UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FISHER & PAYKEL HEALTHCARE LIMITED,
Petitioners

v.

RESMED LIMITED,
Patent Owner

Case No. IPR2017-01659
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 1503, 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. 1501). 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 January 18, 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. 61/071893, 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. 1506
- U.S. Provisional Application No. 61/071,893, Ex. 1507
- U.S. Provisional Application No. 61/136,617, Ex. 1508
- Excerpts from the File History of U.S. Patent No. 9,119,931, Ex. 1509
- PCT Publication No. WO 2007/041751 (D'Souza), Ex. 1510
- PCT Publication No. WO 2006/000046 (Hitchcock), Ex. 1511
- U.S. Publication No. 2007/0044804 (Matula-II), Ex. 1512
- U.S. Patent No. 6,412,488 (Barnett), Ex. 1513
- U.S. Patent No. 6,631,718 (Lovell), Ex. 1514
- U.S. Patent No. 6,851,425 (Jaffre), Ex. 1515
- Affidavit of Christopher Butler, Ultra Mirage Brochure (Ultra Mirage), dated September 6, 2016, Ex. 1516
- Affidavit of Christopher Butler, FlexiFit Instructions (FlexiFit), dated September 6, 2016, Ex. 1517
- Declaration of Fiona Cresswell, dated September 21, 2016, Ex. 1518

- U.S. Publication No. 2004/0226566 (Gunaratnam-II), Ex. 1519
- U.S. Publication No. 2004/0182398 (Sprinkle), Ex. 1520
- U.S. Patent No. 7,827,990 (Melidis), Ex. 1521
- PCT Publication No. WO 2007/045008 (Worboys), Ex. 1522
- PCT Publication No. WO 2007/147088 (Matula-I), Ex. 1523
- U.S. Patent No. 6,796,308 (Gunaratnam-I), Ex. 1524
- PCT Publication No. WO 2005/123166 (Frater), Ex. 1525
- U.S. Publication No. 2006/0124131 (Chandran), Ex. 1526
- PCT Publication No. WO 2007/048174 (Ng), Ex. 1527
- U.S. Publication No. 2005/0011524 (Thomlinson), Ex. 1528
- U.S. Patent No. 5,662,101 (Ogden), Ex. 1529
- U.S. Publication No. 2004/0067333 (Amarasinghe), Ex. 1530
- U.S. Publication No. 2006/0060200 (Ho), Ex. 1531
- U.S. Publication No. 2005/0155604 (Ging), Ex. 1532
- PCT Publication No. WO/2005/021075 (McAuley), Ex. 1533
- U.S. Publication No. 2004/0118406 (Lithgow), Ex. 1534
- U.S. Publication No. 2006/0042629 (Geist), Ex. 1535
- U.S. Patent No. 5,921,239 (McCall), Ex. 1536
- U.S. Patent No. 6,435,181 (Jones, Jr.), Ex. 1537

- U.S. Publication No. 2006/0201514 (Jones), Ex. 1538
- PCT Publication No. WO 2004/041342 (Berthon-Jones), Ex. 1539
- PCT Publication No. WO 2006/074515 (Hitchcock-II), Ex. 1540
- U.S. Patent No. 5,657,752 (Landis), Ex. 1541
- PCT Publication No. WO2005051468 (Darkin), Ex. 1542
- Malloy, Robert A., Plastic Part Design for Injection Molding: An Introduction, pp. 336–345 (Hanser Gardner Publications, Inc. 1994) (Malloy), Ex. 1543
- U.S. Patent No. 6,581,594 (Drew), Ex. 1544
- U.S. Patent No. 6,561,190 (Kwok), Ex. 1545
- PCT Publication No. WO 00/50122 (Fecteau), Ex. 1546
- Excerpt from Webster's II New College Dictionary, Ex. 1547
- Excerpt from Oxford American College Dictionary, Ex. 1548

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 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 during 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

[1] Ex. 1501 at col. 6:20–28.

patient.[2] Headgear is removably attached to the shroud to maintain the mask system in a desired position on the patient's face.[3]

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

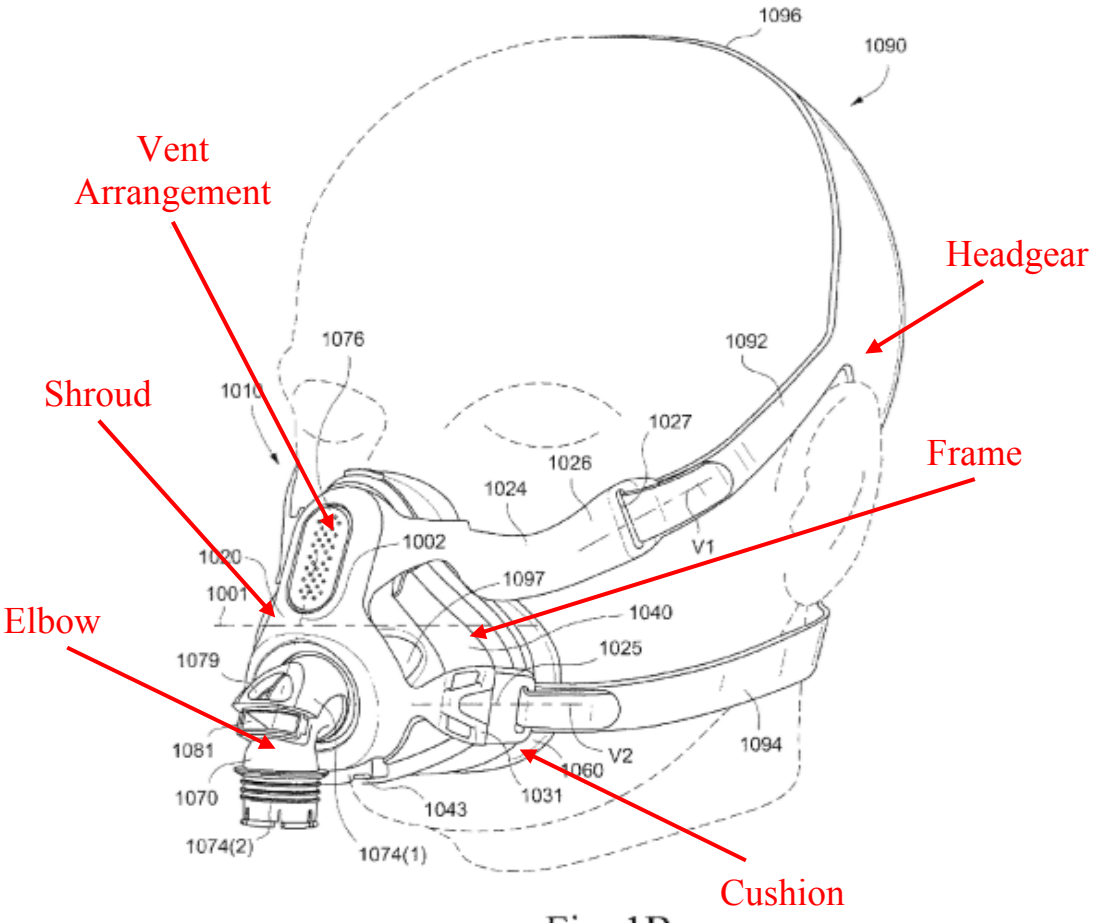


Fig. 1B

[2] *Id.* at col. 6:18–23.

[3] *Id.* at col. 6:23–25.

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 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]

[4] *Id.* at col. 6:51–54.

[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.

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. 1506), 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 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. The headgear has upper straps 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 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]

[10] Ex. 1506; Ex. 1507; Ex. 1508

[11] Ex. 1506; Ex. 1507.

[12] Ex. 1501 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]

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 feature is "a discrete vent

[18] *Id*. at col. 17:19–27.

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.

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, means 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

[19] Ex. 1509 at 391–393, 417–419.

(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 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.

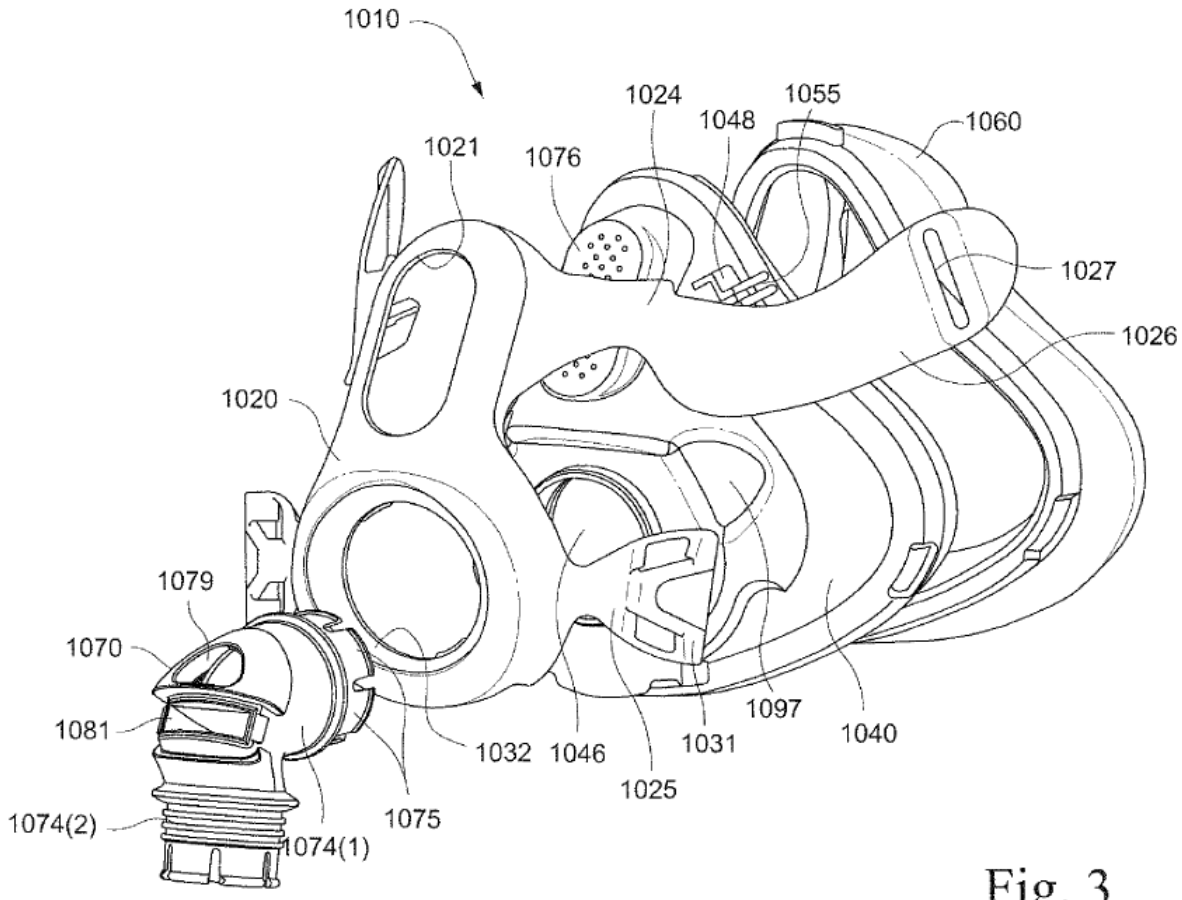


Fig. 3

[20] Ex. 1501 at col. 7:21–27.

41. This is consistent with the ordinary understanding 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, 6–8, 10, 11, 18, 31, and 32 of the '931 Patent would have been obvious over D'Souza (Ex. 1510) in view of Hitchcock (Ex. 1511) under 35 U.S.C. § 103.

43. It is my opinion that Claims 4, 5, and 26 of the '931 Patent would have been obvious over D'Souza (Ex. 1510) in view of Hitchcock (Ex. 1511) and Matula-II (Ex. 1512) under 35 U.S.C. § 103.

44. It is my opinion that Claims 12, 14, and 16 of the '931 Patent would have been obvious over D'Souza (Ex. 1510) in view of Hitchcock (Ex. 1511) and Barnett (Ex. 1513) under 35 U.S.C. § 103.

[21] Ex. 1547 at 7.

[22] Ex. 1548 at 7.

45. It is my opinion that Claim 13 of the ’931 Patent would have been obvious over D’Souza (Ex. 1510) in view of Hitchcock (Ex. 1511) and Lovell (Ex. 1514) under 35 U.S.C. § 103.

46. It is my opinion that Claim 15 of the ’931 Patent would have been obvious over D’Souza (Ex. 1510) in view of Hitchcock (Ex. 1511) and Jaffre (Ex. 1515) under 35 U.S.C. § 103.

47. It is my opinion that Claim 17 of the ’931 Patent would have been obvious over D’Souza (Ex. 1510) in view of Hitchcock (Ex. 1511), Barnett (Ex. 1513), and Ultra Mirage (Ex. 1516) under 35 U.S.C. § 103.

48. It is my opinion that Claims 19, 21 and 25 of the ’931 Patent would have been obvious over D’Souza (Ex. 1510) in view of Hitchcock (Ex. 1511), FlexiFit (Ex. 1517), and Gunaratnam-II (Ex. 1519) under 35 U.S.C. § 103.

49. It is my opinion that Claim 20 of the ’931 Patent would have been obvious over D’Souza (Ex. 1510) in view of Hitchcock (Ex. 1511), FlexiFit (Ex. 1517), Gunaratnam-II (Ex. 1519), and Sprinkle (Ex. 1520) under 35 U.S.C. § 103.

50. It is my opinion that Claim 22 of the ’931 Patent would have been obvious over D’Souza (Ex. 1510) in view of Hitchcock (Ex. 1511), FlexiFit (Ex. 1517), Gunaratnam-II (Ex. 1519), and Matula-II (Ex. 1512) under 35 U.S.C. § 103.

51. It is my opinion that Claims 28–30 and 65 of the ’931 Patent would have been obvious over D’Souza (Ex. 1510) in view of Hitchcock (Ex. 1511), Matula-II (Ex. 1512), and Barnett (Ex. 1513) under 35 U.S.C. § 103.

52. It is my opinion that Claims 46, 51, and 53–56 of the ’931 Patent would have been obvious over D’Souza (Ex. 1510) in view of Hitchcock (Ex. 1511), Flexifit (Ex. 1517), Barnett (Ex. 1513), Jaffre (Ex. 1515), Matula-II (Ex. 1512), Gunaratnam-II (Ex. 1519), Ultra Mirage (Ex. 1516), and Sprinkle (Ex. 1520) under 35 U.S.C. § 103.

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, 6–8, 10, 11, 18, 31, and 32 would have been obvious over D'Souza in view of Hitchcock

1. D'Souza (PCT Publication No. WO 2007/041751)

53. D'Souza describes a mask assembly for use in the treatment of sleep disordered breathing (SDB), which enables a supply of air at positive pressure to be delivered to the patient's airways.[23] The mask assembly includes a cushion that is adapted to be removably connected to a frame via a cushion to frame assembly mechanism.[24] The cushion to frame assembly mechanism provides an interface between the cushion and frame to facilitate assembly and disassembly and includes a polycarbonate frame 414 interlocked with a liquid silicone rubber cushion 416.[25] In addition, the cushion to frame assembly mechanism may be structured to provide a compliant seal between the cushion and frame and reduce or eliminate the risk of leakage.[26] As pictured in Figure 7 on the next page, D'Souza discloses

[23] Ex. 1510 ¶ 3.

[24] *Id.* ¶ 79.

[25] *Id.* ¶¶ 80, 97–98.

[26] *Id.* ¶ 80.

a skeleton frame 412 that is adapted to removably interlock with a cushion/frame sub-assembly 430.[27]

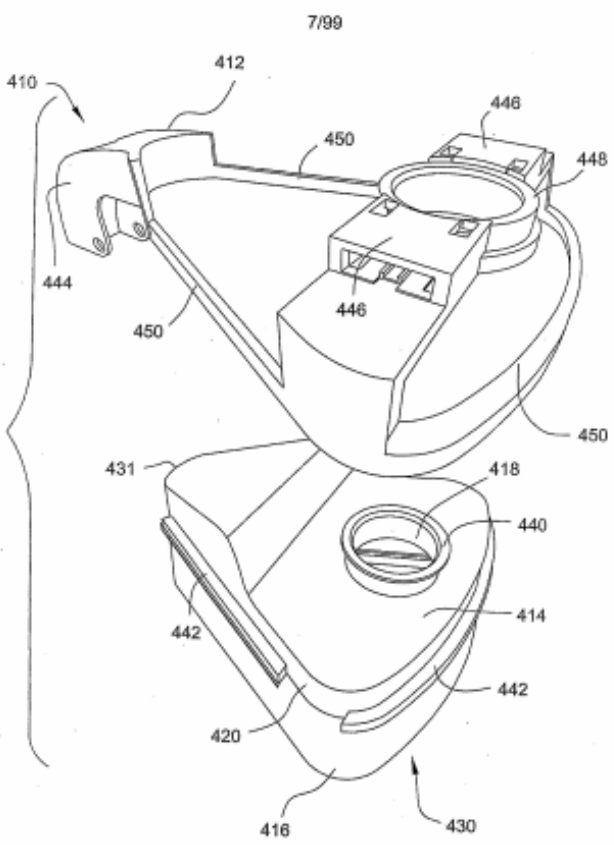


Fig. 7

[27] *Id.* ¶ 96.

54. The skeleton frame 412 includes an upper support member 444 adapted to support a forehead support and lower headgear clip receptacles 446 adapted to be engaged with clips provided to straps of a headgear assembly.[28] The skeleton frame 412 is engaged with the cushion/frame sub-assembly 430 such that the annular elbow connection seal 448 interlocks with the annular wall 440 of the cushion/frame sub-assembly 430, the upper support member 444 engages with a top portion 431 of the cushion/frame sub-assembly 430, and the elongated frame members 450 engage with respective protrusions 442 provided around the perimeter of the cushion/frame sub-assembly 430.[29]

2. Hitchcock (PCT Publication No. WO 2006/000046)

55. Hitchcock describes a mask assembly used in treating sleep disordered breathing.[30] The mask assembly 500 includes a frame 508 adapted to support a cushion 510 for placement against the patient's face.[31] As pictured in Figures 2 and 8 below, Hitchcock discloses an air vent (shaded red) protruding

[28] *Id.* ¶ 100.

[29] *Id.* ¶ 101.

[30] Ex. 1511 ¶ 4

[31] *Id.* ¶ 35

from the frame in the nasal bridge region of the mask.[32] The mask assembly is secured to the patient's face via upper side straps 504 and lower side straps 502, with Velcro® material 503 used to secure each strap.[33]

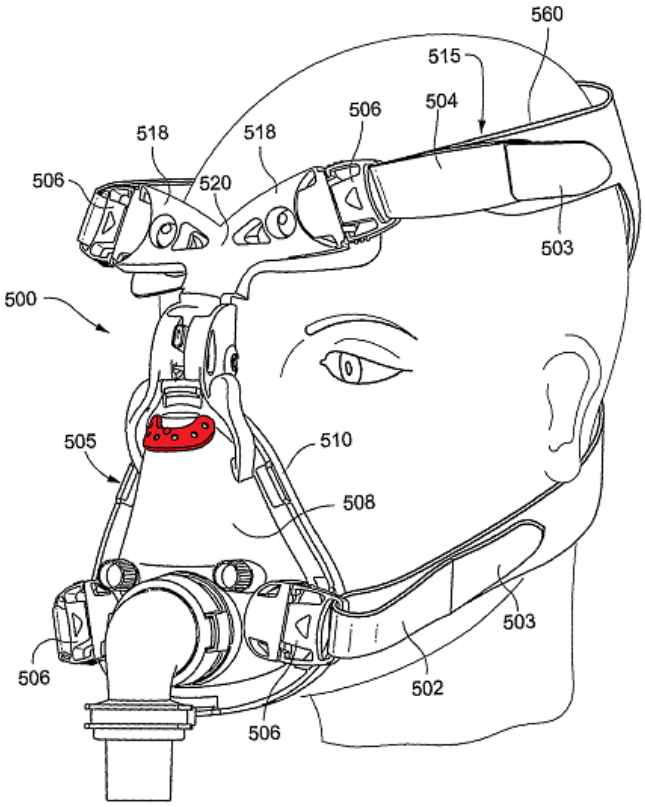


Fig. 8

56. The frame is connected to the forehead support 120, which is generally "Y"-shaped, and includes a pair of arms 130 at an angle EBD of less than

[32] *Id.* at Fig. 2 and Fig. 8

[33] *Id.* ¶ 38

180°, preferably 120°.[34] Each arm includes a slot arrangement 140 adapted to receive a removable forehead support clip 150 connected to a forehead support strap 160.[35] The angle EBD of less than 180° allows for a vertical component to the forces provided by each forehead support strap 160, which pulls the mask up the face not just more tightly against the face.[36]

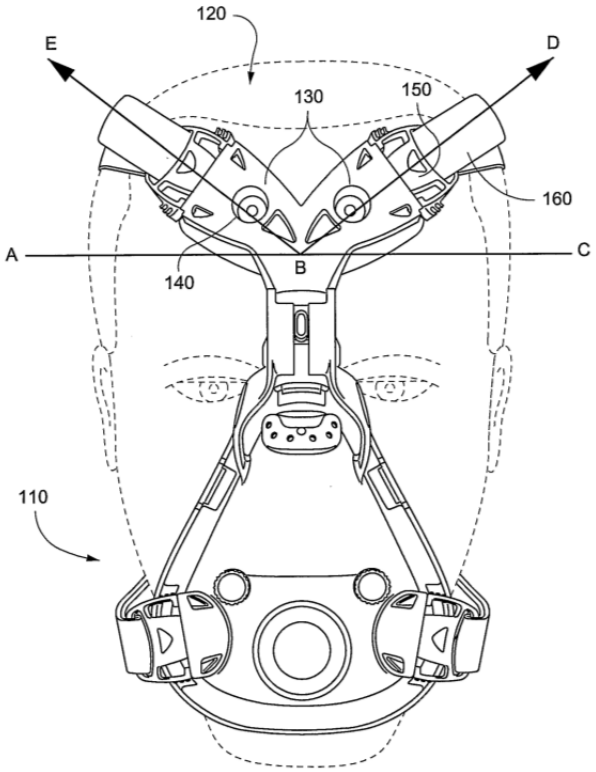


Fig. 2

[34] *Id.* ¶ 25

[35] *Id.*

[36] *Id.* ¶ 25–26

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

57. As shown in the claim charts I provide below, D'Souza includes and discloses nearly all of the limitations of Claims 1, 6–8, 10, 11, 18, 31, and 32. Any minor differences were common in CPAP masks, such as Hitchcock, and were well-known at the time of the invention.

58. With respect to Claim 1, D'Souza teaches a mask system, comprising: (i) a shroud module (skeleton frame 412); wherein the shroud module includes headgear connectors adapted to removably attach to respective headgear straps of headgear (headgear clip receptacles 446); and (ii) a cushion module (cushion/frame sub-assembly 430).[37] The cushion module comprises a rigid or semi-rigid frame defining a breathing chamber (frame 414); 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 (cushion 416).[38] 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 (cushion 416 is constructed of liquid silicone rubber and frame 414 is constructed from polycarbonate).[39] The shroud

[37] Ex. 1510 ¶¶ 96–97, 100.

[38] *Id.* ¶¶ 81, 97–98.

[39] *Id.* ¶¶ 97–98.

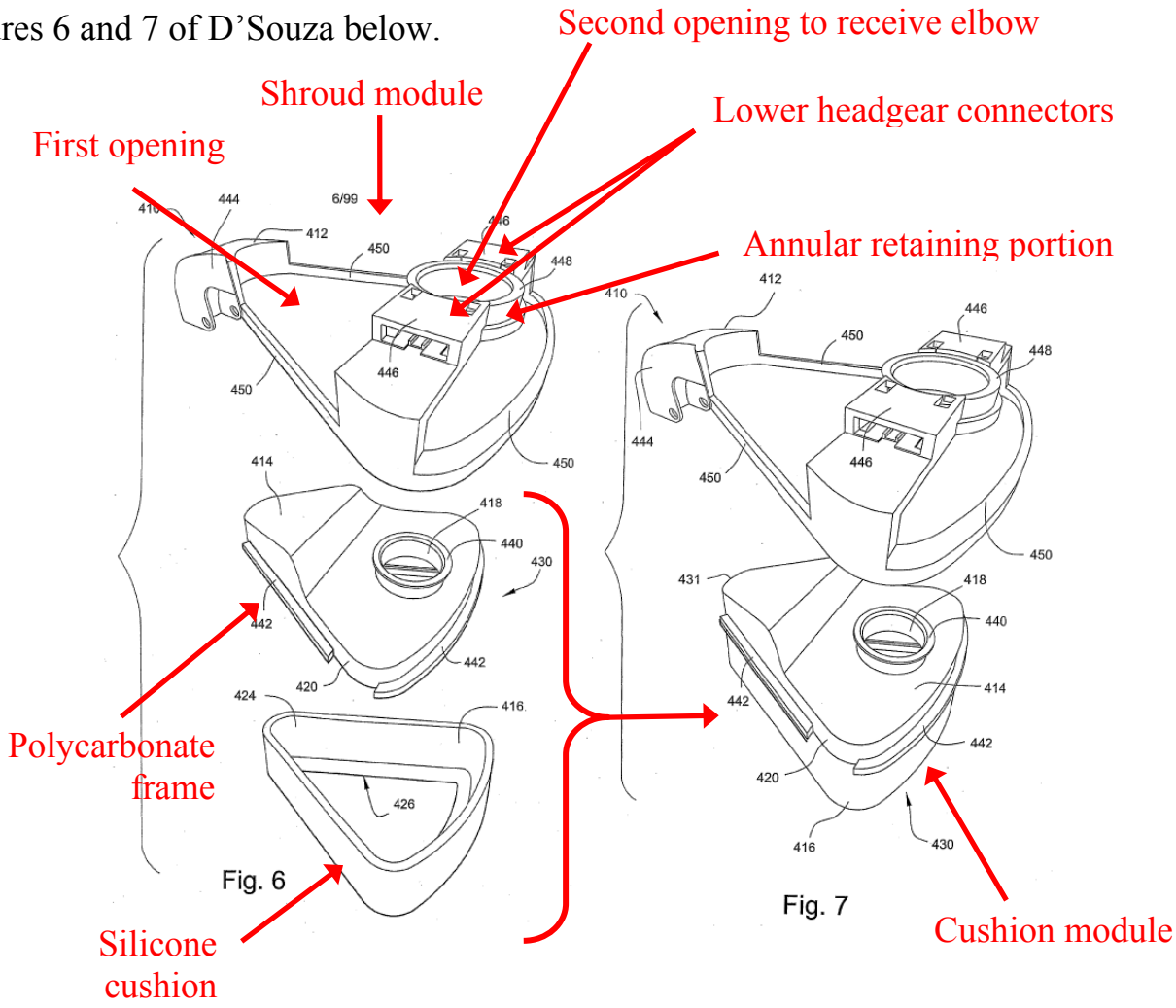
module and the cushion module are configured to be removably and non-rotatably coupleable to one another.[40] The shroud module includes a first opening to accommodate a protruding portion (opening defined by elongated frame members 450).[41] The shroud module includes a second opening positioned to align with a frame opening of the frame leading to the breathing chamber (annular elbow connection seal 448).[42]

[40] *Id.* ¶ 101.

[41] *Id.*

[42] *Id.*

59. I have identified many of these claimed features with arrows in Figures 6 and 7 of D'Souza below.



60. With respect to Claim 1, D'Souza 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 Hitchcock.[43] Moreover, as detailed below, any additional differences between the Challenged Claims and the

[43] *See infra* ¶¶ 62–82.

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

61. Because D'Souza and Hitchcock both describe mask assemblies to deliver positive airway pressure for the treatment of sleep-disordered breathing,[44] the features of Hitchcock would have been readily compatible with and easily incorporated into the D'Souza mask with a reasonable expectation of success. Combining these familiar CPAP mask 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"

62. Independent Claim 1 includes "headgear connectors adapted to removably attach to respective headgear straps of headgear."

63. D'Souza disloses that "the skeleton frame 412 includes . . . lower headgear clip receptacles 446 adapted to be engaged with clips provided to straps of the headgear assembly (not shown)."[45] A person of skill in the art would have understood that these clip receptacles 446 would removably attach to clips on the headgear straps.

[44] Ex. 1510 ¶ 3; Ex. 1511 ¶ 2.

[45] Ex. 1510 ¶ 100.

64. Headgear connectors adapted to removably attach to headgear straps were well-known and commonly used in CPAP masks prior to the '931 Patent. For example, Hitchcock discloses upper and lower straps that are removably connected to the mask.[46] As shown in Figure 1 of Hitchcock, the shroud module includes upper and lower headgear clips adapted to be removably connected to straps 504, 502.[47]

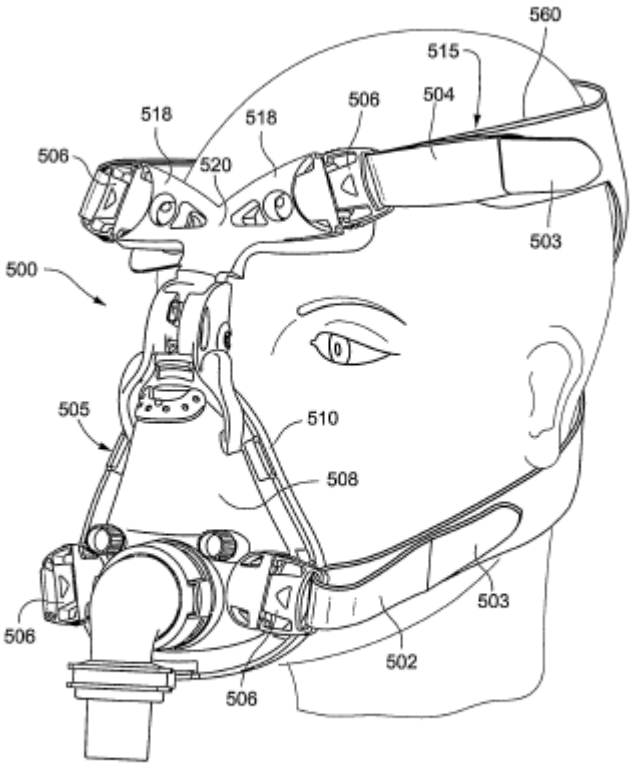


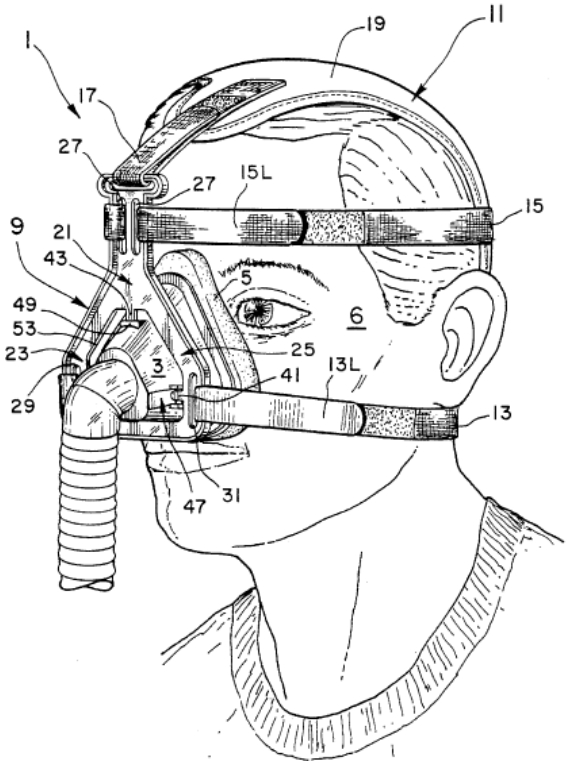
Fig. 8

[46] Ex. 1511 ¶ 36.

[47] *Id.* ¶ 38.

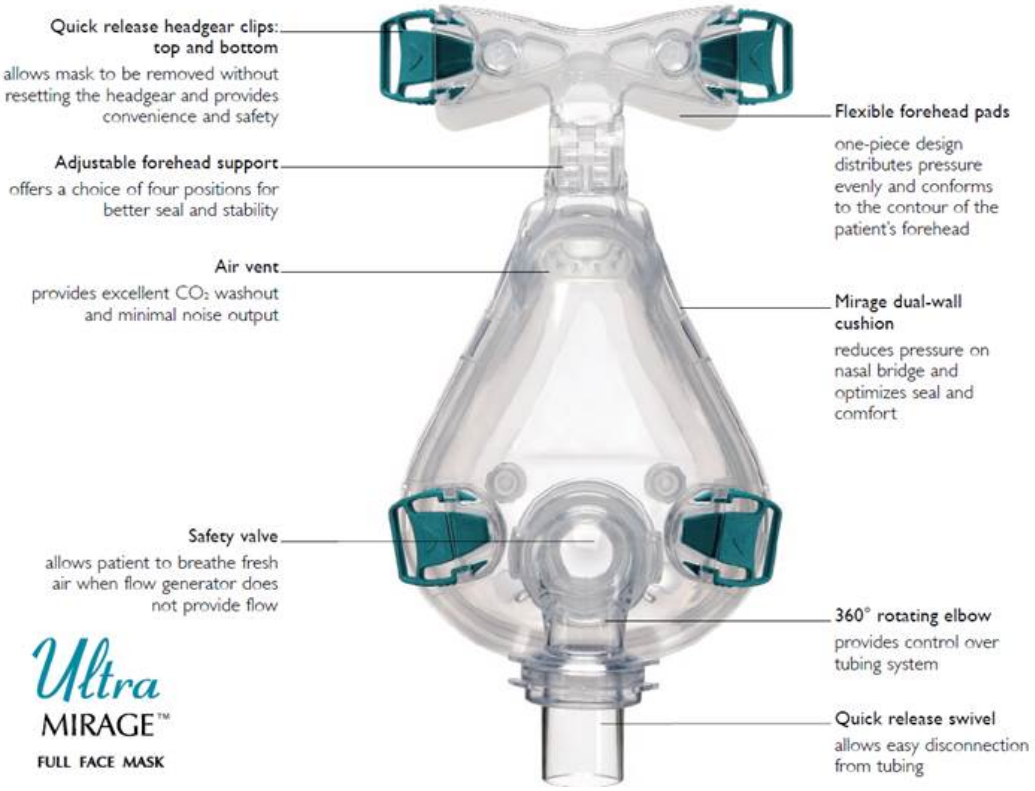
65. Removability is one of the main purposes for using Velcro® on straps. As shown in Figure 1 of Ogden below, it was common and well-known in the industry that headgear straps are typically removable from the headgear connectors on the shroud using hook and loop material (e.g., Velcro®).[48]

Fig. 1



[48] Ex. 1529 at col. 2:62—3:17.

66. Another method to provide removable straps is using headgear clips. For example, Ultra Mirage also discloses "[q]uick release headgear clips: top and bottom allows mask to be removed without resetting the headgear and provides convenience and safety."[49]



67. 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.[50] Such headgear connectors

[49] Ex. 1516 at 6.

[50] *See* Ex. 1517 at 10 ("FITTING YOUR MASK").

also facilitate removal of the headgear for cleaning or replacing the mask.[51] It was common knowledge that cleaning masks with fixed headgear straps is more difficult and may structurally or functionally impair the headgear.[52] Further, releasable mechanisms, such as clips, provide a convenient way to separate the headgear at night time and remove the mask in an emergency.[53] As explained above, removable headgear also allows the mask to be removed without resetting the headgear, or even without removing the headgear from the user's head.[54]

b. "protruding vent arrangement"

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

69. As shown in Figures 7 and 8 of D'Souza on the next page, when the mask assembly 410 is assembled, the top portion 431 of the cushion/frame sub-

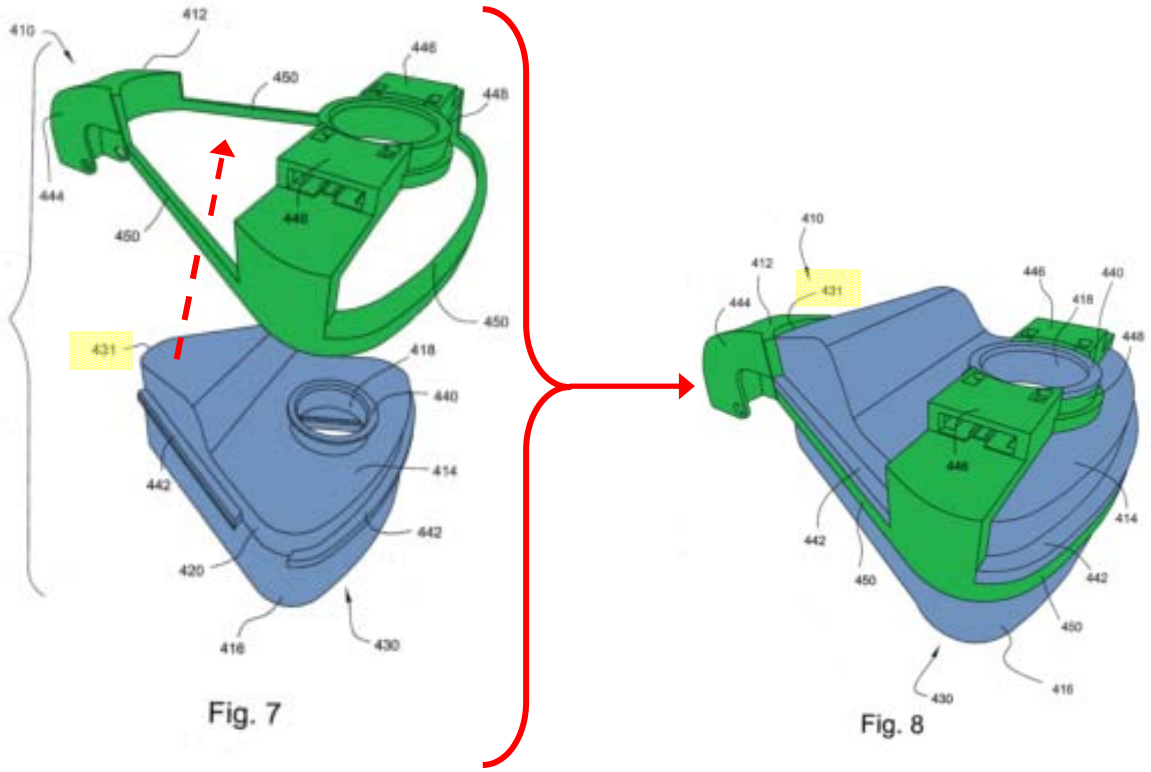
[51] Ex. 1535 ¶¶ 7–8

[52] *Id.*

[53] *See id.*; Ex. 1530 ¶ 14.

[54] *See* Ex. 1516 at 6; Ex. 1535 ¶ 8.

assembly 430 extends through and is received by the opening (between the elongated frame members 450) in the shroud module 412.[55]



70. D 'Souza does not expressly disclose a discrete protruding vent arrangement on the mask frame. However, as outlined in the Claim Chart I provide below, Hitchcock and many other prior art references disclose protruding vents on CPAP mask frames.[56] For 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

[55] Ex. 1510 ¶ 101.

[56] *See infra* ¶ 243.

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

71. For example, as shown below, Hitchcock discloses a discrete vent structure (shaded red on the next page) with multiple vent holes that extends above the surrounding surface of the frame.[57] The figure clearly shows that the discrete vent structure protrudes out further from the surrounding surfaces of the frame. A person of skill would have been familiar with these types of vents and would have understood that this structure in Hitchcock is a discrete protruding vent structure that is commonly made from an elastomeric material.

[57] Ex. 1511 at Fig. 8.

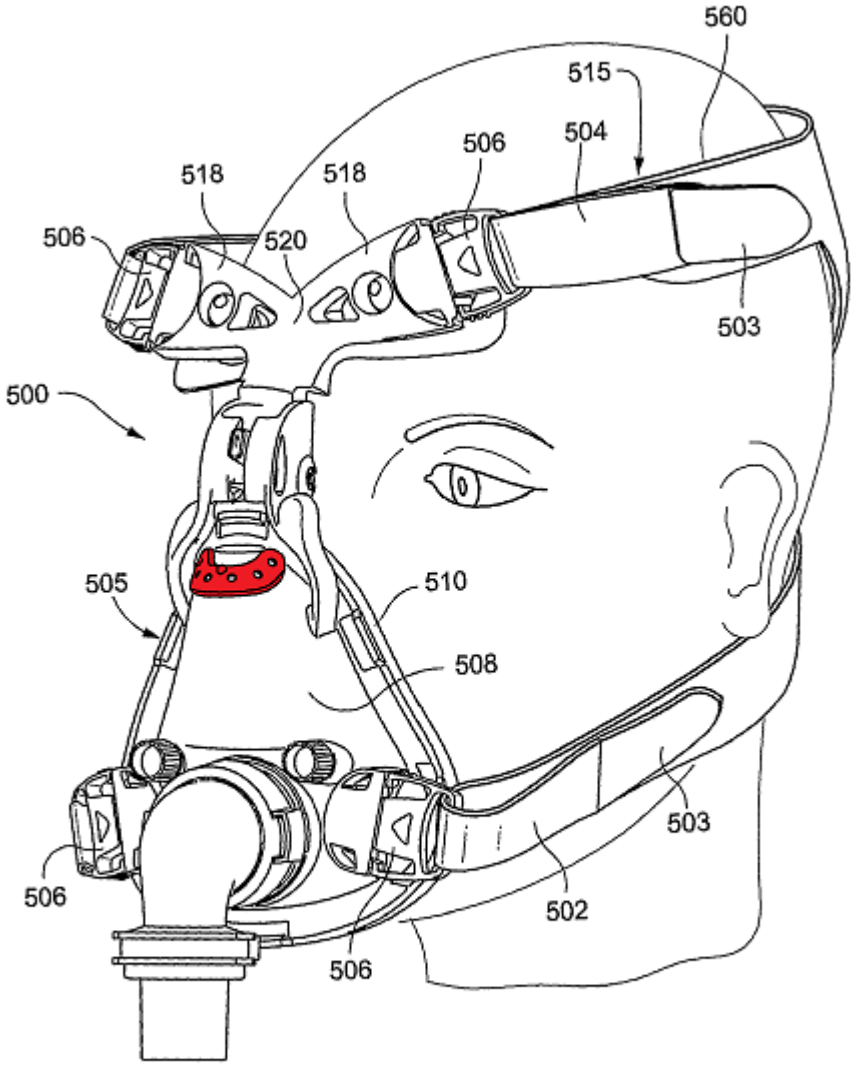
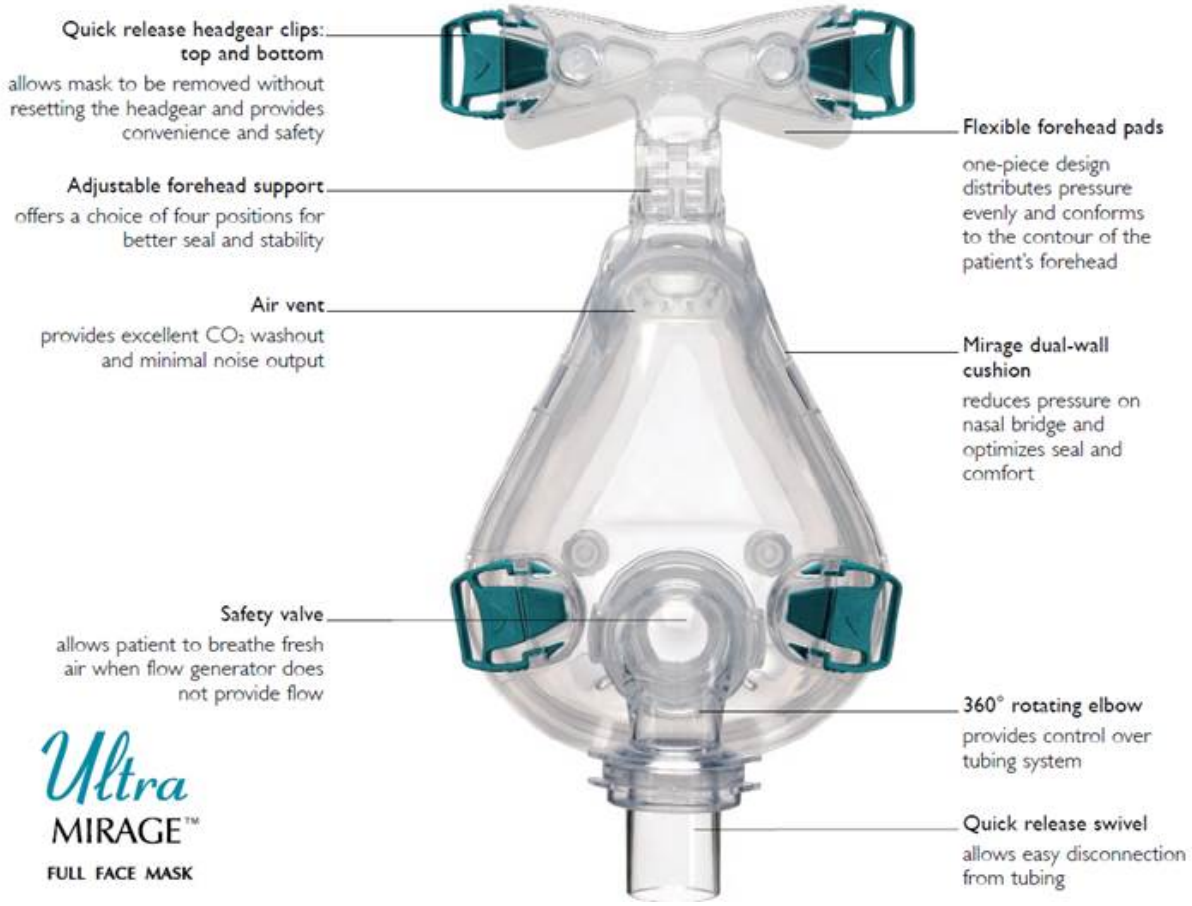

560
515
504
506
518
518
506
520
503
500
505
510
508
503
506
502
506

Fig. 8

72. As another example and shown below, Ultra Mirage discloses a discrete vent arrangement that provides CO_2 washout and is positioned in the nasal bridge region of the mask assembly to provide washout and minimize noise output.[58]



[58] Ex. 1516 at 6.

73. As another example, Jones, Jr. discloses a protruding vent arrangement 11 extending above the surrounding surface of the mask body 12.[59] A circular opening 19 is formed in the mask body 12 for receiving the exhaust port member 11.[60] A plurality of vent holes 22 extend through the protruding vent arrangement 11 at a predetermined angle relative to the axis of rotation 20.[61]

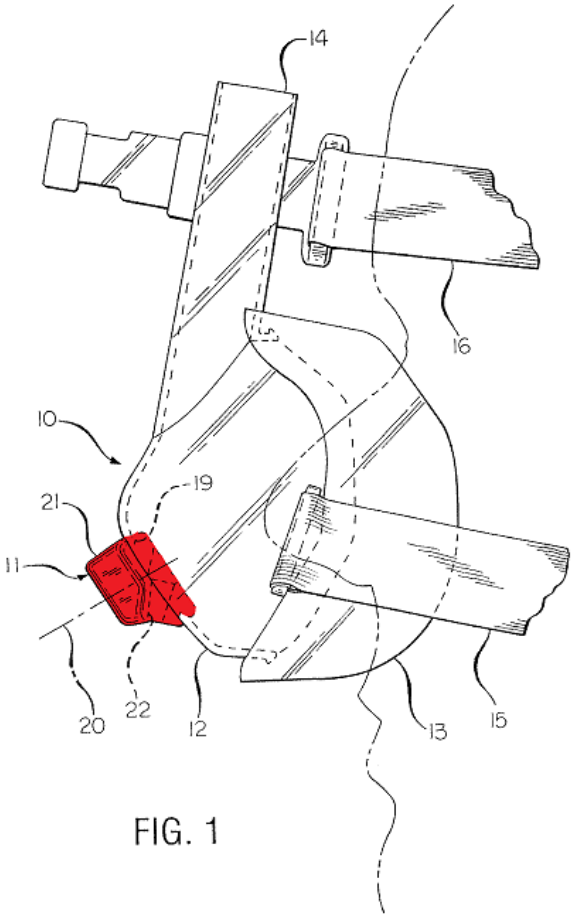


FIG. 1

[59] Ex. 1537 at col. 3:3–8.

[60] *Id.*

[61] *Id.* at col. 3:23–25.

74. As another example, Jones discloses a frame 130 with a protruding vent arrangement 30.10 having a plurality of vent holes 30.9.[62] The protruding vent arrangement 30.10 is a thicker wall section formed integrally on the frame 130.[63] The protruding vent arrangement 30.10 forms a channel for receiving the headgear connector 40.[64]

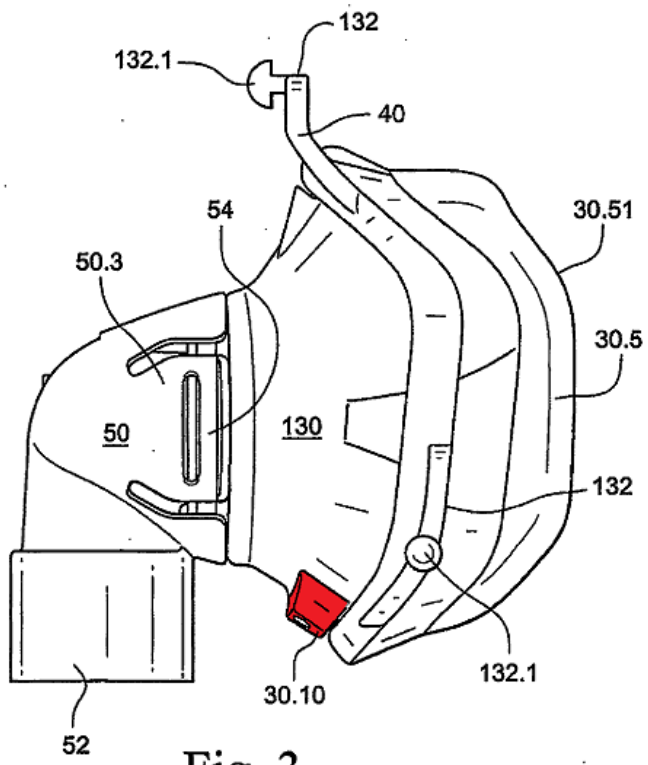


Fig. 3

[62] Ex. 1538 ¶ 226.

[63] *Id.*

[64] *Id.*

75. Kwok also discloses masks with various vent configurations. For example, as shown below, the mask 10 includes an insert 20 protruding from the mask shell 12.[65] The insert 20 has multiple orifices 22 for gas washout.[66] Kwok discloses that masks with flexible inserts 20 produce less noise than an identical mask formed directly in the mask shell.[67] "It is thought that the noise reduction occurs due to the flexible insert 20 damping vibrations caused by air passage through the orifice(s) 22 which produce vibrations or similar in the mask shell 12."[68]

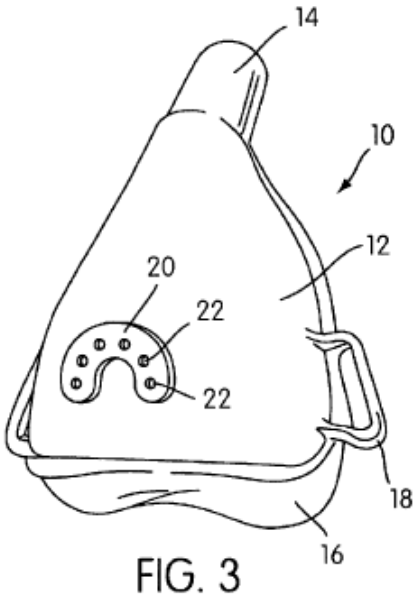


FIG. 3

[65] Ex. 1545 at col. 3:54–60.

[66] *Id.* at col. 3:60–65.

[67] *Id.* at col. 4:13–16.

[68] *Id.* at col. 4:16–19.

76. A person of skill would have been motivated to provide a protruding vent arrangement on the D'Souza frame for CO_2 washout.[69] 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.[70] In particular, a person of skill would have been motivated to modify the D'Souza frame to include a discrete vent structure, as disclosed by Hitchcock, in the same position shown in Hitchcock (*e.g.*, in the nasal bridge region), as shown in the annotated drawings on the next page. The discrete vent structure would extend above the surrounding surfaces of the top portion 431 of the D'Souza frame 414.

[69] *See* Ex. 1516 at 6.

[70] Ex. 1535 ¶ 40.

D'Souza (reversed) **Hitchcock**

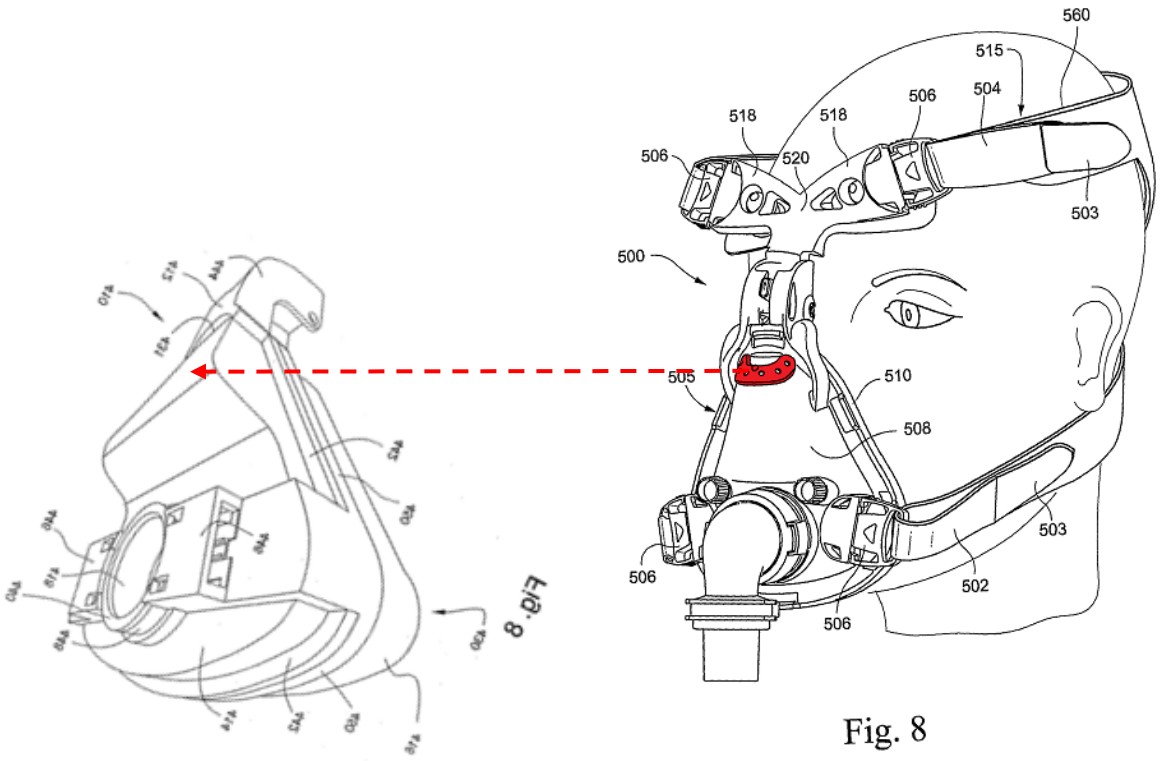


Fig. 8

77. The need to provide a vent or opening in such a mask to allow venting of exhaled air from the breathing chamber was well-known in the industry at the time of the invention and a typical location for such a vent on the mask frame was adjacent the nasal bridge region, especially on full-face masks. 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 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 and minimize re-breathing of the patient's exhaled air.

78. 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 direct the exhaust air away from the user.[71] With protruding vent arrangements, there is more design flexibility with the shape and orientation of the vent holes.[72] The protruding vent arrangement would also provide a thicker wall, which would enable deeper and/or angled holes that better direct the vented air and reduce the velocity of the airflow. A person of skill would have recognized that orientation of the vent holes can minimize interference between the vented air and the surrounding structures, which also

[71] *See* Ex. 1537 at 3:33–38; Ex. 1538 ¶ 226.

[72] *See* Ex. 1537 at 3:23–42; Ex. 1528 at Fig. 8.

minimizes turbulence, draft, and noise.[73] Further, a protruding vent arrangement also allows for a vent design having longer holes with tapered diameters to minimize the noise output.

79. 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.[74] Further, separable vent arrangements would have been desirable for interchangeable vent arrangements.[75] A first vent may be desirable for generally low pressure treatment, but a second vent may be desirable for higher treatment

[73] *See* Ex. 1537 at 3:28–30.

[74] *See* Ex. 1545 at cols. 2:28–31, 4:13–20.

[75] *See* [Darkin] ¶ 89.

pressures.[76] Separable vent arrangements also would have been desirable for "single use" vents that are replaced after each use.[77]

80. Protruding vent arrangements made from a separate part were common in the prior art. As discussed, Jones, Jr. discloses a separate protruding vent arrangement. As another example, Gunaratnam-I includes a separate air vent arrangement 940, as shown below.[78]

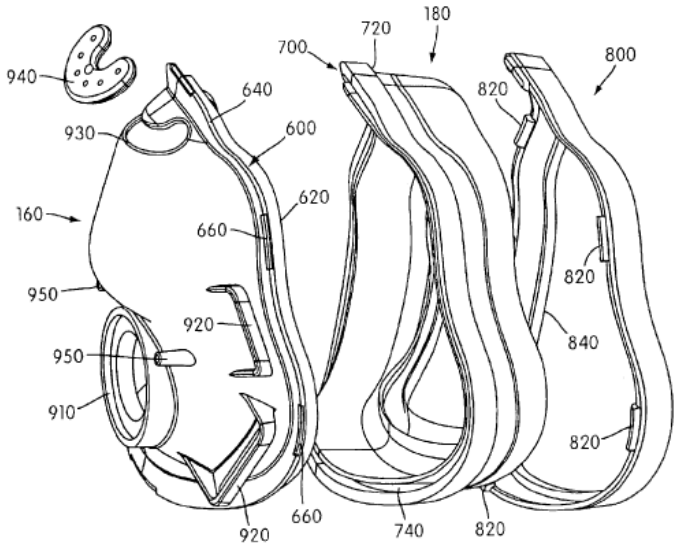


FIG. 15

c. "first opening to accommodate said protruding vent"

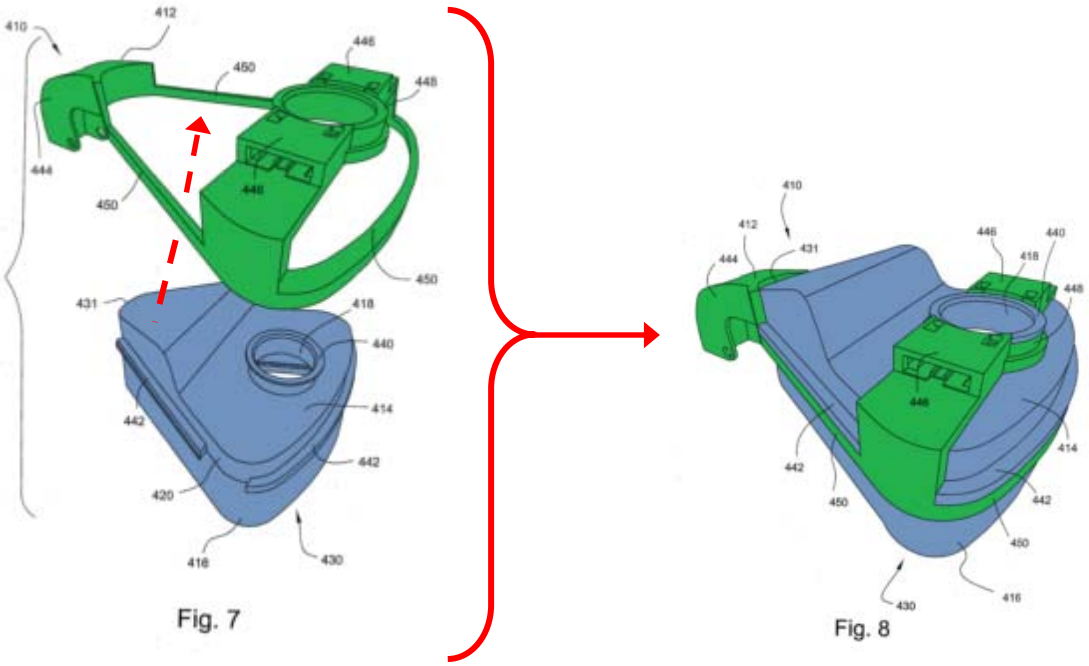
81. Claim 1 further includes "wherein the shroud module includes a first opening to accommodate said protruding vent arrangement."

[76] *See id.*

[77] *See id.* ¶ 90.

[78] Ex. 1524 at col. 6:25–29.

82. As discussed above, a person of skill would have been motivated to modify D'Souza to include a protruding vent arrangement, as taught by Hitchcock.[79] As modified, the first opening in the D'Souza shroud 412 would receive and allow access to the protruding vent arrangement when the mask is assembled, as shown below. A person of skill would have known that the first opening would be necessary to allow the vented gas to exit the frame without being blocked by the shroud. Because the first opening of D'Souza provides enough space for the discrete vent arrangement, a person of skill would have understood this modification of D'Souza to add the protruding vent arrangement to teach this feature of Claim 1.



[79] *See supra* ¶¶ 68–80.

d. "upper and lower headgear connectors"

83. Claim 6 depends from Claim 1 and includes the additional limitation "the shroud module includes upper and lower headgear connectors on each side of the shroud module."

84. As shown in Figure 7 of D'Souza below, the shroud module 412 includes an upper support member 444 adapted to support a forehead support (not shown) and lower headgear clip receptacles 446 adapted to engage headgear clips (not shown).[80] A person of skill in the art would have understood that the D'Souza mask also includes headgear connectors on the forehead support to support the forehead support and the mask on the patient. Although separately connected, the forehead support could be considered part of the shroud module.

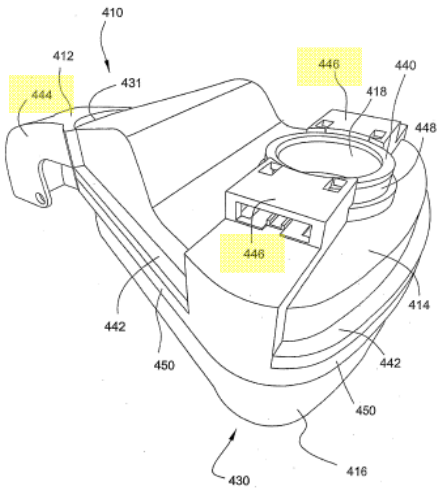


Fig. 8

[80] Ex. 1510 ¶ 100, Fig. 7.

85. Although D'Souza may not show upper headgear connectors, it was common for prior art masks to have such connectors, especially masks with forehead supports. For example, as shown below, Hitchcock discloses a shroud having a forehead support 520 with headgear connectors 506.[81] A skilled artisan would have known to add upper headgear connectors as taught by Hitchcock to the D'Souza forehead support to secure the upper portion of the mask assembly and to stabilize the mask assembly.

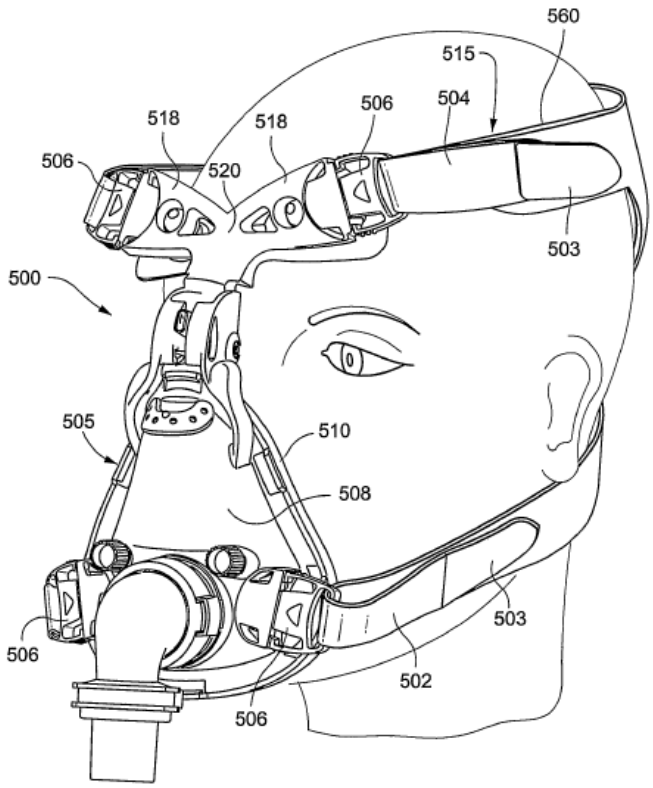
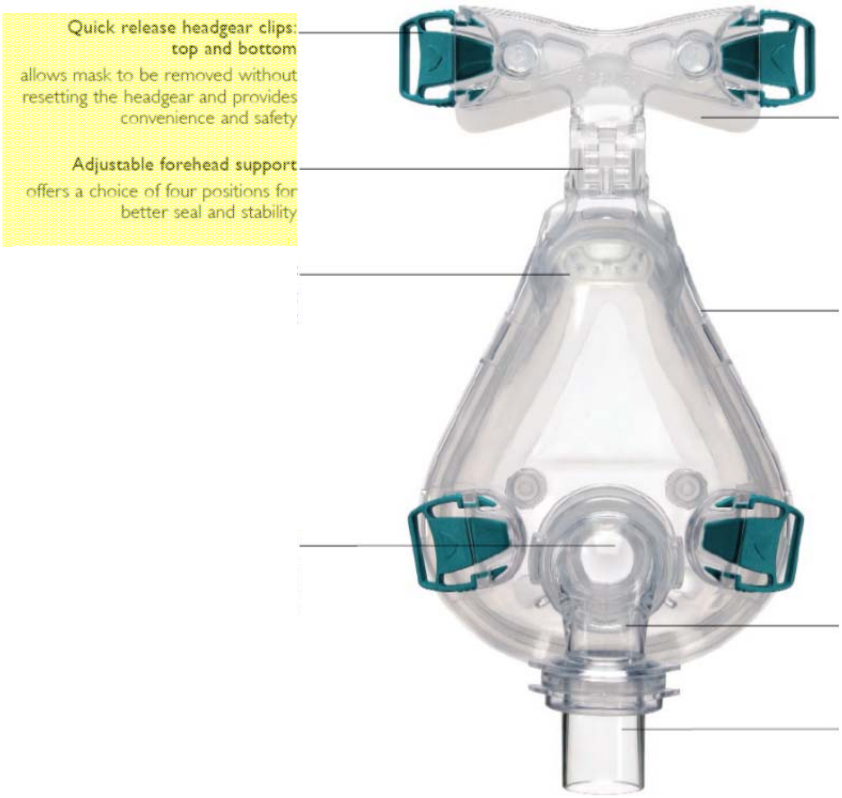


Fig. 8

[81] Ex. 1511 ¶ 36.

86. Ultra Mirage also discloses a mask having a forehead support with headgear connectors adapted to receive headgear clips, as shown below.[82] A person of skill in the art at the time of the invention would have known that similar headgear connectors could and would be included on the forehead support of D'Souza. Also, it was common and a person of skill in the art would have been motivated to include upper headgear connectors on a full-face respiratory mask.



[82] Ex. 1516 at 6.

e. "each upper headgear connector includes a slot"

87. Claim 7 depends from independent Claim 1 and includes the additional limitation "wherein each upper headgear connector includes a slot adapted to receive a respective headgear strap in use."

88. D'Souza does not expressly disclose upper headgear connector slots, but such slots were common in masks prior to the '931 Patent. For example, Hitchcock discloses that Resmed's own products included upper headgear slots 40 adapted to receive headgear straps, as shown below.[83]

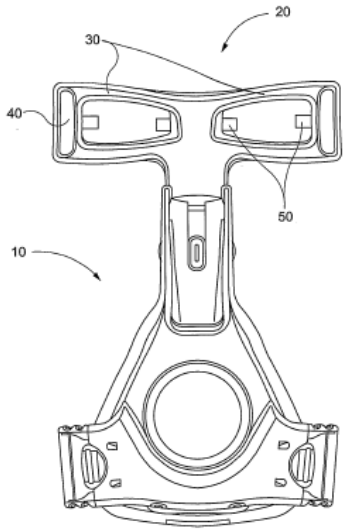
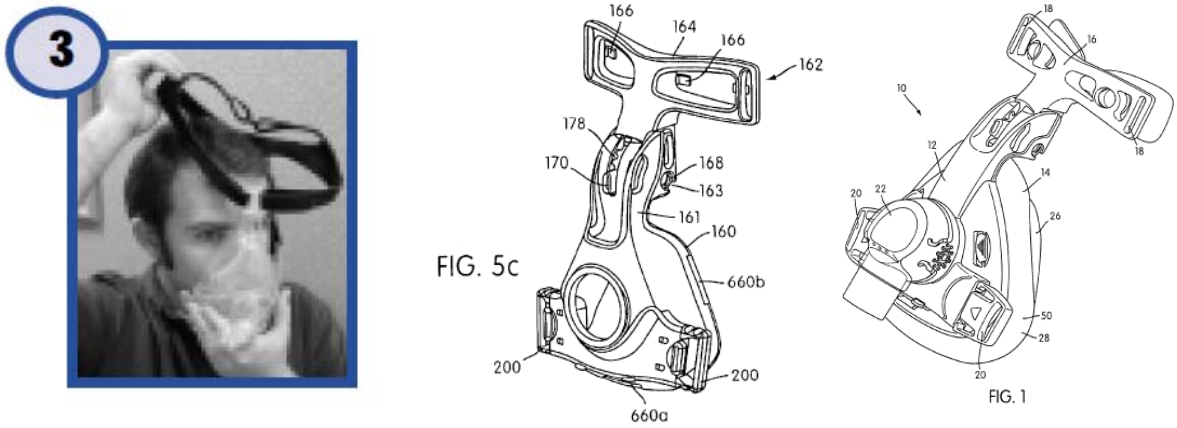


Fig. 1
Prior Art

[83] Ex. 1511 ¶ 24.

89. 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.[84]

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



90. A person of skill in the art at the time of the invention would have been motivated to modify the mask assembly of D'Souza to include upper headgear connectors with slots, as taught by Hitchcock and other prior art references, in order to facilitate donning/doffing the mask (see FlexiFit image above) while maintaining simplicity in design and manufacturing.[85] 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

[84] *See* Ex. 1524 at Fig. 5c; Ex. 1517 at 10 ("ASSEMBLING THE MASK"); Ex. 1534 at Fig. 1.

[85] Ex. 1514 at col. 7:6–13.

headgear connection as this part of the headgear assembly undergoes less tension than the lower headgear straps and is only drawn into tension as the mask reaches its wearing position, as addressed in more detail below.[86]

91. 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®.[87]

f. "each lower headgear connector is adapted to be removably interlocked with a headgear clip"

92. Claim 8 depends from independent Claim 1 and includes the additional limitation "wherein each lower headgear connector is adapted to be removably interlocked with a headgear clip associated with a respective headgear strap."

93. D'Souza describes lower headgear connectors adapted to engage clips.[88] A person of skill in the art would have understood that these clips were removably attached. However, to the extent D'Souza provides insufficient description for the removability of the clips, this was a common feature in CPAP masks prior to the '931 Patent."

[86] *See infra* ¶ 99.

[87] *Id.*

[88] Ex. 1510 ¶ 100.

94. For example, Hitchcock discloses that Resmed's own products included upper headgear slots 40 and lower headgear clips adapted to removably receive headgear straps, as shown below.[89]

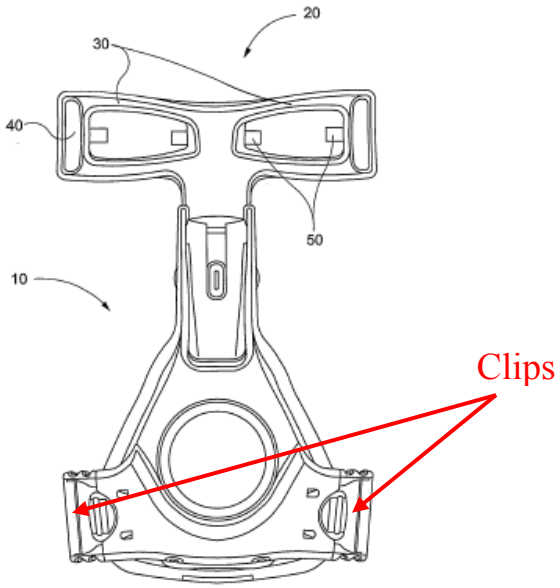


Fig. 1
Prior Art

[89] Ex. 1511 ¶ 24.

95. Other embodiments of Hitchcock also disclose lower headgear clips 506 adapted to removably connect with lower side straps 502, as shown in Figure 8 below.[90]

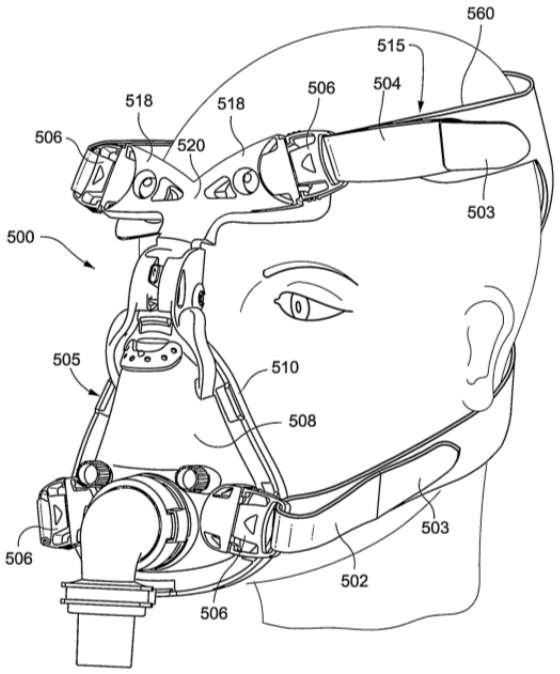


Fig. 8

96. As discussed above, Gunaratnam-I discloses upper headgear slots.[91] 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. Gunaratnam-I discloses that "[o]n the front surface of the frame, are

[90] *Id.* ¶ 38.

strap connection points (630) for connection of the mask to patient headgear. Connectors (200) are shown in FIGS. 5c-5 f."[92]

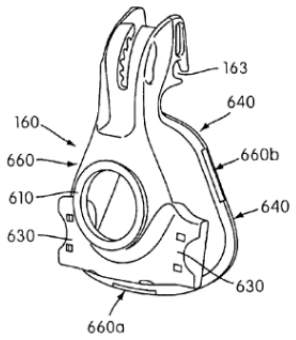


FIG. 5a

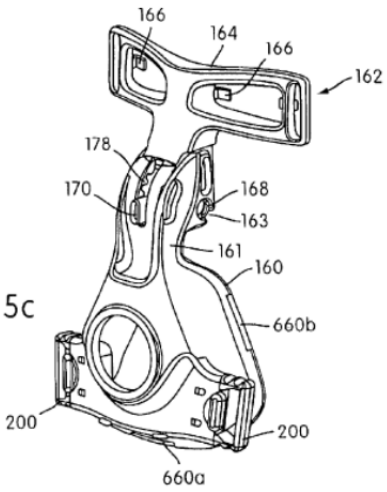


FIG. 5c

97. As shown below, Lithgow also discloses the combination of upper headgear slots and lower headgear clips.[93]

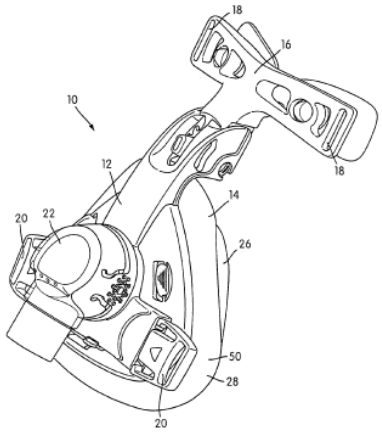


FIG. 1

[91] *See supra* ¶ 89.

[92] Ex. 1524 at col. 4:32–34.

[93] Ex. 1534 ¶ 111.

98. 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.[94] Further, quick release mechanisms, such as clips, provide a convenient way to separate the headgear and remove the mask in an emergency.[95]

99. 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, as 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.

100. 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

[94] *See* Ex. 1516 at 6.

[95] *See* Ex. 1530 ¶ 14.

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

g. "air delivery tube"

101. Claim 11 depends from independent Claim 1 and includes the additional limitation "further comprising an elbow module adapted to be connected to an air delivery tube that delivers breathable gas to the patient." Claim 32 depends from Claim 1 and includes the additional limitation "an air delivery tube configured to deliver the supply of air from the flow generator to the mask system."

102. D'Souza discloses mask assemblies for use with flow generators and adapted to engage an elbow, but may not specifically describe an air delivery tube connecting the elbow to the flow generator.[96] However, 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,

[96] Ex. 1510 ¶¶ 3, 100.

Hitchcock discloses an aperture 314 adapted to receive pressurized gas from an air delivery tube via a swivel elbow.[97] Ultra Mirage also specifically describes air delivery tubing connected to the elbow.[98]

103. It was well-known at the time of the invention to use tubing, as taught by Hitchcock, to connect an elbow or inlet conduit of a mask assembly to a flow generator. The D'Souza 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.

h. "the shroud module and the frame comprise polycarbonate"

104. Claim 18 depends from independent Claim 1 and includes the additional limitation "wherein the shroud module and the frame comprise polycarbonate and the cushion comprises silicone."

105. D'Souza describes a cushion 416 constructed of liquid silicone rubber and a frame 414 constructed of polycarbonate.[99] D'Souza also describes the

[97] Ex. 1511 ¶ 28.

[98] Ex. 1516 at 6.

[99] Ex. 1510 ¶¶ 97–98.

shroud being formed of plastic, and a person of skill in the art would have understood that this plastic is most likely polycarbonate like the frame.[100] 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.[101] Lovell also discloses a CPAP mask assembly including a polycarbonate shroud.[102]

106. 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.[103] Polycarbonate is also a relatively good insulator and provides good mechanical properties of strength, rigidity, and toughness.[104] Polycarbonate grades are available that comply with the biocompatibility testing standards with which masks for sleep

[100] *Id.* ¶ 101.

[101] Ex. 1524 at cols. 1:34–39, 5:33–34.

[102] Ex. 1514 at cols. 6:13–14, 7:46–53.

[103] *See* Ex. 1533 at 6:21-24; Ex. 1524 at col. 4:22–26.

[104] *See* Ex. 1533 at 6:21-24; Ex. 1534 ¶ 139; Ex. 1524 at col. 4:22–26.

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.

B. Claims 4, 5, and 26 of the '931 Patent would have been obvious over D'Souza in view of Hitchcock and Matula-II

1. Matula-II (U.S. Patent Application No. US 2007/0044804 A1)

107. Matula-II describes a patient interface mask assembly for use in a pressure support or ventilation system that supplies a flow of gas to the airway of a patient, and, in particular, to a patient interface having a seal member that is selectively adjustable relative to a faceplate or other seal-supporting structure so that the user can control the position of the seal to optimize comfort and fit while also minimizing gas leaks.[105]

[105] Ex. 1512 ¶ 3.

108. As illustrated in Figure 4 below, the patient interface of Matula-II includes a faceplate 36 and a seal or cushion member 38 that forms a breathing chamber.[106] The cushion member 38 is mounted to the faceplate 36 at a seal support portion 40 of the faceplate 36.[107]

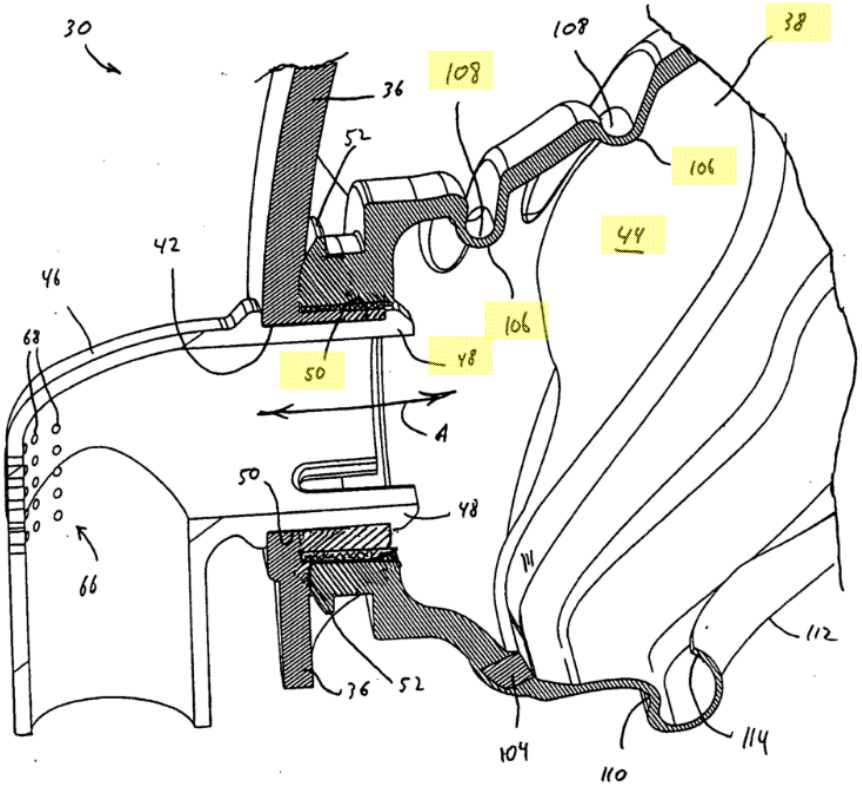


Fig. 4

[106] *Id.* ¶¶ 51–52, Fig. 4.

[107] *Id.* ¶ 52.

109. An orifice 42 is provided in seal support portion of faceplate 36 to enable a flow of gas from patient circuit 34 to be communicated to a chamber 44 defined by the seal member 38.[108] A coupling member 46 connects the patient circuit to the interface device via orifice 42, and includes a pair of prongs 48 that define a channel 50 to receive the wall of the faceplate 36 and the end of seal member 38.[109] In one arrangement described in Matula-II, the end of the 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.[110]

[108] *Id.* ¶ 52.

[109] *Id.* ¶ 53.

[110] *Id.*

110. As shown in Figure 4 below, the seal member 38 is also described as having at least one fold 106 provided at an upper portion of the seal member "so that the seal member has the desired degree of flexibility."[111]

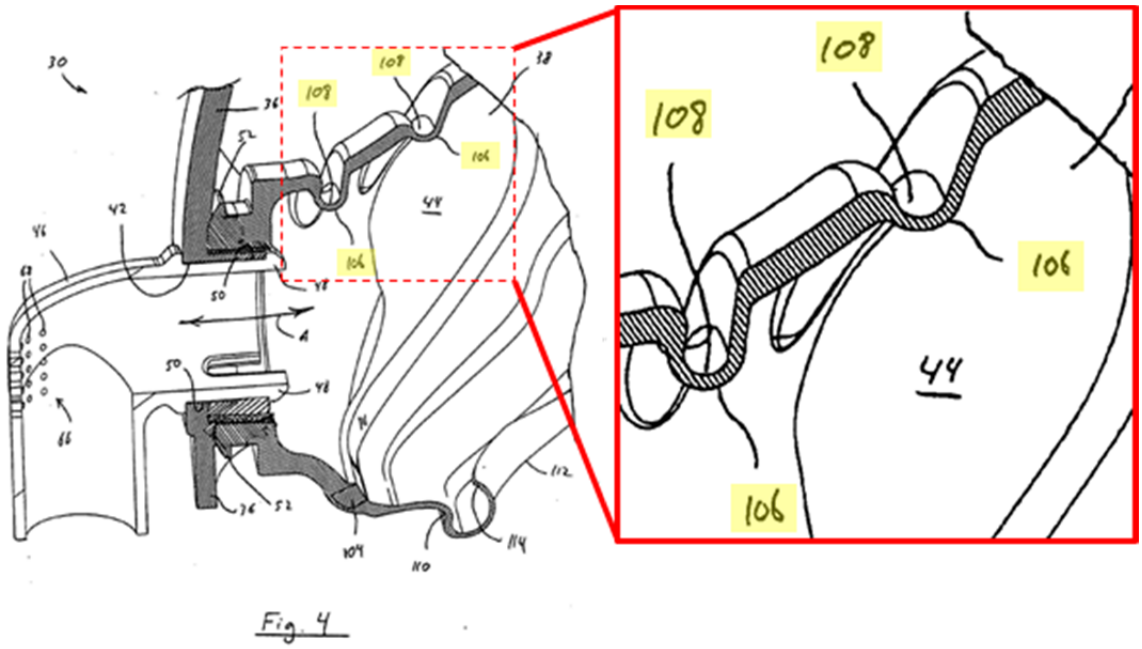


Fig. 4

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

111. A person of skill in the art would have been motivated to combine D'Souza, Hitchcock, and Matula-II for at least the reasons provided above.[112] Similar to D'Souza and Hitchcock, Matula-II discloses a CPAP mask for treatment of sleeping disorders.[113] The teachings of Matula-II would have been readily

[111] *Id.* ¶ 66.

[112] *See supra* ¶¶ 60–106.

[113] *See* Ex. 1512 ¶¶ 3, 5.

compatible with and easily incorporated into the D'Souza 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 D'Souza, Hitchcock, and Matula-II would have been a mere combination of familiar mask features that would have yielded only predictable results.

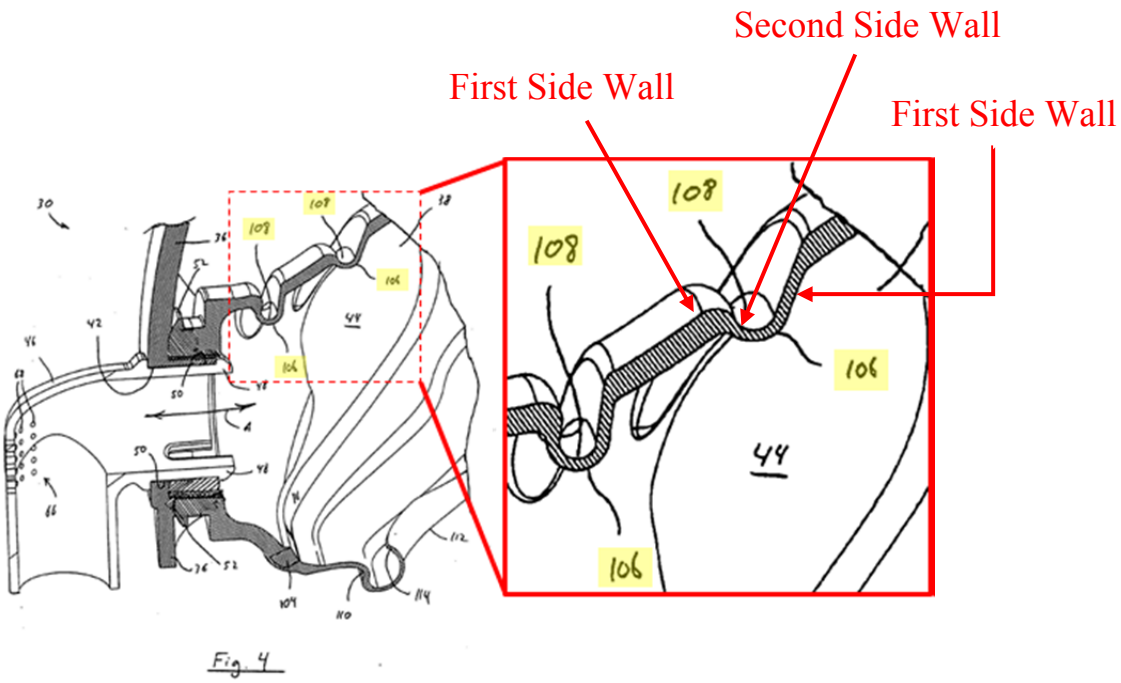
a. "one or more folds"

112. Claim 4 depends from independent Claim 1 and includes the additional limitation, "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."

113. D'Souza does not disclose a fold. Hitchcock discloses a gusseted portion, but does not specify that the fold provides a higher level of flexibility in the nasal bridge region relative to another region of the cushion module.[114] However, such folds were well-known in the prior art. For example, Matula-II discloses folds 106 (also referred to as pleats or gussets) positioned only in the

[114] Ex. 1511 ¶ 32.

nasal bridge portion of the cushion 38, which provides "the desired degree of flexibility."[115] 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.



[115] Ex. 1512 ¶ 66.

114. 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.[116]

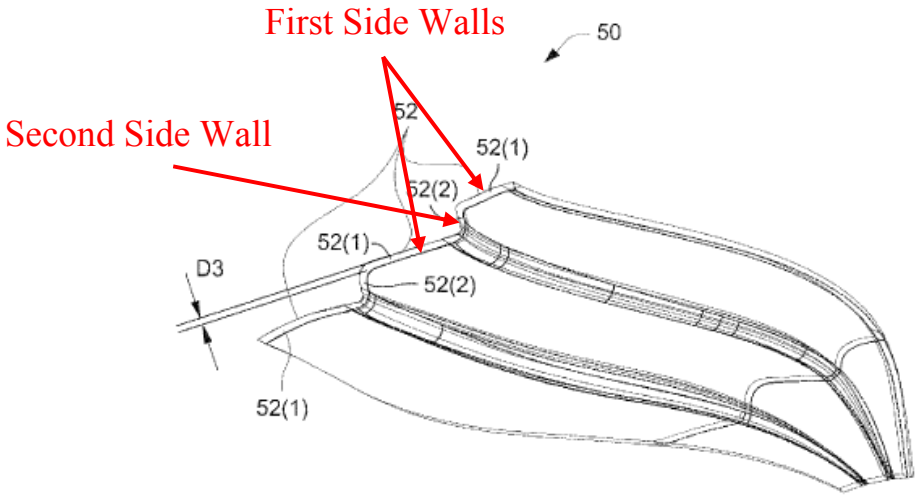


Fig. 32-3

115. 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.[117] The fold 9 has the greatest indentation depth t in the region of the end which is towards the bridge of the nose.[118] Figure 10 (on the next page) shows a

[116] Ex. 1501 at col. 14:40–42, Fig. 32–3.

[117] Ex. 1521 at 5:55–57.

[118] *Id.* at 8:18–20.

cross-section view of a portion of a cushion with a plurality of fold indentations 39, 40.[119] These fold arrangements provide a higher degree of flexibility in the nasal bridge region.[120] The fold structures in Melidis also have folds with adjacent first side walls interconnected by a second side wall.[121]

Fig.10

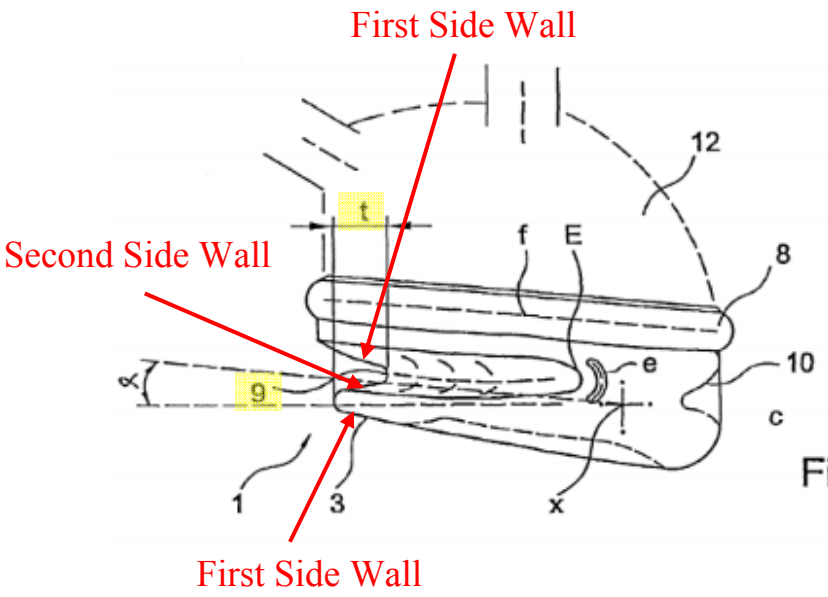
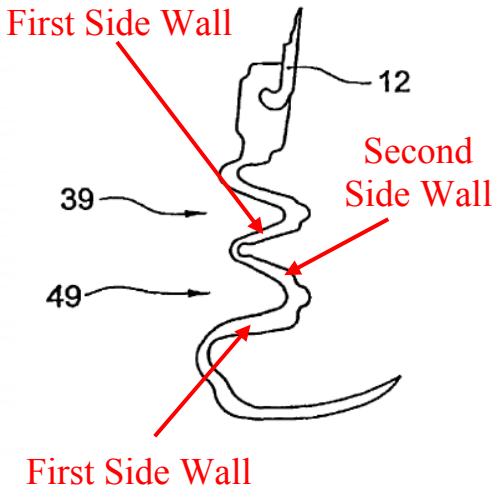


Fig.2



[119] *Id.* at col. 6:15–17.

[120] *Id.* at 8:38–42.

[121] *Id.* at 11:6–12.

116. As another example, Frater also discloses one or more folds in the nasal bridge region.[122]

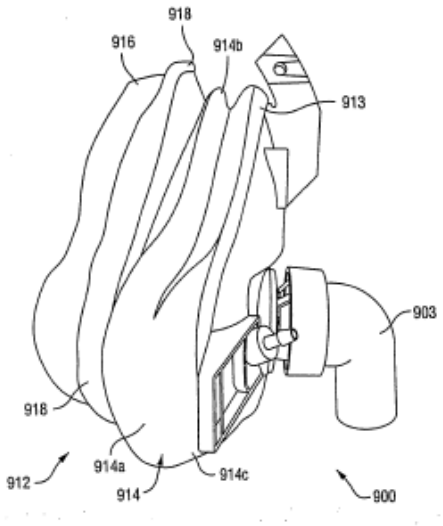


Fig. 51

[122] Ex. 1525 ¶ 164.

117. A person of skill in the art would have been motivated to include the Matula-II fold configuration in the D'Souza mask to increase patient comfort and optimize the distribution of sealing force against the user's face.[123] It was well-known in the industry that decreasing pressure on the nasal bridge is needed due to the thinness of the soft tissue in this area over the bony structure of the nose.[124] 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.

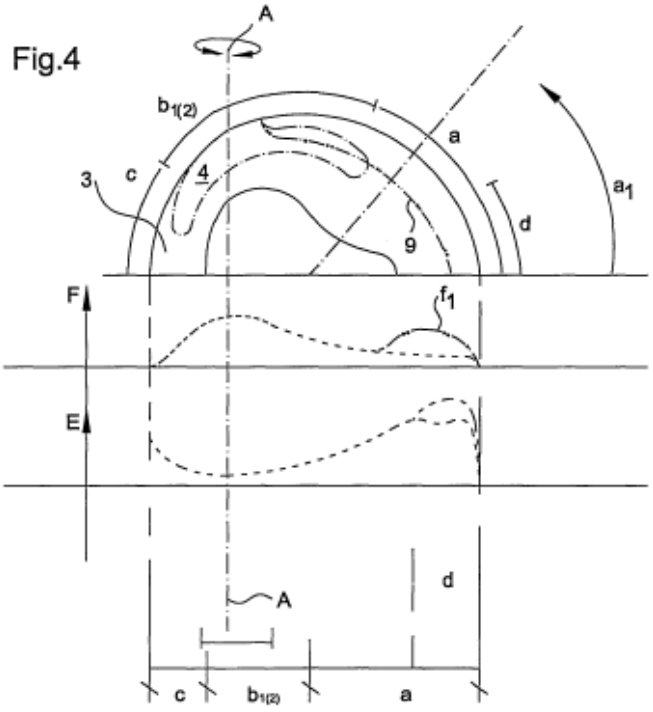
118. To address these concerns, a person of skill would have been motivated to provide more flexibility in the nasal bridge region than other regions of the mask. One skilled in the art would have recognized that there is an inverse relationship between the level of flexibility and the amount of pressure force transmitted to the wearer's face. This is demonstrated in Figure 4 of Melidis (on the next page), which shows a simplified view of the cushion and diagrams of the load-bearing capability and flexibility in each region of the cushion.[125] These graphs show that the highest level of flexibility E in the nasal bridge region *a* and

[123] *See* Ex. 1521 at col. 1:30–61; Ex. 1512 ¶ 3; Ex. 1525 ¶ 163.

[124] *See* Ex. 1534 ¶ 130–131.

[125] Ex. 1521 at col. 8:53–55.

the lowest level of pressure force F transmitted in that same region.[126] 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.[127]



[126] *Id.* at col. 8:53—9:2.

[127] *Id.* at col. 2:42–47.

b. "plurality of snap fingers"

119. Claim 5 depends from independent Claim 1 and includes the additional limitation "wherein the shroud includes a retaining portion with a plurality [of] snap fingers structured to engage the collar with a snap-fit."

120. As shown in Figures 7 and 8 of D'Souza on the next page, the frame 414 has a collar 440 surrounding the opening 418.[128] The shroud 412 includes a retaining structure 448 that interlocks with the collar 440.[129] The collar 440 passes through the retaining structure 448 and ends up interlocked on the top/front side of the retaining structure, as shown in the figures. In this manner, the shroud 412 is adapted to removably interlock with the cushion/frame sub-assembly 430.[130]

[128] Ex. 1510 ¶ 9, Figs. 7–8.

[129] *Id.* ¶ 101.

[130] *Id.* ¶ 96.

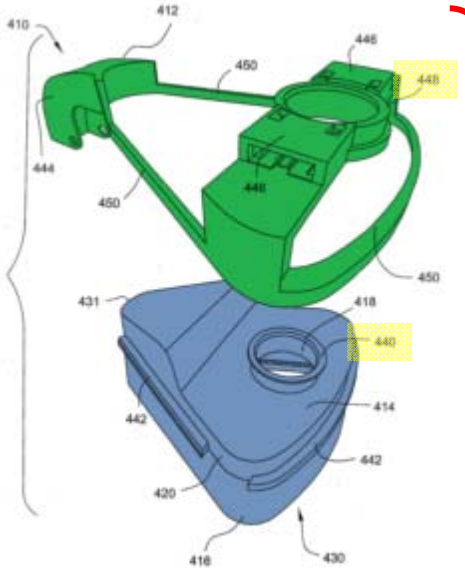


Fig. 7

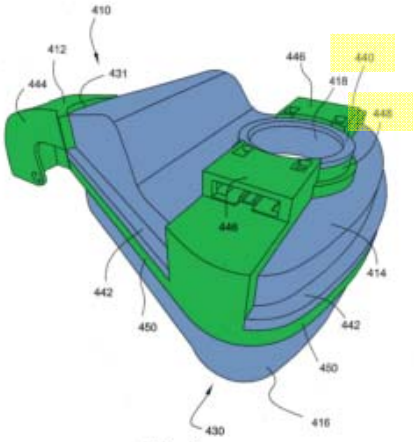


Fig. 8

121. D'Souza discloses that the frame 414 may be constructed of polycarbonate.[131] The shroud 412 of D'Souza is composed of plastic and adds rigidity to the cushion/frame subassembly.[132] Thus, a person of skill in the art would have recognized that D'Souza teaches a rigid plastic frame that interlocks with a rigid plastic shroud.

122. Figures 7 and 8 of D'Souza show that the outer diameter of the frame collar 440 is larger than the inner diameter of the retaining portion 448 of the shroud 412. Accordingly, a person of skill in the art would have understood that the collar 440 and the retaining portion 448 removably interlock with a snap-fit as

[131] *Id.* ¶ 98.

[132] *Id.* ¶ 100.

the collar 440 passes through the annular opening of the shroud 412 and releases to interlock with the top/front side of the retaining portion 448. Although D'Souza does not describe how the collar 440 passes through the retaining portion 448, it would have been clear to one of skill in the art that in this arrangement the collar 440 snaps into its final interlocked position with the retaining portion 448.

123. Such an assembly operation, 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."[133] This type of removable snap-fit, specifically an annular snap-fit, would have been familiar to a person of skill in the art and was common in CPAP mask components.

124. D'Souza does not describe a plurality of snap fingers in the interlocking arrangement of the shroud and frame. However, snap fingers were common and well-known at the time of the invention for use in CPAP masks. For

[133] Ex. 1543 at 342.

example, as shown in Figures 4 and 5 on the next page, Matula-II shows a plurality of snap fingers 48 structured to mechanically couple the seal member to the faceplate.[134] 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.[135]

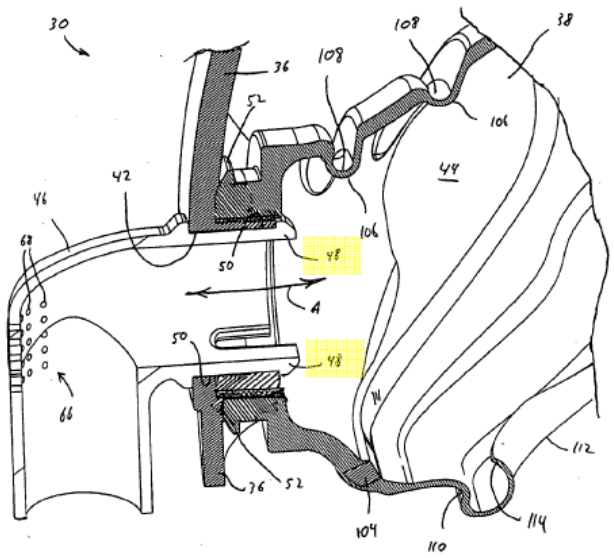


Figure 4

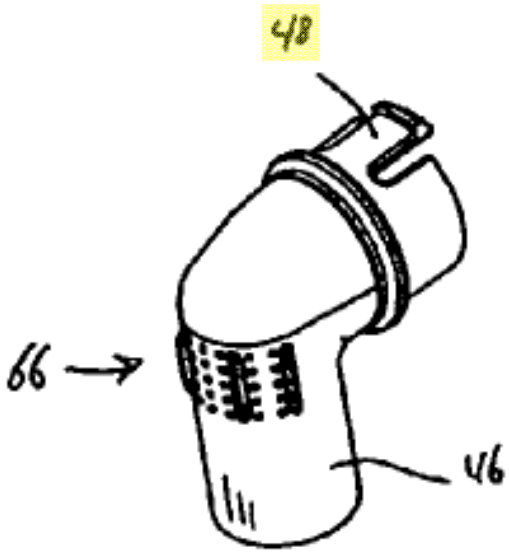


Figure 5 (partial)

125. A person of skill in the art desiring to couple the shroud module to the cushion module in D'Souza would have recognized that the components could and would be joined together with an annular snap-fit. When joining the components

[134] Ex. 1512 ¶ 53, Fig. 4.

[135] *Id.*

with an annular snap-fit, a person of skill in the art would have been motivated to modify the retaining structure 48 of D'Souza to include a plurality of snap fingers sized to engage the D'Souza collar 440, as taught by Matula-II, that extend rearward from the second opening of the shroud module. As modified, the snap fingers would extend rearward into the frame opening to engage the inside diameter or underside surface of the collar with a snap-fit similar to the Matula-II snap-fit arrangement.[136] Alternatively, the snap fingers would extend rearward from the second opening of the shroud module and engage the outer periphery of the collar.

126. Although the snap fingers described in Matula-II are on the elbow, incorporating snap fingers into the D'Souza shroud module would have involved a simple substitution to obtain predictable results and achieve the same purpose of providing a secure connection between the shroud module and the cushion module. The location of the snap fingers would have been a matter of design preference, and one of skill in the art would have recognized that it would have been advantageous to add snap fingers to the shroud rather than the mask frame based on the simplicity of molding the required snap finger geometry without compromising the airtight surfaces of the mask frame.

[136] *See id.*

127. Since the D'Souza frame has a collar, it would have been simple to provide snap fingers on the shroud 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.

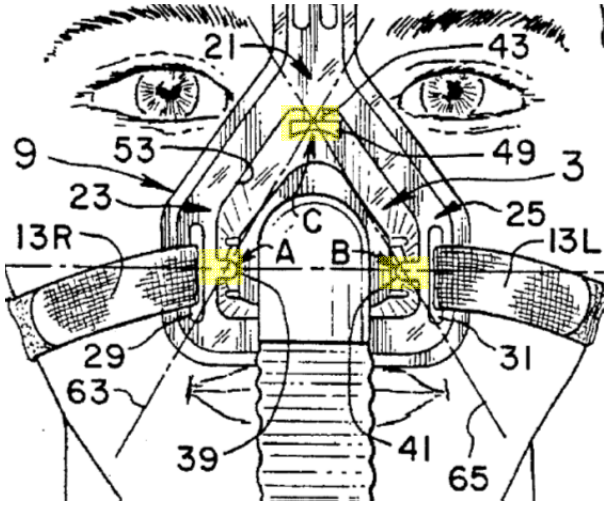
128. The book *Plastic Part Design for Injection Molding*, Robert A. Malloy (1994), also confirms that snap fingers were commonly used in annular snap-fit arrangements and were part of the common knowledge of a person of skill in the art.[137] As further evidence that snap fingers on shroud modules were common knowledge to one skilled in the art, Ogden discloses that the rigid shroud 9 is snap-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 on the next page.[138] The 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."[139] The

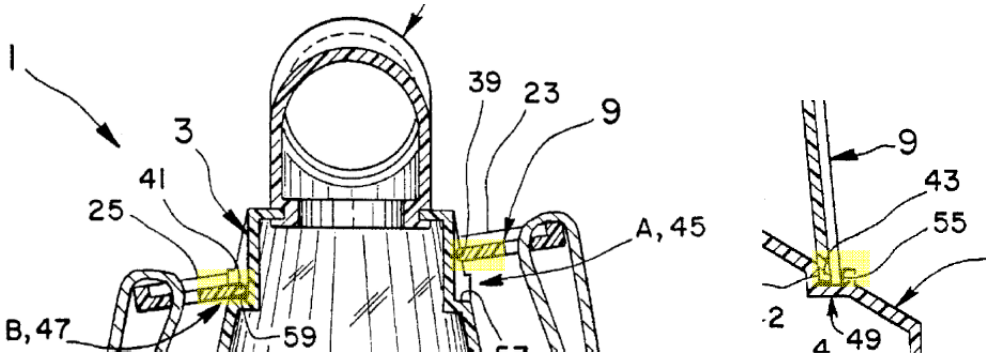
[137] Ex. 1543 at 345.

[138] Ex. 1529 at col. 4:20–23.

[139] *Id*. at col. 5:14–18.

removable snap-fit interlock results from moving the shroud module and the cushion module towards one another along a longitudinal axis.





129. Lovell provides another example of an annular snap-fit connection with snap fingers. As shown in Figure 10A of Lovell (below), the snap fingers (edges of aperture between slots 213, 215) that are on the shroud module 212 engage the depressed annular regions 280 between the tabs 211 on the frame 204.[140] The interference fit, elastic recovery, and engagement of the depressed annular regions 280 of Lovell provides retention between the mask frame and headgear connector, and constitutes a removable snap-fit attachment.

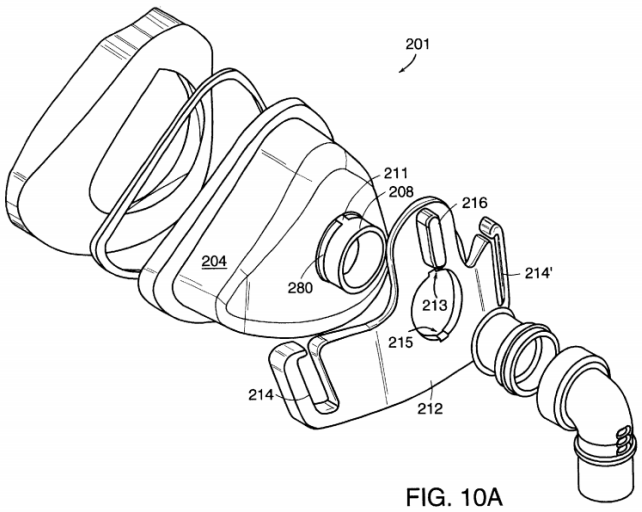


FIG. 10A

130. 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

[140] Ex. 1514 at col. 9:59–64.

axis.[141] Further, a person of skill would have recognized that snap assemblies could be configured to be reversible,[142] so the cushion module could be removed or replaced for cleaning.

131. 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.[143]

132. 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.

---

[141] *See* Ex. 1543 at 342.

[142] *See id.*

[143] *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 D'Souza to include a plurality of snap fingers on the shroud module to facilitate the engagement of the shroud and cushion module.

133. A person of skill in the art seeking to practice the arrangement described in D'Souza would have recognized that the degree of deformation required to allow assembly of the collar and the rearward extending retaining portion, as shown in the figures, appears to exceed acceptable material strain limits of commonly used rigid plastics such as polycarbonate, and thus could have made it difficult or even impossible to assemble these components. A well-known solution to the problem of snap-fit features exceeding material strain limits was to create slots that segment the interfering features on one or both mating parts into one or more fingers or beams.[144] These fingers or beams can deform along the length of the finger or beam by bending, and allow greater deflection than could be achieved by the radial compression/expansion of cylindrical features, such as those depicted in D'Souza.

144

c. "removably snap-fit"

134. Claim 26 depends from independent Claim 1 and includes the additional limitation "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."

135. D'Souza teaches a shroud module adapted to "removably interlock" in a snap-fit arrangement with the cushion module.[145] As I have explained above, because the collar and retaining portion of D'Souza experience interference and elastic deformation of one or both components as they are assembled, the shroud module and the cushion module of D'Souza form a snap-fit as the collar releases on the outside of the retaining portion in its interlocked position.[146] Such engagement is formed by moving the shroud module and the cushion module towards one another along the longitudinal axis. Thus, D'Souza teaches a removable snap-fit between the shroud module and the cushion module.

136. To the extent the teachings of D'Souza are insufficient for this feature, snap-fit arrangements between cushion modules and shroud modules were well-

[145] Ex. 1510 ¶ 96.

[146] *See supra* ¶ 120.

known prior to the '931 Patent. For at least the reasons explained above, a person of skill would have been motivated to modify the shroud module of D'Souza to include a plurality of snap fingers.[147] D'Souza, as modified in view of Matula-II, provides a snap-fit arrangement in which the snap fingers elastically deform to removably couple the cushion module to the shroud module by moving the cushion module and the shroud module towards one another along the longitudinal axis. As modified, the snap fingers would extend into the frame opening to engage the D'Souza collar with a snap-fit, as taught by Matula-II.[148] Alternatively, the snap fingers would extend rearward from the second opening of the shroud module and engage the outer periphery of the collar.[149]

137. 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 an

[147] *See supra* ¶¶ 119–133.

[148] *See* Ex. 1512 ¶ 53.

[149] *See* Ex. 1522 ¶ 179.

axis.[150] Mating features which simply require moving the two parts along one axis where annular features of complementary shape engage provide the simplest and most intuitive means of engagement. Further, a person of skill would have recognized that snap assemblies can be configured to be reversible,[151] so the cushion module could be removed or replaced for cleaning.

138. For at least the reasons provided above, a person of skill would have been motivated to include a plurality of snap-fit fingers in the D'Souza arrangement to allow for deformation and to facilitate insertion of the rigid collar 440 through the retaining portion 448, resulting in a removable snap-fit.[152] A person skilled in the art would have known to look to other mask assembly designs where mating cylindrical features were intended to axially engage in a snap fit. This type of snap-finger arrangement is taught by Matula-II, where engaging geometry on the elbow is segmented to create a plurality of snap fingers that permit deflection during assembly to the shroud, then elastically recover to an assembled and interlocked position.[153]

---

[150] *See* Ex. 1543 at 342.

[151] *See id.*

[152] *See supra* ¶¶ 119–137.

[153] *See* Ex. 1512 ¶ 53.

C. Claims 12, 14, and 16 of the '931 Patent would have been obvious over D'Souza in view of Hitchcock and Barnett

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

139. Barnett relates to nasal CPAP mask assemblies having a seal member that defines a breathing cavity and a collar that connects to the seal member and includes multiple headgear attachment points.[154] As shown in Figure 6 below, nasal mask assembly 30 includes a seal member 32 that contacts the patient's face and a collar 34 that is fixed and not movable relative to the seal member 32.[155] 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.[156]

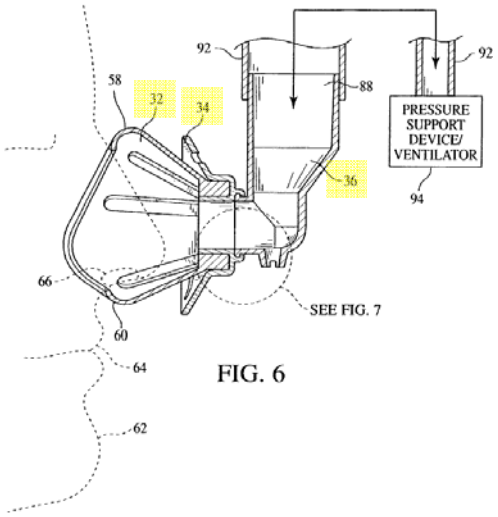


FIG. 6

[154] Ex. 1513 at Abstract, col. 1:7–32.

[155] *Id.* at col. 3:48–52.

[156] *Id.* at col. 3:52–56.

140. Additionally, as shown below, Barnett discloses seal members 32, 32' that differ in the "contour of the first end portion, size, and shape" to accommodate different patient populations (e.g., adults and children).[157] "[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."[158]

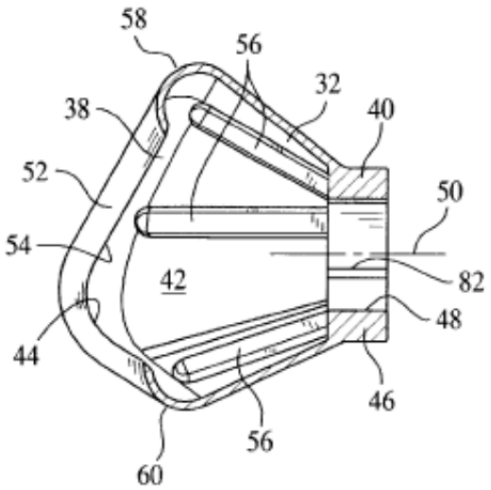


FIG. 2A

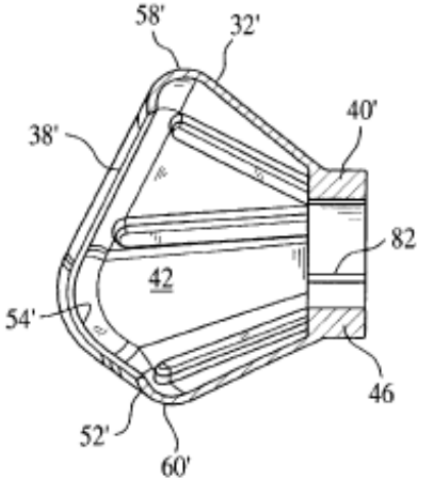


FIG. 3B

[157] *Id*. at cols. 6:1–4, 5:52–67.

[158] *Id.* at col. 6:9–13.

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

141. A person of skill in the art would have been motivated to combine D'Souza, Hitchcock, and Barnett for at least the reasons provided above.[159] Similar to D'Souza and Hitchcock, Barnett discloses a CPAP mask for treatment of sleeping disorders.[160] The teachings of Barnett would have been readily compatible with and easily incorporated into the D'Souza 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 D'Souza, Hitchcock, and Barnett would have been a mere combination of familiar mask features that would have yielded only predictable results.

a. "elbow module"

142. Claim 12 depends from independent Claim 1 and includes the additional limitation "wherein the elbow module is provided to the shroud module."

143. D'Souza discloses an elbow adapted to engage the mask assembly, but may not show the elbow being directly attached to the shroud module.[161] Further, although D'Souza does not disclose any structures that would prevent the

[159] *See supra* ¶¶ 60–106.

[160] Ex. 1513 at Abstract, col. 1:7–32.

[161] Ex. 1510 ¶ 100.

elbow from rotating, D'Souza does not expressly disclose that the elbow is rotatable 360 degrees.

144. To the extent shroud module is required to directly contact the elbow, such configurations were also well-known. For example, Barnett discloses an elbow module 36 that is directly mounted to the shroud 34.[162] As shown below, it was common to provide a flange 100 to the front side of the shroud module 34 to accommodate the elbow.[163]

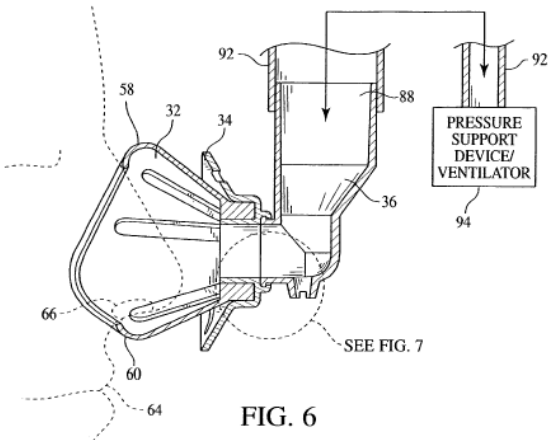


FIG. 6

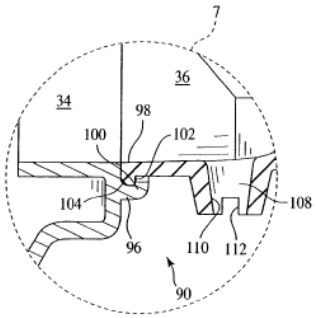


FIG. 7

[162] Ex. 1513 at col. 3:52–57.

[163] *Id.* at col. 9:31–39.

145. A person of skill would have known and been motivated to directly attach the elbow to the shroud module, e.g., by providing features on the front side of the D'Souza shroud module. One of the finite number of ways to do this is to provide a flange to the front side of the D'Souza shroud module, as shown below.

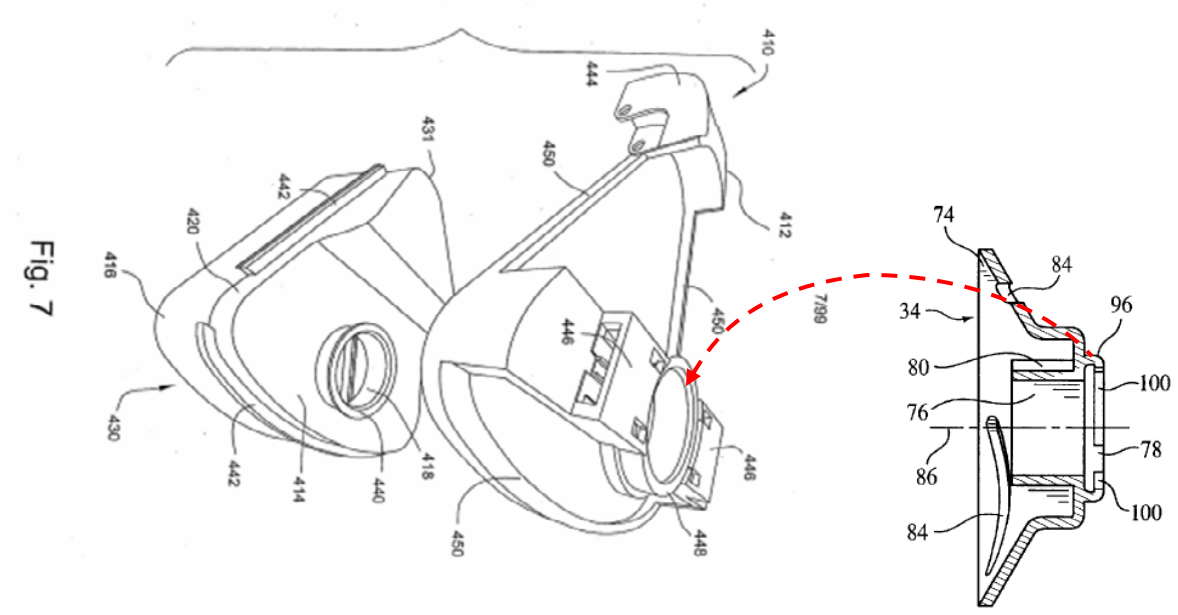


FIG. 4B

146. As another example, Matula-I discloses an elbow 1270 that directly engages rim 1252 of the shroud module 1246 using claims 1272.[164]

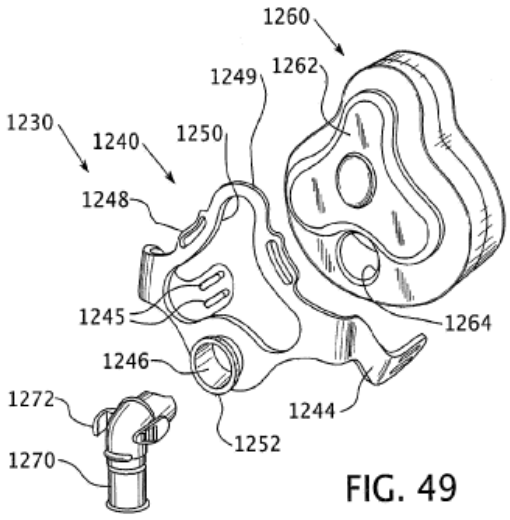


FIG. 49

147. D'Souza and Barnett represent two design choices for establishing a connection between the breathing chamber and the elbow module. Each option has advantages. D'Souza 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-frame sub-assembly from the second frame. Although Barnett describes this two-seal

[164] Ex. 1523 ¶ 105.

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.

148. 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 on a part that is not required to be airtight can be incorporated on 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.[165]

[165] *See infra* ¶¶ 150–155.

149. 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 be 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. "360 degree rotation of the elbow module"

150. Claim 14 depends from independent Claim 1 and includes the additional limitation "wherein the elbow module and the shroud module are directly connected with a mechanical interlock while allowing 360 degree rotation of the elbow module."

151. D'Souza 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.[166]

[166] *See supra* ¶¶ 142–149.

152. 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 that freely rotates over a range of 360 degrees in direction A.[167]

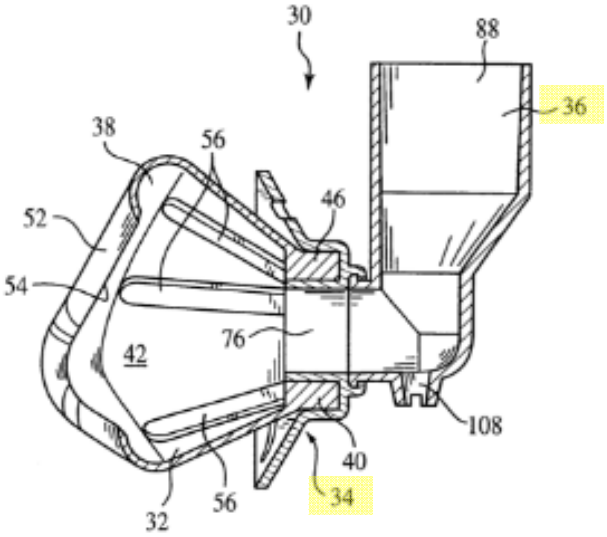


FIG. 1A

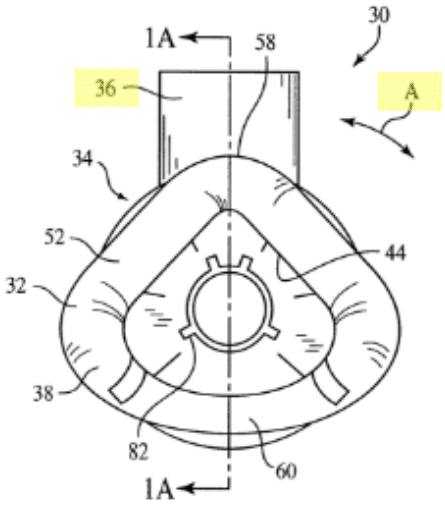
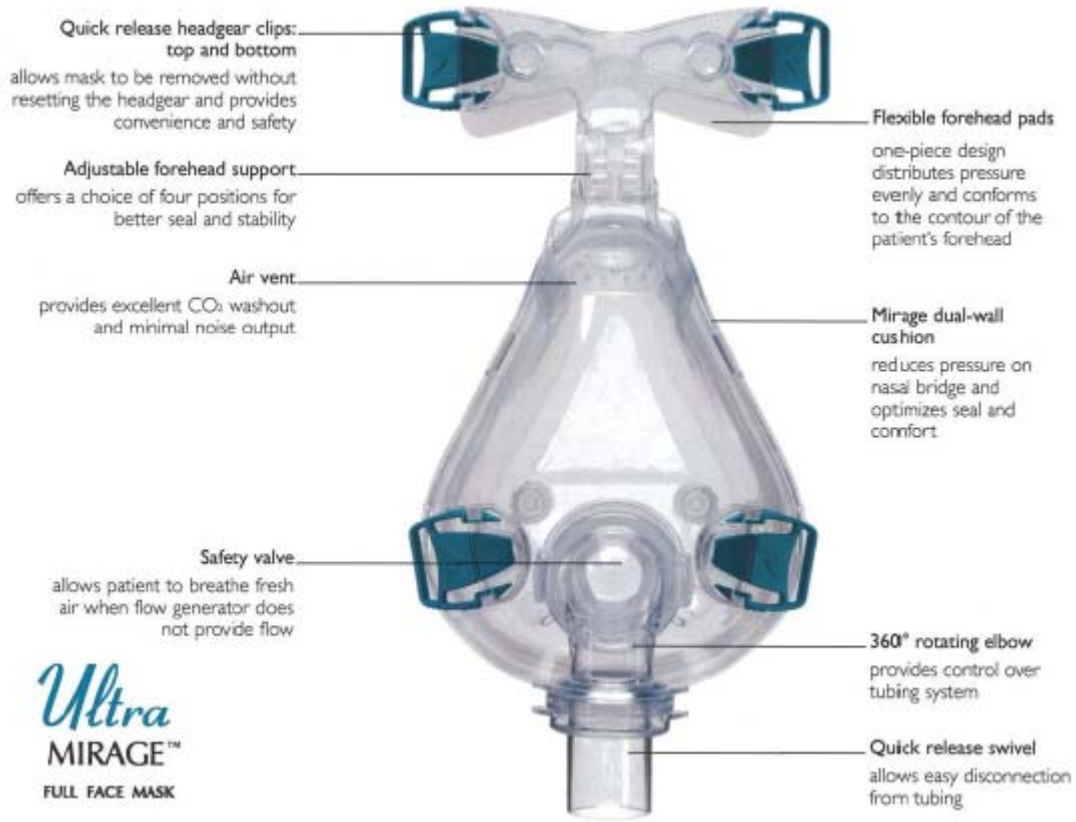


FIG. 1B

[167] Ex. 1513 at col. 3:52–57.

153. Ultra Mirage also discloses a 360 degree rotating elbow to provide control over the tubing system.[168]



154. 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 D'Souza mask. D'Souza does not have any structures that would prevent its mask from providing a 360 degree rotatable elbow.

155. 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.[169] It

[168] Ex. 1516 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.

[169] Ex. 1516 at 6.

c. "at least first and second cushion modules"

156. Claim 16 depends from independent Claim 1 and includes the additional limitation, "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."

157. D'Souza does not expressly disclose this feature, but it was common knowledge to include interchangeable cushion modules that differ in at least one respect. For example, Barnett describes different sized cushion modules 32, 32'.[170] The different cushions 32, 32' are meant to be used with the same shroud 34 and elbow 36.[171]

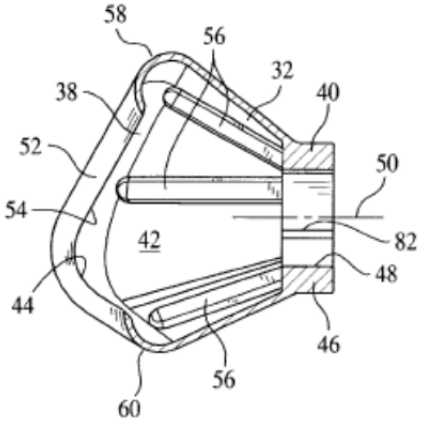


FIG. 2A

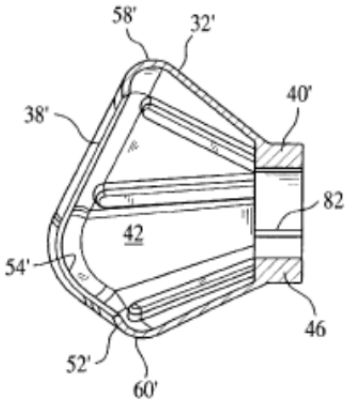


FIG. 3B

[170] Ex. 1513 at cols. 6:1–4, 5:52–67.

[171] *Id.* at col. 6:1–14.

158. Because different users (*e.g.*, adults and children) have different facial features, a person of skill would have recognized that providing different cushion components would have allowed the user to select a cushion component that better corresponds to that user's facial features to improve comfort and reduce leaks. [172] A skilled artisan would have recognized that providing different-sized, interchangeable cushion modules to fit a common shroud would reduce the number of components required (as compared to distinct shroud sizes to match distinct cushion module sizes). Reducing the number of components would also reduce mold tooling cost and manufacturing costs.

159. Multiple different cushion components would have been a simple addition since D'Souza discloses a mask assembly having a shroud module that releasably connects to the cushion module.[173] A person of skill would have recognized that the shroud module of D'Souza could and would be configured to connect to different cushion components with a reasonable expectation of success.

[172] *See id.* at 6:1–14.

[173] Ex. 1510 ¶ 96.

D. Claim 13 of the '931 Patent would have been obvious over D'Souza in view of Hitchcock and Lovell

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

160. Lovell generally describes CPAP mask assemblies "useful for providing pressurized air or therapeutic gas to a patient suffering from an airflow limitation or other respiratory ailment."[174] Lovell is another example of a CPAP mask having a shroud that engages a cushion module. The CPAP mask assemblies described in Lovell include a polycarbonate conduit elbow 10, as shown below in Figure 1.[175]

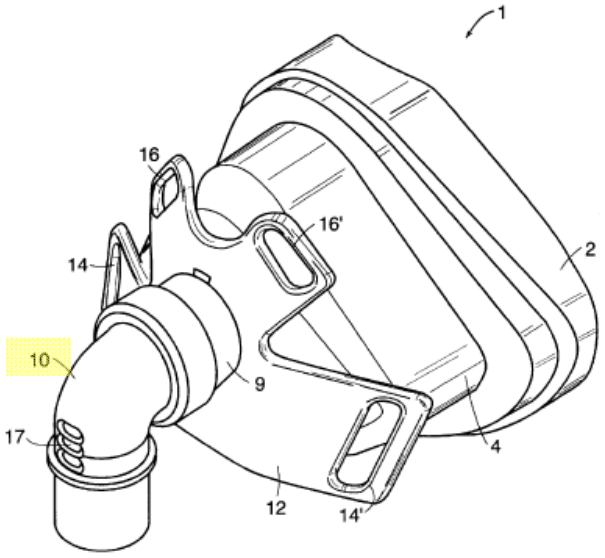


FIG. 1

[174] Ex. 1514 at col. 1:5–8.

[175] *Id.* at col. 5:29–33.

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

a. "elbow module comprises polycarbonate"

161. Claim 13 depends from dependent Claim 11 and includes the additional limitation "wherein the elbow module comprises polycarbonate."

162. D'Souza and Hitchcock each disclose an elbow, but do not state that the elbow is a polycarbonate elbow. However, it was common to use polycarbonate CPAP mask components, including the elbow, as disclosed by Lovell.[176] Worboys also discloses a polycarbonate elbow.[177]

163. 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.[178] Polycarbonate also provides good mechanical properties of strength, rigidity, and toughness.[179] Polycarbonate grades are available that comply with biocompatibility testing standards to which masks for sleep disordered breathing

[176] *Id.* at col. 5:33–35.

[177] Ex. 1522 ¶ 105.

[178] *See* Ex. 1533 at 6:21-24.

[179] *See id.*; Ex. 1522 ¶ 105.

must comply. Further, polycarbonate also 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. Combining the features of D'Souza, Hitchcock, and Lovell would have been a mere combination of familiar mask features that would have yielded only predictable results.

E. Claim 15 would have been obvious over D'Souza in view of Hitchcock and Jaffre

1. Jaffre (U.S. Patent No. 6,851,425)

164. Jaffre describes CPAP mask devices having an exhaust port assembly.[180] As shown in Figures 8 and 9 below, the exhaust port assembly 62 includes an auxiliary opening 88 having a valve member 68.[181]

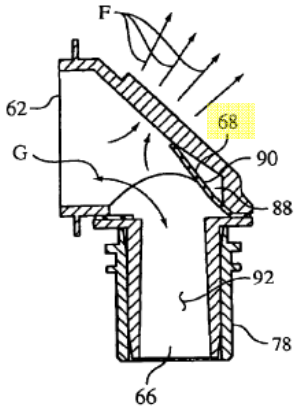


FIG. 8

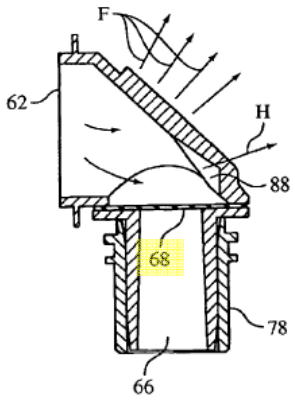


FIG. 9

165. When the pressure system is functioning properly, a cantilevered member 90 of the valve member 68 flexes to block the opening 88 as shown in Figure 8.[182] If the pressure of the gas in the interior 92 is not greater than ambient atmosphere, cantilever member 90 returns to its normal position and unblocks

[180] Ex. 1515 at col. 1:13–33.

[181] *Id.* at col. 10:11–14.

[182] *Id.* at col. 10:14–17.

auxiliary opening 88 so that the patient has access to ambient atmosphere as shown in Figure 9.[183]

2. Potential Differences from Prior Art

166. A person of skill in the art at the time of the purported invention would have been motivated to combine the teachings of D'Souza, Hitchcock, and Jaffre for at least the reasons provided above.[184] Similar to D'Souza and Hitchcock, Jaffre discloses a CPAP mask for treatment of sleeping disorders.[185] The teachings of Jaffre would have been readily compatible with and easily incorporated into the D'Souza 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 D'Souza, Hitchcock, and Jaffre would have been a mere combination of familiar mask features that would have yielded only predictable results.

[183] *Id.* at col. 10:23–28.

[184] *See supra* ¶¶ 60–106.

[185] Ex. 1515 at col. 1:21–33.

a. "anti-asphyxia valve"

167. Claim 15 depends from Claim 11 and includes the additional limitation "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."

168. D'Souza discloses a mask assembly adapted to engage an elbow, but does not expressly disclose an anti-asphyxia valve (AAV).[186] However, such valve assemblies in CPAP elbows was common and well-known to include such flap-based safety valve assemblies in CPAP elbows.

[186] Ex. 1510 ¶ 100.

169. 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.[187] 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.[188]

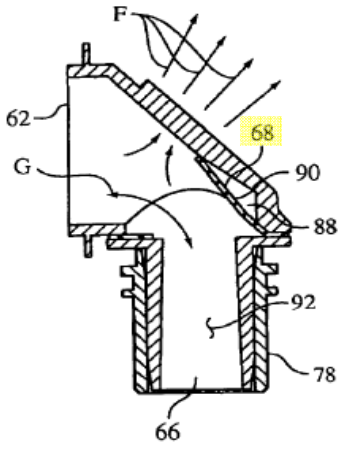


FIG. 8

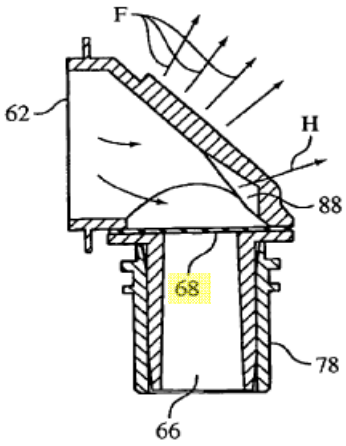


FIG. 9

[187] Ex. 1515 at col. 10:4–8.

[188] *Id.* at col. 10:14–28.

170. Worboys also 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.[189]

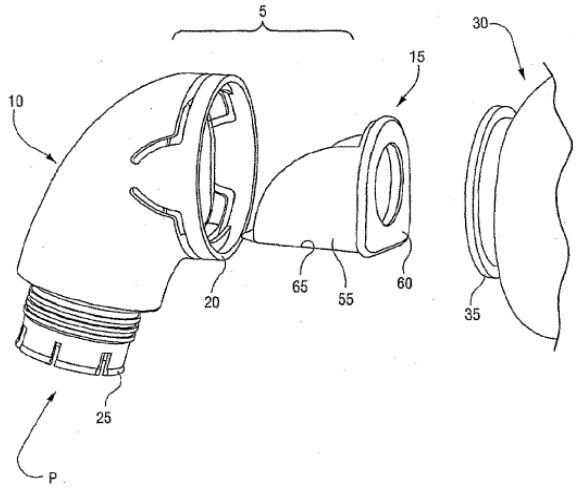


Fig. 1

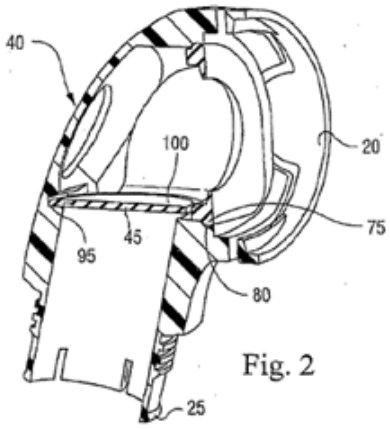


Fig. 2

[189] Ex. 1522 ¶ 106.

171. A person of skill in the art at the time of the invention would have known to provide the anti-asphyxia valve of Jaffre to the D'Souza 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 anti-asphyxia valve as a safety device.[190] 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 present a health risk to the patient.[191]

172. 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 anti-asphyxia valve is nothing more than a combination of

[190] *Id.* at ¶ 4.

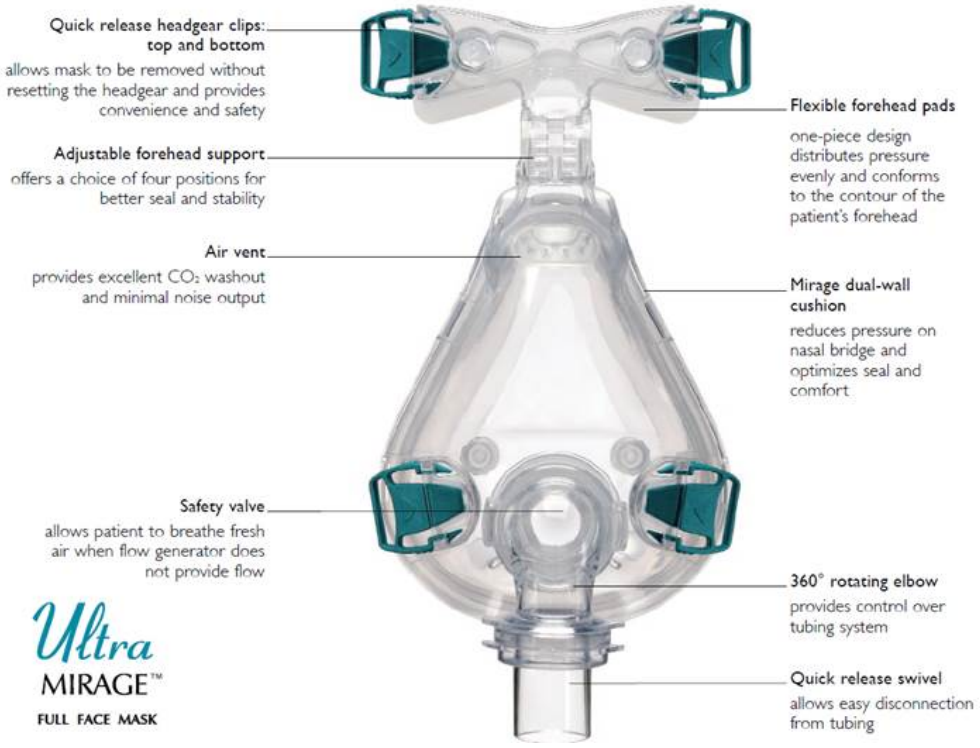
[191] *Id.* ¶ 8.

well-known elements that produces results that would have been predictable to one of ordinary skill in the art.

F. Claim 17 of the '931 Patent would have been obvious over D'Souza in view of Hitchcock, Barnett, and Ultra Mirage

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

173. The Ultra Mirage brochure from 2006 discloses a mask assembly for use by CPAP and bilevel therapy users.[192] The mask covers both the nose and mouth to provide effective therapy in the presence of mouth breathing.



[192] Ex. 1516 at 6.

174. The mask assembly includes an air vent positioned on the mask frame, which provides "excellent CO_2 washout and minimal noise output."[193] The mask assembly claims superior airflow characteristics to minimize CO_2 rebreathing.[194]

175. The Ultra Mirage Full Face Mask assembly includes an inlet in the form of an elbow, which rotates 360° with respect to the mask frame.[195] 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.[196]

176. A person having ordinary skill in the art would have continuously been educating 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, including Fisher & Paykel, ResMed, and Respironics. Each of these

[193] *Id*.

[194] *Id*.

[195] *Id*.

[196] *Id*.

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.

177. 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.

178. 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.[197] 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.[198]

179. The Wayback Machine also shows that the public had access to a Fisher & Paykel webpage publicizing the FlexiFit™ by at least October 16, 2006.[199] 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

---

[197] *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.

[198] *See id.*

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

instructions by following the hyperlinks under "FlexFit™ 431 User Instructions" and "FlexFit™ 431 Product Brochure" on the FlexiFit™ webpage.[200]

180. These websites show that a person of skill in the art would have had access to at least the Ultra Mirage Brochure (Ex. 1516) and FlexiFit Instructions (Ex. 1517) well before the March 4, 2008 priority date of the '931 Patent.

2. Potential Differences form Prior Art

181. A person of skill in the art would have been motivated to combine D'Souza, Hitchcock, and Ultra Mirage for at least the reasons provided above.[201] Similar to D'Souza and Hitchcock, Ultra Mirage discloses a CPAP mask.[202] A person of ordinary skill in the art would have been aware of and looked to known CPAP masks when contemplating design features. Combining the features of D'Souza, Hitchcock, and Ultra Mirage would have been a mere combination of familiar mask features that would have yielded only predictable results.

[200] *See id.*

[201] *See supra* ¶¶ 60–106.

[202] Ex. 1516 at 6.

a. "a small cushion module, a medium cushion module and a large cushion module"

182. Claim 17 depends from independent Claim 1 and includes the additional limitation "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."

183. As explained above, Barnett teaches different sized cushion modules 32, 32' meant to be used with a commonly sized shroud 34 and elbow 36.[203] Barnett specifically describes larger cushion modules for a relatively large population of adult patients and smaller cushion modules for small adults and children,[204] but does not describe a medium-sized cushion module.

184. However, it was common and well-known that cushions used in CPAP mask assemblies could be 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.[205] Ging also discloses providing

[203] *See supra* ¶¶ 157–159.

[204] Ex. 1513 at col. 5:52–67.

[205] Ex. 1516 at 6.

different-sized cushions, preferably one to three sizes, which provide a good fit in a wide range of patients without having an excessive inventory.[206]

185. As further evidence that different-sized cushion modules were commonly applied to the same shroud module, Ho discloses that "any interface suitable for sealing against the user can be used in the mask assembly of [Ho]."[207] Different sized cushions or nasal prongs can be supported by the same support body.[208] 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."[209]

186. 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

[206] Ex. 1532 ¶¶ 184, 193.

[207] Ex. 1531 ¶ 36.

[208] *Id.*

[209] *Id.*

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 masks to the same interchangeable shroud/cushion module interface to accommodate a range of facial shapes without having to carry excessive inventory.[210] If leaks persist, the user can easily change to an alternate mask size.[211]

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

[210] *See* Ex. 1532 ¶¶ 8, 20, 193.

[211] *See* Ex. 1517 at 10 ("FITTING YOUR MASK").

G. Claims 19, 21, and 25 of the '931 Patent would have been obvious over D'Souza in view of Hitchcock, FlexiFit, and Gunaratnam-II

1. FlexiFit (FlexiFit Instructions)

188. 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.[212] Users are instructed to gently adjust the top horizontal straps, then the lower horizontal straps, then the top crown straps.[213] 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.[214] If leaks occur around the upper half of the mask, the user is instructed to gently tighten the top horizontal straps.[215] If leaks occur around the lower half of the mask, the user is instructed to gently tighten the lower horizontal straps.[216] The four straps of the headgear are to be attached to the corresponding slots in the mask base and the Glider™

[212] Ex. 1517 at 10 ("FITTING YOUR MASK").

[213] *Id*.

[214] *Id*.

[215] *Id*.

[216] *Id*.

strap (E).[217] This can be done without undoing the Velcro® tabs by sliding the headgear into the slots.[218]

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

[218] *Id*.

189. 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).[219] The top and lower horizontal straps can be re-adjusted to prevent leaks.[220]

[219] *Id*.

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

2. Gunaratnam-II (U.S. Patent No. 6,796,308)

190. Gunaratnam-II generally describes a nasal assembly having a headgear assembly.[221] As shown in Figure 135 below, Gunaratnam-II teaches headgear having a pair of top straps and rear straps.[222] The top straps are removably and adjustably coupled with a buckle.[223]

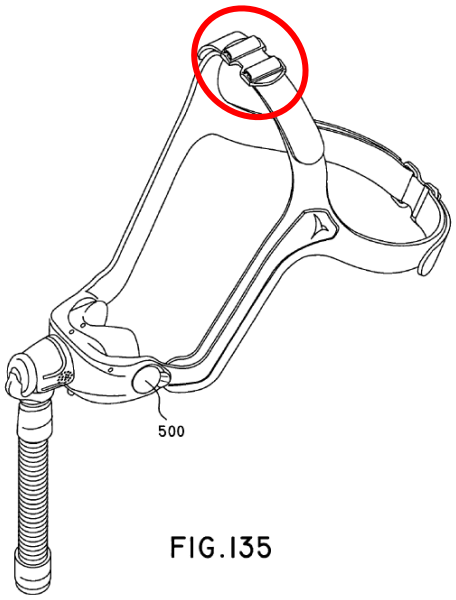


FIG.135

[221] Ex. 1519 at Abstract.

[222] *Id.* at Fig. 135.

[223] *Id.* at ¶ 316.

3. Potential Differences and Reasons to Combine

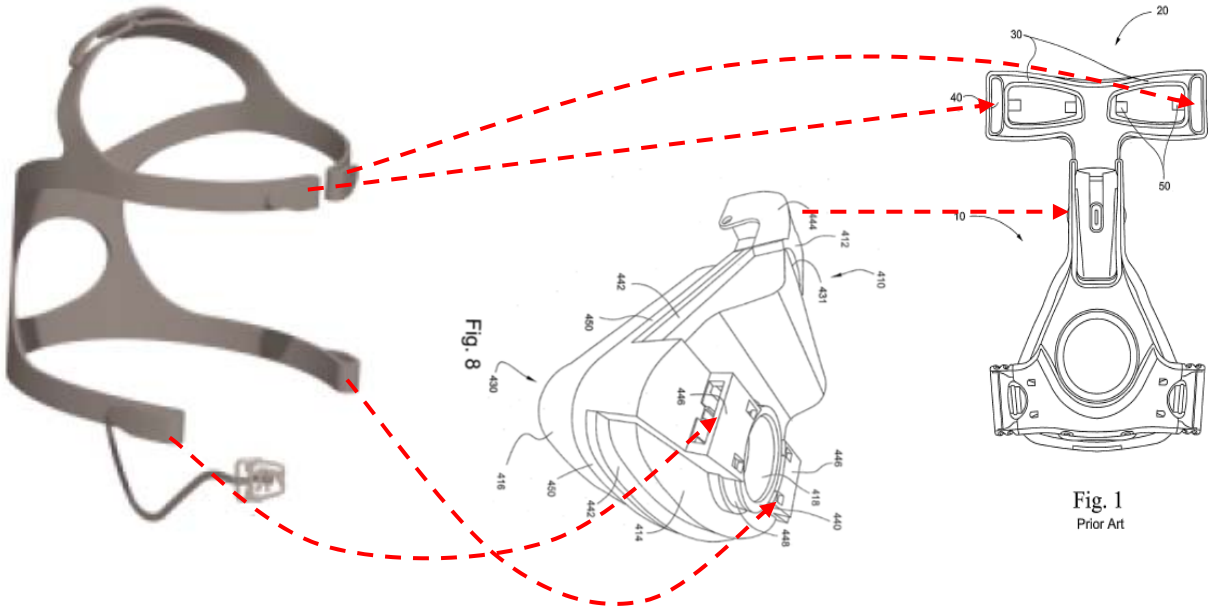
191. Claim 19 depends from independent Claim 1 and includes additional headgear features that are discussed below. Claims 20, 21, and 25 depend from Claim 19 and include additional features that are commonly included in respiratory mask assemblies.

192. D'Souza does not disclose each of these headgear features, but the claimed headgear features were well-known in the CPAP industry prior to the '931 Patent. In fact, as detailed below, the combination of claimed headgear features was embodied in the FlexiFit HC 431 headgear.[224] FlexiFit discloses headgear with upper and lower straps, which would have been compatible with the upper and lower headgear connectors of the D'Souza shroud, as modified by Hitchcock.[225] This is represented by the drawings on the next page. Thus, the teachings of FlexiFit would have been readily compatible with and easily incorporated into the D'Souza mask assembly.

[224] *See infra* ¶¶ 193–214.

[225] *See supra* ¶¶ 62–67, 83–100.

FlexiFit (partial) **D'Souza (rotated)** **Hitchcock**



193. 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 D'Souza, Hitchcock, Flexifit, and Gunaratnam-II would have been a mere combination of familiar mask features that would have yielded only predictable results.

a. "a pair of upper straps and pair of lower straps"

194. Claim 19 depends from independent Claim 1 and includes various additional headgear features, including "the headgear includes a pair of upper straps and a 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."

195. As explained above, a person of skill in the art would have understood that the D'Souza mask includes lower headgear connectors 448 and upper headgear connectors on the forehead support to support the forehead support and the mask on the patient.[226] To the extent D'Souza is somehow deficient, the combination of D'Souza and Hitchcock teaches the upper and lower headgear connectors, as discussed above.[227] The upper and lower headgear connectors would have been adapted to removably attach to headgear straps.[228] FlexiFit also discloses removably attachable upper and lower headgear straps.[229]

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

196. Claim 19 depends from independent Claim 1 and further 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."

197. D'Souza does not expressly disclose that each headgear strap includes hook and loop fastening elements, but this feature was commonly used in CPAP

[226] *See supra* ¶¶ 84–86.

[227] *See supra* ¶¶ 62–67, 83–100.

[228] *See supra* ¶¶ 62–67.

[229] Ex. 1517 at 10 ("ASSEMBLING YOUR MASK").

masks. For example, Hitchcock discloses that "[t]he free end of each of the upper and lower side straps 504, 502 includes a strip of Velcro® material 503 for use in securing each of the straps 504, 502 to a respective clip 506." [230] FlexiFit also discloses Velcro® tabs on the straps.[231]

Hitchcock

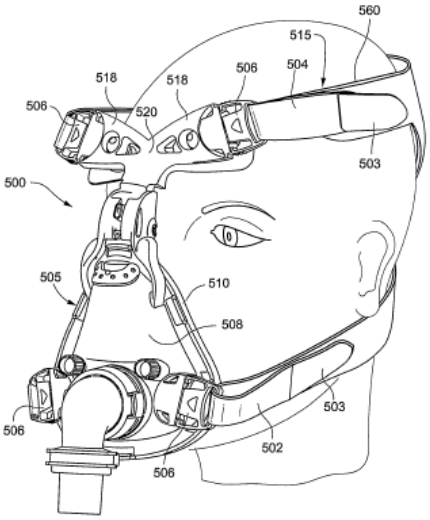
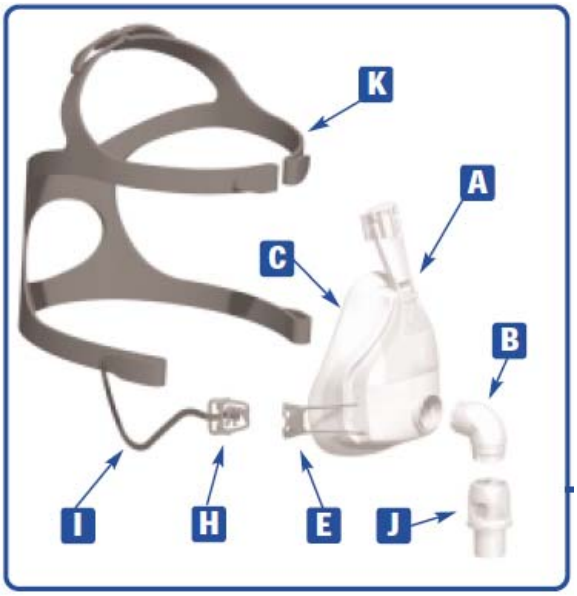


Fig. 8

FlexiFit



198. As further evidence that positioning Velcro® at the 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."[232]

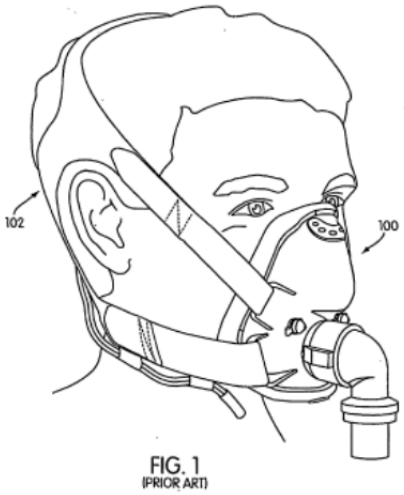
[230] Ex. 1511 at 38.

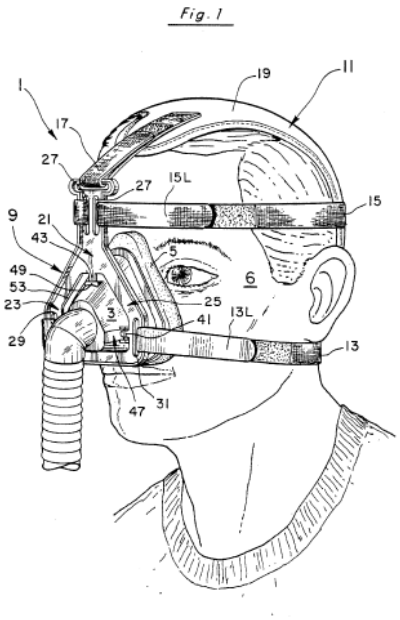
[231] Ex. 1517 at 10 ("ASSEMBLING YOUR MASK").

[232] Ex. 1530 ¶ 12.

Figure 1 of Ogden also discloses hook and loop material at the free end of each of the upper and lower headgear straps.[233]

Amarasinghe **Ogden**





199. 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

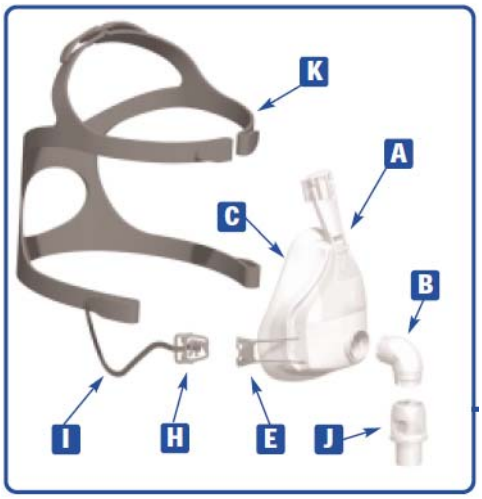
[233] Ex. 1529 at col. 3:10–20

adjustment and maintain the straps in the adjusted position.[234] Properly adjusted headgear straps ensure proper contact between the mask and the user's face.[235]

c. "a pair of top straps and a pair of rear straps"

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

201. D'Souza does not disclose this commonly used headgear feature, but FlexiFit specifically discloses upper straps that split into top straps and rear straps, as shown below.[236]



202. 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)

[234] *See* Ex. 1514 at col. 7:6–13.

[235] *See id.* at col. 7:19–22.

[236] Ex. 1517 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

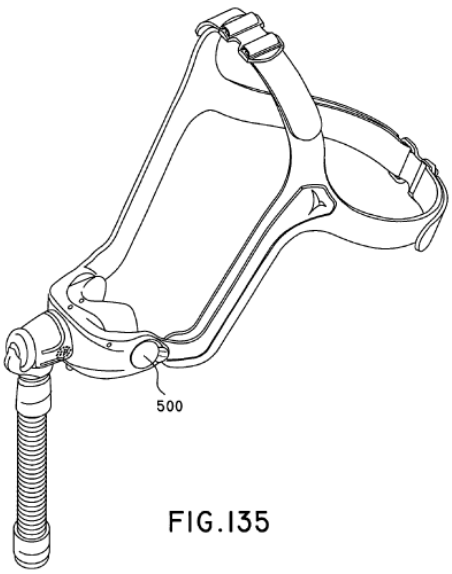


FIG.135

Amarasinghe

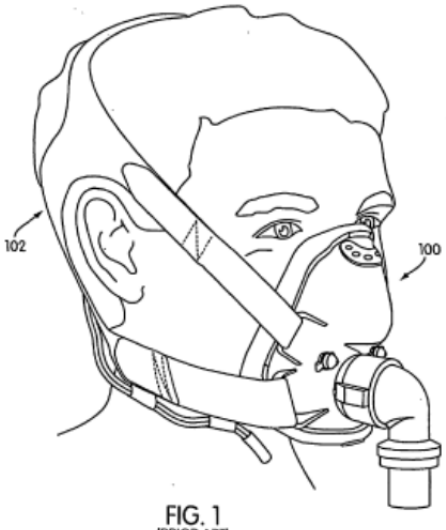


FIG. 1
(PRIOR ART)

203. A person of skill in the art would have been motivated to provide pairs of top and rear straps, as shown in FlexiFit and Gunaratnam-II 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"

204. 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."

205. D'Souza does not expressly disclose top straps being connected together by a buckle, but this was a common feature in CPAP masks prior to the '931 Patent. As shown below, FlexiFit discloses that the top crown straps are connected together by a buckle that passes over the top of the patient's head.[237]

[237] *See* Ex. 1517 at 10 ("FITTING YOUR MASK").

206. As further evidence that it was common in the industry to provide top straps connected by buckles, Figure 135 of Gunaratnam-II (below) discloses top straps being connected together by a buckle.

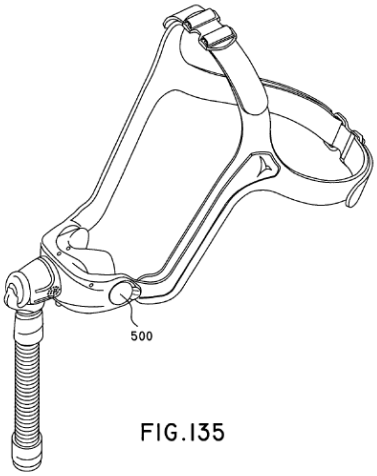


FIG.135

207. 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.[238] Positioning a buckle at the top of the head would prevent pressure from the buckle 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 strap and top strap

[238] *See* Ex. 1532 ¶ 149.

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"

208. 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."

209. As explained above, it was common practice to provide a hook tab on a free end of each strap.[239] 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"

210. Claim 21 depends from dependent Claim 19 and includes the additional limitation "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."

211. As explained above, a person of skill would have been motivated to provide upper straps that split to form a pair of top straps and a pair of rear

[239] *See supra* ¶¶ 196–199.

straps.[240] 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.

212. For example, as shown in Figure 16 of Ng (below, left), the top straps and the rear straps form a closed loop. As another example, FlexiFit (below, right) discloses top straps and rear straps forming a closed loop.[241]

Ng

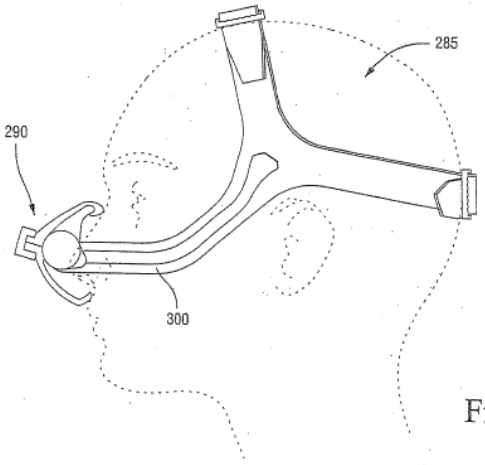
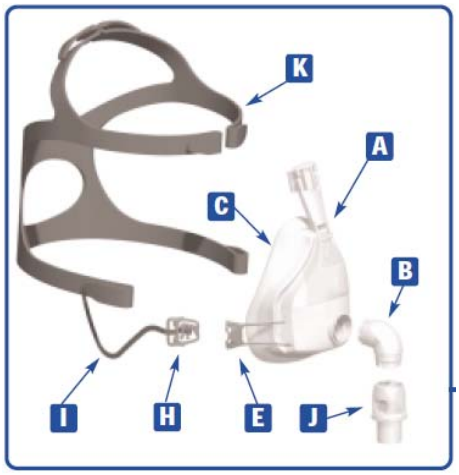


Fig. 16

FlexiFit



[240] *See supra* ¶¶ 200–203.

[241] Ex. 1517 at 10.

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

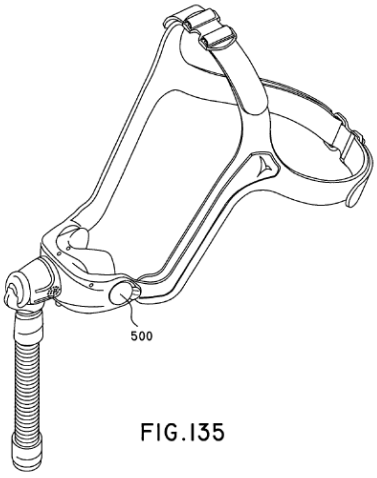


FIG.135

214. 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 of the '931 Patent would have been obvious over D'Souza in view of Hitchcock, FlexiFit, Gunaratnam-II, and Sprinkle

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

215. As shown in Figure 2 (below), Sprinkle relates to a mask 10 having headgear 80.[242] 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.[243]

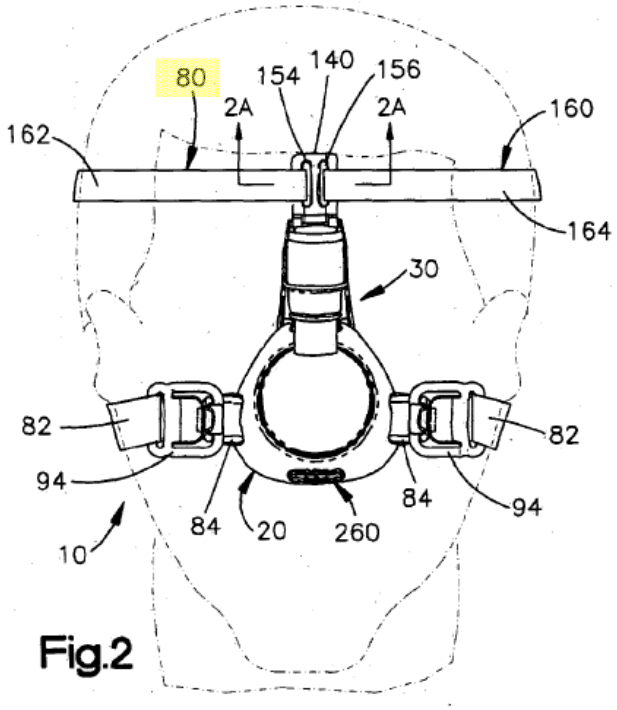


Fig.2

[242] Ex. 1520 ¶ 72.

[243] *Id.* ¶ 74.

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

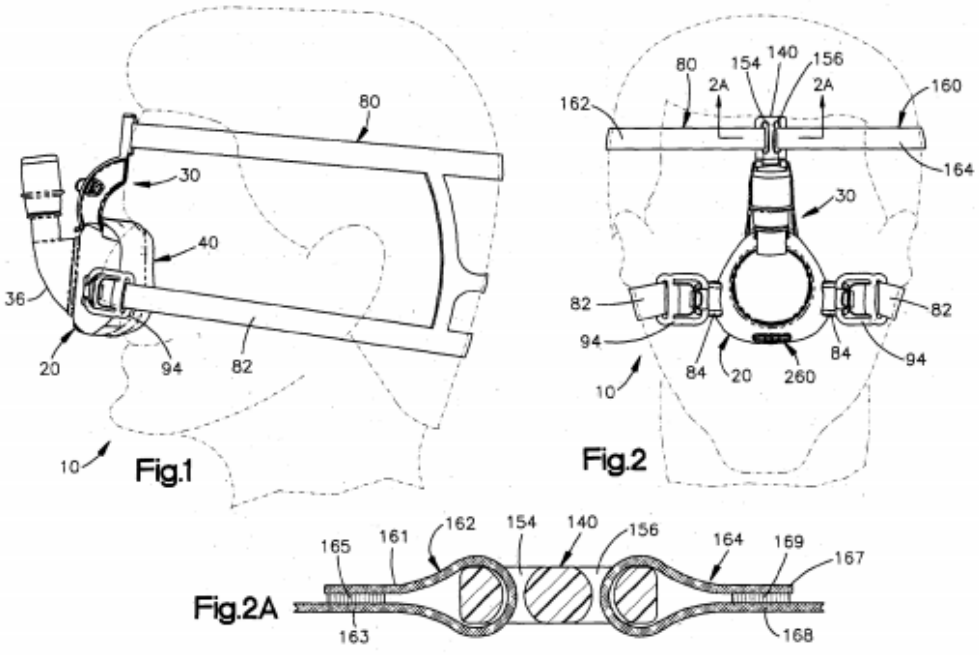
216. A person of skill in the art would have been motivated to combine D'Souza in view of Hitchcock, FlexiFit, Gunaratnam-II, and Sprinkle for at least the reasons provided above. Similar to D'Souza, Hitchcock, FlexiFit, and Gunaratnam-II, Sprinkle discloses a CPAP mask.[244] A person of ordinary skill in the art would have been aware of and looked to known CPAP masks when contemplating design features. Combining the features of D'Souza, Hitchcock, FlexiFit, Gunaratnam-II, and Sprinkle would have been a mere combination of familiar mask features that would have yielded only predictable results.

[244] *Id.* at ¶ 3.

a. "the upper straps provide padding"

217. 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 in use."

218. D'Souza does not expressly disclose that the 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.[245]



[245] Ex. 1520 ¶ 74.

219. As further evidence that this feature was common, Lovell discloses headgear straps manufactured from neoprene and that may further include padding.[246]

220. 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.[247] 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 of the '931 Patent would have been obvious over D'Souza in view of Hitchcock, FlexiFit, Gunaratnam-II, and Matula-II

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

221. 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.[248] The only difference is that the front opening in Claim 22 is the second opening in Claim 26.

---

[246] Ex. 1514 at col. 6:30–34.

[247] *See* Ex. 1529 at col. 3:10–24.

[248] *See supra* ¶¶ 134–138.

222. Claim 22 recites "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." As I explained above, D'Souza discloses the claimed snap-fit arrangement.[249] However, to the extent the teachings of D'Souza are insufficient for this feature, D'Souza as modified by Matula-II provides the claimed snap-fit arrangement.[250]

223. 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 D'Souza, Hitchcock, FlexiFit, Gunaratnam-II, and Matula-II to arrive at the claimed features of Claim 22.[251] None of these common features produced unexpected results and their combination does no more than yield predictable results.

[249] *See supra* ¶¶ 120–123, 135.

[250] *See supra* ¶¶ 124–133, 136–138.

[251] *See supra* ¶¶ 60–106, 111–138, 192–214.

J. Claims 28–30 and 65 of the '931 Patent would have been obvious over D'Souza in view of Hitchcock, Matula-II, and Barnett

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

a. Claims 28-30

224. 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.[252] There are a couple differences between Claims 28–30 and claim limitations I discussed above, but these 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."

225. As detailed in the Claim Charts I provide below, D'Souza discloses nearly all of the features of Claims 28–30. Any differences between Claims 28–30 and D'Souza were well-known in the industry at the time of the invention and taught by Hitchcock, Matula-II, and/or Barnett.

226. 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

[252] *See supra* ¶¶ 83–106, 119–133, 142–155.

teachings of D'Souza, Hitchcock, Matula-II, and Barnett to arrive at the claimed features of Claims 28–30.[253] None of these common features produced unexpected results and their combination does no more than yield predictable results.

227. In particular, a person of skill would have been motivated to combine the teachings of D'Souza and Hitchcock to arrive at the claimed headgear connectors, which are also embodied in Gunaratnam-I.[254] Further, a person of skill would have modified the D'Souza 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 Barnett to directly engage the shroud module and the elbow module to accommodate the elbow module.[255] A person of skill would have recognized that the inclusion of each of the features in Claims 28–30 would have been desirable so individual components (e.g., the headgear, cushion module, and/or shroud) could be easily removed without disassembling the entire system.

[253] *See supra* ¶¶ 60–106, 111–138, 141–159.

[254] *See supra* ¶¶ 62–67, 83–100.

[255] *See supra* ¶¶ 119–138, 142–155.

b. Claim 65

228. As detailed in the Claim Charts I provide below, D'Souza discloses nearly all of the features in Claim 57.[256] Any differences between Claim 57 and D'Souza are discussed below with respect to Claims 1, 6, 11, 14, 19, 22, 26, 43, and 46.[257] The protruding vent arrangement in Claim 65 is discussed above with respect to Claim 1.[258] Claim 65 depends from Claim 57 and includes the protruding vent arrangement recited in Claim 1.

229. 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 D'Souza, Hitchcock, Barnett, and Matula-II to arrive at the claimed features of Claim 65.[259] Each of these references discloses a CPAP mask 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

[256] *See infra* ¶¶ 243.

[257] *See supra* ¶¶ 62–86, 101–103, 119–138, 142–155, 194–209, 221–223; *see infra* ¶¶ 230–242.

[258] *See supra* ¶¶ 68–80.

[259] *See supra* ¶¶ 60–106, 111–138, 141–159.

taught in the prior art. The combination of these features would have done no more than yield predictable results.

K. Claims 46, 51, and 53–56 of the '931 Patent would have been obvious over D'Souza in view of Hitchcock, Flexifit, Barnett, Jaffre, Matula-II, Gunaratnam-II, Ultra Mirage, and Sprinkle

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

230. 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, D'Souza 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 D'Souza and Claims 46, 51, and 53–56 were well-known in the industry at the time of the invention and taught by Hitchcock, Flexifit, Barnett, Jaffre, Matula-II, Gunaratnam-II, Ultra Mirage, and Sprinkle.

231. As I discussed above, a person of skill would have been motivated to modify D'Souza in view of Hitchcock to arrive at the claimed protruding vent configuration.[260]

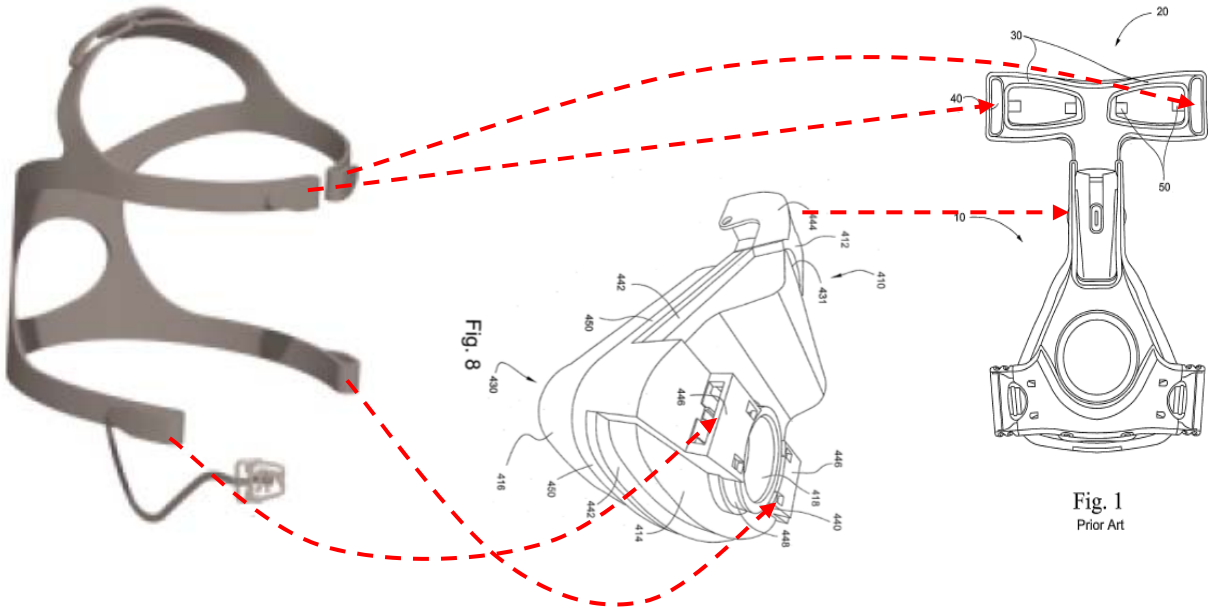
232. Further, as explained above, the claimed headgear configuration is entirely embodied in the FlexiFit headgear.[261] As shown below, because the

[260] *See supra* ¶¶ 68–80.

[261] *See supra* ¶¶ 188–189, 191–214.

combination of D'Souza and Hitchcock teaches pairs of upper and lower headgear connectors, the FlexiFit headgear would have been compatible with the D'Souza mask assembly.

FlexiFit (partial) **D'Souza (rotated)** **Hitchcock**



233. Additionally, prior to the '931 Patent, it was well-known to include snap-fingers to form snap-fit arrangements between CPAP components, as I discussed above.[262] A person of skill would have been motivated to modify D'Souza in view of the teachings of Matula-II to include rearward extending snap-fingers on the shroud to engage the cushion module.[263]

[262] *See supra* ¶¶ 119–138.

[263] *See supra* ¶¶ 119–133.

234. D'Souza discloses that its shroud module is adapted to engage an elbow,[264] but does not describe the particulars of this connection. However, as explained above, it was a well-known option to directly engage the shroud module and the elbow module, so the second opening of the shroud module would accommodate the elbow module.[265]

235. I have discussed nearly all of these potential differences above with respect to Claims 1, 5–7, 10, 11, 14, 15, 19, 20, 22, 25, 26, and 32.[266] The only feature not described above is the swivel feature in Claim 43 from which Claim 46 depends. I discuss this feature further below.[267]

236. For at least the reasons provided above, a person of skill would have been motivated to combine the teachings of D'Souza, Hitchcock, Flexifit, Barnett, Jaffre, Matula-II, Gunaratnam-II, Ultra Mirage, and 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.

---

[264] Ex. 1510 ¶ 100.

[265] *See supra* ¶¶ 143–149.

[266] *See supra* ¶¶ 62–91, 101–103, 119–138, 150–155, 167–172, 194–209, 217–223.

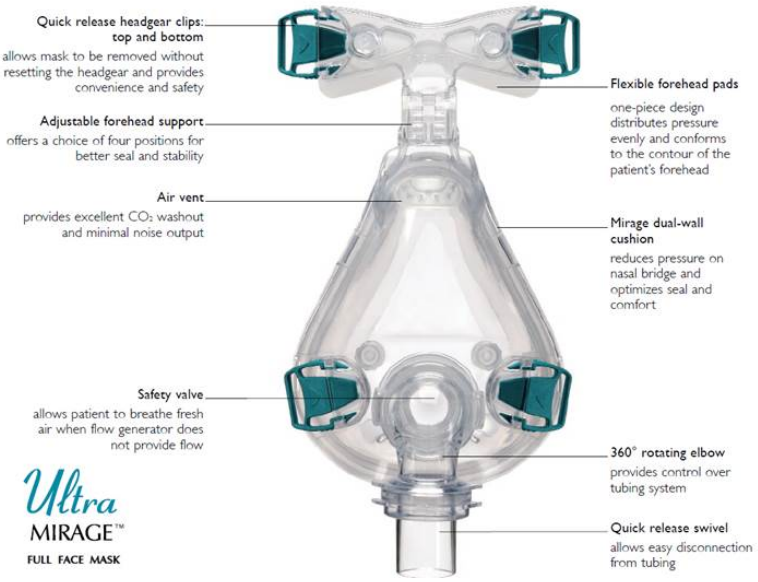
[267] *See infra* ¶¶ 237–242.

a. "the elbow including a swivel"

237. Claim 46 depends from Claim 43, and Claim 43 includes "the elbow including a swivel adapted to connect to an air delivery tube."

238. D'Souza 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. For example, Hitchcock discloses a mask assembly with an air delivery tube connected to a mask using a swivel elbow.[268]

239. Further, as shown below, ResMed's own Ultra Mirage also discloses a quick release swivel between the elbow and the air delivery tubing.[269]



[268] Ex. 1511 ¶ 28.

[269] Ex. 1516 at 6.

240. 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."[270]

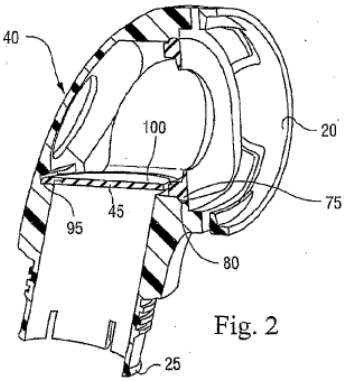


Fig. 2

241. As another example, Ging discloses a swivel connector member 300 between the elbow and the delivery tube 300.[271]

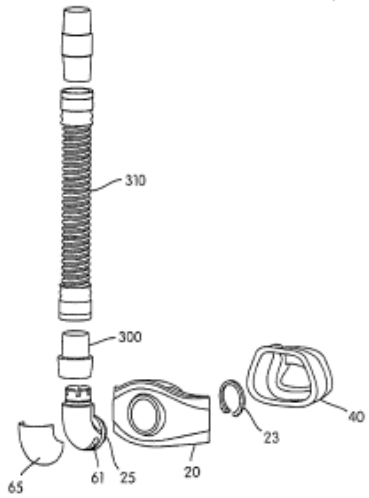


FIG. 6b

[270] Ex. 1522 ¶ 105.

[271] Ex. 1532 ¶ 153.

242. 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.[272] 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 the wearer.[273] Swivel connectors provide an additional degree of freedom of movement without increasing the undesirable torque.[274] This additional degree of movement also helps prevent the air delivery tubing from twisting.[275] Adding the swivel feature to the D'Souza mask assembly would have done no more than yield predictable results.

[272] *See* Ex. 1516 at 6.

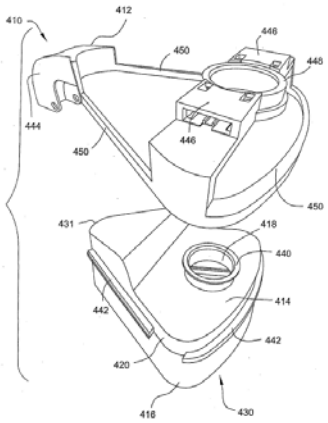
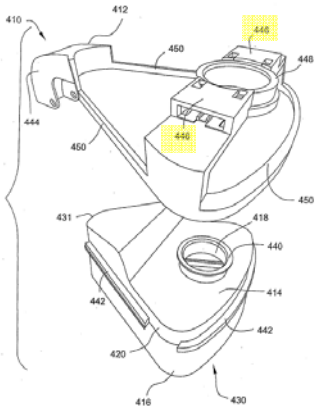
[273] *See* Ex. 1529 at col. 5:56–61.

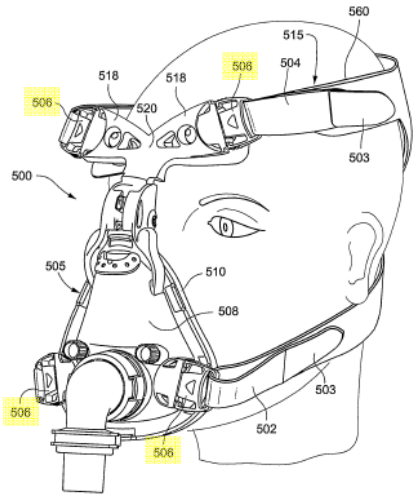
[274] *See* Ex. 1532 ¶ 114.

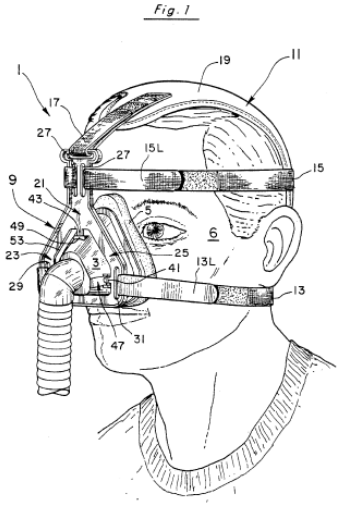
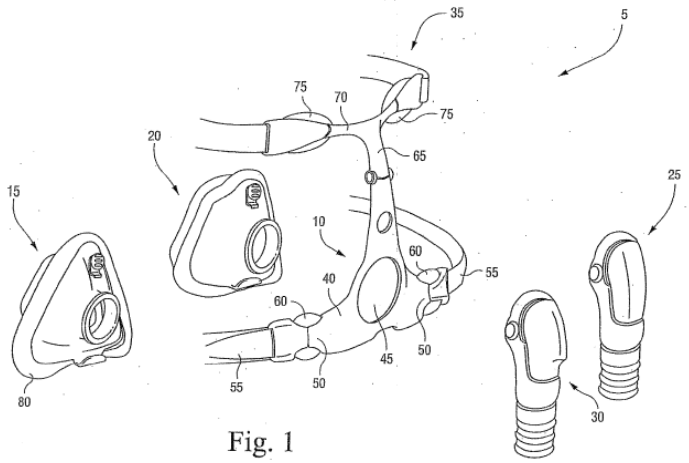
[275] *See* Ex. 1536 at col. 1:38–41.

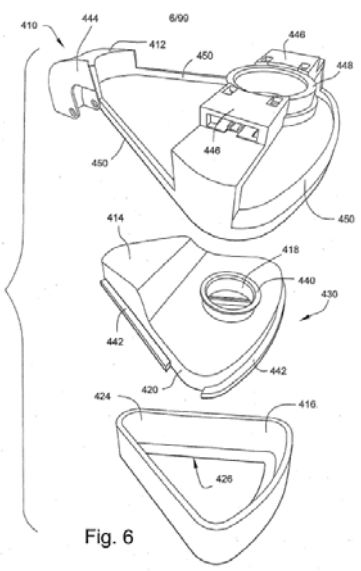
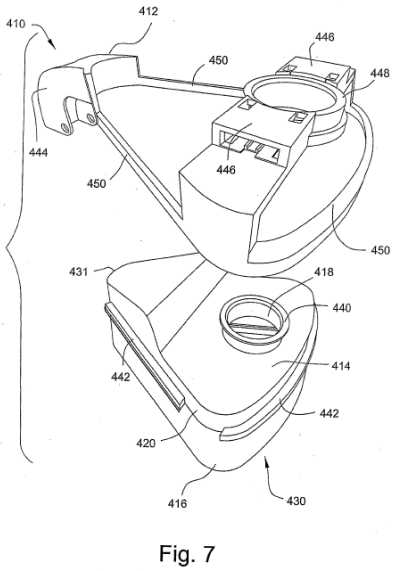
IX. CLAIM CHARTS

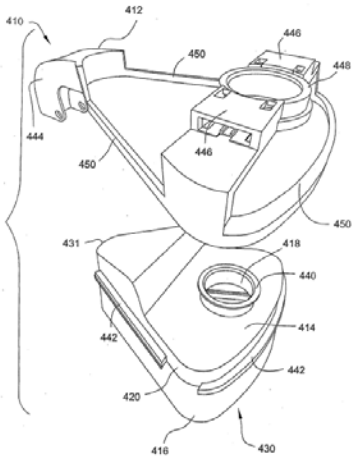
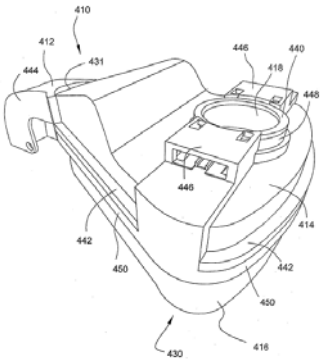
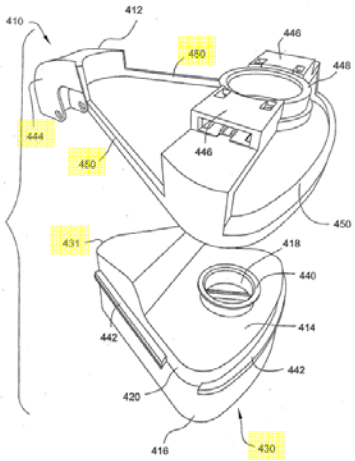
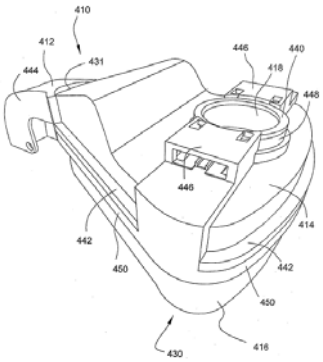
243. The claim chart below summarizes the disclosure in the prior art that a person of ordinary skill would understand to teach each limitation of Claims 1, 4–8, 10–22, 25, 26, 28–32, 46, 51, 53–56, and 65 of the '931 Patent.

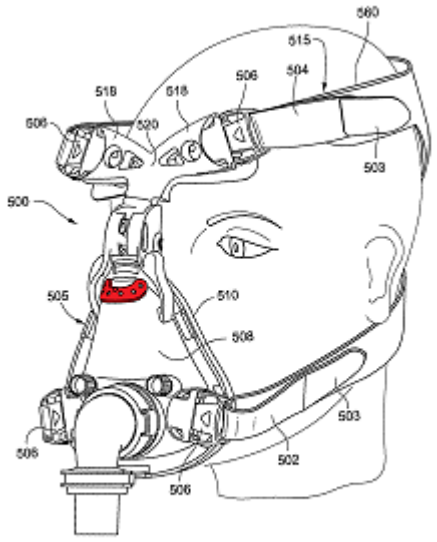
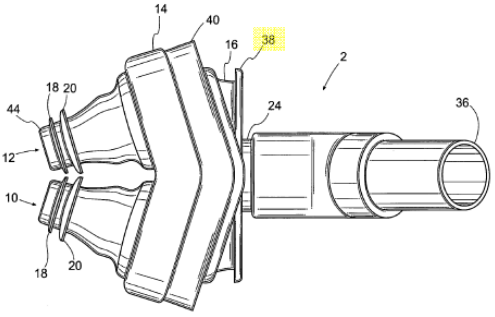
'931 Patent	Prior Art
1. A mask system, comprising:	**D'Souza:** "[M]ask assembly 410 including a cushion to frame assembly mechanism." Ex. 1510 ¶ 96.  Fig. 7
(i) a shroud module; wherein the shroud module includes headgear connectors adapted to removably attach to respective headgear straps of headgear; and	**D'Souza:** "[S]keleton frame 412 includes . . . lower headgear clip receptacles 446 adapted to be engaged with clips provided to straps of a headgear assembly (not shown)." Ex. 1510 ¶ 100.  Fig. 7

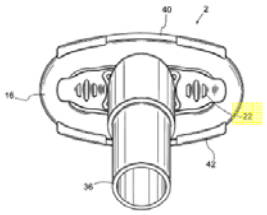
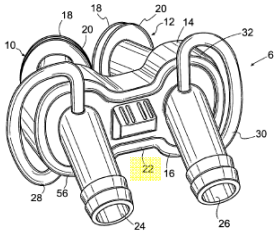
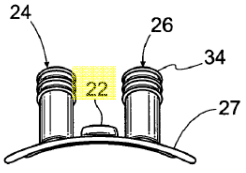
’931 Patent	Prior Art
	Hitchcock: “Each side portion 560, 570 includes an upper side strap 504 that is removably connected to a respective arm 518 of the Y-shaped forehead support 520, and a lower side strap 502 that that is removably connected to a lower portion of the mask frame 508.” Ex. 1511 ¶ 36. “In the illustrated embodiment, the upper side straps 504 are removably connected to respective arms 518 of the Y-shaped forehead support 520 via clips 506, which operate in a manner similar to the clips described above. Also, the lower side straps 502 are removably connected to a lower portion of the mask frame 508 via clips 506.” *Id.* ¶ 38.  Fig. 8 **Ultra Mirage:** “Quick release headgear clips: top and bottom allows mask to be removed without resetting the headgear and provides convenience and safety.” Ex. 1516 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,

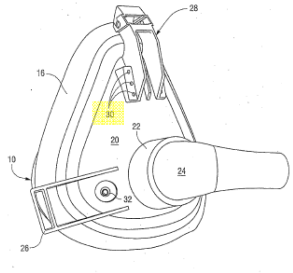
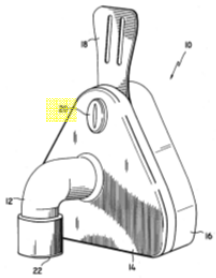
’931 Patent	Prior Art
	and 17 are also individually attachable in this manner.” Ex. 1529 at col. 3:10–20.  **Ng:** “The common frame 10 has a main body 40 defining a central opening 45. Main body 40 includes at least two lateral arms 50, each of which can be coupled to a headgear strap 55 of headgear. The straps may be connected to the frame using a press-fit connector 60, as is known in the art.” Ex. 1527 ¶ 30.  Fig. 1
(ii) a cushion module, comprising: a rigid or semi-rigid frame defining a breathing chamber; and	**D’Souza:** “[F]rame 414 and a cushion 416 are . . . interlocked to provide a cushion/frame sub-assembly 430. . . . [C]ushion 416 is constructed of liquid silicone rubber (LSR).” Ex. 1510 ¶ 97. “[F]rame 414 includes an upper wall that provides an

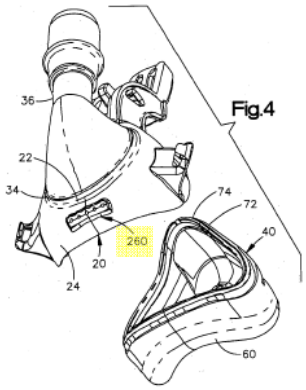
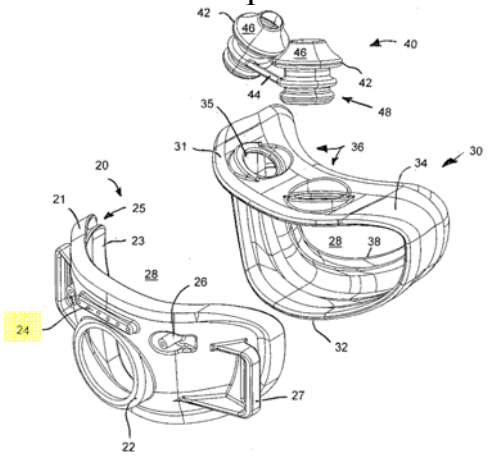
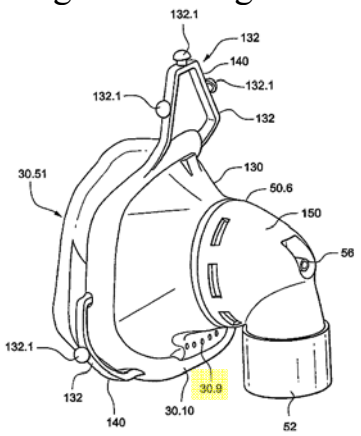
’931 Patent	Prior Art
a cushion to form a seal with the patient's face in a nasal bridge region, a cheek region and a lower lip/chin region of the patient's face, wherein the cushion is constructed of a first, relatively soft, elastomeric material and the frame is constructed of a second material that is more rigid than the cushion,	opening 418 for communicating with an inlet conduit. . . . A side wall 420 extends from the upper wall . . . . [F]rame 414 is constructed of polycarbonate.” *Id.* ¶ 98. “[C]ushion provides a seal around the patient's nose and mouth to enable the delivery of breathable gas to the patient's nose and mouth.” *Id.* ¶ 81.  Fig. 6  Fig. 7

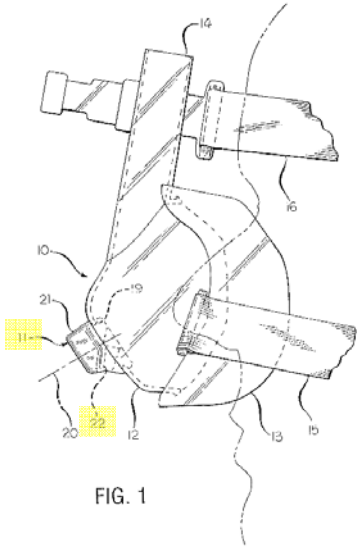
’931 Patent	Prior Art
[A] wherein the shroud module and the cushion module are configured to be removably and non-rotatably coupleable to one another; and	**D’Souza:** “[S]keleton frame 412 that is adapted to removably interlock with a cushion/frame sub-assembly 430.” Ex. 1510 ¶ 96. “[A]nnular elbow connection seal 448 interlocks with the annular wall 440 . . . upper support member 444 interlocks with a top portion 431 . . . and the elongated frame members 450 interlock with respective protrusions 442.” *Id*. ¶ 101.  Fig. 7  Fig. 8
[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	**D’Souza:** “[S]keleton frame 412 is engaged with the cushion/frame sub-assembly 430 such that . . . upper support member 444 interlocks with a top portion 431 . . . and the elongated frame members 450 interlock with respective protrusions 442.” Ex. 1510 ¶ 101.  Fig. 7  Fig. 8

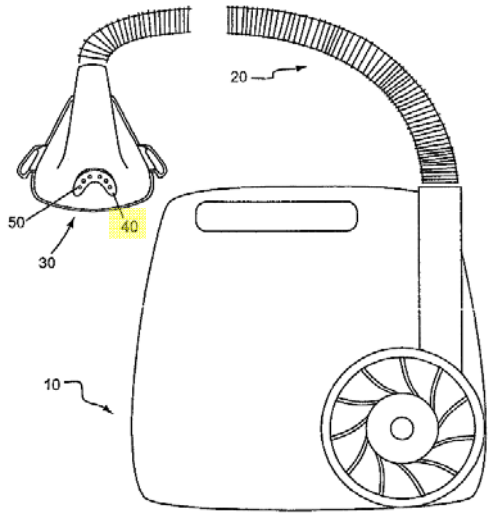
’931 Patent	Prior Art
	Hitchcock: *See* Ex. 1511 at Fig. 8.  Fig. 8 **Thomlinson:** “A nasal interface body 2 according to the present invention can also include one or more locking tabs 38 on the distal portion 16. The locking tabs 38 can be used to releasably engage a strap attachment plate 92, as depicted in FIG. 37 and described further below.” Ex. 1528 ¶ 203.  Fig. 1

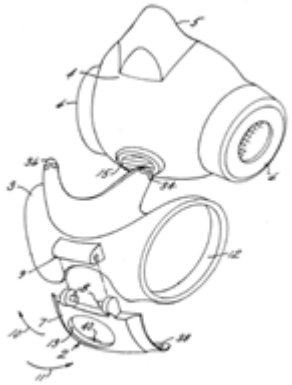
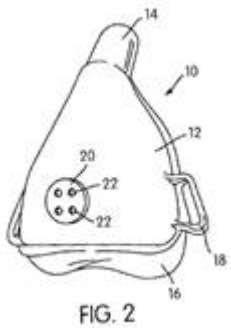
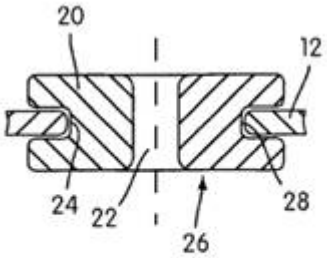
’931 Patent	Prior Art
	“Further, and as shown in FIG. 3, one embodiment of a nasal interface can also include one or more exhalation portion 22, which are described in more detail below.” *Id.* ¶ 204.  Fig. 3 “As shown in FIG. 8, nasal interface body 6 can also include first inlet 24 and a second inlet 26, as well as exhalation port 22. In one embodiment, exhalation port 22 is positioned between inlet 24 and the 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. “[E]xhalation ports may be located on any portion of the body of the nasal interface of the present invention, including distal portion 16 and/or proximal portion 14.” *Id.* ¶ 278.  Fig. 14A

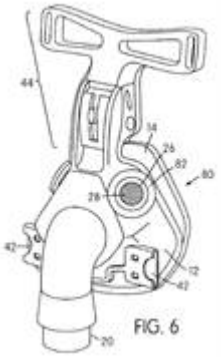
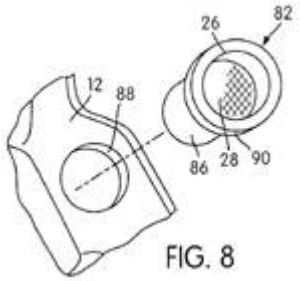
’931 Patent	Prior Art
	Hitchcock-II: “A number of vents 30 may be provided so as to allow gas exhaled by the patient to vent to atmosphere.” Ex. 1540 ¶ 42.  Fig. 1-2 **Landis:** “[T]he aperture in mask frame 14 to receive variable orifice member 20 is configured as a cylindrical wall projecting outward from the mask frame to engage a variable orifice member cap, as described in greater detail below.” Ex. 1541 at col. 5:35–39.  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. **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

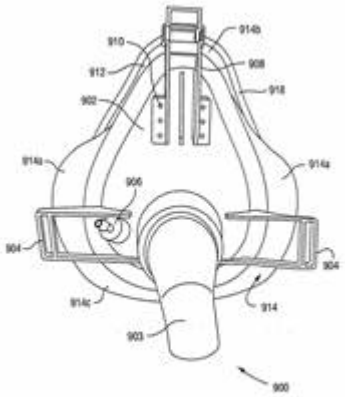
’931 Patent	Prior Art
	openings 264 enable exhaled air to flow out of the mask 10.” Ex. 1520 ¶ 99.  **Chandran:** “The ventilation interface 20 is configured with at least one exhalation port 24.” Ex. 1526 ¶ 60.  **Jones:** “[T]he lip region 30.8 has a series of four vent orifices 30.9 passing therethrough” Ex. 1538 ¶ 221. 

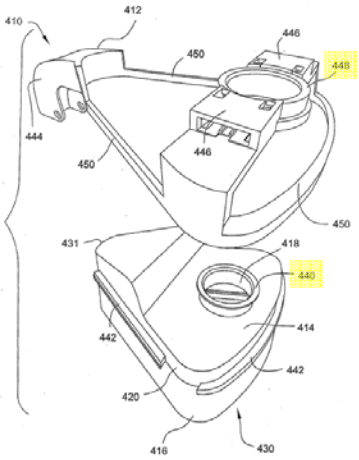
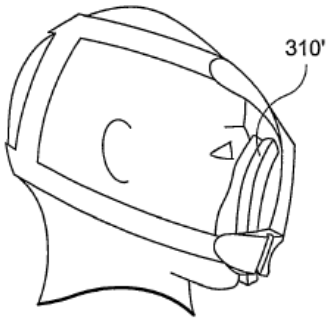
’931 Patent	Prior Art
	“The shell/cushion 130 includes a series of vents or vent orifices 30.9, which in a preferred form comprises four orifices. The vent orifices 30.9 are formed through a thicker wall section 30.10 formed integrally on the shell/cushion 30. The wall section 30.10 is shown in FIG. 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. **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. 1537 at col. 3:3–18.  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.

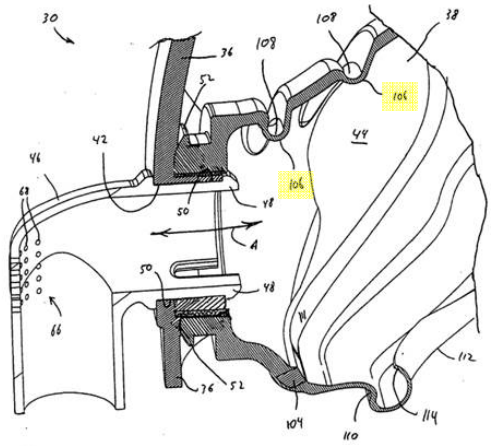
’931 Patent	Prior Art
	Darkin: “The patient interface 30 includes a vent 40. The vent 40 includes one or more holes, e.g., six holes 50.” Ex. 1542 ¶ 55.  Fig. 1 “Another advantage of the invention is to provide different vents for different pressure ranges. For example, at low pressures, it may be appropriate 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.

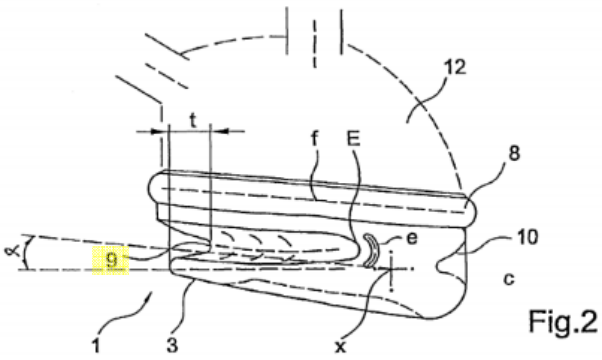
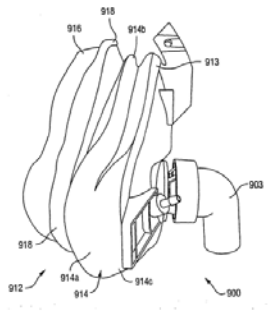
’931 Patent	Prior Art
	Fecteau: “[A] respirator 1 incorporates a quick release mechanism 2 into a facepiece support system, or yoke, 3.” Ex. 1546 at 4:24–25. “[Q]uick release mechanism 2 consists of an over center cam latch 7 pivotly attached to yoke 3 via hinge pins 8 disposed within hinge 9 and further 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. 1545 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

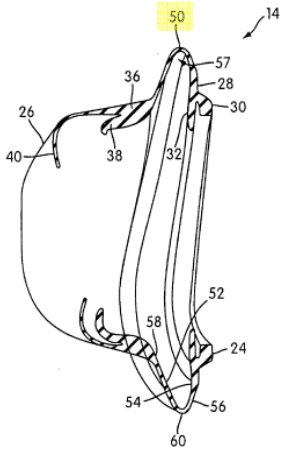
’931 Patent	Prior Art
	Drew: “The mask 10 includes a gas washout vent constituted by an opening 26 in the shell 12 across which extends a thin air permeable membrane 28.” Ex. 1444 at col. 4:32–34. “FIG. 6 shows a nasal respiratory mask 80.” *Id.* at col. 5:31. “In the mask 40 of FIG. 2, the [gas washout] 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

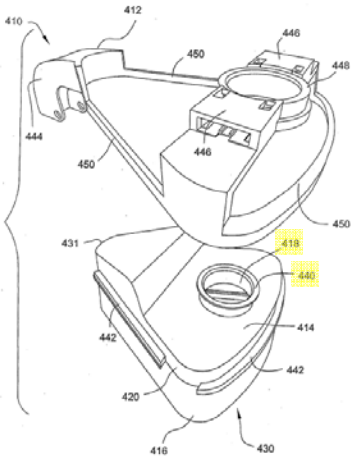
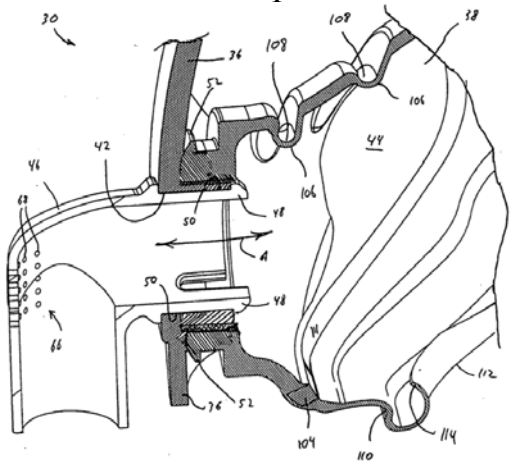
’931 Patent	Prior Art
	Frater: “Shell 902 may also be provided with one or more vents 910.” Ex. 1525 ¶ 163.  Fig. 50

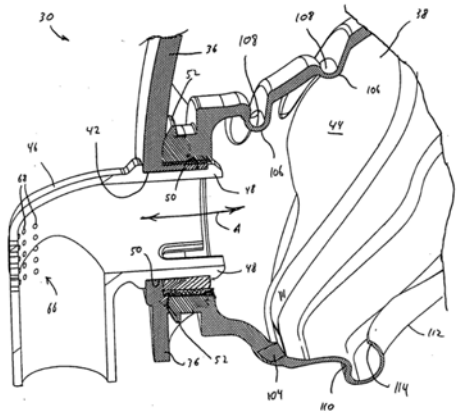
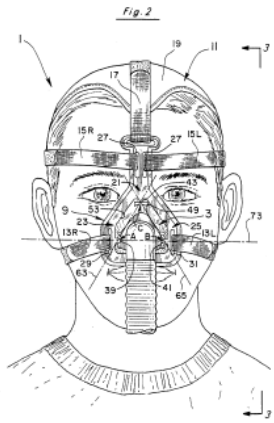
’931 Patent	Prior Art
[C] further wherein the shroud module includes a second opening positioned to align with a frame opening of the frame leading to the breathing chamber.	**D’Souza:** “[A]nnular elbow connection seal 448 interlocks with the annular wall 440.” Ex. 1510 ¶ 101.  Fig. 7
4. The mask system 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.	**Hitchcock:** “Figs. 6A-6C include a frame which supports a cushion 310’ having a gusseted portion (as best seen in Fig. 6C). Operation of the gusseted portion is more fully described in U.S. Patent Application No. 09/885,445, filed June 21, 2001, incorporated herein by reference in its entirety.” Ex. 1511 ¶ 32  Fig. 6C

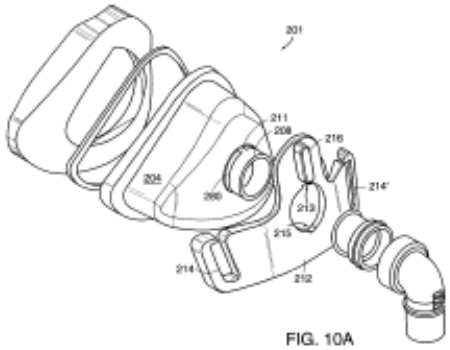
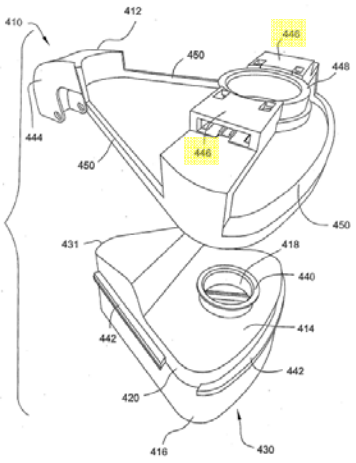
’931 Patent	Prior Art
	Matula-II: “[S]eal member 38 includes at least one pleat 106 (which can also be referred to as a fold or gusset) provided at a portion of the seal member so that the seal member has the desired degree of flexibility. In this case, pleats 106 are provided at and upper portion of the seal member so that this portion of the seal member can expand and contract with adjustment of the adjustment mechanism.” Ex. 1512 ¶ 66.  Fig. 4 “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*.

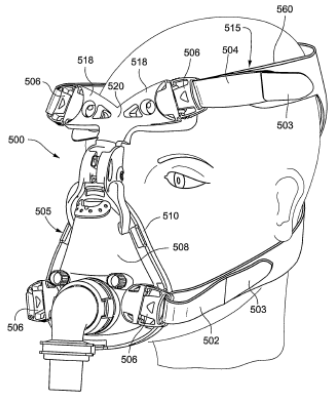
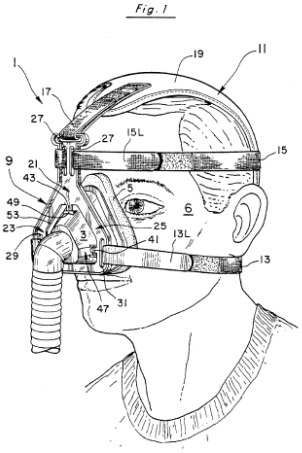
’931 Patent	Prior Art
	Melidis: “[S]ealing lip is elastically yieldingly arranged in such a way that in the region of the bridge of the nose there is a higher degree of flexibility than in the region of the nostrils and/or the upper lip.” Ex. 1521 at col. 1:33–43. “This embodiment also has a local folding 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. 1525 ¶¶ 163–164.  Fig. 51

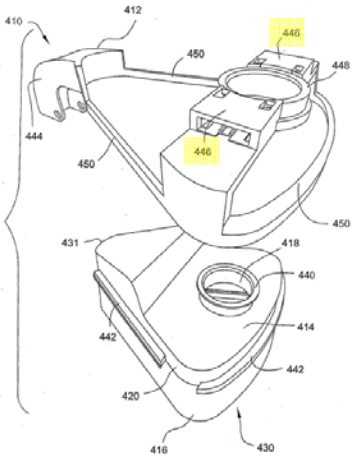
’931 Patent	Prior Art
	Lithgow: “The contact force applied to the contact line on the patient’s face can be further tailored by adjusting a thickness of the arcuate wall 56 of the gusset portion, as shown in FIGS. 6, 6C, and 13A-C. The arcuate wall 56 acts as a spring structure to provide a component of the contact force on the patient’s face through the membrane 40.” Ex. 1534 ¶ 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

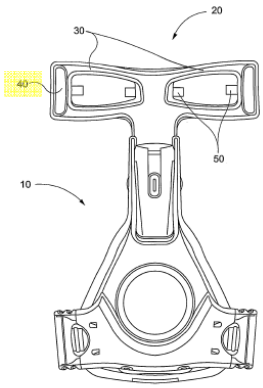
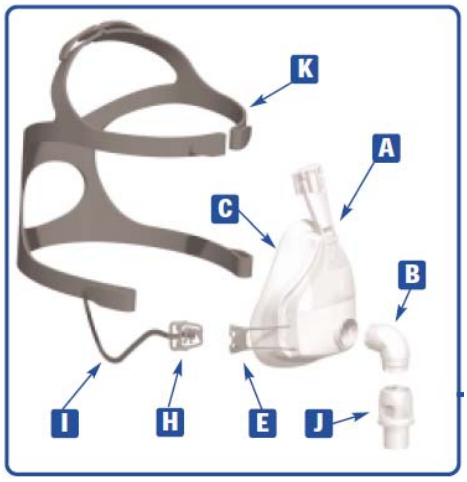
’931 Patent	Prior Art
5. The mask system of claim 1, wherein the frame includes a collar surrounding said frame opening,	**D’Souza:** “[A]nnular wall 440 surrounds the opening 418 [of the frame 414].” Ex. 1510 ¶ 98.  Fig. 7 **Matula-II:** “[T]he end of seal member 38 is joined to a ring 52 that is more rigid than the end of the seal member to provide a strong, stable mechanical coupling of the seal member to the faceplate.” Ex. 1512 ¶ 53.  Fig. 4

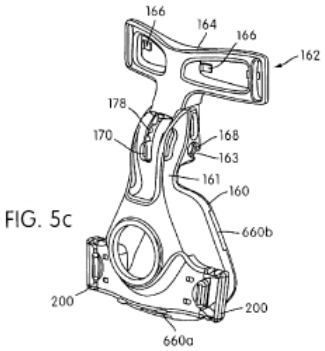
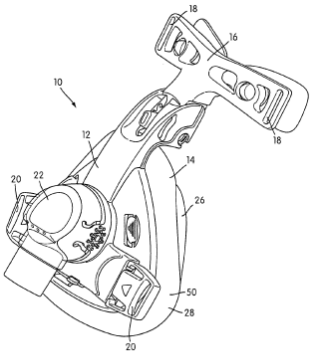
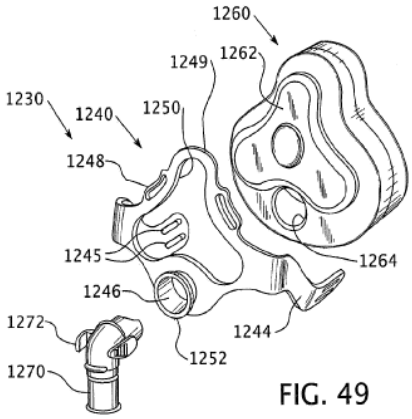
’931 Patent	Prior Art
and wherein the shroud includes a retaining portion with a plurality snap fingers structured to engage the collar with a snap-fit.	**D’Souza:** “[A]nnular elbow connection seal 448 interlocks with the annular wall 440.” Ex. 1510 ¶ 101. **Matula-II:** “Coupling member 46 includes 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. 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. 1529 at col. 4:59—5:19.  Fig. 2

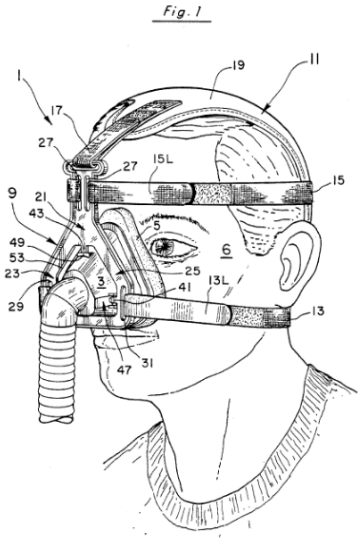
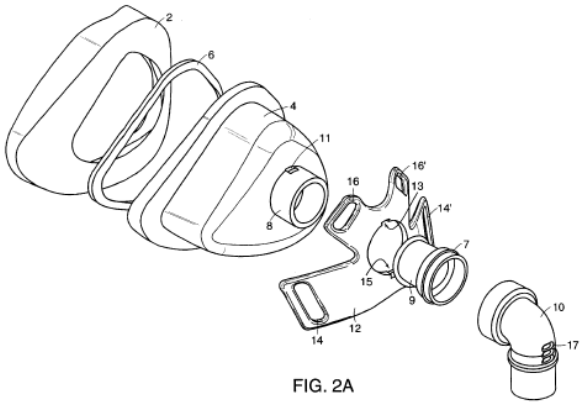
’931 Patent	Prior Art
	Lovell: “The retainer 212 is disposed about the inlet 208 to facilitate retention of the mask 201 on a user. . . . Two tabs 211, 211′ included on the inlet 208 mate with two slots 213, 215 formed in the retainer 212 in a particular angular orientation. . . . The retainer aperture 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. 1514 at col. 9:43–48; *see also id.* at col. 9:59–64.  FIG. 10A
6. The mask system of claim 1, wherein the shroud module includes upper and lower headgear connectors on each side of the shroud module.	**D’Souza:** “[S]keleton frame 412 includes an upper support member 444 adapted to support a forehead support, lower headgear clip receptacles 446.” Ex. 1510 ¶ 100.  Fig. 7

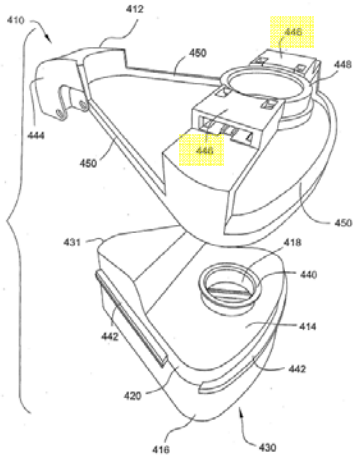
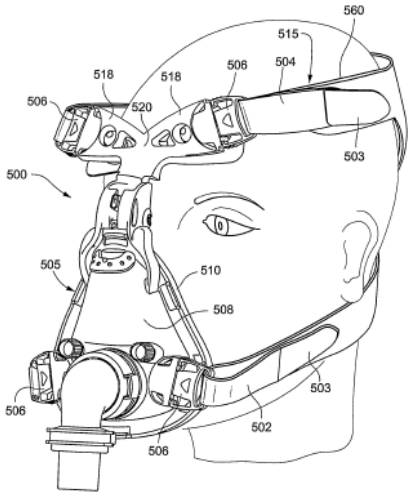
’931 Patent	Prior Art
	Hitchcock: “In the illustrated embodiment, the upper side straps 504 are removably connected to respective arms 518 of the Y-shaped forehead support 520 via clips 506, which operate in a manner similar to the clips described above. Also, the lower side straps 502 are removably connected to a lower portion of the mask frame 508 via clips 506.” Ex. 1511 ¶ 38.  Fig. 8 **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. 1529 at col. 3:10–20. 

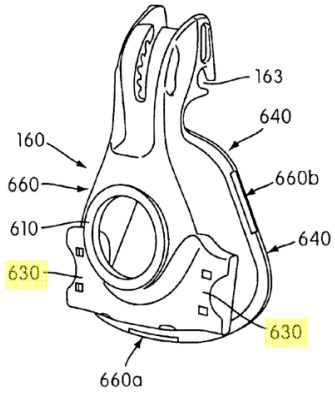
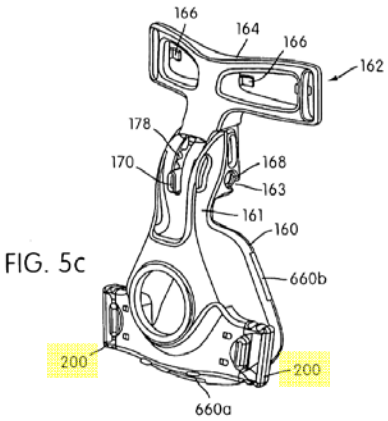
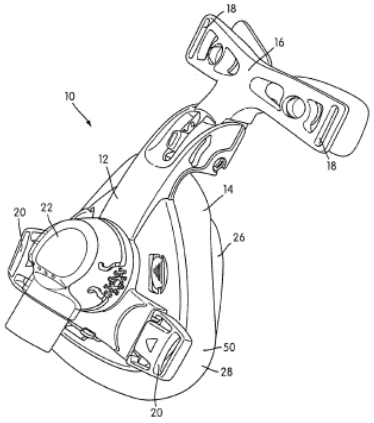
’931 Patent	Prior Art
	Ultra Mirage: “Quick release headgear clips: top and bottom allows mask to be removed without resetting the headgear and provides convenience and safety.” Ex. 1516 at 6.
7. The mask system of claim 6, wherein each upper headgear connector includes a slot adapted to receive a respective headgear strap in use.	*See supra* Claim 6. **D’Souza:** “[S]keleton frame 412 includes an upper support member 444 adapted to support a forehead support, lower headgear clip receptacles 446.” Ex. 1510 ¶ 100.  Fig. 7

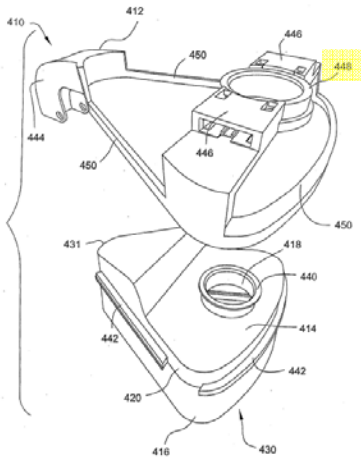
’931 Patent	Prior Art
	Hitchcock: “A prior art mask assembly 10 such as ResMed's ULTRA MIRAGE® mask as shown in Fig. 1 includes a forehead support 20 having a pair of arms 30, each having a slot 40 adapted to receive a strap (not shown). Each arm 30 includes a pair of forehead pad receiving lugs 50. The forehead support has a general ‘T’-shape, with the arms arranged along the upper cross portion of the ‘T’.” Ex. 1511 ¶ 24.  Fig. 1 Prior Art **FlexiFit:** “[A]ttach the four straps in to the corresponding slots in the Mask Base.” Ex. 1517 at 10 (“ASSEMBLING YOUR MASK”). 

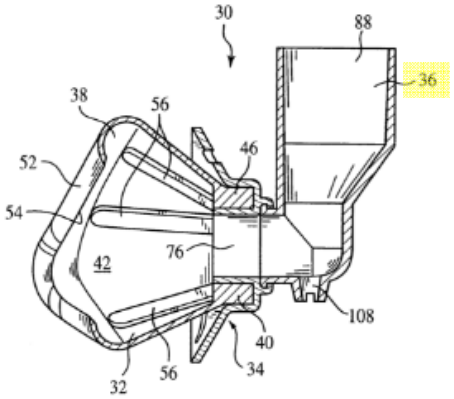
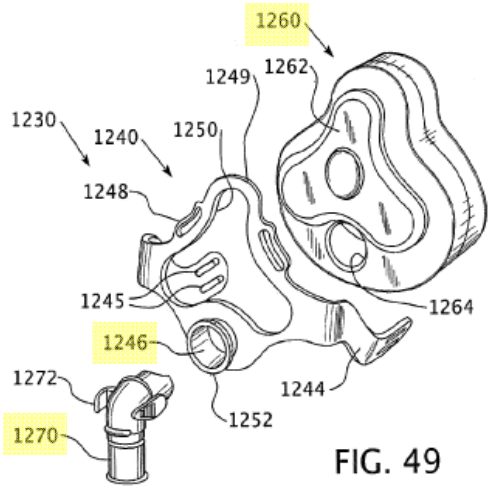
’931 Patent	Prior Art
	Gunaratnam-I: “As compared to FIGS. 5a-5b, FIGS. 5c-5f also show an adjustable forehead support (162) connected to the frame (160).” Ex. 1524 at col. 4:46–48.  FIG. 5c **Lithgow:** *See* Ex. 1534 at Fig. 1.  FIG. 1 **Matula-I:** “[A]ttachment elements 1248 are provided in the form of slots provided . . . [o]n a central portion 1249 of the body member.” Ex. 1523 ¶ 103.  FIG. 49

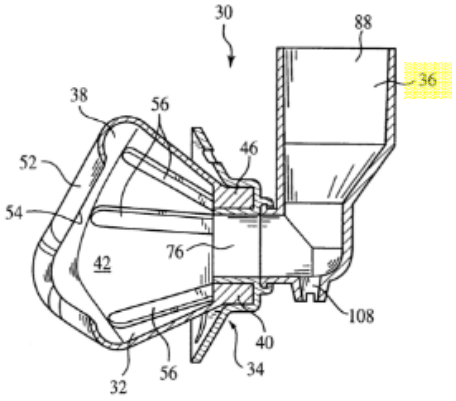
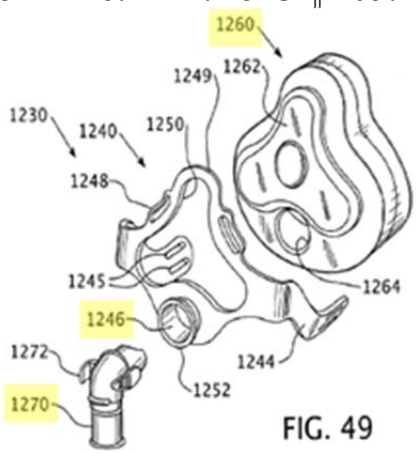
’931 Patent	Prior Art
	Ogden: “The upper side straps in this last regard could be the two straps 15R and 15L as illustrated or one continuous strap passing through loops 27 and anchoring the top portion 21 of the rigid plate 9 (see FIGS. 1-3).” Ex. 1529 at col. 3:7–10.  **Lovell:** “These connection 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. 1514 at col. 6:10–13.  FIG. 2A

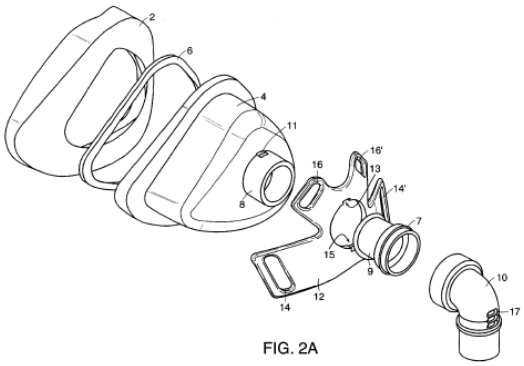
’931 Patent	Prior Art
8. The mask system of claim 7, wherein each lower headgear connector is adapted to be removably interlocked with a headgear clip associated with a respective headgear strap.	**D’Souza:** “[L]ower headgear clip receptacles 446 adapted to be engaged with clips provided to straps of a headgear assembly (not shown).” Ex. 1510 ¶ 100.  Fig. 7 **Hitchcock:** “[T]he lower side straps 502 are removably connected to a lower portion of the mask frame 508 via clips 506.” Ex. 1511 ¶ 38.  Fig. 8 **Ultra Mirage:** “Quick release headgear clips: top and bottom.” Ex. 1516 at 6.

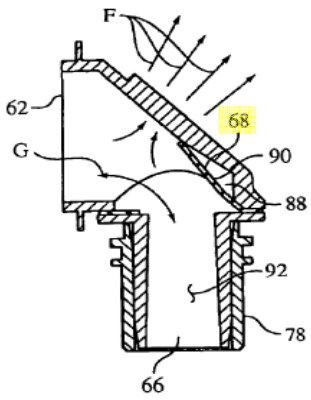
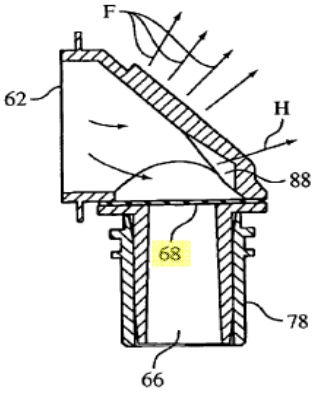
’931 Patent	Prior Art
	Gunaratnam-I: “On the front surface of the frame, are strap connection points (630) for connection of the mask to patient headgear. Connectors (200) are shown in FIGS. 5c-5f.” Ex. 1524 at col. 4:31–33.  FIG. 5a  FIG. 5c **Lithgow:** “For example, the headgear assembly may include 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. 1534 ¶ 111.  FIG. 1

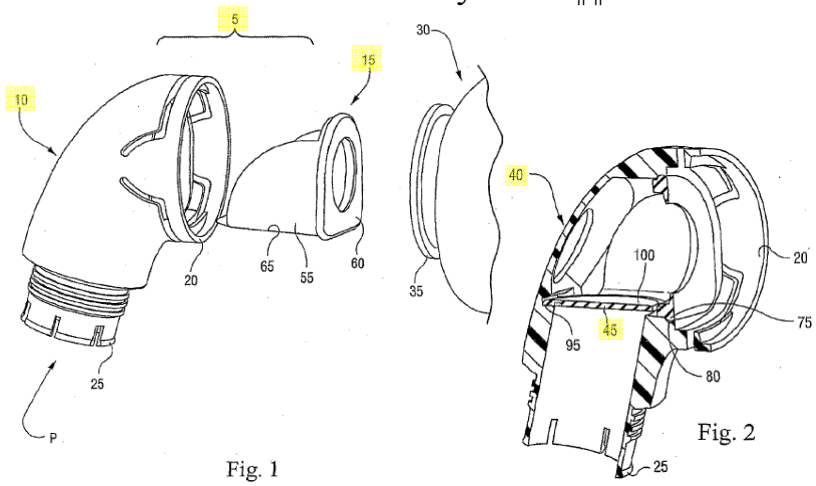
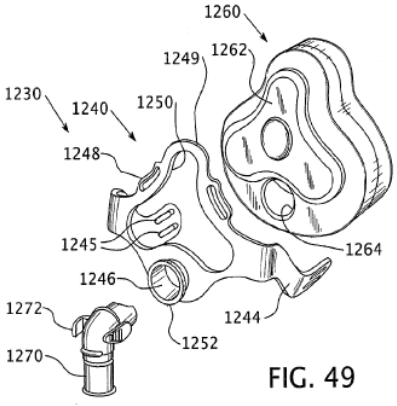
’931 Patent	Prior Art
10. The mask system of claim 1, wherein the shroud module includes an annular or part annular cushion retaining portion structured to retain the cushion module.	**D’Souza:** “[A]nnular elbow connection seal 448 interlocks with the annular wall 440 of the cushion/frame sub-assembly 430.” Ex. 1510 ¶ 101.  Fig. 7
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.	**D’Souza:** “[S]keleton frame 412 includes . . . an annular elbow connection seal 448 adapted to engage an inlet conduit, e.g., elbow.” Ex. 1510 ¶ 100. **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. 1511 ¶ 28. **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. 1528 ¶ 316. **Ultra Mirage:** “360° rotating elbow provides control over tubing system.” Ex. 1516 at 6.
12. The mask system of claim 11, wherein the elbow module is provided to the shroud module.	**D’Souza:** “[S]keleton frame 412 includes . . . an annular elbow connection seal 448 adapted to engage an inlet conduit, e.g., elbow.” Ex. 1510 ¶ 100. “[S]keleton frame 412 . . . provides attachment points for . . . an inlet conduit.” *Id.* ¶ 101.

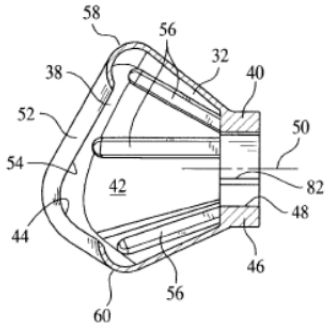
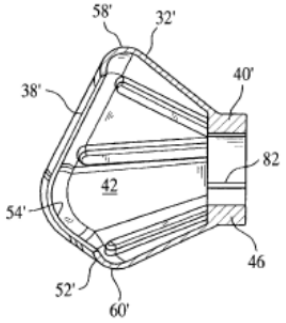
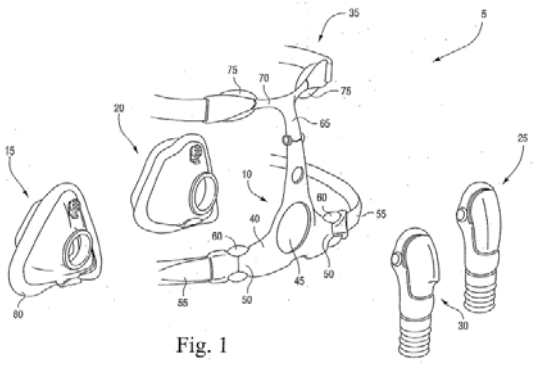
’931 Patent	Prior Art
	Barnett: “[C]onduit coupling member 36 is preferably rotateably mounted on a second side of collar 34.” Ex. 1513 at col. 3:52–57; *see also id.* at col. 8:66—9:43.  FIG. 1A **Matula-I:** “Circuit coupling portion 1246 provides a connection to a patient circuit coupling 1270.” Ex. 1523 ¶ 105.  FIG. 49
13. The mask system of claim 11, wherein the elbow module comprises polycarbonate.	**Lovell:** “[C]onduit elbow 10 also can be manufactured from . . . a polycarbonate material.” Ex. 1514 at col. 5:33–35. **Worboys:** “The elbow 10 can be made from a relatively rigid material, such as polycarbonate or other plastic.” Ex. 1522 ¶ 105.

’931 Patent	Prior Art
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.	*See supra* Claim 12. **D’Souza:** “[S]keleton frame 412 includes . . . an annular elbow connection seal 448 adapted to engage an inlet conduit, e.g., elbow.” Ex. 1510 ¶ 100. “[S]keleton frame 412 . . . provides attachment points for . . . an inlet conduit.” *Id.* ¶ 101. **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. 1513 at col. 3:52–57; *see also id.* at col. 8:66—col. 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. 1523 ¶ 105.  FIG. 49

’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. 1514 at col. 5:20–24.  FIG. 2A **Ultra Mirage:** “360° rotating elbow provides control over tubing system.” Ex. 1516 at 6.

'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.	**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. . . . [A] cantilever member 90 of valve member 68 flexes, as shown to FIG. 8, to block auxiliary opening 88. . . . If, however, the pressure of the gas in interior 92 is not greater than ambient atmosphere, cantilever member 90 returns to its normal, undeflected position shown in FIG. 9 and unblocks auxiliary opening 88 so that the patient has access to the ambient atmosphere as indicated by arrow H." Ex. 1515 at col. 10:4–28.  FIG. 8  FIG. 9

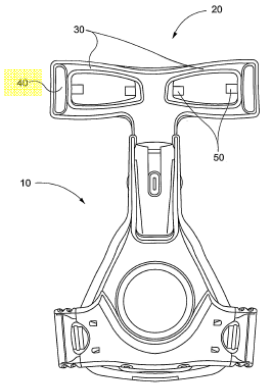
’931 Patent	Prior Art
	Worboys: “[E]lbow assembly 5 generally comprises an elbow 10 and an anti–asphyxia valve 15 (AAV) assembly.” Ex. 1522 ¶ 103. “[E]lbow 10 includes a port 40 that may be selectively closed by a flap portion 45 of the AAV assembly.” *Id*. ¶¶ 105–106.  Fig. 1 Fig. 2 **Matula-I:** “[T]he 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. 1523 ¶ 106.  FIG. 49
16. The mask system of claim 1, wherein the cushion module includes at least first and second	**Barnett**: The seal members 32, 32’ differ in the “contour of the first end portion, size, and shape.” Ex. 1513 at col. 6:1–4. The seal member 32 is configured for a relatively large population of adult

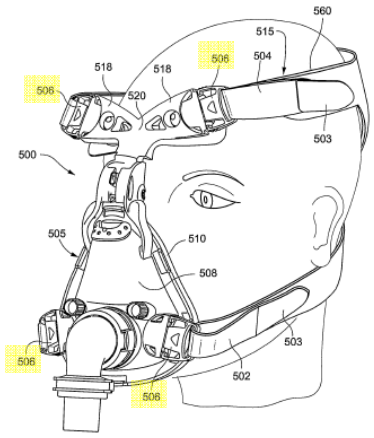
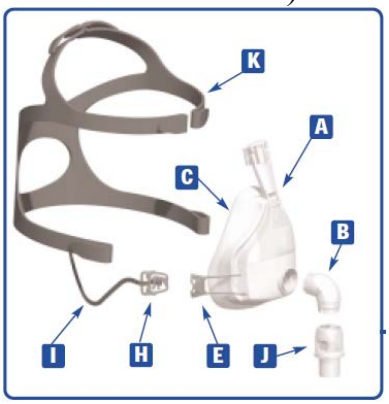
’931 Patent	Prior Art
cushion modules adapted to be provided to the shroud module, said at least first and second cushion modules being different from one another in at least one aspect.	patients and the seal member 32’ is configured for small adults and children, and “seal members 32 and 32′ can be used in conjunction with a commonly sized collar 34.” *Id.* at col. 5:52–67, 6:1–13.  FIG. 2A  FIG. 3B **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 ca 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. 1527 ¶ 31.  Fig. 1

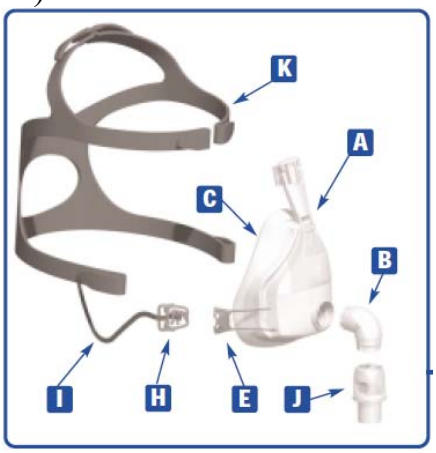
’931 Patent	Prior Art
	Ultra Mirage: Brochure provides product codes for small, medium, and large sizes. Ex. 1516 at 7, 9. **Ging:** “It is to be understood that these dimensions refer to a particular embodiment of the invention, and a differently sized mask (for example, a “small” size versus a “large” 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. 1532 ¶ 193. **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. 1531 ¶ 36. **FlexiFit:** “If leaks persist, change to the alternate size Silicone Seal, which is found in your FlexiFit™ HC431 Mask box.” Ex. 1517 at 10 (“FITTING YOUR MASK”).

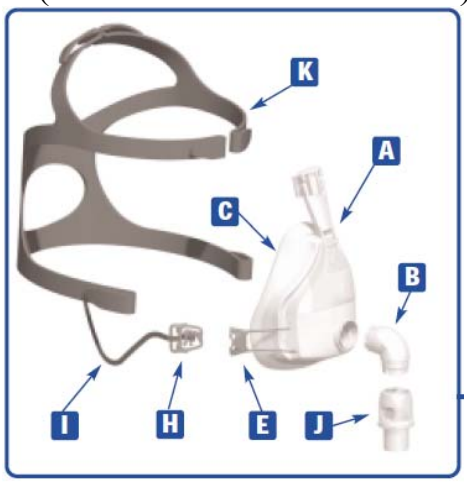
'931 Patent	Prior Art
17. The mask system of claim 1 comprising a small cushion module, a medium cushion module and a large cushion module, wherein each of said small cushion module, said medium cushion module and said large cushion module is removably coupleable to the same shroud module.	*See supra* Claims 1[A] and 16. **Ultra Mirage:** Brochure provides product codes for small, medium, and large sizes. Ex. 1516 at 7, 9. **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. 1532 ¶ 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. 1513 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. 1531 ¶ 36.

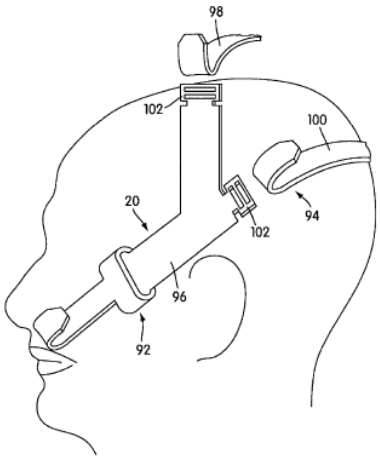
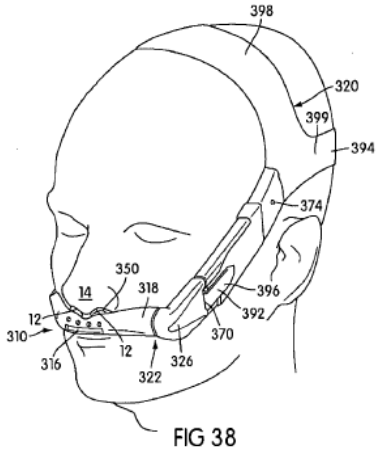
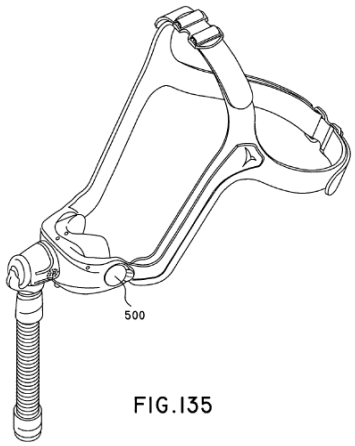
'931 Patent	Prior Art
	FlexiFit: "If leaks persist, change to the alternate size Silicone Seal, which is found in your FlexiFit™ HC431 Mask box." Ex. 1517 at 10 ("FITTING YOUR MASK").
18. The mask system of claim 1, wherein the shroud module and the frame comprise polycarbonate and the cushion comprises silicone.	**D'Souza:** "[C]ushion 416 is constructed of liquid silicone rubber (LSR)." Ex. 1510 ¶ 97. "[T]he frame 414 is constructed of polycarbonate." *Id*. ¶ 98. "[T]he skeleton frame 412 is formed of plastic." *Id.* ¶ 100. **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. 1524 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. 1514 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. **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. 1533 at 6:21–24. **Lithgow:** "The cushion 14 is constructed from a soft, flexible skin-compatible material such as silicone." Ex. 1534 ¶ 139.

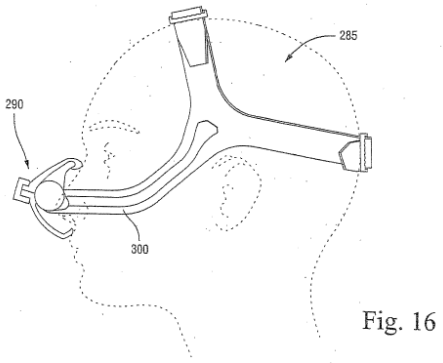
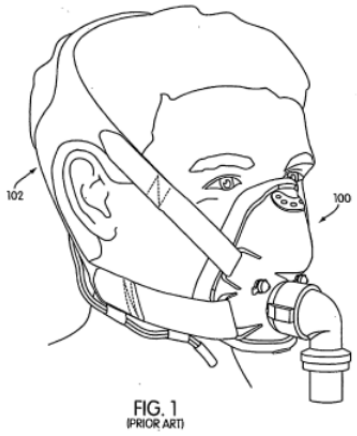
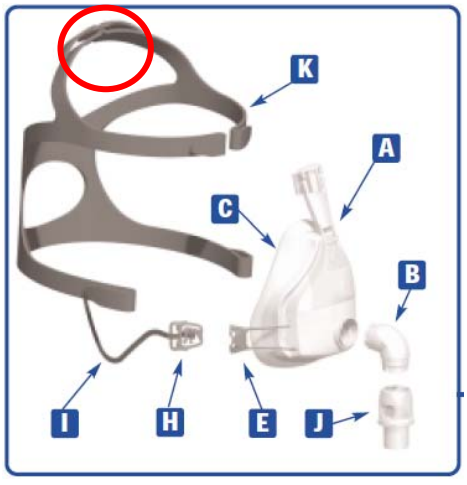
’931 Patent	Prior Art
19. The mask system of claim 1, wherein: **[A]** the headgear includes a pair of upper straps and pair of lower straps, with the upper straps being removably attached to respective ones of the headgear connectors and the lower straps being connected to respective ones of the headgear connectors,	**D’Souza:** “[P]atient interface is held in a sealing position by headgear.” Ex. 1510 ¶ 3. “[S]keleton frame 412 includes an upper support member 444 adapted to support a forehead support, lower headgear clip receptacles 446 adapted to be engaged with clips provided to straps of a headgear assembly (not shown).” *Id.* ¶ 100. **Hitchcock:** “A prior art mask assembly 10 such as ResMed's ULTRA MIRAGE® mask as shown in Fig. 1 includes a forehead support 20 having a pair of arms 30, each having a slot 40 adapted to receive a strap (not shown). Each arm 30 includes a pair of forehead pad receiving lugs 50. The forehead support has a general ‘T’-shape, with the arms arranged along the upper cross portion of the ‘T’.” Ex. 1511 ¶ 24.  Fig. 1 Prior Art

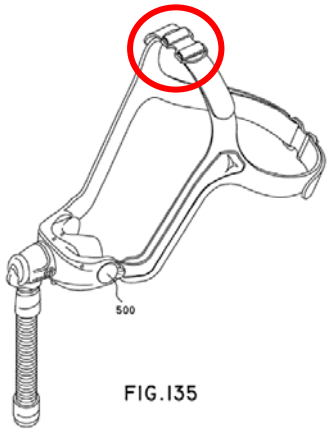
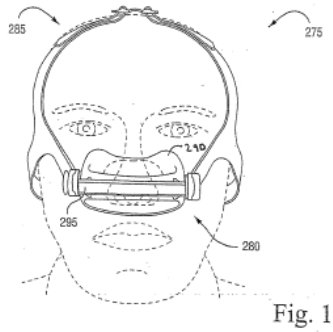
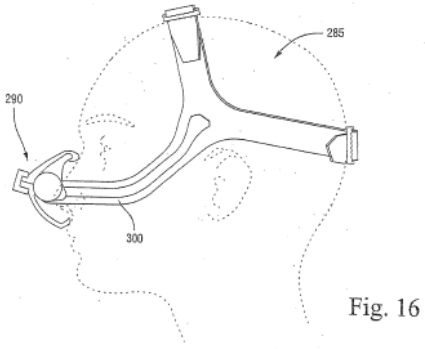
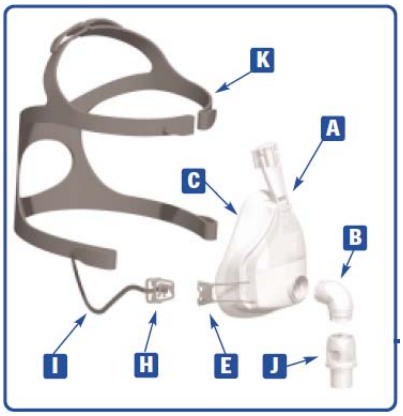
’931 Patent	Prior Art
	“In the illustrated embodiment, the upper side straps 504 are removably connected to respective arms 518 of the Y-shaped forehead support 520 via clips 506, which operate in a manner similar to the clips described above. Also, the lower side straps 502 are removably connected to a lower portion of the mask frame 508 via clips 506.” *Id.* ¶ 38.  Fig. 8 **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. 1517 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”). 

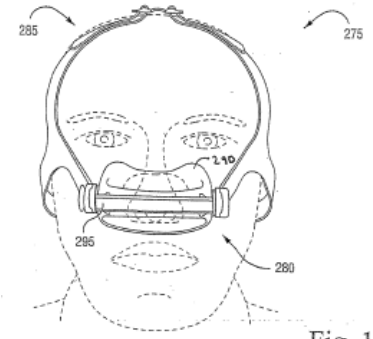
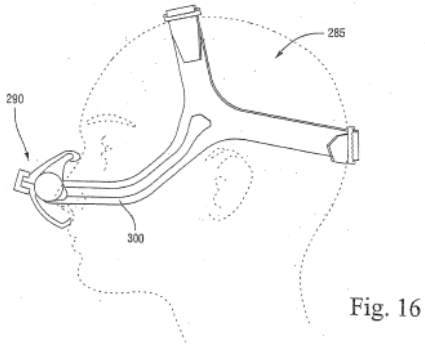
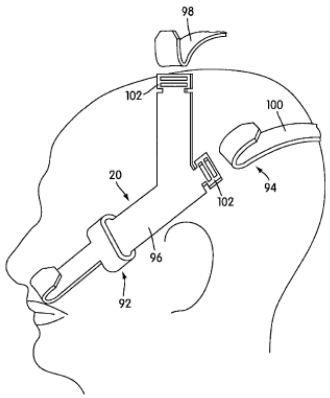
’931 Patent	Prior Art
[B] a free end of each of the upper straps and the lower straps includes a hook tab structured to engage a remainder of the respective upper strap and respective lower strap to secure the upper and lower straps in place in a length adjustable manner,	**Hitchcock**: “The free end of each of the upper and lower side straps 504, 502 includes a strip of Velcro® material 503 for use in securing each of the straps 504, 502 to a respective clip 506.” Ex. 1511 ¶ 38. **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. 1517 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. 1529 at col. 3:10–20.

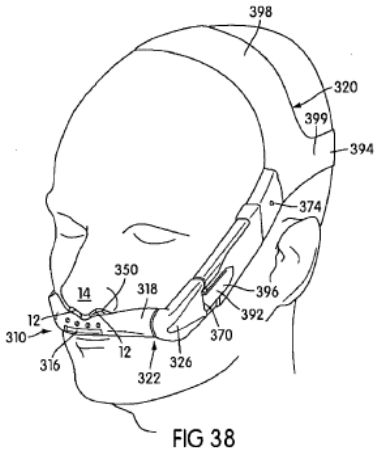
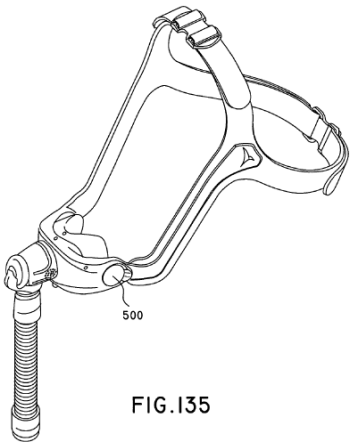
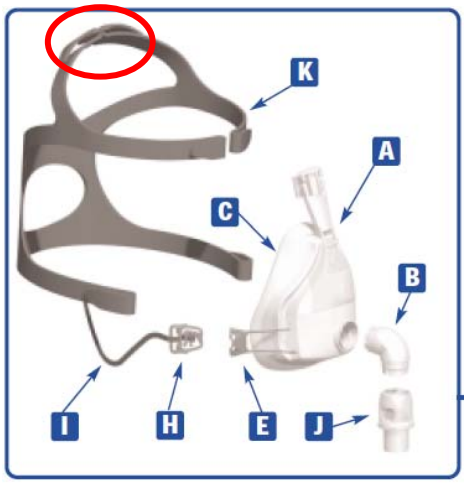
’931 Patent	Prior Art
	Amarasinghe: “At the end of each strap is secured a piece of hook material, which, in use, passes through a headgear attachment point and fastens on corresponding loop material on the strap.” Ex. 1530 ¶ 12. **Lovell:** “A hook and loop fastener system can be used to maintain the 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. 1514 at col. 7:6–13.
[C] the upper straps split to form a pair of top straps and a pair of rear straps,	**FlexiFit:** “Gently adjust . . . Top Crown straps.” Ex. 1517 at 10 (“FITTING YOUR MASK”). 

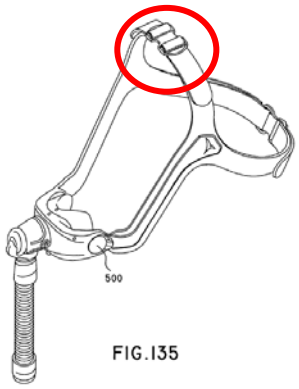
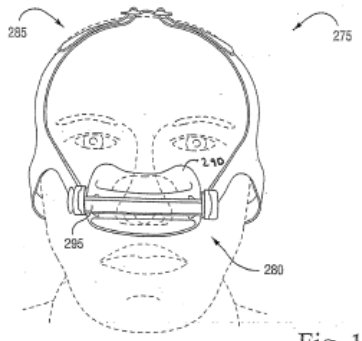
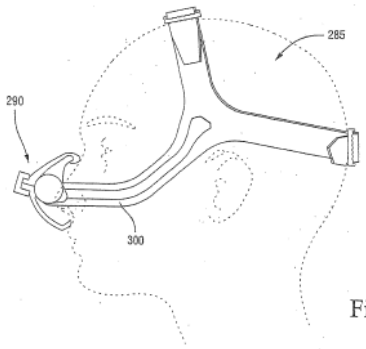
'931 Patent	Prior Art
	Gunaratnam-II: "The upper strap 98 and rear strap 100 are removably connected to the side straps 96 by buckles 102 provided on the side straps 96." Ex. 1519 ¶ 211.  FIG. 18 "The rear portion 394, which interconnects the two side portions 392, includes an upper strap 398 that passes 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

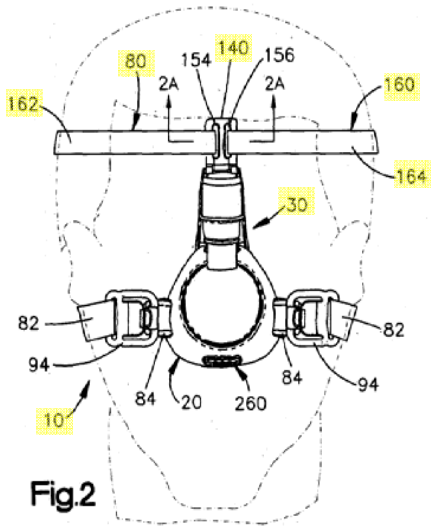
’931 Patent	Prior Art
	Ng: *See* Ex. 1527 at Fig. 16.  Fig. 16 **Amarasinghe:** *See* Ex. 1530 at Fig. 1.  FIG. 1 (PRIOR ART)
[D] the top straps being connected together by a buckle and configured to pass over the top of the patient's head in use,	**FlexiFit:** Ex. 1517 at 10. 

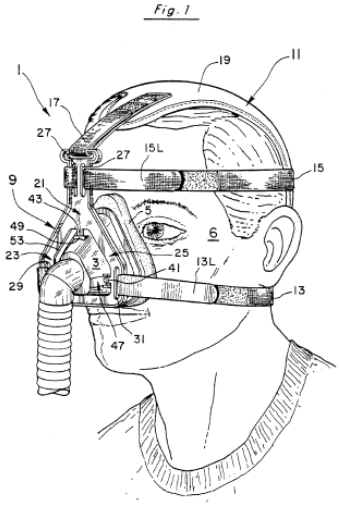
’931 Patent	Prior Art
	Gunaratnam-II: “[U]pper straps 598 are coupled to one another by a headgear buckle 570.” Ex. 1519 ¶ 316, Fig. 135.  FIG.135 **Ng:** “Further, as shown in Fig. 16, the vectors formed by the headgear straps 300 are slightly different than as shown in described in relation to Fig. 13.” Ex. 1527 ¶ 46.  Fig. 15  Fig. 16
[E] the rear straps being adapted to pass behind the patient's head in use,	**FlexiFit:** Ex. 1517 at 10. 

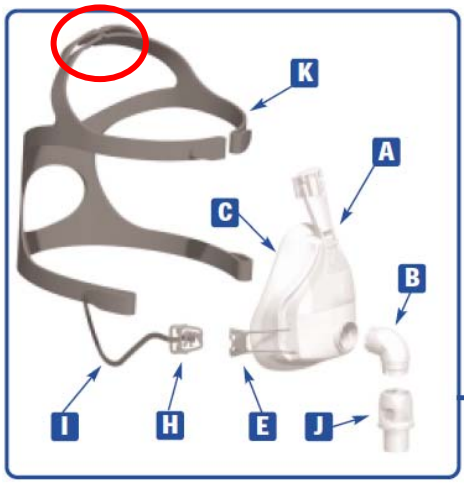
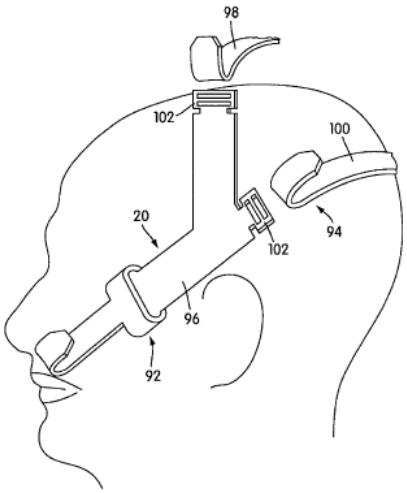
'931 Patent	Prior Art
	Ng: "Further, as shown in Fig. 16, the vectors formed by the headgear straps 300 are slightly different than as shown in described in relation to Fig. 13." Ex. 1527 ¶ 46.  Fig. 15  Fig. 16 **Gunaratnam-II:** "The upper strap 98 and rear strap 100 are removably connected to the side straps 96 by buckles 102 provided on the side straps 96." Ex. 1519 ¶ 211.  FIG. 18

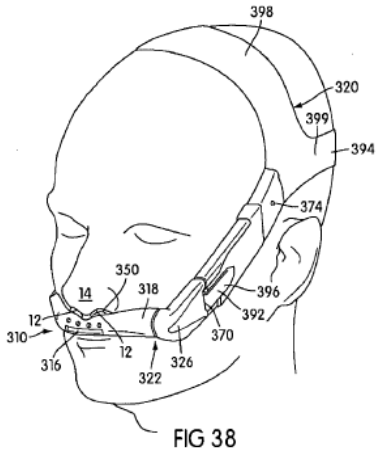
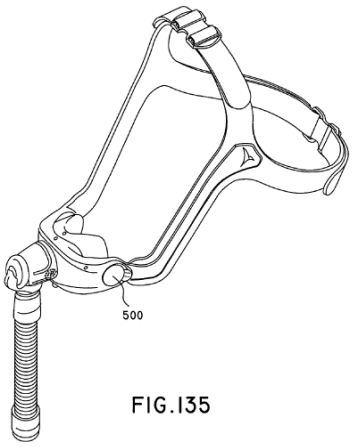
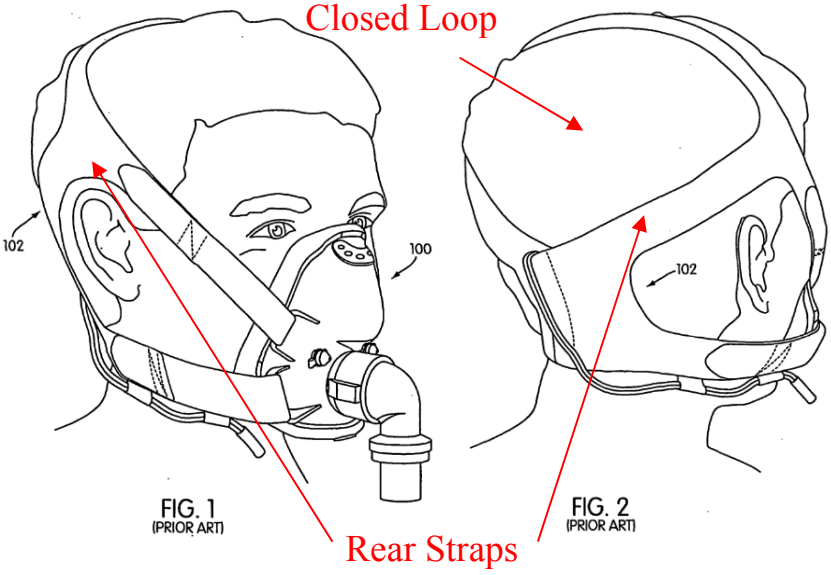
’931 Patent	Prior Art
	“The rear portion 394, which interconnects the two side portions 392, includes an upper strap 398 that passes over the top of the patient's head and a rear strap 399 that passes around the rear portion of the patient's head.” *Id.* ¶ 263 and Figs. 38 and 135.  FIG 38  FIG.135
[F] 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.	**FlexiFit:** “Gently adjust the . . . Top Crown straps.” Ex. 1517 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”). 

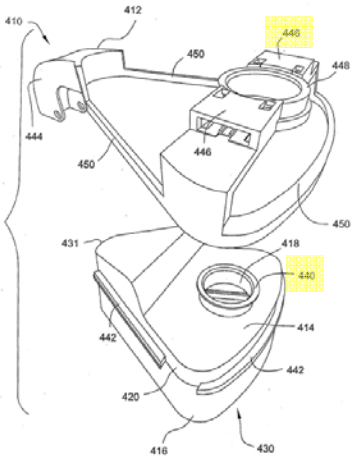
’931 Patent	Prior Art
	Gunaratnam-II: “[H]eadgear buckle 570 includes a first locking portion 571 and a second locking portion 572. The first locking portion 571 is adapted to be removably and adjustably coupled with one of the upper straps 598 . . . and the second locking portion 572 is adapted to be removably and adjustably coupled with the other of the upper straps 598 . . . . Each of the upper straps 598 may be wrapped around the cross-bar of the associated locking portion 571, 572.” Ex. 1519 ¶ 316, Fig. 135.  FIG.135 **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. 1527 ¶ 46. “Each strap includes hook and loop fastening elements, e.g., Velcro®.” *Id.* ¶ 67.  Fig. 15  Fig. 16

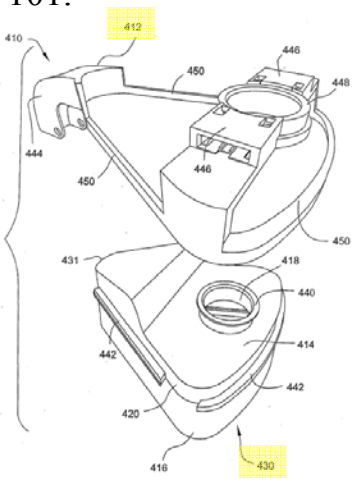
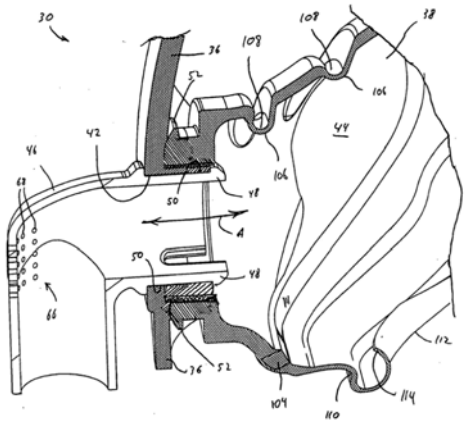
’931 Patent	Prior Art
20. The mask system of claim 19, wherein the upper straps provide padding to the respective headgear connectors of the shroud module on the patient's face in use.	**Sprinkle:** “When the left and right straps 162 and 164 are connected with the forehead adjuster 140 in this manner, 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. 1520 ¶ 74, *see also id.* ¶¶ 3, 72.  Fig.2

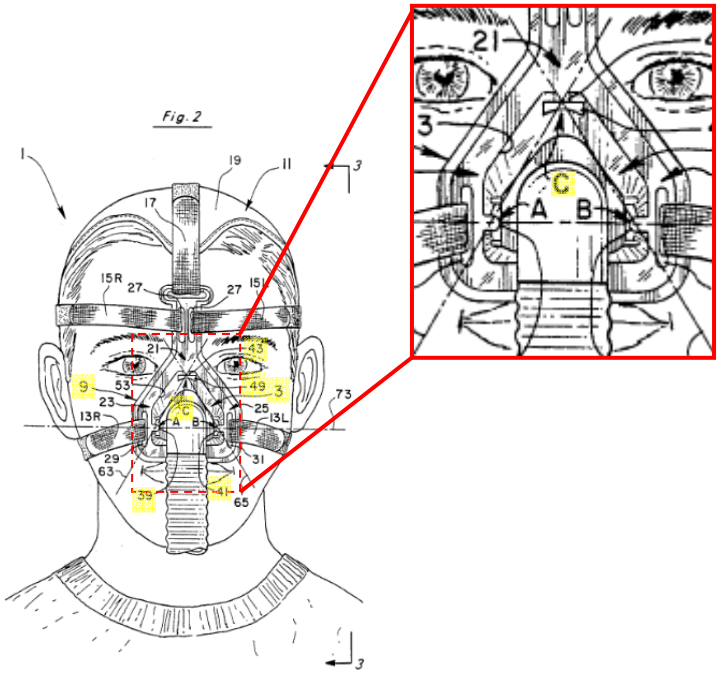
’931 Patent	Prior Art
	Ogden: “[L]ooping the straps 13R and 13L through the openings 29, 31 in the rigid plate 9 and fastening them back on themselves by hook and loop materials on the straps themselves. . . . The remaining straps 15R, 15L, and 17 are also individually attachable in this manner . . . . 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. 1529 at col. 3:10–24.  **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. 1514 at col. 6:30–34.

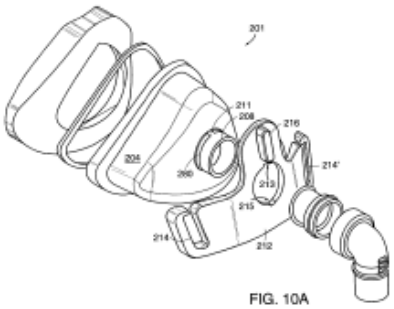
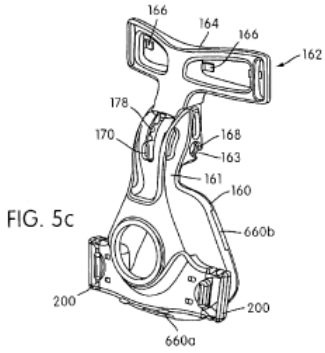
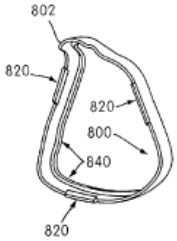
’931 Patent	Prior Art
21. The mask system of claim 19, wherein the rear straps and the top straps form a closed loop to encircle a rear portion of the patient's head when in use.	**FlexiFit:** Ex. 1517 at 10.  **Gunaratnam-II:** “The upper strap 98 and rear strap 100 are removably connected to the side straps 96 by buckles 102 provided on the side straps 96.” Ex. 1519 ¶ 211.  FIG. 18

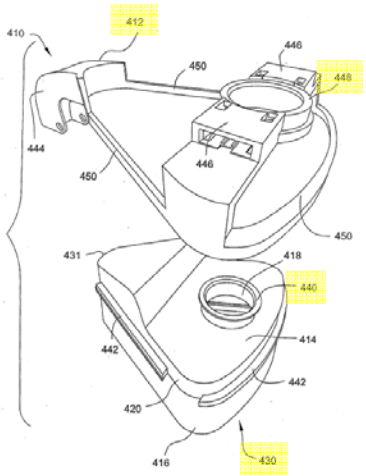
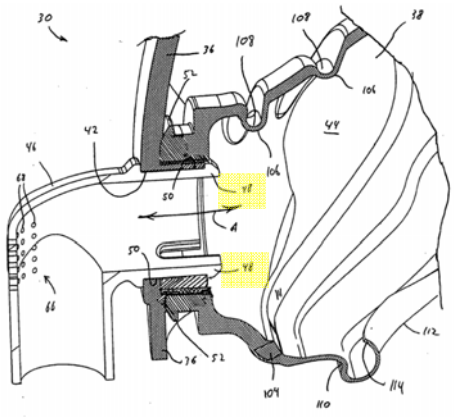
’931 Patent	Prior Art
	“The rear portion 394, which interconnects the two side portions 392, includes an upper strap 398 that passes over the top of the patient's head and a rear strap 399 that passes around the rear portion of the patient's head.” *Id.* ¶ 263 and Figs. 38 and 135.  FIG 38  FIG.135 **Amarasinghe:** “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. 1530 ¶ 12.  FIG. 1 (PRIOR ART) FIG. 2 (PRIOR ART)

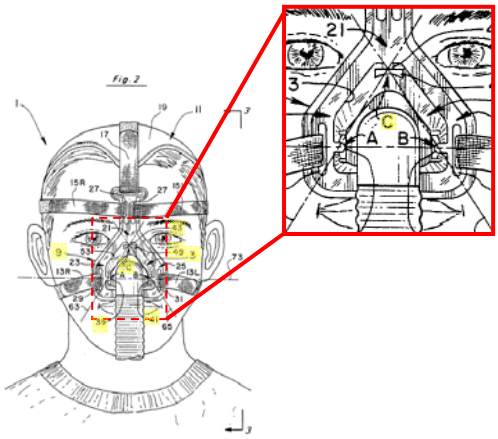
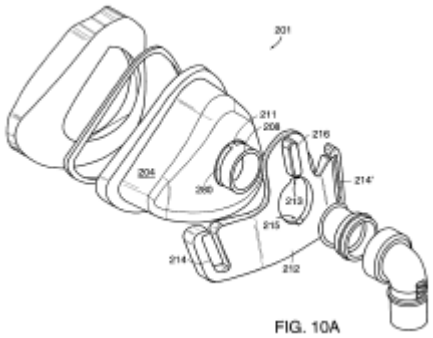
’931 Patent	Prior Art
22. The mask system of claim 19, **[A]** wherein the frame includes a frame opening leading to the breathing chamber, and wherein the front opening of the shroud module and the frame opening of the frame are aligned along a common longitudinal axis,	*See supra* Claim 1[C]. **D’Souza:** “[A]nnular elbow connection seal 448 interlocks with the annular wall 440.” Ex. 1510 ¶ 101.  Fig. 7

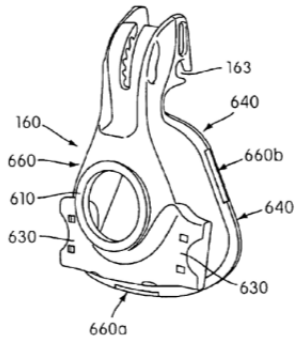
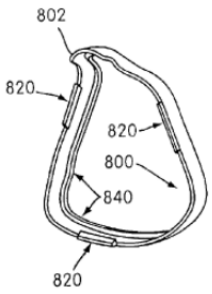
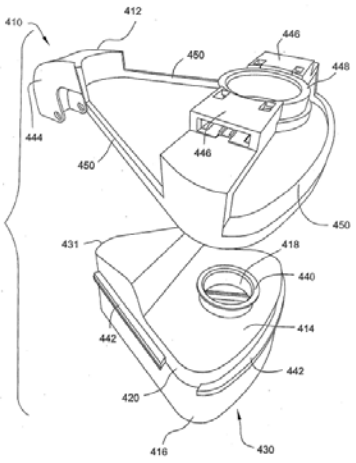
’931 Patent	Prior Art
[B] and wherein the shroud module and the cushion module are removably snap-fit attached to one another by moving the shroud module and the cushion module towards one another along the longitudinal axis.	**D’Souza:** “[S]keleton frame 412 that is adapted to removably interlock with a cushion/frame sub-assembly 430.” Ex. 1510 ¶ 96. “[A]nnular elbow connection seal 448 interlocks with the annular wall 440.” *Id.* ¶ 101.  Fig. 7 **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

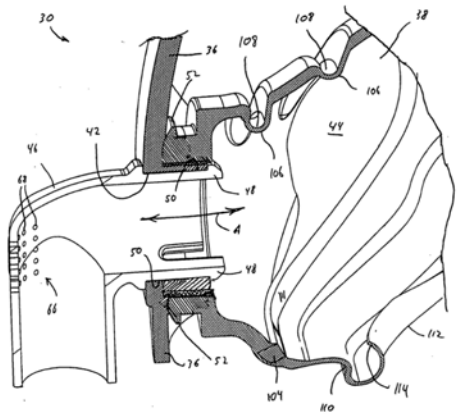
’931 Patent	Prior Art
	Ogden: “[R]igid plate 9 is preferably mounted to the rigid shell 3 at first, second, and third locations A, B, and C. . . . Further, although the detent-channel 43, 49 at the top of the shell 3 at the third location C is preferably dimensioned to snap together to hold or maintain the rigid plate 9 on the rigid shell 3.” Ex. 1529 at col. 4:59–5:19. 

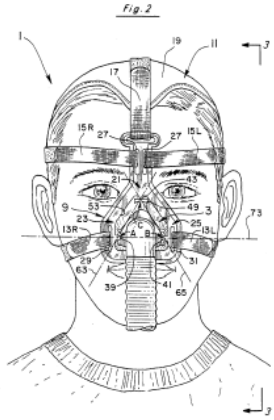
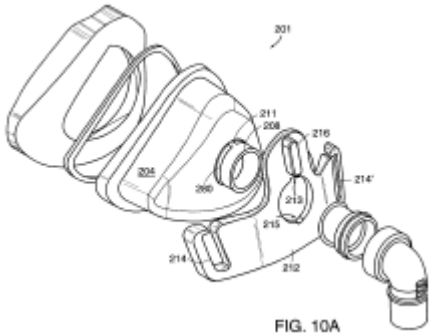
’931 Patent	Prior Art
	Lovell: “The retainer 212 is disposed about the inlet 208 to facilitate retention of the mask 201 on a user. . . . Two tabs 211, 211′ included on the inlet 208 mate with two slots 213, 215 formed in the retainer 212 in a particular angular orientation. . . . The retainer aperture 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; *see also id.* at 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. 1524 at col. 5:34–43.  FIG. 5c  FIG. 7a

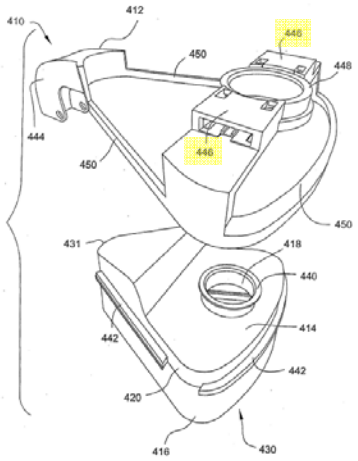
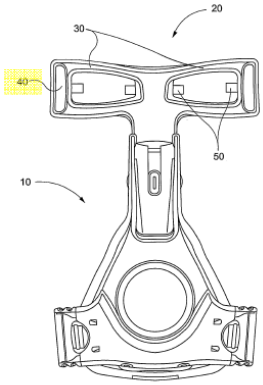
’931 Patent	Prior Art
25. The mask system of claim 19, wherein the frame is rigid.	**D’Souza:** “[F]rame 414 is constructed of polycarbonate.” Ex. 1510 ¶ 98.
26. The mask system of claim 1, wherein the second opening of the shroud module and the frame opening of the frame are aligned along a common longitudinal axis, and 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]. **D’Souza:** “[S]keleton frame 412 that is adapted to removably interlock with a cushion/frame sub-assembly 430.” *Id.* ¶ 96. “[A]nnular elbow connection seal 448 interlocks with the annular wall 440.” *Id.* ¶ 101.  Fig. 7 **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

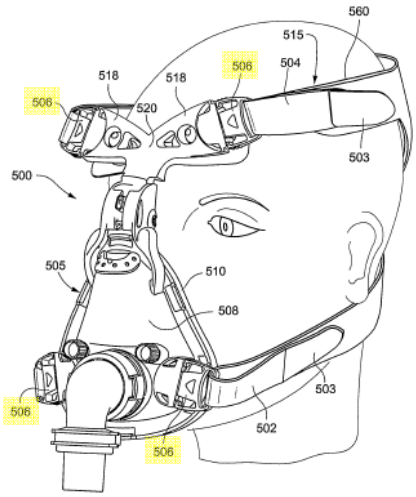
’931 Patent	Prior Art
	Ogden: “[R]igid plate 9 is preferably mounted to the rigid shell 3 at first, second, and third locations A, B, and C. . . . Further, although the detent-channel 43, 49 at the top of the shell 3 at the third location C is preferably dimensioned to snap together to hold or maintain the rigid plate 9 on the rigid shell 3.” Ex. 1529 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. 1514 at col. 9:43–48; *see also id.* at 9:59–64.  FIG. 10A

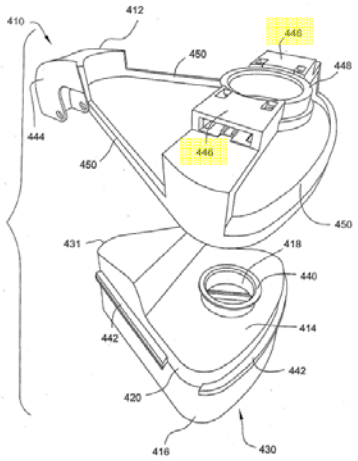
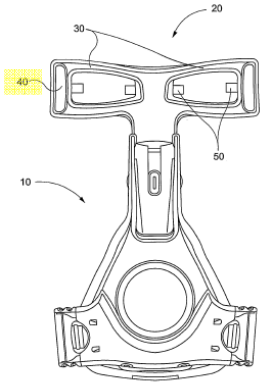
’931 Patent	Prior Art
	Gunaratnam-I: “[T]he clip (800) includes three securing tabs (820) such that inwards projections on the detents are formed as resilient detents which extend past the outer edge of flange (640) to be retained in recesses (660) on the front of the flange (640). To disengage, for 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. 1524 at col. 5:34–43.  FIG. 5a  FIG. 7a
28. The mask system of claim 1, wherein: the frame includes a collar surrounding said frame opening, and wherein the shroud includes a retaining portion with at least one snap finger structured to engage the collar with a snap-fit,	*See supra* Claim 5. **D’Souza:** “[A]nnular wall 440 surrounds the opening 418 [of the frame 414].” Ex. 1510 ¶ 98.  Fig. 7

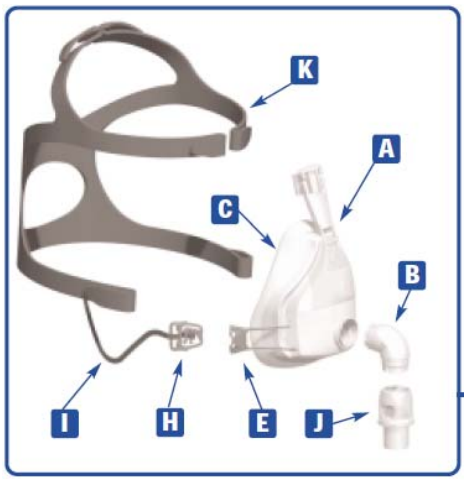
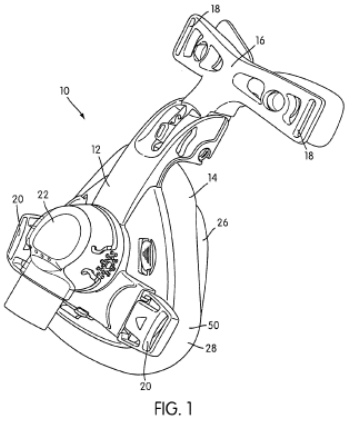
’931 Patent	Prior Art
	Matula-II: “Coupling member 46 includes a pair of prongs 48 that define a channel 50 to receive the wall of the faceplate and the end of seal member 38. In an exemplary embodiment, the end of seal member 38 is joined to a ring 52 that is more rigid than the end of the seal member to provide a strong, stable mechanical coupling of the seal member to the faceplate.” Ex. 1512 ¶ 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

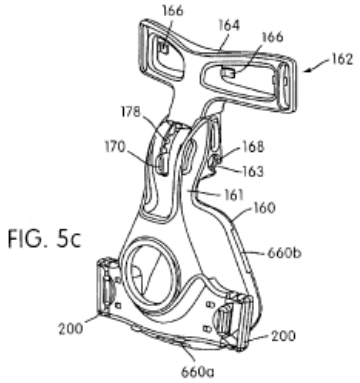
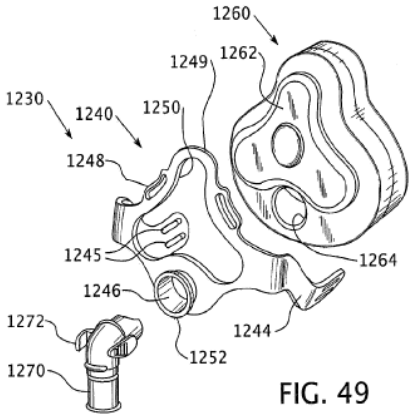
’931 Patent	Prior Art
	Ogden: “[R]igid plate 9 is preferably mounted to the rigid shell 3 at first, second, and third locations A, B, and C. . . . Further, although the detent-channel 43, 49 at the top of the shell 3 at the third location C is preferably dimensioned to snap together to hold or maintain the rigid plate 9 on the rigid shell 3.” Ex. 1529 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. 1514 at col. 9:43–48; *see also id.* at col. 9:59–64.  FIG. 10A

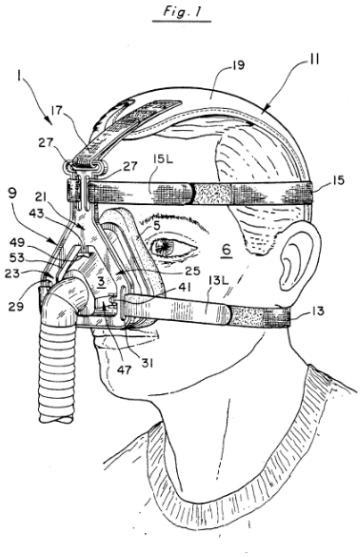
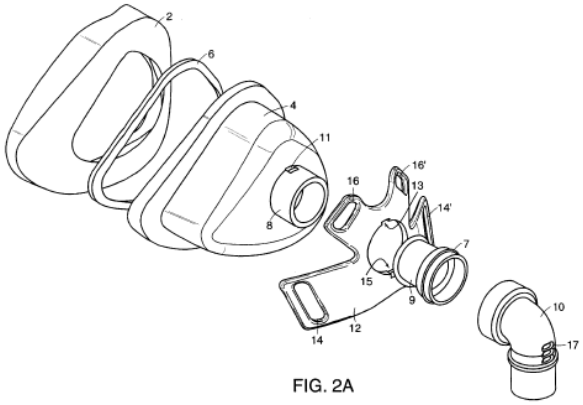
’931 Patent	Prior Art
the shroud module includes upper and lower headgear connectors on each side of the shroud module,	*See supra* Claim 6. **D’Souza:** “[S]keleton frame 412 includes an upper support member 444 adapted to support a forehead support, lower headgear clip receptacles 446.” Ex. 1510 ¶ 100.  Fig. 7 **Hitchcock:** “A prior art mask assembly 10 such as ResMed's ULTRA MIRAGE® mask as shown in Fig. 1 includes a forehead support 20 having a pair of arms 30, each having a slot 40 adapted to receive a strap (not shown). Each arm 30 includes a pair of forehead pad receiving lugs 50. The forehead support has a general "T"-shape, with the arms arranged along the upper cross portion of the "T".” Ex. 1511 ¶ 24.  Fig. 1 Prior Art

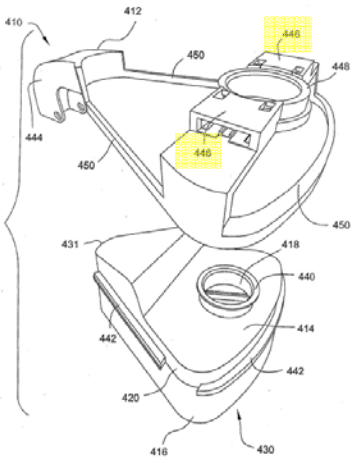
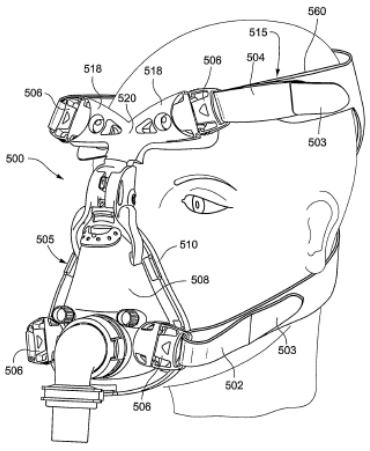
’931 Patent	Prior Art
	“In the illustrated embodiment, the upper side straps 504 are removably connected to respective arms 518 of the Y-shaped forehead support 520 via clips 506, which operate in a manner similar to the clips described above. Also, the lower side straps 502 are removably connected to a lower portion of the mask frame 508 via clips 506.” *Id.* ¶ 38.  Fig. 8 **Ultra Mirage:** “Quick release headgear clips: top and bottom allows mask to be removed without resetting the headgear and provides convenience and safety.” Ex. 1516 at 6.

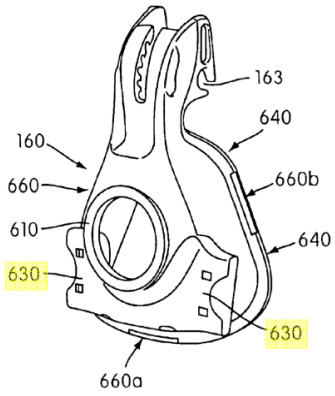
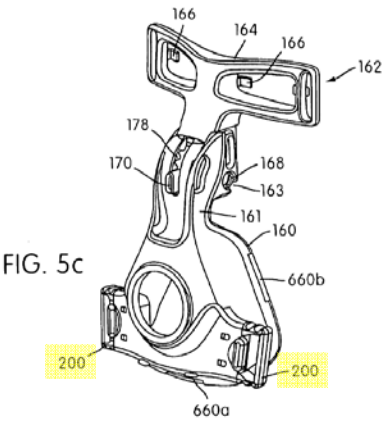
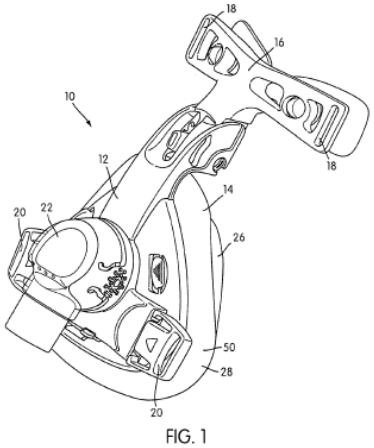
’931 Patent	Prior Art
each upper headgear connector includes a slot adapted to receive a respective headgear strap in use,	*See supra* Claim 7. **D’Souza:** “[S]keleton frame 412 includes an upper support member 444 adapted to support a forehead support, lower headgear clip receptacles 446.” Ex. 1510 ¶ 100.  Fig. 7 **Hitchcock:** “A prior art mask assembly 10 such as ResMed's ULTRA MIRAGE® mask as shown in Fig. 1 includes a forehead support 20 having a pair of arms 30, each having a slot 40 adapted to receive a strap (not shown). Each arm 30 includes a pair of forehead pad receiving lugs 50. The forehead support has a general "T"-shape, with the arms arranged along the upper cross portion of the "T".” Ex. 1511 ¶ 24.  Fig. 1 Prior Art

’931 Patent	Prior Art
	FlexiFit: “[A]ttach the four straps in to the corresponding slots in the Mask Base.” Ex. 1517 at 10 (“ASSEMBLING YOUR MASK”).  **Lithgow:** *See* Ex. 1534 at Fig. 1.  FIG. 1

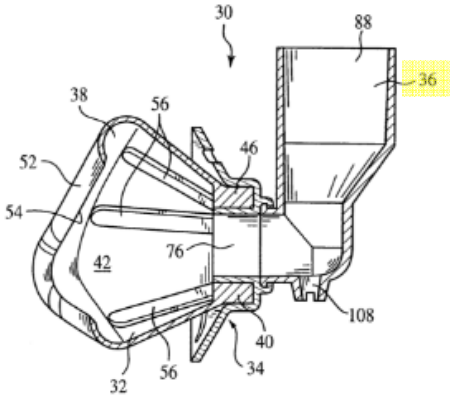
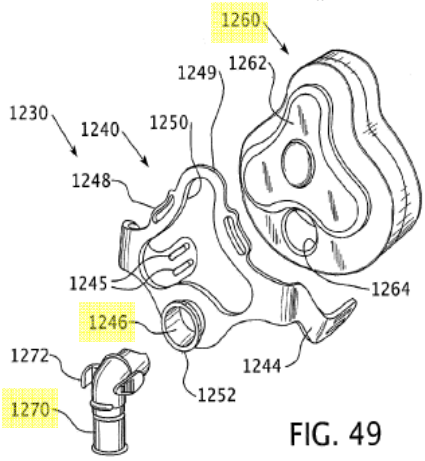
’931 Patent	Prior Art
	Gunaratnam-I: “As compared to FIGS. 5a-5b, FIGS. 5c-5f also show an adjustable forehead support (162) connected to the frame (160).” Ex. 1524 at col. 4:46–48.  FIG. 5c **Matula-I:** “[A]ttachment elements 1248 are provided in the form of slots provided . . . [o]n a central portion 1249 of the body member.” Ex. 1523 ¶ 103.  FIG. 49

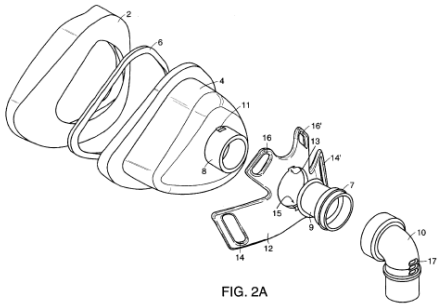
’931 Patent	Prior Art
	Ogden: “The upper side straps in this last regard could be the two straps 15R and 15L as illustrated or one continuous strap passing through loops 27 and anchoring the top portion 21 of the rigid plate 9 (see FIGS. 1-3).” Ex. 1529 at col. 3:7–10.  **Lovell:** “These connection 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. 1514 at col. 6:10–13.  FIG. 2A

’931 Patent	Prior Art
each lower headgear connector is adapted to be removably interlocked with a headgear clip associated with a respective headgear strap,	*See supra* Claim 8. **D’Souza:** “[L]ower headgear clip receptacles 446 adapted to be engaged with clips provided to straps of a headgear assembly (not shown).” Ex. 1510 ¶ 100.  Fig. 7 **Hitchcock:** “In the illustrated embodiment, the upper side straps 504 are removably connected to respective arms 518 of the Y-shaped forehead support 520 via clips 506, which operate in a manner similar to the clips described above. Also, the lower side straps 502 are removably connected to a lower portion of the mask frame 508 via clips 506.” Ex. 1511 ¶ 38.  Fig. 8

’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. 1524 at col. 4:31–33.  FIG. 5a  FIG. 5c **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. 1534 ¶ 111.  FIG. 1 **Ultra Mirage:** “Quick release headgear clips: top and bottom.” Ex. 1516 at 6.

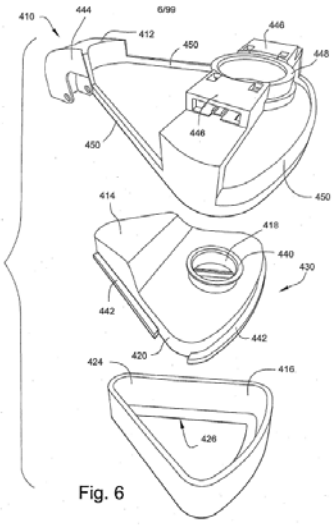
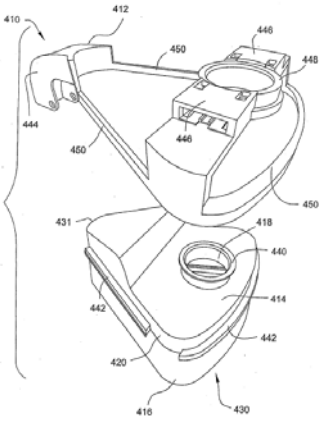
'931 Patent	Prior Art
the mask assembly further comprises an elbow module adapted to be connected to an air delivery tube that delivers breathable gas to the patient, and	*See supra* Claim 11. **D'Souza:** "[S]keleton frame 412 includes . . . an annular elbow connection seal 448 adapted to engage an inlet conduit, e.g., elbow." Ex. 1510 ¶ 100. **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. 1511 ¶ 28. **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. 1528 ¶ 316. **Ultra Mirage:** "360° rotating elbow provides control over tubing system." Ex. 1516 at 6.
the elbow module is rotatably attached to the shroud module while allowing 360 degree rotation of the elbow module.	*See supra* Claim 14. **D'Souza:** "[S]keleton frame 412 includes . . . an annular elbow connection seal 448 adapted to engage an inlet conduit, e.g., elbow." Ex. 1510 ¶ 100. "[S]keleton frame 412 . . . provides attachment points for . . . an inlet conduit." *Id.* ¶ 101.

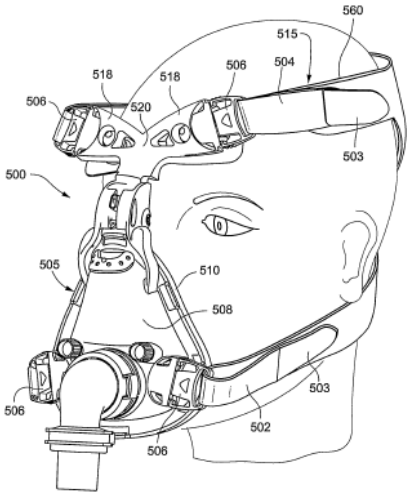
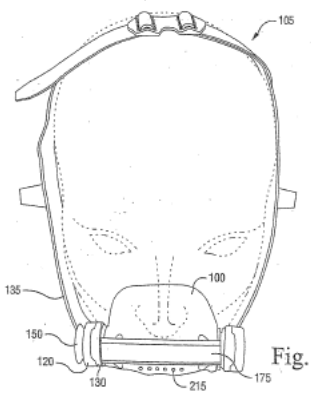
’931 Patent	Prior Art
	Barnett: “[C]onduit coupling member 36 is preferably rotateably mounted on a second side of collar 34 opposite the first side so that conduit coupling member 36 freely rotates over a range of 360° about a central axis of collar 34. . . .” Ex. 1513 at col. 3:52–57; *see also id.* 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. 1523 ¶ 105.  FIG. 49

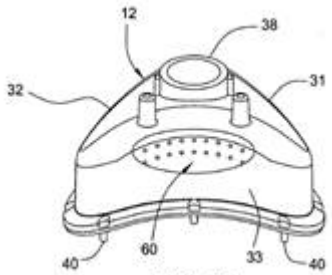
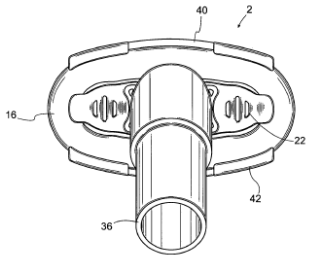
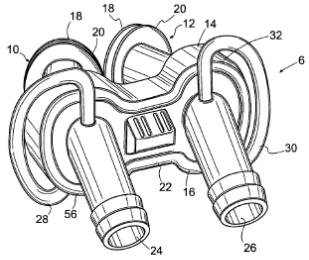
’931 Patent	Prior Art
	Lovell: “[S]wivel connector 9 produces a swivel mount connection between the conduit elbow 10 and the inlet 8. In this type of connection, the conduit elbow 10 is capable of rotating 360 degrees about the centerline of the inlet 8 and the connector 9.” Ex. 1514 at col. 5:20–24.  FIG. 2A **Ultra Mirage:** “360° rotating elbow provides control over tubing system.” Ex. 1516 at 6.
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. **D’Souza:** “[C]ushion 416 is constructed of liquid silicone rubber (LSR).” Ex. 1510 ¶ 97. “[T]he frame 414 is constructed of polycarbonate.” *Id*. ¶ 98. “[T]he skeleton frame 412 is formed of plastic.” *Id.* ¶ 100. **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. 1524 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. 1514 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.

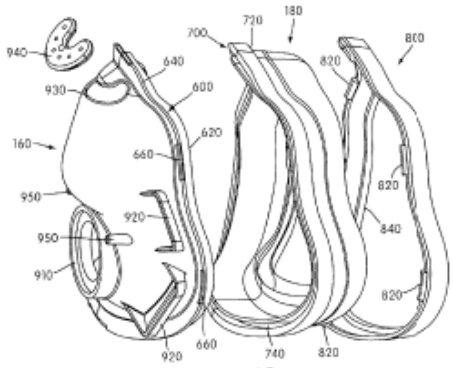
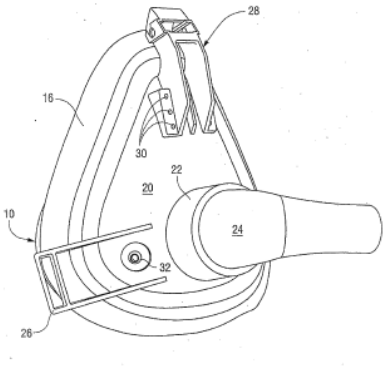
'931 Patent	Prior Art
	McAuley: "The hollow body 30 and insert 32 are injection moulded in a relatively inflexible material, for example, polycarbonate plastic. Such a material would provide the requisite rigidity for the mask as well as being transparent and a relatively good insulator." Ex. 1533 at 6:21–24. **Lithgow:** "The cushion 14 is constructed from a soft, flexible skin-compatible material such as silicone." Ex. 1534 ¶ 139.
30. The mask system of claim 28, wherein the frame is rigid.	*See supra* Claim 25. **D'Souza:** "[F]rame 414 is constructed of polycarbonate." Ex. 1510 ¶ 98.
31. The mask system of claim 1, wherein the frame is rigid.	*See supra* Claim 25. **D'Souza:** "[F]rame 414 is constructed of polycarbonate." Ex. 1510 ¶ 98.
32. A system for treating a patient with sleep disordered breathing, comprising: the mask system of claim 1; a flow generator to generate a supply of air at positive pressure to be delivered to the mask system; and	*See supra* Claim 1. **D'Souza:** "[M]ask assembl[ies] for use with blowers and flow generators in the treatment of sleep disordered breathing (SDB) . . . . [P]atient interface is held in a sealing position by headgear so as to enable a supply of air at positive pressure to be delivered to the patient's airways." Ex. 1510 ¶ 3.
an air delivery tube configured to deliver the supply of air from the flow generator to the mask system.	*See supra* Claim 11. **D'Souza:** "[S]keleton frame 412 includes . . . an annular elbow connection seal 448 adapted to engage an inlet conduit, e.g., elbow." Ex. 1510 ¶ 100. **Hitchcock:** "Frame 308 includes a front plate 312 including an aperture 314 adapted to receive pressurized

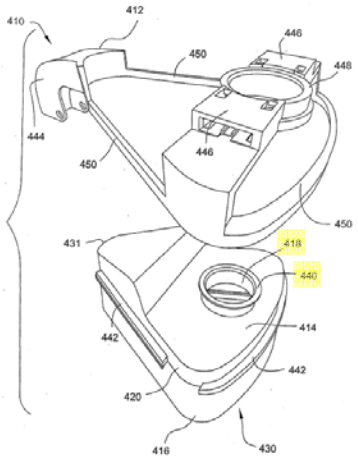
’931 Patent	Prior Art
	gas from an air delivery tube, e.g., via a swivel elbow." Ex. 1511 ¶ 28. **Thomlinson:** "In one embodiment, the present invention includes tubing 90, shown in FIGS. 26, 27, 29 and 35 through 38. Tubing 90 can supply gas to the nasal interface of the present invention." Ex. 1528 ¶ 316. **Ultra Mirage:** "360° rotating elbow provides control over tubing system." Ex. 1516 at 6.
43. A mask system for delivery of a supply of air at positive pressure to a patient's airway, the mask system comprising:	**D'Souza:** "[M]ask assembl[ies] for use with blowers and flow generators in the treatment of sleep disordered breathing (SDB) . . . . [P]atient interface is held in a sealing position by headgear so as to enable a supply of air at positive pressure to be delivered to the patient's airways." Ex. 1510 ¶ 3.

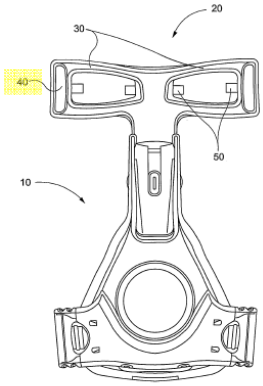
'931 Patent	Prior Art
[A] a cushion module comprising a frame defining a breathing chamber configured to receive the positive pressure air, and a cushion to form a seal with the patient's face in a nasal bridge region, a cheek region and a lower lip/chin region of the patient's face, wherein the cushion 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,	**D'Souza:** "[F]rame 414 and a cushion 416 are . . . interlocked to provide a cushion/frame sub-assembly 430. . . . [C]ushion 416 is constructed of liquid silicone rubber (LSR)." Ex. 1510 ¶ 97. "[F]rame 414 includes an upper wall that provides an opening 418 for communicating with an inlet conduit. . . . A side wall 420 extends from the upper wall . . . . [F]rame 414 is constructed of polycarbonate." *Id.* ¶ 98. "[C]ushion provides a seal around the patient's nose and mouth to enable the delivery of breathable gas to the patient's nose and mouth." *Id.* ¶ 81.  Fig. 6  Fig. 7

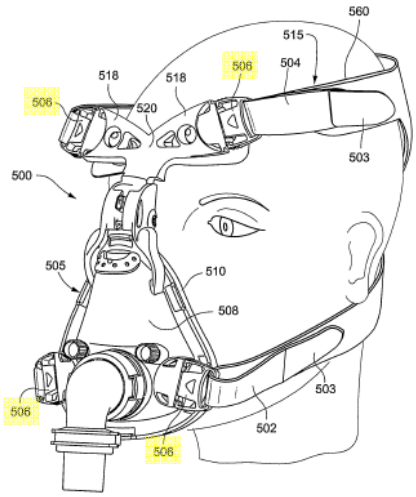
’931 Patent	Prior Art
[B] the frame including a washout vent,	*See supra* Claim 1[B]. **Hitchcock:** *See* Ex. 1511 at Fig. 8.  Fig. 8 **Ng:** “As shown in Figs. 3, 7-8, and 11, the mask assembly includes a gas washout vent 215. The vent 215 could be on the frame and/or the cushion component.” Ex. 1527 ¶ 43.  Fig. 11 **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. 1535 ¶ 35. “The vent holes are exit vent holes and are for venting the

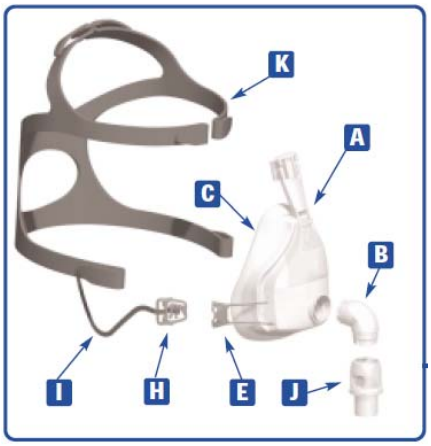
’931 Patent	Prior Art
	exhaled breath of a wearer of the mask 10. As shown in FIGS. 10 . . . the plurality or curved array of vent holes are indicated by general numerical designation 60 in FIGS. 10 and 11.” *Id.* ¶ 40.  FIG. 10 **<u>Thomlinson</u>:** “Further, and as shown in FIG. 3, one embodiment of a nasal interface can also include one or more exhalation portion 22, which are described in more detail below.” Ex. 1528 ¶ 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 the second inlet 26.” *Id*. ¶ 209.  Fig. 8

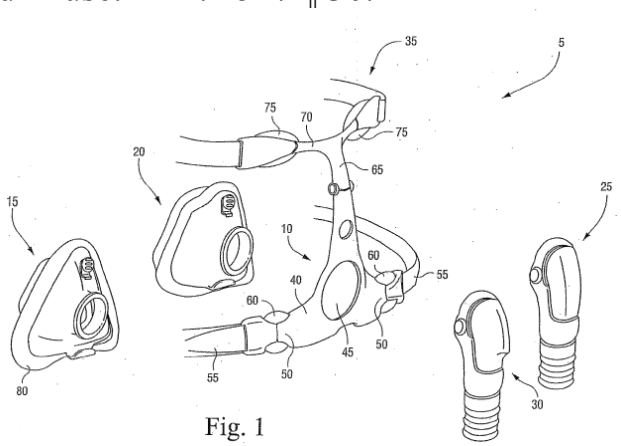
’931 Patent	Prior Art
	Gunaratnam-I: “The frame (160) is adapted to cover both the mouth and nose region of the patient's face, and includes a gas inlet aperture (910), connection points (920) for headgear straps, an aperture (930) for receiving an air vent (940) (FIG. 15) and ports (950).” Ex. 1524 6:25-29  FIG. 15 **Hitchcock-II:** “A number of vents 30 may be provided so as to allow gas exhaled by the patient to vent to atmosphere.” Ex. 1540 ¶ 42.  Fig. 1-2

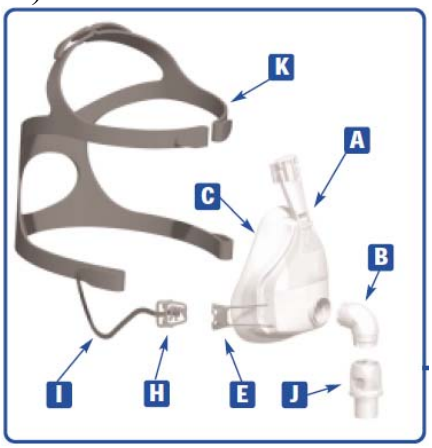
’931 Patent	Prior Art
[C] the frame including an opening;	**D’Souza:** “[A]nnular wall 440 surrounds the opening 418 [of the frame 414].” Ex. 1510 ¶ 98.  Fig. 7
[D] headgear to maintain the mask system in a desired position on the patient's face, the headgear comprising a pair of upper headgear straps 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]. **D’Souza:** “[P]atient interface is held in a sealing position by headgear.” Ex. 1510 ¶ 3. “[S]keleton frame 412 includes an upper support member 444 adapted to support a forehead support, lower headgear clip receptacles 446 adapted to be engaged with clips provided to straps of a headgear assembly (not shown).” *Id.* ¶ 100.

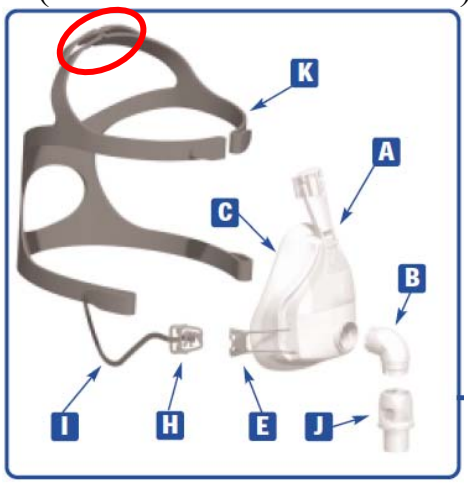
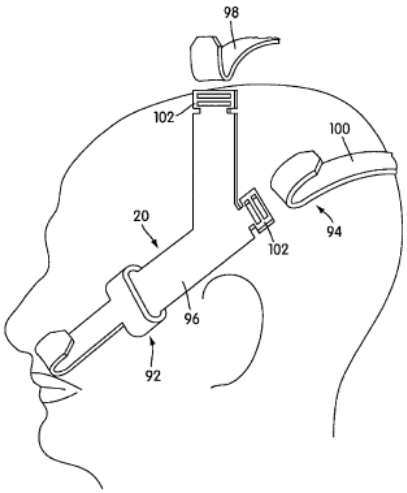
’931 Patent	Prior Art
	Hitchcock: “A prior art mask assembly 10 such as ResMed's ULTRA MIRAGE® mask as shown in Fig. 1 includes a forehead support 20 having a pair of arms 30, each having a slot 40 adapted to receive a strap (not shown). Each arm 30 includes a pair of forehead pad receiving lugs 50. The forehead support has a general "T"-shape, with the arms arranged along the upper cross portion of the "T".” Ex. 1511 ¶ 24.  Fig. 1 Prior Art

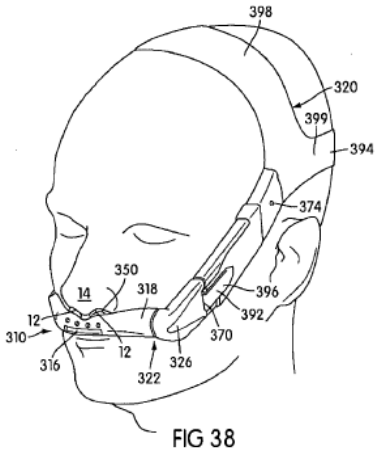
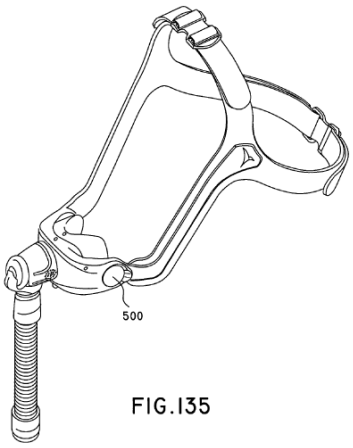
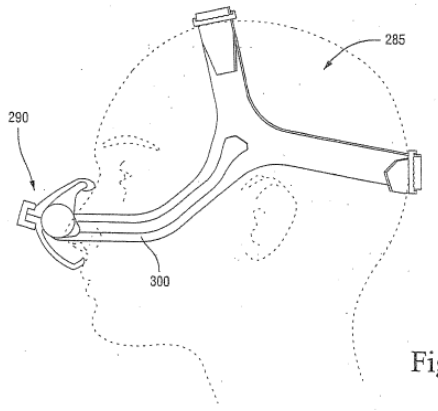
’931 Patent	Prior Art
	“In the illustrated embodiment, the upper side straps 504 are removably connected to respective arms 518 of the Y-shaped forehead support 520 via clips 506, which operate in a manner similar to the clips described above. Also, the lower side straps 502 are removably connected to a lower portion of the mask frame 508 via clips 506.” *Id.* ¶ 38.  Fig. 8

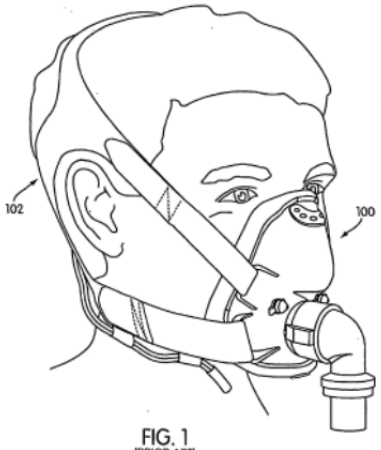
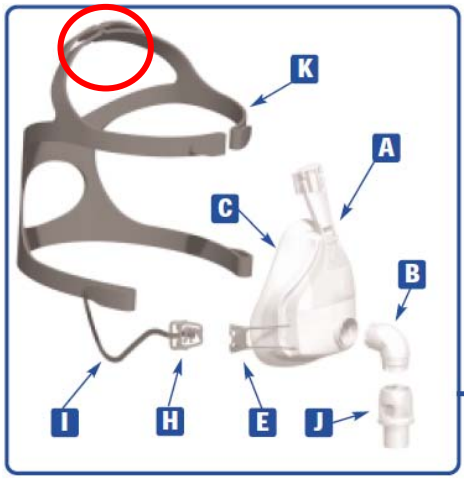
’931 Patent	Prior Art
	FlexiFit: “2) Unclip the Headgear (K) from the Glider™ strap (E) . . . . 4) Re-attach the Headgear Clip (H) to the Glider™ Strap. 5) Gently adjust the Top Horizontal straps then the Lower Horizontal straps.” Ex. 1517 at 10 (“FITTING YOUR MASK”). “[A]ttach the four straps in to the corresponding slots in the Mask Base and the Glider™ strap (E).” *Id.* at 10 (“ASSEMBLING YOUR MASK”).  

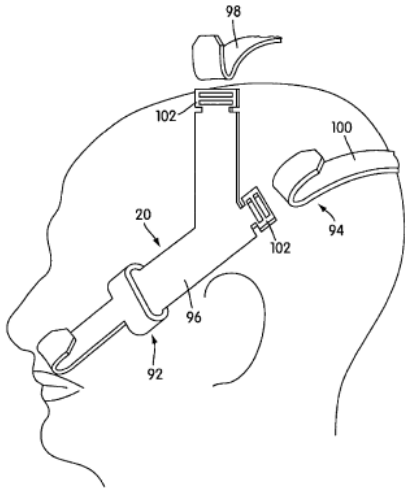
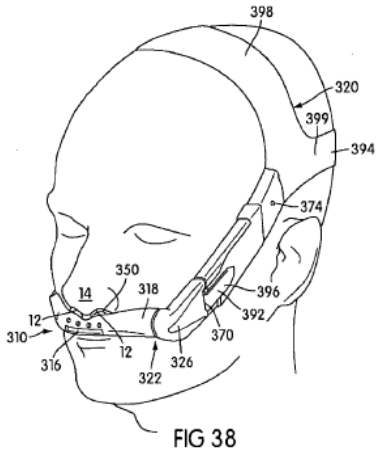
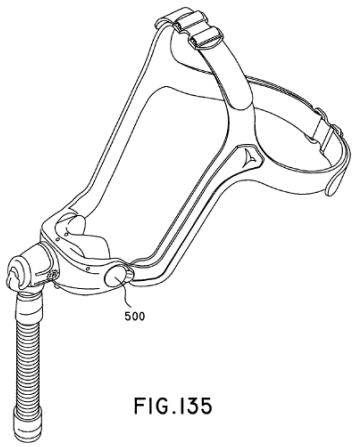
’931 Patent	Prior Art
	Ng: “The common frame 10 has a main body 40 defining a central opening 45. Main body 40 includes at least two lateral arms 50, each of which can be coupled to a headgear strap 55 of headgear. The straps may be connected to the frame using a press-fit connector 60, as is known in 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. 1527 ¶ 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 lower straps in place in a length adjustable manner,	*See supra* Claim 19[B]. **Hitchcock**: “The free end of each of the upper and lower side straps 504, 502 includes a strip of Velcro® material 503 for use in securing each of the straps 504, 502 to a respective clip 506.” Ex. 1511 ¶ 38. **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. 1517 at 10 (“FITTING YOUR MASK”).

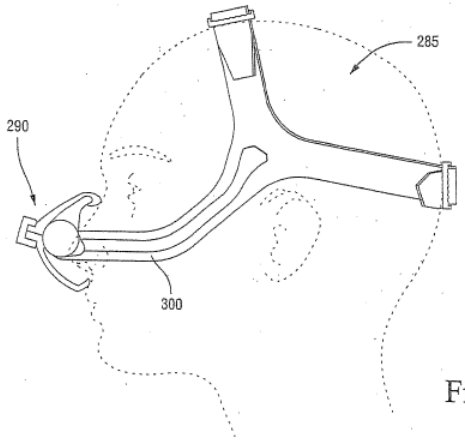
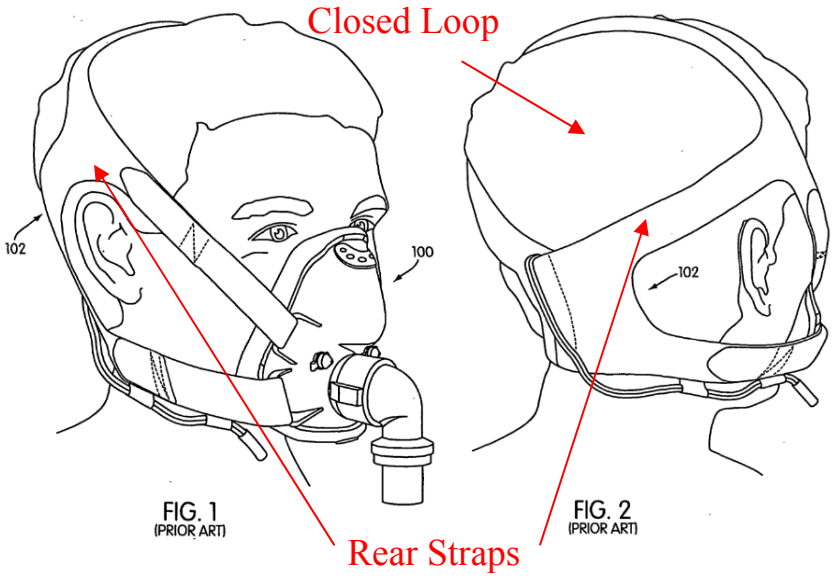
’931 Patent	Prior Art
	“[A]ttach the four straps in to the corresponding slots in the Mask Base and the Glider™ strap (E). This can be done without undoing the Velcro® Tabs by sliding the Headgear into the slots.” *Id.* at 10 (“ASSEMBLING YOUR MASK”).  **Ogden:** “[E]ach side strap 13R and 13L is preferably 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. 1529 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. 1530 ¶ 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 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. 1514 at col. 7:6–13.

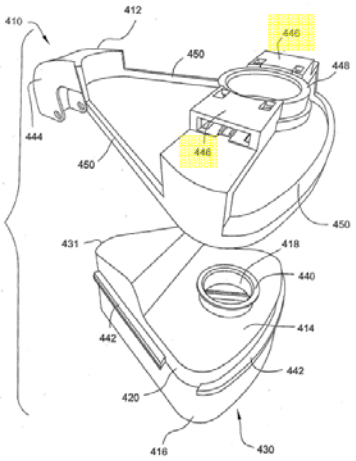
’931 Patent	Prior Art
[F] wherein the headgear includes a pair of top straps and a pair of rear straps, each said top strap being configured to extend from generally above a respective ear of the patient such that the top straps cross over the top of the patient's head in use, the rear straps being adapted to pass behind the patient's head in use, and	*See supra* Claim 19[C] and [D]. **FlexiFit:** “Gently adjust . . . Top Crown straps.” Ex. 1517 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. 1519 ¶ 211.  FIG. 18

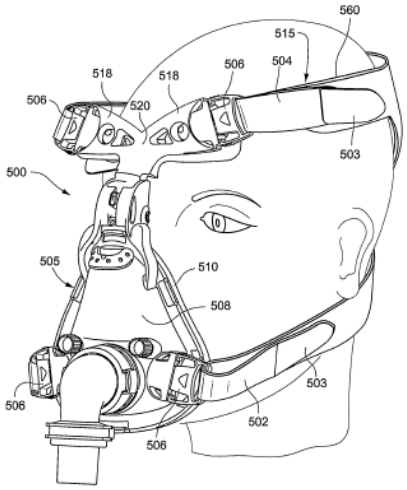
’931 Patent	Prior Art
	“The rear portion 394, which interconnects the two side portions 392, includes an upper strap 398 that passes over the top of the patient's head and a rear strap 399 that passes around the rear portion of the patient's head.” *Id.* ¶ 263 and Figs. 38 and 135.  FIG 38  FIG.135 **Ng**: “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. 1527 ¶ 46.  Fig. 16

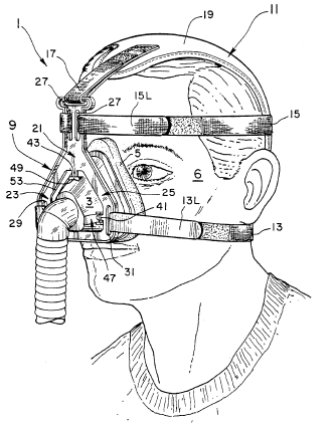
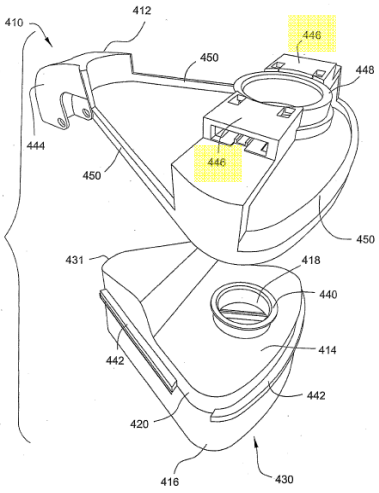
’931 Patent	Prior Art
	Amarasinghe: “The headgear similarly comprises a pair of upper (104) and a pair of lower straps (106) and a generally triangular back portion (108).” Ex. 1530 ¶ 14, Fig. 1.  FIG. 1 (PRIOR ART)
[G] wherein the rear straps and the top straps together at least partly form a closed loop to encircle a rear portion of the patient's head when in use;	*See supra* Claim 21. **FlexiFit:** Ex. 1517 at 10. 

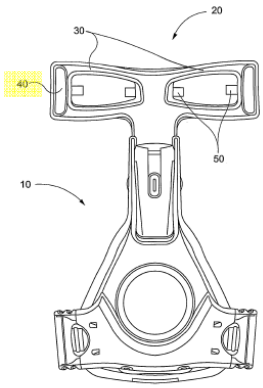
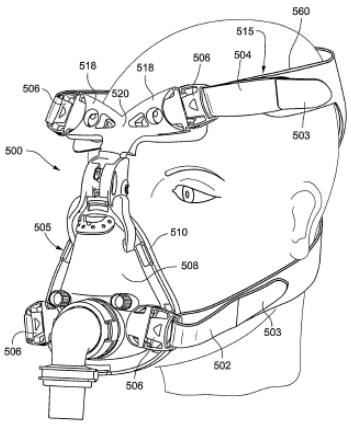
'931 Patent	Prior Art
	Gunaratnam-II: "[U]pper strap 98 and rear strap 100 are removably connected to the side straps 96 by buckles 102 provided on the side straps 96." Ex. 1519 ¶ 211.  FIG. 18 "[R]ear portion 394, which interconnects the two side portions 392, includes an upper strap 398 that passes 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

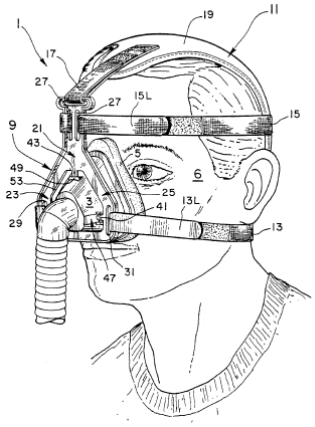
’931 Patent	Prior Art
	Ng: “Further, as shown in Fig. 16, the vectors formed by the headgear straps 300 are slightly different than as shown in described in relation to Fig. 13.” Ex. 1527 ¶ 46.  Fig. 16 **Amarasinghe:** “Another known patient interface is the MIRAGE® nasal mask (by ResMed Ltd). This 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. 1530 ¶ 12. 

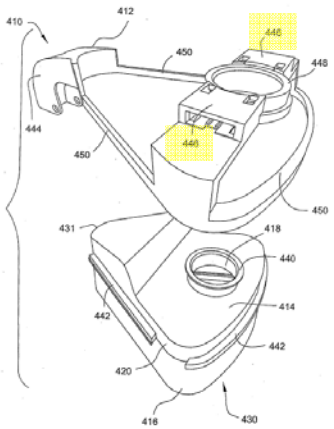
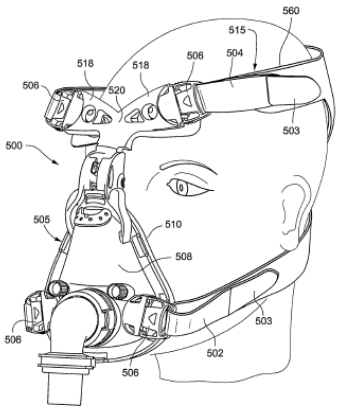
’931 Patent	Prior Art
[H] a shroud module including headgear connectors adapted to removably attach to the headgear,	*See supra* Claim 1(i). **D’Souza:** “[S]keleton frame 412 includes . . . lower headgear clip receptacles 446 adapted to be engaged with clips provided to straps of the headgear assembly (not shown).” Ex. 1510 ¶ 100.  Fig. 7

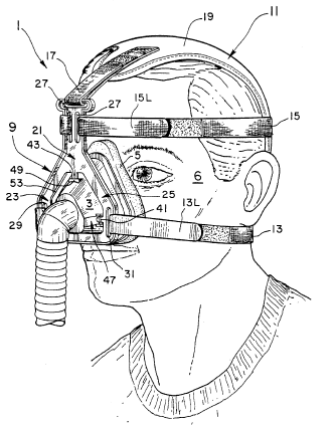
’931 Patent	Prior Art
	Hitchcock: “[E]ach arm includes a slot arrangement 140 adapted to receive a forehead support clip 150. Each forehead support clip 150 is in turn adapted to engage with a forehead support strap 160.” Ex. 1511 ¶ 25. “In the illustrated embodiment, the upper side straps 504 are removably connected to respective arms 518 of the Y-shaped forehead support 520 via clips 506, which operate in a manner similar to the clips described above. Also, the lower side straps 502 are removably connected to a lower portion of the mask frame 508 via clips 506.” *Id.* ¶ 38.  Fig. 8 **Ultra Mirage:** “Quick release headgear clips: top and bottom allows mask to be removed without resetting the headgear and provides convenience and safety.” Ex. 1516 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,

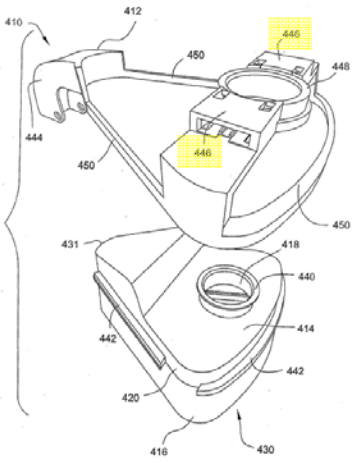
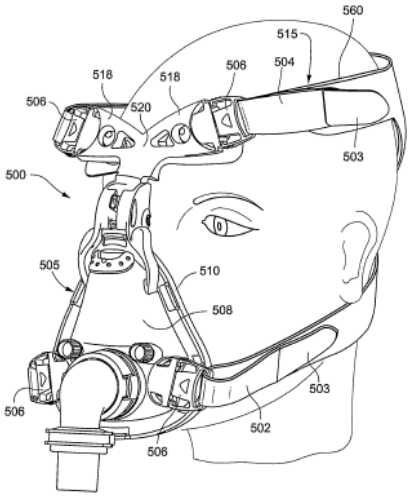
’931 Patent	Prior Art
	and 17 are also individually attachable in this manner.” Ex. 1529 at col. 3:10–20. Fig. 1 
[I] wherein the headgear connectors include two upper connectors associated with the upper headgear straps,	*See supra* Claim 6. **D’Souza:** “[S]keleton frame 412 includes an upper support member 444 adapted to support a forehead support, lower headgear clip receptacles 446.” Ex. 1510 ¶ 100.  Fig. 7

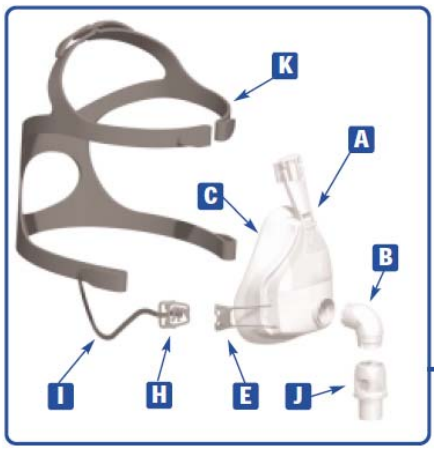
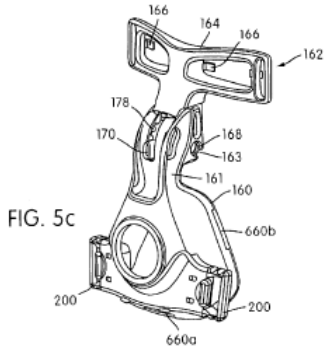
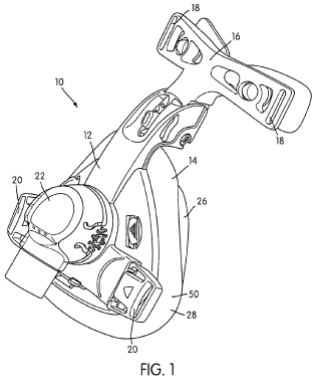
’931 Patent	Prior Art
	Hitchcock: “A prior art mask assembly 10 such as ResMed's ULTRA MIRAGE® mask as shown in Fig. 1 includes a forehead support 20 having a pair of arms 30, each having a slot 40 adapted to receive a strap (not shown). Each arm 30 includes a pair of forehead pad receiving lugs 50. The forehead support has a general "T"-shape, with the arms arranged along the upper cross portion of the "T".” Ex. 1511 ¶ 24.  Fig. 1 Prior Art “In the illustrated embodiment, the upper side straps 504 are removably connected to respective arms 518 of the Y-shaped forehead support 520 via clips 506, which operate in a manner similar to the clips described above. Also, the lower side straps 502 are removably connected to a lower portion of the mask frame 508 via clips 506.” *Id.* ¶ 38.  Fig. 8

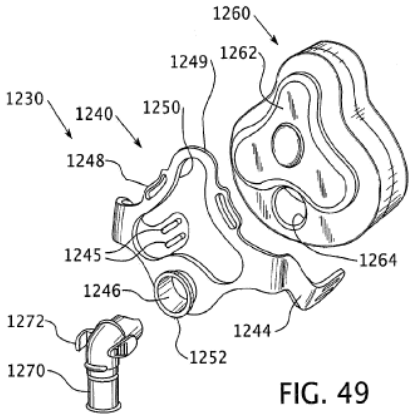
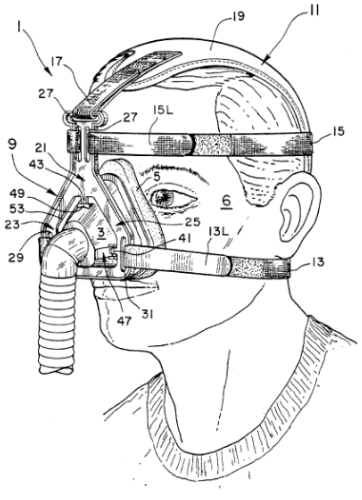
’931 Patent	Prior Art
	Ultra Mirage: “Quick release headgear clips: top and bottom allows mask to be removed without resetting the headgear and provides convenience and safety.” Ex. 1516 at 6. **Ogden:** “[E]ach side strap 13R and 13L is preferably attached to a respective side portion 23, 25 of the 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. 1529 at col. 3:10–20. Fig. 1 

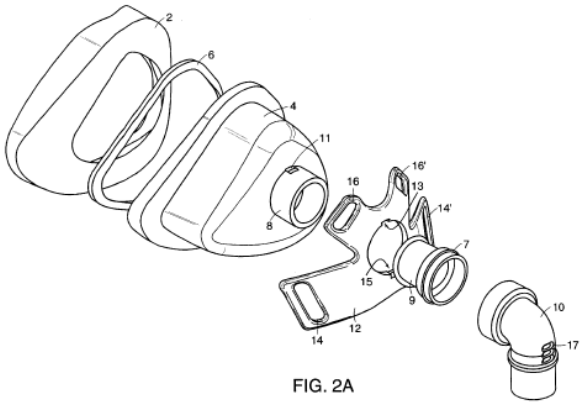
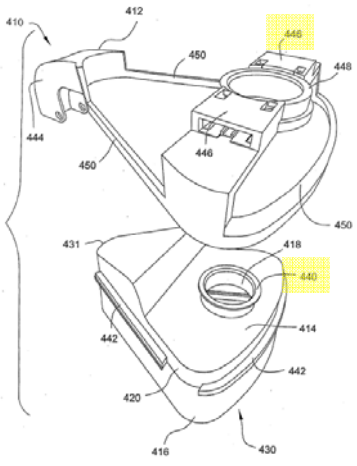
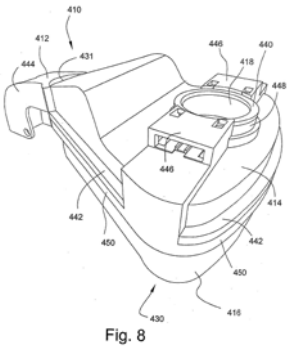
’931 Patent	Prior Art
[J] the shroud module having an opening of circular shape, and two lower connectors associated with the lower headgear straps,	*See supra* Claims 6 and 10. **D’Souza:** “[S]keleton frame 412 includes an upper support member 444 adapted to support a forehead support, lower headgear clip receptacles 446 . . . .” Ex. 1510 ¶ 100. “[A]nnular elbow connection seal 448 interlocks with the annular wall 440 of the cushion/frame sub-assembly 430. *Id.* ¶ 101, Fig. 7.  Fig. 7 **Hitchcock:** “In the illustrated embodiment, the upper side straps 504 are removably connected to respective arms 518 of the Y-shaped forehead support 520 via clips 506, which operate in a manner similar to the clips described above. Also, the lower side straps 502 are removably connected to a lower portion of the mask frame 508 via clips 506.” Ex. 1511 ¶ 38.  Fig. 8

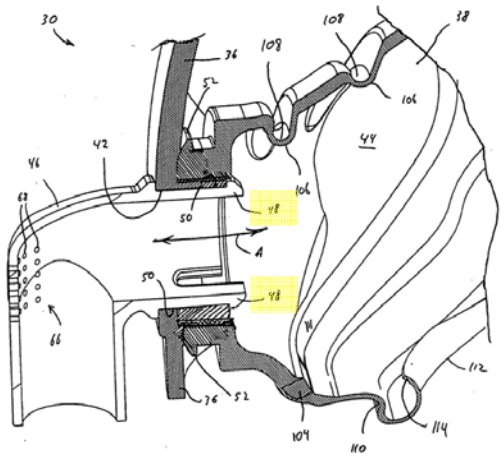
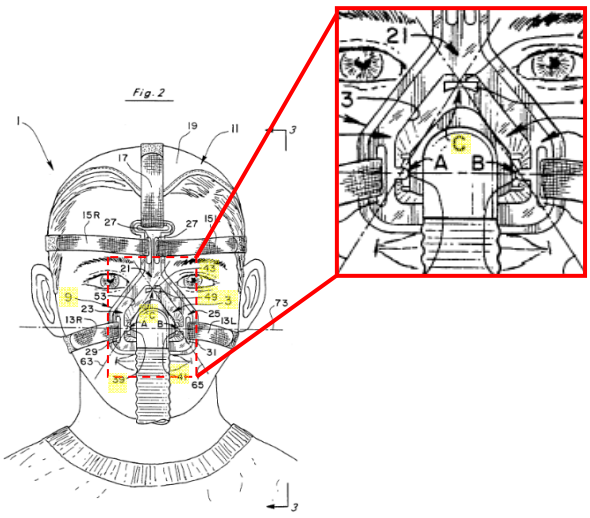
’931 Patent	Prior Art
	Ultra Mirage: “Quick release headgear clips: top and bottom allows mask to be removed without resetting the headgear and provides convenience and safety.” Ex. 1516 at 6. **Ogden:** “[E]ach side strap 13R and 13L is preferably attached to a respective side portion 23, 25 of the 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. 1529 at col. 3:10–20. Fig. 1 

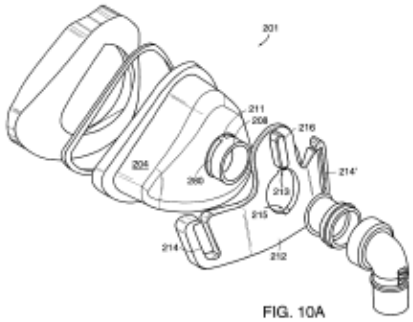
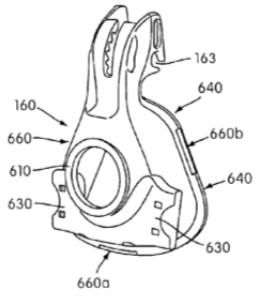
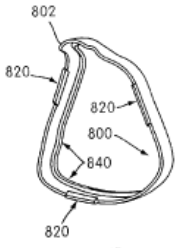
’931 Patent	Prior Art
[K] each said upper headgear connector including a slot or receiving hole adapted to receive one of the upper headgear straps,	*See supra* Claim 7. **D’Souza:** “[L]ower headgear clip receptacles 446 adapted to be engaged with clips provided to straps of a headgear assembly (not shown).” Ex. 1510 ¶ 100.  Fig. 7 **Hitchcock:** “[T]he lower side straps 502 are removably connected to a lower portion of the mask frame 508 via clips 506.” Ex. 1511 ¶ 38.  Fig. 8

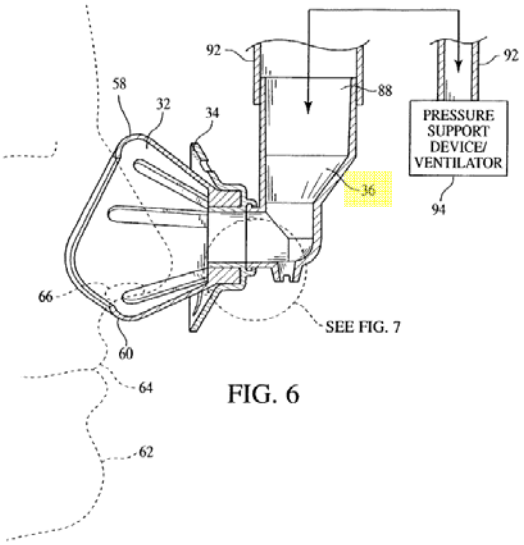
’931 Patent	Prior Art
	FlexiFit: “[A]ttach the four straps in to the corresponding slots in the Mask Base.” Ex. 1517 at 10 (“ASSEMBLING YOUR MASK”).  **Gunaratnam-I:** “As compared to FIGS. 5a-5b, FIGS. 5c-5f also show an adjustable forehead support (162) connected to the frame (160).” Ex. 1524 at col. 4:46–48.  FIG. 5c **Lithgow:** *See* Ex. 1534 at Fig. 1.  FIG. 1

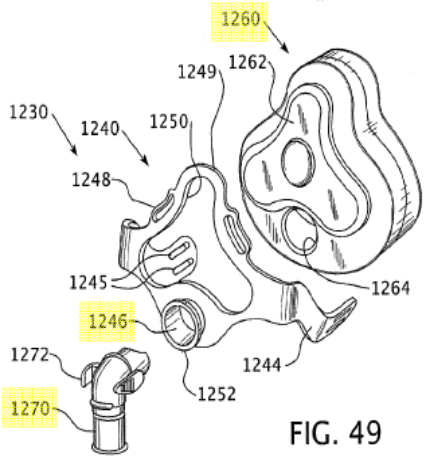
’931 Patent	Prior Art
	Matula-I: “[A]ttachment elements 1248 are provided in the form of slots provided . . . [o]n a central portion 1249 of the body member.” Ex. 1523 ¶ 103.  FIG. 49 **Ogden:** “The upper side straps in this last regard could be the two straps 15R and 15L as illustrated or one continuous strap passing through loops 27 and anchoring the top portion 21 of the rigid plate 9 (see FIGS. 1-3).” Ex. 1529 at col. 3:7–10. Fig. 1 

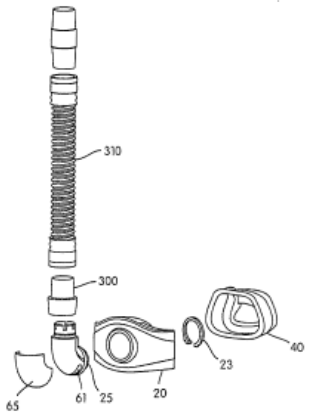
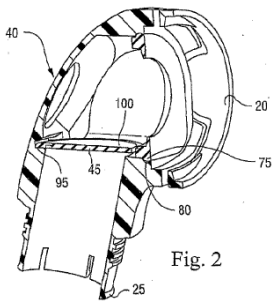
’931 Patent	Prior Art
	Lovell: “These connection points 14, 14′, 16, 16′ form slots which allow for connection of the retainer 12 with straps of a headgear apparatus, as shown in FIG. 3.” Ex. 1514 at col. 6:10–13.  FIG. 2A
[L] wherein the shroud module and the frame of the cushion module are configured 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. **D’Souza:** “[S]keleton frame 412 that is adapted to removably interlock with a cushion/frame sub-assembly 430.” Ex. 1102 ¶ 96. “[A]nnular elbow connection seal 448 interlocks with the annular wall 440 . . . upper support member 444 interlocks with a top portion 431 . . . and the elongated frame members 450 interlock with respective protrusions 442.” *Id*. ¶ 101.  Fig. 7  Fig. 8

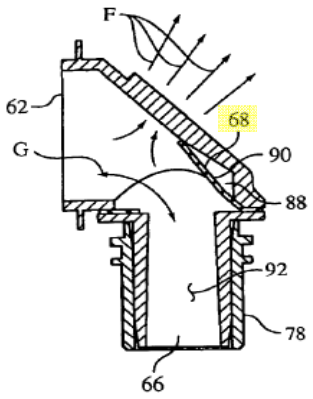
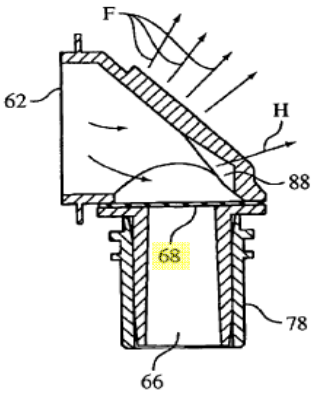
’931 Patent	Prior Art
	Matula-II: “Coupling member 46 includes a pair of prongs 48 that define a channel 50 to receive the wall of the faceplate and the end of seal member 38.” Ex. 1512 ¶ 53.  Fig. 4 **Ogden:** “[R]igid plate 9 is preferably mounted to the rigid shell 3 at first, second, and third locations A, B, and C. . . . Further, although the detent-channel 43, 49 at the top of 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. 1529 at col. 4:59–5:19. 

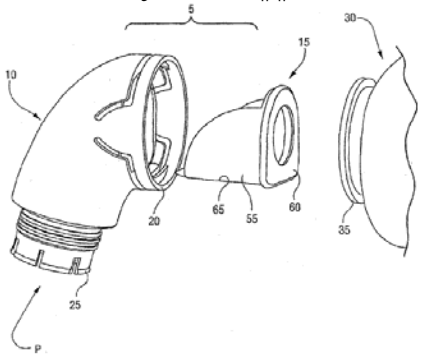
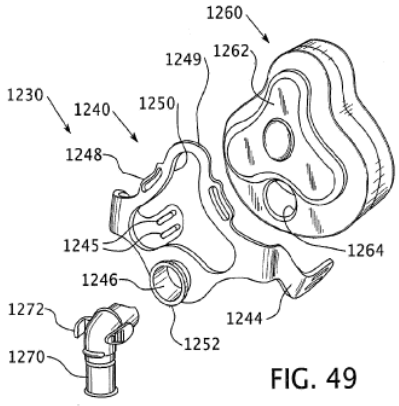
’931 Patent	Prior Art
	Lovell: “The retainer 212 is disposed about the inlet 208 to facilitate retention of the mask 201 on a user. . . . Two tabs 211, 211′ included on the inlet 208 mate with two slots 213, 215 formed in the retainer 212 in a particular angular orientation. . . . The retainer aperture 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; *see also id.* at 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. 1524 at col. 5:34–43.  FIG. 5a  FIG. 7a

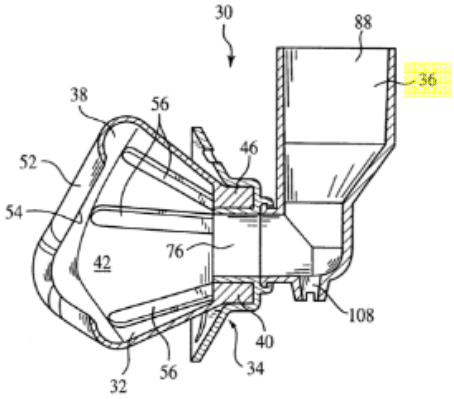
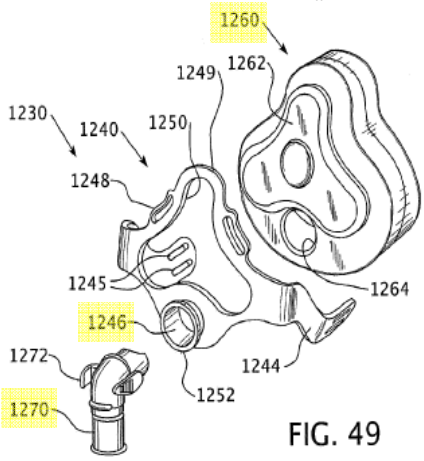
’931 Patent	Prior Art
[M] and an elbow rotatably attached to and carried by the shroud module or the frame of the cushion module, the elbow being configured to deliver the positive pressure air to the breathing chamber,	*See supra* Claims 11 and 14. **D’Souza:** “[S]keleton frame 412 includes . . . an annular elbow connection seal 448 adapted to engage an inlet conduit, e.g., elbow.” Ex. 1510 ¶ 100. “[S]keleton frame 412 . . . provides attachment points for . . . an inlet conduit.” *Id.* ¶ 101. **Barnett:** “[C]onduit coupling member 36 is preferably rotateably mounted on a second side of collar 34 . . . so that conduit coupling member 36 freely rotates over a range of 360°.” Ex. 1513 at col. 3:52–57; *see also id.* at col. 8:66—9:43. “Conduit coupling portion 88 attaches conduit coupling member 36 to a patient circuit 92, . . . which carries a flow of breathing gas generated by a flow generating device 94 . . . to nose receiving cavity 42.” *Id.* at col. 8:49–54.  FIG. 6

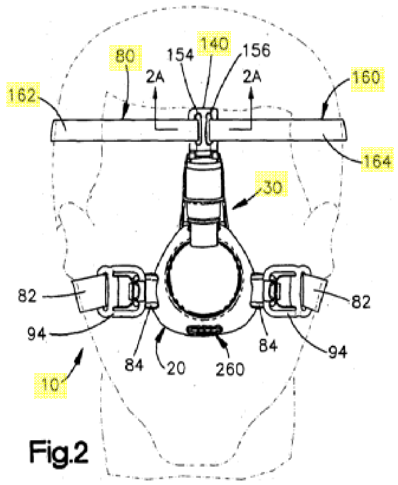
’931 Patent	Prior Art
	Matula-I: “[P]atient circuit coupling 1270 is an elbow coupling that rotatably and releasably attaches to circuit coupling portion 1246.” Ex. 1523 ¶ 105.  FIG. 49 **Lovell:** “[S]wivel connector 9 produces a swivel mount connection between the conduit elbow 10 and the inlet 8. 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. 1514 at col. 5:20–24.
[N] the elbow including a swivel adapted to connect to an air delivery tube,	**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. 1511 ¶ 28. **Ultra Mirage:** “360° rotating elbow provides control over tubing system.” Ex. 1516 at 6. “Quick release swivel allows easy disconnection from tubing.” *Id.* **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. 1529 at col. 5:35–37. **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

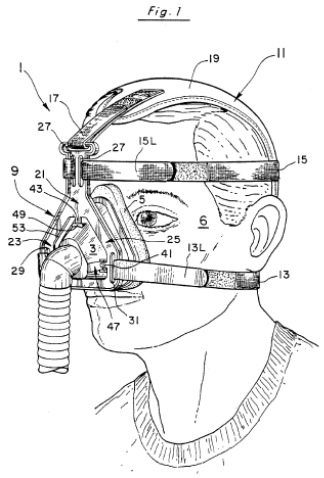
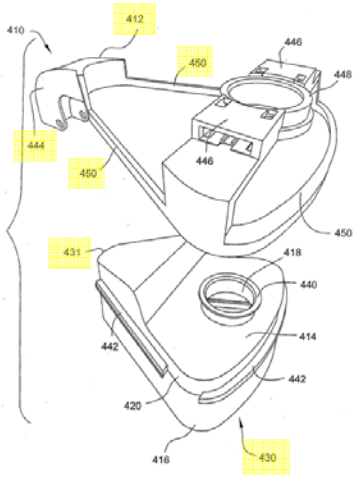
’931 Patent	Prior Art
	C-clip member, as described above. The elbow assembly 60 of FIG. 6a is intended to be used with a connector tube 300 (FIG. 23). The connector tube 300 is provided between the elbow assembly 60 and the gas delivery tube 310 (FIG. 26).” Ex. 1532 ¶ 153.  FIG. 6b **Worboys:** “The 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. 1522 ¶¶ 104–105.  Fig. 2
[O] 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. **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.

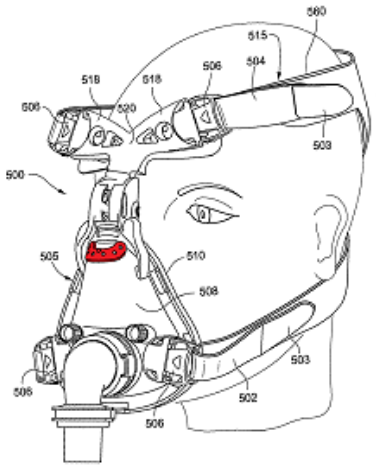
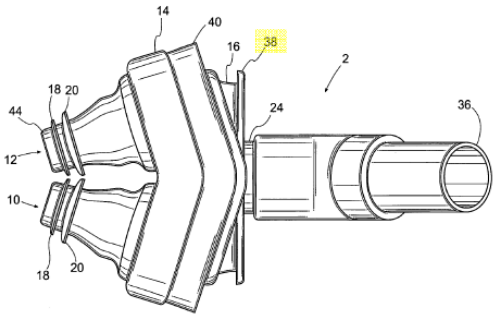
’931 Patent	Prior Art
	See, e.g. U.S. Pat. No. 5,438,981, which teaches the function of such a valve and describes several embodiments of such a valve.” Ex. 1515 at col. 10:4–8. “During normal use, where the pressure support system is functioning properly, a cantilever member 90 of valve member 68 flexes, 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. 10:14–28.  FIG. 8  FIG. 9

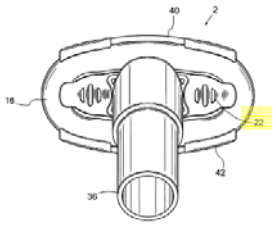
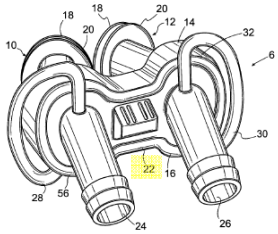
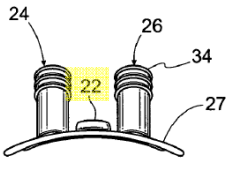
’931 Patent	Prior Art
	Worboys: “[E]lbow assembly 5 generally comprises an elbow 10 and an anti–asphyxia valve 15 (AAV) assembly.” Ex. 1522 ¶ 103. “[E]lbow 10 includes a port 40 that may be selectively closed by a flap portion 45 of the AAV assembly.” *Id*. ¶¶ 105–106.  Fig. 1 **Matula-I:** “[T]he present 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. 1523 ¶ 106.  FIG. 49
46. The mask system of claim 43, wherein: **[A]** the elbow is rotatably attached the shroud module,	*See supra* Claims 11 and 14. **D’Souza:** “[S]keleton frame 412 includes . . . an annular elbow connection seal 448 adapted to engage an inlet conduit, e.g., elbow.” Ex. 1510 ¶ 100.

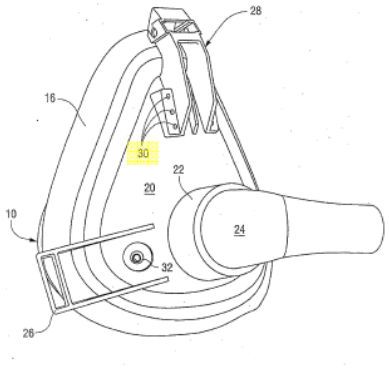
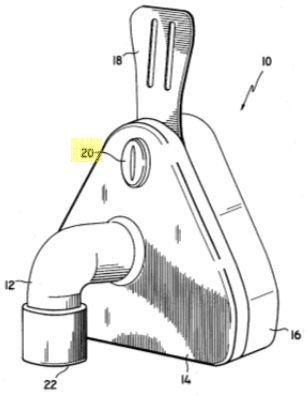
’931 Patent	Prior Art
	Barnett: “[C]onduit coupling member 36 is preferably rotateably mounted on a second side of collar 34 opposite the first side so that conduit coupling member 36 freely rotates over a range of 360° about a central axis of collar 34. . . .” Ex. 1513 at col. 3:52–57; *see also id.* at col. 8:66—col. 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. 1523 ¶ 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. 1514 at col. 5:20–24.

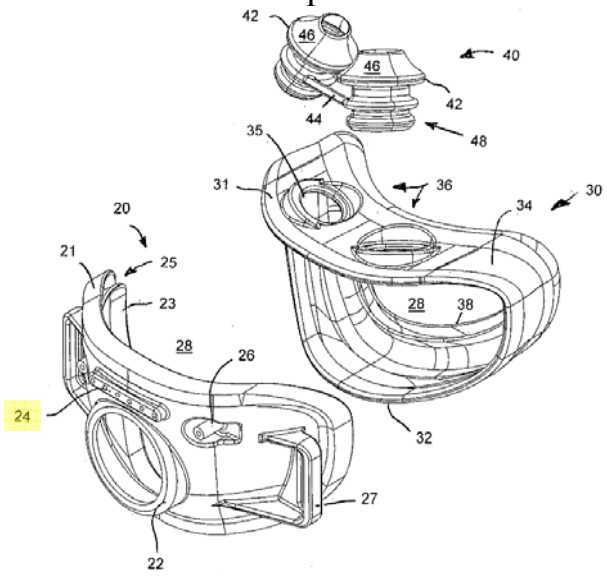
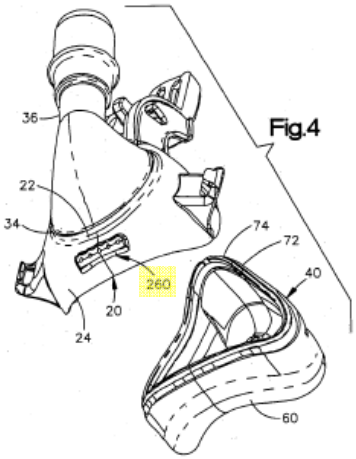
’931 Patent	Prior Art
[B] the upper headgear straps provide padding to the respective headgear connectors of the shroud on the patient's face in use,	**Sprinkle:** “When the left and right straps 162 and 164 are connected with the forehead adjuster 140 in this manner, a relatively large amount of strap 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. 1520 ¶ 74, *see also id.* ¶¶ 3, 72.  Fig.2 **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. 1514 at col. 6:30–34. **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

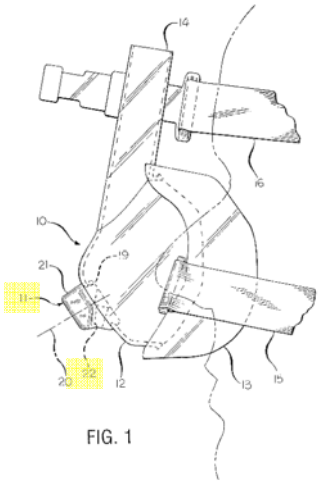
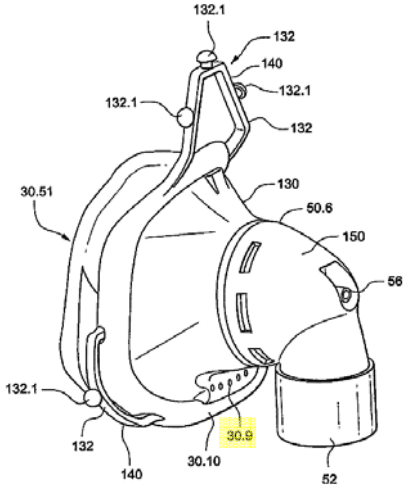
’931 Patent	Prior Art
	comfortably fit about the patient's head." Ex. 1529 at col. 3:10–24. 
[C] the frame includes a protruding vent arrangement having a plurality of holes, wherein the shroud module includes a first opening to accommodate said protruding vent arrangement,	*See supra* Claim 1[B]. **D’Souza:** "[S]keleton frame 412 is engaged with the cushion/frame sub-assembly 430 such that . . . upper support member 444 interlocks with a top portion 431 . . . and the elongated frame members 450 interlock with respective protrusions 442 . . . ." Ex. 1510 ¶ 101.  Fig. 7

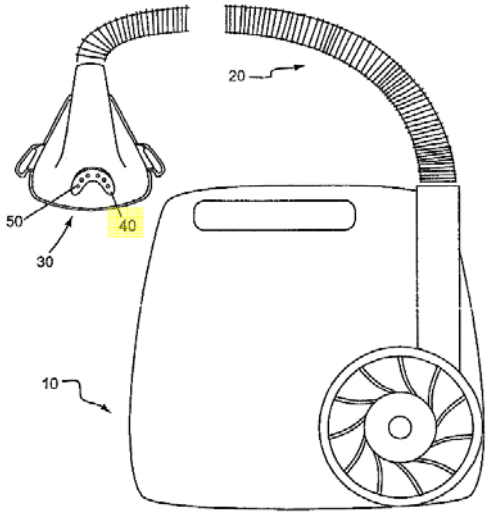
’931 Patent	Prior Art
	Hitchcock: *See* Ex. 1511 at Fig. 8.  Fig. 8 **Thomlinson:** “A nasal interface body 2 according to the present invention can also include one or more locking tabs 38 on the distal portion 16. The locking tabs 38 can be used to releasably engage a strap attachment plate 92, as depicted in FIG. 37 and described further below.” Ex. 1528 ¶ 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 the 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. “[E]xhalation ports may be located on any portion of the body of the nasal interface of the present invention, including distal portion 16 and/or proximal portion 14.” *Id*. ¶ 278.  Fig. 14A

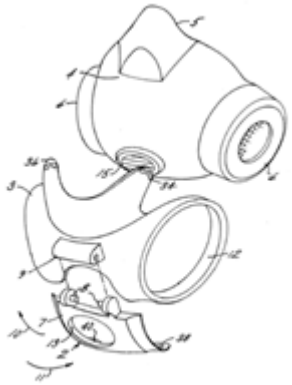
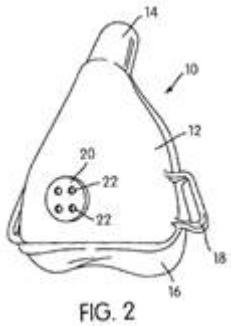
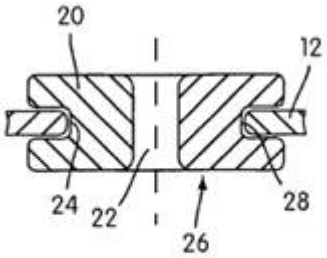
’931 Patent	Prior Art
	Hitchcock-II: “A number of vents 30 may be provided so as to allow gas exhaled by the patient to vent to atmosphere.” Ex. 1540 ¶ 42.  Fig. 1-2 **Landis:** “[T]he aperture in mask frame 14 to receive variable orifice member 20 is configured as a cylindrical wall projecting outward from the mask frame to engage a variable orifice member cap, as described in greater detail below.” Ex. 1541 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.

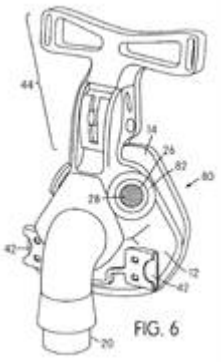
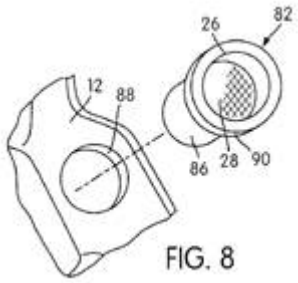
’931 Patent	Prior Art
	Chandran: “The ventilation interface 20 is configured with at least one exhalation port 24.” Ex. 1526 ¶ 60.  **Sprinkle:** “FIGS. 4 and 23 illustrate an exhalation vent portion 260 of the mask 10. The vent portion 260 includes a thickened wall area 262 in the lower part of the 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. 1520 ¶ 99. 

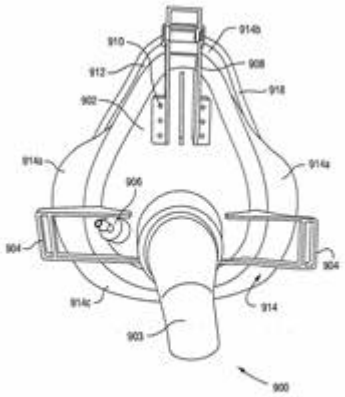
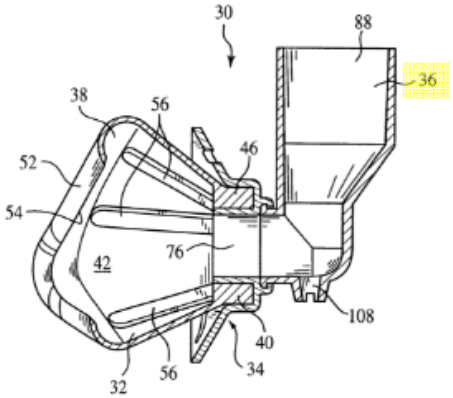
’931 Patent	Prior Art
	Jones, Jr.: “[T]he exhaust port member 11 is shown as having a generally circular perimeter 17 with a recessed or reduced diameter annular groove 18 formed in the perimeter 17, as shown in FIG. 4. A circular opening 19 is formed in the mask body 12 for receiving the exhaust port member 11.” Ex. 1537 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. 1538 ¶ 221. 

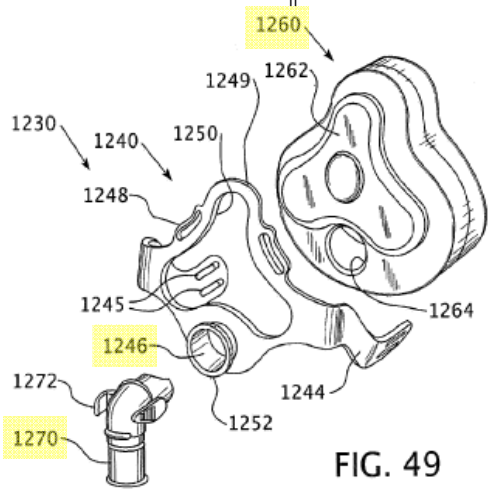
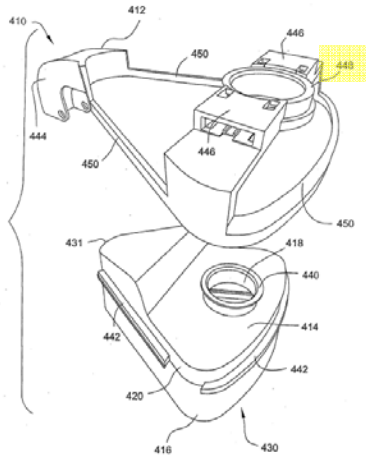
’931 Patent	Prior Art
	“The shell/cushion 130 includes a series of vents or vent orifices 30.9, which in a preferred form comprises four orifices. The vent orifices 30.9 are formed through a thicker wall section 30.10 formed integrally on the shell/cushion 30. The wall section 30.10 is shown in FIG. 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. 1542 ¶ 55.  Fig. 1

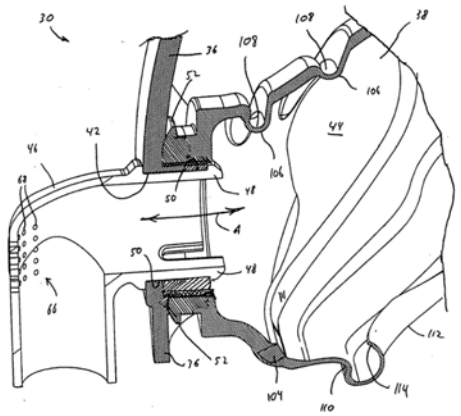
’931 Patent	Prior Art
	“Another advantage of the invention is to provide different vents for different pressure ranges. For example, at low pressures, it may be appropriate to have a vent with large holes in order to provide sufficient vent flow. The same vent at higher pressures would have unnecessarily 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.

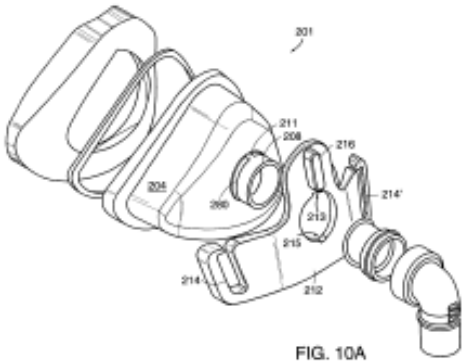
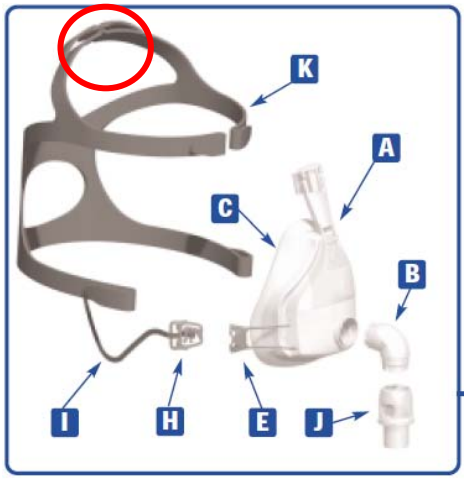
'931 Patent	Prior Art
	Fecteau: "[A] respirator 1 incorporates a quick release mechanism 2 into a facepiece support system, or yoke, 3." Ex. 1546 at 4:24–25. "[Q]uick release mechanism 2 consists of an over center cam latch 7 pivotly attached to yoke 3 via hinge pins 8 disposed within hinge 9 and further 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. 1545 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

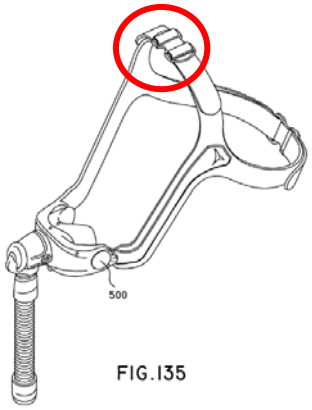
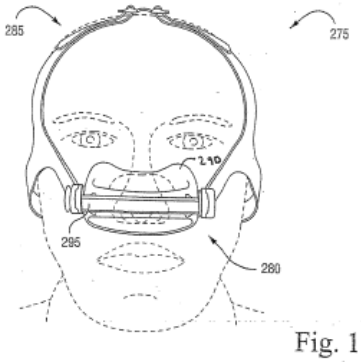
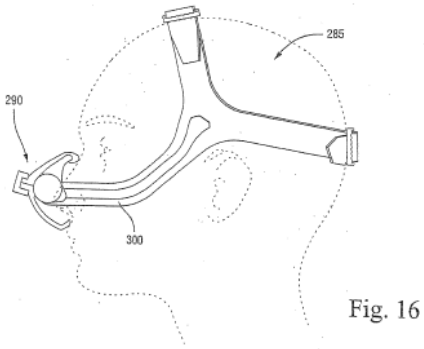
’931 Patent	Prior Art
	Drew: “The mask 10 includes a gas washout vent constituted by an opening 26 in the shell 12 across which extends a thin air permeable membrane 28.” Ex. 1444 at col. 4:32–34. “FIG. 6 shows a nasal respiratory mask 80.” *Id.* at col. 5:31. “In the mask 40 of FIG. 2, the [gas washout] 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

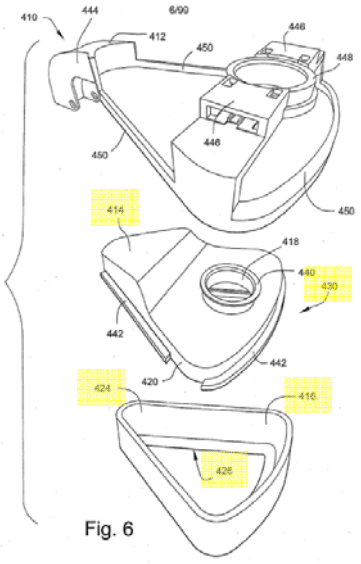
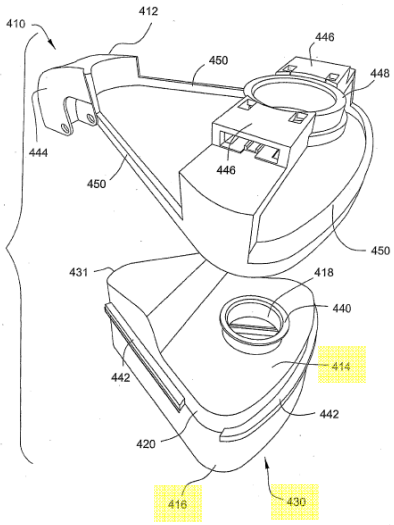
’931 Patent	Prior Art
	Frater: “Shell 902 may also be provided with one or more vents 910.” Ex. 1525 ¶ 163.  Fig. 50
[D] further wherein the shroud module includes a second opening to accommodate the elbow,	*See supra* Claim 1[C] and 12. **D’Souza:** “[S]keleton frame 412 includes . . . an annular elbow connection seal 448 adapted to engage an inlet conduit, e.g., elbow.” Ex. 1510 ¶ 100. **Barnett:** “[C]onduit coupling member 36 is preferably rotateably mounted on a second side of collar 34.” Ex. 1513 at col. 3:52–57; *see also id.* at col. 8:66—9:43.  FIG. 1A

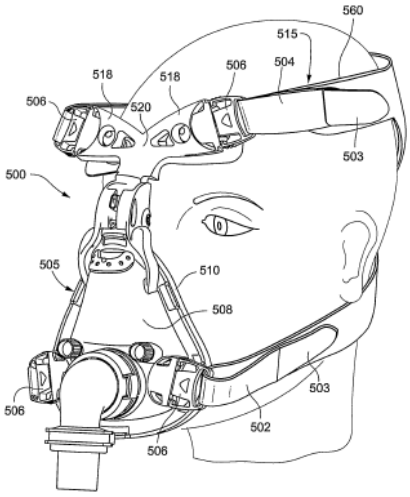
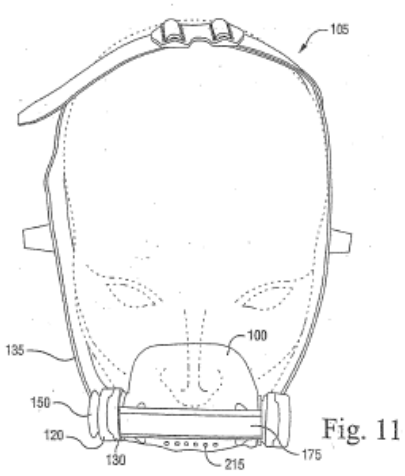
’931 Patent	Prior Art
	Matula-I: “[P]atient circuit coupling 1270 is an elbow coupling that rotatably and releasably attaches to circuit coupling portion 1246.” 1523 ¶ 105.  FIG. 49
[E] the frame includes an opening and the frame further includes a collar surrounding said opening, and wherein the shroud module includes a retaining portion with one or more rearward extending snap fingers structured to engage the collar with a snap-fit, and	*See supra* Claim 5 and 28. **D’Souza:** “[A]nnular wall 440 surrounds the opening 418 [of the frame 414].” Ex. 1510 ¶ 98. “[A]nnular elbow connection seal 448 interlocks with the annular wall 440.” *Id.* ¶ 101.  Fig. 7

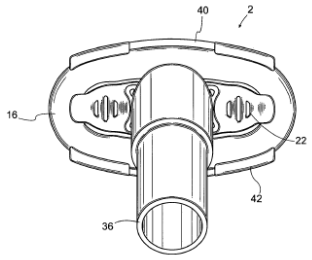
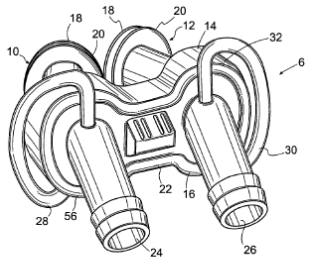
’931 Patent	Prior Art
	Matula-II: “Coupling member 46 includes a pair of prongs 48 that define a channel 50 to receive the wall of the faceplate and the end of seal member 38. In an exemplary embodiment, the end of seal member 38 is joined to a ring 52 that is more rigid than the end of the seal member to provide a strong, stable mechanical coupling of the seal member to the faceplate.” Ex. 1512 ¶ 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 A person of skill in the art would have understood that the “prongs” of Matula-II could also be referred to as “snap fingers.” **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. 1529 at col. 4:59—5:19.

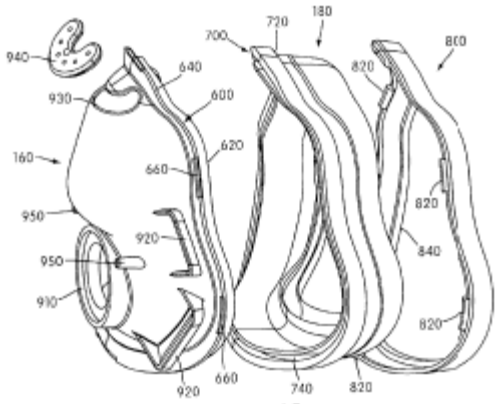
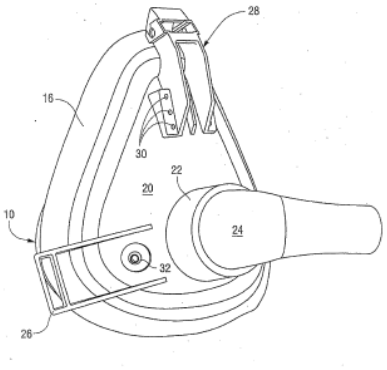
’931 Patent	Prior Art
	Lovell: “The retainer 212 is disposed about the inlet 208 to facilitate retention of the mask 201 on a user. . . . Two tabs 211, 211′ included on the inlet 208 mate with two slots 213, 215 formed in the retainer 212 in a particular angular orientation. . . . The retainer aperture 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; *see also id.* at col. 9:59–64.  FIG. 10A
[F] the top straps are connected together with a buckle allowing independent adjustment of each of the top straps.	*See supra* Claim 19[D]. **FlexiFit:** Ex. 1517 at 10. 

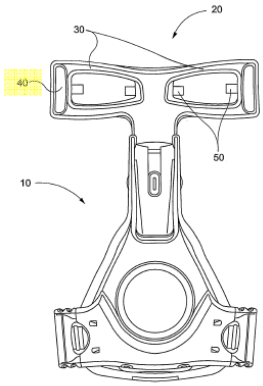
’931 Patent	Prior Art
	Gunaratnam-II: “[U]pper straps 598 are coupled to one another by a headgear buckle 570.” Ex. 1519 ¶ 316, Fig. 135.  FIG.135 **Ng:** “Further, as shown in Fig. 16, the vectors formed by the headgear straps 300 are slightly different than as shown in described in relation to Fig. 13.” Ex. 1527 ¶ 46.  Fig. 15  Fig. 16
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 43, preamble. **D’Souza:** “[M]ask assembl[ies], for use with blowers and flow generators in the treatment of sleep disordered breathing (SDB) . . . . [P]atient interface is held in a sealing position by headgear so as to enable a supply of air at positive pressure to be delivered to the patient's airways.” Ex. 1510 ¶ 3.

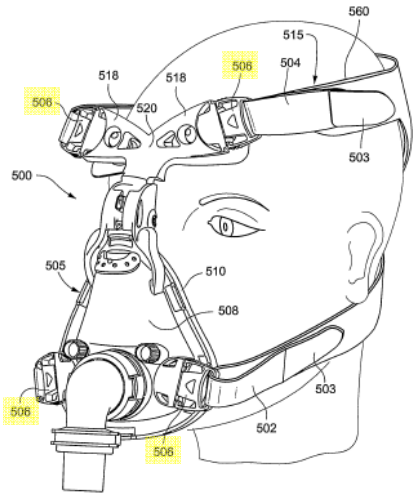
’931 Patent	Prior Art
a cushion module comprising	*See supra* Claim 1(ii).
a frame defining a breathing chamber configured to receive the positive pressure air, and	**D’Souza:** “[F]rame 414 and a cushion 416 are . . . interlocked to provide a cushion/frame sub-assembly 430. . . . [C]ushion 416 is constructed of liquid silicone rubber (LSR).” Ex. 1510 ¶ 97.
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,	“[F]rame 414 includes an upper wall that provides an opening 418 for communicating with an inlet conduit. . . . A side wall 420 extends from the upper wall . . . . [F]rame 414 is constructed of polycarbonate.” *Id.* ¶ 98. “[C]ushion provides a seal around the patient's nose and mouth to enable the delivery of breathable gas to the patient's nose and mouth.” *Id.* ¶ 81.
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,	 Fig. 6  Fig. 7

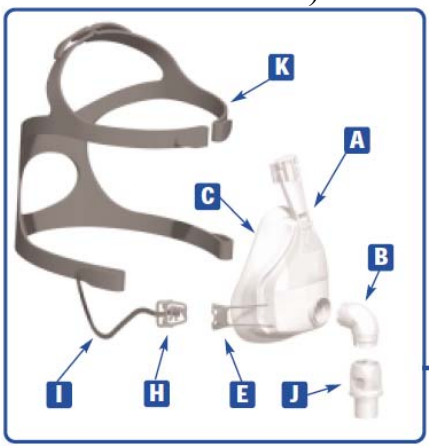
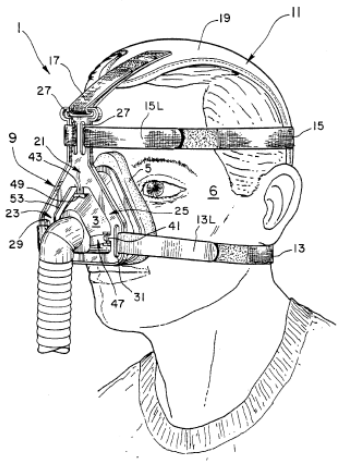
’931 Patent	Prior Art
the frame including a washout vent;	*See supra* Claim 43[B]. **Hitchcock:** *See* Ex. 1511 at Fig. 8.  Fig. 8 **Ng:** “As shown in Figs. 3, 7-8, and 11, the mask assembly includes a gas washout vent 215. The vent 215 could be on the frame and/or the cushion component.” Ex. 1527 ¶ 43.  Fig. 11

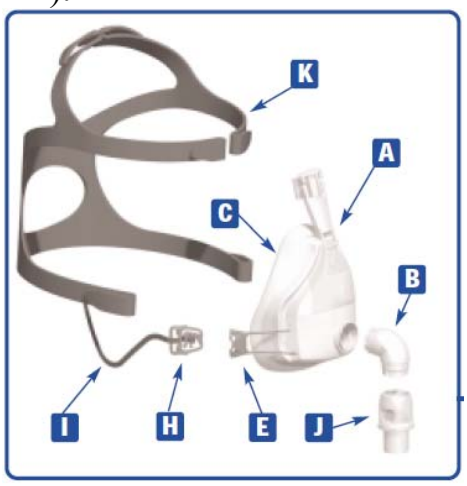
’931 Patent	Prior Art
	Thomlinson: “Further, and as shown in FIG. 3, one embodiment of a nasal interface can also include one or more exhalation ports 22, which are described in more detail below.” Ex. 1528 ¶ 204.  Fig. 3 “As shown in FIG. 8, nasal interface body 6 can also include first inlet 24 and a second inlet 26, as well as exhalation port 22. In one embodiment, exhalation port 22 is positioned between inlet 24 and the 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. “[E]xhalation ports may be located on any portion of the body of the nasal interface of the present invention, including distal portion 16 and/or proximal portion 14.” *Id*. ¶ 278.

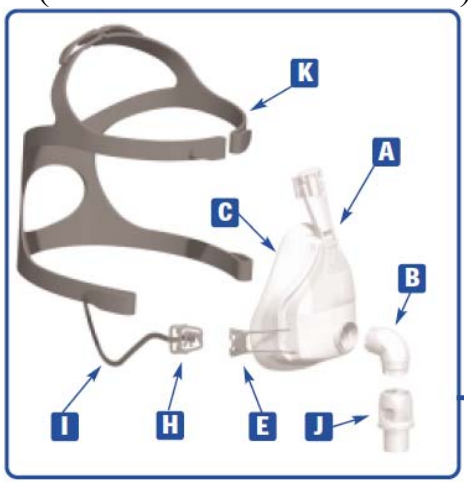
'931 Patent	Prior Art
	Gunaratnam-I: "The frame (160) is adapted to cover both the mouth and nose region of the patient's face, and includes a gas inlet aperture (910), connection points (920) for headgear straps, an aperture (930) for receiving an air vent (940) (FIG. 15) and ports (950)." Ex. 1524 at col. 6:25-29.  FIG. 15 **Hitchcock-II:** "A number of vents 30 may be provided so as to allow gas exhaled by the patient to vent to atmosphere." Ex. 1540 ¶ 42.  Fig. 1-2

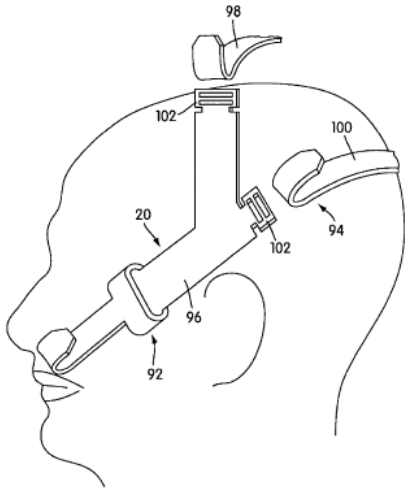
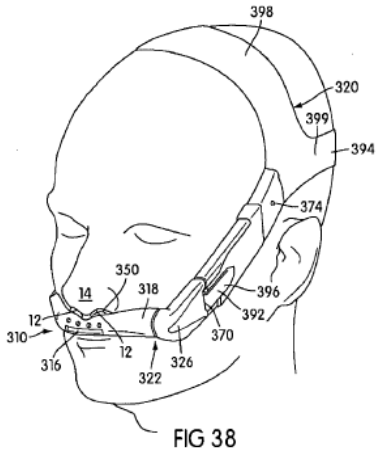
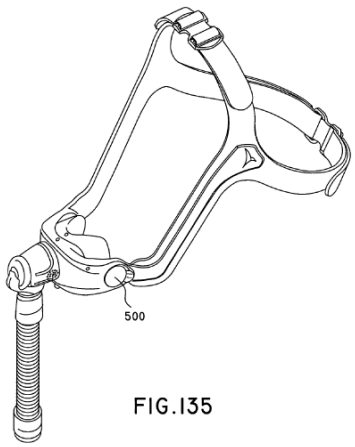
’931 Patent	Prior Art
headgear to maintain the mask system in a desired position on the patient's face, the headgear comprising a pair of upper headgear straps each configured to extend above a respective one of the patient's ears in use and a pair of lower headgear straps each configured to extend below a respective one of the patient's ears in use,	*See supra* Claim 19[A]. **D’Souza:** “[P]atient interface is held in a sealing position by headgear.” Ex. 1510 ¶ 3. “[S]keleton frame 412 includes an upper support member 444 adapted to support a forehead support, lower headgear clip receptacles 446 adapted to be engaged with clips provided to straps of a headgear assembly (not shown).” *Id.* ¶ 100. **Hitchcock:** “A prior art mask assembly 10 such as ResMed's ULTRA MIRAGE® mask as shown in Fig. 1 includes a forehead support 20 having a pair of arms 30, each having a slot 40 adapted to receive a strap (not shown). Each arm 30 includes a pair of forehead pad receiving lugs 50. The forehead support has a general ‘T’-shape, with the arms arranged along the upper cross portion of the ‘T’.” Ex. 1511 ¶ 24.  Fig. 1 Prior Art

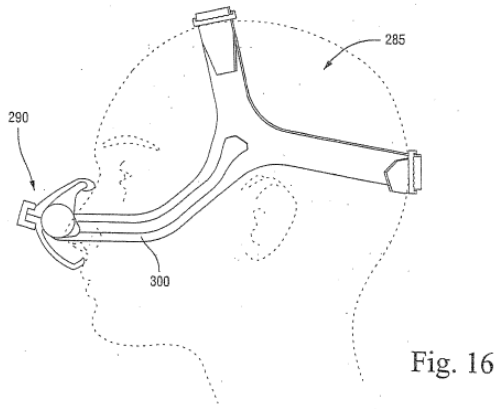
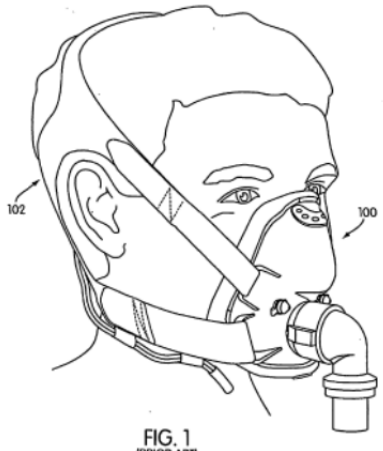
’931 Patent	Prior Art
	“In the illustrated embodiment, the upper side straps 504 are removably connected to respective arms 518 of the Y-shaped forehead support 520 via clips 506, which operate in a manner similar to the clips described above. Also, the lower side straps 502 are removably connected to a lower portion of the mask frame 508 via clips 506.” *Id.* ¶ 38.  Fig. 8 **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. 1517 at 10 (“FITTING YOUR MASK”).

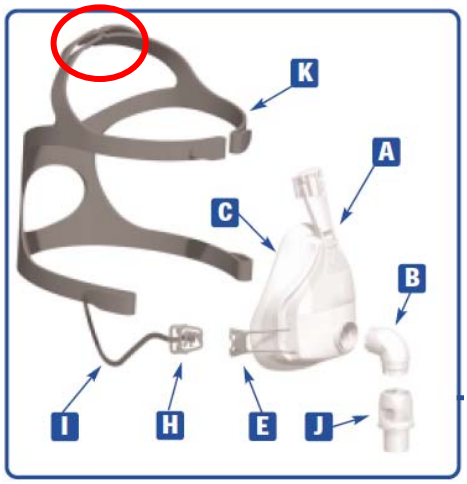
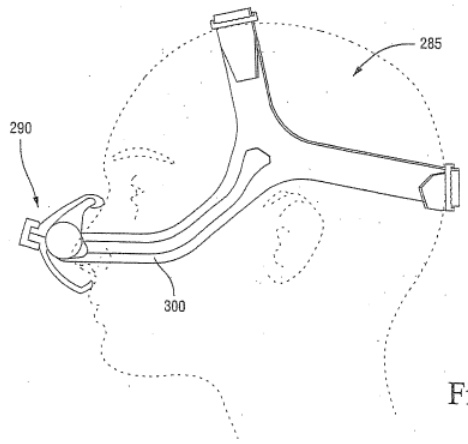
’931 Patent	Prior Art
	“[A]ttach the four straps in to the corresponding slots in the Mask Base and the Glider™ strap (E).” *Id.* at 10 (“ASSEMBLING YOUR MASK”).  **Ogden:** “[E]ach side strap 13R and 13L is preferably attached to a respective side portion 23, 25 of the rigid plate 9 on respective sides 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. 1529 at col. 3:10–20. Fig. 1 

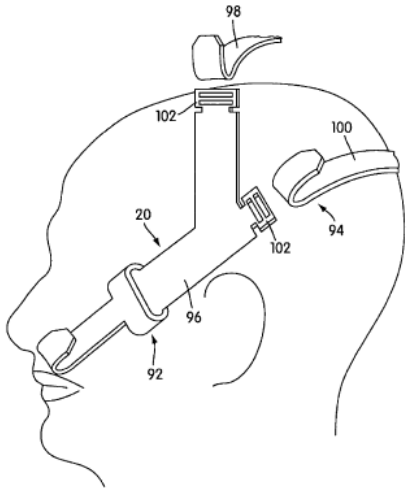
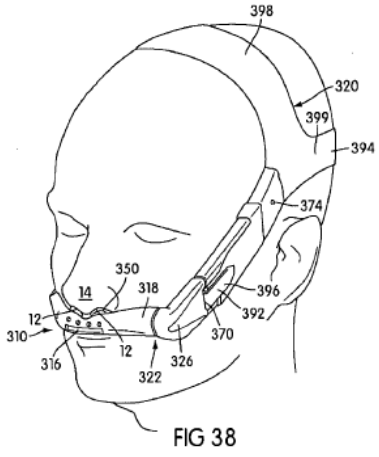
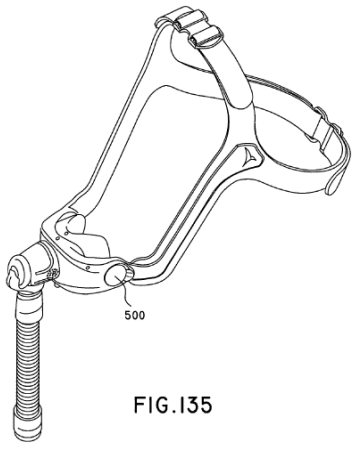
’931 Patent	Prior Art
wherein a free end of each of the upper headgear straps and the lower headgear straps includes a hook tab structured to engage a remainder of the respective upper headgear strap and respective lower headgear strap to secure the upper and lower straps in place in a length adjustable manner,	*See supra* Claim 19[B]. **Hitchcock**: “The free end of each of the upper and lower side straps 504, 502 includes a strip of Velcro® material 503 for use in securing each of the straps 504, 502 to a respective clip 506.” Ex. 1511 ¶ 38. **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. 1517 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. 1529 at col. 3:10–20.

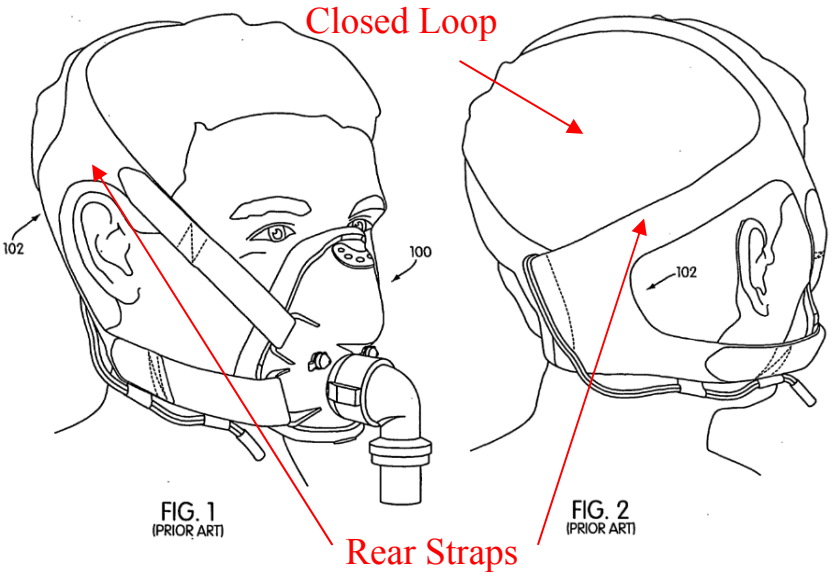
’931 Patent	Prior Art
	Amarasinghe: “At the end of each strap is secured a piece of hook material, which, in use, passes through a headgear attachment point and fastens on corresponding loop material on the strap.” Ex. 1530 ¶ 12. **Lovell:** “A hook and loop fastener system can be used to maintain the 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. 1514 at col. 7:6–13.
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]. **FlexiFit:** “Gently adjust . . . Top Crown straps.” Ex. 1517 at 10 (“FITTING YOUR MASK”). 

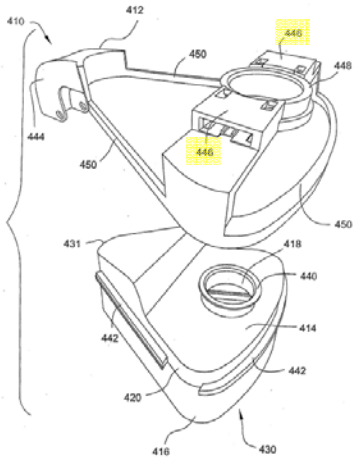
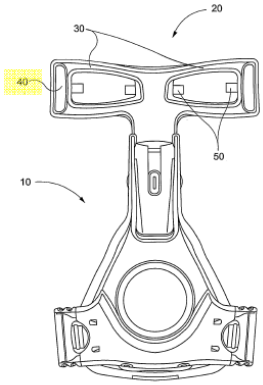
’931 Patent	Prior Art
	Gunaratnam-II: “The upper strap 98 and rear strap 100 are removably connected to the side straps 96 by buckles 102 provided on the side straps 96.” Ex. 1519 ¶ 211.  FIG. 18 “The rear portion 394, which interconnects the two side portions 392, includes an upper strap 398 that passes 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

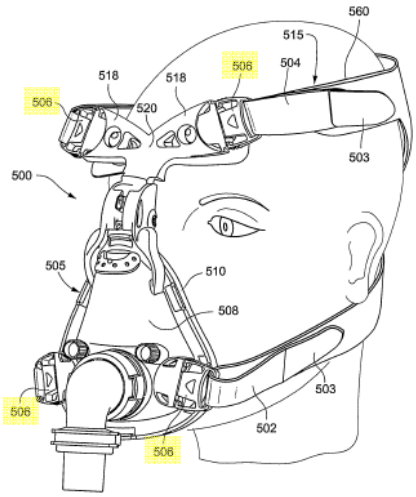
’931 Patent	Prior Art
	Ng: *See* Ex. 1527 at Fig. 16.  Fig. 16 **Amarasinghe:** *See* Ex. 1530 at Fig. 1.  FIG. 1 (PRIOR ART)

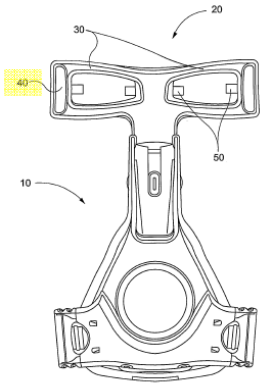
’931 Patent	Prior Art
wherein the rear straps and the top straps together at least partly form a closed loop to encircle a rear portion of the patient's head when in use;	*See supra* Claim 21. **FlexiFit:** Ex. 1517 at 10.  **Ng**: “Further, as shown in Fig. 16, the vectors formed by the headgear straps 300 are slightly different than as shown in described in relation to Fig. 13.” Ex. 1527 ¶ 46.  Fig. 16

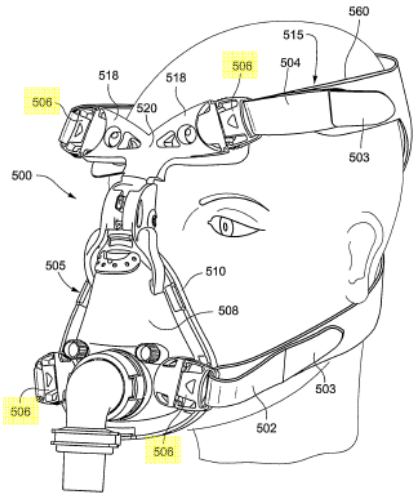
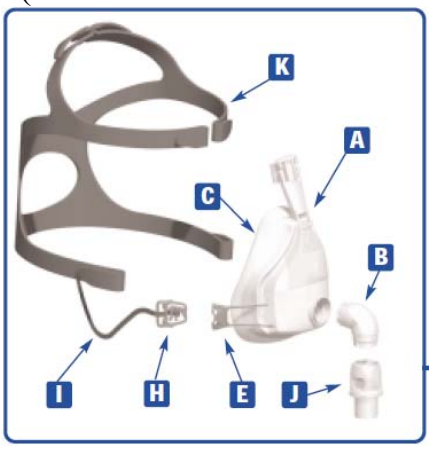
’931 Patent	Prior Art
	<u>Gunaratnam-II</u>: “The upper strap 98 and rear strap 100 are removably connected to the side straps 96 by buckles 102 provided on the side straps 96.” Ex. 1519 ¶ 211.  FIG. 18 “The rear portion 394, which interconnects the two side portions 392, includes an upper strap 398 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

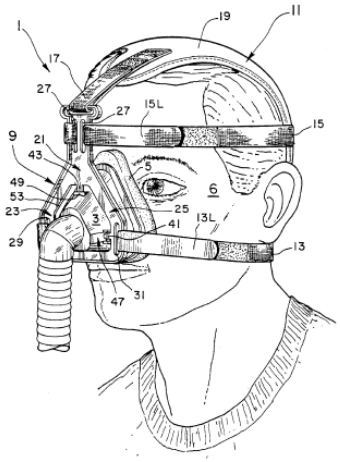
’931 Patent	Prior Art
	Amarasinghe: “Another known patient interface is the MIRAGE® nasal mask (by ResMed Ltd). This nasal mask includes a pair of headgear attachment points in the nasal region of the mask shell and a forehead support that includes another pair of headgear attachment points. The headgear includes a single piece of a soft, flexible composite fabric with a generally triangular back portion and four straps.” Ex. 1530 ¶ 12. 

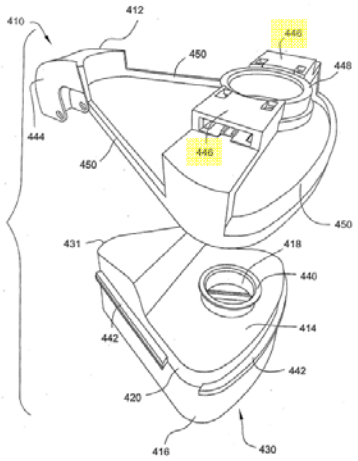
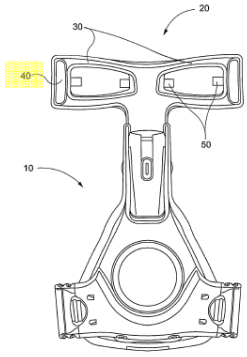
’931 Patent	Prior Art
a shroud module including headgear connectors adapted to removably attach to the headgear,	*See supra* Claim 1(i). **D’Souza:** “[S]keleton frame 412 includes . . . lower headgear clip receptacles 446 adapted to be engaged with clips provided to straps of the headgear assembly (not shown).” Ex. 1510 ¶ 100.  Fig. 7 **Hitchcock:** “A prior art mask assembly 10 such as ResMed's ULTRA MIRAGE® mask as shown in Fig. 1 includes a forehead support 20 having a pair of arms 30, each having a slot 40 adapted to receive a strap (not shown). Each arm 30 includes a pair of forehead pad receiving lugs 50. The forehead support has a general ‘T’-shape, with the arms arranged along the upper cross portion of the ‘T’.” Ex. 1511 ¶ 24.  Fig. 1 Prior Art

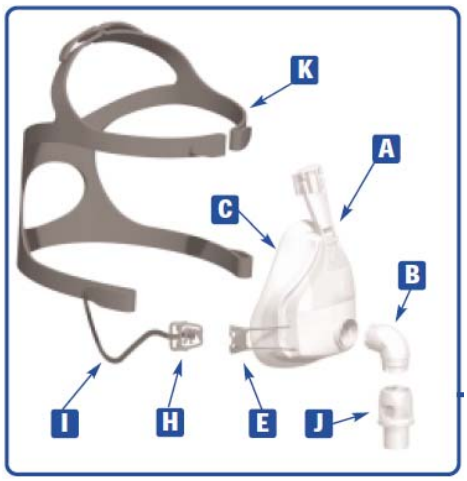
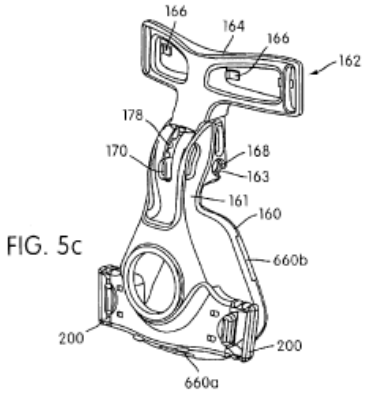
’931 Patent	Prior Art
	“In the illustrated embodiment, the upper side straps 504 are removably connected to respective arms 518 of the Y-shaped forehead support 520 via clips 506, which operate in a manner similar to the clips described above. Also, the lower side straps 502 are removably connected to a lower portion of the mask frame 508 via clips 506.” *Id.* ¶ 38.  Fig. 8 **Ultra Mirage:** “Quick release headgear clips: top and bottom allows mask to be removed without resetting the headgear and provides convenience and safety.” Ex. 1516 at 6. **Ogden:** “[H]arness arrangement 11 . . . is preferably attached to a respective side portion 23, 25 of the rigid plate 9 . . . . This can be done in any number of well-known, adjustable manners . . . . Snaps and similar arrangements could also be used.” Ex. 1529 at col. 2:62–3:22.

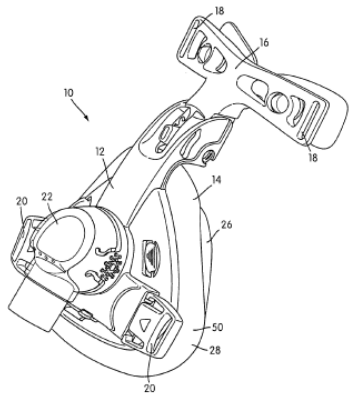
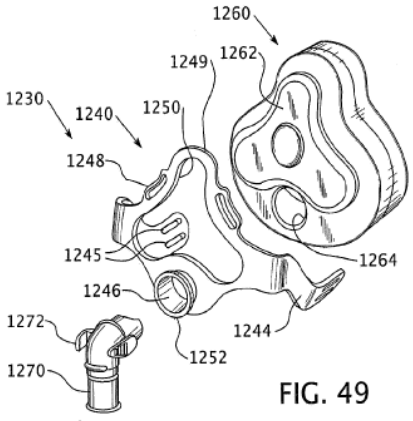
’931 Patent	Prior Art
wherein the headgear connectors include two upper connectors associated with the upper headgear straps and two lower connectors associated with the lower headgear straps,	*See supra* Claim 6. **D’Souza:** “[P]atient interface is held in a sealing position by headgear.” Ex. 1510 ¶ 3. “[S]keleton frame 412 includes an upper support member 444 adapted to support a forehead support, lower headgear clip receptacles 446 adapted to be engaged with clips provided to straps of a headgear assembly (not shown).” *Id.* ¶ 100. **Hitchcock:** “A prior art mask assembly 10 such as ResMed's ULTRA MIRAGE® mask as shown in Fig. 1 includes a forehead support 20 having a pair of arms 30, each having a slot 40 adapted to receive a strap (not shown). Each arm 30 includes a pair of forehead pad receiving lugs 50. The forehead support has a general "T"-shape, with the arms arranged along the upper cross portion of the "T".” Ex. 1511 ¶ 24.  Fig. 1 Prior Art

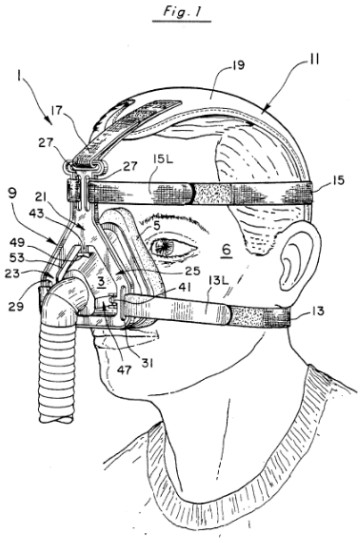
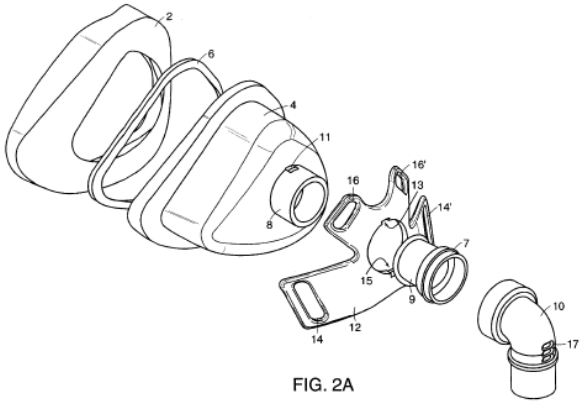
’931 Patent	Prior Art
	“In the illustrated embodiment, the upper side straps 504 are removably connected to respective arms 518 of the Y-shaped forehead support 520 via clips 506, which operate in a manner similar to the clips described above. Also, the lower side straps 502 are removably connected to a lower portion of the mask frame 508 via clips 506.” *Id.* ¶ 38.  Fig. 8 **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. 1517 at 10 (“FITTING YOUR MASK”). 

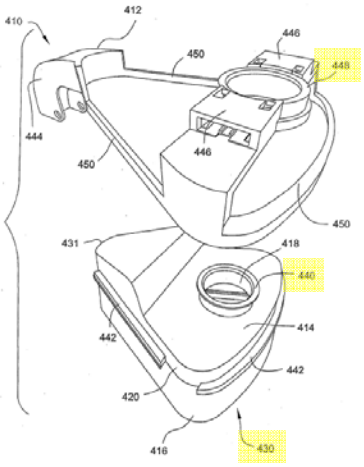
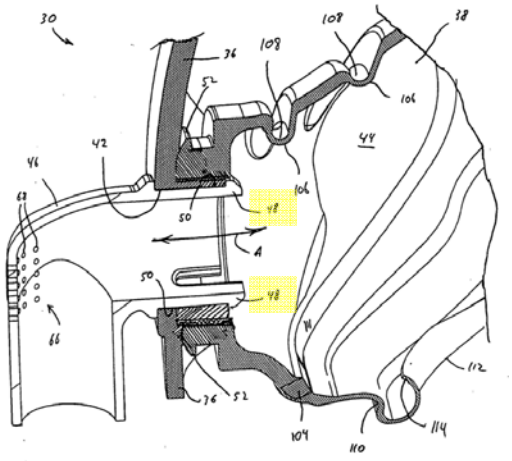
’931 Patent	Prior Art
	"[A]ttach the four straps in to the corresponding slots in the Mask Base and the Glider™ strap (E)." *Id.* at 10 ("ASSEMBLING YOUR MASK"). **Ogden:** "[E]ach side strap 13R and 13L is preferably attached to a respective side portion 23, 25 of the rigid plate 9 on respective sides 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. 1529 at col. 3:10–20. Fig. 1  **Ultra Mirage:** "Quick release headgear clips: top and bottom allows mask to be removed without resetting the headgear and provides convenience and safety." Ex. 1516 at 6.

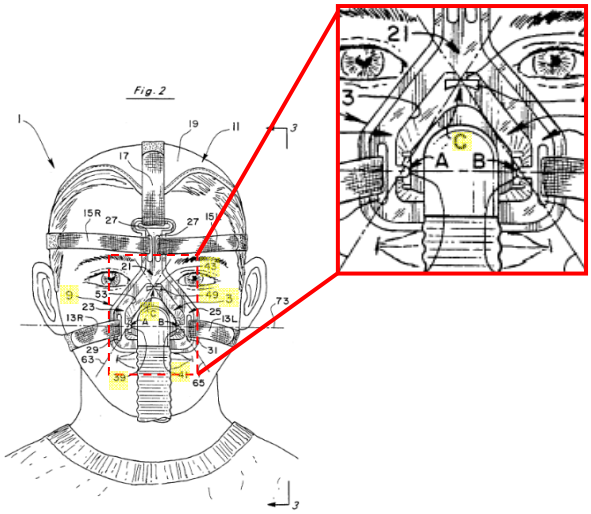
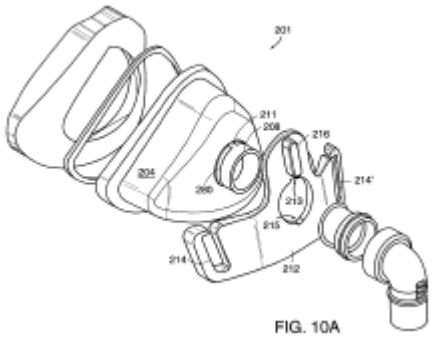
’931 Patent	Prior Art
each said upper headgear connector including a slot or receiving hole adapted to receive one of the upper headgear straps,	*See supra* Claim 7. **D’Souza:** “[S]keleton frame 412 includes an upper support member 444 adapted to support a forehead support, lower headgear clip receptacles 446.” Ex. 1510 ¶ 100.  Fig. 7 **Hitchcock:** “A prior art mask assembly 10 such as ResMed's ULTRA MIRAGE® mask as shown in Fig. 1 includes a forehead support 20 having a pair of arms 30, each having a slot 40 adapted to receive a strap (not shown). Each arm 30 includes a pair of forehead pad receiving lugs 50. The forehead support has a general ‘T’-shape, with the arms arranged along the upper cross portion of the ‘T’.” Ex. 1511 ¶ 24.  Fig. 1 Prior Art

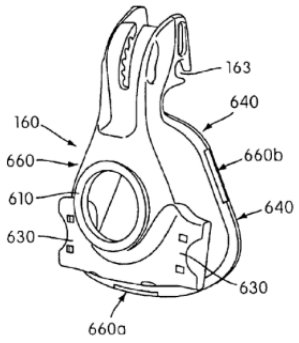
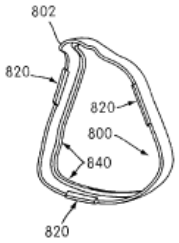
’931 Patent	Prior Art
	FlexiFit: “[A]ttach the four straps in to the corresponding slots in the Mask Base.” Ex. 1517 at 10 (“ASSEMBLING THE MASK”).  **Gunaratnam-I:** “As compared to FIGS. 5a-5b, FIGS. 5c-5f also show an adjustable forehead support (162) connected to the frame (160).” Ex. 1524 at col. 4:46–48.  FIG. 5c

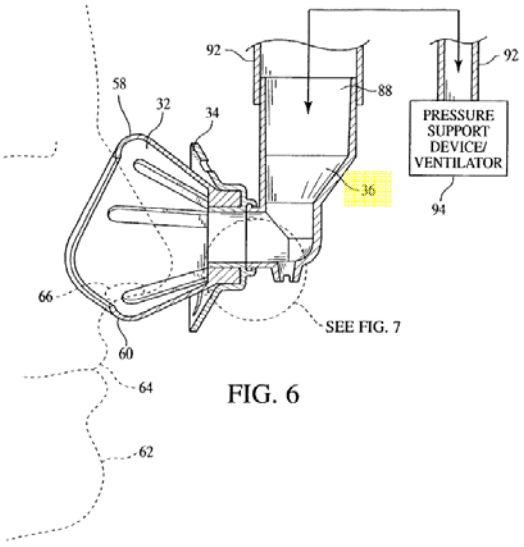
’931 Patent	Prior Art
	Lithgow: *See* Ex. 1534 at Fig. 1.  FIG. 1 **Matula-I:** “[A]ttachment elements 1248 are provided in the form of slots provided . . . [o]n a central portion 1249 of the body member.” Ex. 1523 ¶ 103.  FIG. 49

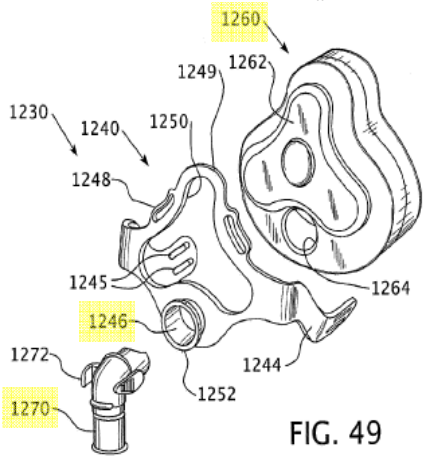
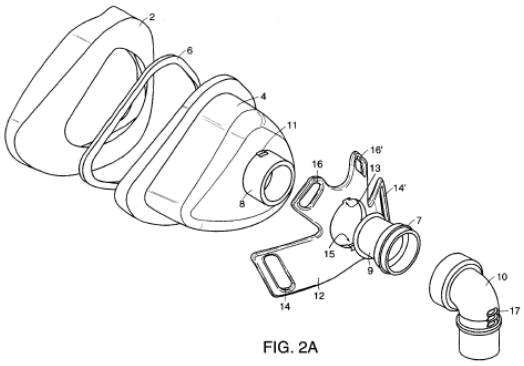
’931 Patent	Prior Art
	Ogden: “The upper side straps in this last regard could be the two straps 15R and 15L as illustrated or one continuous strap passing through loops 27 and anchoring the top portion 21 of the rigid plate 9 (see FIGS. 1-3).” Ex. 1529 at col. 3:7–10.  **Lovell:** “These connection 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. 1514 at col. 6:10–13.  FIG. 2A

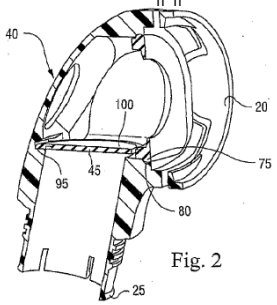
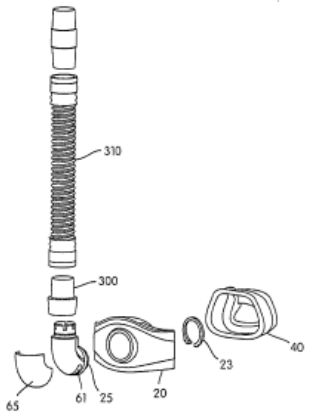
’931 Patent	Prior Art
wherein the shroud module and the frame of the cushion module are configured to be removably snap-fit attached to one another in a non-rotatable manner;	*See supra* Claims 1[A] and 26. **D’Souza:** “[S]keleton frame 412 that is adapted to removably interlock with a cushion/frame sub-assembly 430.” Ex. 1510 ¶ 96. “[A]nnular elbow connection seal 448 interlocks with the annular wall 440.” *Id.* ¶ 101.  Fig. 7 **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,

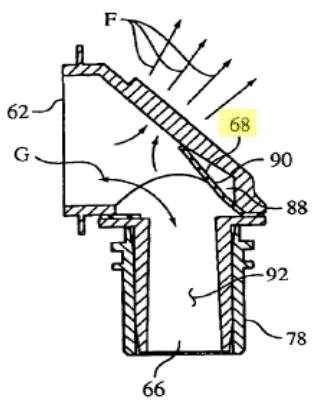
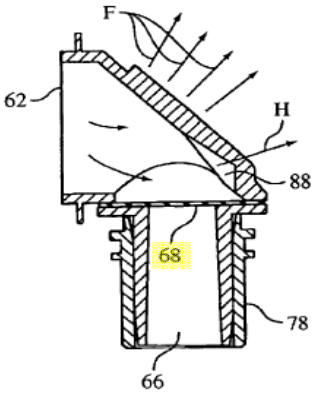
’931 Patent	Prior Art
	and C. . . . Further, although the detent-channel 43, 49 at the top of the shell 3 at the third location C is preferably dimensioned to snap together to hold or maintain the rigid plate 9 on the rigid shell 3.” Ex. 1529 at col. 4:59–5:19.  **Lovell:** “The retainer 212 is disposed 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. 1514 at col. 9:43–48; *see also id.* at 9:59–64. 

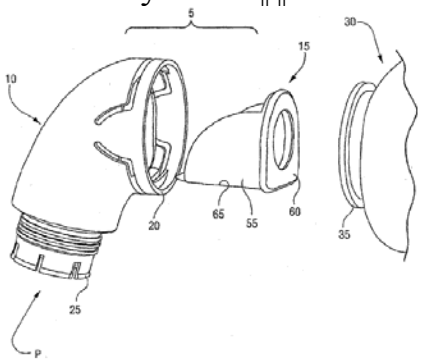
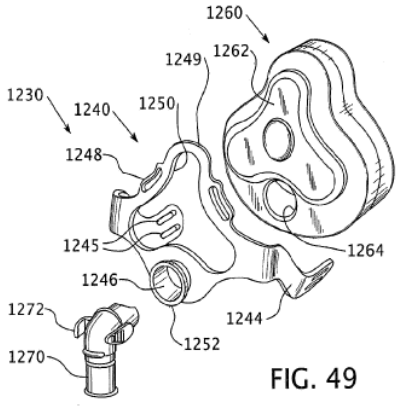
’931 Patent	Prior Art
	Gunaratnam-I: “[T]he clip (800) includes three securing tabs (820) such that inwards projections on the detents are formed as resilient detents which extend past the outer edge of flange (640) to be retained in recesses (660) on the front of the flange (640). To disengage, for 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. 1524 at col. 5:34–43.  FIG. 5a  FIG. 7a

’931 Patent	Prior Art
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. **D’Souza:** “[S]keleton frame 412 includes . . . an annular elbow connection seal 448 adapted to engage an inlet conduit, e.g., elbow.” Ex. 1510 ¶ 100. “[S]keleton frame 412 . . . provides attachment points for . . . an inlet conduit.” *Id.* ¶ 101. **Barnett:** “[C]onduit coupling member 36 is preferably rotateably mounted on a second side of collar 34 . . . so that conduit coupling member 36 freely rotates over a range of 360°.” Ex. 1513 at col. 3:52–57; *see also id.* at col. 8:66—9:43. “Conduit coupling portion 88 attaches conduit coupling member 36 to a patient circuit 92, . . . which carries a flow of breathing gas generated by a flow generating device 94 . . . to nose receiving cavity 42.” *Id.* at col. 8:49–54.  FIG. 6

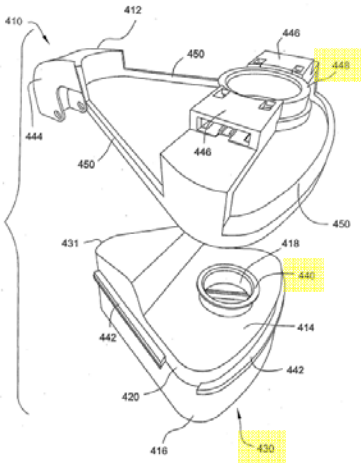
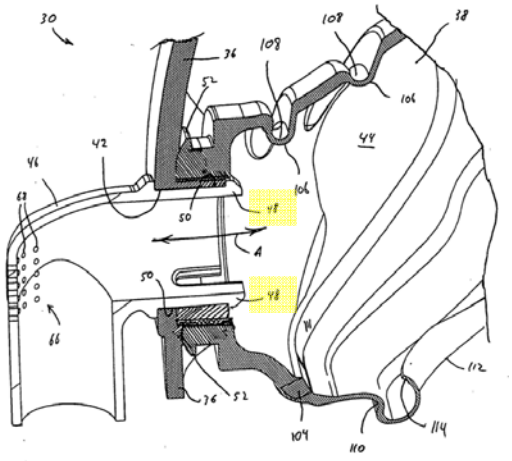
’931 Patent	Prior Art
	Matula-I: “[P]atient circuit coupling 1270 is an elbow coupling that rotatably and releasably attaches to circuit coupling portion 1246.” Ex. 1523 ¶ 105.  FIG. 49 **Lovell:** “[S]wivel connector 9 produces a swivel mount connection between the conduit elbow 10 and the inlet 8. 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. 1514 at col. 5:20–24.  FIG. 2A
the elbow including a swivel adapted to connect to an air delivery tube,	*See supra* Claim 43[N]. **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. 1511 ¶ 28.

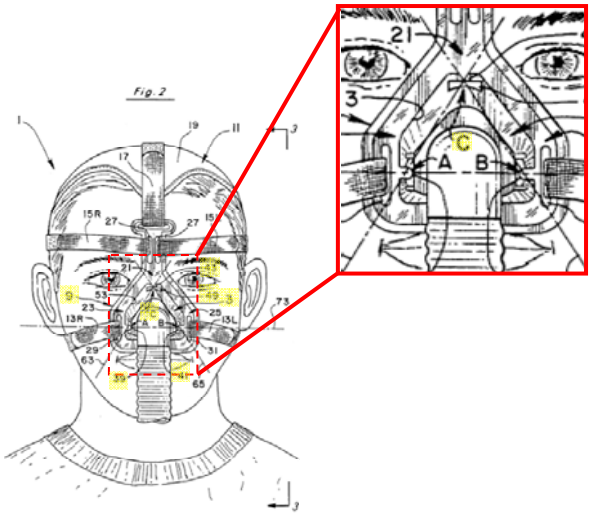
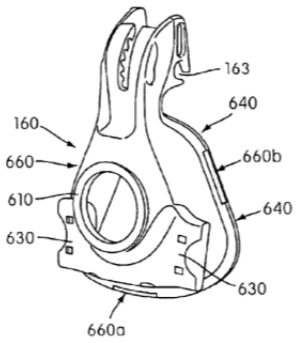
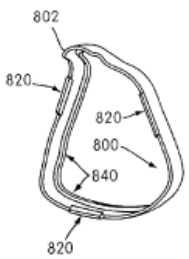
’931 Patent	Prior Art
	Ultra Mirage: “360° rotating elbow provides control over tubing system.” Ex. 1516 at 6. “Quick release swivel allows easy disconnection from tubing.” *Id.* **Worboys:** “The elbow has a first portion 20 and a second portion 25. . . . The second portion 25 typically will be provided with a swivel joint which in turn is connected to an air delivery tube in communication with a flow generator.” Ex. 1522 ¶¶ 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. 1532 ¶ 153.  FIG. 6b

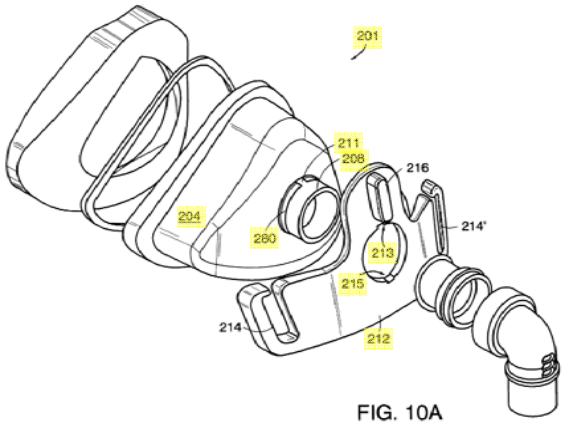
’931 Patent	Prior Art
	Ogden: “Another feature of the facial mask assembly 1 of the present invention is the swivel hose coupling 10 of FIGS. 8 and 9 connecting the rigid shell 3 to the flexible hose 12.” Ex. 1529 at col. 5:35–37.
the elbow including an anti-asphyxia valve (AAV) and a port that is selectively closed by a flap portion of the AAV;	*See supra* Claim 15. **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. 1515 at col. 10:4–8. “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. 10:14–28.  FIG. 8  FIG. 9 **Worboys:** “[E]lbow assembly 5 generally comprises an elbow 10 and an anti–asphyxia valve 15 (AAV) assembly.” Ex. 1522 ¶ 103. “[E]lbow 10 includes a

’931 Patent	Prior Art
	port 40 that may be selectively closed by a flap portion 45 of the AAV assembly.” *Id*. ¶¶ 105–106.  Fig. 1 **<u>Matula-I</u>:** “[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. 1523 ¶ 106.  FIG. 49
the elbow is rotatably attached the shroud module, the upper headgear straps provide padding to the respective headgear connectors of the shroud on the	*See supra* Claim 46.

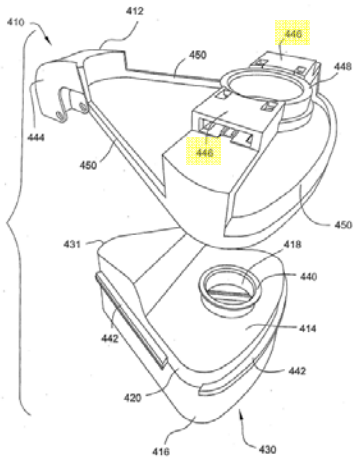
’931 Patent	Prior Art
patient's face in use, the frame includes a protruding vent arrangement having a plurality of holes, wherein the shroud module includes a first opening to accommodate said protruding vent arrangement, further wherein the shroud module includes a second opening to accommodate the elbow, the frame includes a frame opening and the frame further includes a collar surrounding said frame opening, 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, and the top straps are connected together with a buckle allowing independent adjustment of each of the top straps.	

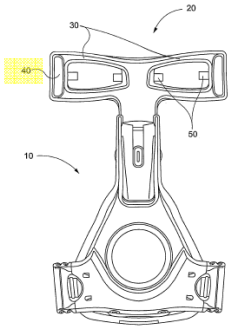
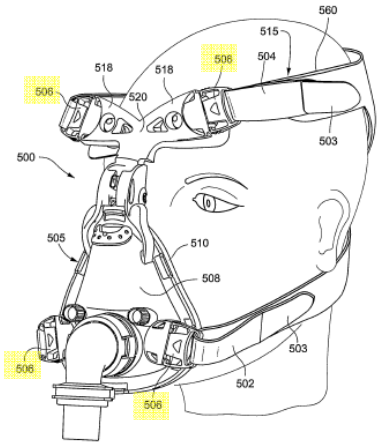
’931 Patent	Prior Art
53. The mask system of claim 51, wherein the second shroud opening and the frame opening are aligned along a common longitudinal axis, and wherein the shroud and the frame are removably snap-fit attached to one another by moving the shroud and the frame towards one another along the longitudinal axis.	*See supra* Claim 26. **D’Souza:** “[S]keleton frame 412 that is adapted to removably interlock with a cushion/frame sub-assembly 430.” Ex. 1510 ¶ 96. “[A]nnular elbow connection seal 448 interlocks with the annular wall 440.” *Id.* ¶ 101.  Fig. 7 **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,

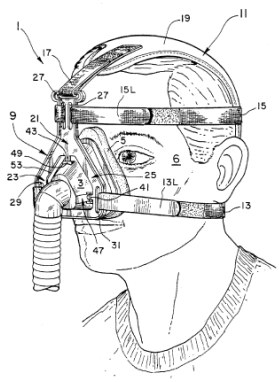
’931 Patent	Prior Art
	and C. . . . Further, although the detent-channel 43, 49 at the top of the shell 3 at the third location C is preferably dimensioned to snap together to hold or maintain the rigid plate 9 on the rigid shell 3.” Ex. 1529 at col. 4:59—5:19.  **Gunaratnam-I:** “[T]he clip (800) includes 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. 1524 at col. 5:34–43.  FIG. 5a  FIG. 7a

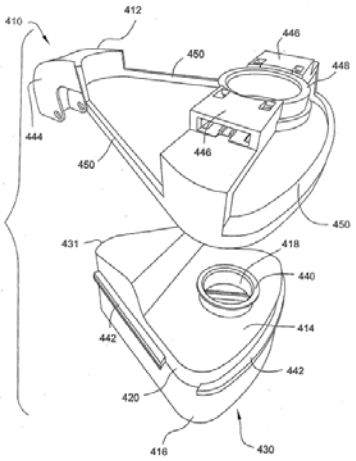
’931 Patent	Prior Art
	Lovell: “The retainer 212 is disposed about the inlet 208 to facilitate retention of the mask 201 on a user. . . . Two tabs 211, 211′ included on the inlet 208 mate with two slots 213, 215 formed in the retainer 212 in a particular angular orientation. . . . The retainer aperture 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; *see also id.* at 9:59–64.  FIG. 10A
54. The mask system of claim 51, wherein the frame is semi-rigid or rigid.	*See supra* Claim 1(ii). **D’Souza:** [F]rame 414 is constructed of polycarbonate.” Ex. 1510 ¶ 98.
55. The mask system of claim 54, wherein the frame is rigid.	*See supra* Claim 1(ii). **D’Souza:** [F]rame 414 is constructed of polycarbonate.” Ex. 1510 ¶ 98.
56. A system for treating a patient with sleep disordered breathing, comprising: the mask system of	*See supra* Claims 1, 11, and 51. **D’Souza:** “[M]ask assembl[ies] for use with blowers and flow generators in the treatment of sleep disordered breathing (SDB) . . . . [P]atient interface is held in a

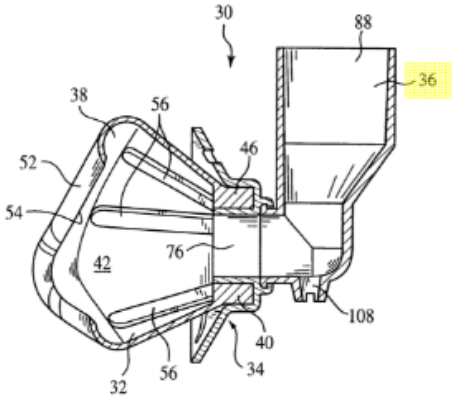
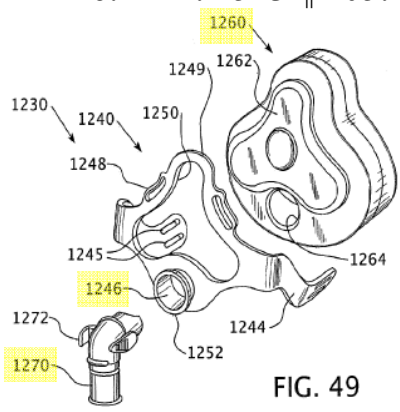
'931 Patent	Prior Art
claim 51; and a flow generator to generate a supply of air at positive pressure to be delivered to the mask system,	sealing position by headgear so as to enable a supply of air at positive pressure to be delivered to the patient's airways." Ex. 1510 ¶ 3.
wherein the air delivery tube is configured to deliver the supply of air from the flow generator to the mask system.	**D'Souza:** "[S]keleton frame 412 includes . . . an annular elbow connection seal 448 adapted to engage an inlet conduit, e.g., elbow." Ex. 1510 ¶ 100. **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. 1511 ¶ 28. **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. 1528 ¶ 316. **Ultra Mirage:** "360° rotating elbow provides control over tubing system." Ex. 1516 at 6.
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. **D'Souza:** "[M]ask assembl[ies] for use with blowers and flow generators in the treatment of sleep disordered breathing (SDB) . . . . [P]atient interface is held in a sealing position by headgear so as to enable a supply of air at positive pressure to be delivered to the patient's airways." Ex. 1510 ¶ 3.
headgear including headgear straps;	**D'Souza:** "[P]atient interface is held in a sealing position by headgear." Ex. 1510 ¶ 3. "[S]keleton frame 412 includes an upper support member 444 adapted to support a forehead support, lower headgear clip receptacles 446 adapted to be

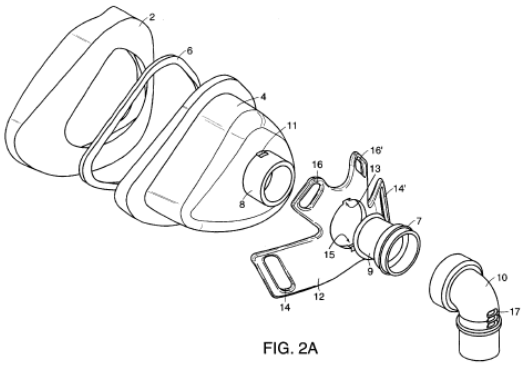
’931 Patent	Prior Art
	engaged with clips provided to straps of a headgear assembly (not shown).” Ex. *Id.* ¶ 100.
a shroud module having a pair of upper headgear connectors and a pair of lower headgear connectors adapted to removably attach to the respective headgear straps of the headgear,	*See supra* Claims 1(i), 6, 19[A]. **D’Souza:** “[S]keleton frame 412 includes . . . lower headgear clip receptacles 446 adapted to be engaged with clips provided to straps of the headgear assembly (not shown).” Ex. 1510 ¶ 100.  Fig. 7

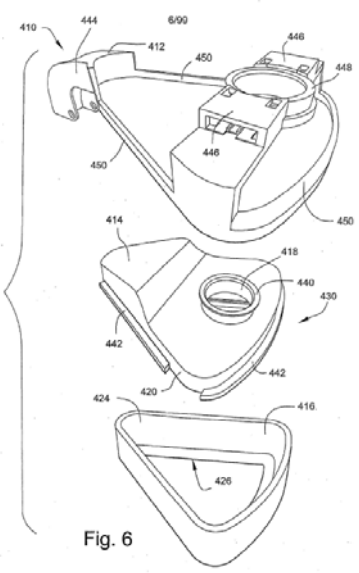
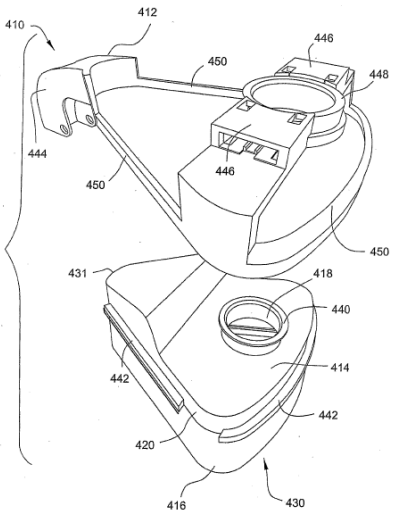
’931 Patent	Prior Art
	Hitchcock: “A prior art mask assembly 10 such as ResMed's ULTRA MIRAGE® mask as shown in Fig. 1 includes a forehead support 20 having a pair of arms 30, each having a slot 40 adapted to receive a strap (not shown). Each arm 30 includes a pair of forehead pad receiving lugs 50. The forehead support has a general ‘T’-shape, with the arms arranged along the upper cross portion of the ‘T’.” Ex. 1511 ¶ 24.  Fig. 1 Prior Art “In the illustrated embodiment, the upper side straps 504 are removably connected to respective arms 518 of the Y-shaped forehead support 520 via clips 506, which operate in a manner similar to the clips described above. Also, the lower side straps 502 are removably connected to a lower portion of the mask frame 508 via clips 506.” *Id.* ¶ 38.  Fig. 8

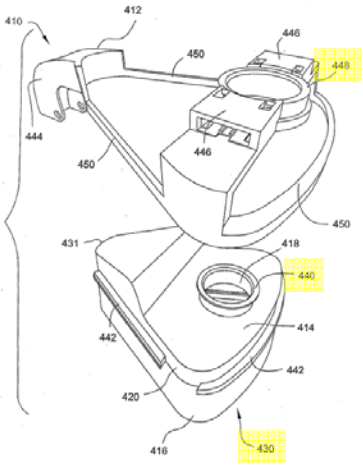
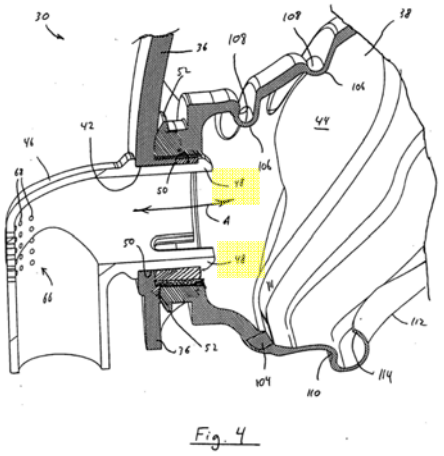
’931 Patent	Prior Art
	Ultra Mirage: “Quick release headgear clips: top and bottom allows mask to be removed without resetting the headgear and provides convenience and safety.” Ex. 1516 at 6. **Ogden:** “[E]ach side strap 13R and 13L is preferably attached to a respective side portion 23, 25 of the 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. 1529 at col. 3:10–20. Fig. 1 

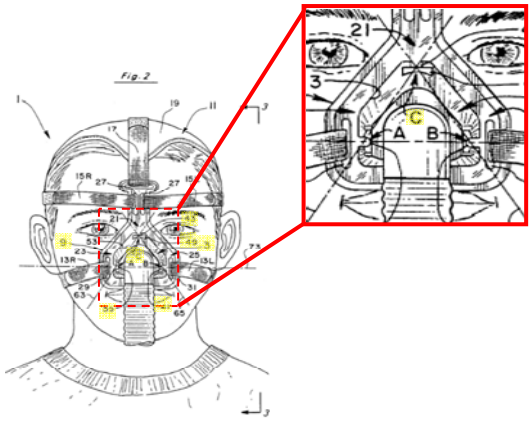
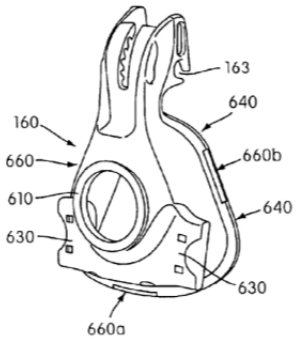
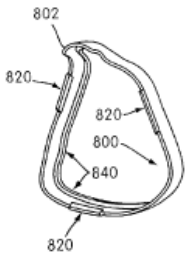
’931 Patent	Prior Art
the shroud module having a front opening;	*See supra* Claim 43[J]. **D’Souza:** “[A]nnular elbow connection seal 448 interlocks with the annular wall 440 of the cushion/frame sub-assembly 430. Ex. 1510 ¶ 101, Fig. 7.  Fig. 7

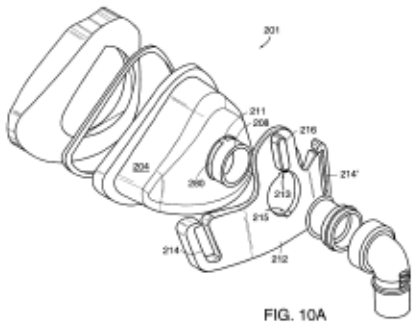
’931 Patent	Prior Art
a rotatable elbow directly attached to the shroud; and	*See supra* Claims 11 and 14. **D’Souza:** “[S]keleton frame 412 includes . . . an annular elbow connection seal 448 adapted to engage an inlet conduit, e.g., elbow.” Ex. 1510 ¶ 100. “[S]keleton frame 412 . . . provides attachment points for . . . an inlet conduit.” *Id.* ¶ 101. **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. 1513 at col. 3:52–57; *see also id.* at col. 8:66—col. 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. 1523 ¶ 105.  FIG. 49

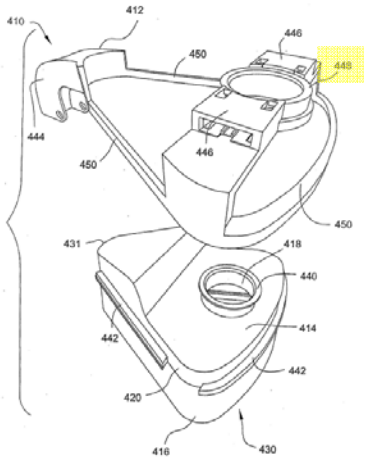
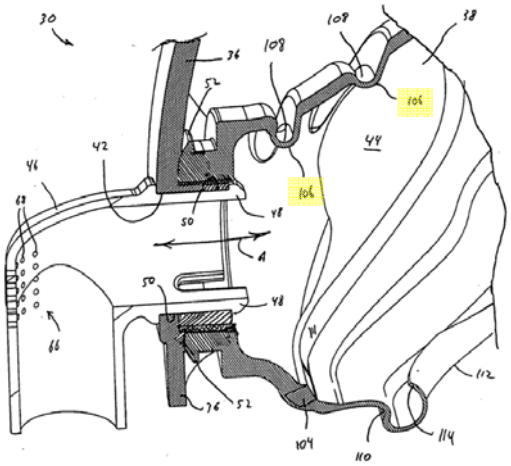
’931 Patent	Prior Art
	<u>Lovell</u>: “[S]wivel connector 9 produces a swivel mount connection between the conduit elbow 10 and the inlet 8. In this type of connection, the conduit elbow 10 is capable of rotating 360 degrees about the centerline of the inlet 8 and the connector 9.” Ex. 1514 at col. 5:20–24.  FIG. 2A

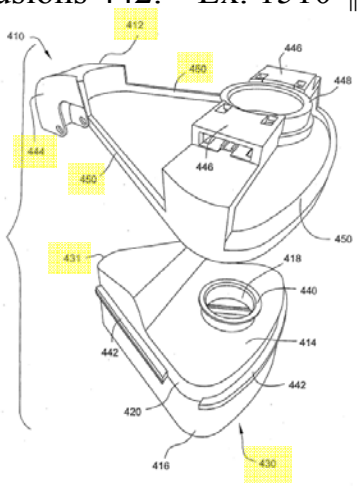
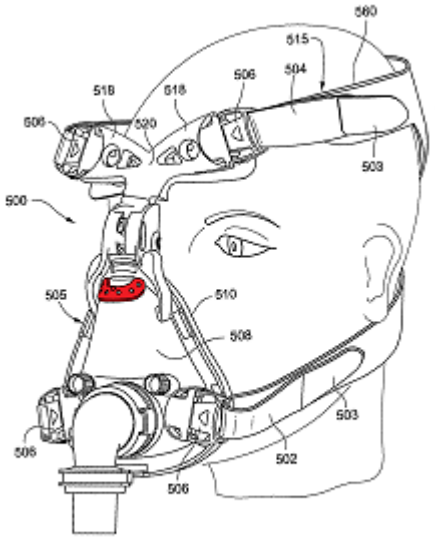
’931 Patent	Prior Art
a cushion module, the cushion module comprising a frame defining a breathing chamber, the frame having a frame opening leading to the breathing chamber; and a cushion to form a seal with the patient's face, wherein the cushion comprises a first, relatively soft, elastomeric material and the frame comprises a second material that is more rigid than the cushion;	*See supra* Claims 1(ii). **D’Souza:** “[F]rame 414 and a cushion 416 are . . . interlocked to provide a cushion/frame sub-assembly 430. . . . [C]ushion 416 is[] constructed of liquid silicone rubber (LSR).” Ex. 1510 ¶ 97. “[F]rame 414 includes an upper wall that provides an opening 418 for communicating with an inlet conduit. . . . A side wall 420 extends from the upper wall . . . . [F]rame 414 is constructed of polycarbonate.” *Id.* ¶ 98. “[C]ushion provides a seal around the patient's nose and mouth to enable the delivery of breathable gas to the patient's nose and mouth.” *Id.* ¶ 81.  Fig. 6  Fig. 7

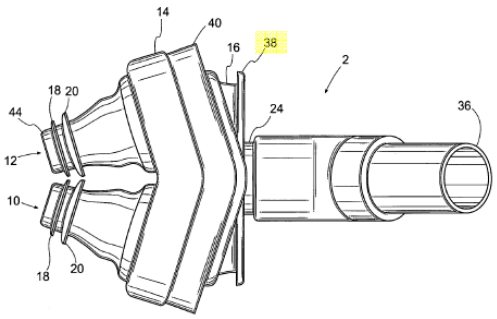
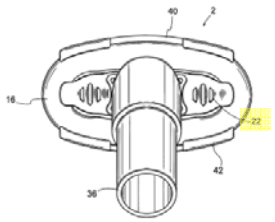
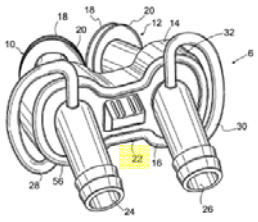
’931 Patent	Prior Art
wherein: the front opening of the shroud module and the frame opening of the frame are aligned along a common longitudinal axis, and wherein the shroud module and the cushion module are structured and arranged to be removably snap-fit attached to one another by moving the shroud module and the cushion module towards one another along the longitudinal axis,	*See supra* Claim 26. **D’Souza:** “[S]keleton frame 412 that is adapted to removably interlock with a cushion/frame sub-assembly 430.” Ex. 1510 ¶ 96. “[A]nnular elbow connection seal 448 interlocks with the annular wall 440.” *Id.* ¶ 101.  Fig. 7 **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,

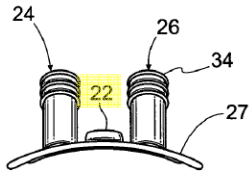
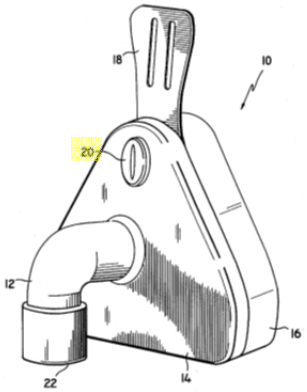
’931 Patent	Prior Art
	and C. . . . Further, although the detent-channel 43, 49 at the top of the shell 3 at the third location C is preferably dimensioned to snap together to hold or maintain the rigid plate 9 on the rigid shell 3.” Ex. 1529 at col. 4:59—5:19.  **<u>Gunaratnam-I</u>:** “[T]he clip (800) 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. 1524 at col. 5:34–43.  FIG. 5a  FIG. 7a

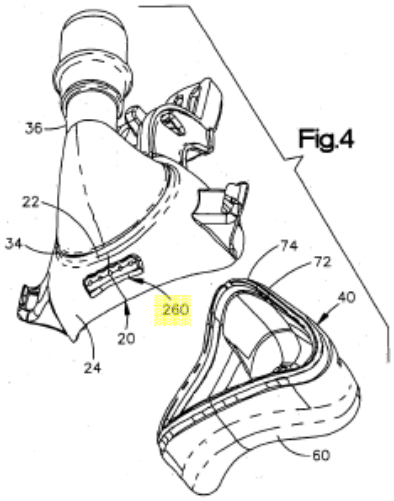
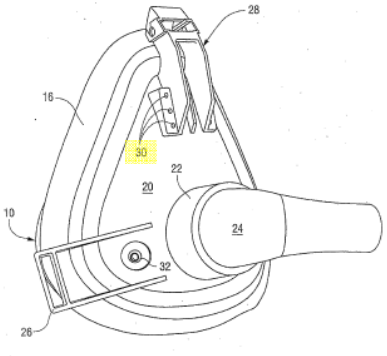
’931 Patent	Prior Art
	Lovell: “The retainer 212 is disposed about the inlet 208 to facilitate retention of the mask 201 on a user. . . . Two tabs 211, 211′ included on the inlet 208 mate with two slots 213, 215 formed in the retainer 212 in a particular angular orientation. . . . The retainer aperture 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; *see also id.* at 9:59–64.  FIG. 10A

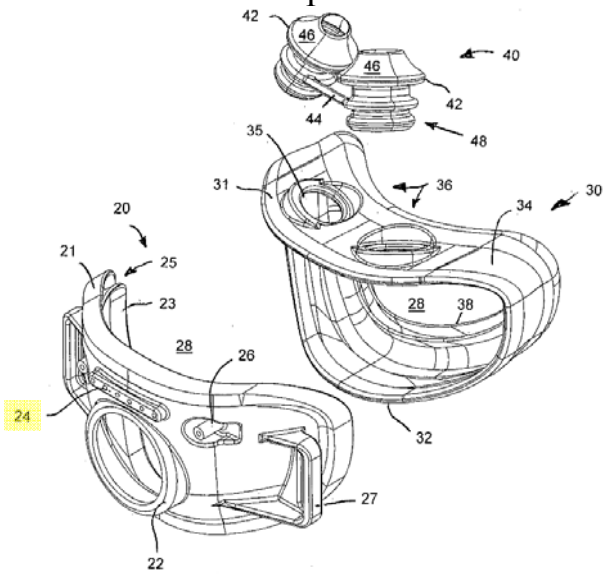
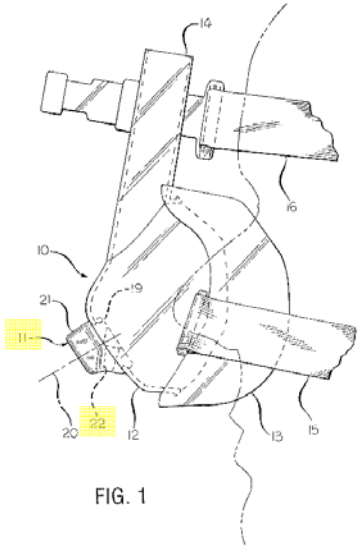
’931 Patent	Prior Art
and the shroud module includes a retaining portion positioned rearwardly of the front opening, towards the frame, and structured to snap fit with the cushion module.	*See supra* Claim 5. **D’Souza:** “[A]nnular wall 440 surrounds the opening 418 [of the frame 414].” Ex. 1510 ¶ 98. “[A]nnular elbow connection seal 448 interlocks with the annular wall 440.” *Id.* ¶ 101.  Fig. 7 **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 A person of skill in the art would have understood that the “prongs” of Matula-II could also be referred to as “snap fingers.”

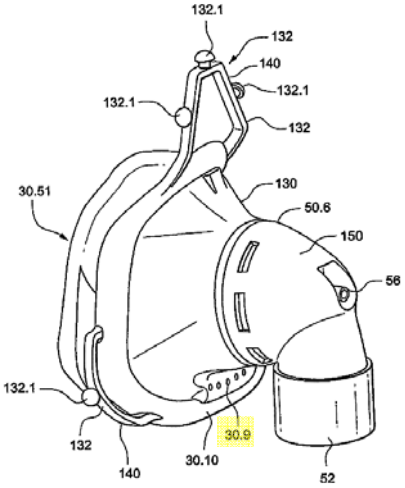
’931 Patent	Prior Art
65. The mask system of claim 57, wherein the frame includes a protruding vent arrangement having a plurality of gas washout holes, wherein the shroud module includes an upper opening to accommodate said protruding vent arrangement.	*See supra* Claim 1[B]. **D’Souza:** “[S]keleton frame 412 is engaged with the cushion/frame sub-assembly 430 such that . . . upper support member 444 interlocks with a top portion 431 . . . and the elongated frame members 450 interlock with respective protrusions 442.” Ex. 1510 ¶ 101.  Fig. 7 **Hitchcock:** *See* Ex. 1511 at Fig. 8.  Fig. 8

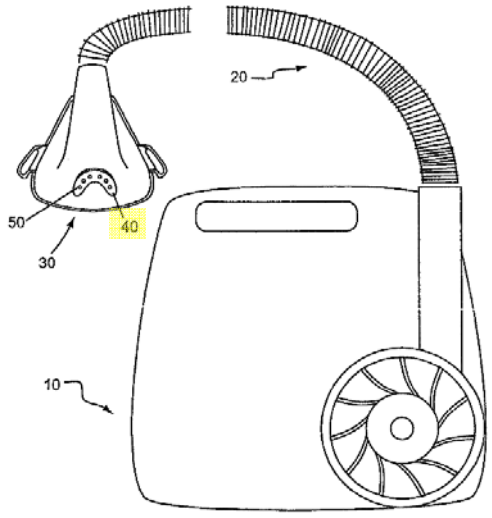
’931 Patent	Prior Art
	Thomlinson: “A nasal interface body 2 according to the present invention can also include one or more locking tabs 38 on the distal portion 16. The locking tabs 38 can be used to releasably engage a strap attachment plate 92, as depicted in FIG. 37 and described further below.” Ex. 1528 ¶ 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 the second inlet 26.” *Id*. ¶ 209.  Fig. 8

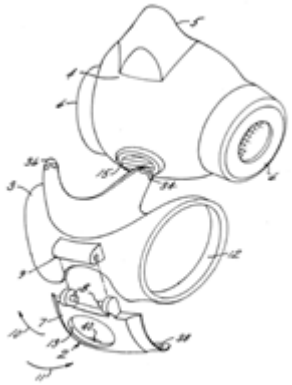
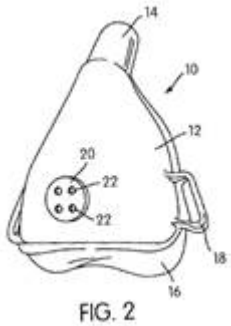
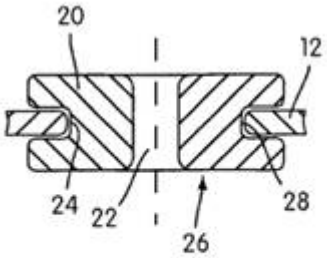
’931 Patent	Prior Art
	“As shown in the figures and in particular FIGS. 3, 14A, 15D, 15F, 16C and 16F, distal portion 16 can also include one or more exhalation ports 22, described further below.” *Id*. ¶ 247. “[E]xhalation ports may be located on any portion of the body of the nasal interface of the present invention, including distal portion 16 and/or proximal portion 14.” *Id*. ¶ 278.  Fig. 14A **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. 1541 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.

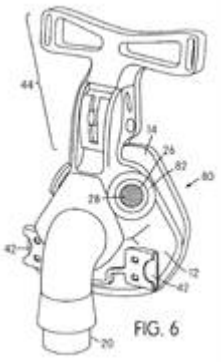
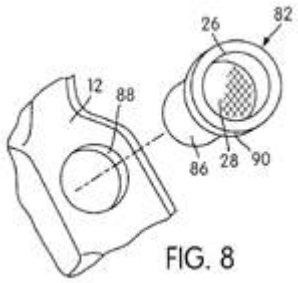
'931 Patent	Prior Art
	Sprinkle: "FIGS. 4 and 23 illustrate an exhalation vent portion 260 of the mask 10. The vent portion 260 includes a thickened wall area 262 in the lower part of the side wall 24 of the shell 20. Five circular exhalation openings 264 are formed at equally spaced intervals in the 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. 1520 ¶ 99.  **Hitchcock-II:** "A number of vents 30 may be provided so as to allow gas exhaled by the patient to vent to atmosphere." Ex. 1540 ¶ 42.  Fig. 1-2

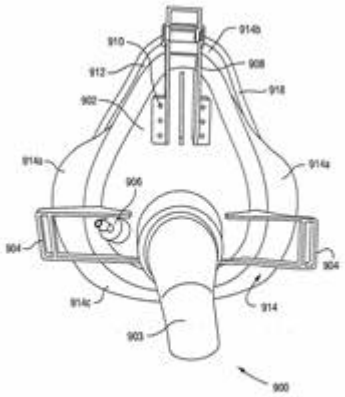
’931 Patent	Prior Art
	Chandran: “The ventilation interface 20 is configured with at least one exhalation port 24.” Ex. 1526 ¶ 60.  **Jones, Jr.:** “[T]he exhaust port member 11 is shown as having a generally circular perimeter 17 with a recessed or reduced diameter annular groove 18 formed in the perimeter 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. 1537 at col. 3:3–15.  FIG. 1

’931 Patent	Prior Art
	“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. 1538 ¶ 221.  “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. 1542 ¶ 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. 1546 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. 1545 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. 1525 ¶ 163.  Fig. 50

X. CONCLUSION

244. 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.

25992552