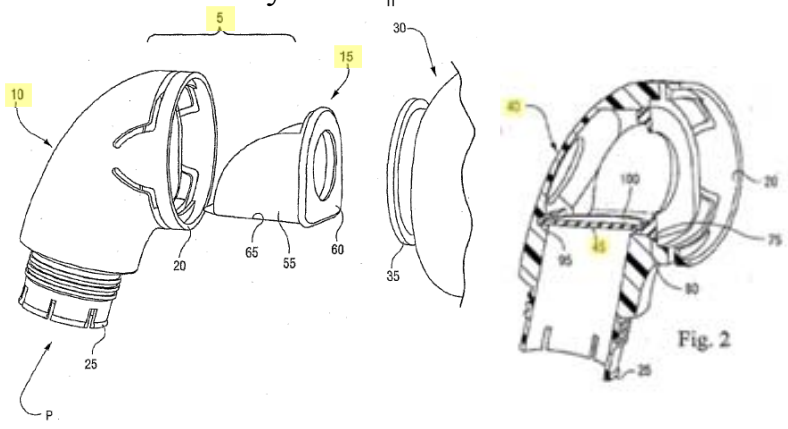
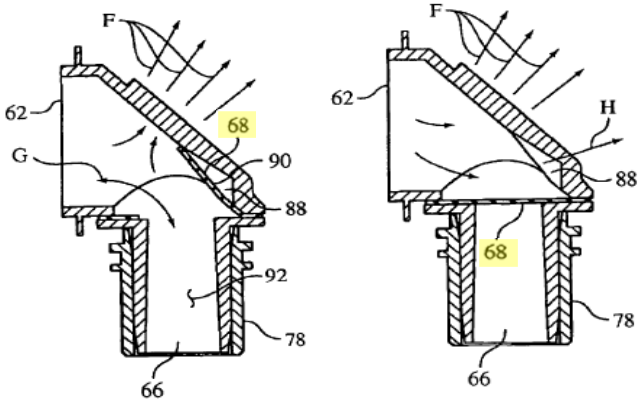
’931 Patent	Prior Art
	Lovell: “The retainer 212 is disposed about the inlet 208 to facilitate retention of the mask 201 on a user.” Ex. 1426 at col. 9:43–44.  FIG. 10A **D’Souza:** “[A]nnular elbow connection seal 448 interlocks with the annular wall 440 of the cushion/frame sub-assembly 430.” Ex. 1420 ¶ 101.  Fig. 7

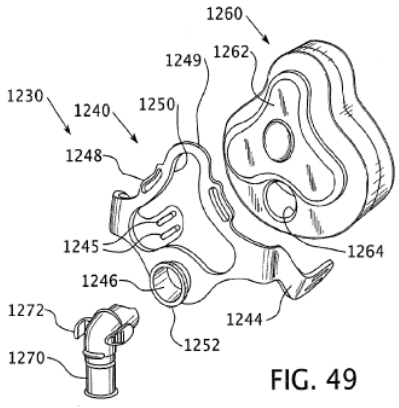
’931 Patent	Prior Art
11. The mask system of claim 1, further comprising an elbow module adapted to be connected to an air delivery tube that delivers breathable gas to the patient.	**Ng:** “Mask system includes a common frame component 10, one of two cushion components 15, 20, one of two elbow components 25, 30, and headgear 35. The mask system is intended for use in positive pressure therapy for users with obstructive sleep apnea (OSA) or another respiratory disorder.” Ex. 1410 ¶ 29.  Fig. 1 **Thomlinson:** “In one embodiment, the present invention includes tubing 90, shown in FIGS. 26, 27, 29 and 35 through 38. Tubing 90 can supply gas to the nasal interface of the present invention.” Ex. 1411 ¶ 316.

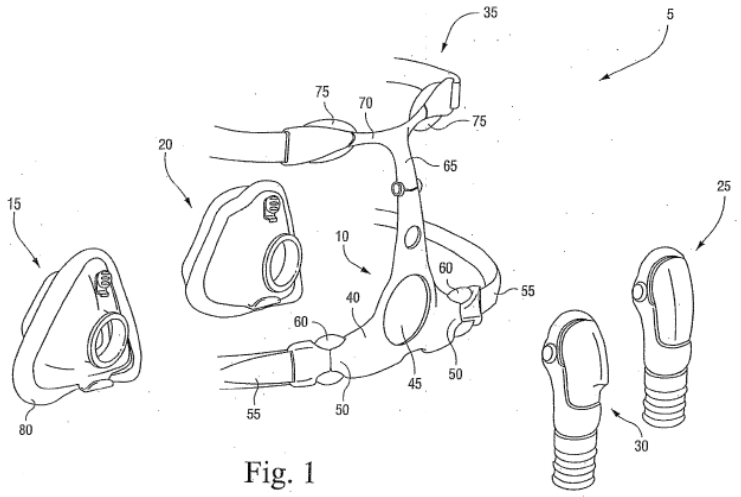
’931 Patent	Prior Art
12. The mask system of claim 11, wherein the elbow module is provided to the shroud module.	**Ng:** “Common frame 10 is configured to be selectively coupled to one of cushion components 15, 20 and to one of elbow components 25, 30.” Ex. 1410 ¶ 31. **Barnett:** “[C]onduit coupling member 36 is preferably rotateably mounted on a second side of collar 34 opposite the first side so that conduit coupling member 36 freely rotates over a range of 360° about a central axis of collar 34.” Ex. 1414 at col. 3:52–57; *see also id.* at col. 8:66—9:43.  FIG. 1A **Matula-I:** “Circuit coupling portion 1246 provides a connection to a patient circuit coupling 1270.” Ex. 1423 ¶ 105.  FIG. 49

’931 Patent	Prior Art
13. The mask system of claim 11, wherein the elbow module comprises polycarbonate.	**Worboys:** “The elbow 10 can be made from a relatively rigid material, such as polycarbonate or other plastic.” Ex. 1415 ¶ 105. **Lovell:** “[C]onduit elbow 10 also can be manufactured from . . . polycarbonate.” Ex. 1426 at col. 5:33–35.
14. The mask system of claim 11, wherein the elbow module and the shroud module are directly connected with a mechanical interlock while allowing 360 degree rotation of the elbow module.	**Ng:** “Common frame 10 is configured to be selectively coupled to one of cushion components 15, 20 and to one of elbow components 25, 30.” Ex. 1410 ¶ 31. **Barnett:** “[C]onduit coupling member 36 is preferably rotateably mounted on a second side of collar 34 opposite the first side so that conduit coupling member 36 freely rotates over a range of 360° about a central axis of collar 34.” Ex. 1414 at col. 3:52–57; *see also id.* at col. 8:66—9:43.  FIG. 1A **Ultra Mirage:** “360° rotating elbow provides control over tubing system.” Ex. 1416 at 6.

’931 Patent	Prior Art
	Matula-I: “[P]atient circuit coupling 1270 is an elbow coupling that rotatably and releasably attaches to circuit coupling portion 1246.” Ex. 1423 ¶ 105.  FIG. 49 **Lovell:** “[S]wivel connector 9 produces a swivel mount connection between the conduit elbow 10 and the inlet 8. In this type of connection, the conduit elbow 10 is capable of rotating 360 degrees about the centerline of the inlet 8 and the connector 9.” Ex. 1426 at col. 5:20–24.  FIG. 2A

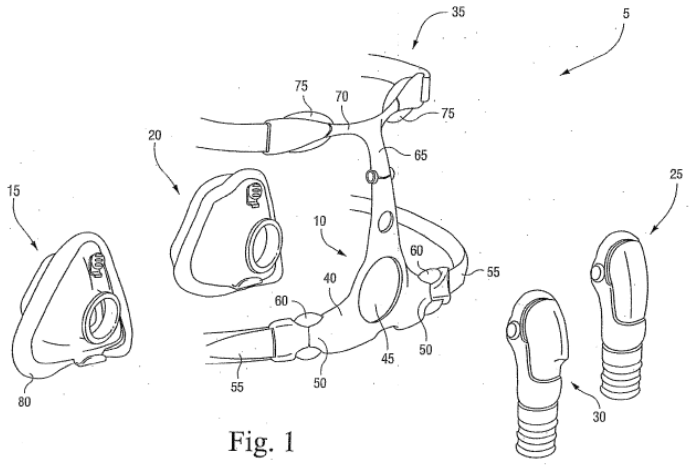
’931 Patent	Prior Art
15. The mask system of claim 11, wherein the elbow module includes an anti-asphyxia valve and wherein the anti-asphyxia valve includes a flap portion adapted to selectively close a port provided in the elbow module.	**Worboys:** “[E]lbow assembly 5 generally comprises an elbow 10 and an anti–asphyxia valve 15 (AAV) assembly.” Ex. 1415 ¶ 103. “[E]lbow 10 includes a port 40 that may be selectively closed by a flap portion 45 of the AAV assembly.” *Id*. ¶ 106.  Fig. 1 **Jaffre:** “It is common when using a full face mask, to provide a valve in the patient circuit that automatically allows the patient access to the ambient atmosphere in the event of a failure of the pressure support system. See, e.g. U.S. Pat. No. 5,438,981, which teaches the function of such a valve and describes several embodiments of such a valve.” Ex. 1427 at col. 10:4–10.  FIG. 8 FIG. 9

’931 Patent	Prior Art
	“During normal use, where the pressure support system is functioning properly, a cantilever member 90 of valve member 68 flexes, as shown to FIG. 8, to block auxiliary opening 88. If the gas pressure in an interior 92 of the conduit is greater than the ambient atmosphere, cantilever member 90 moves to the position shown in FIG. 8 to block opening 88, so that gas is able to flow between the patient and the pressure generating system, as indicated by arrow G.” *Id.* at col. 10:14–22. **Matula-I:** “[T]he present invention contemplates providing an entrainment valve and/or exhaust assembly on patient circuit coupling 1270. . . . the exhaust assembl[y] can be provided at other locations, such as in the patient interface portion [1260], the body member, or in any combination of locations.” Ex. 1423 ¶ 106.  FIG. 49

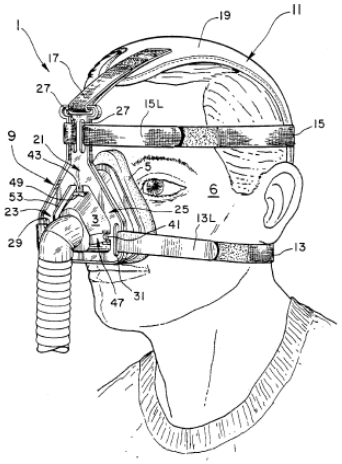
’931 Patent	Prior Art
16. The mask system of claim 1, wherein the cushion module includes at least first and second cushion modules adapted to be provided to the shroud module, said at least first and second cushion modules being different from one another in at least one aspect.	**Ng:** “Common frame 10 is configured to be selectively coupled to one of cushion components 15, 20 and to one of elbow components 25, 30. Cushion components 15, 20 differ in at least one respect such that one may be more optimal or preferable for use with one user, while another may be more suitable or preferably for use with another user. For example, cushion component 15 may be an Activa™ component, while cushion component 20 may be an UltraMirage™ Series II cushion component, both available from ResMed. These cushion components can be significantly different from one another, e.g., the Activa™ includes a gusset portion 80 and a cushion clip assembly (not shown) which is not incorporated in the UltraMirage™ cushion design.” Ex. 1410 ¶ 31.  Fig. 1
17. The mask system of claim 1 comprising a small cushion module, a medium cushion module and a large cushion module, wherein each of said small cushion module, said medium cushion	**Ultra Mirage:** Brochure provides product codes for small, medium, and large sizes. Ex. 1416 at 7, 9.

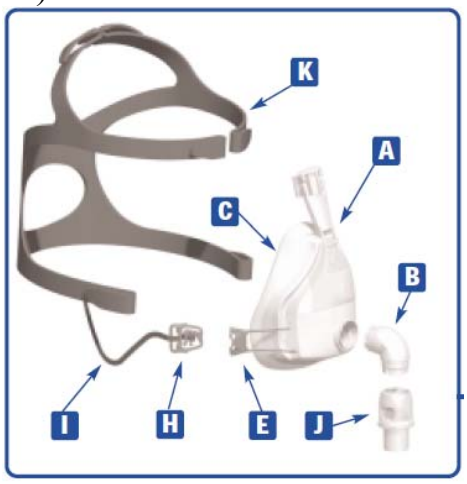
’931 Patent	Prior Art
module and said large cushion module is removably coupleable to the same shroud module.	**Ging:** “It is to be understood that these dimensions refer to a particular embodiment of the invention, and a differently sized mask (for example, a “small” size versus a “large” size) while having the same shape would have different dimensions and nevertheless be within the scope of the invention. Further, while the “standard” size cushion, “deep” size cushion, and “wide/shallow” size cushion may be provided individually, these cushions may be provided together as a set of cushions. This set of three cushions provides a good fit in a wide range of patients without having an excessive inventory.” Ex. 1431 ¶ 193. **Barnett:** The seal members 32, 32’ differ in the “contour of the first end portion, size, and shape … [and] can be used in conjunction with a commonly sized collar 34.” Ex. 1414 at col. 6:1–13. **Ho:** “While the present invention has been described above as having a cushion that encapsulates the nasal region, it is to be understood that the present invention contemplates using other types of devices in conjunction with support body 36. For example, larger cushions that encapsulate the nose and mouth can be attached to the support body. Conversely, smaller cushions, or nasal prongs, that seal in or near the nares can be supported by the support body. In short, any interface suitable for sealing against the user can be used in the mask assembly of the present invention.” Ex. 1430 ¶ 36. **FlexiFit:** “If leaks persist, change to the alternate size Silicone Seal, which is found in your FlexiFit™ HC431 Mask box.” Ex. 1417 at 10 (“FITTING YOUR MASK”).

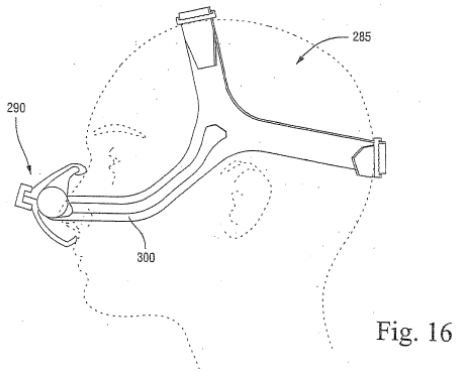
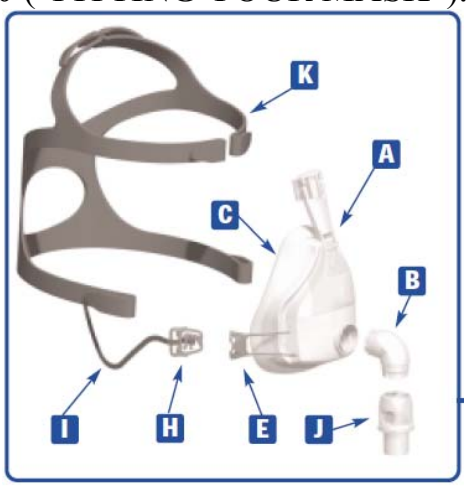
’931 Patent	Prior Art
18. The mask system of claim 1, wherein the shroud module and the frame comprise polycarbonate and the cushion comprises silicone.	**Gunaratnam-I:** “The frame may be constructed from a material such as polycarbonate . . . . The soft cushion may be constructed from a material such as silicone.” Ex. 1413 at col. 1:34–39. “The clip is conducted from polycarbonate or similar material.” *Id.* at col. 5:33–34. **Lovell:** “The retainer 12 can be constructed from . . . polycarbonate.” Ex. 1426 at col. 6:13–14. “[T]he seal 2 is a bladder that is . . . filled with a soft material 62. . . . For example, certain types of silicone gel meet this durometer value.” *Id*. at col. 7:46–53. **D’Souza:** “[C]ushion 416 is constructed of liquid silicone rubber (LSR).” Ex. 1420 ¶ 97. “[T]he frame 414 is constructed of polycarbonate.” *Id*. ¶ 98. “[T]he skeleton frame 412 is formed of plastic.” *Id.* ¶ 100. **McAuley:** “The hollow body 30 and insert 32 are injection moulded in a relatively inflexible material, for example, polycarbonate plastic. Such a material would provide the requisite rigidity for the mask as well as being transparent and a relatively good insulator.” Ex. 1432 at 6:21–24. **Lithgow:** “The cushion 14 is constructed from a soft, flexible skin-compatible material such as silicone.” Ex. 1433 ¶ 139.

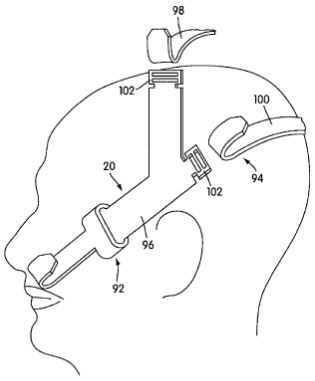
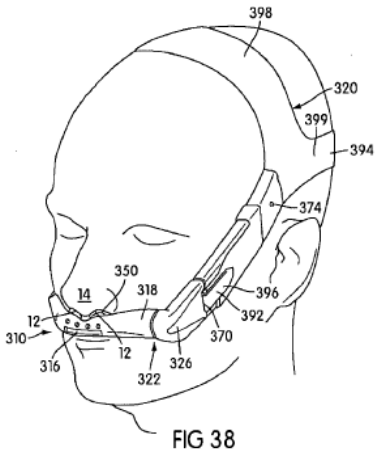
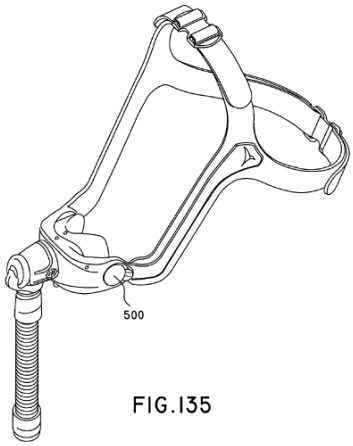
’931 Patent	Prior Art
19. The mask system of claim 1, wherein: **[A]** the headgear includes a pair of upper straps and pair of lower straps, with the upper straps being removably attached to respective ones of the headgear connectors and the lower straps being connected to respective ones of the headgear connectors,	*See supra* Claim 1(i). **Ng:** “The common frame 10 has a main body 40 defining a central opening 45. Main body 40 includes at least two lateral arms 50, each of which can be coupled to a headgear strap 55 of headgear. The straps may be connected to the frame using a press-fit connector 60, as is known in the art. Common frame 10 may also include a forehead support 65 that has a bridge 70 provided with forehead pads 75 to rest against the user’s forehead in use.” Ex. 1410 ¶ 30.  Fig. 1 **Thomlinson:** “Strap attachment plate 92 can facilitate the use of a strap system 102 by increasing the ease at which a strap can be connected to or removed from the nasal interface. Because the strap attachment plate is not integral to the nasal interface, the strap attachment plate, and any attached straps, can be more easily added or removed from the system.” Ex. 1411 ¶ 307. “A strap system can be fasted/unfastened using alternative methods to Velcro, such as snaps, buckles, buttons and ties.” *Id*. ¶ 312.

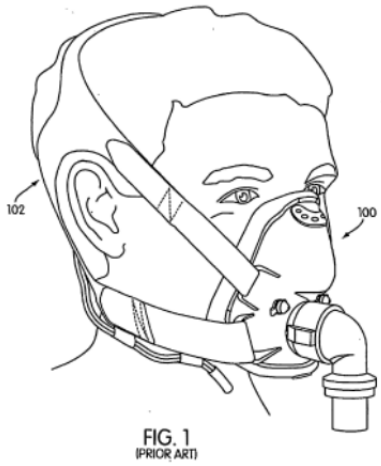
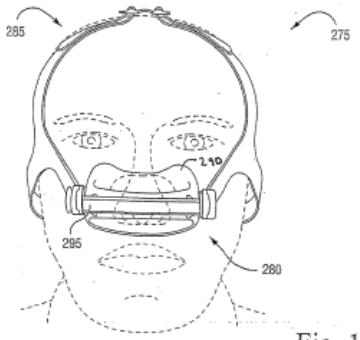
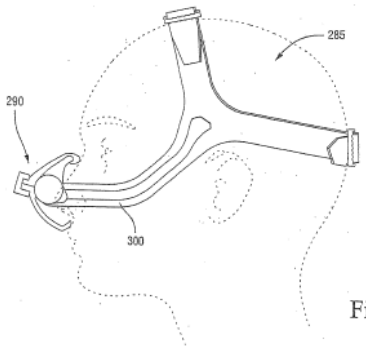
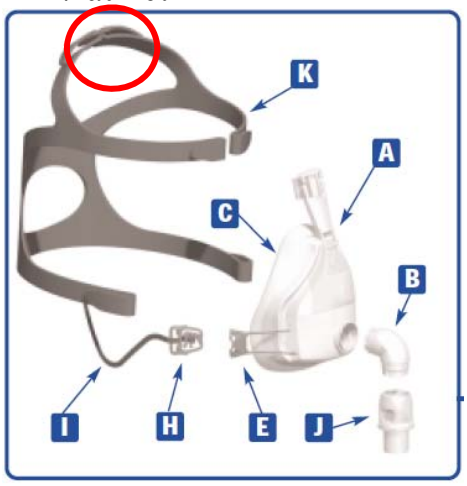
’931 Patent	Prior Art
	FlexiFit: “2) Unclip the Headgear (K) from the Glider™ strap (E) . . . . 4) Re-attach the Headgear Clip (H) to the Glider™ Strap. 5) Gently adjust the Top Horizontal straps then the Lower Horizontal straps.” Ex. 1417 at 10 (“FITTING YOUR MASK”). “[A]ttach the four straps in to the corresponding slots in the Mask Base and the Glider™ strap (E).” *Id.* at 10 (“ASSEMBLING YOUR MASK”). 

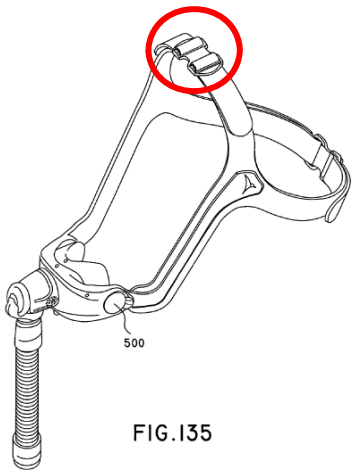
’931 Patent	Prior Art
	Ogden: “[E]ach side strap 13R and 13L is preferably attached to a respective side portion 23, 25 of the rigid plate 9 on respective sides of the patient's nose 2. This can be done in any number of well-known, adjustable manners including . . . hook and loop materials on the straps themselves. . . . The remaining straps 15R, 15L, and 17 are also individually attachable in this manner.” Ex. 1422 at col. 3:10–20. Fig. 1 
[B] a free end of each of the upper straps and the lower straps includes a hook tab structured to engage a remainder of the respective upper strap and respective lower strap to secure the upper and lower straps in place in a length adjustable manner,	**Ng:** “Each strap includes hook and loop fastening elements, e.g., Velcro®.” Ex. 1410 ¶ 67.

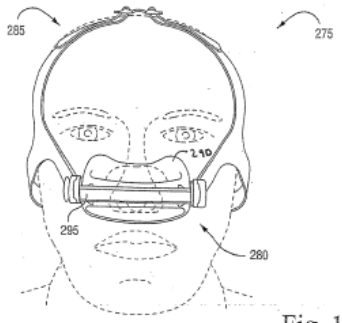
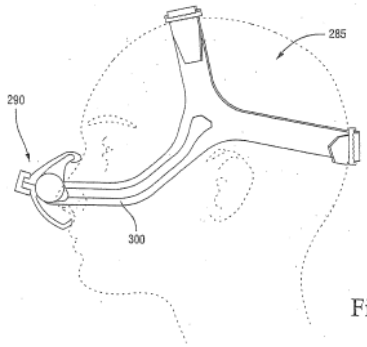
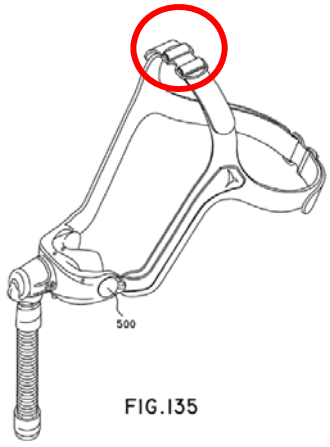
’931 Patent	Prior Art
	FlexiFit: “Gently adjust the Top Horizontal straps then the Lower Horizontal straps . . . . If leaks occur . . . tighten the top horizontal straps. . . . If leaks occur . . . tighten the lower horizontal straps.” Ex. 1417 at 10 (“FITTING YOUR MASK”). “[A]ttach the four straps in to the corresponding slots in the Mask Base and the Glider™ strap (E). This can be done without undoing the Velcro® Tabs by sliding the Headgear into the slots.” *Id.* at 10 (“ASSEMBLING YOUR MASK”).  **Ogden:** “[E]ach side strap 13R and 13L is preferably attached to a respective side portion 23, 25 of the rigid plate 9 on respective sides of the patient's nose 2. This can be done in any number of well-known, adjustable manners including . . . hook and loop materials on the straps themselves. . . . The remaining straps 15R, 15L, and 17 are also individually attachable in this manner.” Ex. 1422 at col. 3:10–20. **Amarasinghe:** “At the end of each strap is secured a piece of hook material, which, in use, passes through a headgear attachment point and fastens on corresponding loop material on the strap.” Ex. 1428 ¶ 12.

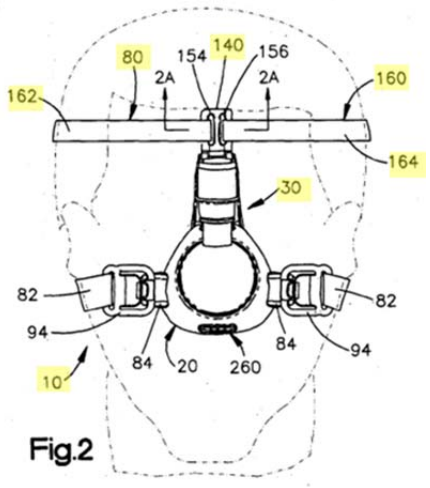
’931 Patent	Prior Art
	Lovell: “A hook and loop fastener system can be used to maintain the straps 59, 58 at a desired adjustment. The loops may be located along the majority of the lengths of the straps 59, 58 to provide a wide range of adjustment, with the hooks being located on the distal tip portions of the straps 59, 58, such that when the distal tip of a strap is passed through a slot in a connector, the strap folds over on itself and the hooks engage the loops.” Ex. 1426 at col. 7:6–13.
[C] the upper straps split to form a pair of top straps and a pair of rear straps,	**Ng:** *See* Ex. 1410 at Fig. 16.  Fig. 16 **FlexiFit:** “Gently adjust . . . Top Crown straps.” Ex. 1417 at 10 (“FITTING YOUR MASK”). 

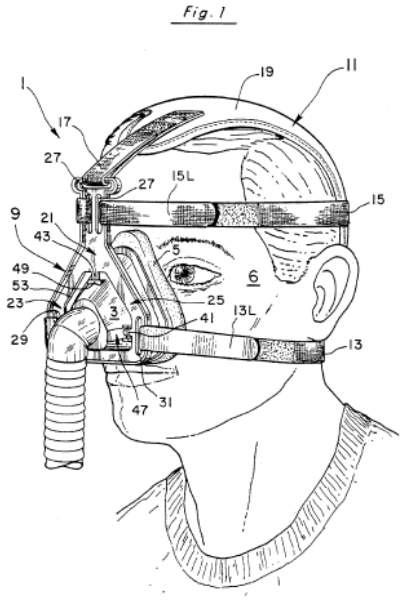
’931 Patent	Prior Art
	Gunaratnam-II: “The upper strap 98 and rear strap 100 are removably connected to the side straps 96 by buckles 102 provided on the side straps 96.” Ex. 1429 ¶ 211.  FIG. 18 “The rear portion 394, which interconnects the two side portions 392, includes an upper strap 398 that passes over the top of the patient's head and a rear strap 399 that passes around the rear portion of the patient's head.” *Id.* ¶ 263 and Figs. 38 and 135.  FIG 38  FIG.135

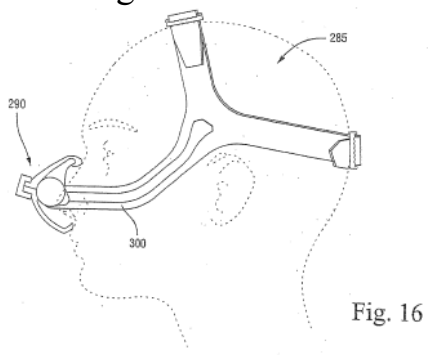
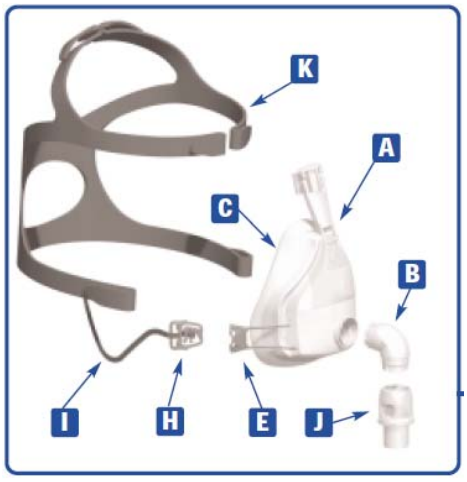
’931 Patent	Prior Art
	Amarasinghe: *See* Ex. 1428 at Fig. 1.  FIG. 1 (PRIOR ART)
[D] the top straps being connected together by a buckle and configured to pass over the top of the patient's head in use, the rear straps being adapted to pass behind the patient's head in use,	**Ng:** *See* Ex. 1410 at Figs. 15 and 16.  Fig. 15  Fig. 16 **FlexiFit:** Ex. 1417 at 10. 

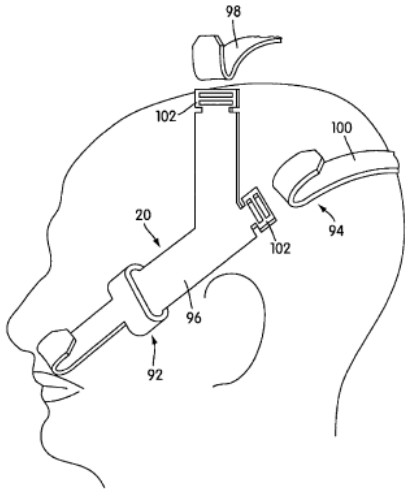
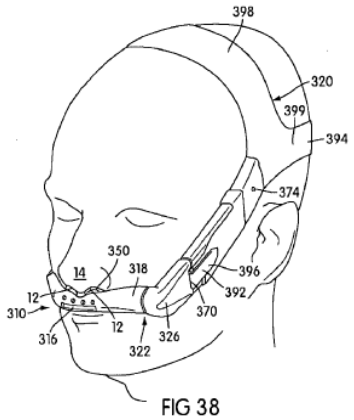
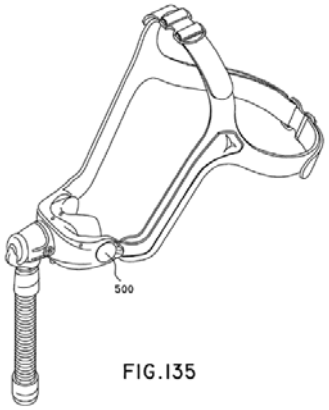
’931 Patent	Prior Art
	Gunaratnam-II: “[U]pper straps 598 are coupled to one another by a headgear buckle 570.” Ex. 1429 ¶ 316, Fig. 135.  FIG.135

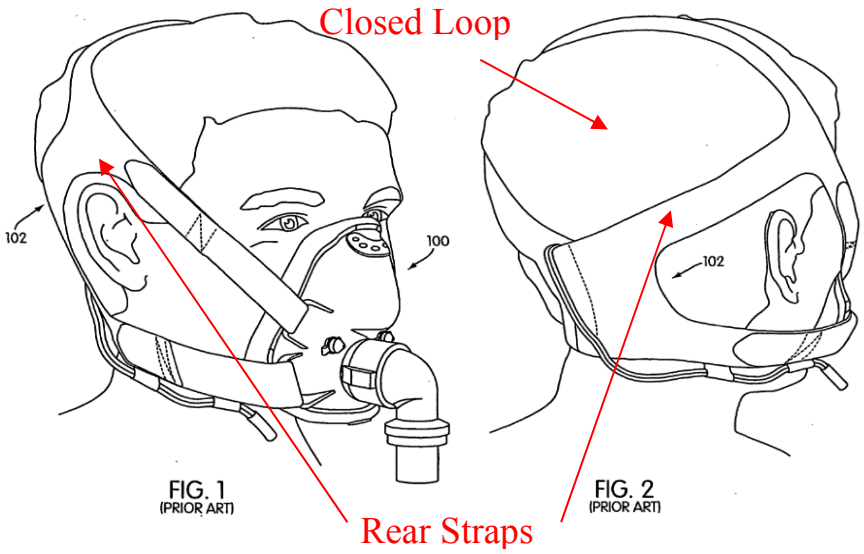
’931 Patent	Prior Art
[E] and a free end of each of the top straps has a hook tab threaded through the buckle to engage a remainder of the respective top strap to secure the top straps in place relative to the buckle in a length adjustable manner.	**Ng**: “Further, as shown in Fig. 16, the vectors formed by the headgear straps 300 are slightly different than as shown in described in relation to Fig. 13.” Ex. 1410 ¶ 46. “Each strap includes hook and loop fastening elements, e.g., Velcro®.” *Id.* ¶ 67.  Fig. 15  Fig. 16 **FlexiFit:** Ex. 1417 at 10.  **Gunaratnam-II:** “[U]pper straps 598 are coupled to one another by a headgear buckle 570.” Ex. 1429 ¶ 316, Fig. 135.  FIG.135

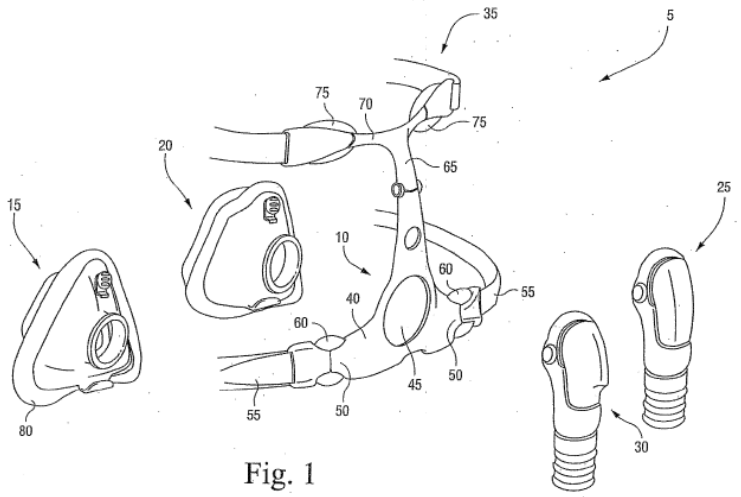
’931 Patent	Prior Art
20. The mask system of claim 19, wherein the upper straps provide padding to the respective headgear connectors of the shroud module on the patient's face in use.	**Sprinkle:** “When the left and right straps 162 and 164 are connected with the forehead adjuster 140 in this manner, a relatively large amount of strap material is present between the forehead adjuster 140 and the user's forehead. This strap material, as mentioned above, is resilient. Therefore, a substantial cushion is present between the forehead support assembly 30 and the user's forehead. This cushion provides a very comfortable strap attachment, without the necessity for separate cushion members or cushioning pieces on the adjuster 140.” Ex. 1419 ¶ 74, *see also id.* ¶¶ 3, 72.  Fig.2

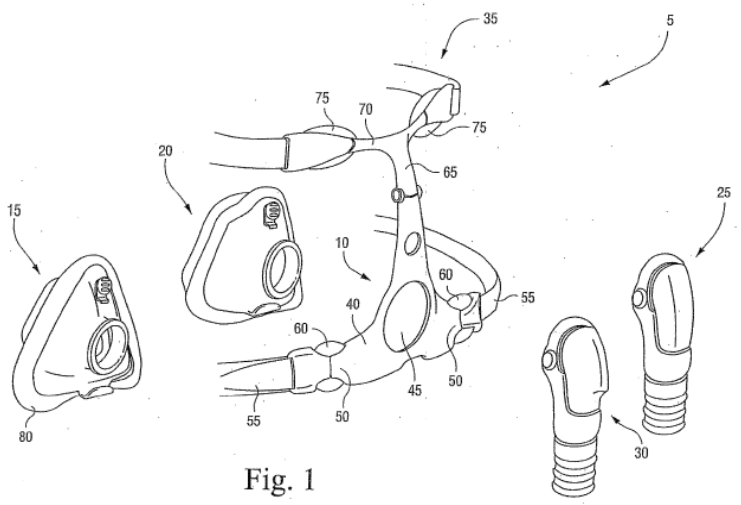
’931 Patent	Prior Art
	Ogden: “[L]ooping the straps 13R and 13L through the openings 29, 31 in the rigid plate 9 and fastening them back on themselves by hook and loop materials on the straps themselves. . . . The remaining straps 15R, 15L, and 17 are also individually attachable in this manner . . . . The straps themselves are preferably made of flexible material and may have some slight elasticity to them to comfortably fit about the patient's head.” Ex. 1422 at col. 3:14–24.  **Lovell:** “The straps 52, 54, 56 may be manufactured from inelastic or elastic materials such as, but not limited to, nylon webbing, nylon covered neoprene or Velstretch™, available from Velcro USA Inc., Manchester, N.H., and may further include optional padding, if desired.” Ex. 1426 at col. 6:30–34.

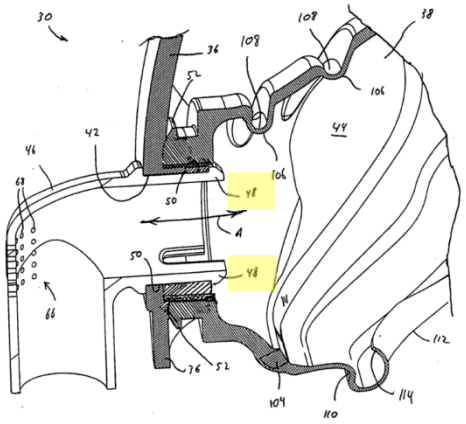
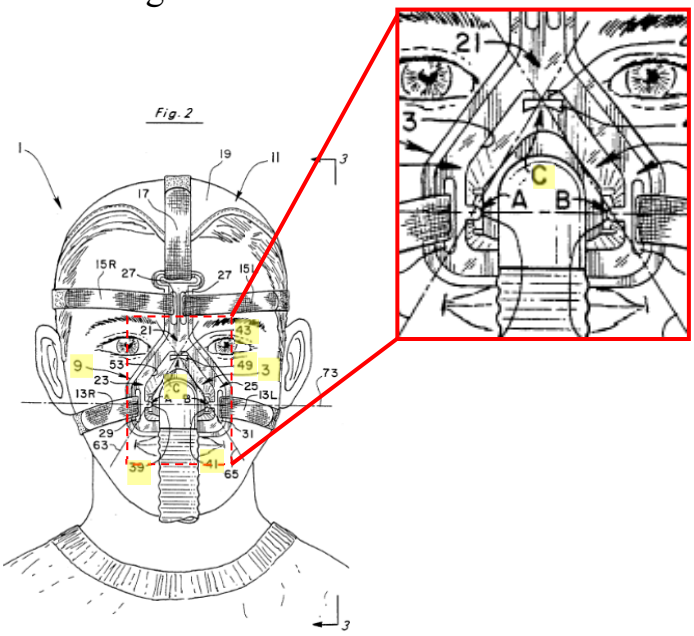
’931 Patent	Prior Art
21. The mask system of claim 19, wherein the rear straps and the top straps form a closed loop to encircle a rear portion of the patient's head when in use.	**Ng**: *See* Ex. 1410 at Fig. 16.  Fig. 16 **FlexiFit:** Ex. 1417 at 10. 

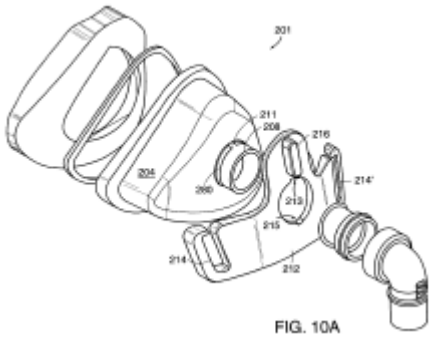
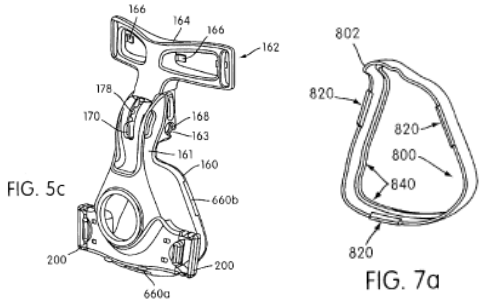
’931 Patent	Prior Art
	<u>Gunaratnam-II</u>: “[U]pper strap 98 and rear strap 100 are removably connected to the side straps 96 by buckles 102 provided on the side straps 96.” Ex. 1429 ¶ 211.  FIG. 18 “[R]ear portion 394, which interconnects the two side portions 392, includes an upper strap 398 that passes over the top of the patient's head and a rear strap 399 that passes around the rear portion of the patient's head.” *Id.* ¶ 263.  FIG 38  FIG.135

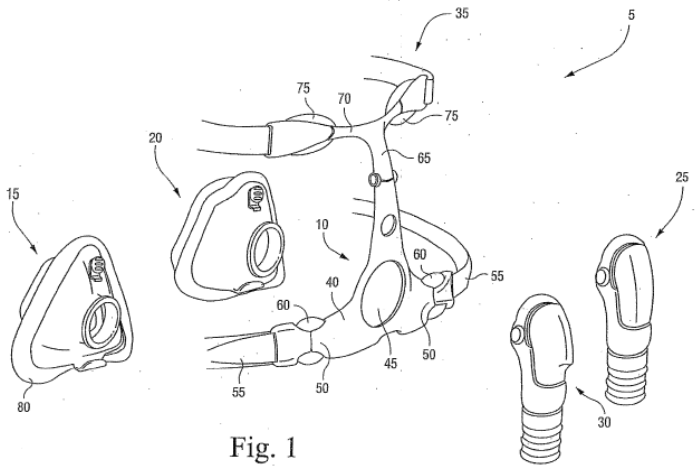
’931 Patent	Prior Art
	<u>Amarasinghe</u>: “Another known patient interface is the MIRAGE® nasal mask (by ResMed Ltd). This nasal mask includes a pair of headgear attachment points in the nasal region of the mask shell and a forehead support that includes another pair of headgear attachment points. The headgear includes a single piece of a soft, flexible composite fabric with a generally triangular back portion and four straps.” Ex. 1428 ¶ 12. 

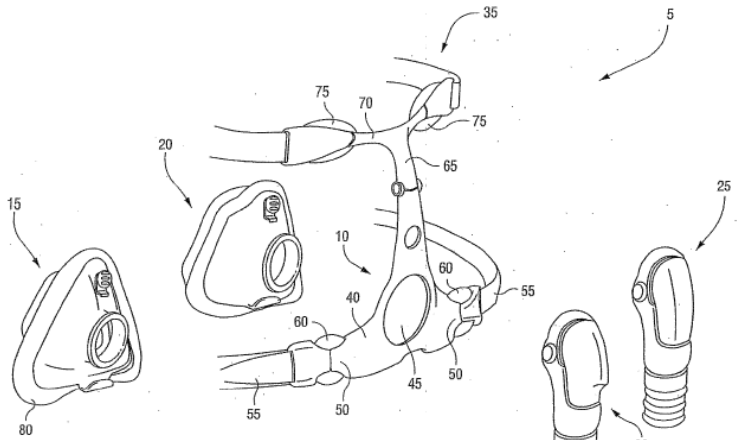
’931 Patent	Prior Art
22. The mask system of claim 19, **[A]** wherein the frame includes a frame opening leading to the breathing chamber, and wherein the front opening of the shroud module and the frame opening of the frame are aligned along a common longitudinal axis, and	*See supra* Claim 1[C]. **Ng:** “The common frame 10 has a main body 40 defining a central opening 45.” Ex. 1410 ¶ 30. “Common frame 10 is configured to be selectively coupled to one of cushion components 15, 20 and to one of elbow components 25, 30.” *Id* ¶ 31.  Fig. 1

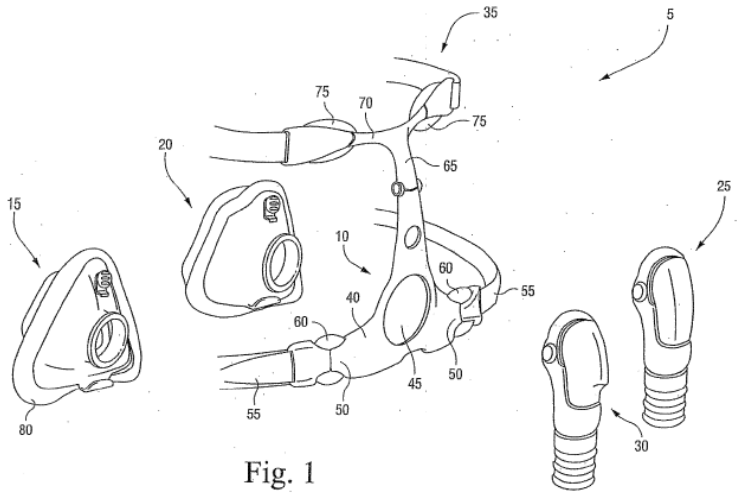
’931 Patent	Prior Art
[B] wherein the shroud module and the cushion module are removably snap-fit attached to one another by moving the shroud module and the cushion module towards one another along the longitudinal axis.	**Ng:** “The common frame 10 has a main body 40 defining a central opening 45.” Ex. 1410 ¶ 30. “Common frame 10 is configured to be selectively coupled to one of cushion components 15, 20 and to one of elbow components 25, 30. Cushion components 15, 20 differ in at least one respect such that one may be more optimal or preferable for use with one user, while another may be more suitable or preferably for use with another user. For example, cushion component 15 may be an Activa™ component, while cushion component 20 may be an UltraMirage™ Series II cushion component, both available from ResMed. These cushion components can be significantly different from one another, e.g., the Activa™ includes a gusset portion 80 and a cushion clip assembly (not shown) which is not incorporated in the UltraMirage™ cushion design.” *Id.* ¶ 31.  Fig. 1

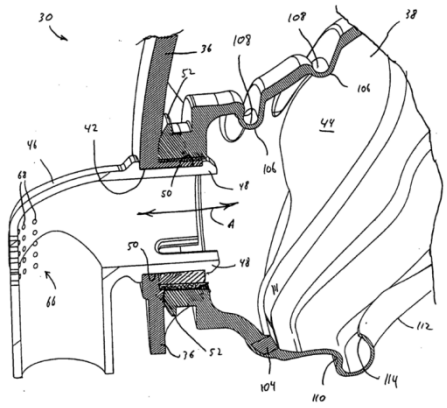
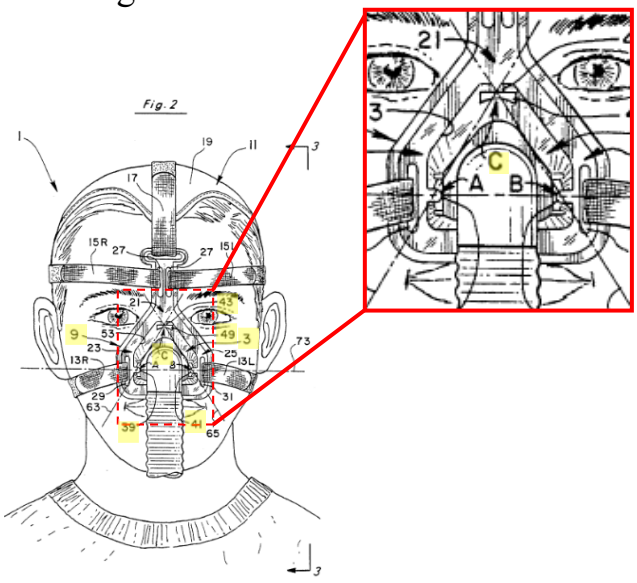
’931 Patent	Prior Art
	Matula-II: “Coupling member 46 includes a pair of prongs 48 that define a channel 50 to receive the wall of the faceplate and the end of seal member 38.” Ex. 1412 ¶ 53.  Fig. 4 **Ogden:** “[R]igid plate 9 is preferably mounted to the rigid shell 3 at first, second, and third locations A, B, and C. . . . 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.” Ex. 1422 at col. 4:59—5:19.  Fig. 2

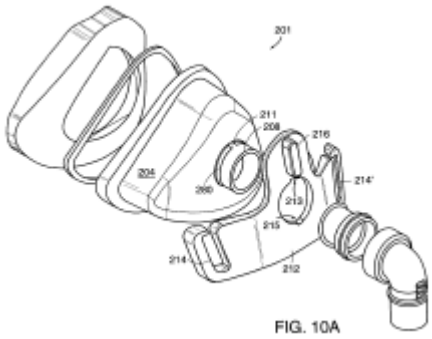
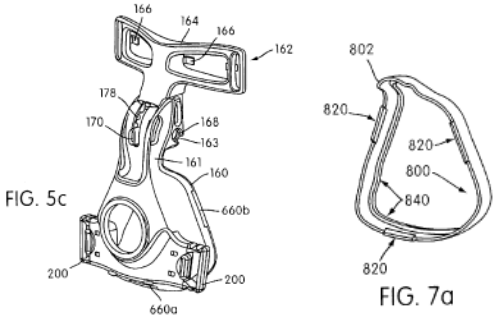
’931 Patent	Prior Art
	Lovell: “The retainer 212 is disposed about the inlet 208 to facilitate retention of the mask 201 on a user. . . . Two tabs 211, 211′ included on the inlet 208 mate with two slots 213, 215 formed in the retainer 212 in a particular angular orientation. . . . The retainer aperture and the inlet 208 are generally sized in an interference fit so that the retainer 212 is properly retained by the cooperation of the tabs 211, 211’, the slots 213, 215, and the depressed annular region 280 when fully seated against the shell 204.” Ex. 1426 at col. 9:43–48, 9:59–64.  FIG. 10A **Gunaratnam-I:** “[T]he 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). 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. 1413 at col. 5:34–43.  FIG. 5c FIG. 7a

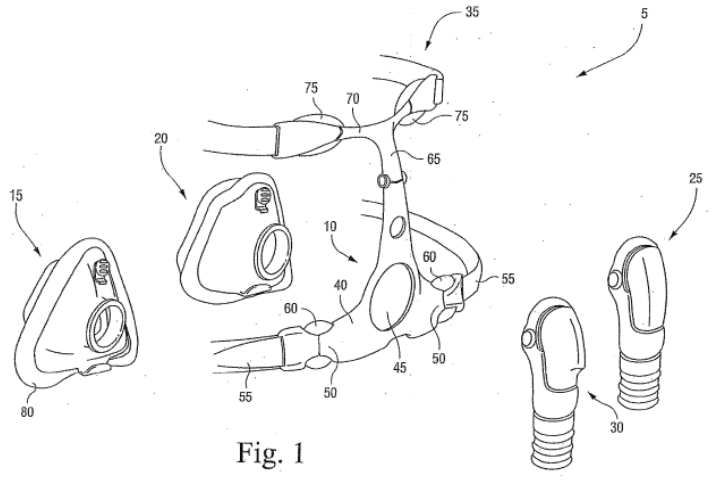
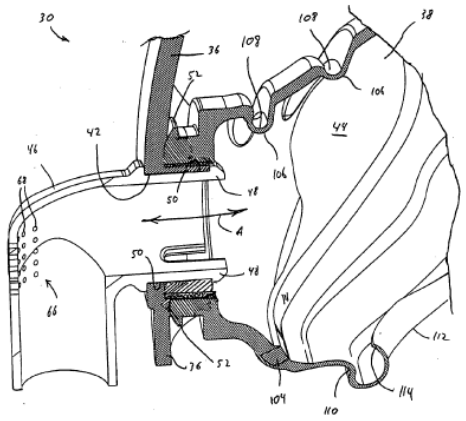
’931 Patent	Prior Art
25. The mask system of claim 19, wherein the frame is rigid.	**Ng:** “Interfaces, such as a nasal mask assembly, for use with blowers and flow generators in treatment of sleep disordered breathing (SDB) typically include a soft-face contacting portion, such as a cushion, and a rigid shell or frame.” Ex. 1410 ¶ 3.  Fig. 1 **Ogden:** “[R]igid, cup-shaped shell 3 made of hard plastic.” Ex. 1422 at col. 2:52–53. **Gunaratnam-I:** “[F]rame (160) is constructed as a substantially rigid shell of polycarbonate or similar transparent plastics material.” Ex. 1413 at col. 4:22–23. “The clip is conducted from polycarbonate or similar material.” *Id.* at col. 5:33–34. **D’Souza:** “[T]he frame 414 is constructed of polycarbonate.” Ex. 1420 ¶ 98.

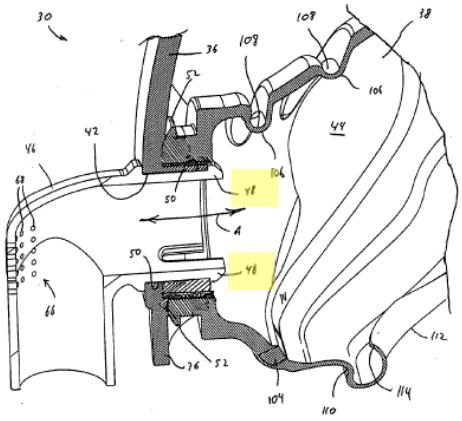
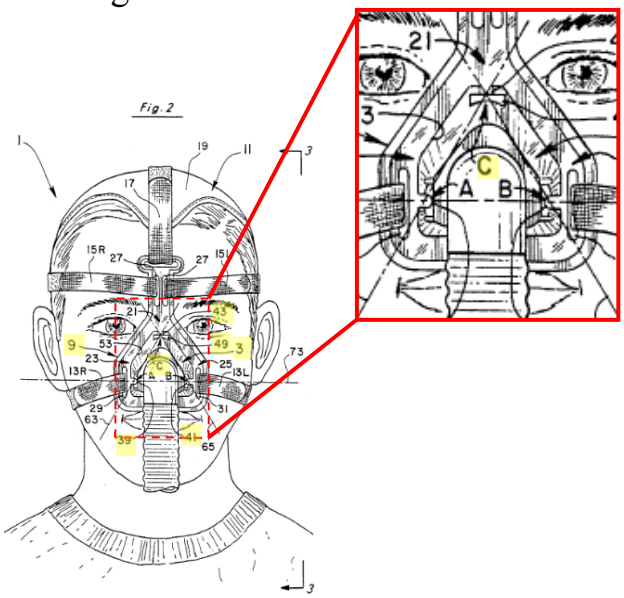
’931 Patent	Prior Art
26. The mask system of claim 1, **[A]** wherein the second opening of the shroud module and the frame opening of the frame are aligned along a common longitudinal axis, and	*See supra* Claim 22[A]. **Ng:** “The common frame 10 has a main body 40 defining a central opening 45.” Ex. 1410 ¶ 30. “Common frame 10 is configured to be selectively coupled to one of cushion components 15, 20 and to one of elbow components 25, 30. Cushion components 15, 20 differ in at least one respect such that one may be more optimal or preferable for use with one user, while another may be more suitable or preferably for use with another user. For example, cushion component 15 may be an Activa™ component, while cushion component 20 may be an UltraMirage™ Series II cushion component, both available from ResMed. These cushion components can be significantly different from one another, e.g., the Activa™ includes a gusset portion 80 and a cushion clip assembly (not shown) which is not incorporated in the UltraMirage™ cushion design.” Ex. 1410 ¶ 31.  Fig. 1

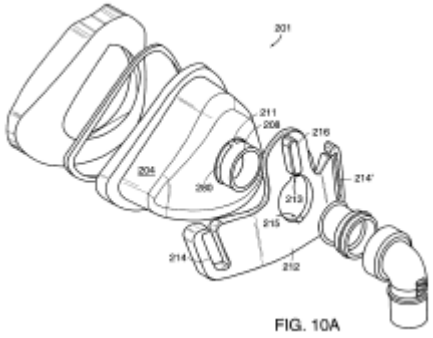
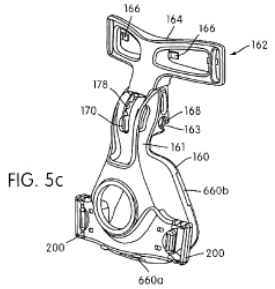
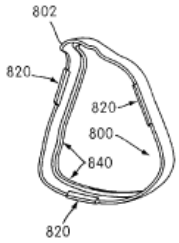
’931 Patent	Prior Art
[B] wherein the mask system further comprises a snap-fit arrangement to removably snap-fit attach the shroud module and the cushion module to one another by moving the shroud module and the cushion module towards one another along the longitudinal axis.	*See supra* Claim 22[B] **Ng:** “The common frame 10 has a main body 40 defining a central opening 45.” Ex. 1410 ¶ 30. “Common frame 10 is configured to be selectively coupled to one of cushion components 15, 20 and to one of elbow components 25, 30. Cushion components 15, 20 differ in at least one respect such that one may be more optimal or preferable for use with one user, while another may be more suitable or preferably for use with another user. For example, cushion component 15 may be an Activa™ component, while cushion component 20 may be an UltraMirage™ Series II cushion component, both available from ResMed. These cushion components can be significantly different from one another, e.g., the Activa™ includes a gusset portion 80 and a cushion clip assembly (not shown) which is not incorporated in the UltraMirage™ cushion design.” *Id.* ¶ 31.  Fig. 1

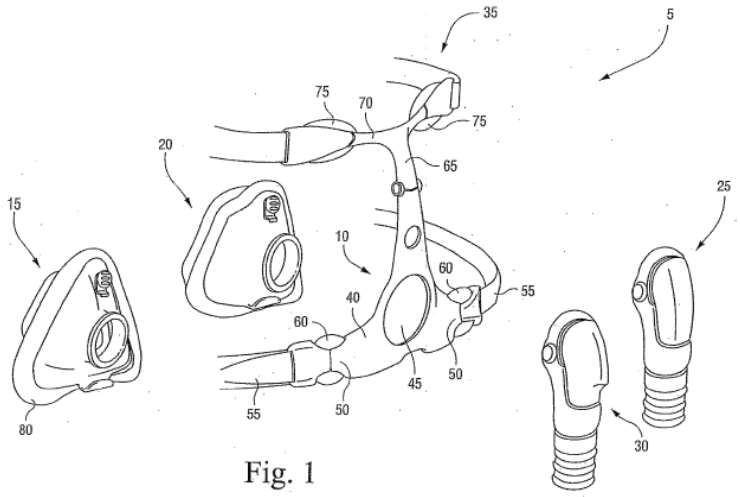
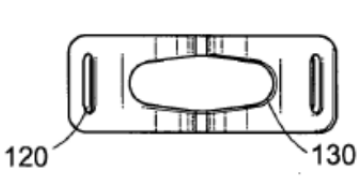
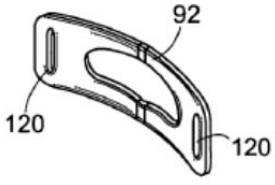
’931 Patent	Prior Art
	Matula-II: “Coupling member 46 includes a pair of prongs 48 that define a channel 50 to receive the wall of the faceplate and the end of seal member 38.” Ex. 1412 ¶ 53.  Fig. 4 **Ogden:** “[R]igid plate 9 is preferably mounted to the rigid shell 3 at first, second, and third locations A, B, and C. . . . 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.” Ex. 1422 at col. 4:59—5:19. 

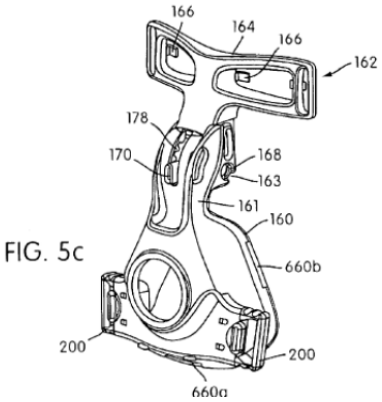
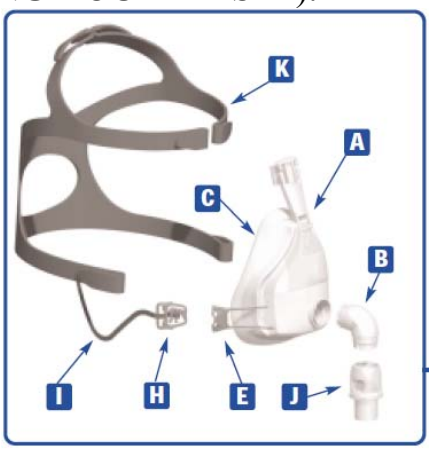
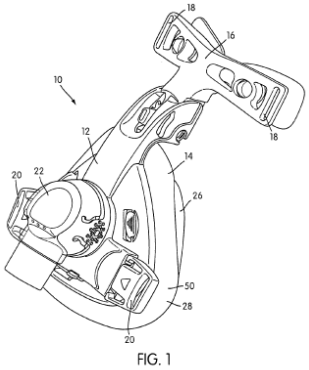
’931 Patent	Prior Art
	Lovell: “The retainer 212 is disposed about the inlet 208 to facilitate retention of the mask 201 on a user. . . . Two tabs 211, 211′ included on the inlet 208 mate with two slots 213, 215 formed in the retainer 212 in a particular angular orientation. . . . The retainer aperture and the inlet 208 are generally sized in an interference fit so that the retainer 212 is properly retained by the cooperation of the tabs 211, 211’, the slots 213, 215, and the depressed annular region 280 when fully seated against the shell 204.” Ex. 1426 at col. 9:43–48, 9:59–64.  FIG. 10A **Gunaratnam-I:** “[T]he 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). 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. 1413 at col. 5:34–43.  FIG. 5c FIG. 7a

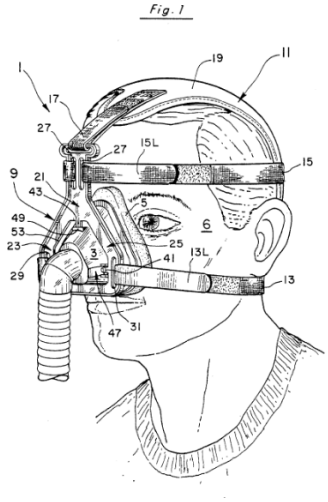
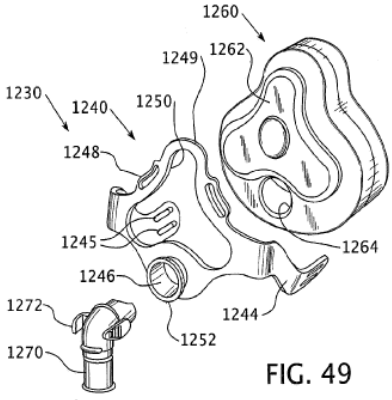
’931 Patent	Prior Art
28. The mask system of claim 1, **[A]** wherein: the frame includes a collar surrounding said frame opening, and	*See supra* Claim 5[A]. **Ng**: The cushion frame includes an annular collar around the opening. *See* Ex. 1410 at Fig. 1.  Fig. 1 **Matula-II:** “[T]he end of seal member 38 is joined to a ring 52 that is more rigid than the end of the seal member to provide a strong, stable mechanical coupling of the seal member to the faceplate.” Ex. 1412 ¶ 53.  Fig. 4
[B] wherein the shroud includes a retaining portion with at least one snap finger	*See supra* Claim 5[B]. **Matula-II:** “Coupling member 46 includes a pair of prongs 48 that define a channel 50 to receive the wall of

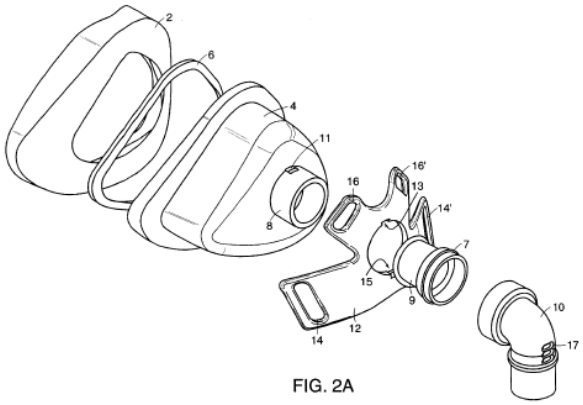
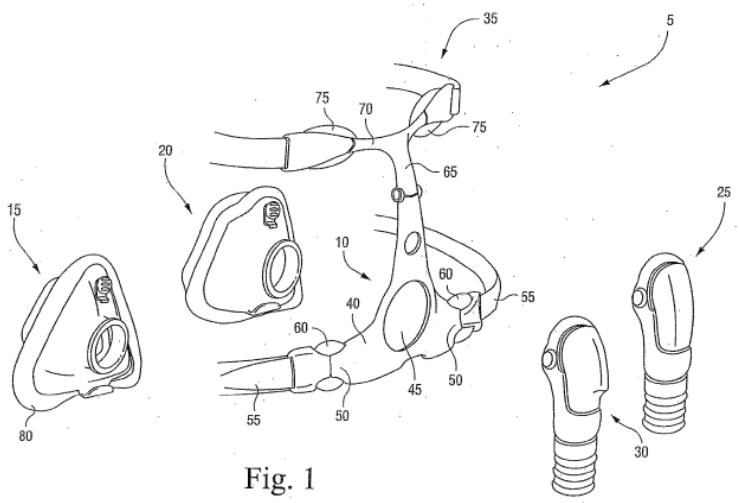
’931 Patent	Prior Art
structured to engage the collar with a snap-fit,	the faceplate and the end of seal member 38.” Ex. 1412 ¶ 53. A person of skill in the art would have understood that the “prongs” of Matula-II could also be referred to as “snap fingers.”  Fig. 4 **Ogden:** “[R]igid plate 9 is preferably mounted to the rigid shell 3 at first, second, and third locations A, B, and C. . . . 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.” Ex. 1422 at col. 4:59–5:19. 

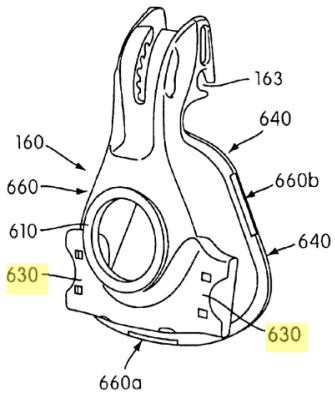
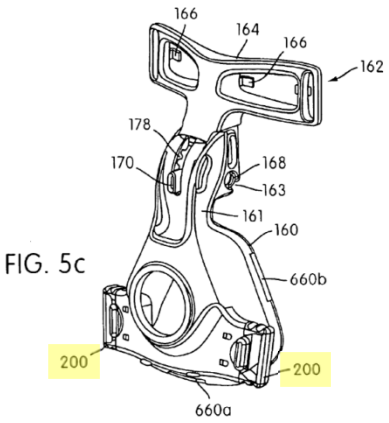
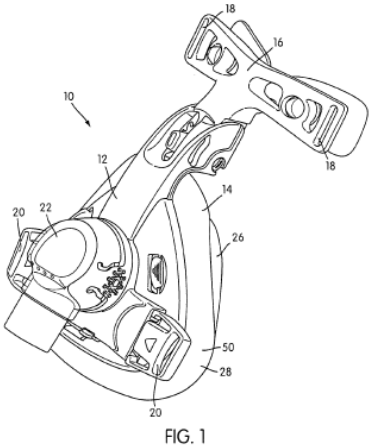
’931 Patent	Prior Art
	Lovell: “The retainer 212 is disposed about the inlet 208 to facilitate retention of the mask 201 on a user. . . . Two tabs 211, 211′ included on the inlet 208 mate with two slots 213, 215 formed in the retainer 212 in a particular angular orientation. . . . The retainer aperture and the inlet 208 are generally sized in an interference fit so that the retainer 212 is properly retained by the cooperation of the tabs 211, 211’, the slots 213, 215, and the depressed annular region 280 when fully seated against the shell 204.” Ex. 1426 at col. 9:43–48, 9:59–64.  FIG. 10A **Gunaratnam-I:** “[T]he 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). 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. 1413 at col. 5:34–43.  FIG. 5c  FIG. 7a

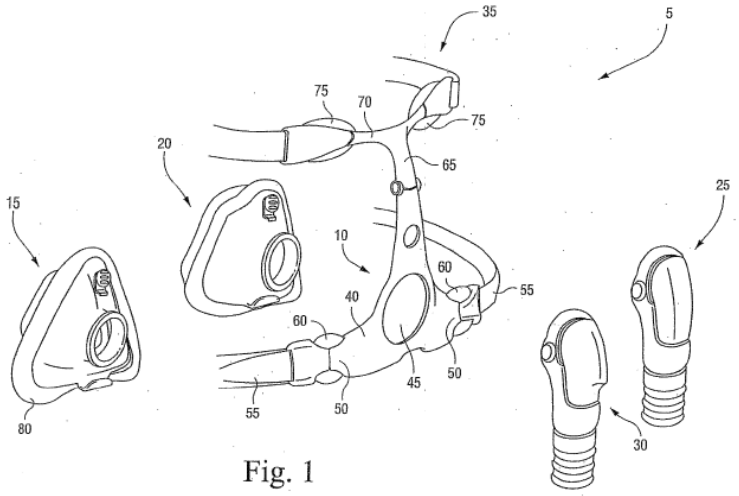
’931 Patent	Prior Art
[C] the shroud module includes upper and lower headgear connectors on each side of the shroud module,	*See supra* Claim 6. **Ng:** “The common frame 10 has a main body 40 defining a central opening 45. Main body 40 includes at least two lateral arms 50, each of which can be coupled to a headgear strap 55 of headgear. The straps may be connected to the frame using a press-fit connector 60, as is known in the art. Common frame 10 may also include a forehead support 65 that has a bridge 70 provided with forehead pads 75 to rest against the user’s forehead in use.” Ex. 1410 ¶ 30.  Fig. 1
[D] each upper headgear connector includes a slot adapted to receive a respective headgear strap in use,	*See supra* Claim 7. **Thomlinson:** “As shown in FIG. 28B, strap attachment plate 92 . . . includes one or more strap connections 120 for receiving a strap system 102.” Ex. 1411 ¶ 306.  Fig. 28D  Fig. 28A

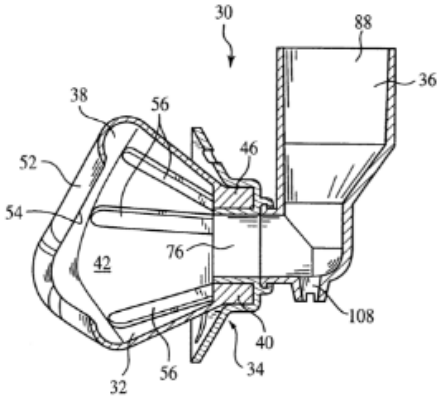
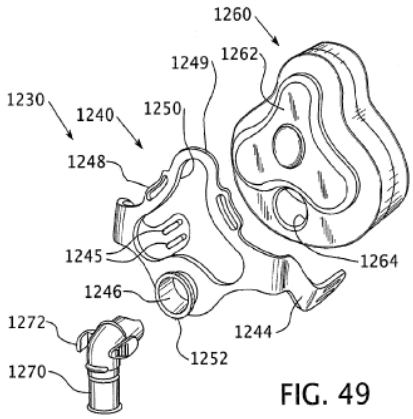
’931 Patent	Prior Art
	Gunaratnam-I: “As compared to FIGS. 5a-5b, FIGS. 5c-5f also show an adjustable forehead support (162) connected to the frame (160).” Ex. 1413 at col. 4:46–48.  FIG. 5c **FlexiFit:** “[A]ttach the four straps in to the corresponding slots in the Mask Base.” Ex. 1417 at 10 (“ASSEMBLING YOUR MASK”).  **Lithgow:** *See* Ex. 1433 at Fig. 1.  FIG. 1

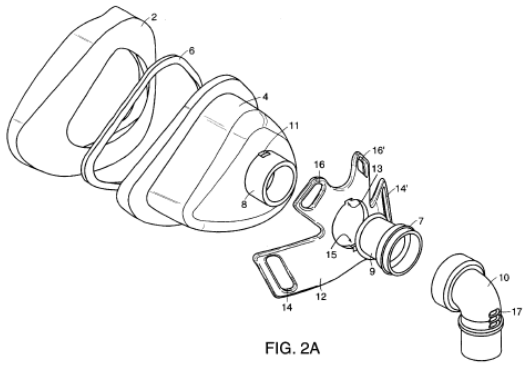
’931 Patent	Prior Art
	Ogden: “The upper side straps in this last regard could be the two straps 15R and 15L as illustrated or one continuous strap passing through loops 27 and anchoring the top portion 21 of the rigid plate 9 (see FIGS. 1-3).” Ex. 1422 at col. 3:7–10.  **Matula-I:** “[A]ttachment elements 1248 are provided in the form of slots provided . . . [o]n a central portion 1249 of the body member.” Ex. 1423 ¶ 103.  FIG. 49

’931 Patent	Prior Art
	Lovell: “These connection points 14, 14', 16, 16' form slots which allow for connection of the retainer 12 with straps of a headgear apparatus, as shown in FIG. 3.” Ex. 1426 at col. 6:10–13.  FIG. 2A
[**E**] each lower headgear connector is adapted to be removably interlocked with a headgear clip associated with a respective headgear strap,	*See supra* Claim 8. **Ng:** “Main body 40 includes at least two lateral arms 50, each of which can be coupled to a headgear strap 55 of headgear. The straps may be connected to the frame using a press-fit connector 60, as is known in the art.” Ex. 1410 ¶ 30.  Fig. 1

’931 Patent	Prior Art
	Gunaratnam-I: “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. 1413 at col. 4:31–33.  FIG. 5a  FIG. 5c **Ultra Mirage:** “Quick release headgear clips: top and bottom.” Ex. 1416 at 6. **Lithgow:** “For example, the headgear assembly may include a pair of upper and lower straps with the upper straps removably connected to clip structures 18 provided on the forehead support 16 and the lower straps removably connected to clip structures 20 provided on the frame 12.” Ex. 1433 ¶ 111.  FIG. 1

’931 Patent	Prior Art
[**F**] the mask assembly further comprises an elbow module adapted to be connected to an air delivery tube that delivers breathable gas to the patient, and	*See supra* Claim 11. **Ng:** “Mask system includes a common frame component 10, one of two cushion components 15, 20, one of two elbow components 25, 30, and headgear 35. The mask system is intended for use in positive pressure therapy for users with obstructive sleep apnea (OSA) or another respiratory disorder.” Ex. 1410 ¶ 29.  Fig. 1
[**G**] the elbow module is rotatably attached to the shroud module while allowing 360 degree rotation of the elbow module.	*See supra* Claim 14. **Ng:** “Common frame 10 is configured to be selectively coupled to one of cushion components 15, 20 and to one of elbow components 25, 30.” Ex. 1410 ¶ 31.

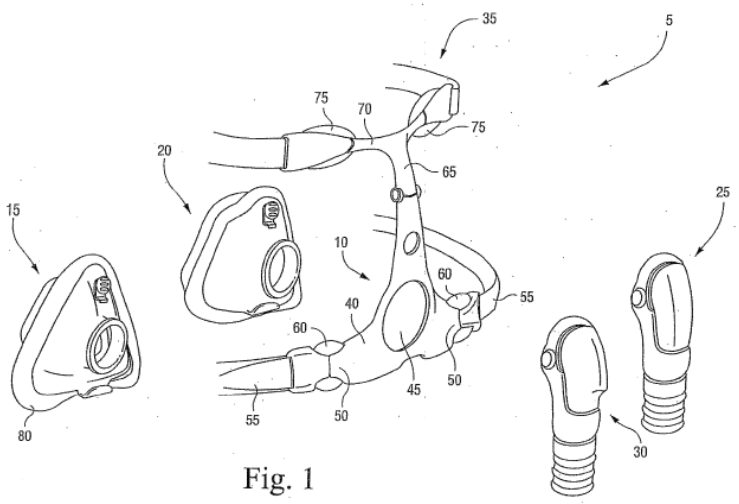
’931 Patent	Prior Art
	Barnett: “[C]onduit coupling member 36 is preferably rotateably mounted on a second side of collar 34 opposite the first side so that conduit coupling member 36 freely rotates over a range of 360° about a central axis of collar 34.” Ex. 1414 at col. 3:52–57; *see also id.* at col. 8:66—9:43.  FIG. 1A **Matula-I:** “[P]atient circuit coupling 1270 is an elbow coupling that rotatably and releasably attaches to circuit coupling portion 1246.” Ex. 1423 ¶ 105.  FIG. 49 **Ultra Mirage:** “360° rotating elbow provides control over tubing system.” Ex. 1416 at 6.

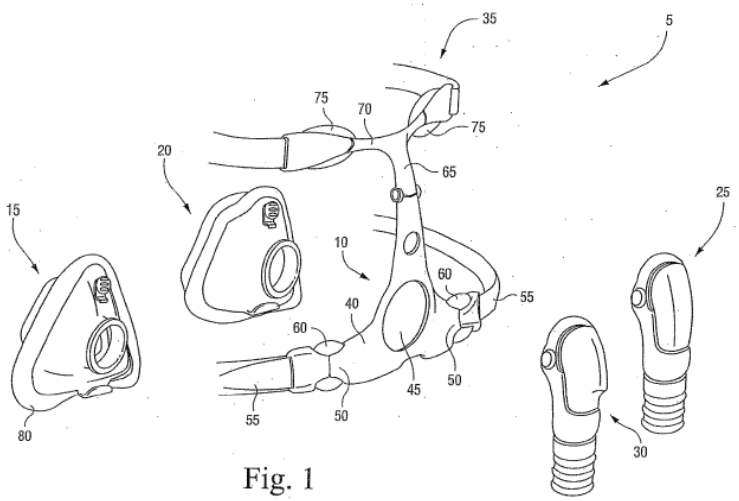
’931 Patent	Prior Art
	Lovell: “[S]wivel connector 9 produces a swivel mount connection between the conduit elbow 10 and the inlet 8. In this type of connection, the conduit elbow 10 is capable of rotating 360 degrees about the centerline of the inlet 8 and the connector 9.” Ex. 1426 at col. 5:20–24.  FIG. 2A
29. The mask system of claim 28, wherein each of the shroud module and the frame comprises polycarbonate, and the cushion comprises silicone.	*See supra* Claim 18. **Gunaratnam-I:** “The frame may be constructed from a material such as polycarbonate . . . . The soft cushion may be constructed from a material such as silicone.” Ex. 1413 at col. 1:34–39. “The clip is conducted from polycarbonate or similar material.” *Id.* at 5:33–34. **Lovell:** “The retainer 12 can be constructed from . . . polycarbonate.” Ex. 1426 at col. 6:13–14. “[T]he seal 2 is a bladder that is . . . filled with a soft material 62. . . . For example, certain types of silicone gel meet this durometer value.” *Id*. at col. 7:46–53. **D’Souza:** “[C]ushion 416 is constructed of liquid silicone rubber (LSR).” Ex. 1420 ¶ 97. “[T]he frame 414 is constructed of polycarbonate.” *Id*. ¶ 98. “[T]he skeleton frame 412 is formed of plastic.” *Id.* ¶ 100.

’931 Patent	Prior Art
	McAuley: “The hollow body 30 and insert 32 are injection moulded in a relatively inflexible material, for example, polycarbonate plastic. Such a material would provide the requisite rigidity for the mask as well as being transparent and a relatively good insulator.” Ex. 1432 at 6:21–24. **Lithgow:** “The cushion 14 is constructed from a soft, flexible skin-compatible material such as silicone.” Ex. 1433 ¶ 139.
30. The mask system of claim 28, wherein the frame is rigid.	*See supra* Claim 25. **Ng:** “Interfaces, such as a nasal mask assembly, for use with blowers and flow generators in treatment of sleep disordered breathing (SDB) typically included a soft-face contacting portion, such as a cushion, and a rigid shell or frame.” Ex. 1410 ¶ 3. **Ogden:** “[R]igid, cup-shaped shell 3 made of hard plastic.” Ex. 1422 at col. 2:52–53. **Gunaratnam-I:** “[F]rame (160) is constructed as a substantially rigid shell of polycarbonate or similar transparent plastics material.” Ex. 1413 at col. 4:22–23. “The clip is conducted from polycarbonate or similar material.” *Id.* at col. 5:33–34. **D’Souza:** “[T]he frame 414 is constructed of polycarbonate.” Ex. 1420 ¶ 98.

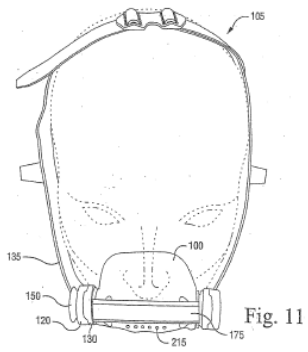
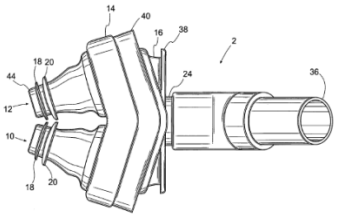
’931 Patent	Prior Art
31. The mask system of claim 1, wherein the frame is rigid.	*See supra* Claim 25. **Ng:** “Interfaces, such as a nasal mask assembly, for use with blowers and flow generators in treatment of sleep disordered breathing (SDB) typically included a soft-face contacting portion, such as a cushion, and a rigid shell or frame.” Ex. 1410 ¶ 3. **Ogden:** “[R]igid, cup-shaped shell 3 made of hard plastic.” Ex. 1422 at col. 2:52–53. **Gunaratnam-I:** “[F]rame (160) is constructed as a substantially rigid shell of polycarbonate or similar transparent plastics material.” Ex. 1413 at col. 4:22–23. “The clip is conducted from polycarbonate or similar material.” *Id.* at col. 5:33–34. **Lovell:** “The retainer 12 can be constructed from . . . polycarbonate.” Ex. 1426 at col. 6:13–14. **D’Souza:** “[T]he frame 414 is constructed of polycarbonate.” Ex. 1420 ¶ 98.
32. A system for treating a patient with sleep disordered breathing, comprising:	*See supra* Claim 1, preamble.
[A] the mask system of claim 1;	*See supra* Claim 1.

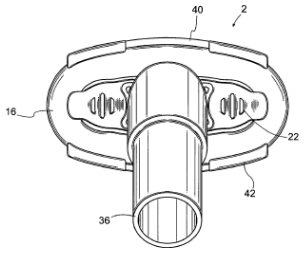
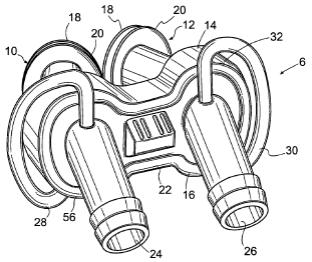
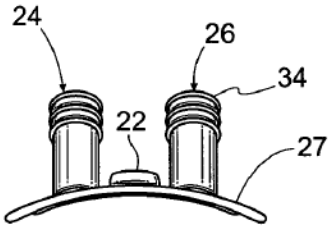
’931 Patent	Prior Art
[B] a flow generator to generate a supply of air at positive pressure to be delivered to the mask system; and	**Ng:** “Mask system includes a common frame component 10, one of two cushion components 15, 20, one of two elbow components 25, 30, and headgear 35. The mask system is intended for use in positive pressure therapy for users with obstructive sleep apnea (OSA) or another respiratory disorder.” Ex. 1410 ¶ 29. “Interfaces, such as a nasal mask assembly, for use with blowers and flow generators in the treatment of sleep disordered breathing (SDB) typically include a soft-face contacting portion, such as a cushion, and a rigid shell or frame.” *Id*. ¶ 3.
[C] an air delivery tube configured to deliver the supply of air from the flow generator to the mask system.	**Thomlinson:** “In one embodiment, the present invention includes tubing 90, shown in FIGS. 26, 27, 29 and 35 through 38. Tubing 90 can supply gas to the nasal interface of the present invention.” Ex. 1411 ¶ 316.

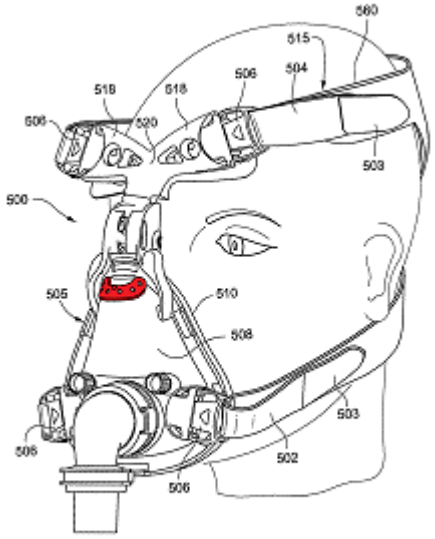
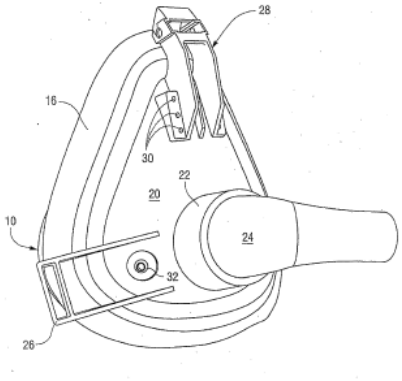
’931 Patent	Prior Art
43. A mask system for delivery of a supply of air at positive pressure to a patient's airway, the mask system comprising:	*See supra* Claim 1, preamble. **Ng:** “The mask system is intended for use in positive pressure therapy for users with obstructive sleep apnea (OSA) or another respiratory disorder.” Ex. 1410 ¶ 29.  Fig. 1
[A] a cushion module comprising a frame defining a breathing chamber configured to receive the positive pressure air, and a cushion to form a seal with the patient's face in a nasal bridge region, a cheek region and a lower lip/chin region of the patient's face,	*See supra* Claim 1(ii). **Ng:** “Common frame 10 is configured to be selectively coupled to one of cushion components 15, 20 and to one of elbow components 25, 30. Cushion components 15, 20 differ in at least one respect such that one may be more optimal or preferable for use with one user, while another may be more suitable or preferably for use with another user. For example, cushion component 15 may be an Activa™ component, while cushion component 20 may be an UltraMirage™ Series II cushion component, both available from ResMed. These cushion components can be significantly different from one another, e.g., the Activa™ includes a gusset portion 80 and a cushion clip assembly (not shown) which is not incorporated in the UltraMirage™ cushion design.” Ex. 1410 ¶ 31.

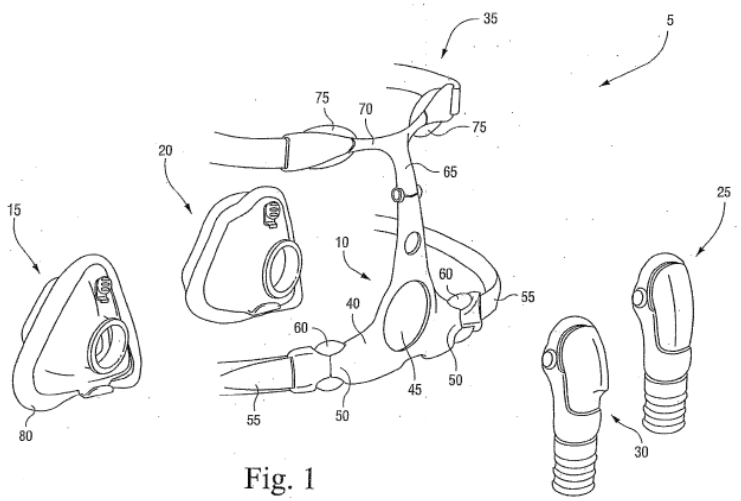
’931 Patent	Prior Art
	“Interfaces, such as a nasal mask assembly, for use with blowers and flow generators in treatment of sleep disordered breathing (SDB) typically include a soft-face contacting portion, such as a cushion, and a rigid shell or frame.” *Id*. ¶ 3. “[A] supplemental cushion component in the form of a nasal cushion or a full-face cushion, wherein the cushion component and the supplemental cushion component cooperatively seal with the user’s face in use.” *Id*. ¶ 13. “A system of breathing arrangements for delivering breathable gas to a patient, comprising at least first and second cushion components (15, 20), e.g., full-face, nasal, nasal prongs, nose tip, and/or a combination of any of the above, including a nasal or full-face cushion and nasal prongs/nozzles combination, etc., that are different from one another in at least one aspect, and a common frame assembly (10) configured to support each of the first and second cushion components (15, 20). Various embodiments are directed to a full-face or nasal mask used with a frame having lateral connector portions having a stiffening member.” *Id*. at Abstract.  Fig. 1

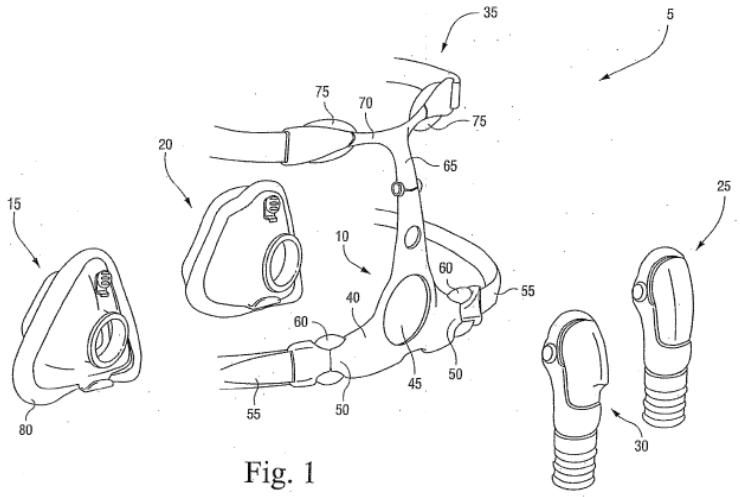
’931 Patent	Prior Art
[B] wherein the cushion is constructed of a first, relatively soft, elastomeric material and the frame is constructed of a second material that is more rigid than the cushion,	*See supra* Claim 1(ii). **Ng:** “Interfaces, such as a nasal mask assembly, for use with blowers and flow generators in treatment of sleep disordered breathing (SDB) typically include a soft-face contacting portion, such as a cushion, and a rigid shell or frame.” Ex. 1410 ¶ 3. **Lithgow:** “The cushion 14 is constructed from a soft, flexible skin-compatible material such as silicone. The cushion 14 may be formed, for example, in a one shot injection molding process as is known in the art. However, the cushion 14 may be formed with any suitable material and may be formed by any suitable process. For example, while face contacting portion 26 of cushion 14 may have a softer grade material, the gusset portion may have a harder grade material to provide stiffness as a spring element. The non-face contacting portion 24 may have a stiffer grade material so a direct assembly to frame without a cushion clip may be possible.” Ex. 1433 ¶ 139.

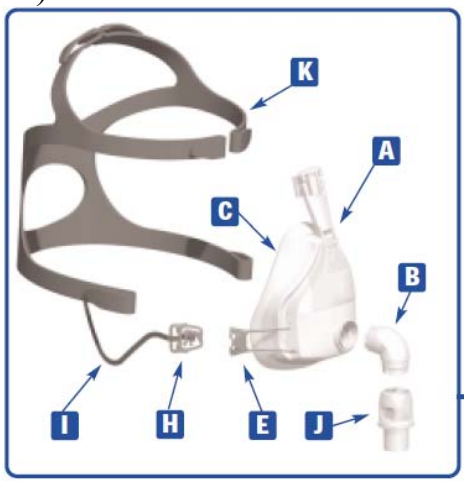
’931 Patent	Prior Art
[C] the frame including a washout vent,	*See supra* Claim 1[B]. **Ng:** “As shown in Figs. 3, 7-8, and 11, the mask assembly includes a gas washout vent 215. The vent 215 could be on the frame and/or the cushion component.” Ex. 1410 ¶ 43.  Fig. 11 **Thomlinson:** “A nasal interface body 2 according to the present invention can also include one or more locking tabs 38 on the distal portion 16. The locking tabs 38 can be used to releasably engage a strap attachment plate 92, as depicted in FIG. 37 and described further below.” Ex. 1411 ¶ 203.  Fig. 1

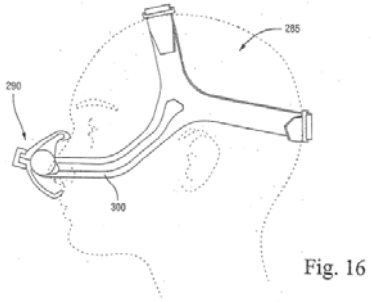
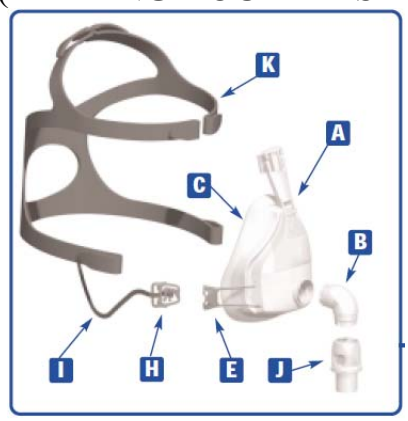
’931 Patent	Prior Art
	“Further, and as shown in FIG. 3, one embodiment of a nasal interface can also include one or more exhalation ports 22, which are described in more detail below.” *Id.* ¶ 204.  Fig. 3 “As shown in FIG. 8, nasal interface body 6 can also include first inlet 24 and a second inlet 26, as well as exhalation port 22. In one embodiment, exhalation port 22 is positioned between inlet 24 and second inlet 26.” *Id*. ¶ 209.  Fig. 8 “As shown in the figures and in particular FIGS. 3, 14A, 15D, 15F, 16C and 16F, distal portion 16 can also include one or more exhalation ports 22, described further below.” *Id*. ¶ 247.  Fig. 14A

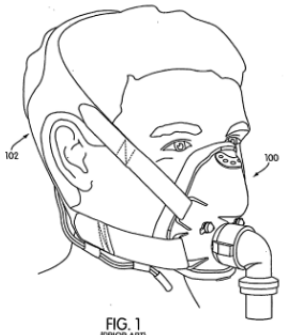
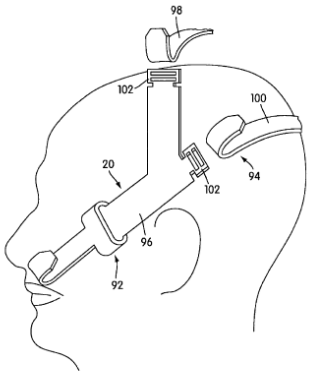
’931 Patent	Prior Art
	Hitchcock: *See* Ex. 1421 at Fig. 8.  Fig. 8 **Hitchcock-II:** “A number of vents 30 may be provided so as to allow gas exhaled by the patient to vent to atmosphere.” Ex. 1440 ¶ 42.  Fig. 1-2

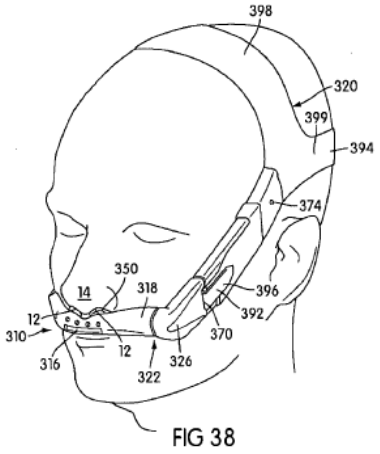
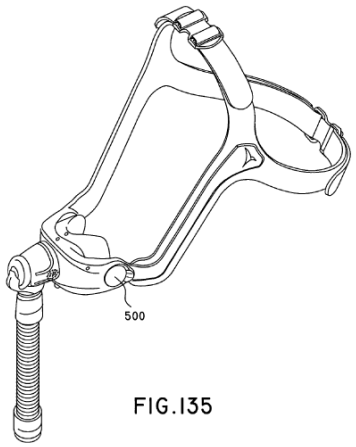
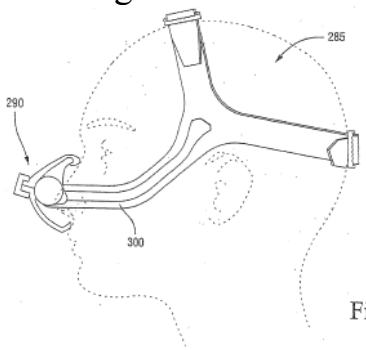
’931 Patent	Prior Art
[D] the frame including an opening;	*See supra* Claim 22[A]. **Ng:** *See* Ex. 1410 at Fig. 1.  Fig. 1

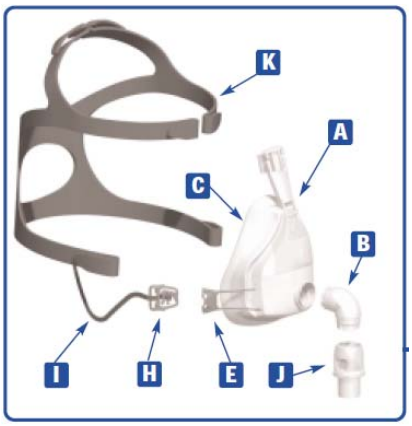
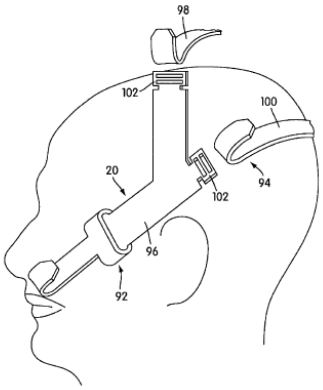
’931 Patent	Prior Art
[E] headgear to maintain the mask system in a desired position on the patient's face, the headgear comprising a pair of upper headgear straps each configured to extend above a respective one of the patient's ears in use and a pair of lower headgear straps each configured to extend below a respective one of the patient's ears in use,	*See supra* Claim 19[A]. **Ng:** “The common frame 10 has a main body 40 defining a central opening 45. Main body 40 includes at least two lateral arms 50, each of which can be coupled to a headgear strap 55 of headgear. The straps may be connected to the frame using a press-fit connector 60, as is known in the art. Common frame 10 may also include a forehead support 65 that has a bridge 70 provided with forehead pads 75 to rest against the user’s forehead in use.” Ex. 1410 ¶ 30.  Fig. 1
[F] wherein a free end of each of the upper headgear straps and the lower headgear straps includes a hook tab structured to engage a remainder of the respective upper headgear strap and respective lower headgear strap to secure the upper and	*See supra* Claim 19[B]. **Ng:** “Each strap includes hook and loop fastening elements, e.g., Velcro®.” Ex. 1410 ¶ 67.

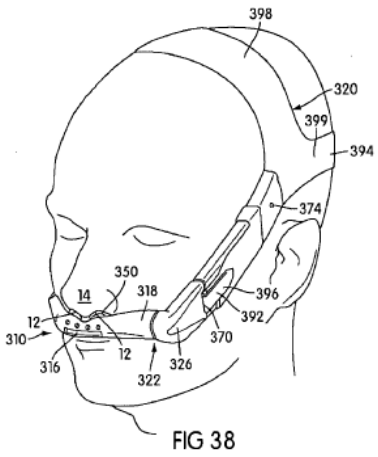
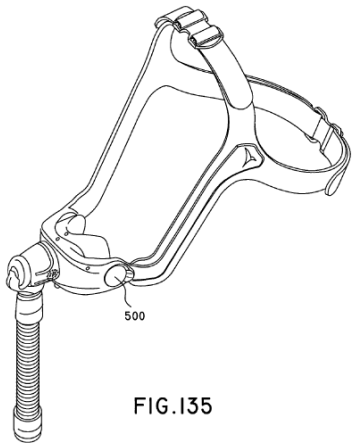
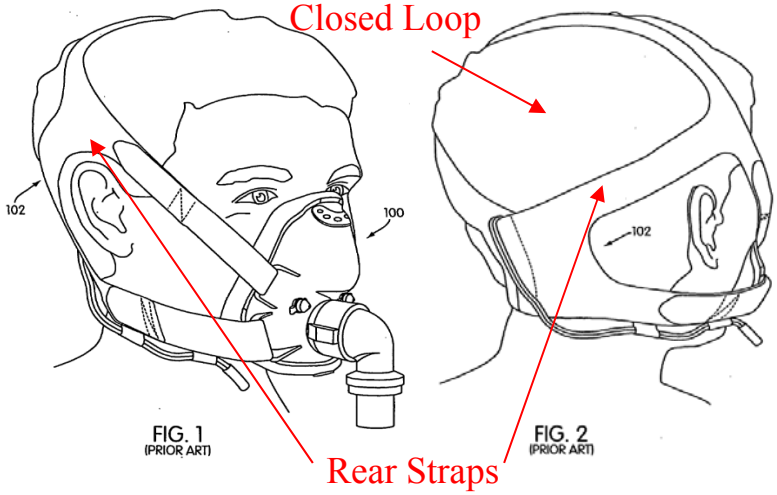
’931 Patent	Prior Art
lower straps in place in a length adjustable manner,	**FlexiFit:** “Gently adjust the Top Horizontal straps then the Lower Horizontal straps . . . . If leaks occur . . . tighten the top horizontal straps. . . . If leaks occur . . . tighten the lower horizontal straps.” Ex. 1417 at 10 (“FITTING YOUR MASK”). “[A]ttach the four straps in to the corresponding slots in the Mask Base and the Glider™ strap (E). This can be done without undoing the Velcro® Tabs by sliding the Headgear into the slots.” *Id.* at 10 (“ASSEMBLING YOUR MASK”).  **Ogden:** “[E]ach side strap 13R and 13L is preferably attached to a respective side portion 23, 25 of the rigid plate 9 on respective sides of the patient's nose 2. This can be done in any number of well-known, adjustable manners including . . . hook and loop materials on the straps themselves. . . . The remaining straps 15R, 15L, and 17 are also individually attachable in this manner.” Ex. 1422 at col. 3:10–20. **Amarasinghe:** “At the end of each strap is secured a piece of hook material, which, in use, passes through a headgear attachment point and fastens on corresponding loop material on the strap.” Ex. 1428 ¶ 12.

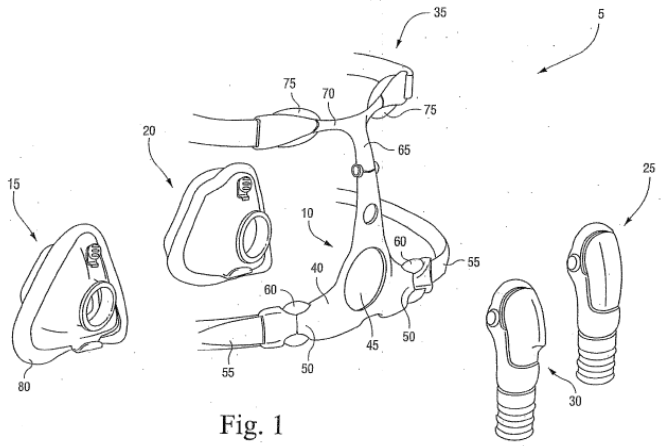
’931 Patent	Prior Art
	Lovell: “A hook and loop fastener system can be used to maintain the straps 59, 58 at a desired adjustment. The loops may be located along the majority of the lengths of the straps 59, 58 to provide a wide range of adjustment, with the hooks being located on the 10 distal tip portions of the straps 59, 58, such that when the distal tip of a strap is passed through a slot in a connector, the strap folds over on itself and the hooks engage the loops.” Ex. 1426 at col. 7:6–13.
[G] wherein the headgear includes a pair of top straps and a pair of rear straps, each said top strap being configured to extend from generally above a respective ear of the patient such that the top straps cross over the top of the patient's head in use, the rear straps being adapted to pass behind the patient's head in use, and	*See supra* Claim 19[C] and [D]. **Ng**: *See* Ex. 1410 at Fig. 16.  Fig. 16 **FlexiFit:** “Gently adjust . . . Top Crown straps.” Ex. 1417 at 10 (“FITTING YOUR MASK”). 

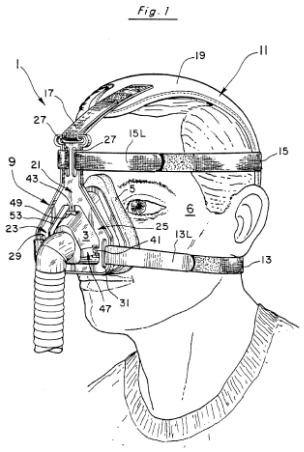
’931 Patent	Prior Art
	Amarasinghe: “The headgear similarly comprises a pair of upper (104) and a pair of lower straps (106) and a generally triangular back portion (108).” Ex. 1428 ¶ 14.  FIG. 1 (PRIOR ART) **Gunaratnam-II:** “The upper strap 98 and rear strap 100 are removably connected to the side straps 96 by buckles 102 provided on the side straps 96.” Ex. 1429 ¶ 211.  FIG. 18

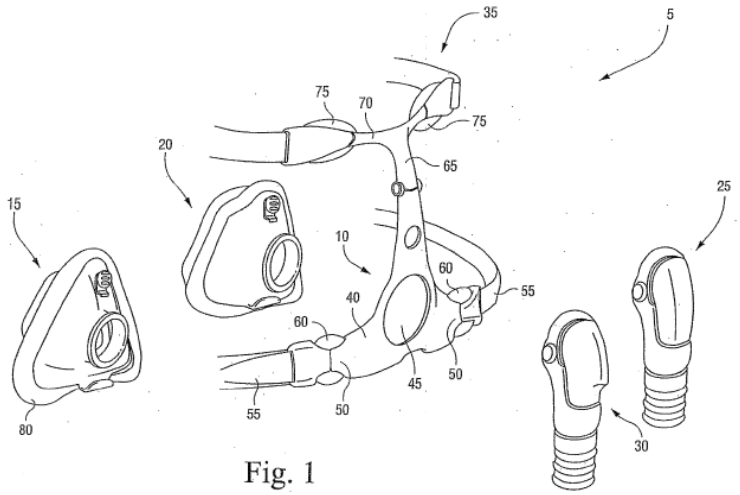
’931 Patent	Prior Art
	“The rear portion 394, which interconnects the two side portions 392, includes an upper strap 398 that passes over the top of the patient's head and a rear strap 399 that passes around the rear portion of the patient's head.” *Id.* ¶ 263 and Figs. 38 and 135.  FIG 38  FIG.135
[H] wherein the rear straps and the top straps together at least partly form a closed loop to encircle a rear portion of the patient's head when in use;	*See supra* Claim 21. **Ng**: *See* Ex. 1410 at Fig. 16.  Fig. 16

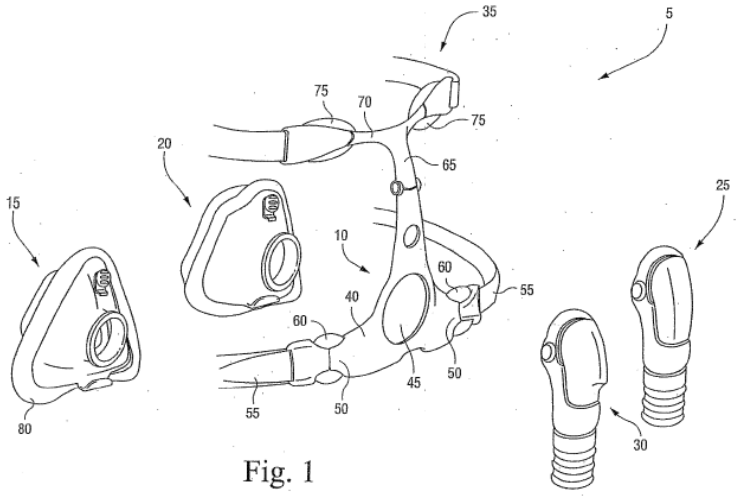
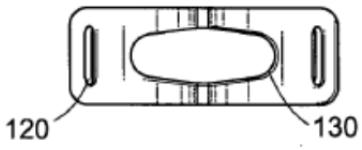
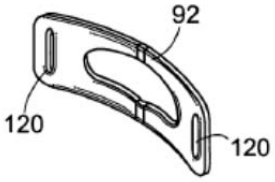
’931 Patent	Prior Art
	FlexiFit: Ex. 1417 at 10.  **Gunaratnam-II: “**[U]pper strap 98 and rear strap 100 are removably connected to the side straps 96 by buckles 102 provided on the side straps 96.” Ex. 1429 ¶ 211.  FIG. 18

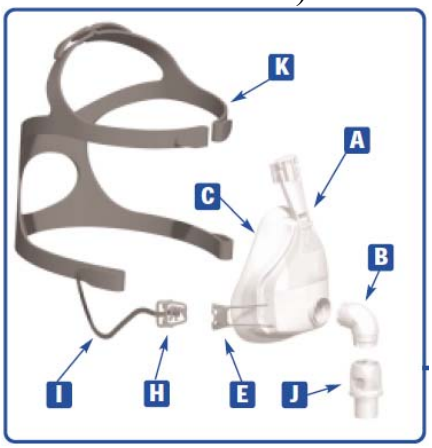
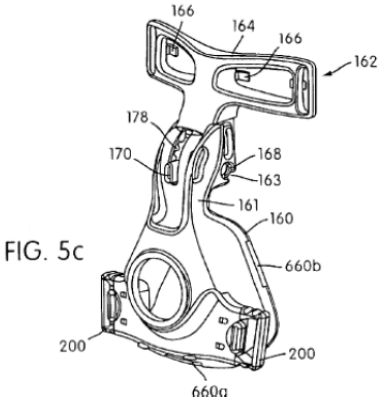
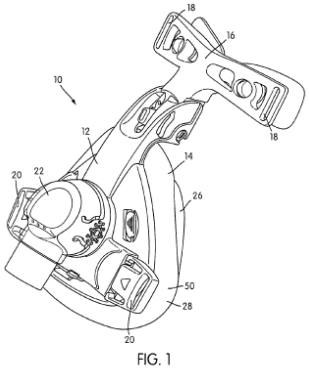
’931 Patent	Prior Art
	“[R]ear portion 394, which interconnects the two side portions 392, includes an upper strap 398 that passes over the top of the patient's head and a rear strap 399 that passes around the rear portion of the patient's head.” *Id.* ¶ 263.  FIG 38  FIG.135 **Amarasinghe:** “Another known patient interface is the MIRAGE® nasal mask (by ResMed Ltd). This nasal mask includes a pair of headgear attachment points in the nasal region of the mask shell and a forehead support that includes another pair of headgear attachment points. The headgear includes a single piece of a soft, flexible composite fabric with a generally triangular back portion and four straps.” Ex. 1428 ¶ 12.  FIG. 1 (PRIOR ART) FIG. 2 (PRIOR ART)

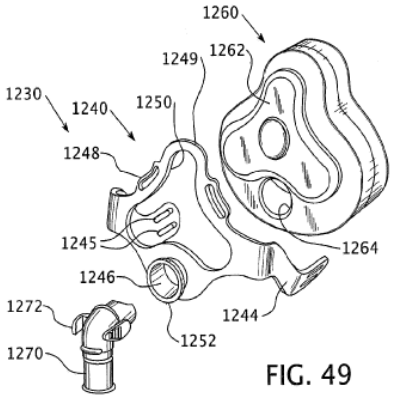
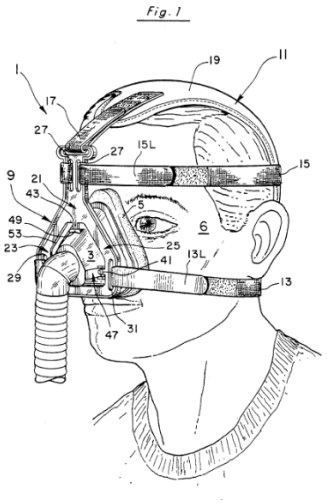
’931 Patent	Prior Art
[I] a shroud module including headgear connectors adapted to removably attach to the headgear,	*See supra* Claim 1(i). **Ng:** “The common frame 10 has a main body 40 defining a central opening 45. Main body 40 includes at least two lateral arms 50, each of which can be coupled to a headgear strap 55 of headgear. The straps may be connected to the frame using a press-fit connector 60, as is known in the art.” Ex. 1410 ¶ 30.  Fig. 1 **Thomlinson:** “Strap attachment plate 92 can facilitate the use of a strap system 102 by increasing the ease at which a strap can be connected to or removed from the nasal interface. Because the strap attachment plate is not integral to the nasal interface, the strap attachment plate, and any attached straps, can be more easily added or removed from the system.” Ex. 1411 ¶ 307. “A strap system can be fasted/unfastened using alternative methods to Velcro, such as snaps, buckles, buttons and ties.” *Id*. ¶ 312. **Ultra Mirage:** “Quick release headgear clips: top and bottom allows mask to be removed without resetting the headgear and provides convenience and safety.” Ex. 1416 at 6.

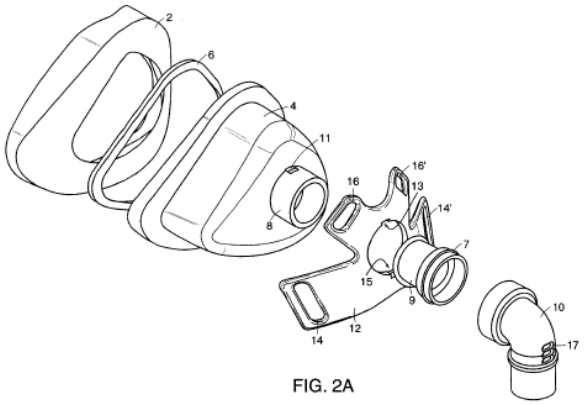
’931 Patent	Prior Art
	Ogden: “[E]ach side strap 13R and 13L is preferably attached to a respective side portion 23, 25 of the rigid plate 9 on respective sides of the patient's nose 2. This can be done in any number of well-known, adjustable manners including . . . hook and loop materials on the straps themselves. . . . The remaining straps 15R, 15L, and 17 are also individually attachable in this manner.” Ex. 1422 at col. 3:10–20. 

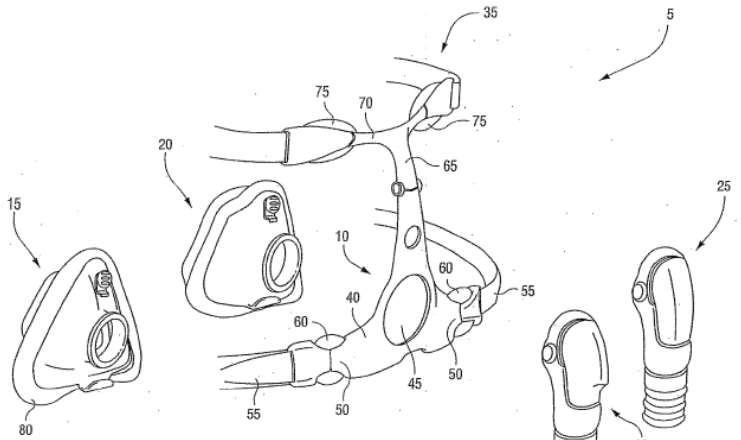
’931 Patent	Prior Art
[J] wherein the headgear connectors include two upper connectors associated with the upper headgear straps,	*See supra* Claim 6. **Ng:** “The common frame 10 has a main body 40 defining a central opening 45. Main body 40 includes at least two lateral arms 50, each of which can be coupled to a headgear strap 55 of headgear. The straps may be connected to the frame using a press-fit connector 60, as is known in the art. Common frame 10 may also include a forehead support 65 that has a bridge 70 provided with forehead pads 75 to rest against the user’s forehead in use.” Ex. 1410 ¶ 30.  Fig. 1

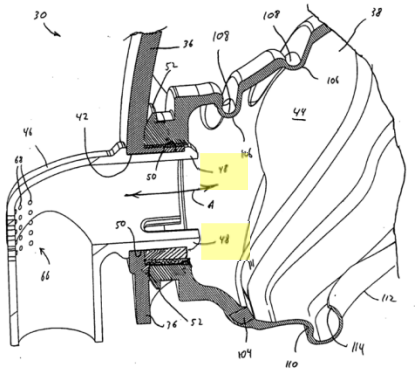
’931 Patent	Prior Art
[K] the shroud module having an opening of circular shape, and two lower connectors associated with the lower headgear straps,	*See supra* Claims 6 and 22[A]. **Ng:** “The common frame 10 has a main body 40 defining a central opening 45. Main body 40 includes at least two lateral arms 50, each of which can be coupled to a headgear strap 55 of headgear. The straps may be connected to the frame using a press-fit connector 60, as is known in the art.” Ex. 1410 ¶ 30.  Fig. 1
[L] each said upper headgear connector including a slot or receiving hole adapted to receive one of the upper headgear straps,	*See supra* Claim 7. **Thomlinson:** “As shown in FIG. 28B, strap attachment plate 92 . . . includes one or more strap connections 120 for receiving a strap system 102.” Ex. 1411 ¶ 306.  Fig. 28D  Fig. 28A

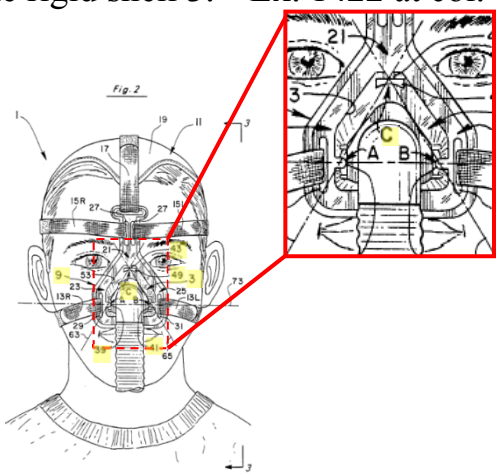
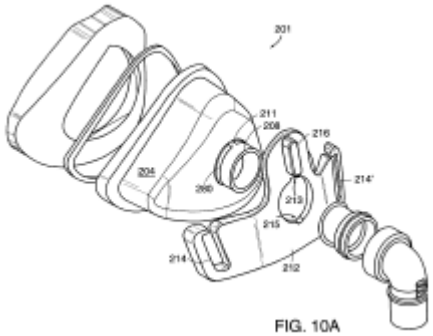
’931 Patent	Prior Art
	FlexiFit: “[A]ttach the four straps in to the corresponding slots in the Mask Base.” Ex. 1417 at 10 (“ASSEMBLING YOUR MASK”).  **Gunaratnam-I:** “As compared to FIGS. 5a-5b, FIGS. 5c-5f also show an adjustable forehead support (162) connected to the frame (160).” Ex. 1413 at col. 4:46–48.  FIG. 5c **Lithgow:** *See* Ex. 1433 at Fig. 1.  FIG. 1

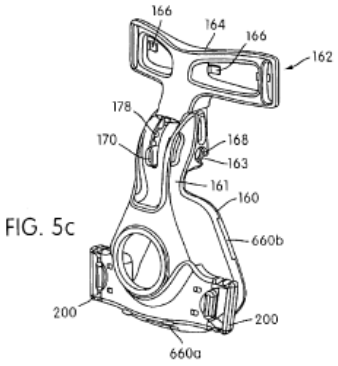
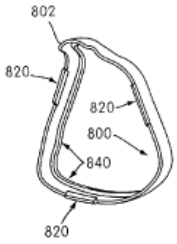
’931 Patent	Prior Art
	Matula-I: “[A]ttachment elements 1248 are provided in the form of slots provided . . . [o]n a central portion 1249 of the body member.” Ex. 1423 ¶ 103.  FIG. 49 **Ogden:** “The upper side straps in this last regard could be the two straps 15R and 15L as illustrated or one continuous strap passing through loops 27 and anchoring the top portion 21 of the rigid plate 9 (see FIGS. 1-3).” Ex. 1422 at col. 3:7–10. 

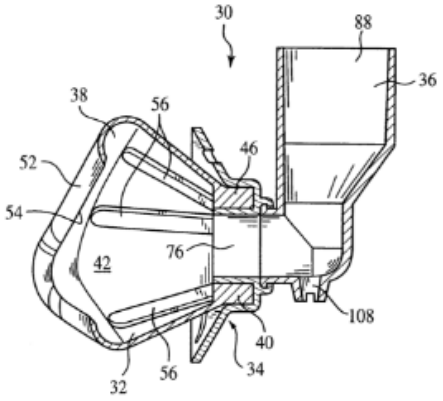
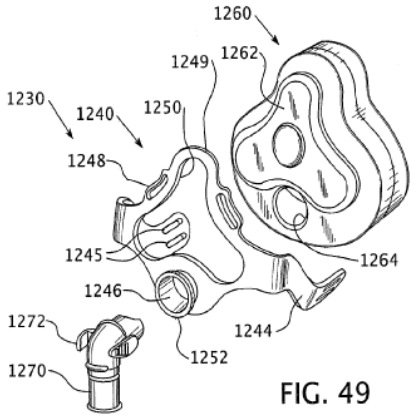
’931 Patent	Prior Art
	Lovell: “These connection points 14, 14', 16, 16' form slots which allow for connection of the retainer 12 with straps of a headgear apparatus, as shown in FIG. 3.” Ex. 1426 at col. 6:10–13.  FIG. 2A

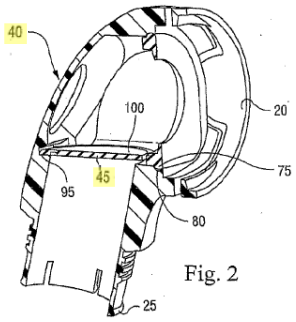
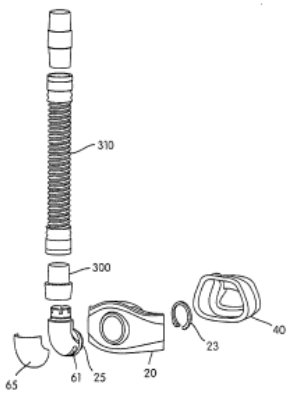
’931 Patent	Prior Art
[M] wherein the shroud module and the frame of the cushion module are configured to be removably snap-fit attached to one another in a non-rotatable manner by pushing the shroud module towards the frame along a longitudinal axis of both the opening of the frame and the opening of the shroud;	*See supra* Claims 1[A] and 26[B]. **Ng:** “The common frame 10 has a main body 40 defining a central opening 45.” Ex. 1410 ¶ 30. “Common frame 10 is configured to be selectively coupled to one of cushion components 15, 20 and to one of elbow components 25, 30. Cushion components 15, 20 differ in at least one respect such that one may be more optimal or preferable for use with one user, while another may be more suitable or preferably for use with another user. For example, cushion component 15 may be an Activa™ component, while cushion component 20 may be an UltraMirage™ Series II cushion component, both available from ResMed. These cushion components can be significantly different from one another, e.g., the Activa™ includes a gusset portion 80 and a cushion clip assembly (not shown) which is not incorporated in the UltraMirage™ cushion design.” Ex. 1410 ¶ 31.  Fig. 1

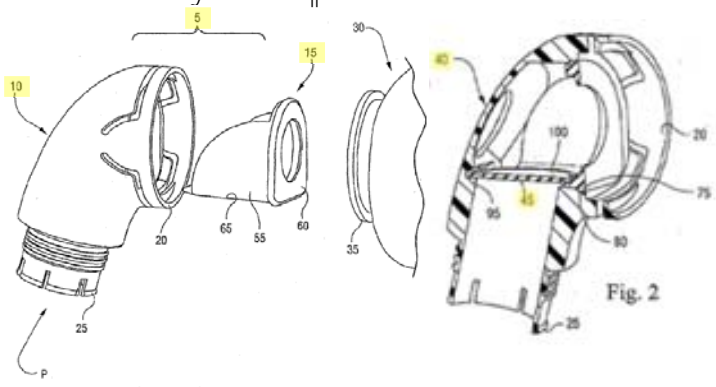
’931 Patent	Prior Art
	A person of skill would have understood that the shroud module 10 and cushion module 15, 20 are non-rotatably coupleable because the cushion module attaches to the shroud at two points (annular opening 45 and the clip located above the annular opening). This arrangement would have prevented relative rotation between the two parts. **<u>Matula-II</u>:** “Coupling member 46 includes a pair of prongs 48 that define a channel 50 to receive the wall of the faceplate and the end of seal member 38.” Ex. 1412 ¶ 53. A person of skill in the art would have understood that the “prongs” of Matula-II could also be referred to as “snap fingers.”  Fig. 4

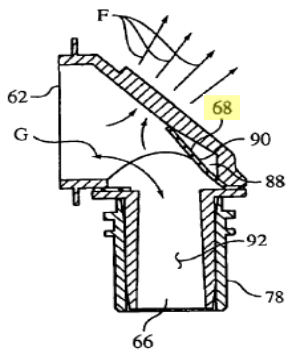
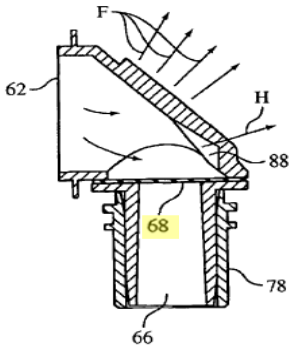
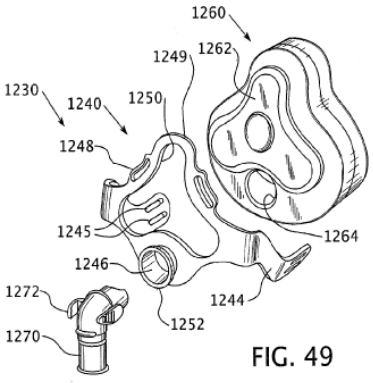
’931 Patent	Prior Art
	Ogden: “[R]igid plate 9 is preferably mounted to the rigid shell 3 at first, second, and third locations A, B, and C. . . . Further, although the detent-channel 43, 49 at the top of the shell 3 at the third location C is preferably dimensioned to snap together to hold or maintain the rigid plate 9 on the rigid shell 3.” Ex. 1422 at col. 4:59–5:19.  **Lovell:** “The retainer 212 is disposed about the inlet 208 to facilitate retention of the mask 201 on a user. . . . Two tabs 211, 211' included on the inlet 208 mate with two slots 213, 215 formed in the retainer 212 in a particular angular orientation. . . . The retainer aperture and the inlet 208 are generally sized in an interference fit so that the retainer 212 is properly retained by the cooperation of the tabs 211, 211', the slots 213, 215, and the depressed annular region 280 when fully seated against the shell 204.” Ex. 1426 at col. 9:43–48, 9:59–64.  FIG. 10A

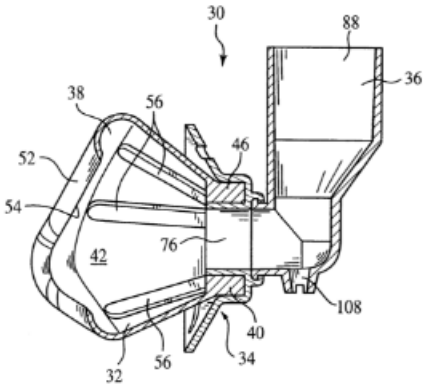
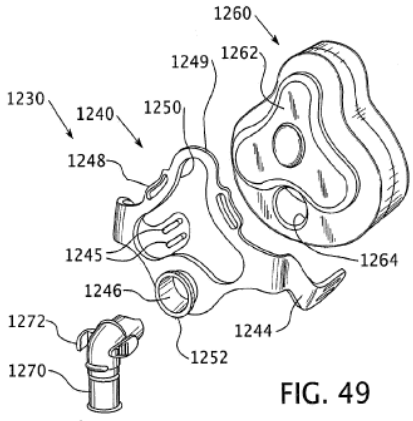
’931 Patent	Prior Art
	Gunaratnam-I: “[T]he clip (800) includes three securing tabs (820) such that inwards projections on the detents are formed as resilient detents which extend past the outer edge of flange (640) to be retained in recesses (660) on the front of the flange (640). To disengage, for 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. 1413 at col. 5:34–43.  FIG. 5c  FIG. 7a
[N] and an elbow rotatably attached to and carried by the shroud module or the frame of the cushion module, the elbow being configured to deliver the positive pressure air to the breathing chamber,	*See supra* Claims 11 and 14. **Ng:** “Common frame 10 is configured to be selectively coupled to one of cushion components 15, 20 and to one of elbow components 25, 30.” Ex. 1410 ¶ 31.

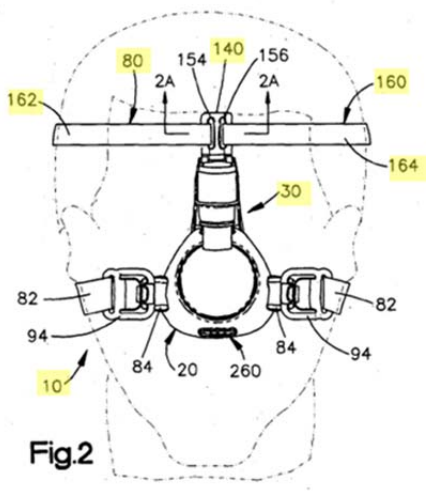
’931 Patent	Prior Art
	Barnett: “[C]onduit coupling member 36 is preferably rotateably mounted on a second side of collar 34 opposite the first side so that conduit coupling member 36 freely rotates over a range of 360° about a central axis of collar 34.” Ex. 1414 at col. 3:52–57; *see also id.* at col. 8:66—9:43.  FIG. 1A **Ultra Mirage:** “360° rotating elbow provides control over tubing system.” Ex. 1416 at 6. **Matula-I:** “[P]atient circuit coupling 1270 is an elbow coupling that rotatably and releasably attaches to circuit coupling portion 1246.” 1423 ¶ 105.  FIG. 49 **Lovell:** “[S]wivel connector 9 produces a swivel mount connection between the conduit elbow 10 and the inlet 8. In this type of connection, the conduit elbow 10 is capable

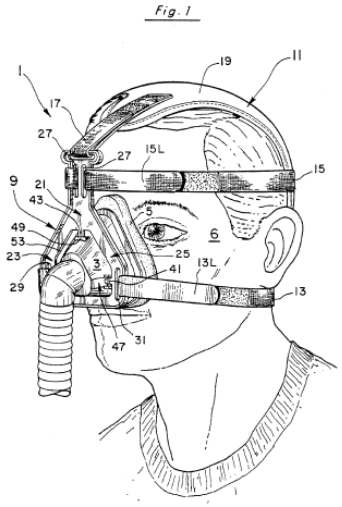
’931 Patent	Prior Art
	of rotating 360 degrees about the centerline of the inlet 8 and the connector 9.” Ex. 1426 at col. 5:20–24.
[O] the elbow including a swivel adapted to connect to an air delivery tube,	**Worboys:** “The elbow has a first portion 20 and a second portion 25. . . . The second portion 25 typically will be provided with a swivel joint which in turn is connected to an air delivery tube in communication with a flow generator.” Ex. 1415 ¶¶ 104–105.  Fig. 2 **Ging:** “The swivel elbow assembly 60 of FIG. 6a may be the same as is currently used in ResMed Limited's ULTRA MIRAGE® mask, which employs an internal C-clip member, as described above. The elbow assembly 60 of FIG. 6a is intended to be used with a connector tube 300 (FIG. 23). The connector tube 300 is provided between the elbow assembly 60 and the gas delivery tube 310 (FIG. 26).” Ex. 1431 ¶ 153.  FIG. 6b

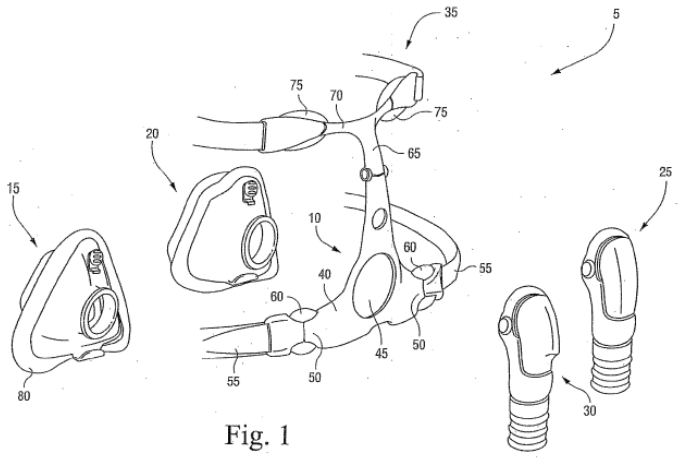
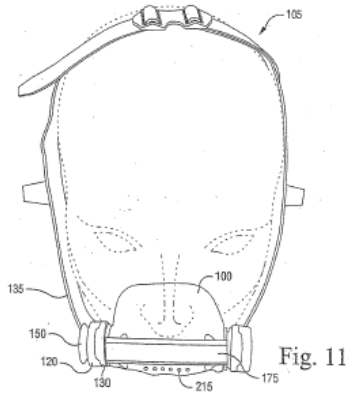
’931 Patent	Prior Art
	Ultra Mirage: “Quick release swivel allows easy disconnection from tubing.” Ex. 1416 at 6. **Ogden:** “Another feature of the facial mask assembly 1 of the present invention is the swivel hose coupling 10 of FIGS. 8 and 9 connecting the rigid shell 3 to the flexible hose 12.” Ex. 1422 at col. 5:35–37. **Hitchcock:** “Frame 308 includes a front plate 312 including an aperture 314 adapted to receive pressurized gas from an air delivery tube, e.g., via a swivel elbow.” Ex. 1421 ¶ 28.
[P] the elbow including an anti-asphyxia valve (AAV) and a port that is selectively closed by a flap portion of the AAV.	*See supra* Claim 15. **Worboys:** “[E]lbow assembly 5 generally comprises an elbow 10 and an anti–asphyxia valve 15 (AAV) assembly.” Ex. 1415 ¶ 103. “[E]lbow 10 includes a port 40 that may be selectively closed by a flap portion 45 of the AAV assembly.” *Id*. ¶ 106.  Fig. 1 **Jaffre:** “It is common when using a full face mask, to provide a valve in the patient circuit that automatically allows the patient access to the ambient atmosphere in the event of a failure of the pressure support system. See, e.g. U.S. Pat. No. 5,438,981, which teaches the function of such a valve and describes several embodiments of such a valve.” Ex. 1427 at col. 10:4–8.

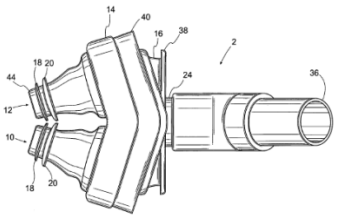
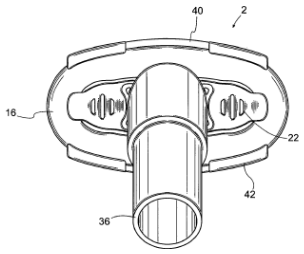
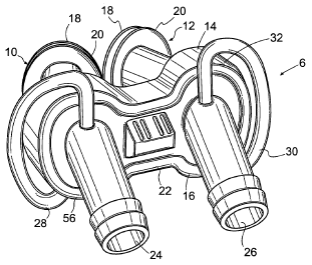
’931 Patent	Prior Art
	“During normal use, where the pressure support system is functioning properly, a cantilever member 90 of valve member 68 flexes, as shown to FIG. 8, to block auxiliary opening 88. If the gas pressure in an interior 92 of the conduit is greater than the ambient atmosphere, cantilever member 90 moves to the position shown in FIG. 8 to block opening 88, so that gas is able to flow between the patient and the pressure generating system, as indicated by arrow G.” *Id.* at col. 10:14–22.  FIG. 8  FIG. 9 **Matula-I:** “[T]he present invention contemplates providing an entrainment valve and/or exhaust assembly on patient circuit coupling 1270. . . . the exhaust assembl[y] can be provided at other locations, such as in the patient interface portion [1260], the body member, or in any combination of locations.” Ex. 1423 ¶ 106.  FIG. 49

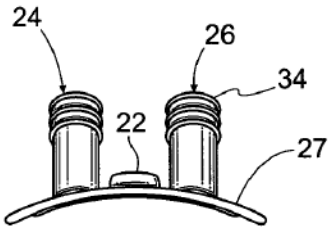
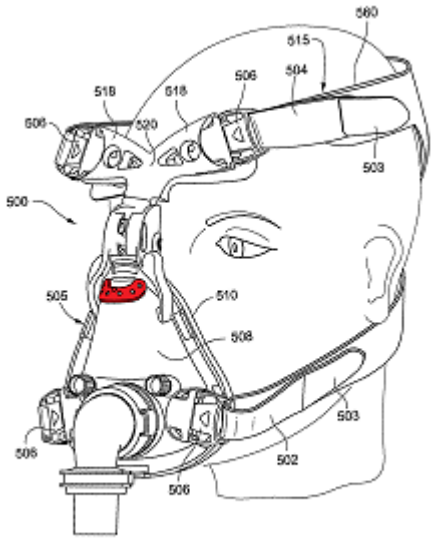
’931 Patent	Prior Art
46. The mask system of claim 43, wherein: **[A]** the elbow is rotatably attached the shroud module,	*See supra* Claims 11 and 14. **Ng:** “Common frame 10 is configured to be selectively coupled to one of cushion components 15, 20 and to one of elbow components 25, 30.” Ex. 1410 ¶ 31. **Barnett:** “[C]onduit coupling member 36 is preferably rotateably mounted on a second side of collar 34 opposite the first side so that conduit coupling member 36 freely rotates over a range of 360° about a central axis of collar 34.” Ex. 1414 at col. 3:52–57; *see also id.* at col. 8:66—9:43.  FIG. 1A **Matula-I:** “[P]atient circuit coupling 1270 is an elbow coupling that rotatably and releasably attaches to circuit coupling portion 1246.” 1423 ¶ 105.  FIG. 49

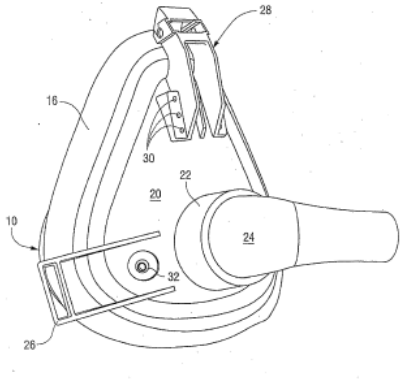
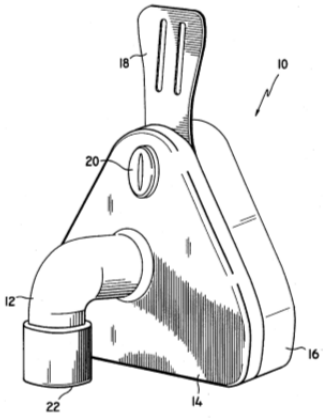
’931 Patent	Prior Art
	Ultra Mirage: “360° rotating elbow provides control over tubing system.” Ex. 1416 at 6. **Lovell:** “[S]wivel connector 9 produces a swivel mount connection between the conduit elbow 10 and the inlet 8. In this type of connection, the conduit elbow 10 is capable of rotating 360 degrees about the centerline of the inlet 8 and the connector 9.” Ex. 1426 at col. 5:20–24.
[B] the upper headgear straps provide padding to the respective headgear connectors of the shroud on the patient's face in use,	*See supra* Claim 20. **Sprinkle:** “When the left and right straps 162 and 164 are connected with the forehead adjuster 140 in this manner, a relatively large amount of strap material is present between the forehead adjuster 140 and the user's forehead. This strap material, as mentioned above, is resilient. Therefore, a substantial cushion is present between the forehead support assembly 30 and the user's forehead. This cushion provides a very comfortable strap attachment, without the necessity for separate cushion members or cushioning pieces on the adjuster 140.” Ex. 1419 ¶ 74, *see also id.* ¶¶ 3, 72.  Fig.2

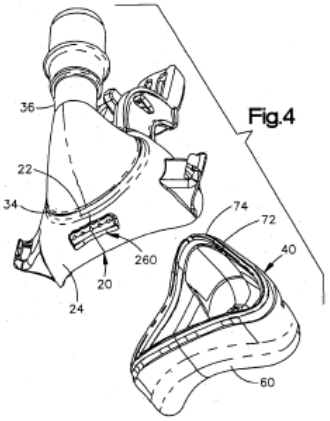
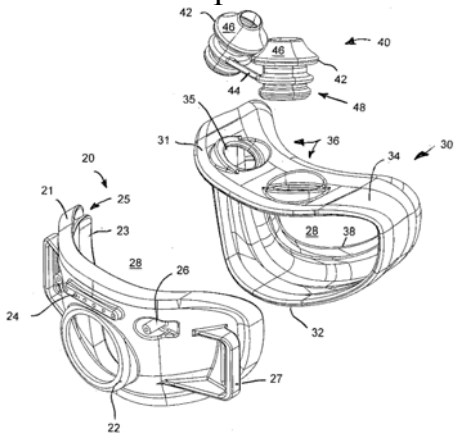
’931 Patent	Prior Art
	Ogden: “[L]ooping the straps 13R and 13L through the openings 29, 31 in the rigid plate 9 and fastening them back on themselves by hook and loop materials on the straps themselves. . . . The remaining straps 15R, 15L, and 17 are also individually attachable in this manner . . . . The straps themselves are preferably made of flexible material and may have some slight elasticity to them to comfortably fit about the patient's head.” Ex. 1422 at col. 3:14–24.  **Lovell:** “The straps 52, 54, 56 may be manufactured from inelastic or elastic materials such as, but not limited to, nylon webbing, nylon covered neoprene or Velstretch™, available from Velcro USA Inc., Manchester, N.H., and may further include optional padding, if desired.” Ex. 1426 at col. 6:30–34.

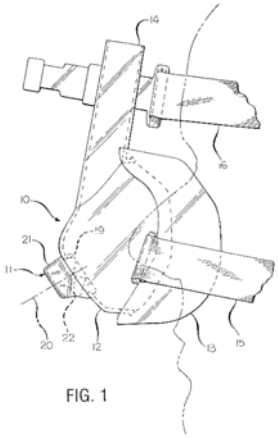
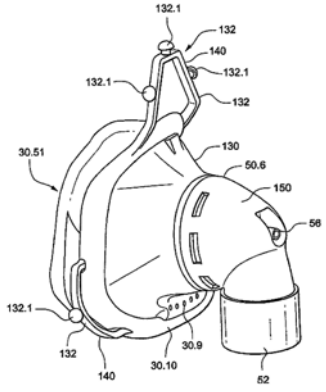
’931 Patent	Prior Art
[C] the frame includes a protruding vent arrangement having a plurality of holes, wherein the shroud module includes a first opening to accommodate said protruding vent arrangement,	*See supra* Claim 1[B]. **Ng:** “Common frame 10 is configured to be selectively coupled to one of cushion components 15, 20 and to one of elbow components 25, 30.” Ex. 1410 ¶ 31.  Fig. 1 “As shown in Figs. 3, 7-8, and 11, the mask assembly includes a gas washout vent 215. The vent 215 could be on the frame and/or the cushion component.” *Id.* ¶ 43.  Fig. 11

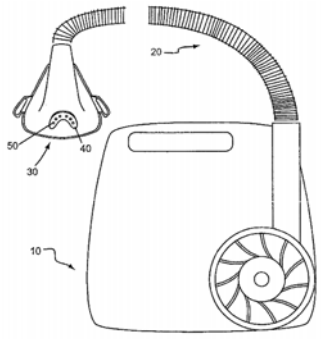
’931 Patent	Prior Art
	Thomlinson: “A nasal interface body 2 according to the present invention can also include one or more locking tabs 38 on the distal portion 16. The locking tabs 38 can be used to releasably engage a strap attachment plate 92, as depicted in FIG. 37 and described further below.” Ex. 1411 ¶ 203.  Fig. 1 “Further, and as shown in FIG. 3, one embodiment of a nasal interface can also include one or more exhalation ports 22, which are described in more detail below.” *Id.* ¶ 204.  Fig. 3 “As shown in FIG. 8, nasal interface body 6 can also include first inlet 24 and a second inlet 26, as well as exhalation port 22. In one embodiment, exhalation port 22 is positioned between inlet 24 and second inlet 26.” *Id*. ¶ 209.  Fig. 8

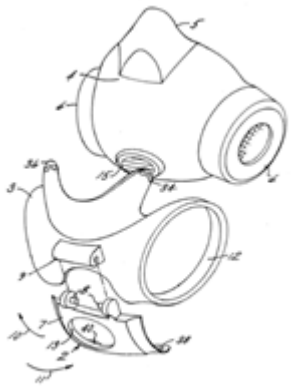
’931 Patent	Prior Art
	“As shown in the figures and in particular FIGS. 3, 14A, 15D, 15F, 16C and 16F, distal portion 16 can also include one or more exhalation ports 22, described further below.” *Id*. ¶ 247.  Fig. 14A **Hitchcock:** *See* Ex. 1421 at Fig. 8.  Fig. 8

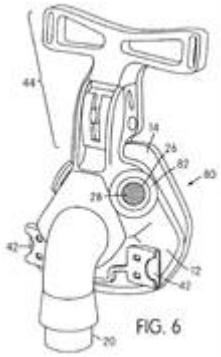
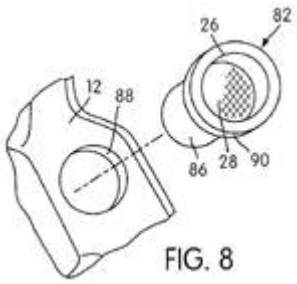
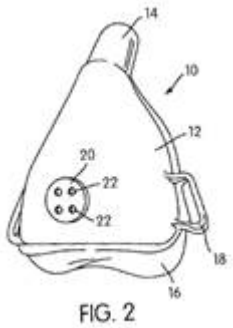
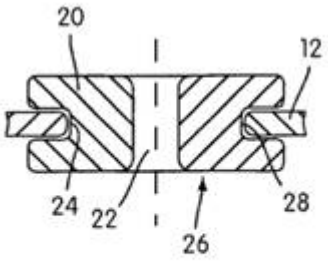
’931 Patent	Prior Art
	Hitchcock-II: “A number of vents 30 may be provided so as to allow gas exhaled by the patient to vent to atmosphere.” Ex. 1440 ¶ 42.  Fig. 1-2 **Landis:** “[T]he aperture in mask frame 14 to receive variable orifice member 20 is configured as a cylindrical wall projecting outward from the mask frame to engage a variable orifice member cap, as described in greater detail below.” Ex. 1441 at col. 5:35–38.  FIG. 1 “In one construction, variable orifice vent aperture member 20 is configured as a cap to mount onto and engage projecting walls of a cylindrical opening in the mask frame or other associated structure (not shown).” *Id.* at col. 6:19–23.

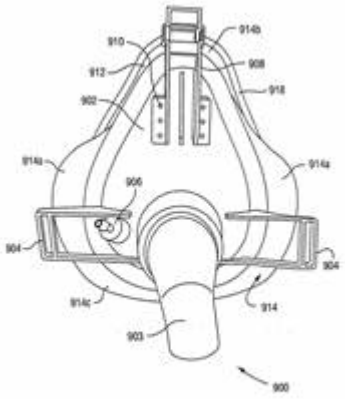
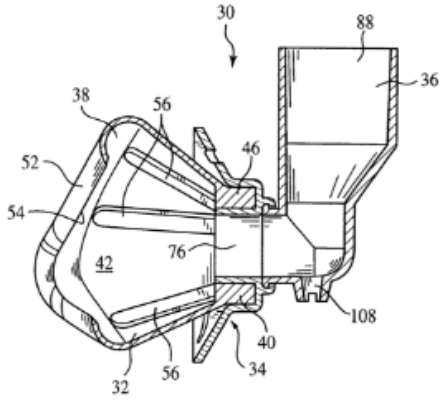
’931 Patent	Prior Art
	Sprinkle: “FIGS. 4 and 23 illustrate an exhalation vent portion 260 of the mask 10. The vent portion 260 includes a thickened wall area 262 in the lower part of the side wall 24 of the shell 20. Five circular exhalation openings 264 are formed at equally spaced intervals in the thickened area 262. The exhalation openings 264 extend from the exterior of the mask 10 to the central chamber 32 of the shell 20. The exhalation openings 264 enable exhaled air to flow out of the mask 10.” Ex. 1419 ¶ 99.  **Chandran:** “The ventilation interface 20 is configured with at least one exhalation port 24.” Ex. 1439 ¶ 60.  *Id.* at Fig. 2.

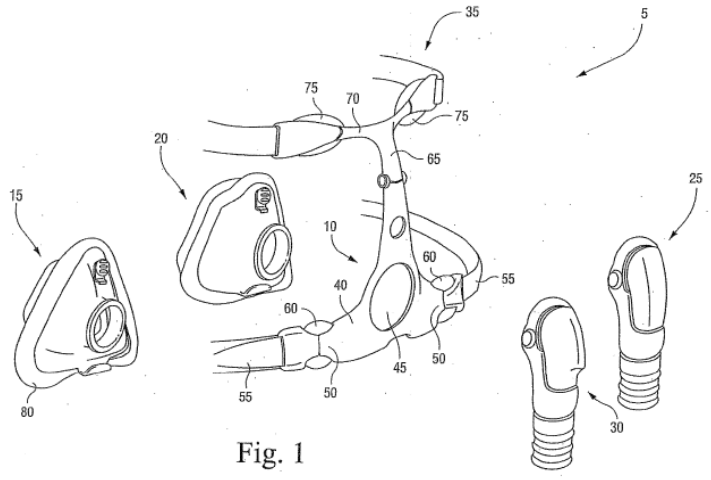
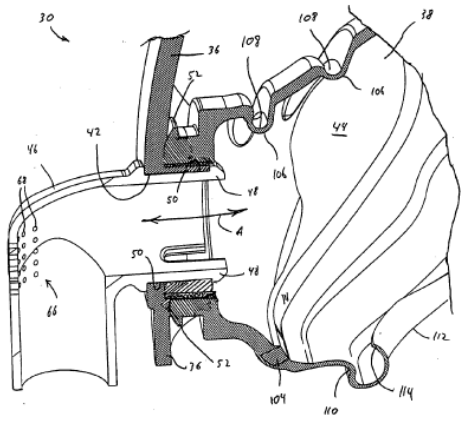
’931 Patent	Prior Art
	Jones, Jr.: “[T]he exhaust port member 11 is shown as having a generally circular perimeter 17 with a recessed or reduced diameter annular groove 18 formed in the perimeter 17, as shown in FIG. 4. A circular opening 19 is formed in the mask body 12 for receiving the exhaust port member 11.” Ex. 1436 at col. 3:3–15.  FIG. 1 “At least one and preferably two vent ports 22 extend through the exhaust port member 11 at a predetermined angle relative to the axis of rotation 20.” *Id.* at col. 3:23–25. **Jones:** “[T]he lip region 30.8 has a series of four vent orifices 30.9 passing therethrough” Ex. 1437 ¶ 221.  *Id.* at Fig. 10.

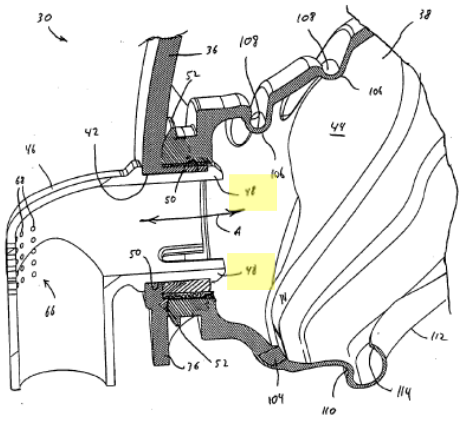
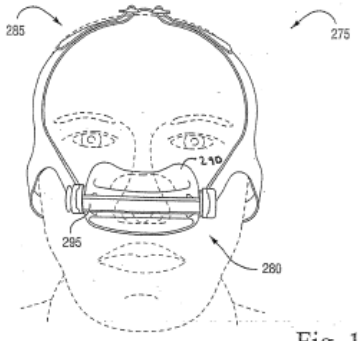
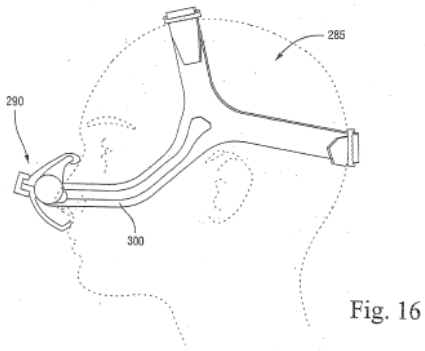
’931 Patent	Prior Art
	“The shell/cushion 130 includes a series of vents or vent orifices 30.9, which in a preferred form comprises four orifices. The vent orifices 30.9 are formed through a thicker wall section 30.10 formed integrally on the shell/cushion 30. The wall section 30.10 is shown in FIG. 3. The wall section 30.10 has two functions. The first is to form a front flange which with the rear flange 36 in the lip region 30.8 forms the lower channel 140.4. The second function is that the wall section 30.10 allows the vent orifices 30.9 to be positioned at an angle with respect to the elbow.” *Id.* ¶ 226. **Darkin:** “The patient interface 30 includes a vent 40. The vent 40 includes one or more holes, e.g., six holes 50.” Ex. 1442 ¶ 55.  Fig. 1 “Another advantage of the invention is to provide different vents for different pressure ranges. For example, at low pressures, it may be appropriate to have a vent with large holes in order to provide sufficient vent flow. The same vent at higher pressures would have unnecessarily high vent flow which leads to increased noise. Hence in accordance with an embodiment of the invention, when a patient is using a generally low pressure treatment, they can utilize a first vent, but when treatment pressures are higher they can use a second vent.” *Id.* ¶ 89.

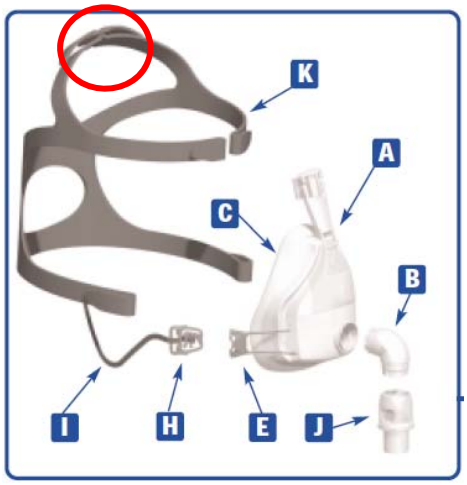
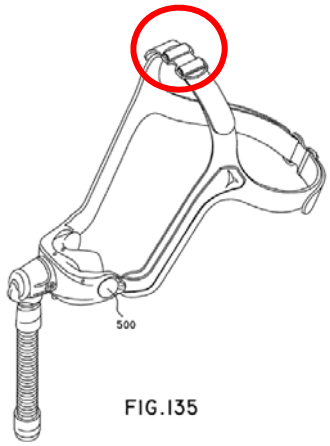
’931 Patent	Prior Art
	“Another advantage of the invention is that it provides a quick and simple system of replacing disposable vents. For example, certain styles of vents may clog easily and be designed for a single night's use. In accordance with an embodiment of the invention a vent assembly can comprise a set of "single use" vents. After a first night's use, the patient can switch to the second vent. After a second night's use, the patient can switch to a third vent, and so on.” *Id.* ¶ 90. **Fecteau:** “[A] respirator 1 incorporates a quick release mechanism 2 into a facepiece support system, or yoke, 3.” Ex. 1446 at 4:24–25. “[Q]uick release mechanism 2 consists of an over center cam latch 7 pivotly attached to yoke 3 via hinge pins 8 disposed within hinge 9 and further includes relief cut 13 to accommodate exhale valve 15 while in the latched position.” *Id.* at 4:29–32.  FIG. 2 **Drew:** “The mask 10 includes a gas washout vent constituted by an opening 26 in the shell 12 across which extends a thin air permeable membrane 28.” Ex. 1444 at col. 4:32–34. “FIG. 6 shows a nasal respiratory mask 80.” *Id.* at col. 5:31. “In the mask 40 of FIG. 2, the [gas washout] vent is provided in the gas inlet 20, whereas in the mask 80 the vent is provided in the shell 12. More particularly, the mask 80 includes two cylindrical inserts

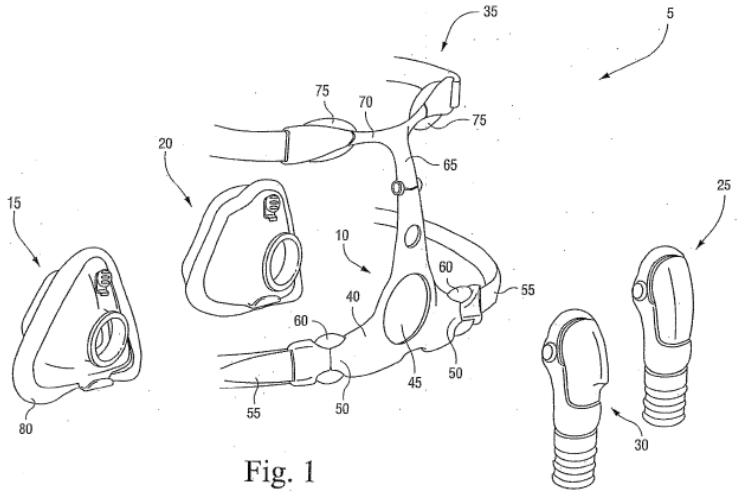
’931 Patent	Prior Art
	82 which have an inner opening 26 across which extends the thin air permeable material 28.” *Id.* at col. 5:35–40. “[T]he insert 82 [] comprises a cylindrical portion 86 sized to be a snug fit into a circular orifice 88 provided in the mask shell 12.” *Id.* at col. 6:2–4.  FIG. 6  FIG. 8 **<u>Kwok</u>:** “The mask includes a Silastic™ insert 20 through which is provided an orifice 22 for gas washout.” Ex. 1445 at col. 3:43–44. “[T]he insert 20 has an external groove or recess 24 which engages the rim 28 of a corresponding shaped opening 26 in the mask shell 12 to retain the insert 20 in place.” *Id.* at col. 3:57–60. “In the embodiment shown in FIGS. 2 to 5 and 7 the insert 20 includes more than one orifice 22.” *Id.* at col. 3:61–62.  FIG. 2  FIG. 8

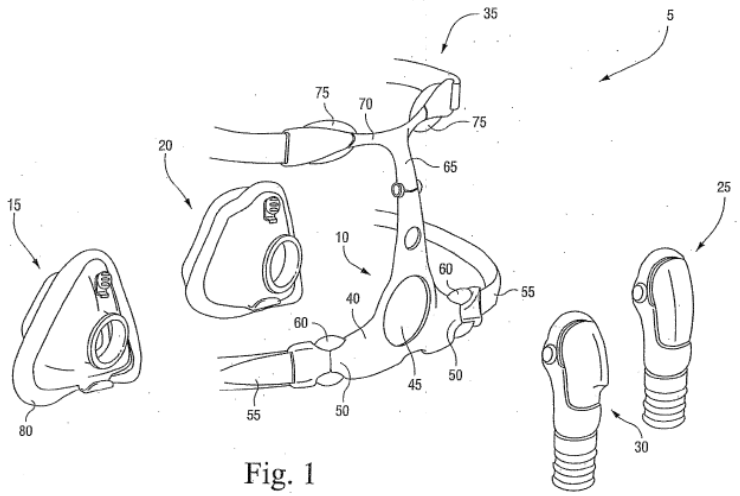
’931 Patent	Prior Art
	Frater: “Shell 902 may also be provided with one or more vents 910.” Ex. 1425 ¶ 163.  Fig. 50
[D] further wherein the shroud module includes a second opening to accommodate the elbow,	*See supra* Claim 12. **Ng:** “Common frame 10 is configured to be selectively coupled to one of cushion components 15, 20 and to one of elbow components 25, 30.” Ex. 1410 ¶ 31. **Barnett:** “[C]onduit coupling member 36 is preferably rotateably mounted on a second side of collar 34 opposite the first side so that conduit coupling member 36 freely rotates over a range of 360° about a central axis of collar 34.” Ex. 1414 at col. 3:52–57; *see also id.* at col. 8:66—9:43.  FIG. 1A

’931 Patent	Prior Art
[E] the frame includes an opening and the frame further includes a collar surrounding said opening, and	*See supra* Claim 5[A]. **Ng**: The cushion frame includes an annular collar around the opening. *See* Ex. 1410 at Fig. 1.  Fig. 1 **Matula-II:** “[T]he end of seal member 38 is joined to a ring 52 that is more rigid than the end of the seal member to provide a strong, stable mechanical coupling of the seal member to the faceplate.” Ex. 1412 ¶ 53.  Fig. 4

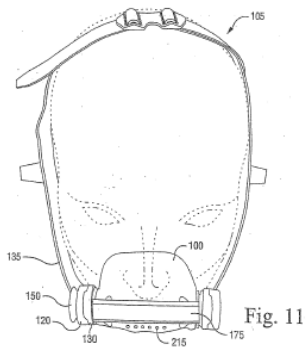
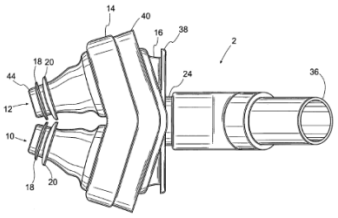
’931 Patent	Prior Art
[F] wherein the shroud module includes a retaining portion with one or more rearward extending snap fingers structured to engage the collar with a snap-fit, and	*See supra* Claim 5[B]. **Matula-II:** “Coupling member 46 includes a pair of prongs 48 that define a channel 50 to receive the wall of the faceplate and the end of seal member 38.” Ex. 1412 ¶ 53. A person of skill in the art would have understood that the “prongs” of Matula-II could also be referred to as “snap fingers.”  Fig. 4
[G] the top straps are connected together with a buckle allowing independent adjustment of each of the top straps.	*See supra* Claim 19[D]. **Ng:** *See* Ex. 1410 at Figs. 15 and 16.  Fig. 15  Fig. 16

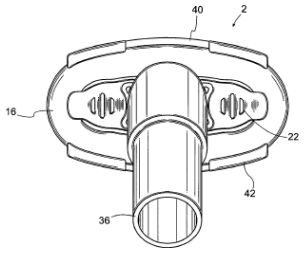
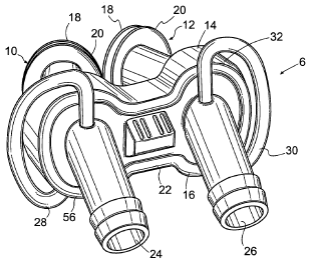
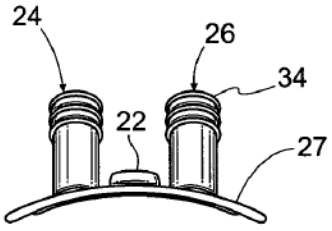
’931 Patent	Prior Art
	FlexiFit: Ex. 1417 at 10.  **Gunaratnam-II:** “[U]pper straps 598 are coupled to one another by a headgear buckle 570.” Ex. 1429 ¶ 316, Fig. 135. 

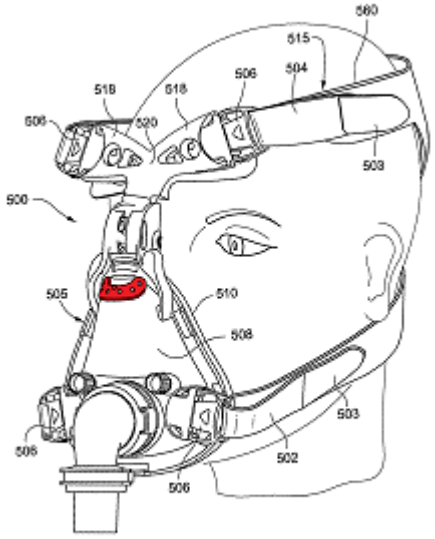
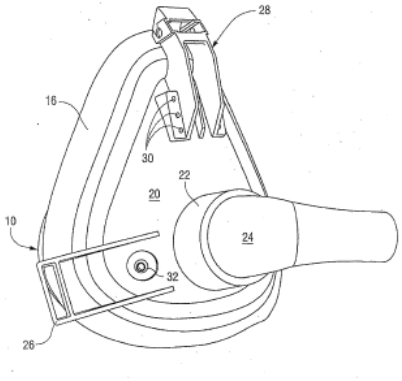
’931 Patent	Prior Art
51. A mask system for delivery of a supply of air at positive pressure to a patient's airway, the mask system comprising:	*See supra* Claim 1, preamble. “The mask system is intended for use in positive pressure therapy for users with obstructive sleep apnea (OSA) or another respiratory disorder.” Ex. 1410 ¶ 29.  Fig. 1
[A] a cushion module comprising a frame defining a breathing chamber configured to receive the positive pressure air, and a cushion to form a seal with the patient's face in a nasal bridge region, a cheek region and a lower lip/chin region of the patient's face,	*See supra* Claim 1(ii). **Ng:** “Common frame 10 is configured to be selectively coupled to one of cushion components 15, 20 and to one of elbow components 25, 30. Cushion components 15, 20 differ in at least one respect such that one may be more optimal or preferable for use with one user, while another may be more suitable or preferably for use with another user. For example, cushion component 15 may be an Activa™ component, while cushion component 20 may be an UltraMirage™ Series II cushion component, both available from ResMed. These cushion components can be significantly different from one another, e.g., the Activa™ includes a gusset portion 80 and a cushion clip assembly (not shown) which is not incorporated in the UltraMirage™ cushion design.” Ex. 1410 ¶ 31.

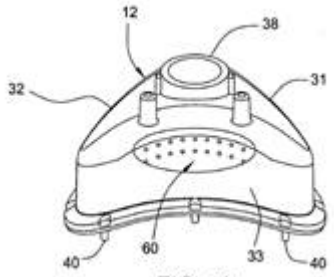
’931 Patent	Prior Art
	“Interfaces, such as a nasal mask assembly, for use with blowers and flow generators in treatment of sleep disordered breathing (SDB) typically included a soft-face contacting portion, such as a cushion, and a rigid shell or frame.” *Id*. ¶ 3. “[A] supplemental cushion component in the form of a nasal cushion or a full-face cushion, wherein the cushion component and the supplemental cushion component cooperatively seal with the user’s face in use.” *Id*. ¶ 13. “A system of breathing arrangements for delivering breathable gas to a patient, comprising at least first and second cushion components (15, 20), e.g., full-face, nasal, nasal prongs, nose tip, and/or a combination of any of the above, including a nasal or full-face cushion and nasal prongs/nozzles combination, etc., that are different from one another in at least one aspect, and a common frame assembly (10) configured to support each of the first and second cushion components (15, 20). Various embodiments are directed to a full-face or nasal mask used with a frame having lateral connector portions having a stiffening member.” *Id*. at Abstract.  Fig. 1

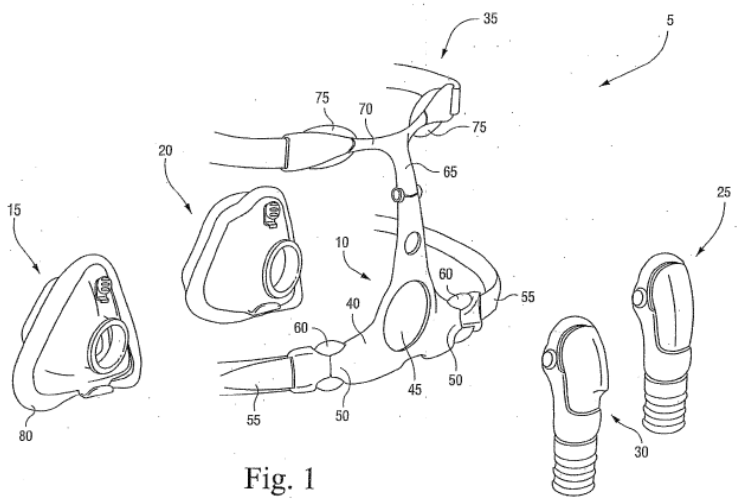
’931 Patent	Prior Art
[B] wherein the cushion is constructed of a first, relatively soft, elastomeric material and the frame is constructed of a second material that is more rigid than the cushion,	*See supra* Claim 1(ii). **Ng:** “Interfaces, such as a nasal mask assembly, for use with blowers and flow generators in treatment of sleep disordered breathing (SDB) typically included a soft-face contacting portion, such as a cushion, and a rigid shell or frame.” Ex. 1410 ¶ 3. **Lithgow:** “The cushion 14 is constructed from a soft, flexible skin-compatible material such as silicone. The cushion 14 may be formed, for example, in a one shot injection molding process as is known in the art. However, the cushion 14 may be formed with any suitable material and may be formed by any suitable process. For example, while face contacting portion 26 of cushion 14 may have a softer grade material, the gusset portion may have a harder grade material to provide stiffness as a spring element. The non-face contacting portion 24 may have a stiffer grade material so a direct assembly to frame without a cushion clip may be possible.” Ex. 1433 ¶ 139.

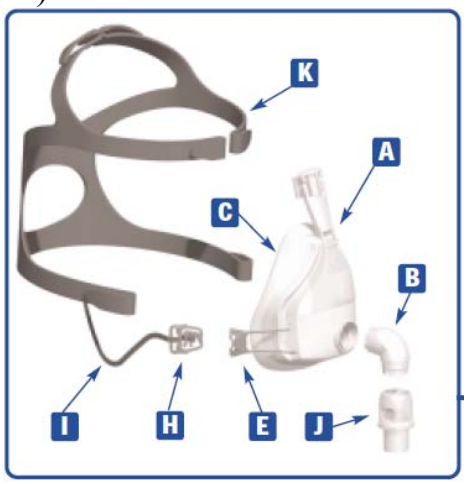
’931 Patent	Prior Art
[C] the frame including a washout vent;	*See supra* Claim 1[B]. **Ng:** “As shown in Figs. 3, 7-8, and 11, the mask assembly includes a gas washout vent 215. The vent 215 could be on the frame and/or the cushion component.” Ex. 1410 ¶ 43.  Fig. 11 **Thomlinson:** “A nasal interface body 2 according to the present invention can also include one or more locking tabs 38 on the distal portion 16. The locking tabs 38 can be used to releasably engage a strap attachment plate 92, as depicted in FIG. 37 and described further below.” Ex. 1411 ¶ 203.  Fig. 1

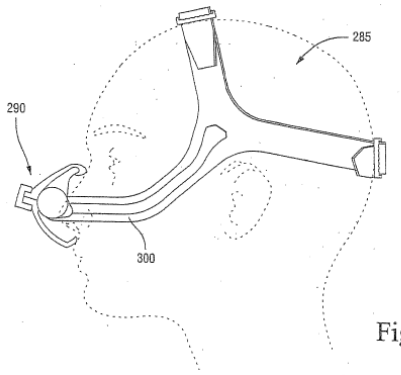
’931 Patent	Prior Art
	“Further, and as shown in FIG. 3, one embodiment of a nasal interface can also include one or more exhalation ports 22, which are described in more detail below.” *Id.* ¶ 204.  Fig. 3 “As shown in FIG. 8, nasal interface body 6 can also include first inlet 24 and a second inlet 26, as well as exhalation port 22. In one embodiment, exhalation port 22 is positioned between inlet 24 and second inlet 26.” *Id*. ¶ 209.  Fig. 8 “As shown in the figures and in particular FIGS. 3, 14A, 15D, 15F, 16C and 16F, distal portion 16 can also include one or more exhalation ports 22, described further below.” *Id*. ¶ 247.  Fig. 14A

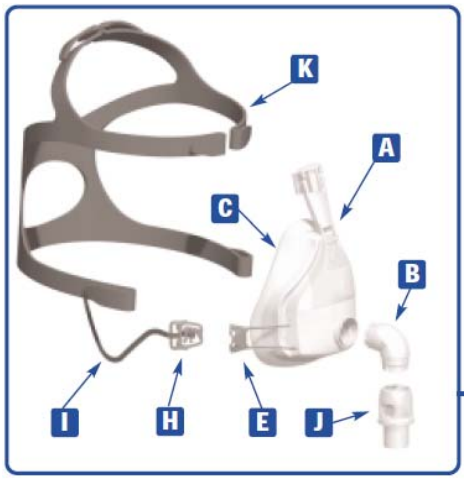
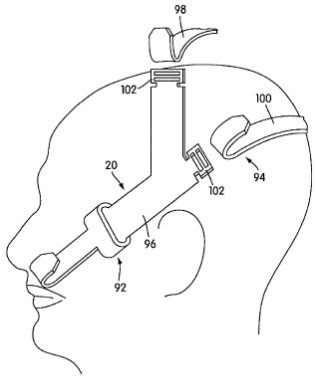
’931 Patent	Prior Art
	Hitchcock: *See* Ex. 1421 at Fig. 8.  Fig. 8 **Hitchcock-II:** “A number of vents 30 may be provided so as to allow gas exhaled by the patient to vent to atmosphere.” Ex. 1440 ¶ 42.  Fig. 1-2

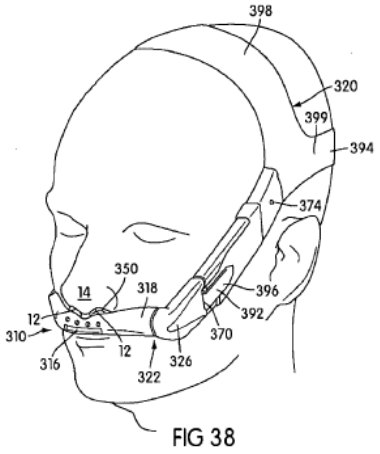
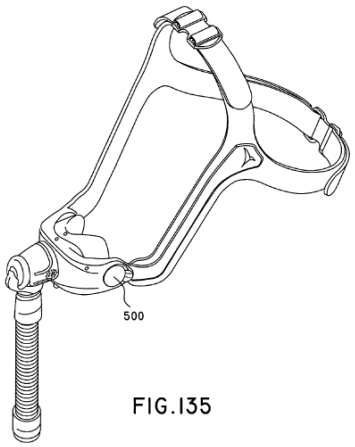
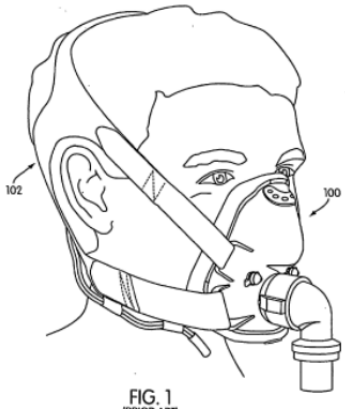
’931 Patent	Prior Art
	Geist: “The mask 10, referring particularly to FIGS. 1 and 2A-2D, includes a mask shell indicated by general numerical designation 12 [and] a mask seal indicated by general numerical designation 14.” Ex. 1434 ¶ 35. “The vent holes are exit vent holes and are for venting the exhaled breath of a wearer of the mask 10. As shown in FIGS. 10 . . . the plurality or curved array of vent holes are indicated by general numerical designation 60 in FIGS. 10 and 11.” *Id.* ¶ 40.  FIG. 10

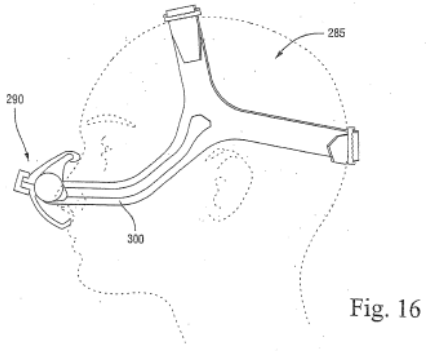
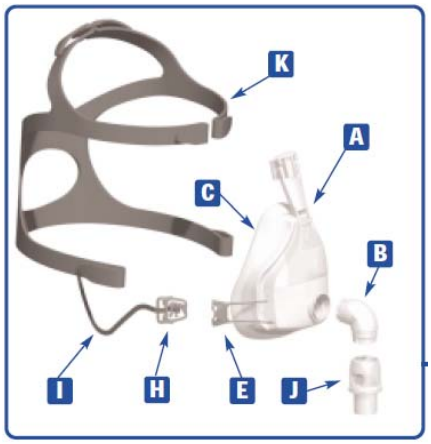
’931 Patent	Prior Art
[D] headgear to maintain the mask system in a desired position on the patient's face, the headgear comprising a pair of upper headgear straps each configured to extend above a respective one of the patient's ears in use and a pair of lower headgear straps each configured to extend below a respective one of the patient's ears in use,	*See supra* Claim 19[A]. **Ng:** “The common frame 10 has a main body 40 defining a central opening 45. Main body 40 includes at least two lateral arms 50, each of which can be coupled to a headgear strap 55 of headgear. The straps may be connected to the frame using a press-fit connector 60, as is known in the art. Common frame 10 may also include a forehead support 65 that has a bridge 70 provided with forehead pads 75 to rest against the user’s forehead in use.” Ex. 1410 ¶ 30.  Fig. 1
[E] wherein a free end of each of the upper headgear straps and the lower headgear straps includes a hook tab structured to engage a remainder of the respective upper headgear strap and respective lower headgear strap to secure the upper and	*See supra* Claim 19[B]. **Ng:** “Each strap includes hook and loop fastening elements, e.g., Velcro®.” Ex. 1410 ¶ 67.

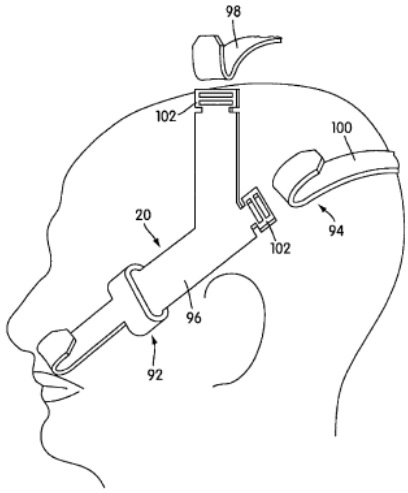
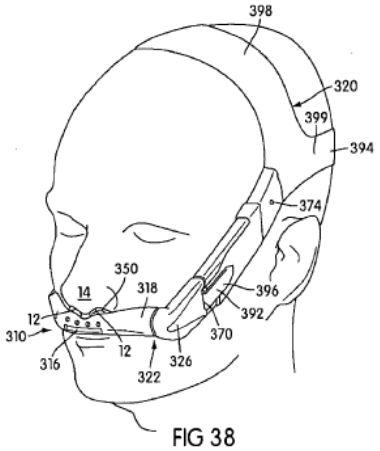
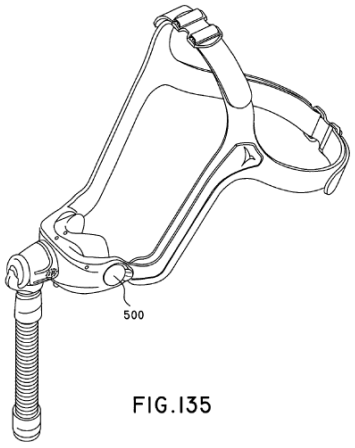
’931 Patent	Prior Art
lower straps in place in a length adjustable manner,	**FlexiFit:** “Gently adjust the Top Horizontal straps then the Lower Horizontal straps . . . . If leaks occur . . . tighten the top horizontal straps. . . . If leaks occur . . . tighten the lower horizontal straps.” Ex. 1417 at 10 (“FITTING YOUR MASK”). “[A]ttach the four straps in to the corresponding slots in the Mask Base and the Glider™ strap (E). This can be done without undoing the Velcro® Tabs by sliding the Headgear into the slots.” *Id.* at 10 (“ASSEMBLING YOUR MASK”).  **Ogden:** “[E]ach side strap 13R and 13L is preferably attached to a respective side portion 23, 25 of the rigid plate 9 on respective sides of the patient's nose 2. This can be done in any number of well-known, adjustable manners including . . . hook and loop materials on the straps themselves. . . . The remaining straps 15R, 15L, and 17 are also individually attachable in this manner.” Ex. 1422 at col. 3:10–20.

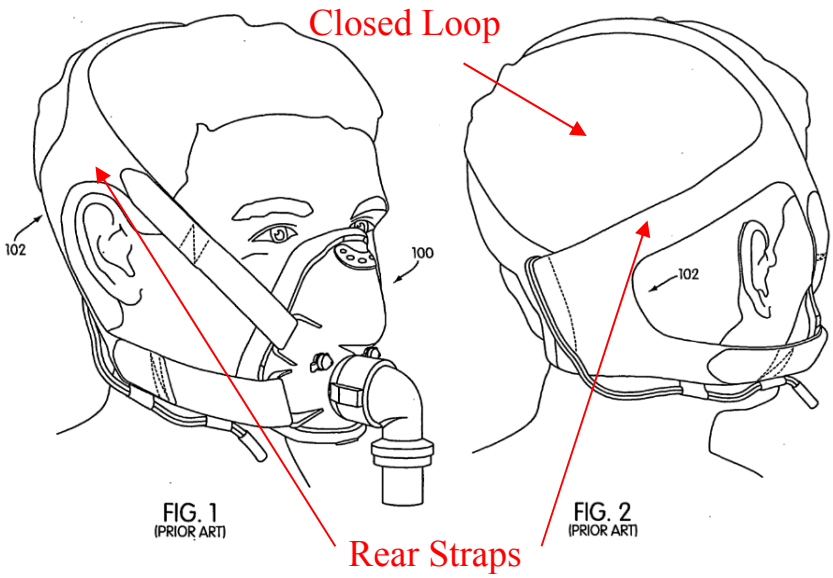
’931 Patent	Prior Art
	Amarasinghe: “At the end of each strap is secured a piece of hook material, which, in use, passes through a headgear attachment point and fastens on corresponding loop material on the strap.” Ex. 1428 ¶ 12. **Lovell:** “A hook and loop fastener system can be used to maintain the straps 59, 58 at a desired adjustment. The loops may be located along the majority of the lengths of the straps 59, 58 to provide a wide range of adjustment, with the hooks being located on the 10 distal tip portions of the straps 59, 58, such that when the distal tip of a strap is passed through a slot in a connector, the strap folds over on itself and the hooks engage the loops.” Ex. 1426 at col. 7:6–13.
[F] wherein the headgear includes a pair of top straps and a pair of rear straps, each said top strap being configured to extend from generally above a respective ear of the patient such that the top straps cross over the top of the patient's head in use, the rear straps being adapted to pass behind the patient's head in use, and	*See supra* Claim 19[C] and [D]. **Ng:** *See* Ex. 1410 at Fig. 16.  Fig. 16

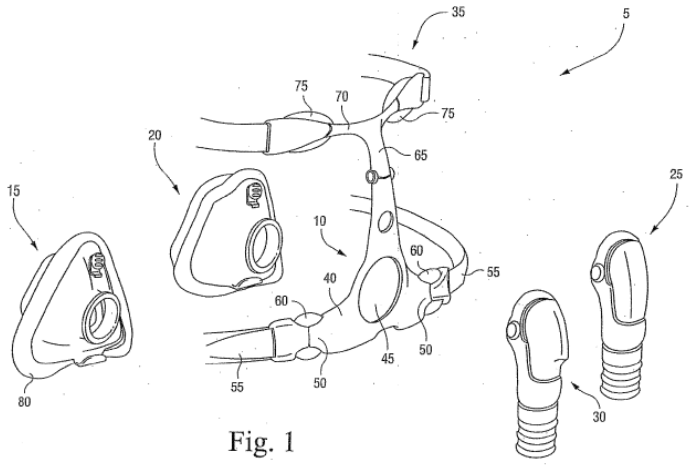
’931 Patent	Prior Art
	FlexiFit: “Gently adjust . . . Top Crown straps.” Ex. 1417 at 10 (“FITTING YOUR MASK”).  **Gunaratnam-II:** “The upper strap 98 and rear strap 100 are removably connected to the side straps 96 by buckles 102 provided on the side straps 96.” Ex. 1429 ¶ 211.  FIG. 18

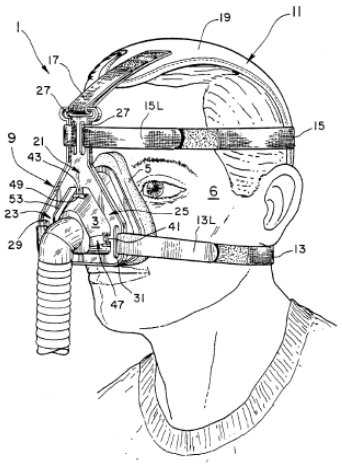
’931 Patent	Prior Art
	“The rear portion 394, which interconnects the two side portions 392, includes an upper strap 398 that passes over the top of the patient's head and a rear strap 399 that passes around the rear portion of the patient's head.” *Id.* ¶ 263 and Figs. 38 and 135.  FIG 38  FIG.135 **Amarasinghe:** *See* Ex. 1428 at Fig. 1.  FIG. 1 (PRIOR ART)

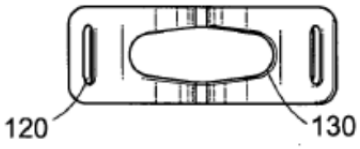
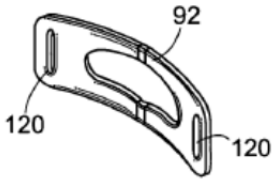
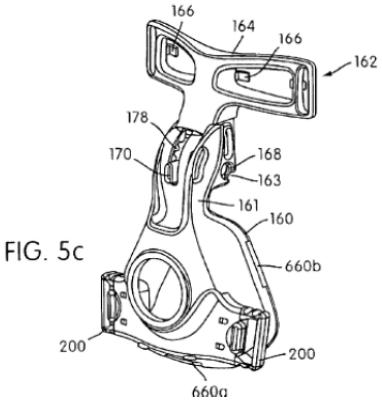
’931 Patent	Prior Art
[G] wherein the rear straps and the top straps together at least partly form a closed loop to encircle a rear portion of the patient's head when in use;	*See supra* Claim 21. **Ng**: *See* Ex. 1410 at Fig. 16.  Fig. 16 **FlexiFit:** Ex. 1417 at 10. 

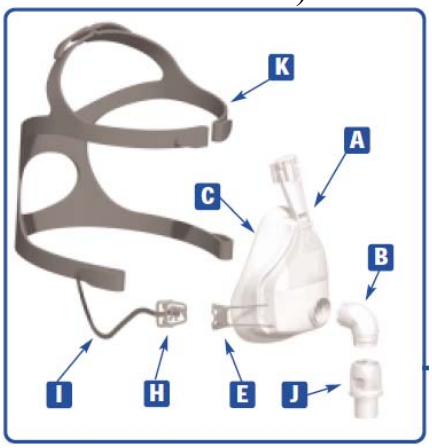
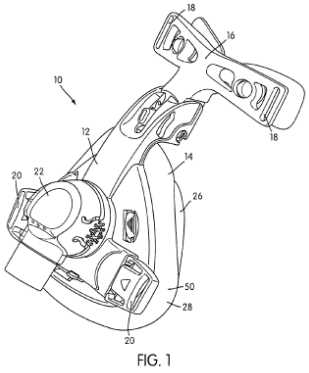
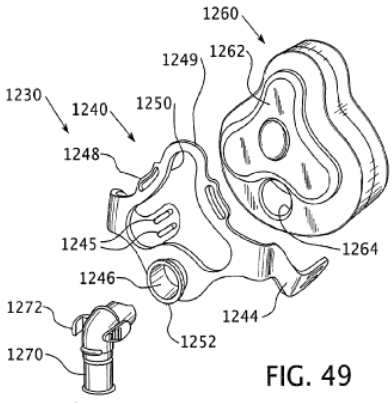
’931 Patent	Prior Art
	Gunaratnam-II: “[U]pper strap 98 and rear strap 100 are removably connected to the side straps 96 by buckles 102 provided on the side straps 96.” Ex. 1429 ¶ 211.  FIG. 18 “[R]ear portion 394, which interconnects the two side portions 392, includes an upper strap 398 that passes over the top of the patient's head and a rear strap 399 that passes around the rear portion of the patient's head.” *Id.* ¶ 263.  FIG 38  FIG.135

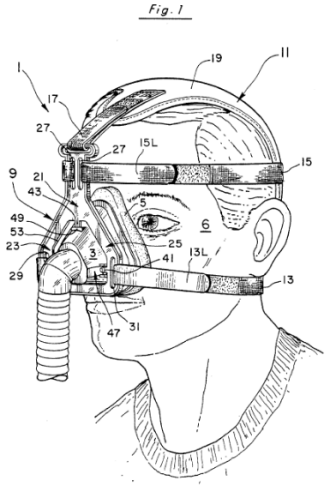
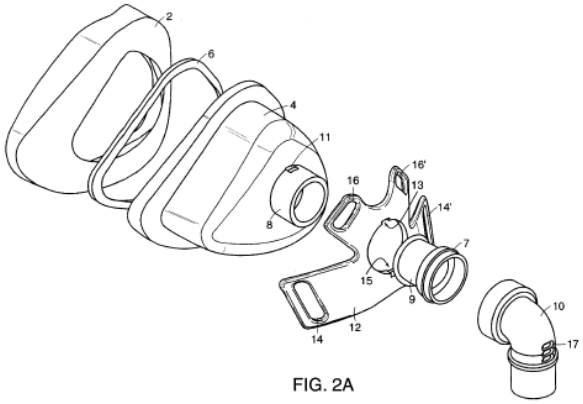
’931 Patent	Prior Art
	Amarasinghe: “Another known patient interface is the MIRAGE® nasal mask (by ResMed Ltd). This nasal mask includes a pair of headgear attachment points in the nasal region of the mask shell and a forehead support that includes another pair of headgear attachment points. The headgear includes a single piece of a soft, flexible composite fabric with a generally triangular back portion and four straps.” Ex. 1428 ¶ 12. 

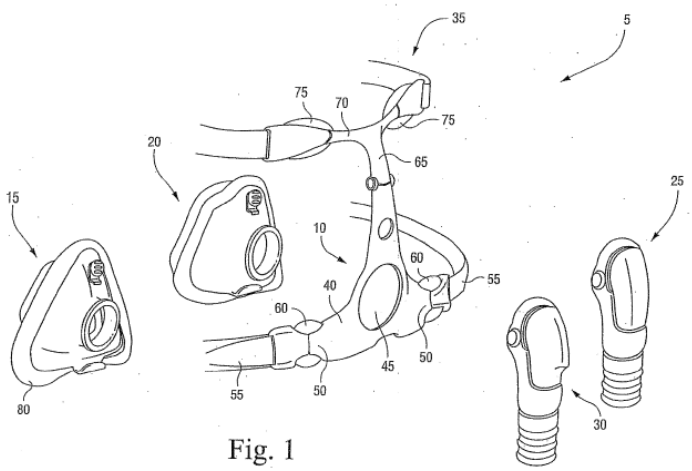
’931 Patent	Prior Art
[H] a shroud module including headgear connectors adapted to removably attach to the headgear, wherein the headgear connectors include two upper connectors associated with the upper headgear straps and two lower connectors associated with the lower headgear straps,	*See supra* Claim 19[A]. **Ng:** “The common frame 10 has a main body 40 defining a central opening 45. Main body 40 includes at least two lateral arms 50, each of which can be coupled to a headgear strap 55 of headgear. The straps may be connected to the frame using a press-fit connector 60, as is known in the art. Common frame 10 may also include a forehead support 65 that has a bridge 70 provided with forehead pads 75 to rest against the user’s forehead in use.” Ex. 1410 ¶ 30.  Fig. 1 **Thomlinson:** “Strap attachment plate 92 can facilitate the use of a strap system 102 by increasing the ease at which a strap can be connected to or removed from the nasal interface. Because the strap attachment plate is not integral to the nasal interface, the strap attachment plate, and any attached straps, can be more easily added or removed from the system.” Ex. 1411 ¶ 307. “A strap system can be fasted/unfastened using alternative methods to Velcro, such as snaps, buckles, buttons and ties.” *Id*. ¶ 312.

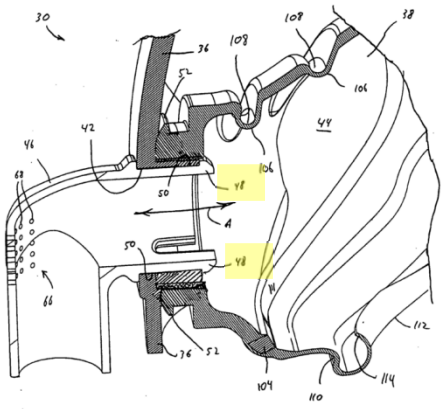
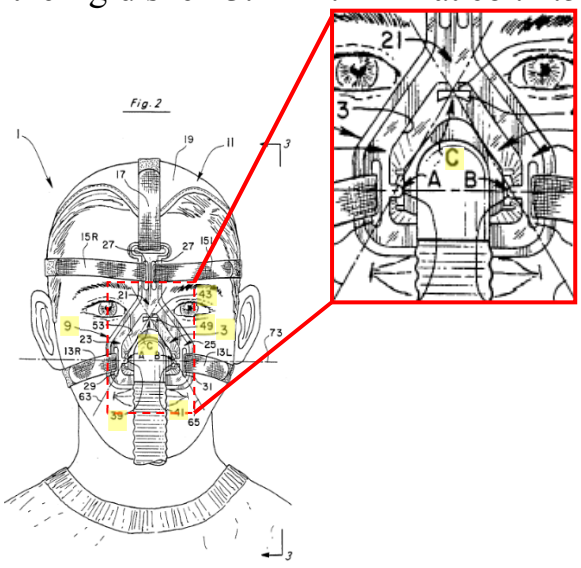
’931 Patent	Prior Art
	Ultra Mirage: “Quick release headgear clips: top and bottom allows mask to be removed without resetting the headgear and provides convenience and safety.” Ex. 1416 at 6. **Ogden:** “[E]ach side strap 13R and 13L is preferably attached to a respective side portion 23, 25 of the rigid plate 9 on respective sides of the patient's nose 2. This can be done in any number of well-known, adjustable manners including . . . hook and loop materials on the straps themselves. . . . The remaining straps 15R, 15L, and 17 are also individually attachable in this manner.” Ex. 1422 at col. 3:10–20. Fig. 1 

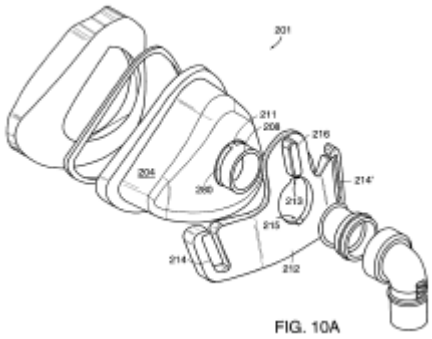
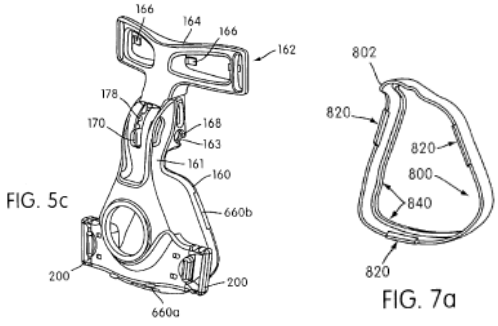
’931 Patent	Prior Art
[I] each said upper headgear connector including a slot or receiving hole adapted to receive one of the upper headgear straps,	*See supra* Claim 7. **Thomlinson:** “As shown in FIG. 28B, strap attachment plate 92 . . . includes one or more strap connections 120 for receiving a strap system 102.” Ex. 1411 ¶ 306.  Fig. 28D  Fig. 28A **Gunaratnam-I:** “As compared to FIGS. 5a-5b, FIGS. 5c-5f also show an adjustable forehead support (162) connected to the frame (160).” Ex. 1413 at col. 4:46–48.  FIG. 5c

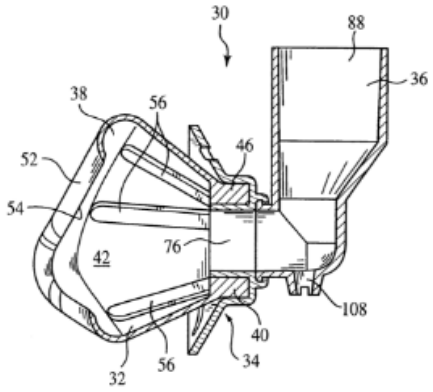
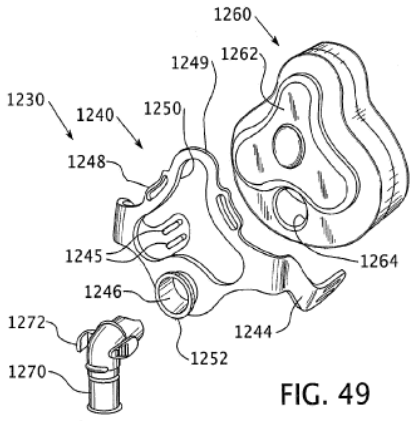
’931 Patent	Prior Art
	FlexiFit: “[A]ttach the four straps in to the corresponding slots in the Mask Base.” Ex. 1417 at 10 (“ASSEMBLING YOUR MASK”).  **Lithgow:** *See* Ex. 1433 at Fig. 1.  FIG. 1 **Matula-I:** “[A]ttachment elements 1248 are provided in the form of slots provided . . . [o]n a central portion 1249 of the body member.” Ex. 1423 ¶ 103.  FIG. 49

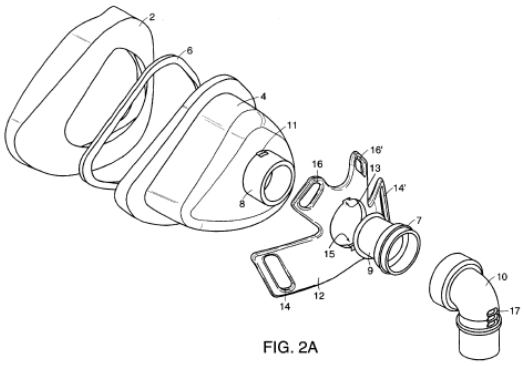
’931 Patent	Prior Art
	Ogden: “The upper side straps in this last regard could be the two straps 15R and 15L as illustrated or one continuous strap passing through loops 27 and anchoring the top portion 21 of the rigid plate 9 (see FIGS. 1-3).” Ex. 1422 at col. 3:7–10.  **Lovell:** “These connection points 14, 14', 16, 16' form slots which allow for connection of the retainer 12 with straps of a headgear apparatus, as shown in FIG. 3.” Ex. 1426 at col. 6:10–13.  FIG. 2A

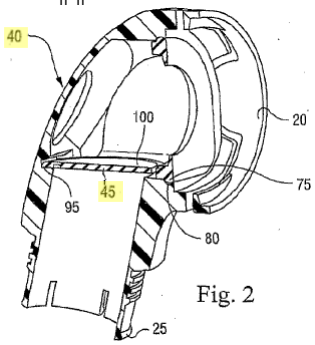
’931 Patent	Prior Art
[J] wherein the shroud module and the frame of the cushion module are configured to be removably snap-fit attached to one another in a non-rotatable manner;	*See supra* Claims 1[A] and 26[B]. **Ng:** “The common frame 10 has a main body 40 defining a central opening 45.” Ex. 1410 ¶ 30. “Common frame 10 is configured to be selectively coupled to one of cushion components 15, 20 and to one of elbow components 25, 30. Cushion components 15, 20 differ in at least one respect such that one may be more optimal or preferable for use with one user, while another may be more suitable or preferably for use with another user. For example, cushion component 15 may be an Activa™ component, while cushion component 20 may be an UltraMirage™ Series II cushion component, both available from ResMed. These cushion components can be significantly different from one another, e.g., the Activa™ includes a gusset portion 80 and a cushion clip assembly (not shown) which is not incorporated in the UltraMirage™ cushion design.” Ex. 1410 ¶ 31.  Fig. 1 A person of skill would have understood that the shroud module 10 and cushion module 15, 20 are non-rotatably coupleable because the cushion module attaches to the shroud at two points (annular opening 45 and the clip located above the annular opening). This arrangement would have prevented relative rotation between the two parts.

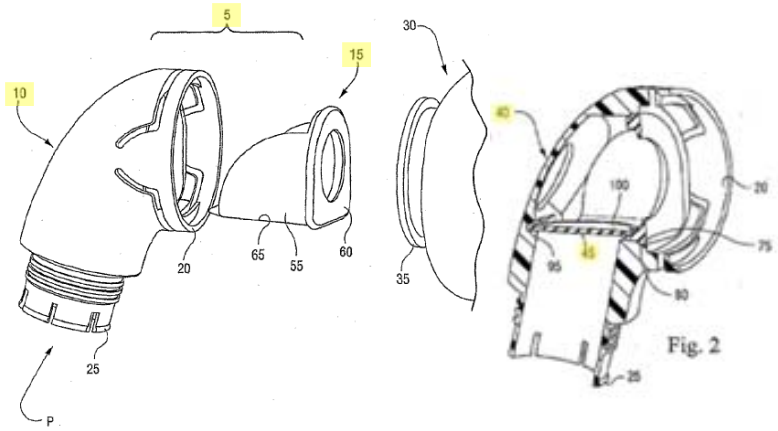
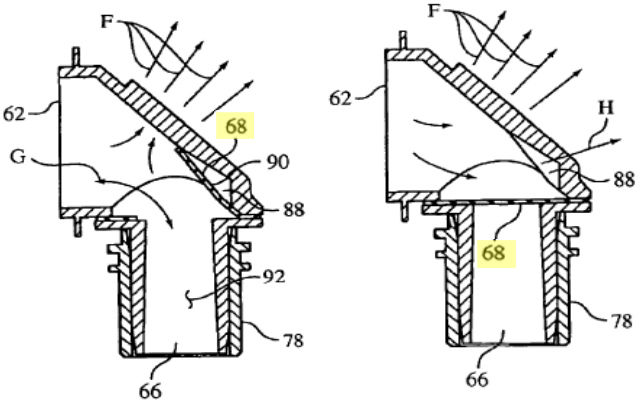
’931 Patent	Prior Art
	Matula-II: “Coupling member 46 includes a pair of prongs 48 that define a channel 50 to receive the wall of the faceplate and the end of seal member 38.” Ex. 1412 ¶ 53. A person of skill in the art would have understood that the “prongs” of Matula-II could also be referred to as “snap fingers.”  Fig. 4 **Ogden:** “[R]igid plate 9 is preferably mounted to the rigid shell 3 at first, second, and third locations A, B, and C. . . . 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.” Ex. 1422 at col. 4:59–5:19. 

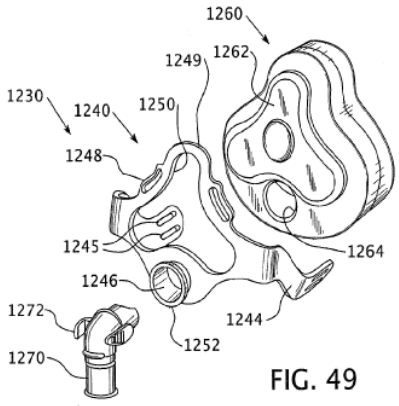
’931 Patent	Prior Art
	Lovell: “The retainer 212 is disposed about the inlet 208 to facilitate retention of the mask 201 on a user. . . . Two tabs 211, 211' included on the inlet 208 mate with two slots 213, 215 formed in the retainer 212 in a particular angular orientation. . . . The retainer aperture and the inlet 208 are generally sized in an interference fit so that the retainer 212 is properly retained by the cooperation of the tabs 211, 211', the slots 213, 215, and the depressed annular region 280 when fully seated against the shell 204.” Ex. 1514 at col. 9:43–48, 9:59–64.  FIG. 10A **Gunaratnam-I:** “[T]he 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). 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. 1413 at col. 5:34–43.  FIG. 5c FIG. 7a

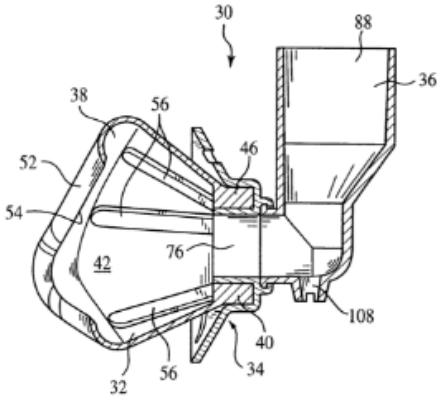
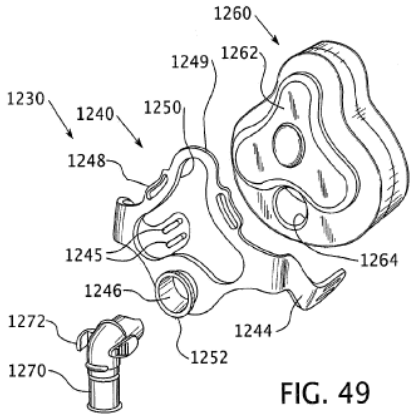
’931 Patent	Prior Art
[K] and an elbow rotatably attached to and carried by the shroud module or the frame of the cushion module, the elbow being configured to deliver the positive pressure air to the breathing chamber,	*See supra* Claims 11 and 14. **Ng:** “Common frame 10 is configured to be selectively coupled to one of cushion components 15, 20 and to one of elbow components 25, 30.” Ex. 1410 ¶ 31. **Barnett:** “[C]onduit coupling member 36 is preferably rotateably mounted on a second side of collar 34 opposite the first side so that conduit coupling member 36 freely rotates over a range of 360° about a central axis of collar 34.” Ex. 1414 at col. 3:52–57; *see also id.* at col. 8:66—9:43.  FIG. 1A **Matula-I:** “[P]atient circuit coupling 1270 is an elbow coupling that rotatably and releasably attaches to circuit coupling portion 1246.” Ex. 1423 ¶ 105.  FIG. 49

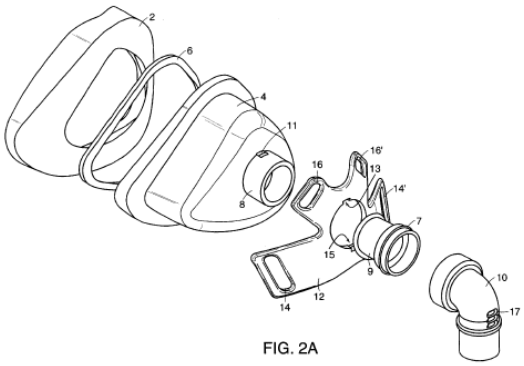
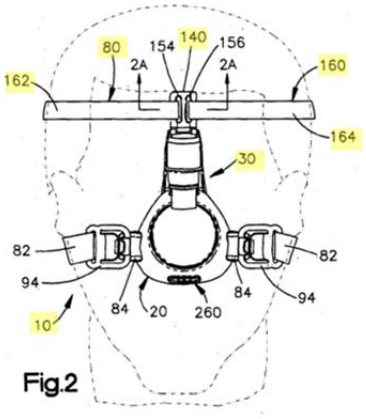
’931 Patent	Prior Art
	Ultra Mirage: “360° rotating elbow provides control over tubing system.” Ex. 1416 at 6. **Lovell:** “[S]wivel connector 9 produces a swivel mount connection between the conduit elbow 10 and the inlet 8. In this type of connection, the conduit elbow 10 is capable of rotating 360 degrees about the centerline of the inlet 8 and the connector 9.” Ex. 1426 at col. 5:20–24.  FIG. 2A

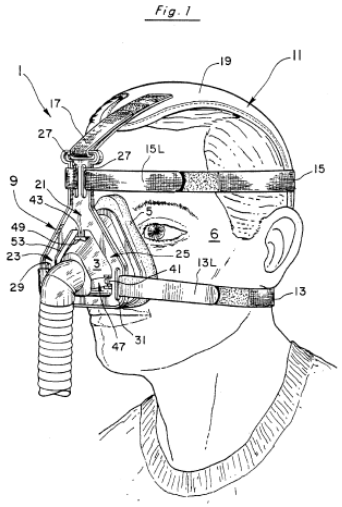
’931 Patent	Prior Art
[L] the elbow including a swivel adapted to connect to an air delivery tube,	*See supra* Claim 43[O]. **Worboys:** “The elbow has a first portion 20 and a second portion 25. . . . The second portion 25 typically will be provided with a swivel joint which in turn is connected to an air delivery tube in communication with a flow generator.” Ex. 1415 ¶¶ 104–105.  Fig. 2 **Ogden:** “Another feature of the facial mask assembly 1 of the present invention is the swivel hose coupling 10 of FIGS. 8 and 9 connecting the rigid shell 3 to the flexible hose 12.” Ex. 1422 at col. 5:35–37. **Hitchcock:** “Frame 308 includes a front plate 312 including an aperture 314 adapted to receive pressurized gas from an air delivery tube, e.g., via a swivel elbow.” Ex. 1421 ¶ 28. **Ultra Mirage:** “Quick release swivel allows easy disconnection from tubing.” Ex. 1416 at 6.

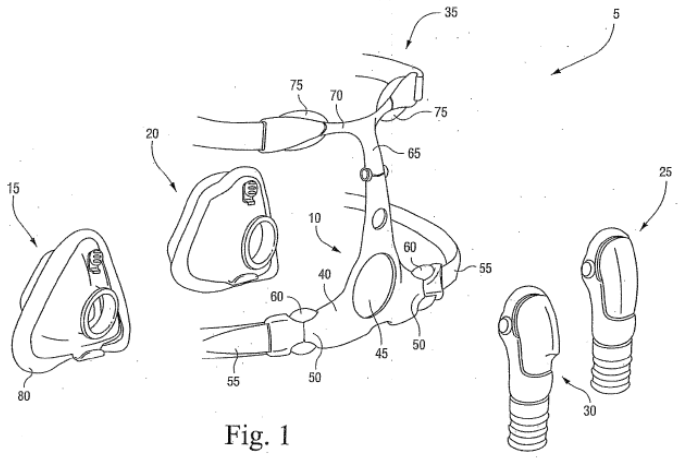
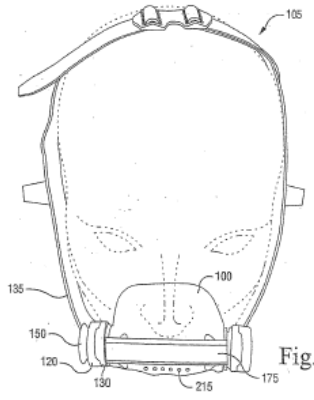
’931 Patent	Prior Art
[M] the elbow including an anti-asphyxia valve (AAV) and a port that is selectively closed by a flap portion of the AAV;	*See supra* Claim 15. **Worboys:** “[E]lbow assembly 5 generally comprises an elbow 10 and an anti–asphyxia valve 15 (AAV) assembly.” Ex. 1415 ¶ 103. “[E]lbow 10 includes a port 40 that may be selectively closed by a flap portion 45 of the AAV assembly.” *Id*. ¶ 106.  Fig. 1 **Jaffre:** “It is common when using a full face mask, to provide a valve in the patient circuit that automatically allows the patient access to the ambient atmosphere in the event of a failure of the pressure support system. See, e.g. U.S. Pat. No. 5,438,981, which teaches the function of such a valve and describes several embodiments of such a valve.” Ex. 1427 at col. 10:4–10.  FIG. 8 FIG. 9

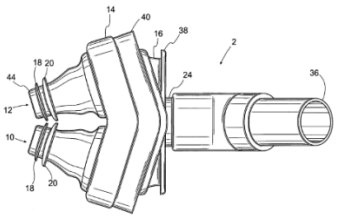
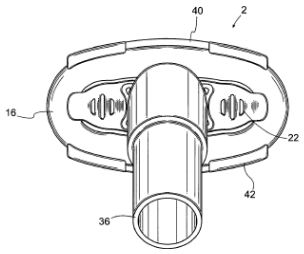
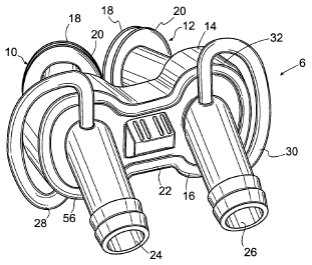
’931 Patent	Prior Art
	"During normal use, where the pressure support system is functioning properly, a cantilever member 90 of valve member 68 flexes, as shown to FIG. 8, to block auxiliary opening 88. If the gas pressure in an interior 92 of the conduit is greater than the ambient atmosphere, cantilever member 90 moves to the position shown in FIG. 8 to block opening 88, so that gas is able to flow between the patient and the pressure generating system, as indicated by arrow G." *Id.* at col. 10:14–22. **Matula-I:** "[T]he present invention contemplates providing an entrainment valve and/or exhaust assembly on patient circuit coupling 1270. . . . the exhaust assembl[y] can be provided at other locations, such as in the patient interface portion [1260], the body member, or in any combination of locations." Ex. 1423 ¶ 106.  FIG. 49
[N] the elbow is rotatably attached the shroud module,	*See supra* Claim 14. **Ng:** "Common frame 10 is configured to be selectively coupled to one of cushion components 15, 20 and to one of elbow components 25, 30." Ex. 1410 ¶ 31.

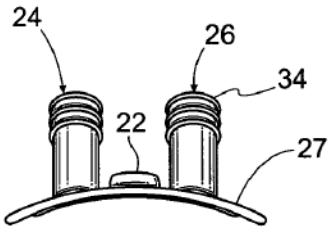
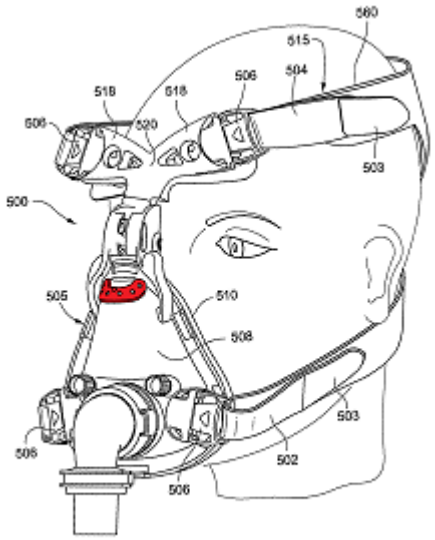
’931 Patent	Prior Art
	Barnett: “[C]onduit coupling member 36 is preferably rotateably mounted on a second side of collar 34 opposite the first side so that conduit coupling member 36 freely rotates over a range of 360° about a central axis of collar 34.” Ex. 1414 at col. 3:52–57; *see also id.* at col. 8:66—9:43.  FIG. 1A **Ultra Mirage:** “360° rotating elbow provides control over tubing system.” Ex. 1416 at 6. **Matula-I:** “[P]atient circuit coupling 1270 is an elbow coupling that rotatably and releasably attaches to circuit coupling portion 1246.” Ex. 1423 ¶ 105.  FIG. 49 **Lovell:** “[S]wivel connector 9 produces a swivel mount connection between the conduit elbow 10 and the inlet 8. In this type of connection, the conduit elbow 10 is capable

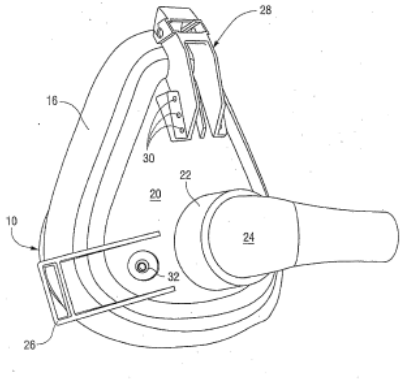
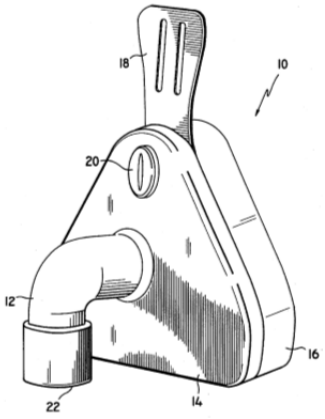
’931 Patent	Prior Art
	of rotating 360 degrees about the centerline of the inlet 8 and the connector 9.” Ex. 1426 at col. 5:20–24.  FIG. 2A
[O] the upper headgear straps provide padding to the respective headgear connectors of the shroud on the patient's face in use,	*See supra* Claim 20. **Sprinkle:** “When the left and right straps 162 and 164 are connected with the forehead adjuster 140 in this manner, a relatively large amount of strap material is present between the forehead adjuster 140 and the user's forehead. This strap material, as mentioned above, is resilient. Therefore, a substantial cushion is present between the forehead support assembly 30 and the user's forehead. This cushion provides a very comfortable strap attachment, without the necessity for separate cushion members or cushioning pieces on the adjuster 140.” Ex. 1419 ¶ 74, *see also id.* ¶¶ 3, 72.  Fig.2

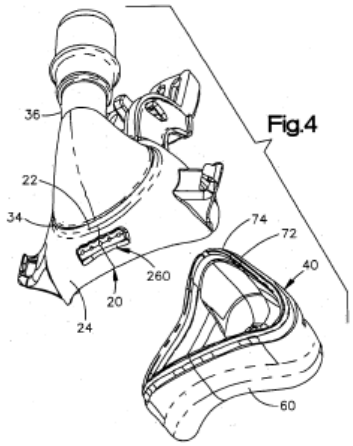
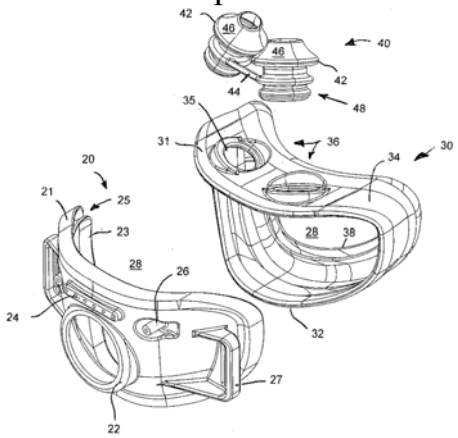
’931 Patent	Prior Art
	Ogden: “[L]ooping the straps 13R and 13L through the openings 29, 31 in the rigid plate 9 and fastening them back on themselves by hook and loop materials on the straps themselves. . . . The remaining straps 15R, 15L, and 17 are also individually attachable in this manner . . . . The straps themselves are preferably made of flexible material and may have some slight elasticity to them to comfortably fit about the patient's head.” Ex. 1422 at col. 3:14–24.  **Lovell:** “The straps 52, 54, 56 may be manufactured from inelastic or elastic materials such as, but not limited to, nylon webbing, nylon covered neoprene or Velstretch™, available from Velcro USA Inc., Manchester, N.H., and may further include optional padding, if desired.” Ex. 1426 at col. 6:30–34.

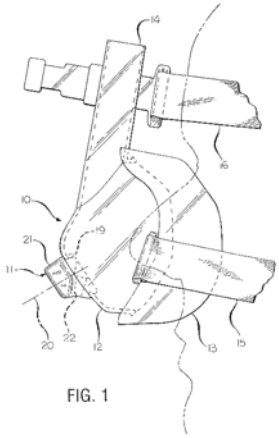
’931 Patent	Prior Art
[P] the frame includes a protruding vent arrangement having a plurality of holes, wherein the shroud module includes a first opening to accommodate said protruding vent arrangement,	*See supra* Claim 1[B]. **Ng:** “Common frame 10 is configured to be selectively coupled to one of cushion components 15, 20 and to one of elbow components 25, 30.” Ex. 1410 ¶ 31.  Fig. 1 “As shown in Figs. 3, 7-8, and 11, the mask assembly includes a gas washout vent 215. The vent 215 could be on the frame and/or the cushion component.” *Id.* ¶ 43.  Fig. 11

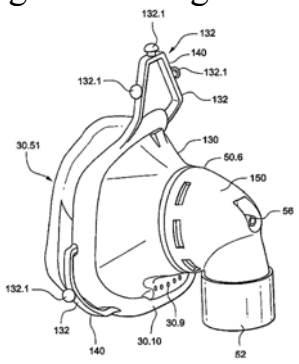
’931 Patent	Prior Art
	Thomlinson: “A nasal interface body 2 according to the present invention can also include one or more locking tabs 38 on the distal portion 16. The locking tabs 38 can be used to releasably engage a strap attachment plate 92, as depicted in FIG. 37 and described further below.” Ex. 1411 ¶ 203.  Fig. 1 “Further, and as shown in FIG. 3, one embodiment of a nasal interface can also include one or more exhalation ports 22, which are described in more detail below.” *Id.* ¶ 204.  Fig. 3 “As shown in FIG. 8, nasal interface body 6 can also include first inlet 24 and a second inlet 26, as well as exhalation port 22. In one embodiment, exhalation port 22 is positioned between inlet 24 and second inlet 26.” *Id*. ¶ 209.  Fig. 8

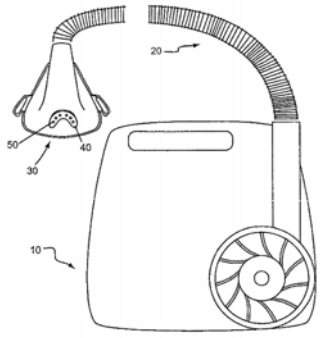
’931 Patent	Prior Art
	“As shown in the figures and in particular FIGS. 3, 14A, 15D, 15F, 16C and 16F, distal portion 16 can also include one or more exhalation ports 22, described further below.” *Id*. ¶ 247.  Fig. 14A **Hitchcock:** *See* Ex. 1421 at Fig. 8.  Fig. 8

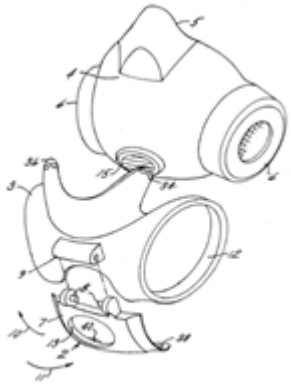
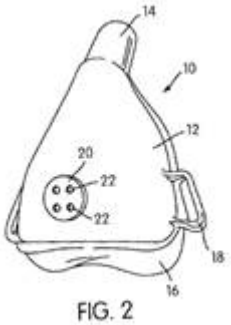
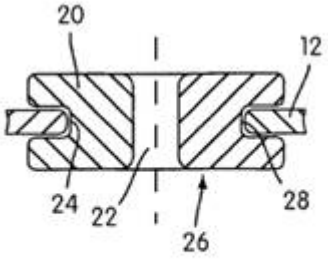
’931 Patent	Prior Art
	Hitchcock-II: “A number of vents 30 may be provided so as to allow gas exhaled by the patient to vent to atmosphere.” Ex. 1440 ¶ 42.  Fig. 1-2 **Landis:** “[T]he aperture in mask frame 14 to receive variable orifice member 20 is configured as a cylindrical wall projecting outward from the mask frame to engage a variable orifice member cap, as described in greater detail below.” Ex. 1441 at col. 5:35–38.  FIG. 1 “In one construction, variable orifice vent aperture member 20 is configured as a cap to mount onto and engage projecting walls of a cylindrical opening in the mask frame or other associated structure (not shown).” *Id.* at col. 6:19–23.

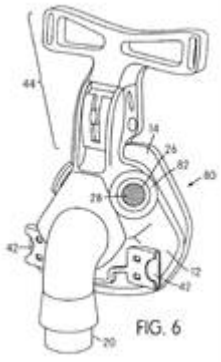
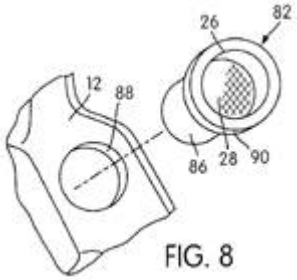
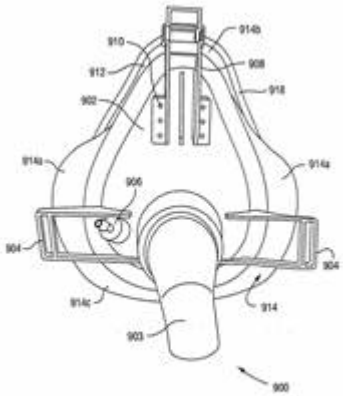
’931 Patent	Prior Art
	Sprinkle: “FIGS. 4 and 23 illustrate an exhalation vent portion 260 of the mask 10. The vent portion 260 includes a thickened wall area 262 in the lower part of the side wall 24 of the shell 20. Five circular exhalation openings 264 are formed at equally spaced intervals in the thickened area 262. The exhalation openings 264 extend from the exterior of the mask 10 to the central chamber 32 of the shell 20. The exhalation openings 264 enable exhaled air to flow out of the mask 10.” Ex. 1419 ¶ 99.  **Chandran:** “The ventilation interface 20 is configured with at least one exhalation port 24.” Ex. 1439 ¶ 60.  *Id.* at Fig. 2.

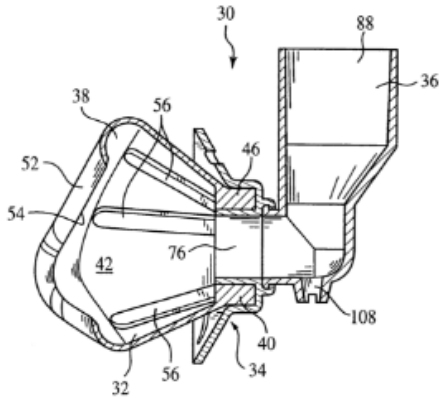
’931 Patent	Prior Art
	Jones, Jr.: “[T]he exhaust port member 11 is shown as having a generally circular perimeter 17 with a recessed or reduced diameter annular groove 18 formed in the perimeter 17, as shown in FIG. 4. A circular opening 19 is formed in the mask body 12 for receiving the exhaust port member 11.” Ex. 1436 at col. 3:3–8.  FIG. 1 “At least one and preferably two vent ports 22 extend through the exhaust port member 11 at a predetermined angle relative to the axis of rotation 20.” *Id.* at col. 3:23–25.

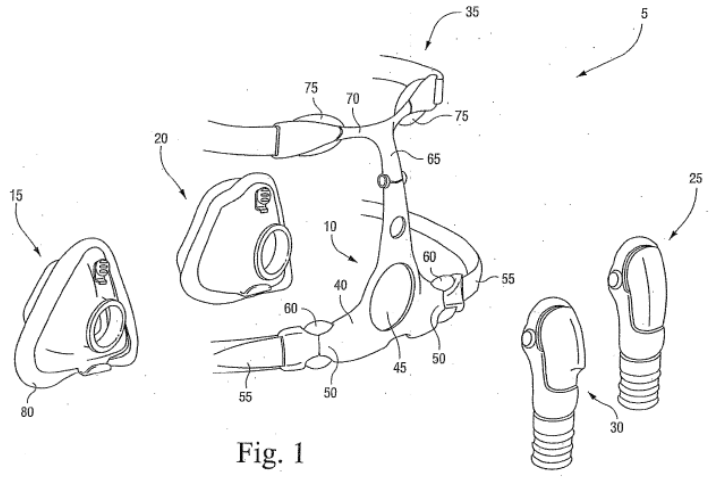
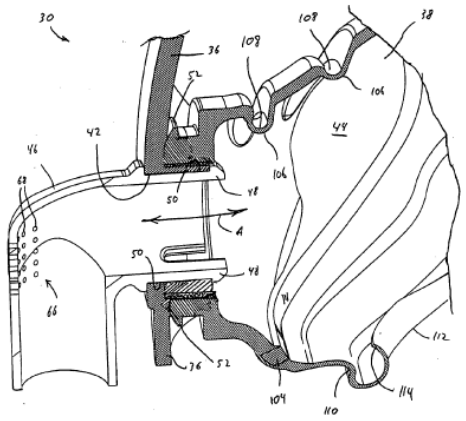
’931 Patent	Prior Art
	Jones: “[T]he lip region 30.8 has a series of four vent orifices 30.9 passing therethrough” Ex. 1437 ¶ 221.  *Id.* at Fig. 10. “The shell/cushion 130 includes a series of vents or vent orifices 30.9, which in a preferred form comprises four orifices. The vent orifices 30.9 are formed through a thicker wall section 30.10 formed integrally on the shell/cushion 30. The wall section 30.10 is shown in FIG. 3. The wall section 30.10 has two functions. The first is to form a front flange which with the rear flange 36 in the lip region 30.8 forms the lower channel 140.4. The second function is that the wall section 30.10 allows the vent orifices 30.9 to be positioned at an angle with respect to the elbow.” *Id.* ¶ 226.

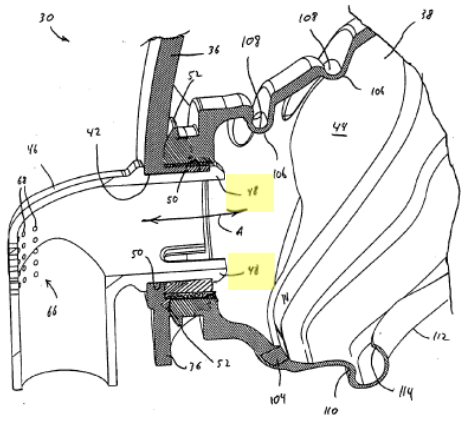
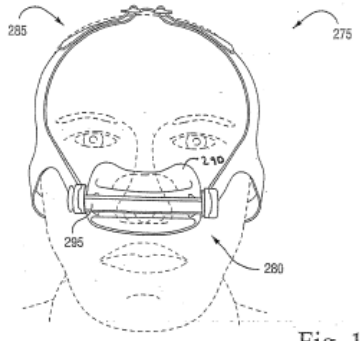
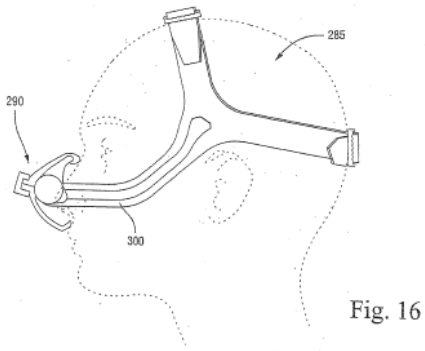
’931 Patent	Prior Art
	Darkin: “The patient interface 30 includes a vent 40. The vent 40 includes one or more holes, e.g., six holes 50.” Ex. 1442 ¶ 55.  Fig. 1 “Another advantage of the invention is to provide different vents for different pressure ranges. For example, at low pressures, it may be appropriate to have a vent with large holes in order to provide sufficient vent flow. The same vent at higher pressures would have unnecessarily high vent flow which leads to increased noise. Hence in accordance with an embodiment of the invention, when a patient is using a generally low pressure treatment, they can utilize a first vent, but when treatment pressures are higher they can use a second vent.” *Id.* ¶ 89. “Another advantage of the invention is that it provides a quick and simple system of replacing disposable vents. For example, certain styles of vents may clog easily and be designed for a single night's use. In accordance with an embodiment of the invention a vent assembly can comprise a set of "single use" vents. After a first night's use, the patient can switch to the second vent. After a second night's use, the patient can switch to a third vent, and so on.” *Id.* ¶ 90.

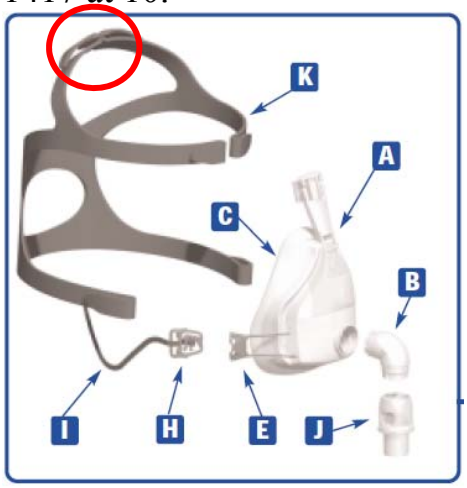
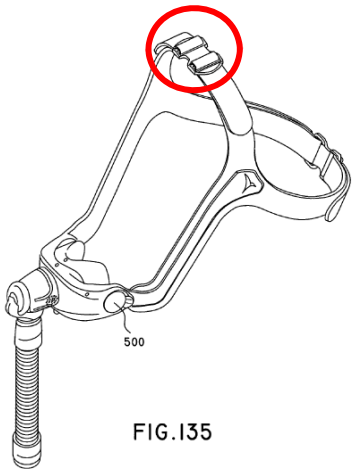
’931 Patent	Prior Art
	Fecteau: “[A] respirator 1 incorporates a quick release mechanism 2 into a facepiece support system, or yoke, 3.” Ex. 1446 at 4:24–25. “[Q]uick release mechanism 2 consists of an over center cam latch 7 pivotly attached to yoke 3 via hinge pins 8 disposed within hinge 9 and further includes relief cut 13 to accommodate exhale valve 15 while in the latched position.” *Id.* at 4:29–32.  FIG. 2 **Kwok:** “The mask includes a Silastic™ insert 20 through which is provided an orifice 22 for gas washout.” Ex. 1445 at col. 3:43–44. “[T]he insert 20 has an external groove or recess 24 which engages the rim 28 of a corresponding shaped opening 26 in the mask shell 12 to retain the insert 20 in place.” *Id.* at col. 3:57–60. “In the embodiment shown in FIGS. 2 to 5 and 7 the insert 20 includes more than one orifice 22.” *Id.* at col. 3:61–62.  FIG. 2  FIG. 8

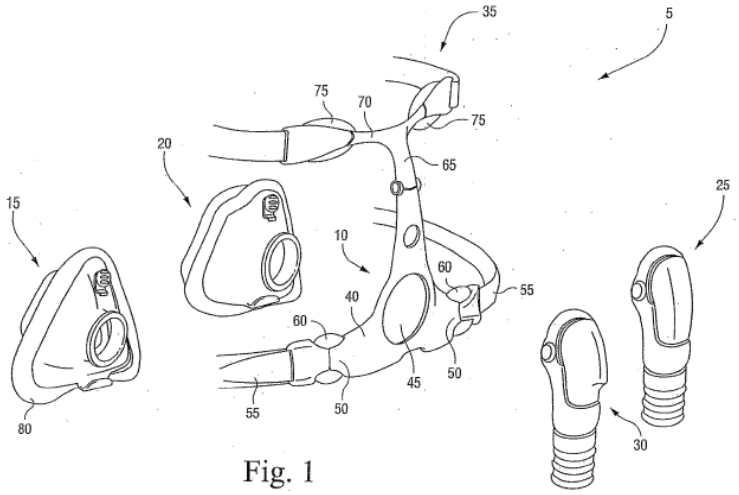
’931 Patent	Prior Art
	Drew: “The mask 10 includes a gas washout vent constituted by an opening 26 in the shell 12 across which extends a thin air permeable membrane 28.” Ex. 1444 at col. 4:32–34. “FIG. 6 shows a nasal respiratory mask 80.” *Id.* at col. 5:31. “In the mask 40 of FIG. 2, the [gas washout] vent is provided in the gas inlet 20, whereas in the mask 80 the vent is provided in the shell 12. More particularly, the mask 80 includes two cylindrical inserts 82 which have an inner opening 26 across which extends the thin air permeable material 28.” *Id.* at col. 5:35–40. “[T]he insert 82 [] comprises a cylindrical portion 86 sized to be a snug fit into a circular orifice 88 provided in the mask shell 12.” *Id.* at col. 6:2–4.  FIG. 6  FIG. 8 **Frater**: “Shell 902 may also be provided with one or more vents 910.” Ex. 1425 ¶ 163.  Fig. 50

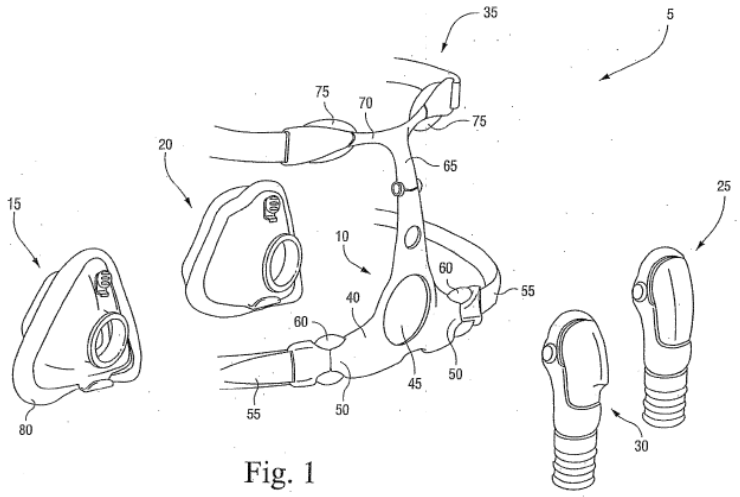
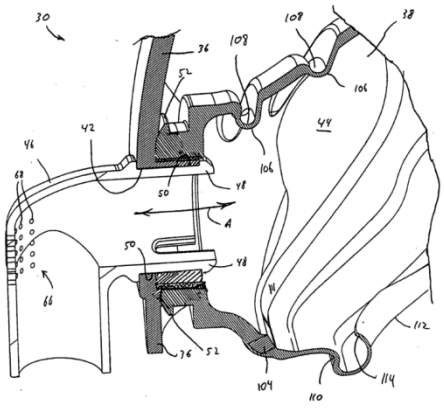
’931 Patent	Prior Art
[Q] further wherein the shroud module includes a second opening to accommodate the elbow,	*See supra* Claims 1[C] and 12. **Ng:** “Common frame 10 is configured to be selectively coupled to one of cushion components 15, 20 and to one of elbow components 25, 30.” Ex. 1410 ¶ 31. **Barnett:** “[C]onduit coupling member 36 is preferably rotateably mounted on a second side of collar 34 opposite the first side so that conduit coupling member 36 freely rotates over a range of 360° about a central axis of collar 34.” Ex. 1414 at col. 3:52–57; *see also id.* at col. 8:66—9:43.  FIG. 1A

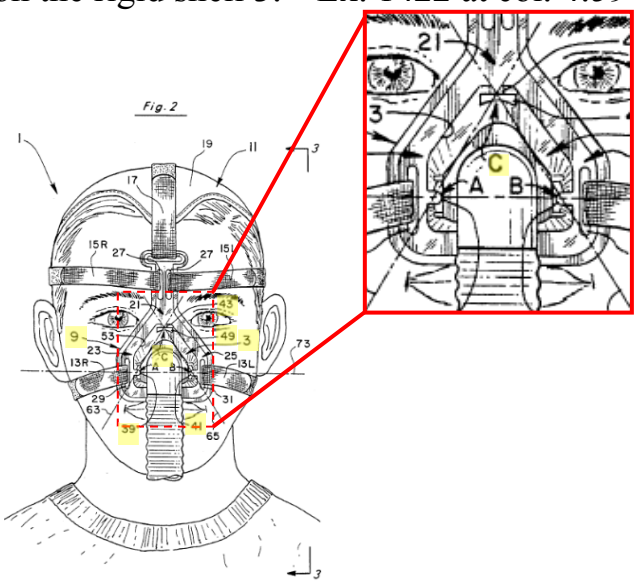
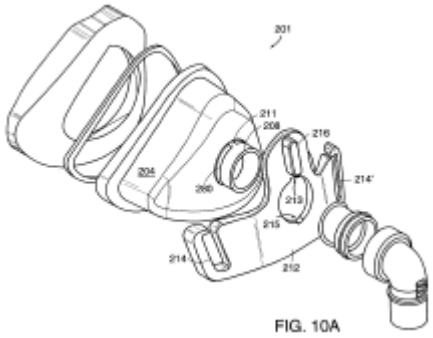
’931 Patent	Prior Art
[R] the frame includes a frame opening and the frame further includes a collar surrounding said frame opening,	*See supra* Claim 5[A]. **Ng**: The cushion frame includes an annular collar around the opening. *See* Ex. 1410 at Fig. 1.  Fig. 1 **Matula-II:** “[T]he end of seal member 38 is joined to a ring 52 that is more rigid than the end of the seal member to provide a strong, stable mechanical coupling of the seal member to the faceplate.” Ex. 1412 ¶ 53.  Fig. 4

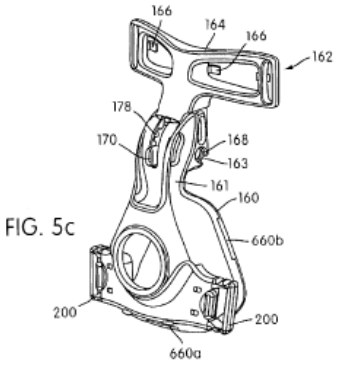
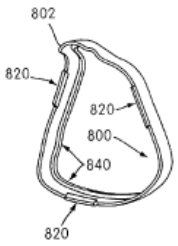
’931 Patent	Prior Art
[S] and wherein the shroud module includes a retaining portion with one or more rearward extending snap fingers structured to engage the collar with a snap-fit,	*See supra* Claim 5[B]. **Matula-II:** “Coupling member 46 includes a pair of prongs 48 that define a channel 50 to receive the wall of the faceplate and the end of seal member 38.” Ex. 1412 ¶ 53. A person of skill in the art would have understood that the “prongs” of Matula-II could also be referred to as “snap fingers.”  Fig. 4
[T] and the top straps are connected together with a buckle allowing independent adjustment of each of the top straps.	*See supra* Claim 19[D]. **Ng:** *See* Ex. 1410 at Figs. 15 and 16.  Fig. 15  Fig. 16

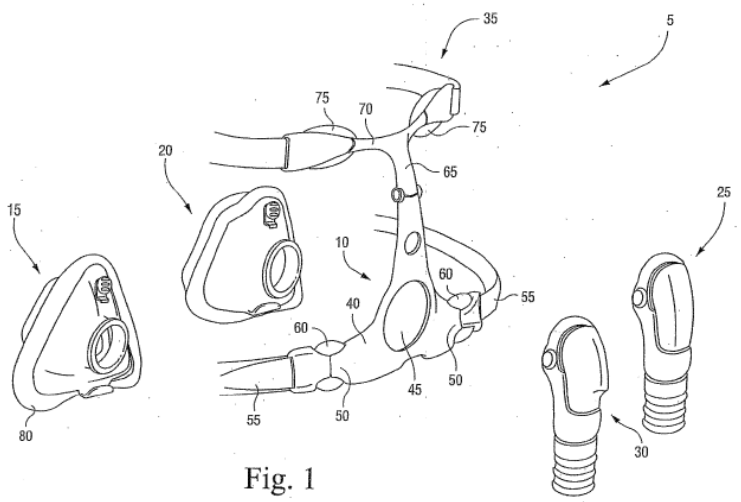
’931 Patent	Prior Art
	FlexiFit: Ex. 1417 at 10.  **Gunaratnam-II:** “[U]pper straps 598 are coupled to one another by a headgear buckle 570.” Ex. 1429 ¶ 316, Fig. 135.  FIG.135
53. The mask system of claim 51, wherein the second shroud opening and the frame opening are aligned along a common longitudinal axis,	*See supra* Claim 26[A]. **Ng:** “The common frame 10 has a main body 40 defining a central opening 45.” Ex. 1410 ¶ 30. “Common frame 10 is configured to be selectively coupled to one of cushion components 15, 20 and to one of elbow components 25, 30. Cushion components 15, 20 differ in at least one respect such that one may be more optimal or

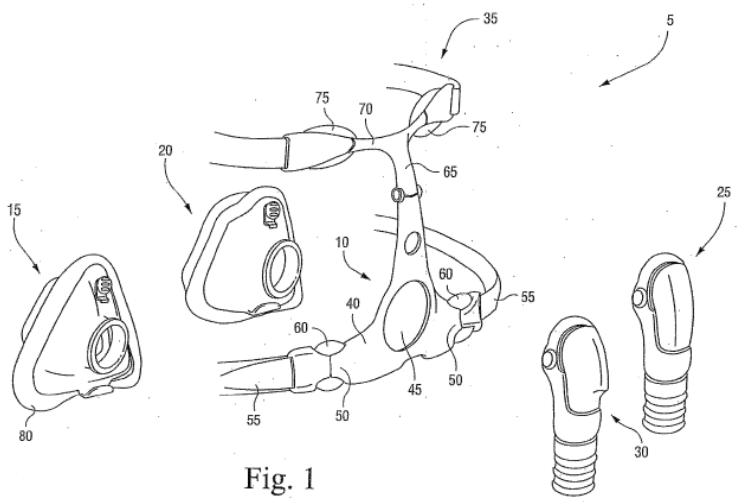
’931 Patent	Prior Art
	preferable for use with one user, while another may be more suitable or preferably for use with another user. For example, cushion component 15 may be an Activa™ component, while cushion component 20 may be an UltraMirage™ Series II cushion component, both available from ResMed. These cushion components can be significantly different from one another, e.g., the Activa™ includes a gusset portion 80 and a cushion clip assembly (not shown) which is not incorporated in the UltraMirage™ cushion design.” Ex. 1410 ¶ 31.  Fig. 1
and wherein the shroud and the frame are removably snap-fit attached to one another by moving the shroud and the frame towards one another along the longitudinal axis.	*See supra* Claim 26[B]. **Ng:** “The common frame 10 has a main body 40 defining a central opening 45.” Ex. 1410 ¶ 30. “Common frame 10 is configured to be selectively coupled to one of cushion components 15, 20 and to one of elbow components 25, 30. Cushion components 15, 20 differ in at least one respect such that one may be more optimal or preferable for use with one user, while another may be more suitable or preferably for use with another user. For example, cushion component 15 may be an Activa™ component, while cushion component 20 may be an

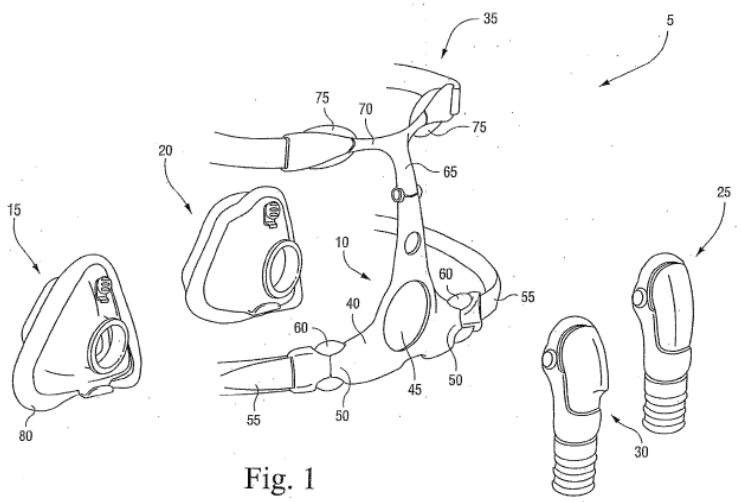
’931 Patent	Prior Art
	UltraMirage™ Series II cushion component, both available from ResMed. These cushion components can be significantly different from one another, e.g., the Activa™ includes a gusset portion 80 and a cushion clip assembly (not shown) which is not incorporated in the UltraMirage™ cushion design." *Id.* ¶ 31.  Fig. 1 **Matula-II:** "Coupling member 46 includes a pair of prongs 48 that define a channel 50 to receive the wall of the faceplate and the end of seal member 38." Ex. 1512 ¶ 53.  Fig. 4 **Ogden:** "[R]igid plate 9 is preferably mounted to the rigid shell 3 at first, second, and third locations A, B, and C. . . . Further, although the detent-channel 43, 49 at the top of

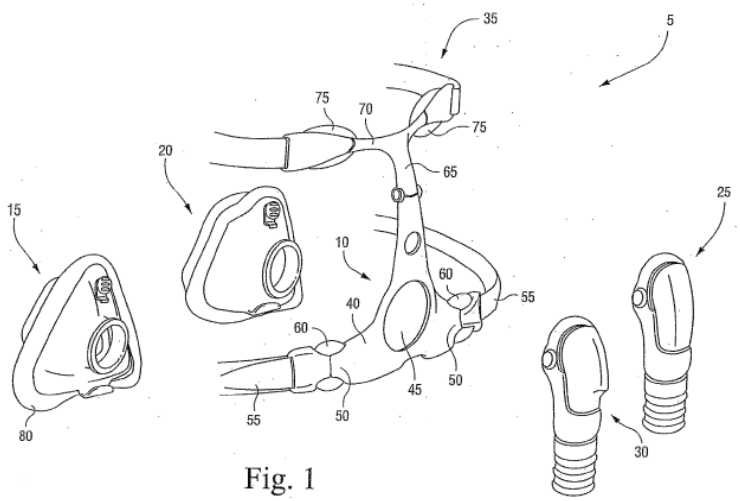
’931 Patent	Prior Art
	the shell 3 at the third location C is preferably dimensioned to snap together to hold or maintain the rigid plate 9 on the rigid shell 3.” Ex. 1422 at col. 4:59—5:19.  **Lovell:** “The retainer 212 is disposed about the inlet 208 to facilitate retention of the mask 201 on a user. . . . Two tabs 211, 211' included on the inlet 208 mate with two slots 213, 215 formed in the retainer 212 in a particular angular orientation. . . . The retainer aperture and the inlet 208 are generally sized in an interference fit so that the retainer 212 is properly retained by the cooperation of the tabs 211, 211', the slots 213, 215, and the depressed annular region 280 when fully seated against the shell 204.” Ex. 1426 at col. 9:43–48, 9:59–64.  FIG. 10A

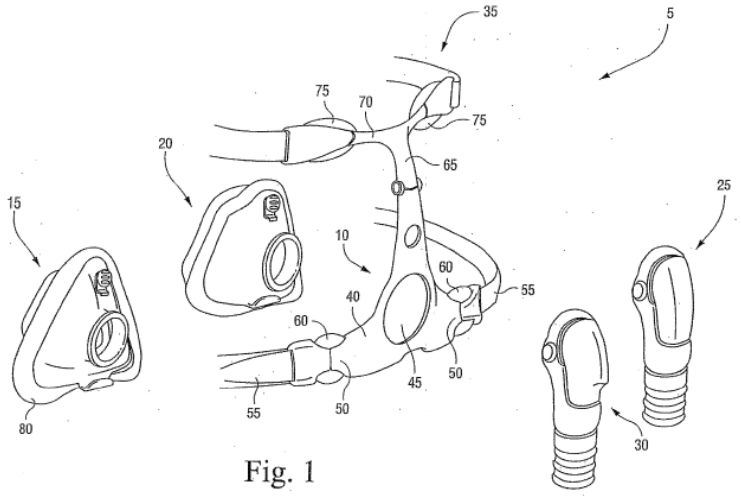
’931 Patent	Prior Art
	<u>Gunaratnam-I</u>: “[T]he clip (800) includes three securing tabs (820) such that inwards projections on the detents are formed as resilient detents which extend past the outer edge of flange (640) to be retained in recesses (660) on the front of the flange (640). To disengage, 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. 1413 at col. 5:34–43.  FIG. 5c  FIG. 7a

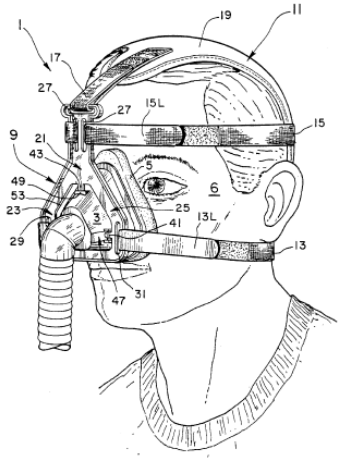
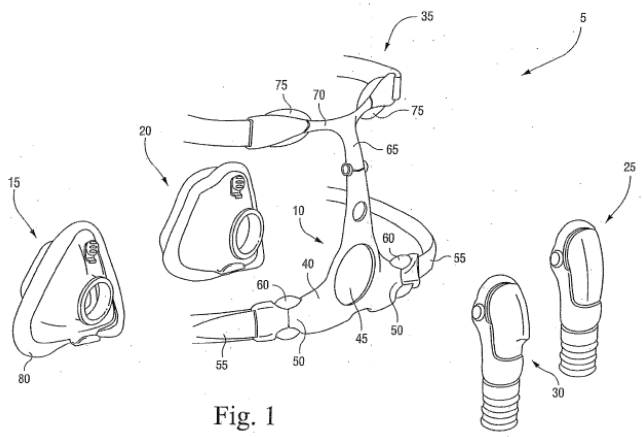
’931 Patent	Prior Art
54. The mask system of claim 51, wherein the frame is semi-rigid or rigid.	*See supra* Claim 1(ii). **Ng:** “Interfaces, such as a nasal mask assembly, for use with blowers and flow generators in treatment of sleep disordered breathing (SDB) typically included a soft-face contacting portion, such as a cushion, and a rigid shell or frame.” Ex. 1410 ¶ 3.  Fig. 1 **Ogden:** “[R]igid, cup-shaped shell 3 made of hard plastic.” Ex. 1422 at col. 2:52–53. **Gunaratnam-I:** “[F]rame (160) is constructed as a substantially rigid shell of polycarbonate or similar transparent plastics material.” Ex. 1413 at col. 4:22–23. “The clip is conducted from polycarbonate or similar material.” *Id.* at col. 5:33–34. **D’Souza:** “[T]he frame 414 is constructed of polycarbonate.” Ex. 1420 ¶ 98.

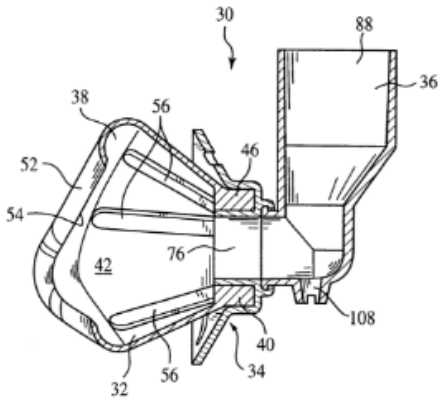
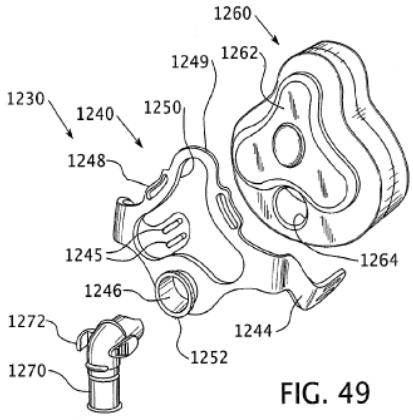
’931 Patent	Prior Art
55. The mask system of claim 54, wherein the frame is rigid.	*See supra* Claim 1(ii). **Ng:** “Interfaces, such as a nasal mask assembly, for use with blowers and flow generators in treatment of sleep disordered breathing (SDB) typically included a soft-face contacting portion, such as a cushion, and a rigid shell or frame.” Ex. 1410 ¶ 3.  Fig. 1 **Ogden:** “[R]igid, cup-shaped shell 3 made of hard plastic.” Ex. 1422 at col. 2:52–53. **Gunaratnam-I:** “[F]rame (160) is constructed as a substantially rigid shell of polycarbonate or similar transparent plastics material.” Ex. 1413 at col. 4:22–23. “The clip is conducted from polycarbonate or similar material.” *Id.* at col. 5:33–34. **D’Souza:** “[T]he frame 414 is constructed of polycarbonate.” Ex. 1420 ¶ 98.

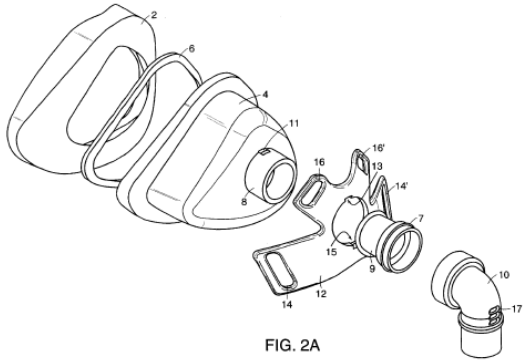
’931 Patent	Prior Art
56. A system for treating a patient with sleep disordered breathing, comprising:	*See supra* Claim 1, preamble.
the mask system of claim 51; and	*See supra* Claim 51.
a flow generator to generate a supply of air at positive pressure to be delivered to the mask system, wherein	*See supra* Claim 32[B]. **Ng:** “Mask system includes a common frame component 10, one of two cushion components 15, 20, one of two elbow components 25, 30, and headgear 35. The mask system is intended for use in positive pressure therapy for users with obstructive sleep apnea (OSA) or another respiratory disorder.” Ex. 1410 ¶ 29. “Interfaces, such as a nasal mask assembly, for use with blowers and flow generators in the treatment of sleep disordered breathing (SDB) typically include a soft-face contacting portion, such as a cushion, and a rigid shell or frame.” *Id*. ¶ 3.  Fig. 1

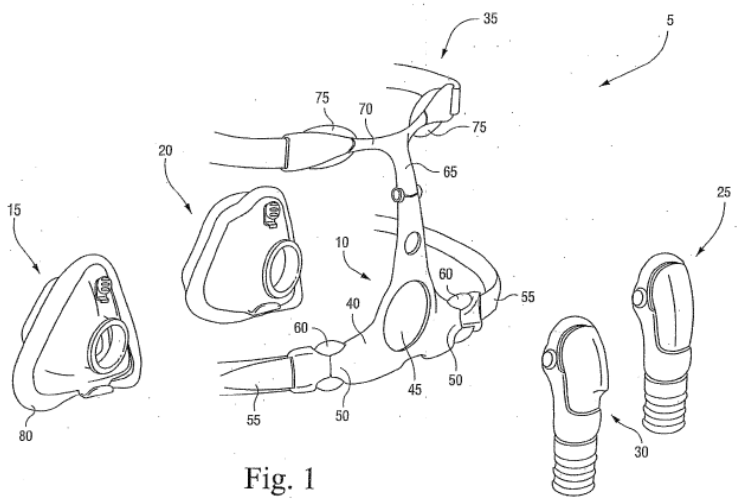
’931 Patent	Prior Art
the air delivery tube is configured to deliver the supply of air from the flow generator to the mask system.	*See supra* Claim 32[C]. **Thomlinson:** “In one embodiment, the present invention includes tubing 90, shown in FIGS. 26, 27, 29 and 35 through 38. Tubing 90 can supply gas to the nasal interface of the present invention.” Ex. 1411 ¶ 316.
57. A mask system for treating a patient with sleep disordered breathing with a supply of air at positive pressure, comprising:	*See supra* Claim 1, preamble. **Ng**: “The mask system is intended for use in positive pressure therapy for users with obstructive sleep apnea (OSA) or another respiratory disorder.” Ex. 1410 ¶ 29.
headgear including headgear straps;	**Ng:** “The common frame 10 has a main body 40 defining a central opening 45. Main body 40 includes at least two lateral arms 50, each of which can be coupled to a headgear strap 55 of headgear. The straps may be connected to the frame using a press-fit connector 60, as is known in the art.” Ex. 1410 ¶ 30.  Fig. 1

’931 Patent	Prior Art
a shroud module having a pair of upper headgear connectors and a pair of lower headgear connectors adapted to removably attach to the respective headgear straps of the headgear,	*See supra* Claims 1(i), 6, and 19[A]. **Ng:** “The common frame 10 has a main body 40 defining a central opening 45. Main body 40 includes at least two lateral arms 50, each of which can be coupled to a headgear strap 55 of headgear. The straps may be connected to the frame using a press-fit connector 60, as is known in the art.” Ex. 1410 ¶ 30.  Fig. 1 **Thomlinson:** “Strap attachment plate 92 can facilitate the use of a strap system 102 by increasing the ease at which a strap can be connected to or removed from the nasal interface. Because the strap attachment plate is not integral to the nasal interface, the strap attachment plate, and any attached straps, can be more easily added or removed from the system.” Ex. 1411 ¶ 307. “A strap system can be fasted/unfastened using alternative methods to Velcro, such as snaps, buckles, buttons and ties.” *Id*. ¶ 312. **Ultra Mirage:** “Quick release headgear clips: top and bottom allows mask to be removed without resetting the headgear and provides convenience and safety.” Ex. 1416 at 6.

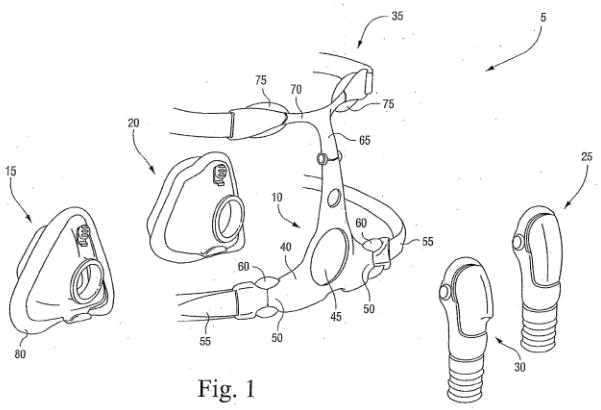
’931 Patent	Prior Art
	Ogden: “[E]ach side strap 13R and 13L is preferably attached to a respective side portion 23, 25 of the rigid plate 9 on respective sides of the patient's nose 2. This can be done in any number of well-known, adjustable manners including . . . hook and loop materials on the straps themselves. . . . The remaining straps 15R, 15L, and 17 are also individually attachable in this manner.” Ex. 1422 at col. 3:10–20. Fig. 1 
the shroud module having a front opening;	*See supra* Claim 1[C]. **Ng:** “The common frame 10 has a main body 40 defining a central opening 45.” Ex. 1410 ¶ 30.  Fig. 1

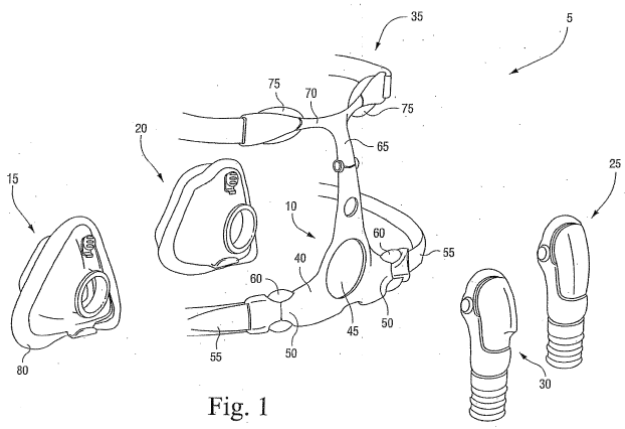
’931 Patent	Prior Art
a rotatable elbow directly attached to the shroud; and	*See supra* Claims 11 and 14. **Ng:** “Common frame 10 is configured to be selectively coupled to one of cushion components 15, 20 and to one of elbow components 25, 30.” Ex. 1410 ¶ 31. **Barnett:** “[C]onduit coupling member 36 is preferably rotateably mounted on a second side of collar 34 opposite the first side so that conduit coupling member 36 freely rotates over a range of 360° about a central axis of collar 34.” Ex. 1414 at col. 3:52–57; *see also id.* at col. 8:66—9:43.  FIG. 1A **Matula-I:** “[P]atient circuit coupling 1270 is an elbow coupling that rotatably and releasably attaches to circuit coupling portion 1246.” Ex. 1423 ¶ 105.  FIG. 49

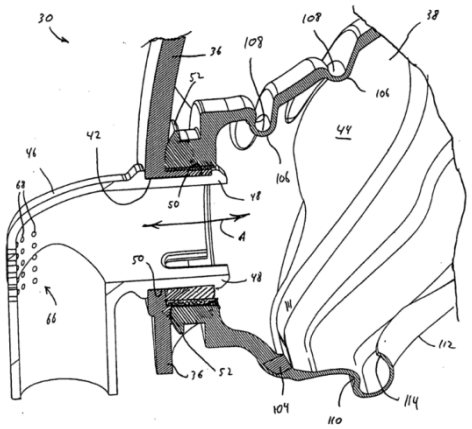
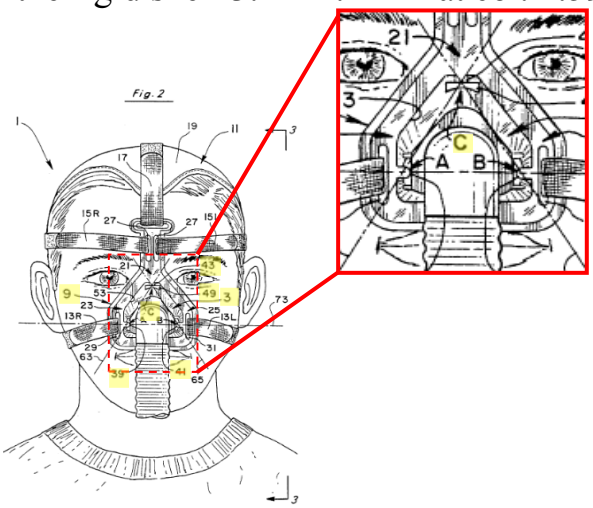
’931 Patent	Prior Art
	Ultra Mirage: “360° rotating elbow provides control over tubing system.” Ex. 1416 at 6. **Lovell:** “[S]wivel connector 9 produces a swivel mount connection between the conduit elbow 10 and the inlet 8. In this type of connection, the conduit elbow 10 is capable of rotating 360 degrees about the centerline of the inlet 8 and the connector 9.” Ex. 1426 at col. 5:20–24.  FIG. 2A
a cushion module, the cushion module comprising a frame defining a breathing chamber, the frame having a frame opening leading to the breathing chamber; and	*See supra* Claims 1(ii) and 22. **Ng:** “Common frame 10 is configured to be selectively coupled to one of cushion components 15, 20 and to one of elbow components 25, 30. Cushion components 15, 20 differ in at least one respect such that one may be more optimal or preferable for use with one user, while another may be more suitable or preferably for use with another user. For example, cushion component 15 may be an Activa™ component, while cushion component 20 may be an UltraMirage™ Series II cushion component, both available from ResMed. These cushion components can be significantly different from one another, e.g., the Activa™ includes a gusset portion 80 and a cushion clip assembly (not shown) which is not incorporated in the UltraMirage™ cushion design.” Ex. 1410 ¶ 31.

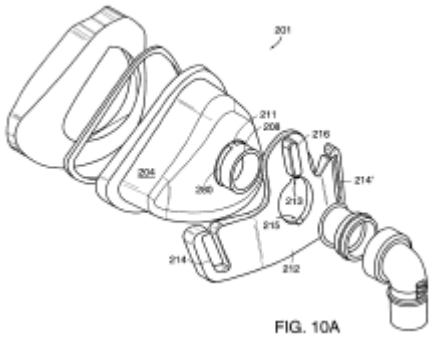
’931 Patent	Prior Art
	“Interfaces, such as a nasal mask assembly, for use with blowers and flow generators in treatment of sleep disordered breathing (SDB) typically included a soft-face contacting portion, such as a cushion, and a rigid shell or frame.” *Id*. ¶ 3. “[A] supplemental cushion component in the form of a nasal cushion or a full-face cushion, wherein the cushion component and the supplemental cushion component cooperatively seal with the user’s face in use.” *Id*. ¶ 13. “A system of breathing arrangements for delivering breathable gas to a patient, comprising at least first and second cushion components (15, 20), e.g., full-face, nasal, nasal prongs, nose tip, and/or a combination of any of the above, including a nasal or full-face cushion and nasal prongs/nozzles combination, etc., that are different from one another in at least one aspect, and a common frame assembly (10) configured to support each of the first and second cushion components (15, 20). Various embodiments are directed to a full-face or nasal mask used with a frame having lateral connector portions having a stiffening member.” *Id*. at Abstract.  Fig. 1

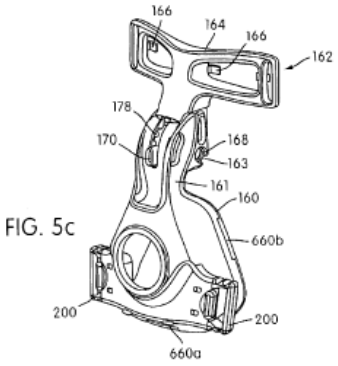
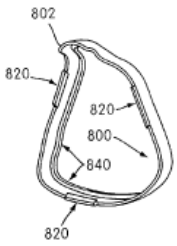
’931 Patent	Prior Art
a cushion to form a seal with the patient's face, wherein the cushion comprises a first, relatively soft, elastomeric material and the frame comprises a second material that is more rigid than the cushion;	*See supra* Claim 1(ii). **Ng:** “Common frame 10 is configured to be selectively coupled to one of cushion components 15, 20 and to one of elbow components 25, 30. Cushion components 15, 20 differ in at least one respect such that one may be more optimal or preferable for use with one user, while another may be more suitable or preferably for use with another user. For example, cushion component 15 may be an Activa™ component, while cushion component 20 may be an UltraMirage™ Series II cushion component, both available from ResMed. These cushion components can be significantly different from one another, e.g., the Activa™ includes a gusset portion 80 and a cushion clip assembly (not shown) which is not incorporated in the UltraMirage™ cushion design.” Ex. 1410 ¶ 31. “Interfaces, such as a nasal mask assembly, for use with blowers and flow generators in treatment of sleep disordered breathing (SDB) typically included a soft-face contacting portion, such as a cushion, and a rigid shell or frame.” *Id*. ¶ 3. “[A] supplemental cushion component in the form of a nasal cushion or a full-face cushion, wherein the cushion component and the supplemental cushion component cooperatively seal with the user’s face in use.” *Id*. ¶ 13.

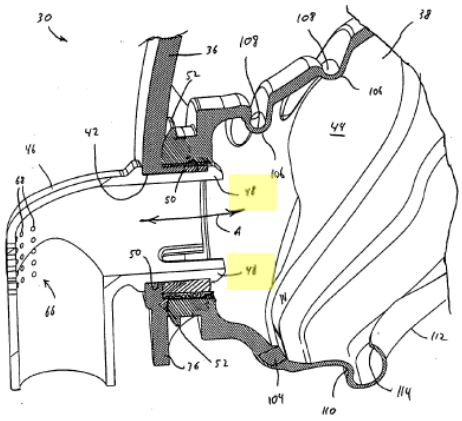
’931 Patent	Prior Art
	“A system of breathing arrangements for delivering breathable gas to a patient, comprising at least first and second cushion components (15, 20), e.g., full-face, nasal, nasal prongs, nose tip, and/or a combination of any of the above, including a nasal or full-face cushion and nasal prongs/nozzles combination, etc., that are different from one another in at least one aspect, and a common frame assembly (10) configured to support each of the first and second cushion components (15, 20). Various embodiments are directed to a full-face or nasal mask used with a frame having lateral connector portions having a stiffening member.” *Id*. at Abstract.  Fig. 1 **<u>Lithgow</u>:** “The cushion 14 is constructed from a soft, flexible skin-compatible material such as silicone. The cushion 14 may be formed, for example, in a one shot injection molding process as is known in the art. However, the cushion 14 may be formed with any suitable material and may be formed by any suitable process. For example, while face contacting portion 26 of cushion 14 may have a softer grade material, the gusset portion may have a harder grade material to provide stiffness as a spring element. The non-face contacting portion 24 may have a stiffer grade material so a direct assembly to frame without a cushion clip may be possible.” Ex. 1433 ¶ 139.

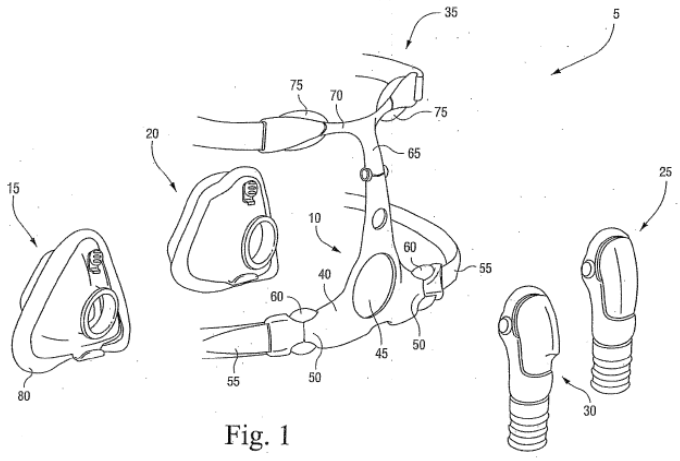
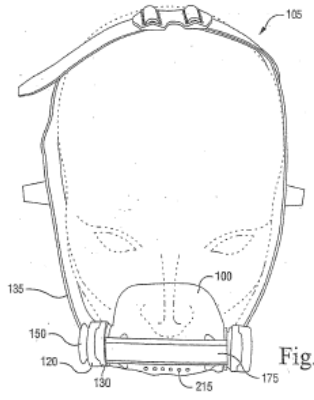
’931 Patent	Prior Art
wherein: the front opening of the shroud module and the frame opening of the frame are aligned along a common longitudinal axis, and wherein the shroud module and the cushion module are structured and arranged to be removably snap-fit attached to one another by moving the shroud module and the cushion module towards one another along the longitudinal axis,	*See supra* Claim 26[B]. **Ng:** “The common frame 10 has a main body 40 defining a central opening 45.” Ex. 1410 ¶ 30. “Common frame 10 is configured to be selectively coupled to one of cushion components 15, 20 and to one of elbow components 25, 30. Cushion components 15, 20 differ in at least one respect such that one may be more optimal or preferable for use with one user, while another may be more suitable or preferably for use with another user. For example, cushion component 15 may be an Activa™ component, while cushion component 20 may be an UltraMirage™ Series II cushion component, both available from ResMed. These cushion components can be significantly different from one another, e.g., the Activa™ includes a gusset portion 80 and a cushion clip assembly (not shown) which is not incorporated in the UltraMirage™ cushion design.” Ex. 1410 ¶ 31.  Fig. 1

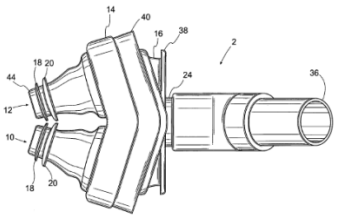
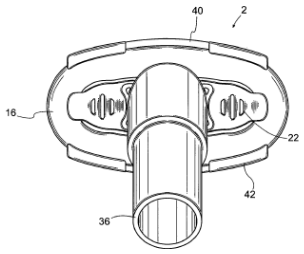
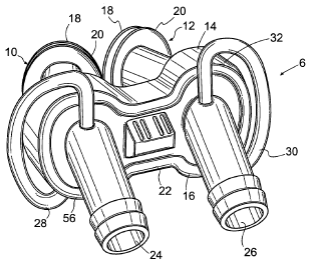
’931 Patent	Prior Art
	Matula-II: “Coupling member 46 includes a pair of prongs 48 that define a channel 50 to receive the wall of the faceplate and the end of seal member 38.” Ex. 1412 ¶ 53.  Fig. 4 **Ogden:** “[R]igid plate 9 is preferably mounted to the rigid shell 3 at first, second, and third locations A, B, and C. . . . 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.” Ex. 1422 at col. 4:59–5:19.  Fig. 2

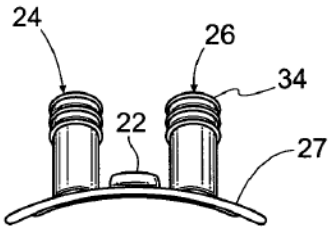
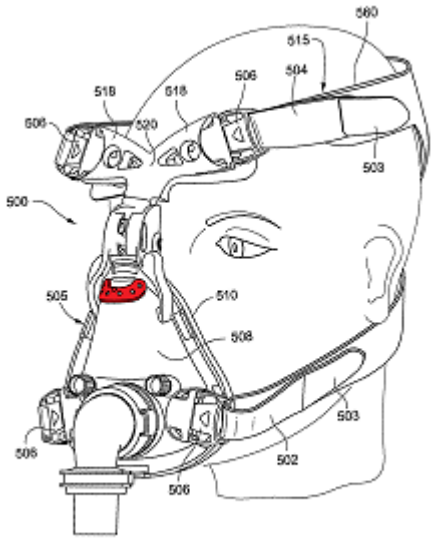
’931 Patent	Prior Art
	Lovell: “The retainer 212 is disposed about the inlet 208 to facilitate retention of the mask 201 on a user. . . . Two tabs 211, 211' included on the inlet 208 mate with two slots 213, 215 formed in the retainer 212 in a particular angular orientation. . . . The retainer aperture and the inlet 208 are generally sized in an interference fit so that the retainer 212 is properly retained by the cooperation of the tabs 211, 211', the slots 213, 215, and the depressed annular region 280 when fully seated against the shell 204.” Ex. 1426 at col. 9:43–48, 9:59–64.  FIG. 10A

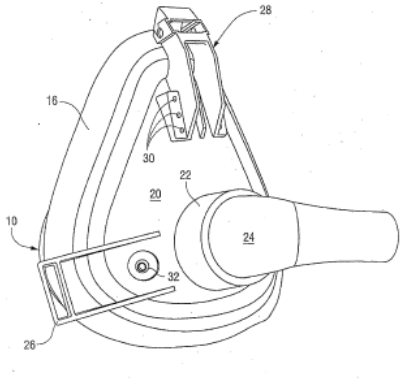
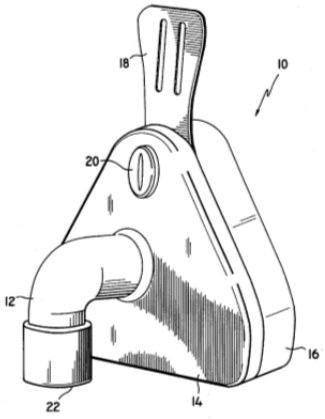
’931 Patent	Prior Art
	<u>Gunaratnam-I</u>: “[T]he clip (800) includes three securing tabs (820) such that inwards projections on the detents are formed as resilient detents which extend past the outer edge of flange (640) to be retained in recesses (660) on the front of the flange (640). To disengage, 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. 1413 at col. 5:34–43.  FIG. 5c  FIG. 7a

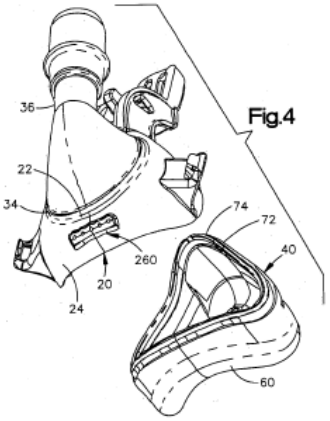
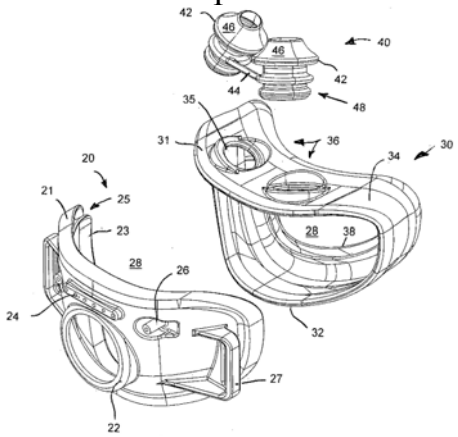
’931 Patent	Prior Art
and the shroud module includes a retaining portion positioned rearwardly of the front opening, towards the frame, and structured to snap fit with the cushion module.	*See supra* Claim 46[F]. **Matula-II:** “Coupling member 46 includes a pair of prongs 48 that define a channel 50 to receive the wall of the faceplate and the end of seal member 38.” Ex. 1412 ¶ 53. A person of skill in the art would have understood that the “prongs” of Matula-II could also be referred to as “snap fingers.”  Fig. 4

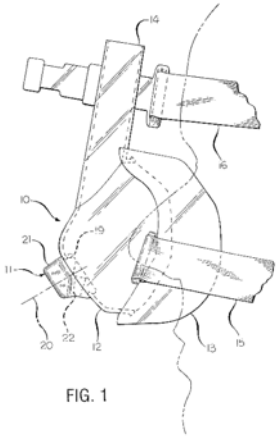
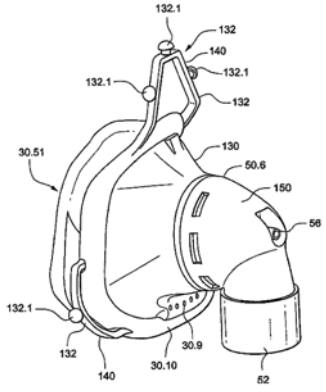
’931 Patent	Prior Art
65. The mask system of claim 57, wherein the frame includes a protruding vent arrangement having a plurality of gas washout holes, wherein the shroud module includes an upper opening to accommodate said protruding vent arrangement.	*See supra* Claim 1[B]. **Ng:** “Common frame 10 is configured to be selectively coupled to one of cushion components 15, 20 and to one of elbow components 25, 30.” Ex. 1410 ¶ 31.  Fig. 1 “As shown in Figs. 3, 7-8, and 11, the mask assembly includes a gas washout vent 215. The vent 215 could be on the frame and/or the cushion component.” *Id.* ¶ 43.  Fig. 11

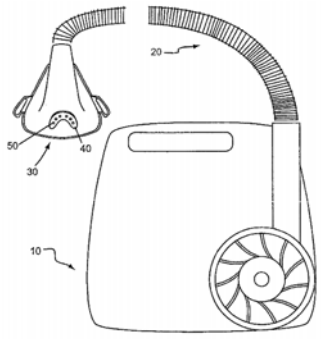
’931 Patent	Prior Art
	Thomlinson: “A nasal interface body 2 according to the present invention can also include one or more locking tabs 38 on the distal portion 16. The locking tabs 38 can be used to releasably engage a strap attachment plate 92, as depicted in FIG. 37 and described further below.” Ex. 1411 ¶ 203.  Fig. 1 “Further, and as shown in FIG. 3, one embodiment of a nasal interface can also include one or more exhalation ports 22, which are described in more detail below.” *Id.* ¶ 204.  Fig. 3 “As shown in FIG. 8, nasal interface body 6 can also include first inlet 24 and a second inlet 26, as well as exhalation port 22. In one embodiment, exhalation port 22 is positioned between inlet 24 and second inlet 26.” *Id*. ¶ 209.  Fig. 8

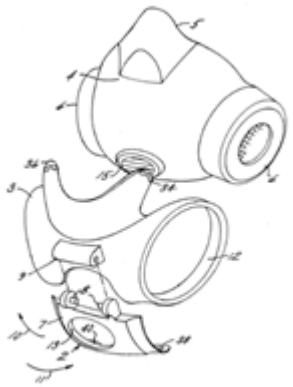
’931 Patent	Prior Art
	“As shown in the figures and in particular FIGS. 3, 14A, 15D, 15F, 16C and 16F, distal portion 16 can also include one or more exhalation ports 22, described further below.” *Id*. ¶ 247.  Fig. 14A **Hitchcock:** *See* Ex. 1421 at Fig. 8.  Fig. 8

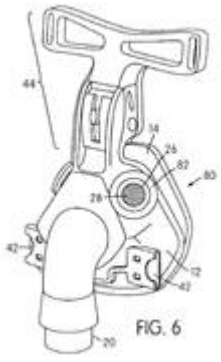
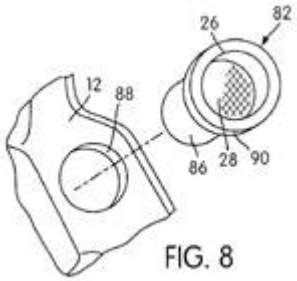
’931 Patent	Prior Art
	Hitchcock-II: “A number of vents 30 may be provided so as to allow gas exhaled by the patient to vent to atmosphere.” Ex. 1440 ¶ 42.  Fig. 1-2 **Landis:** “[T]he aperture in mask frame 14 to receive variable orifice member 20 is configured as a cylindrical wall projecting outward from the mask frame to engage a variable orifice member cap, as described in greater detail below.” Ex. 1441 at col. 5:35–38.  FIG. 1 “In one construction, variable orifice vent aperture member 20 is configured as a cap to mount onto and engage projecting walls of a cylindrical opening in the mask frame or other associated structure (not shown).” *Id.* at col. 6:19–23.

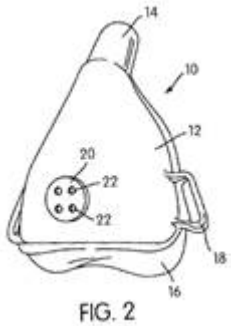
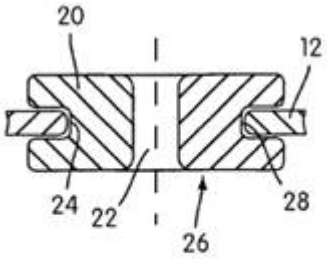
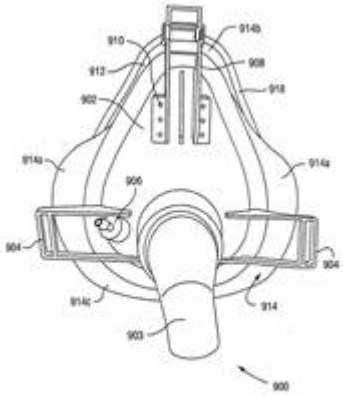
’931 Patent	Prior Art
	Sprinkle: “FIGS. 4 and 23 illustrate an exhalation vent portion 260 of the mask 10. The vent portion 260 includes a thickened wall area 262 in the lower part of the side wall 24 of the shell 20. Five circular exhalation openings 264 are formed at equally spaced intervals in the thickened area 262. The exhalation openings 264 extend from the exterior of the mask 10 to the central chamber 32 of the shell 20. The exhalation openings 264 enable exhaled air to flow out of the mask 10.” Ex. 1419 ¶ 99.  **Chandran:** “The ventilation interface 20 is configured with at least one exhalation port 24.” Ex. 1439 ¶ 60.  *Id.* at Fig. 2.

’931 Patent	Prior Art
	Jones, Jr.: “[T]he exhaust port member 11 is shown as having a generally circular perimeter 17 with a recessed or reduced diameter annular groove 18 formed in the perimeter 17, as shown in FIG. 4. A circular opening 19 is formed in the mask body 12 for receiving the exhaust port member 11.” Ex. 1436 at col. 3:3–8.  FIG. 1 “At least one and preferably two vent ports 22 extend through the exhaust port member 11 at a predetermined angle relative to the axis of rotation 20.” *Id.* at col. 3:23–25. **Jones:** “[T]he lip region 30.8 has a series of four vent orifices 30.9 passing therethrough” Ex. 1437 ¶ 221. 

’931 Patent	Prior Art
	“The shell/cushion 130 includes a series of vents or vent orifices 30.9, which in a preferred form comprises four orifices. The vent orifices 30.9 are formed through a thicker wall section 30.10 formed integrally on the shell/cushion 30. The wall section 30.10 is shown in FIG. 3. The wall section 30.10 has two functions. The first is to form a front flange which with the rear flange 36 in the lip region 30.8 forms the lower channel 140.4. The second function is that the wall section 30.10 allows the vent orifices 30.9 to be positioned at an angle with respect to the elbow.” *Id.* ¶ 226. **Darkin:** “The patient interface 30 includes a vent 40. The vent 40 includes one or more holes, e.g., six holes 50.” Ex. 1442 ¶ 55.  Fig. 1 “Another advantage of the invention is to provide different vents for different pressure ranges. For example, at low pressures, it may be appropriate to have a vent with large holes in order to provide sufficient vent flow. The same vent at higher pressures would have unnecessarily high vent flow which leads to increased noise. Hence in accordance with an embodiment of the invention, when a patient is using a generally low pressure treatment, they can utilize a first vent, but when treatment pressures are higher they can use a second vent.” *Id.* ¶ 89.

’931 Patent	Prior Art
	“Another advantage of the invention is that it provides a quick and simple system of replacing disposable vents. For example, certain styles of vents may clog easily and be designed for a single night's use. In accordance with an embodiment of the invention a vent assembly can comprise a set of "single use" vents. After a first night's use, the patient can switch to the second vent. After a second night's use, the patient can switch to a third vent, and so on.” *Id.* ¶ 90. **Fecteau:** “[A] respirator 1 incorporates a quick release mechanism 2 into a facepiece support system, or yoke, 3.” Ex. 1446 at 4:24–25. “[Q]uick release mechanism 2 consists of an over center cam latch 7 pivotly attached to yoke 3 via hinge pins 8 disposed within hinge 9 and further includes relief cut 13 to accommodate exhale valve 15 while in the latched position.” *Id.* at 4:29–32.  FIG. 2

’931 Patent	Prior Art
	Drew: “The mask 10 includes a gas washout vent constituted by an opening 26 in the shell 12 across which extends a thin air permeable membrane 28.” Ex. 1444 at col. 4:32–34. “FIG. 6 shows a nasal respiratory mask 80.” *Id.* at col. 5:31. “In the mask 40 of FIG. 2, the [gas washout] vent is provided in the gas inlet 20, whereas in the mask 80 the vent is provided in the shell 12. More particularly, the mask 80 includes two cylindrical inserts 82 which have an inner opening 26 across which extends the thin air permeable material 28.” *Id.* at col. 5:35–40. “[T]he insert 82 [] comprises a cylindrical portion 86 sized to be a snug fit into a circular orifice 88 provided in the mask shell 12.” *Id.* at col. 6:2–4.  FIG. 6  FIG. 8

’931 Patent	Prior Art
	Kwok: “The mask includes a Silastic™ insert 20 through which is provided an orifice 22 for gas washout.” Ex. 1445 at col. 3:43–44. “[T]he insert 20 has an external groove or recess 24 which engages the rim 28 of a corresponding shaped opening 26 in the mask shell 12 to retain the insert 20 in place.” *Id.* at col. 3:57–60. “In the embodiment shown in FIGS. 2 to 5 and 7 the insert 20 includes more than one orifice 22.” *Id.* at col. 3:61–62.  FIG. 2  FIG. 8 **Frater**: “Shell 902 may also be provided with one or more vents 910.” Ex. 1425 ¶ 163.  Fig. 50

X. CONCLUSION

258. For these reasons, it is my opinion that Claims 1, 4–8, 10–22, 25, 26, 28–32, 46, 51, 53–56, and 65 of the'931 Patent would have been obvious to a person of ordinary skill in the art.

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 June 22, 2017 at Hunker, Pennsylvania.

By: _____
Jason Eaton, P.E.

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