UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ResMed Inc., ResMed Corp., and ResMed Limited
Petitioners

v.

Fisher & Paykel Healthcare Limited
Patent Owner

Patent No. 8,443,807
IPR Nos. 2016-1726 & 2016-1734

DECLARATION OF JOHN IZUCHUKWU, Ph.D., P.E.

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I, John Izuchukwu, of University City, Missouri declare that:

I. ASSIGNMENT

1. I have been retained on behalf of ResMed Inc., ResMed Corp., and ResMed Limited ("ResMed"). I understand that ResMed is requesting that the Patent Trial and Appeal Board ("PTAB" or "Board") institute *inter partes* review ("IPR") proceedings of U.S. Patent No. 8,443,807 ("the '807 patent") (RMD1001).

2. I have been asked to opine on the subject of the validity of the claims of the '807 patent in light of the grounds of rejection at issue in ResMed's *inter partes* review Petitions.

3. My findings, as explained below, are based on my study, experience, and background in the fields discussed below. I have also relied on my review and analysis of the prior art, information provided to me in connection with this case, and information I have independently reviewed.

4. I am being compensated for my work as an expert on this matter, but my compensation is not contingent in any way on the content of my opinions or the outcome of this proceeding.

II. QUALIFICATIONS

5. I am a Professional Engineer with more than thirty years of experience in medical device technologies, and mechanical and industrial engineering. I have attached my *curriculum vitae* at the conclusion of this

declaration as Appendix A for a fuller overview of my experience and expertise. The following paragraphs summarize some pertinent aspects of the *C.V.*

6. In 1980, I received a Bachelor's of Science degree in Industrial and Mechanical Engineering from the University of Portland in Oregon. Then in 1984, I was awarded a Master's of Science degree in Mechanical Engineering from the University of Portland. In 1994, I received a Ph.D. in Industrial and Mechanical Engineering from Northeastern University. Later, in 2002, I received an MBA from the Kellogg School of Management at Northwestern University. I am also registered as a Professional Engineer in the State of Missouri.

7. I currently serve as the Chief Executive Officer (CEO) and Chief Technical Officer (CTO) of Core Devices Inc., a medical device company that I founded in 2001. In these roles, I have been intimately involved in the development of medical device technologies as well as the development and growth of the business itself. Among other things, I led the design and development of an oxygen conserving device, a conformal oxygen system for persons with respiratory disability, and a backpack-able field anesthesia machine.

8. From 1998-2001, I was employed by Nellcor Puritan Bennett (later Covidien, and now Medtronic) where I held the position of Senior Director of Global Research & Development and Engineering. During this time, I oversaw the development of diagnostic and therapeutic devices for respiratory care, including

devices for the treatment of sleep apnea disorders and chronic obstructive pulmonary disease (COPD). We brought to market more than a dozen new products, including several CPAP machines, and bi-level ventilators for respiratory support, sleep masks, a spirometer for the diagnosis of respiratory disorders, an oxygen conserving device, an oxygen concentrator, and a high efficiency liquid oxygen system.

9. Before joining Nellcor Puritan Bennett, I worked in research and development at Ethicon Endo-Surgery, Inc. from 1994-1998. Our R&D efforts at Ethicon were primarily focused on endoscopic surgical devices. I also worked for more than a decade (1983-1994) at Digital Equipment Corporation in the areas of manufacturing and automation technologies. I am a named inventor on 19 patents. I regularly serve as an adjunct professor at colleges and universities in the areas of medical device, mechanical, and industrial engineering, and have authored or co-authored more than two dozen publications.

10. I am listed in Marquis "Who's Who in Science and Engineering," "Who's Who in the World," and "Who's Who in America." I am also a former member of the Board of Directors of the Rankin Jordan Pediatric Hospital in St. Louis, Missouri.

III. LEGAL STANDARDS

11. In preparing my analysis, I have applied the legal standards described below, which were provided to me by counsel for the Petitioners.

12. It is my understanding that assessing the validity of a U.S. patent based on a prior art analysis requires two essential steps. First, one must construe the terms of the patent claims to understand what meaning one of ordinary skill in the art would have given the terms as of the effective priority date(s) of the claims. Second, after the claim terms have been construed, one may then assess validity by comparing a patent clam to the "prior art." For the purpose of my independent analysis herein, I have assumed that each of the references applied in the Petitions constitutes prior art.

13. I understand that the '807 patent has not expired. As such, I have been informed that the "broadest reasonable interpretation" standard of construction applies in these proceedings. Under this standard, claims are to be interpreted according to their broadest reasonable construction in light of the specification as it would be interpreted by one of ordinary skill in the art as of the time of the respective claims of the '807 patent. I understand that under the broadest reasonable interpretation, words of the claim are given their plain meaning, unless such meaning is inconsistent with the specification. The plain meaning of a term means the ordinary and customary meaning given to the term by

those of ordinary skill in the art at the time of the invention. I have been informed that the broadest reasonable interpretation standard that applies in *inter partes* review proceedings involving unexpired patents is different than the standard applied by courts and in some other forums in which issued patents are litigated.

14. I understand that the teaching of the prior art is viewed through the eyes of a person of ordinary skill in the art at the time the invention was made. To assess the level of ordinary skill in the art, I understand that one can consider the types of problems encountered in the art, the prior solutions to those problems found in prior art references, the rapidity with which innovations are made, the sophistication of the technology, and the level of education of active workers in the field. My opinion as to what constitutes a relevant person of ordinary skill in the art is set forth further below.

15. I understand that a patent claim is invalid as obvious if the subject matter "as a whole" of the claimed invention would have been obvious to a person of ordinary skill in the field at the time the invention was made. In determining the differences between a prior art reference (or a proposed combination of prior art references) and the claims, the question of obviousness is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious.

16. I understand that a patent claim composed of several elements is not proved obvious merely by demonstrating that each of its elements was independently known in the prior art. In evaluating whether any claim of the '807 patent would have been obvious, I have further considered and set forth articulated reasons that would have prompted a person of ordinary skill in the field to combine the elements or concepts from the prior art in the same way as in the claimed invention.

17. I understand that there is no single way to define the line between true inventiveness on one hand (which is patentable) and the application of common sense and ordinary skill to solve a problem on the other hand (which is not patentable). For example, market forces or other design incentives may be what produced a change, rather than true inventiveness. It is my understanding that the decision-maker may consider whether the change was merely the predictable result of using prior art elements according to their known functions, or whether it was the result of true inventiveness. And, the decision-maker may also consider whether there is some teaching or suggestion in the prior art to make the modification or combination of elements recited in the claim at issue. Also, the decision-maker may consider whether the innovation applies a known technique that had been used to improve a similar device or method in a similar way. The decision-maker may also consider whether the claimed invention would have been

obvious to try, meaning that the claimed innovation was one of a relatively small number of possible approaches to the problem with a reasonable expectation of success by those skilled in the art. I understand that the decision-maker must be careful not to determine obviousness using the benefit of hindsight, and that the decision-maker should consider obviousness from the position of a person of ordinary skill in the relevant field at the time the claimed invention was made.

18. I understand that in order to determine whether a patent claim is obvious, one is to make certain factual findings regarding the claimed invention and the prior art. Specifically, I understand that the following factors are to be evaluated to determine whether a claim is obvious: (1) the scope and content of the prior art; (2) the difference or differences, if any, between the claim of the patent and the prior art; (3) the level of ordinary skill in the art at the time the claimed invention was made; and (4) the objective indicia of non-obviousness, also known as "secondary considerations."

19. I understand that the secondary considerations include:

(1) commercial success of a product due to the merits of the claimed invention;

(2) a long felt need for the solution provided by the claimed invention;

(3) unsuccessful attempts by others to find the solution provided by the claimed invention;

(4) copying of the claimed invention by others;

(5) unexpected and superior results from the claimed invention;

(6) acceptance by others of the claimed invention as shown by praise from others in the field or from the licensing of the claimed invention;

(7) teaching away from the conventional wisdom in the art at the time of the invention;

(8) independent invention of the claimed invention by others before or at about the same time as the named inventor thought of it; and

(9) other evidence tending to show obviousness.

20. I have been informed that, in order to establish a secondary consideration, the evidence must demonstrate a nexus between that secondary consideration and the claimed invention.

IV. PERSON OF ORDINARY SKILL IN THE ART

21. It is my opinion that a person of ordinary skill in the art at the time of the effective filing dates of the applications that led to the '807 patent would have had a bachelor's degree in mechanical engineering, biomedical engineering, or a related discipline, and at least five years of relevant product design experience in the field of medical devices or respiratory therapy, or an equivalent advanced education. My opinions are thus based on the perspective of a person of ordinary

skill in the art having this level of knowledge and skill at the time of the effective filing dates of the applications that led to the '807 patent.

22. I understand that the '807 patent claims priority to a pair of New Zealand patent applications that were filed on July 14, 2006, and November 6, 2006, respectively. I have been instructed by counsel for the Petitioners to apply the perspective of a person of ordinary skill in the art from the time leading up to the July and November 2006 filing dates of the New Zealand application. My analysis in this declaration is based on the perspective of one of ordinary skill in the art during this timeframe (as early as July 2006).

V. MATERIALS CONSIDERED

23. In preparing this declaration, I have considered the claims, specification, and prosecution history of the '807 patent. I have also read and considered ResMed's Petitions for *inter partes* review of the '807 patent, the various documents referenced in my declaration, and additional background materials. Among the materials that I have reviewed in preparing this declaration are:

- U.S. Patent No. 8,443,807 to McAuley et al. (RMD1001, "the '807 Patent")
- U.S. Patent Application Publication No. 2004/0226566 to *Gunaratnam* et al. (RMD1004, "*Gunaratnam*")

- U.S. Patent Application Publication No. 2003/0196658 to *Ging* et al. (RMD1005, "*Ging*")
- U.S. Patent No. 6,691,707 to *Gunaratnam* et al. (RMD1007, "the *'707 patent*" or "*Gunaratnam II*")
- File History of U.S. Patent No. 8,443,807 to McAuley et al. (RMD1009) (selected portions)
- U.S. Patent No. 7,219,669 to *Lovell* et al. ("*Lovell*") (RMD1012)
- Merriam-Webster's Collegiate Dictionary, Eleventh Edition (2004) (selected portions) (RMD1014)
- U.S. Patent 4,676,241 to Webb (RMD1016)
- PCT Publication No. WO 2004/022147 to Drew (RMD1018)
- U.S. Patent 4,782,832 to Trimble (RMD1019)
- U.S. Patent 6,431,172 to Bordewick (RMD1020)
- U.S. Patent 6,192,886 to Rudolph (RMD1021)
- U.S. Patent 6,581,594 to Drew (RMD1022)
- Mirage Vista User's Guide (RMD1024)
- PCT Pub. WO 2005/079726 to *McAuley* et al. ("*McAuley*") (RMD1034)
- U.S. Patent No. 7,178,528 ("*Lau*") (RMD1037)

- WeddingBands.com – Men's Wedding Ring Shopping Page (Retrieved October 16, 2015 from *http://www.weddingbands.com/ProductPop_wedding_bands_metal/48214W.html?gclid=Cj0KEQjwwIKxBRDKhOz7ytT30vkBEiQAT1NaPTkynkzziabZ7rGCksELV_JfZn_nYKjW7Cfog4tma3MaAixf8P8HAQ*) (RMD 1038)
- HomeDepot.com – Ring Nut Sales Page (Retrieved October 16, 2015 from *http://www.homedepot.com/p/Everbilt-1-2-in-Galvanized-Hex-Nut-804076/204647893*) (RMD1039)
- ResMed Origins Brochure (Retrieved April 17, 2016 from http://www.resmed.com/us/dam/documents/articles/resmed-origins.pdf) (RMD1040)

VI. BACKGROUND OF THE '807 PATENT

A. Subject Matter Overview

24. The '807 patent (RMD1001) is titled "Breathing Assistance Apparatus," and generally describes devices that "provide[] a nasal interface for the supply of respiratory gases," such as for the treatment of obstructive sleep apnea. RMD1001 at 1:10-33.

25. Obstructive sleep apnea (OSA) is a sleep disorder in which a person's airway closes during sleep, resulting in "repeated sequences of snoring, breathing difficulty, lack of breathing, waking with a start and then returning to sleep." *Id.* at

1:24-33. One way to treat OSA is to deliver a pressurized flow of gas to a patient's airway during sleep to help keep the airway open. This treatment is called continuous positive airway pressure ("CPAP") as would have been well understood by one of ordinary skill in the art at the time of the '807 patent. Notably, one of ResMed's founders, Dr. Colin Sullivan, is widely recognized as a pioneer in CPAP technology, and was the first to apply CPAP to treat OSA. *See* ResMed Origins (RMD1040) at pp. 2, 9-13.

26. A CPAP system generally includes a flow generator (e.g., a blower) that generates pressurized air. *Id.* at 1:45-49. Tubing and a mask deliver the pressurized air to the patient's nasal passages or mouth. *See id.* at 4:43-5:24, Fig. 1. Headgear may help keep the mask on the patients face. *Id.* at 1:47-49.

27. The '807 patent refers to the tubing, mask, and headgear together as a "patient interface." The '807 patent relates to specific features of a patient interface, which the patent contends were useful to overcome disadvantages in the prior art. RMD1001 at 1:15-40, 2:58-60. Namely, the '807 patent states that "[c]onventional nasal masks used for administrating CPAP treatment are [] considered uncomfortable and cumbersome" and can also "be noisy due to air leaks," resulting in reduced patient compliance with prescribed treatment. *Id.* at 2:23-32. The '807 patent claims at issue here relate particularly to patient

interfaces with "nasal-pillow"-type masks, in which small cushions (i.e., nasal pillows) deliver pressurized air to a patients nares (e.g., nostrils).

28. Figures 2 and 3 illustrate a preferred embodiment of a patient interface that generally depicts the features of the claims. The patient interface includes a headgear assembly 21; a mask assembly including mask body 23 with nasal pillows 24 and 25 and mask base 22; and an air delivery tube 31 having an elbow connector 30 and connector end 46 for rotatably connecting to the front of the mask assembly:

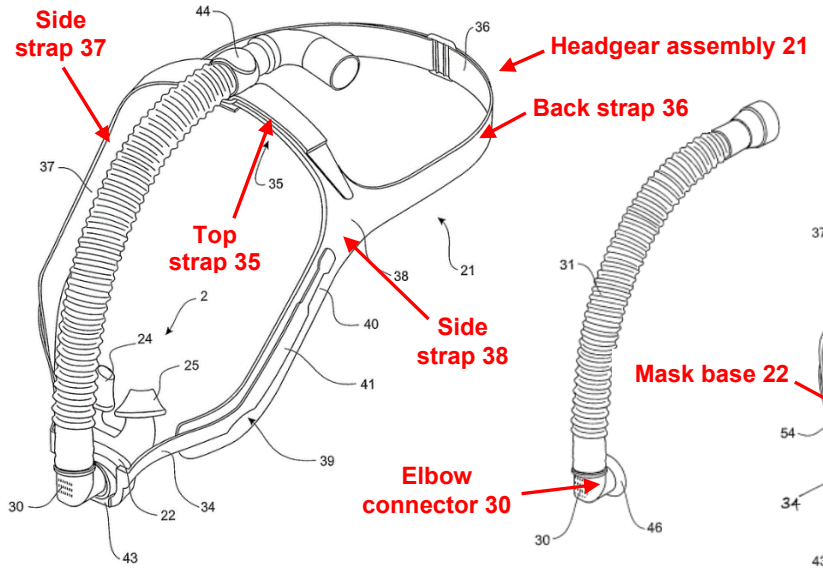


FIGURE 2

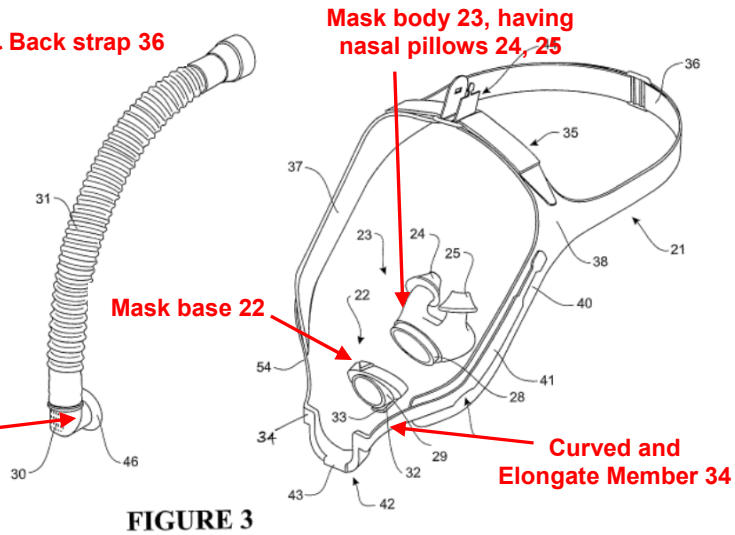


FIGURE 3

29. As shown in Figures 2 and 3 above, the headgear assembly 21 includes a curved and elongate member 34, to which a pair of side straps 37 and 38 are attached. Together, the side straps 37 and 38, along with a back strap 36 and top strap 35, secure the mask to the patient's head. RMD1001 at 6:57-7:3. The

curved and elongate member 34 includes a central section 42 that receives a hard mask base 22 having a ring-like opening. *Id.* at 6:19-45, 7:46-55. On a distal side of the mask base 22 is a channel 45 that receives a lip of the mask body 23, which is generally flexible and softer than the base 22. *Id.* The connector end 46 of the tube assembly (of elbow connector 30) then fits into a proximal side of the mask base 22, and allows the tube assembly to swivel relative to the mask base 22. *Id.* at 6:38-45.

B. File History of the '807 Patent

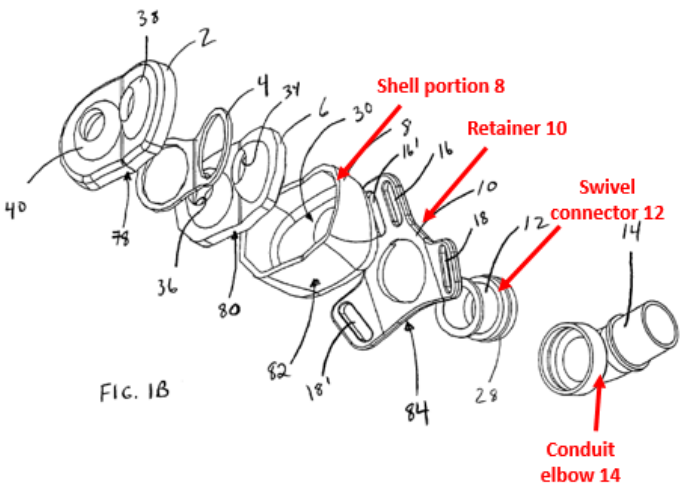
30. I have reviewed select portions of the '807 patent's file history (RMD1009). Based on this review, I understand that the Patent Office mailed an office action in July 2012, which rejected certain of the then-pending claims as being anticipated by *Lovell* (RMD1012), and which rejected certain other claims as being obvious over *Lovell* (RMD1012) in view of *Gunaratnam* (RMD1004). *See* RMD1009, '807 File History, pp. 585-590.

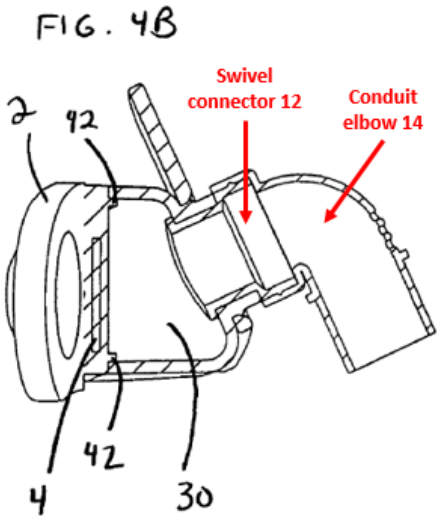
31. I understand that application claim 38 corresponds to issued claim 1 in the '807 patent, and that application claim 47 corresponds to issued claim 8 in the '807 patent. In response to the July 2012 office action, the applicant amended claim 38 as shown on page 614 of the file history (RMD1009), and also amended claim 47 as shown on pages 615-616 of the file history (RMD1009).

32. The amendments to claims 38 and 47 added a number of limitations to the claims, but the applicant only specifically addressed two of the added limitations in the arguments. *See* RMD1009, pp. 620-622.

33. Regarding the first argued limitation, the applicant remarked that *Lovell* does not disclose "an elbow rotatably engaged with the ring such that a portion of the elbow is received ***within the ring***," as recited in amended claim 38. *Id.* at p. 620 ("Furthermore, *Lovell* discloses a 'conduit elbow 14 that fits ***onto*** swivel connector 12.' *Lovell*, col. 5, ll. 26-28, Figure 4B. Thus, *Lovell* fails to teach or suggest a nasal mask having 'an elbow rotatably engaged with the ring such that a portion of the elbow is received ***within the ring***' . . . .") (emphasis in original). To illustrate the applicant's argument, Figures 1B and 4B of *Lovell* (RMD1012) are copied and annotated below. As these figures show, *Lovell's* assembly included a conduit elbow 14 having an end that fit onto a complementary portion of the swivel connector 12, which the Examiner had identified as disclosing the claimed "ring" structure. *See* RMD1009, p. 587. In other words, *Lovell*'s conduit elbow 14 acted as a female connector to receive a portion of the swivel connector 12, and in turn the swivel connector 12 acted as a male connector that fit within the conduit elbow 14. In its argument, the applicant distinguished *Lovell* by pointing to the amendment that required the elbow to be received within

the ring, rather than "onto" it.





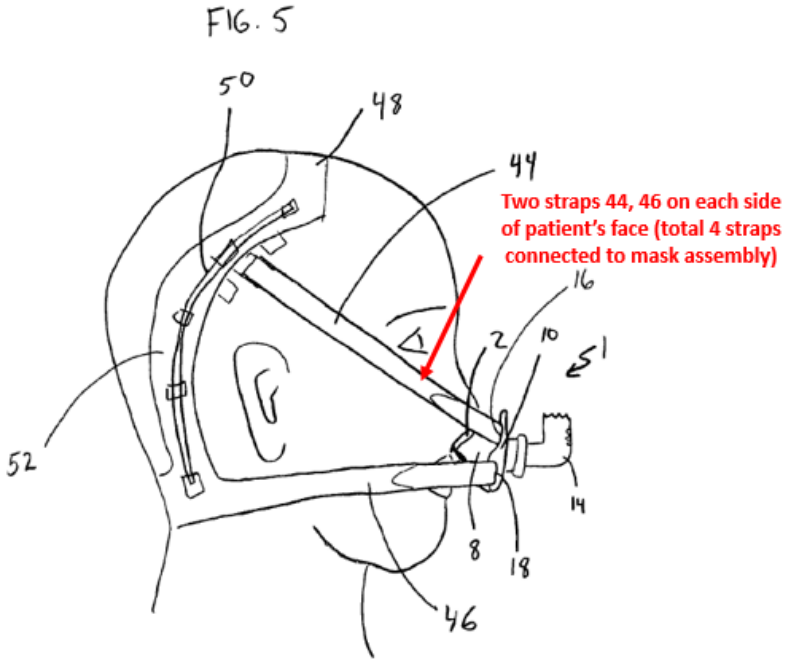
34. In my opinion, and based on my knowledge and experience in the field, one of ordinary skill in the art at the time of the '807 patent would have found the feature of an elbow rotatably engaged with the ring such that a portion of the elbow is received ***within the ring*** (as opposed to the elbow fitting onto the ring), to be an obvious modification of *Lovell's* design. For example, all that is required to meet this feature of amended claim 38 (issued claim 1) is to switch the configuration of the connection between the swivel elbow connector 12 and the conduit elbow 14 such that the swivel connector 12 serves as the *female* connector (rather than the *male* connector) for receiving the conduit elbow 14. The choice of male and female connectors was well-known at the time of the '807 patent, and their selection would have been an obvious engineering design choice. For instance, one of ordinary skill in the art would have understood that the

arrangement of male and female parts often is made based on safety considerations and/or the direction of flow of a medium through a channel formed by two or more connected parts. Thus, electrical connectors generally comply with strict rules regarding connector gender assignment to ensure safety for users making connections among the parts. In other contexts, however, connector gender assignments are generally less critical, such as when fluid flow may be bidirectional and safety concerns are less critical. In my opinion, the design considerations for a CPAP patient interface, unlike considerations in the electrical context, do not dictate a particular connector gender assignment. For example, there is little safety risk present in disconnecting the elbow 14 from the swivel connector 12 in *Lovell's* mask.

35. Moreover, the specific feature of a rotatable elbow received within a ring was conventional at the time of the '807 patent, as evidenced by *Gunaratnam*, *Ging*, and *Gunaratnam* II. *See* RMD1004, *Gunaratnam*, FIGs. 110B and 114 (showing a swivel elbow 612 received within a ring of the cushion assembly 604); RMD1005, *Ging*, FIGs. 6a, 6b, and ¶¶ 0112-0113 (disclosing that a "portion of [an] elbow assembly 60" that "protrudes" into an aperture of a frame 20, the frame 20 or a portion thereof being a ring); RMD1007, *Gunaratnam II*, FIG. 6 (depicting a similar configuration of an elbow assembly protruding through a mask frame as disclosed in *Ging* (RMD1005) Figs. 6a, 6b). One of skill would have seen reason

to implement a connection between a ring and elbow like those described in *Gunaratnam*, *Ging*, and *Gunaratnam II* in order to provide a reliable, cost-effective connection between the components in a manner that was suitable to allow the patient to connect and disconnect the elbow from the ring. Absent special considerations that are not limiting in the context of *Lovell's* design, the choice of which component fits into which would have been a mere design choice.

36. Regarding the second limitation that was argued to overcome the rejections, the applicant remarked that *Lovell* did not disclose a "mask assembly [that] is configured to connect to ***only two*** side straps," as recited in both amended claims 38 and 47, and that "modifying *Lovell* in light of *Gunaratnam* would change the principle of operation of the mask disclosed in *Lovell*." RMD1009, pp. 620-622. For context, Figure 5 of *Lovell* (RMD1012) is copied and annotated below, which shows two of the four straps 44, 46 that connect to the mask assembly to secure the mask on the patient (the other two straps being hidden from view in Figure 5). *See* RMD1012, *Lovell*, 6:44-57 and Fig. 5.



37. Based on my knowledge and experience in the field, and my review of the record, I respectfully disagree with the applicant's argument to the Examiner that "removing two of the straps from the nasal mask of *Lovell* would change the principle of operation of *Lovell* by preventing the nasal mask from being securely positioned against the nares of a user." RMD1009, p. 622.

38. To the contrary, it was well-known in the art at the time of the '807 patent to design patient interfaces in which the mask assembly connected to only two side straps or only two side arms. *See, e.g.*, RMD1004, *Gunaratnam*, Figs. 108, 135 (mask assembly connected to only two side arms); *id.* at Figs. 107G-H (mask assembly having only two headgear connections); RMD1005, *Ging*, Fig. 1 (nasal mask assembly having only two headgear connections). *Gunaratnam* and

Ging evidence what one of skill in the art would have known, namely that only two connections of the mask assembly to a headgear assembly was conventional. Modifying *Lovell*'s patient interface would not have involved a change in the "principle of operation" of the mask, but instead would have amounted to no more than the application of known teachings to yield predictable results. Moreover, one of skill would have seen reason to make such modification in order to simplify the process of securing the device on the patient (fewer connections being necessary to the mask assembly), and to reduce the cost of manufacturing the headgear due to potentially less material and reduced manufacturing complexity.

39. I understand that claims 38 and 47 were allowed following the applicant's amendments and remarks in response to the July 2012 office action, and that no reasons for allowance were provided by the Examiner. *See* RMD1009, pp. 629-633.

VII. CLAIM CONSTRUCTIONS

40. I understand that, in the event the PTAB determines that the term "ring," as recited in claim 1 of the '807 patent requires a construction, ResMed proposes that this phrase refers to a structure with a generally circular inner passage to enable the claimed rotatable engagement with an elbow that fits into the ring, and does not require a particular outside shape for the ring. I also understand that, in the event the PTAB determines that the term "ring-like connector" (and

"ring-like connector end") as used in claim 8 of the '807 patent requires a construction, ResMed similarly proposes that this term refers to a structure with a generally circular inner passage to enable the claimed rotation of the elbow relative to the mask body when the ring-like connector is secured around an outer portion of the elbow, and does not require a particular outside shape for the ring-like connector. I agree with these constructions, as it is how a person of ordinary skill in the art would have understood the terms to mean at the time of the '807 patent when interpreted under the claim construction standard noted in paragraph 13 of this declaration.

41. The term "ring" does not have a special meaning in the field of respiratory patient interfaces. When I look to the '807 patent specification, I see that the "ring" or "ring-like connector" corresponds to the mask base structure 22 shown for example in Figures 3-5. That structure has a perimeter that is not perfectly circular. In addition, the periphery of that structure is in part dictated by the shape of the central section 42 of a yoke-type structure referred to as a curved elongate member 34. That curved elongate member 34 is not a part of the '807 patent claims, which to me means that the particular shape of the outside of the "ring" or "ring-like" structure simply is not important in the context of the '807 patent claims. In addition, I note that, although the term "ring" implies a structure having a generally circular *inner* passage, there is no requirement that its outer

geometry also be circular. Indeed, many objects that are commonly referred to as "rings" do not have a circular outer geometry, such as square wedding/finger "rings" (example depicted below at left) and nut "rings" used in securing bolts (example depicted below at right). *See* RMD1038, WeddingBands.com Sales Page (showing a non-circular finger ring, copied below at left); RMD1039, HomeDepot.com Hardware Ring Sales Page (showing a galvanized nut ring, copied below at right).

42. I understand that, in the event the PTAB determines that the phrases "a plane substantially bisecting the ring, each of the two nasal pillows positioned on opposite sides of the plane" (claim 1) and "wherein a plane bisects the ring-like connector and the first nasal pillow is located on a side of the plane opposite the second nasal pillow" (claim 8) require a construction, that ResMed proposes these phrases refer to the "ring" (claim 1) or "ring-like connector" (claim 8) being "generally at the front center of the mask." I agree with the construction, as it is how a person of ordinary skill in the art would have understood the phrases to

mean at the time of the '807 patent when interpreted under the claim construction standard noted in paragraph 13 of this declaration. For example, when the ring (or ring-like connector) and elbow connector are located at the front center of the mask, one pillow is on each side of a plane that bisects the ring. This can be seen from FIG. 3 of the '807 patent (RMD1001). The annotated version of FIG. 3 shown below at left illustrates a vertical plane bisecting the mask body 22 (i.e., the claimed "ring"), and respective ones of the pair of nasal pillows 24, 25 located on either side of the plane. In contrast, some other prior art designs provided elbows that connected to the side of the mask, rather than at the front center. One such design is shown in *Gunaratnam* at FIG. 109, which is copied below at right by way of example.

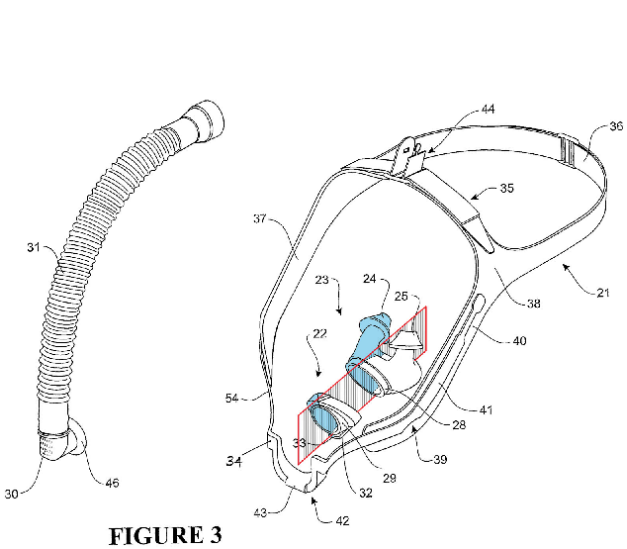


FIGURE 3

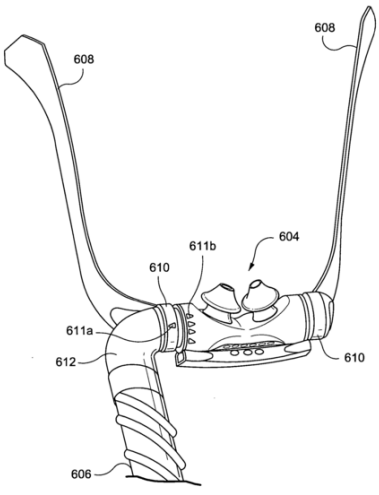


FIG. 109

43. I understand that, in the event the PTAB determines that the phrase "wherein the two side straps are configured to connect and disconnect with the

mask assembly … wherein the mask assembly is configured to connect to only the two side straps” (claim 1) and “wherein the first side strap and the second side strap are configured to connect and disconnect with the mask assembly … wherein the mask assembly is configured to connect to only the two side straps” (claim 8) require a construction, ResMed proposes that these phrases require that the two side straps of the headgear assembly be capable of connecting and disconnecting with the mask assembly, whether that connection be direct or via an intermediate structure, and require that only the side straps and no other strap of the headgear assembly be connectable to the mask assembly. I agree with the construction, as it is how a person of ordinary skill in the art would have understood the phrases to mean at the time of the ’807 patent when interpreted in light of the specification and prosecution history discussed above, and under the claim construction standard noted in paragraph 13 of this declaration. In particular regarding the construction that the connection need not be direct, this is because the ‘807 patent explains that the side straps 37, 38 of the ’’807 patent connect to side arms 41, but the side arms 41 are not recited in claim 1 as being part of the claimed mask assembly, and also because claim 6 adds that the “molded side arms extend away from the ring to connect with the side strap.” Therefore, the mask assembly and the side strap must be able to connect indirectly via a side arm. Additionally, the requirement that only *two* side straps connect to the mask assembly is clearly understood from the

prosecution history, as the applicant distinguished the '807 claims from *Lovell* based in part on the *two*-point connection of the side straps to the mask assembly. RMD1009 at pp. 585-90, 613-23. In contrast, *Lovell*'s design provided a *four*-point connection of the headgear assembly to the mask assembly. *See, e.g.*, RMD1012 at FIG. 5.

VIII. DISCUSSION OF PROPOSED GROUNDS OF UNPATENTABILITY

A. Teachings of the Prior Art References

1. Overview of *Gunaratnam*

44. For the purpose of my analysis in this declaration, I have been instructed by ResMed's counsel to assume that U.S. Patent Publication No. 2004/0226566 to *Gunaratnam et al.* ("*Gunaratnam*") (RMD1004) is prior art to the '807 patent.

45. Based on my review of the *Gunaratnam* reference, and my knowledge and skill in the art, I offer the following overview of *Gunaratnam*'s disclosure and teachings. This overview relates to particular portions of the reference, but it should be understood that *Gunaratnam* also provides additional disclosure and teachings that may not be mentioned in the following paragraphs.

46. Gunaratnam disclosed many varieties of CPAP patient interfaces, including interfaces having nasal pillows. For example, Gunaratnam at Figure 135 illustrates an embodiment of a patient interface in which a swivel elbow, which

connects an air delivery conduit to the mask assembly, is provided at the front, center of the mask frame. *Id.* at Fig. 135, ¶ 403. Although not shown, one of ordinary skill in the art would have recognized that a nasal pillows cushion, such as the nozzle assembly 18 shown in Figure 1, could also be implemented in the Figure 135 embodiment with the swivel elbow at the front of the mask frame. See id. at ¶ 403 (describing that the nasal pillow cushions and full nasal cushion are interchangeable); Figs. 107G-H, ¶¶ 369-70 (disclosing a patient interface having nasal pillows 772 and elbow 770 at the front center of the mask frame 768, although the nasal pillows are located below the nares of the patient in the diagram because the mask is not shown in use); Figs. 1, 5, 6, ¶¶ 185-93 (describing details of a nasal pillows cushion [nozzle assembly 18]).

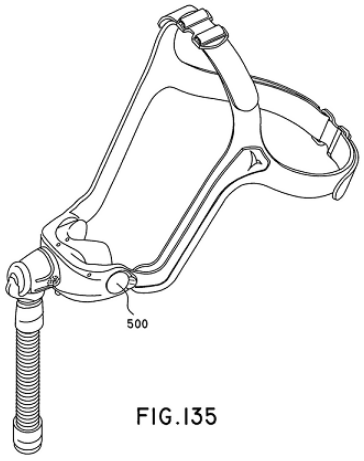


FIG.135

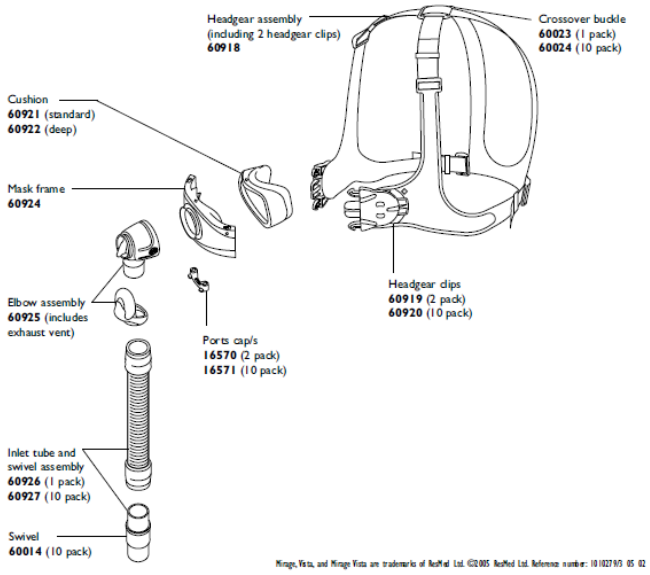
47. *Gunaratnam* states that the swivel elbow in Figure 135 connects to the front center of the mask frame like the swivel elbow in the "VISTA" mask, which I

understand is a commercial product developed and sold by Petitioners.[1] RMD1004 at ¶ 403. Further, *Gunaratnam* discusses and incorporates by reference three provisional applications that form the basis of the subject matter disclosed in the *Ging* reference, which I discuss in the following section. *Id.* at ¶ 341 ("Details of a locking clip receiver assembly and locking clips are provided in U.S. Provisional Applications of Moore et al., Ser. Nos. 60/377,254, 60/397,195, and 60/402,509, all of which are hereby incorporated into the present application by reference in their entireties."); *see also* RMD1005, *Ging*, at Cover Page (claiming priority to each of the provisional applications referred to in ¶ 341 of *Gunaratnam*).

48. The details of the VISTA mask's swivel elbow, as depicted in Figure 135 of *Gunaratnam*, are disclosed in *Ging*. The two illustrations provided beneath this paragraph clearly show that what is disclosed in *Ging* is substantially embodied in ResMed's Mirage Vista nasal mask product. The illustration at left is an exploded view of the Mirage Vista mask from a user's components card (RMD1024). The illustration at right is Fig. 1 of *Ging* (RMD1005). The

[1] Specifically, I understand that the VISTA mask referred to in *Gunaratnam* refers to ResMed's MIRAGE VISTA product, a CPAP nasal mask. *See* RMD1024 (Mirage Vista User's Guide).

similarities among what is shown in each figure would have been apparent to one of ordinary skill in the art.



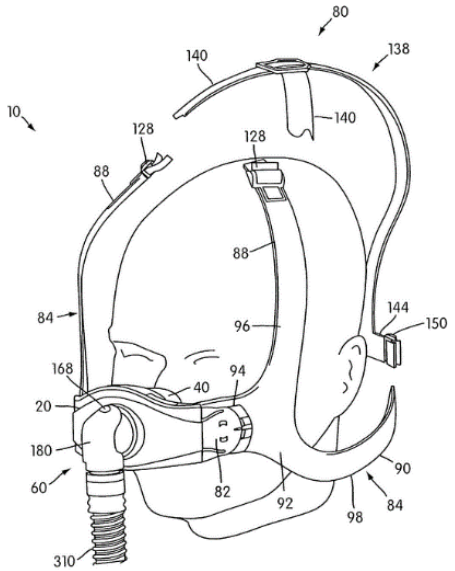


FIG. 1

2. Overview of *Ging*

49. For the purpose of my analysis in this declaration, I have been instructed by ResMed's counsel to assume that U.S. Patent Application Publication No. 2003/0196658 to *Ging et al.* ("*Ging*") (RMD1005) is prior art to the '807 patent.

50. Based on my review of the *Ging* reference, and my knowledge and skill in the art, I offer the following overview of *Ging's* disclosure and teachings. This overview relates to particular portions of the reference, but it should be understood that *Ging* also provides additional disclosure and teachings that may not be mentioned in the following paragraphs.

51. *Ging* generally describes nasal assemblies for patient interfaces used in CPAP and other forms of respiratory therapies. *See* RMD1005 at ¶¶ 14-16. In particular, I understand that *Ging* describes nasal masks that are substantially embodied in the VISTA product referred to in *Gunaratnam*. *See* RMD1004 at Fig. 135, ¶ 403; RMD1024. One example of *Ging's* nasal mask assembly is shown in Figure 1, reproduced below:

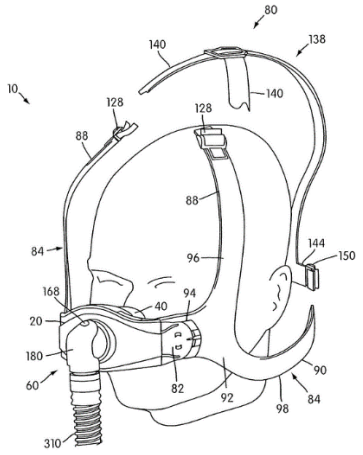


FIG. 1

52. *Ging's* device includes a swivel elbow 160 that connects to the front center of a mask frame 20. In this arrangement, pressurized air flows from an air delivery tube 310, into the mask frame 20, and through a nasal cushion 40 to the patient. RMD1005 at ¶¶ 107, 113, 153. The elbow 60 is configured to swivel with respect to mask frame 20. One of ordinary skill in the art would have understood that a purpose of the swivel elbow would have been to minimize hose strain as the patient tosses and turns during sleep, for example.

53. The details of the swivel elbow 160 (and a variation, namely elbow 360), like that shown in Figure 135 of *Gunaratnam*, are depicted in Figures 16a – 19c-2. *See generally* RMD1005 at ¶¶ 150-162. An outer profile of the elbow 160 is shown in Figures 16a and 16b.

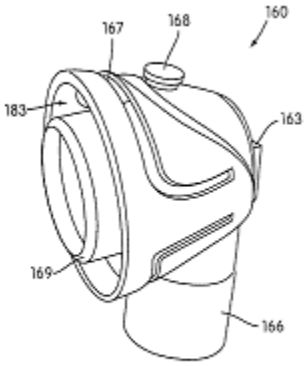


FIG. 16a

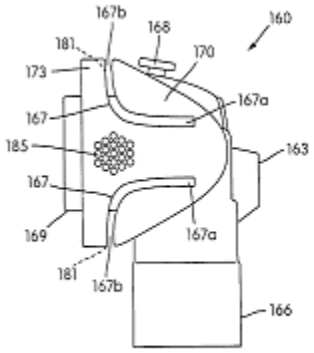


FIG. 16b

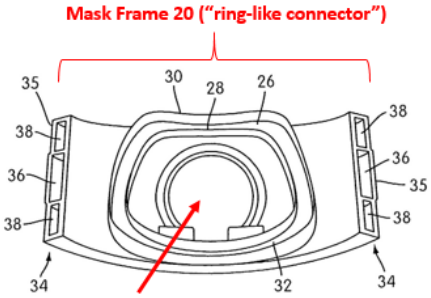


FIG. 5c

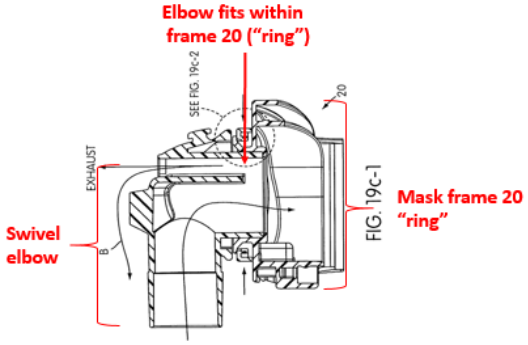


FIG. 19c-1

54. To connect to the mask frame 20, a forward projecting tube-like end portion 169 of the elbow 160 fits into an aperture 24 of the mask frame 20. *Id.* at ¶ 161; *see also id.* at Fig. 5 (showing mask frame 20 with aperture or central bore 24 into which the tube-like end portion 169 is fitted). At the same time, a collar 173 of the elbow 160 slides over a flange 21 of the mask frame 20 that surrounds

aperture 24. *Id.* at ¶¶ 157, 161; *see also id.* at Figs. 5, 5a (showing the flange 21 of the mask frame 20). In this way, the elbow 160 fits into and becomes secured in rotatable engagement with the mask frame 20. *See id.* at Fig. 19a-1 (swivel elbow 160 nearing engagement with mask frame 20); Fig. 19c-1 (swivel elbow 160 fully engaged with mask frame 20).

3. Overview of *McAuley*

55. For the purpose of my analysis in this declaration, I have been instructed by ResMed's counsel to assume that PCT Pub. WO 2005/079726 to *McAuley et al.* ("*McAuley*") (RMD1034) is prior art to the '807 patent.

56. Based on my review of the *McAuley* reference, and my knowledge and skill in the art, I offer the following overview of *McAuley's* disclosure and teachings. This overview relates to particular portions of the reference, but it should be understood that *McAuley* also provides additional disclosure and teachings that may not be mentioned in the following paragraphs.

57. *McAuley* shows a nasal pillows patient interface for the delivery of pressurized gas to the nares of a patient. *See* RMD1034, *McAuley*, Abstract. I understand that *McAuley's* patient interface includes the following components: (1) a mask assembly comprising a prong part 61 with two nasal pillows, and a body part 62; (2) and a ball jointed elbow connector 63 that fits into the mask assembly and rotates with respect to the mask assembly; and (3) a headgear assembly comprising a strap that wraps around the patient's head and connects to the mask assembly through headgear extensions. *Id.* at Figs. 1-17 and 6:11-13. As shown in Figure 9, body part 62 has a generally-circular outer perimeter and serves as a frame to which the ball-jointed connector 63 and the prong part 61 connect. *Id.* at 7:5-10. The ball-joined connector attaches to an inspiratory conduit (not shown in Figure 9). *Id.* at 9:32-10:3. *McAuley's* mask assembly is capable of attaching to a headgear assembly from two attachment points (extensions 72, 73). *Id.* at 11:12-23; *see also* Fig. 1 (showing the headgear having two attachment points to the mask assembly).

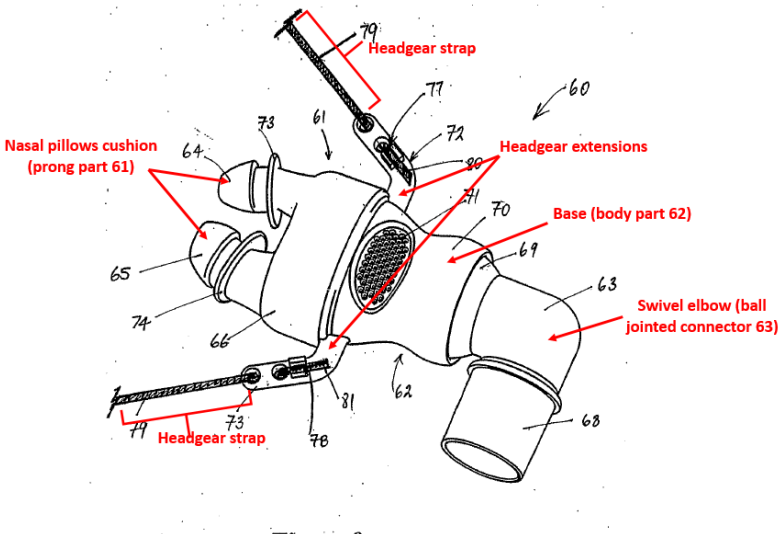


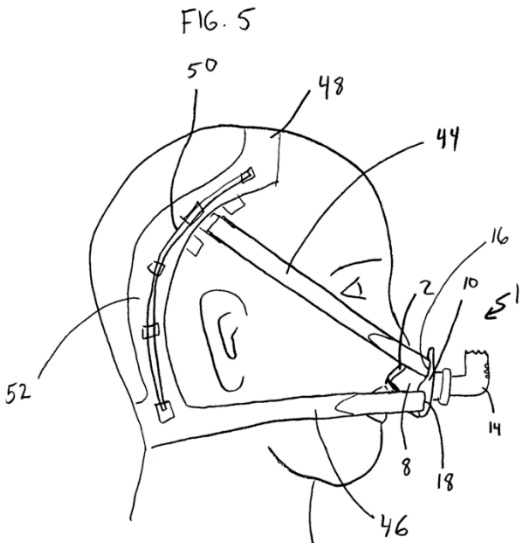
Figure 9

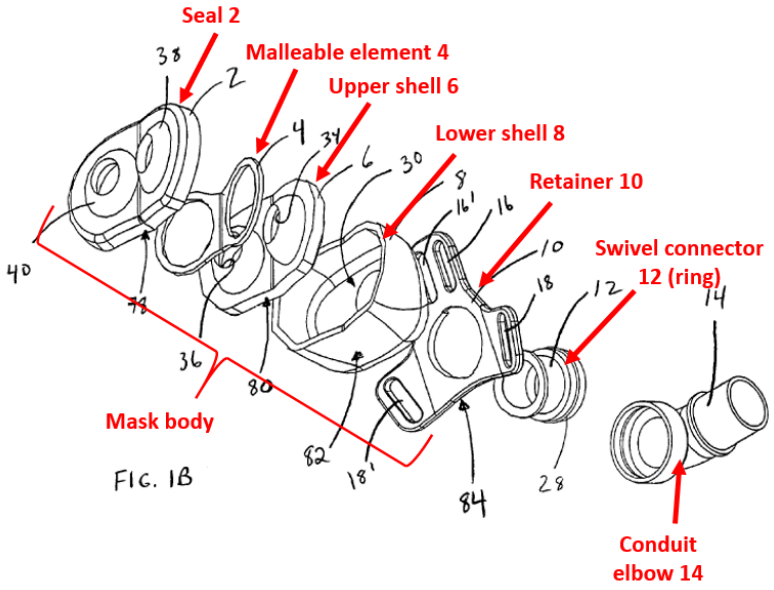
4. Overview of *Lovell*

58. For the purpose of my analysis in this declaration, I have been instructed by ResMed's counsel to assume that U.S. Patent No. 7,219,669 to *Lovell et al.* ("*Lovell*") (RMD1012) is prior art to the '807 patent.

59. Based on my review of the *Lovell* reference, and my knowledge and skill in the art, I offer the following overview of *Lovell's* disclosure and teachings. This overview relates to particular portions of the reference, but it should be understood that *Lovell* also provides additional disclosure and teachings that may not be mentioned in the following paragraphs.

60. *Lovell* discloses a nasal pillows-type mask that uses a ring to connect a swivel elbow to a mask body. As shown in the annotated Figure 1B below, *Lovell's* mask has a number of components, including a swivel connector 12 for connecting to a conduit elbow 14, a retaining structure 10, a lower shell 8, an upper shell 6, a malleable element 4, and a nasal pillows seal 2. *See* RMD1012, Fig. 5 (copied at right) and Fig. 1B (copied and annotated below).





Lovell's mask also includes two nasal pillows as domes 38, 40, and a swivel connector 12 that is rotatably engaged with the conduit elbow 14. The elbow 14 comprises a plurality of vent holes, namely apertures 20. *See* RMD1012, Fig. 2B, 5:46-50 ("The conduit elbow 14 is shown with an angled portion of about ninety degrees, as well as apertures 20 as seen in FIG. 2B, only one aperture being labeled for the sake of clarity. These apertures 20 allow the release of gases exhaled by the user."). As discussed above in paragraphs 30-39, the patent examiner cited *Lovell* during prosecution to reject certain claims of the application that issued as the '807 patent. The applicant distinguished *Lovell* by adding claim limitations that in my opinion do not make claims 1 and 8 patentable. RMD1009 at pp. 585-90, 613-23.

B. Ground 1: *Gunaratnam* in view of *Ging*

1. Motivation to Combine *Gunaratnam* and *Ging* as Proposed by Petitioners

61. Based on my knowledge and experience in the field and my review of the documents listed in Section V above, it is my opinion that a person of ordinary skill in the art would have combined *Gunaratnam* with *Ging* to arrive at the patient interfaces of claims 1-8, 17-21, and 24-27 of the '807 patent.

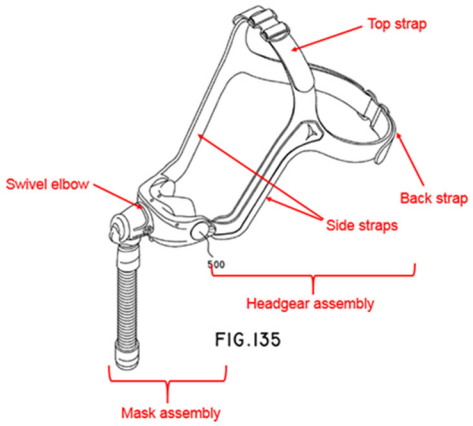
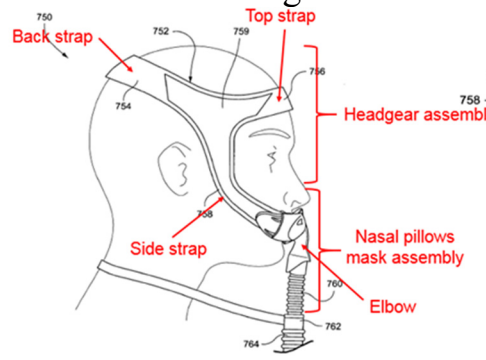
62. As noted in Section VIII.A.1 above, *Gunaratnam* discloses a nasal mask assembly in Figure 135 in which a swivel elbow is provided at the front center of the mask. RMD1004 at Fig. 135, ¶ 403. *Gunaratnam* further indicates that the swivel elbow in Figure 135 connects to the mask frame in a manner like that on Petitioners' MIRAGE VISTA mask. *Id.* I understand that the details of the VISTA swivel elbow and its connection to the mask frame are omitted from *Gunaratnam's* disclosure, but such details had been previously disclosed in *Ging*. In my opinion, one of ordinary skill in the art at the time of the '807 patent would have been prompted by *Gunaratnam's* mention of the VISTA mask to look to *Ging* (as literature that substantially describes the VISTA mask) to further understand the swivel elbow shown in Figure 135 of *Gunaratnam*, in addition to other features of the mask frame, such as the central passage, and the channel for mating with the mask body. *Gunaratnam* also refers to three provisional patent applications, to

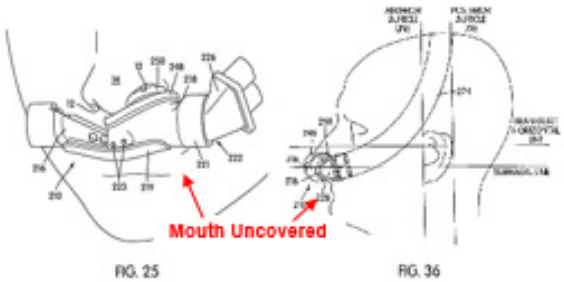
which *Ging* claims priority. *Id.* at ¶ 341. In my opinion, one of ordinary skill would have applied the teachings of *Ging's* swivel elbow/mask frame configuration (including the features such as the central passage and the mating channel) to *Gunaratnam*, to implement the type of mask frame and swivel elbow that was already contemplated in *Gunaratnam.*

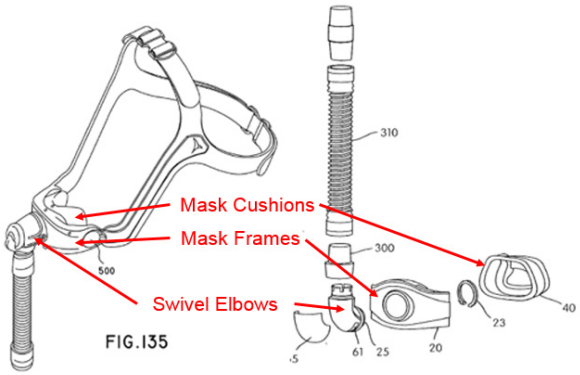
63. *Ging* further discloses additional details about a mask frame 20 and its connections to a mask body (cushion 40) and to a headgear assembly having side arms (yokes) and straps for securing the mask to the patient's face. In my opinion, a person of ordinary skill in the art would have looked to *Ging* to understand additional details about these types of structures in a nasal interface, many of which are included (but not described in detail) in the embodiment of Figure 135 in *Gunaratnam*. And as explained further below, the application of *Ging's* teachings to *Gunaratnam* (including the Figure 135 embodiment) would have involved obvious modifications that would have been well within the capabilities of a person of ordinary skill in the art. Indeed, many of these modifications relate to claimed features for which the '807 patent mentions no specific benefit or significance.

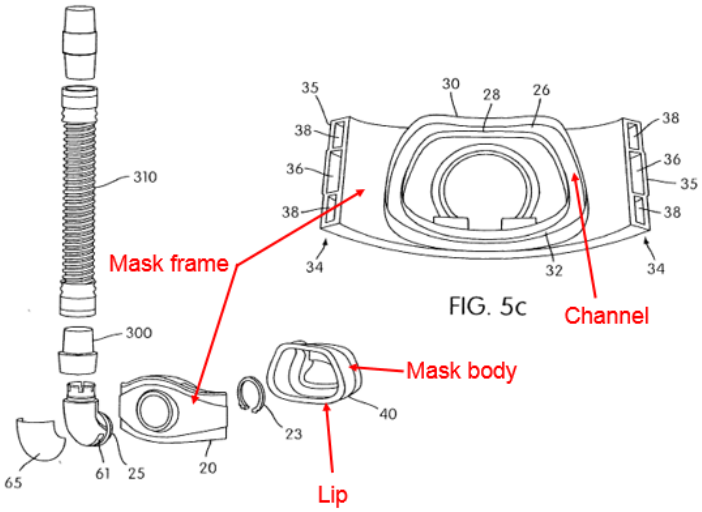
2. Claim Chart Showing Corresponding Disclosure In *Gunaratnam* And *Ging* For Each Element of Claims 1-8, 17-21, And 24-27 Of The '807 Patent

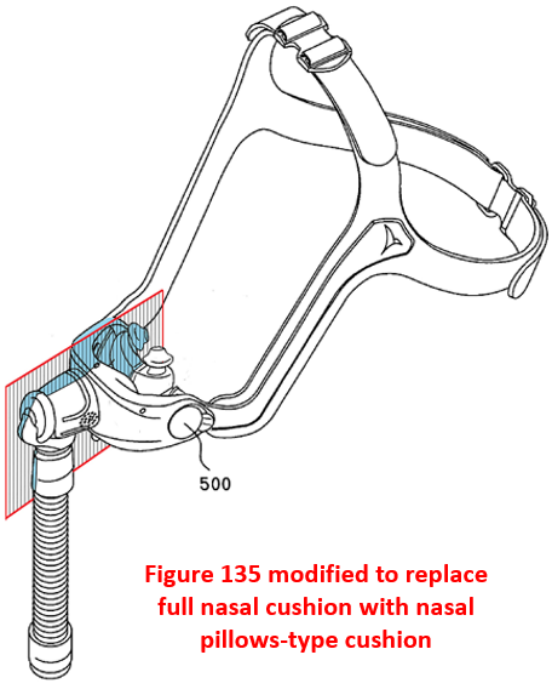
64. ResMed's counsel prepared the following claim charts for claims 1-8, 17-21, and 24-27 of the '807 patent, which is based on the invalidity grounds provided in ResMed's Petitions for *inter partes* review. The claim charts incorporate my analysis of where the respective elements of these claims are disclosed or suggested in the prior art references, *Gunaratnam* (RMD1004) and *Ging* (RMD1005), or in related references as noted in the charts. Based on my review of these prior art references, and the '807 patent and file history, I agree that each element of claims 1-8, 17-21, and 24-27 of the '807 patent is disclosed or suggested by *Gunaratnam*, *Ging*, or both references, or would have been obvious to one of skill in the art in view of the teachings of *Gunaratnam* and *Ging*. I further agree that the following claim charts accurately demonstrate the correspondence between the elements of the '807 claims at issue and exemplary disclosure from *Gunaratnam* and *Ging*. As demonstrated by the claim chart, and my analysis in Section VIII.B.3 below, it is my opinion that claims 1-8, 17-21, and 24-27 of the '807 patent are obvious over *Gunaratnam* in view of *Ging*.

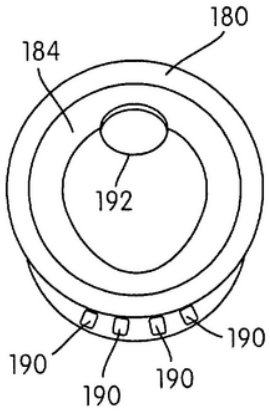
'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
[1.1] A patient interface comprising: a mask assembly . . . and a headgear assembly	*Gunaratnam* discloses numerous examples of patient interfaces for the supply of pressurized breathable gases. *See Gunaratnam*, ¶ 0002 and throughout. The Figure 135 embodiment is the starting point for the obviousness analysis under Ground 1, and it includes a mask assembly and a headgear assembly. *See* annotated Fig. 135 at right. 
[1.2] a mask assembly having:	The full nasal mask assembly of Figure 135 of *Gunaratnam* is a mask assembly. *Gunaratnam* specifically discloses a nasal pillows-type cushion in Figs. 107G-H in combination with a front-positioned elbow and a four-strap headgear assembly like Figure 135 of *Gunaratnam*. *See also id.* at Figs. 1-133 (nasal-pillows type cushions). As discussed above, it would have been obvious to replace the full nasal cushion of Figure 135 with a nasal pillows-type cushion, such as the one shown in Figures 107G-H. 
[1.3] a mask body including two nasal pillows extending from it, which in use rest in a substantially sealed	The nasal-pillows type mask assemblies in *Gunaratnam* (including Figs. 107G-H) have a mask body (cushion) with two nasal pillows extending from the mask body, which in use rest in a substantially sealed manner against the nares of a user. *See, e.g.*, *Gunaratnam*, Figs. 1-8, 19-31, 36-67, 76-133. The

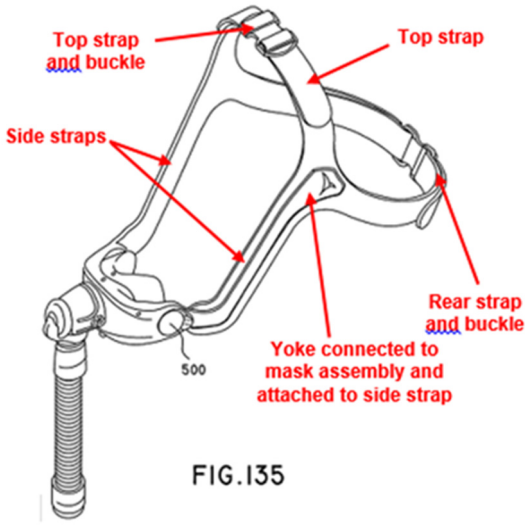
'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
manner against the nares of a user	details of one example nasal pillows cushions are shown in Figures 1-8. Referring to Figure 1, *Gunaratnam* states that it discloses "a nasal assembly 10 structured to deliver breathable gas to nasal passages 12 of a patient's nose 14," which "includes a frame 16 and a nozzle assembly 18." *Id.* at ¶ 0177. The nozzle assembly 18 (the claimed "mask body") includes two nozzles 50 (the claimed "nasal pillows"). *See id.* at Figs. 1, 5-6, ¶¶ 185-93 (disclosing details of the nozzle assembly 18).
[1.4] the mask body sized and shaped to leave the mouth of the user uncovered by the mask body when in use	The nasal cushion shown in *Gunaratnam*'s Figure 135 is sized and shaped to cover only the nose of the user, and to leave the mouth of the user uncovered by the cushion. In addition, if the nasal cushion shown in Figure 135 of *Gunaratnam* was replaced with a nasal pillows cushion shown in other patient interface designs of *Gunaratnam*, such as in Figure 107G-H (as would have been obvious, as discussed above), the nasal pillows cushion in the resulting patient interface would also leave the mouth of the user uncovered when in use. The fact that *Gunaratnam* discloses nasal pillows cushions that are sized and shaped to leave the mouth of the user uncovered is shown, for example in Figures 25, 36-38, 51-52 and 59, examples of which are copied below:  FIG. 25 FIG. 36 One of skill in the art would have understood that the cushion shown in Figures 107G-H is a nasal pillows-type cushion (one of the nasal pillows being specifically shown in Figure 107H as nozzle 772), and as such, the cushion would be sized and shaped to

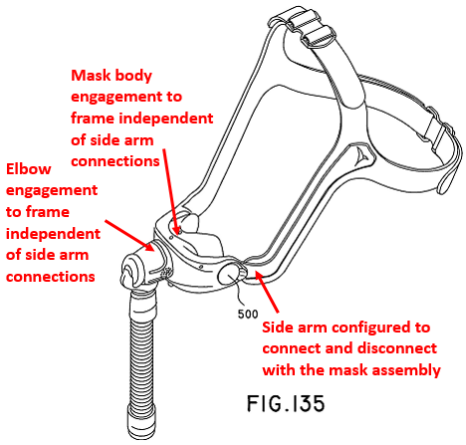
'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
	leave the mouth of the user uncovered by the cushion when in use. One of skill in the art would also recognize that Figure 107G shows the cushion not in use, but rather positioned before placement on the nose for use, and thus appears to cover the mouth. The fact that Figure 107G seems to show the nasal pillows cushion covering the user's mouth is irrelevant with respect to the claim limitation, in that the cushion is not shown in that Figure 107G "in use" with the pillows inserted into the nares of the user.
[1.5] a ring engaged with the mask body	Figure 135 includes a mask frame, which is a "ring" that defines a circular inner passage for receiving a portion of an elbow, and that allows the elbow to rotate. Thus the "ring" element as recited in claim 1 is present in *Gunaratnam*'s Figure 135 design, or is at most an obvious implementation detail of this design in view of the teachings of *Gunaratnam* and *Ging*. *Ging* discloses the details of a mask frame 20 (the claimed "ring") similar to the mask frame provided in the patient interface design depicted in *Gunaratnam* Figure 135 and shows how the ring is engaged with the mask body. *Ging* shows an exploded view in Figure 6b of a patient interface comprising a mask cushion 40 (the claimed "mask body"), a mask frame 20 (the claimed "ring"), and a swivel elbow, similar to *Gunaratnam*'s Figure 135 design, as shown in the figure above.  FIG. 6b

'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
	The mask frame 20 in *Ging* is a "ring" because it has a circular inner passage that allows the elbow to rotate. *See, e.g.,* RMD1005, *Ging*, Figure 6b. Specifically, the central bore 24 (also referred to as aperture 24) of the mask frame 20 is the circular inner passage. *Ging* also discloses that the mask frame 20 is engaged with the mask cushion 40. *See, e.g., Ging*, at 9:60-10:8, 27:48-32:63, Figs. 5, 5c (describing in detail how the mask frame 20 is engaged with the mask cushion 40). Figures 5c and 6b show that a lip of the mask cushion 40 is received by a channel 26 of the mask frame 20. RMD1005, *Ging*, Figs. 5c, 6b, 24, 27-29, ¶¶ 114-15 (describing that channel 26 of the mask frame 20 receives an "edge of the side wall or central portion 215 (Figs. 24e and 27a) of the cushion 40").  FIG. 5c FIG. 6b
[1.6] a plane substantially bisecting the ring, each of the two nasal pillows positioned on opposite sides of the plane	This claim limitation requires that the ring be located generally at the center of the mask. This feature would be present in the modified configuration of *Gunaratnam's* Figure 135 design if a nasal pillows-type cushion (e.g., like nozzle assembly 18 or the pillows in Figs. 107G-H) were substituted for the full nasal cushion of the original design. If one were to consider a plane that bisects the ring (e.g., mask frame)

'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
	present in the Figure 135 mask assembly vertically, that plane would bisect the nasal mask assembly vertically. Moreover, that plane would lie between each of the two nasal pillows, which would position each of the two nasal pillows on opposite sides of the plane. The figure copied here, at left, illustrates a modified version of Figure 135 that shows one example of how a nasal pillows cushion could easily be implemented in the patient interface design of Figure 135.  **Figure 135 modified to replace full nasal cushion with nasal pillows-type cushion**
[1.7] an elbow rotatably engaged with the ring	*Gunaratnam* discloses a swivel elbow in its Figure 135 embodiment, and given that the elbow is referred to as a "swivel" elbow, one of skill would understand that it is rotatably engaged with the ring. *See* RMD1004, *Gunaratnam*, Fig. 135, ¶ 403. *Ging* similarly discloses a swivel elbow 160 rotatably engaged with an opening in the mask frame 20. *See* RMD1005, *Ging*, ¶¶ 0151-62 and Figs. 16a – 16c-2 (describing swivel elbow 160 engagement with mask frame 20); ¶ 0113 ("In Figs. 6a and 6b, the elbow assembly 60 is attached to the mask using a C-clip 23 (Fig. 6b) that can be expanded and contracted to fit within a circumferential groove 25 on a portion of the elbow assembly 60 that protrudes into the frame 20 . . . .").

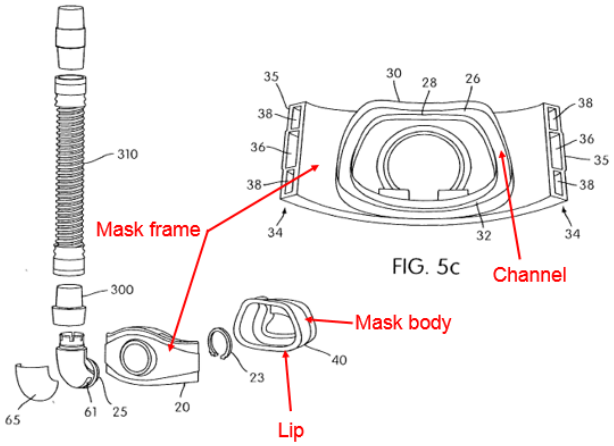
'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
[1.8] the ring forming a socket into which a portion of the elbow fits to facilitate the rotatable engagement between the elbow and the ring	This feature is present in the patient interface design shown in Figure 135 of *Gunaratnam*, which shows a portion of a swivel elbow fitted within a socket of the mask frame, to allow the elbow to rotate with respect to the frame. *See also* Limitation 1.5 above. Additionally, the mask frame 20 in *Ging* constitutes a "ring forming a socket into which a portion of the elbow fits to facilitate the rotatable engagement between the elbow and the ring."
[1.9] the elbow comprising a plurality of vent holes	*Gunaratnam* discloses that the swivel elbow in Fig. 135 "may be provided with appropriate vents to exhaust exhaled gas from the breathing chamber." RMD1004, *Gunaratnam*, ¶ 0403. *Ging* similarly discloses swivel elbows with a plurality of vent holes. For example, *Ging* discloses that "[t]he elbow assembly 60 [Figs. 6a and 6b] may also include one or more vent openings 61 open to atmosphere, for example, for gas washout of exhaled carbon dioxide, among other things." RMD1005, *Ging*, Figs. 6a, 6b, and ¶ 0113. Figure 22 of *Ging* further discloses a component of an elbow assembly – namely, vent cover 180 – that includes a plurality of holes (vents 190) for venting the patient's exhaled gases from the mask assembly. *Id.* at Fig. 22 and ¶¶ 0163-64. In view of the teachings of *Gunaratnam* and *Ging*, one of skill in the art would have understood that locating a plurality of vent holes in the elbow would have been obvious to apply to Figure 135 of *Gunaratnam*, so as to ensure adequate ventilation of exhaled gases from the patient's breathing space.  **Ging, Fig. 22**

'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
[1.10] a tube or conduit extending from the elbow	The patient interface in *Gunaratnam's* Figure 135 embodiment includes a tube or conduit extending from the swivel elbow. RMD1004, *Gunaratnam*, Fig. 135. Additionally, *Ging* shows such a tube or conduit (air delivery tube 310) in greater detail in Figure 26, for example. RMD1005, *Ging*, Fig. 26, ¶ 0153 ("The air tube 310 (Fig. 26) is preferably directly connected to a stem 166 of swivel elbow 160 (without connector tube 300) to supply pressurized breathable air or gas from a pressurized supply through air tube 310, intake port 162 and into cushion 40 for breathing by the patient."); *see also id.* at ¶ 0111; *id.* at Fig. 1.
[1.11] a headgear assembly having	*Gunaratnam* in Figure 135 discloses a headgear assembly, as illustrated in the labeled Figure 135 shown at right. *See also* Fig. 107e (same headgear with nasal pillows type mask). 
[1.12] two side straps that pass down the cheeks of the user to secure the mask body to a face of the user	*Gunaratnam* in Figure 135 discloses that the headgear assembly includes two side straps that pass down the cheeks of the user when the patient interface assembly is worn. The side straps in this embodiment help to secure the mask body to the face of the user. *See Gunaratnam*, Fig. 135 (reproduced and annotated for limitation 1.11 above).
[1.13] a top strap including a buckle configured to facilitate length adjustment of the top strap	*Gunaratnam* in Figure 135 discloses that the headgear assembly includes a top strap including a buckle. The buckle is configured to facilitate length adjustment of the top strap. *See* RMD1004, *Gunaratnam*, Fig. 135 (reproduced and annotated for limitation 1.11 above); *see also id.*, Figs. 18 & 83, and ¶ 211.

'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
[1.14] a back strap adjustably connected to at least one of the top strap and the two side straps	*Gunaratnam* in Figure 135 discloses that the headgear assembly includes a back strap adjustably connected to at least one of the top strap and the two side straps. In particular, the back strap in Figure 135 also includes a buckle that facilitates the adjustable connection. *See* RMD1004, *Gunaratnam*, Fig. 135 (reproduced and annotated in the claim chart for element 1.11 above); *see also id.*, Figs. 18 & 83, and ¶ 211.
[1.15] wherein the two side straps are configured to connect and disconnect with the mask assembly while the elbow remains rotatably engaged with the ring and the ring remains engaged with the mask body	This feature is inherently present in the Figure 135 design of *Gunaratnam*, as evidenced by *Gunaratnam* and *Ging*.  FIG.135 Because the elbow in Figure 135 is located at the front center of the mask assembly, the two side straps are configured to connect and disconnect with the mask assembly while the elbow remains rotatably engaged with the ring and the ring remains engaged with the mask body. The connection between the side straps and the mask assembly are made indirectly via side arms, and this connection is independent of the connection between the elbow, ring, and mask body. *See* RMD1004, *Gunaratnam*, at ¶ 377-81, 0403, Figures 108-13, 135. Even assuming a direct connection of the straps to the mask assembly were required by the claims (which is not the case), it would have been an obvious design modification to *Gunaratnam* Figure 135 to allow the *side straps* to connect and disconnect directly from the mask assembly, rather than the *yokes* as in Figure 135. The obviousness of the design modification is illustrated by *Gunaratnam* also disclosing such a direct connection configuration in the headgear assembly for

'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
	a similar type of nasal interface (having nasal pillows), namely in Figures 107G-H. In the embodiment of Figures 107G-H, the headgear assembly 752 includes a back strap 754, front strap 756, and pair of side straps 758. Here, the side straps 758 connect directly to the frame 768, rather than the yokes 759 connecting to the frame. The side straps 758 in this embodiment are configured to connect and disconnect with the mask assembly while the elbow 770 remains engaged with the frame 768 (or mask frame 20) and the frame 768 (or mask frame 20) remains engaged with the mask body (e.g., nozzle assembly 18) RMD1004, *Gunaratnam*, Figs. 107G-H, ¶¶ 0369-0370. One of ordinary skill in the art would have been motivated to apply the side strap connect and disconnect feature of Figs. 107G-H to the Figure 135 embodiment to provide any of the advantages resulting from such design, such as to allow a quick release of the straps from the headgear assembly.
[1.16] wherein the mask assembly is configured to connect to only the two side straps	*Gunaratnam* in Figure 135 discloses that the only connection of the mask assembly to the headgear assembly is by the two side straps. The fact that the two side straps in the Figure 135 embodiment are connected to the mask assembly via the intervening yoke structures is irrelevant to this claim limitation being met, because properly construed as discussed above, the claim does not require the connection to be direct. And even if the claim were to be construed to require the connection be direct, modifying the Figure 135 patient interface so that it would have a direct connection would have been obvious in view of other patient interface embodiments disclosed in *Gunaratnam* that include a direct connection, as discussed above under Limitation 1.15.
[1.17] wherein the top strap connects only with one or more of the	In the headgear assembly depicted in Figure 135 of *Gunaratnam*, the top strap connects only with one or

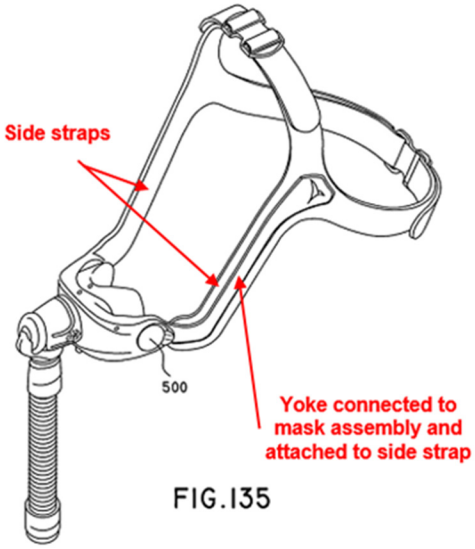
'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
side straps and the back strap	more of the side strap and the back strap. RMD1004, *Gunaratnam*, Fig. 135.
[2] A patient interface as claimed in claim 1, wherein the mask body includes a lip and the ring includes a channel receiving the lip of the mask body	The feature of the mask body including a lip and the ring including a channel receiving the lip of the mask body is inherently present in the *Gunaratnam* Figure 135 patient interface, or at least would have been considered to have been an obvious implementation detail in view of *Gunaratnam* and *Ging*. The mechanism by which the nasal cushion (mask body) connects to the frame (ring) is not specifically discussed in *Gunaratnam* with respect to Figure 135. Elsewhere, however, *Gunaratnam* discloses that the nozzle assembly 18 – one of the many nasal pillows cushions disclosed in *Gunaratnam* that would be obvious to apply to the patient interface design of Figure 135 includes a lip in the form of a rib, groove, or recess. RMD1004, *Gunaratnam*, ¶ 186. Furthermore, *Gunaratnam* discloses that the frame 16, which engages with the nozzle assembly 18, includes a channel, such as a rib or recess, which receives the lip of the nozzle assembly 18. *Id.* at Figs. 1, 5, 6 and ¶ 186. One of skill would understand that the mask body and frame in the Figure 135 would include similar connecting structures for engaging the mask frame and body, including a lip on the mask body and a channel in the mask frame.

'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
	To the extent that the features are not expressly shown in *Gunaratnam's* figures, *Ging* also discloses the structure for connecting a mask body and ring in the manner of claim 2. A channel 26 of the mask frame 20 (ring) receives the lip of the mask cushion 40, as shown in Figures 5c and 6b.s RMD1005, *Ging*, Figs. 5c, 6b, 24, 27-29, ¶¶ 0114-15.  FIG. 5c FIG. 6b It would have been obvious to one of skill in the art to use *Ging's* channel on the mask frame to ensure that the cushion is securely engaged with the mask frame. *See* RMD1005, *Ging*, ¶¶ 0197-98 (describing the advantages of *Ging's* mask frame and cushion connection system, which "allows for the independent determination of forces for engagement of the cushion and disengagement of the cushion from the frame").
[3] A patient interface as claimed in claim 2, wherein the mask body comprises a molded elastomeric material	The fact that *Gunaratnam*'s Figure 135 patient interface includes a mask body comprised of "a molded elastomeric material" is implied or inherent in *Gunaratnam*'s Figure 135 design, or at a minimum is an obvious implementation detail of *Gunaratnam*'s Figure 135 patient interface design in view of the teachings of *Gunaratnam* and *Ging*. Although the material used to make the mask body in the patient interface design of Figure 135 is not specifically discussed in *Gunaratnam*, other portions of

'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
	Gunaratnam's disclosure describe that the mask body (e.g., nozzle assembly 18 from Figs. 1, 5, and 6) can be made of a molded elastomeric material, such as silicone. RMD1004, *Gunaratnam*, ¶ 0182 ("For optimal positioning, in one preferred embodiment, nozzle assembly 18 is formed from a one part molded silicone piece that attaches to frame 16."); *see also id.* at ¶¶ 0191-0192 (describing that "the nozzles are constructed from a substantially flexible polymer material, such as a silicone elastomer"); *id.* at ¶¶ 0266, 332, 334, 357; RMD1005, *Ging*, ¶ 0182 (describing that a frame 200 and membrane 205 of the mask cushion 40 "are formed, for example, in a one-shot injection molding process as is known in the art, using, e.g., silicone such as SILASTIC™ with 40 durometer of hardness"); RMD1005, *Ging*, ¶ 0174. One of skill in the art would have understood that a nasal pillows cushion implemented in the patient interface design of *Gunaratnam* Figure 135 would similarly have been made of a molded elastomeric material, such as silicone, or that such a material selection would have been an obvious design choice.
[4] A patient interface as claimed in claim 1, wherein the elbow is able to swivel in the ring such that the tubing is available to be adjacent to either side strap	The fact that *Gunaratnam*'s Figure 135 patient interface includes an elbow that is capable of swiveling in a ring (e.g., a mask frame) such that tubing connected to the elbow is available to be adjacent to either side strap is implied or inherent in *Gunaratnam*'s Figure 135 design, or at a minimum is an obvious implementation detail of Figure 135's design in view of the teachings of *Gunaratnam* and *Ging*. First, one of skill would recognize that this feature is present in the Figure 135 embodiment of *Gunaratnam*. The elbow shown in Figure 135 is referred to in *Gunaratnam's* specification as a "swivel elbow," meaning that the elbow is capable of swiveling to different orientations relative to the mask frame. Given the location of the elbow at the front center of the

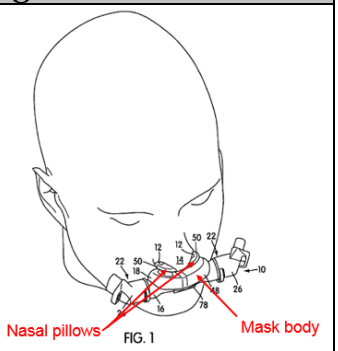
'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
	mask, the tube connected to the elbow would be available to be adjacent to either side strap on the sides of the user's face if the swivel elbow were rotated by about 120-150 degrees in either direction from the "free fall" orientation of the elbow that is illustrated in Figure 135. *See* RMD1004, *Gunaratnam*, FIG. 135 and ¶ 0403; *see also* RMD1004, *Gunaratnam*, Figs. 108A, 108B, ¶ 0394 (describing a tube retainer that can be secured to any of the straps in a headgear assembly to receive and locate tubing proximate to the headgear strap). Second, *Ging* discloses that the swivel elbow 160 is "rotationally connected" to the mask frame 20. In the absence of restrictions to the swivel elbow's 160 range of motion, one of skill would understand that the swivel elbow 160 could rotate a sufficient amount such that the gas delivery tube 310 would be available to be adjacent to either side strap. Because the elbow 160 is provided in the center of the frame, and the elbow 160 can rotate in clockwise and counter-clockwise directions, it would be capable of swiveling by at least the amount necessary to achieve the feature recited in claim 4. RMD1005, *Ging*, ¶ 0151, Figs. 1, 16a – 19c-2. This feature would also be present in the patient interface design shown in Figs. 6a and 6b of *Ging*, as the swivel elbow 60 in these figures is capable of freely rotating 360 degrees relative to the mask frame 20 and cushion 40 when assembled, such that the tubing would be available to be adjacent to either side strap. RMD1005, *Ging*, Figs. 6a, 6b, ¶¶ 0113, 0148-53.
[5] A patient interface as claimed in claim 1, wherein the ring comprises a hard plastic material	The additional feature recited in claim 5 that "the ring comprises a hard plastic material" is implied or inherent in the patient interface design illustrated in Figure 135 of *Gunaratnam*, or at a minimum is an obvious implementation detail in view of the teachings of *Gunaratnam* and *Ging*.

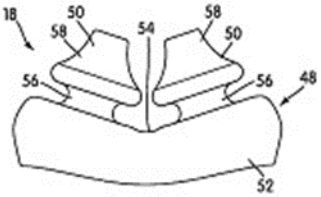
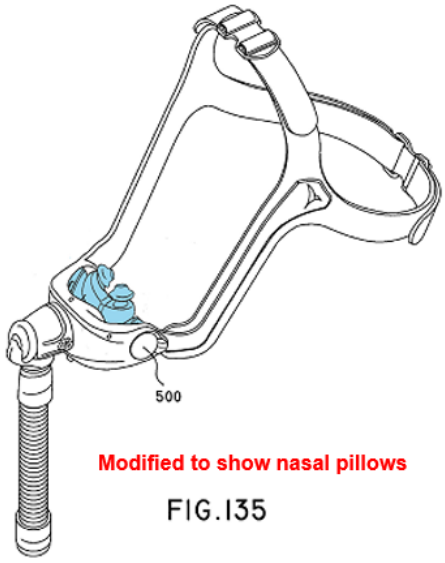
'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
	Recall that *Ging's* mask frame 20 meets the "ring" limitation of claim 1. The description of the mask frame 20 in *Ging* does not include a detailed discussion of the material from which the mask frame 20 is made. Nonetheless, *Ging* notes in its background discussion that "[a] mask assembly typically include ***a rigid shell***, a soft face-contacting cushion, a forehead support and headgear for securing the mask to the head." RMD1005, *Ging*, ¶ 0005; Claim 59, 37:53-55 (claiming "[a] frame for a respiratory mask assembly" that includes "a substantially rigid main body"). In light of *Ging's* teaching that the mask frame 20 could be a "rigid shell," the selection of a hard plastic material would have been an obvious design choice for one of skill in the art. *Gunaratnam* confirms that using a hard, plastic mask frame was the conventional approach at the time. RMD1004, *Gunaratnam*, ¶ 0004 (background discussion of a "nasal assembly [that] generally includes ***a relatively rigid shell, e.g., a frame***, and a pair of nozzles . . . that are mounted on the rigid shell") (emphasis added); ¶ 0178 (describing a mask frame 16 that "***is a rigid or semi-rigid structure formed from a polymer material***") (emphasis added); ¶ 0255 ("Also, the frame 316 adds rigidity or structural integrity to the relatively flexible nozzle assembly 318."). One of ordinary skill in the art would have understood that a rigid "polymer material" as disclosed in *Gunaratnam* would include a hard plastic material as required by claim 5. Moreover, hard plastic materials were conventionally used at the time of the '807 patent for the manufacture of molded products, including CPAP patient interface components, and the choice of such material would have been an obvious implementation detail in view of the teachings of *Gunaratnam* and *Ging*.

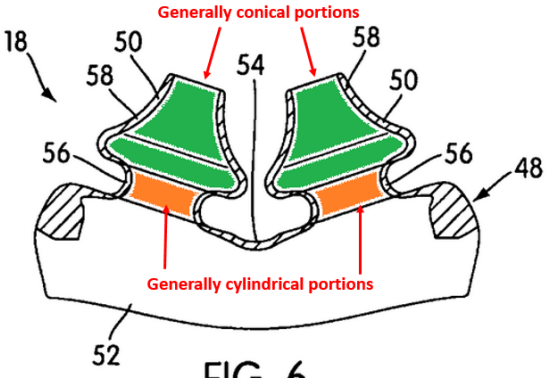
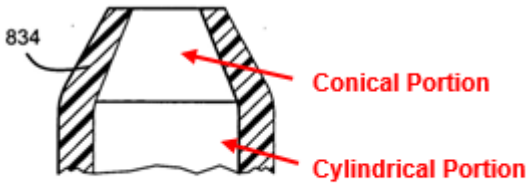
'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
[6] A patient interface as claimed in claim 1 further comprising molded side arms extending away from the ring to connect with the side strap, the molded side arms connecting to the side straps that pass down the cheeks of the user	The patient interface depicted in Figure 135 of *Gunaratnam* includes a pair of yokes (the claimed "molded side arms") that respectively connect to opposite sides of a mask frame. RMD1004, *Gunaratnam*, Fig. 135. Figure 135 is a variation of an embodiment depicted in Figures 108-13, which show the swivel elbow connected to an end side of the mask frame 616, whereas Figure 135 shows the swivel elbow connected to the front of the mask frame. Figures 108-13 illustrate in detail the connection of the yokes 608 to the mask frame 616, which is substantially similar to a manner in which the yokes 608 would connect to the mask frame in the Figure 135 design. In particular, the yokes 608 include end rings 610 that are secured around a portion of the tubular frame 616, and that each extend away from the frame 616 to connect with one of the side straps. *See* RMD1004, *Gunaratnam*, Figs. 108-10b, ¶¶ 0375-84; Fig. 135. Figure 135 shows that yokes 608 connect to the side straps that pass down the cheeks of the user.  FIG.135 One of skill would have understood that molding the yokes would have been an implied or inherent feature in forming the yokes 608 in *Gunaratnam*, or at a minimum would have been an obvious design choice. For example, many different embodiments including similar yoke structures are described throughout

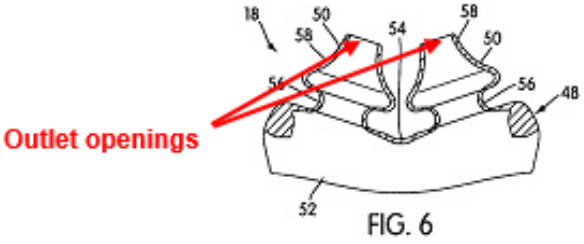
'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
	Gunaratnam, which make clear that the yoke members can be constructed from molded plastic material. *See* RMD1004, *Gunaratnam*, ¶ 0315 ("The headgear yoke 580 acts as a stiffener to add rigidity to the headgear assembly 520. . . . In Fig. 60, the yoke 580 is a semi-rigid layer, such as plastic, which is provided to, e.g., sewn onto, the headgear straps 598 and/or 599."); *see also id.* at ¶¶ 0376, 0379, 0390. This discussion from *Gunaratnam* is consistent with further disclosure in *Ging*, which further describes how yokes may be provided on CPAP headgear straps for added stability, rigidity, and stiffness, for example. RMD1005, *Ging*, ¶¶ 0119-22. *Ging* discloses that the yokes may be "constructed of a somewhat rigid material, e.g., plastic" such as nylon or polypropylene. *Id.* at ¶ 0120. Molded yokes would therefore have been no more than an implementation detail, and one that would have been obvious to one of skill in the art.
[7] A patient interface as claimed in claim 1, wherein, in use, gases flow from the tube or conduit, through the elbow, through the ring, through the mask body and through the pillows	The additional feature recited in claim 7 is implied or inherent in the patient interface design illustrated in Figure 135 of *Gunaratnam*, or at a minimum would have been obvious to one of skill in the art in view of the teachings of *Gunaratnam* and *Ging*. For example, Figure 135 in *Gunaratnam* discloses a patient interface assembly wherein, in use, gases flow from the air delivery tube and then through the swivel elbow, mask frame, and mask body. If the nasal pillows mask body (e.g., nozzle assembly 18 and nozzles 50) were applied to the Figure 135 design as described above, the gas would flow into that mask body and into the pillows. RMD1004, *Gunaratnam*, Fig. 135, ¶ 0403.
[8.1] A patient interface comprising: a mask assembly . . . a	*Gunaratnam* discloses numerous examples of patient interfaces for the supply of pressurized breathable gases. *See Gunaratnam*, ¶ 0002 and throughout. The

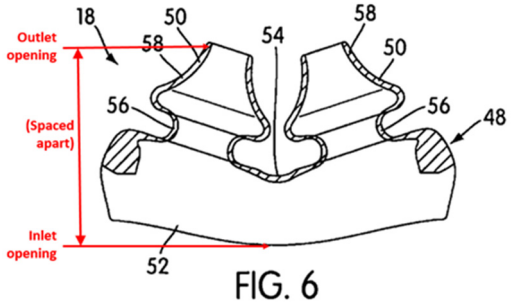
'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
tube assembly . . . and a headgear assembly	Figure 135 embodiment is the starting point for the obviousness analysis under Ground 1, and it includes a mask assembly, a tube assembly, and a headgear assembly. *See* annotated Fig. 135 above.
[8.2] a mask assembly having	The full nasal mask assembly of Figure 135 of *Gunaratnam* is a mask assembly. *See* Annotated Fig. 135 above. *Gunaratnam* specifically discloses a nasal pillows-type cushion in Figs. 107G-H in combination with a front center-positioned elbow and a four-strap headgear assembly like Figure 135 of *Gunaratnam*. *See also id.* at Figs. 1-133 (nasal-pillows type cushions). As discussed above, it would have been obvious to replace the full nasal cushion of Figure 135 with a nasal pillows-type cushion, such as the one shown in Figures 107G-H.
[8.3] a mask body	In *Gunaratnam*, the patient interface shown in Figure 135 includes a full nasal cushion which is a mask body as claimed. The claim further requires, in Limitation 8.5, that the mask body be a nasal pillows type mask body. Well-known nasal pillows mask bodies are disclosed elsewhere in *Gunaratnam*, for example in many examples in Figures 1-133, and particularly in Figures 108G-H where a nasal pillows mask body is shown in combination with the exact headgear assembly as claimed in claim 8. As discussed above and further below in Limitation 8.5, it would have been obvious to have substituted the nasal pillows type mask body disclosed in *Gunaratnam* Figure 107G-H for the nasal cushion type mask body of Figure 135. However, *Gunaratnam* further describes many nasal pillows type patient interface designs throughout its lengthy patent specification (for example, Figs. 1-133), all of which include a mask body (cushion) with two nasal pillows extending from the mask body. *See, e.g.*, *Gunaratnam*, Figs. 1-8, 19-31, 36-67, 76-133. The details of one example nasal pillows mask cushions are shown in Figures 1-8.

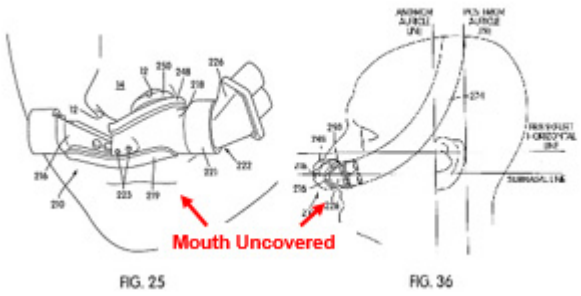
'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
	Referring to Figure 1, *Gunaratnam* states that it discloses "a nasal assembly 10 structured to deliver breathable gas to nasal passages 12 of a patient's nose 14," which nasal assembly "includes a frame 16 and a nozzle assembly 18." *Id.* at ¶ 0177. The nozzle assembly 18 (the claimed "mask body") includes two nozzles 50 (the claimed "nasal pillows"). *See id.* at Figs. 1, 5-6, ¶¶ 0185-93 (disclosing details of the nozzle assembly 18).  As described above, it would have been obvious to replace the nasal cushion that seals around the nose in Figure 135 with a nasal pillows-type cushion. *See Gunaratnam*, ¶ 0403; *see also Ging*, Fig. 24A and col. 23:10-27 (describing a similar nasal mask and/or nasal cushion, and explaining its seal around the nose, not including the mouth). *See, e.g.*, RMD1004, *Gunaratnam*, Figs. 134, 135, ¶ 0403.
[8.4] the mask body comprising a substantially flexible elastomeric material	*Gunaratnam* discloses this feature, in that the nozzle assembly 18 (which would have been obvious to apply to *Gunaratnam's* Figure 135 design as explained for limitation 8.3) comprises a substantially flexible elastomeric material. RMD1004, *Gunaratnam*, ¶ 0182 ("For optimal positioning, in one preferred embodiment, ***nozzle assembly 18 is formed from a one part molded silicone piece that attaches to frame 16***.") (emphasis added); *see also id.* at ¶¶ 0191, 0192, 0266, 0332, 0334 (further describing that all or portions of the nozzle assembly 18, or corresponding structures in other embodiments, may be made of a substantially flexible elastomeric material). One of skill in the art would have recognized that a silicone piece, as described in *Gunaratnam*, is a "substantially flexible elastomeric material."

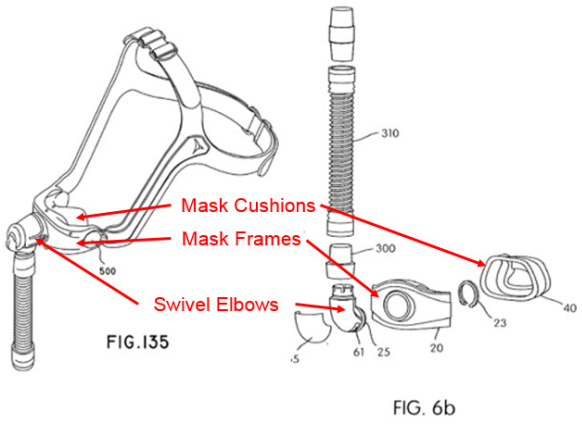
'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
[8.5] the mask body comprising a first nasal pillow and a second nasal pillow	As explained above with respect to claim limitation 8.3, *Gunaratnam* discloses many patient interface designs that employ a mask body having first and second nasal pillows, and that would have been obvious to apply to *Gunaratnam*'s Fig. 135 design. One example is nozzle assembly 18, which includes a first nasal pillow and a second nasal pillow as first and second nozzles 50, respectively. RMD1004, *Gunaratnam*, ¶ 0185.  FIG. 5 One of skill in the art would have understood from *Gunaratnam's* disclosure that the nozzles 50 in nozzle assembly 18 are nasal pillows. In fact, *Gunaratnam* at times refers to structures similar to the nozzles 50 in an alternative embodiment as "nasal pillows." *See* RMD1004, *Gunaratnam*, Figs. 90, 92-93; ¶ 0331 ("In the illustrated embodiment, the nozzles 20, 22 are in the form of ***nasal pillows*** wherein the second portion 32 is contoured (e.g., tapered, cone-shaped, truncated hollow cone, etc.) with a portion that seals on the underside of the nostrils and another portion that enters into the nasal passage of the patient's nose in use."); *see also id.* at ¶¶ 0334-35, 0346-60. A conceptual illustration of a modified Figure 135 design having a nasal-pillows type cushion, rather than a full nasal  Modified to show nasal pillows FIG.135

'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
	cushion as provided in the original figure, is shown above at the left.
[8.6] the first nasal pillow and the second nasal pillow being angled toward one another	*Gunaratnam* discloses that the first nasal pillow (first of the nozzles 50) and the second nasal pillow (second of the nozzles 50) of the mask body (nozzle assembly 18) are angled toward one another. This feature is clearly shown in Figures 1, 5, and 6 of *Gunaratnam*, for example, although other nasal pillows described throughout *Gunaratnam* also have this feature. *See, e.g.*, RMD1004, *Gunaratnam*, Figs. 90, 92-93.
[8.7, 8.8] the first nasal pillow comprising a first generally conical portion and a first generally cylindrical portion (8.7) the second nasal pillow comprising a second generally conical portion and a second generally cylindrical portion (8.8)	*Gunaratnam* discloses that the first and second nasal pillows (e.g., nozzles 50 of nozzle assembly 18) each comprise a generally conical portion and a generally cylindrical portion. In particular, *Gunaratnam* describes that each of the nozzles 50 has a first portion 56 and a second portion 58. The first portion 56 of each nozzle 50 is generally cylindrical, while the second portion 58 of each nozzle is generally conical. *See* RMD1004, *Gunaratnam*, Figs. 1, 5-6, ¶¶ 0185, 0189-90. These features are shown in Figure 6 of *Gunaratnam*, which is annotated above. *See also* RMD1009, p. 589 (Examiner reached same read).  FIG. 6 *Gunaratnam* further discloses an alternate nozzle structure in Figure 107N that would be applicable to  FIG. 107N

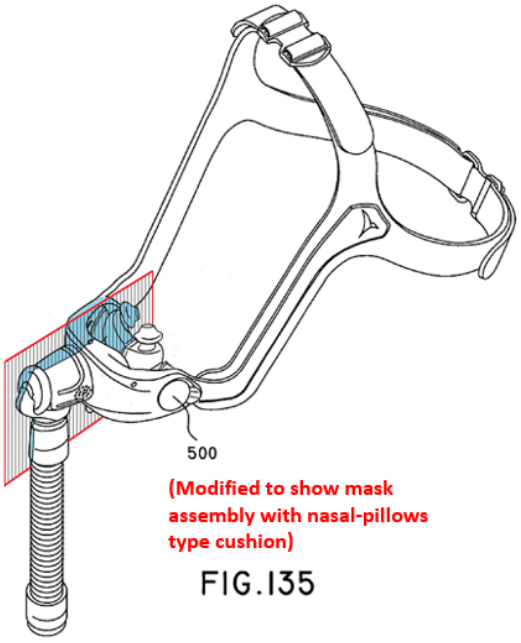
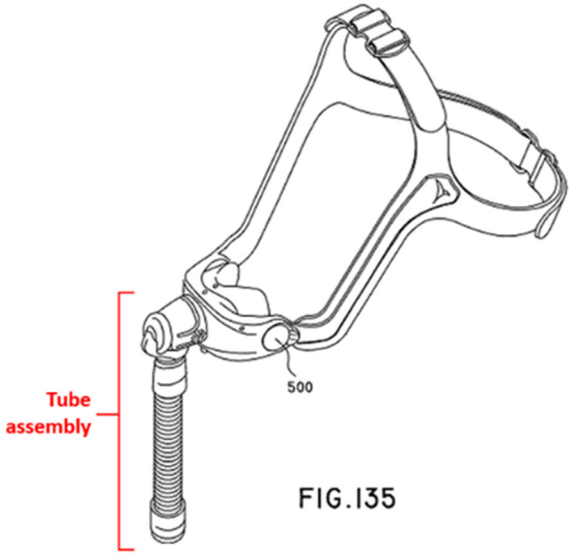
'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
	nozzle assembly 18 or other nasal pillows mask bodies. The Figure 107N structure clearly has a generally conical portion and a generally cylindrical portion, as shown in the annotated Figure 107N at right. *Id.* at Fig. 107N, ¶ 0374.
[8.9] the first nasal pillow comprising a first outlet opening and the second nasal pillow comprising a second outlet opening	*Gunaratnam* discloses the first nasal pillow (first of the nozzles 50 of nozzle assembly 18) comprises a first outlet opening, and the second nasal pillow (second of the nozzles 50 of nozzle assembly 18) comprises a second outlet opening. Although the respective outlets of the pair of nozzles 50 are not specifically labeled in the figures, they are nonetheless shown at the tops of the truncated conical portions (second portions 58) of the nozzles 50 in Figures 5-8. RMD1004, *Gunaratnam*, Figs. 1, 5-8, *see also id.* at ¶ 0185 ("When the nozzle assembly 18 is attached to the frame 16, the nozzle assembly 18 and the frame 16 together form a conduit for directing breathable gas to the patient's nose through the pair of nozzles 50."); Fig. 31 (showing perspective view of a nozzle and its outlet opening); Fig. 107N (top). In any event, one of skill in the art would have understood that outlet openings are inherent or implied in all of the nasal pillows bodies described in *Gunaratnam*, as an outlet would be required for air to be delivered to the nasal passages of the patient.  FIG. 6
[8.10] the mask body also comprising a mask body inlet opening	*Gunaratnam* discloses this feature, in that the nozzle assembly 18 (one of the example nasal pillows cushions that would be applicable to the Figure 135 patient interface design) includes an opening on a side of the nozzle assembly 18 that connects to the frame 16. In particular, the nozzle assembly 18 includes a base portion 48 having side walls 52 that define an inlet opening opposite the nozzles 50. In use, pressurized

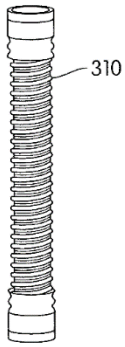
'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
	gas enters the nozzle assembly 18 through the inlet opening. RMD1004, *Gunaratnam*, ¶¶ 0184-0188 (describing the attachment of nozzle assembly 18 to frame 16 and the structure of the nozzle assembly 18 so as to form the claimed mask body inlet opening). Moreover, one of skill in the art would have understood that a mask body inlet opening is inherent or implied in all of the nasal pillows bodies described in *Gunaratnam*, as an inlet would be required in order for air to be delivered through the body, the pillows, and to the patient.
[8.11] the mask body inlet opening being spaced apart from the first outlet opening and the second outlet opening	*Gunaratnam* discloses this feature, in that the mask body inlet opening of the nozzle assembly 18 is spaced apart from the respective outlet openings of the pair of nozzles 50. This is shown, for example, in Figure 6.  FIG. 6
[8.12] the mask body sized and shaped to leave the mouth of a user uncovered by the mask body when in use	The nasal cushion shown in *Gunaratnam*'s Figure 135 is sized and shaped to cover only the nose of the user, and to leave the mouth of the user uncovered by the cushion. In addition, if the nasal cushion shown in Figure 135 of *Gunaratnam* was replaced with a nasal pillows cushion shown in other patient interface designs of *Gunaratnam*, such as in Figure 1 (as would have been obvious, as discussed above), the nasal pillows cushion in the resulting patient interface would also leave the mouth of the user uncovered when in use. To the extent that the view shown in Fig. 1 of *Gunaratnam* does not explicitly show the mouth uncovered, *Gunaratnam* further shows this feature, for example, in Figures 25, 36-38, 51-52 and 59, examples of which are copied below:

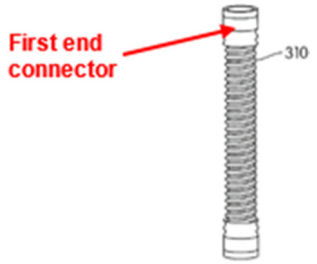
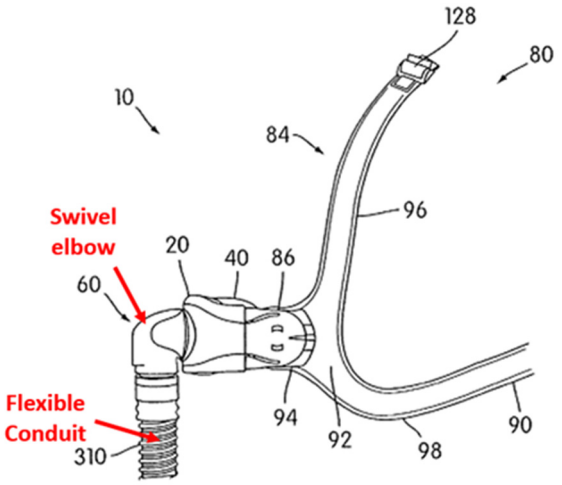
'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
	 FIG. 25 FIG. 36
[8.13] the mask body inlet opening comprising a generally circular opening into the mask body	*Gunaratnam* teaches this feature, in that the base (base portion 48) of the mask body (nozzle assembly 18), which forms the mask body inlet opening, may have "any suitable shape." RMD1004, *Gunaratnam*, ¶ 0188 ("In the illustrated embodiment, the base portion 48 has a generally dog-bone shape. However, ***the base portion 48 may have any suitable shape***, including shapes to avoid contact with sensitive regions of the patient's face . . . ."). A generally circular mask body inlet opening would have been such a suitable shape as contemplated in *Gunaratnam*. In addition, *Ging* describes a "mask body" as mask cushion 40. The mask cushion 40 in *Ging* is a full nasal cushion to cover and surround the patient's nose, rather than nasal pillows, but the principle of how its mask cushion 40 engages with a frame via an inlet opening would also apply to nasal pillows mask bodies as provided in *Gunaratnam*. The mask cushion 40 in *Ging* defines a mask body inlet opening on a side of the mask cushion 40 that connects to a mask frame 20, as shown in Figures 5C and 6b. To connect the mask cushion 40 to the frame 20, a portion of the mask cushion 40 that defines the mask body inlet opening is fitted into a channel 26 in the mask frame 20. The channel 26 and the mask body inlet opening of the mask cushion 40 thus have complementary shapes. Although the shape of channel

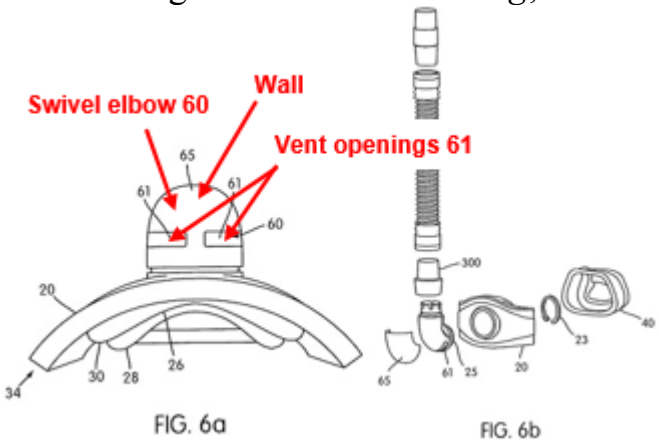
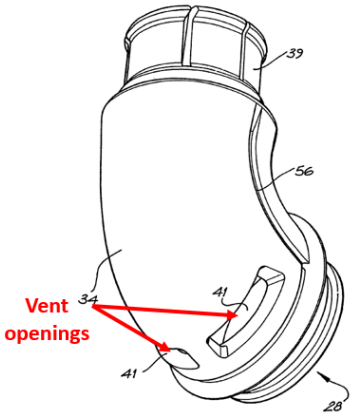
'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
	26 and the mask cushion 40 are shown in the figures as being trapezoidal, *Ging* discloses that a circular-shaped channel 26, and thus a circular-shaped mask body inlet opening, may be employed in the alternative. RMD1005, *Ging*, ¶ 0115 ("The shape of the channel 26, e.g., a generally trapezoid shape as seen in Fig. 5c, is selected so as to achieve guidance to correct cushion orientation relative to the channel 26 without the need for additional guide pieces as would be the case should the channel 26 have a more symmetrical shape such as an equilateral triangle, ***circle***, square, or rectangle. ***Nevertheless, the cushion channel 26 could adopt any of these shapes***.") (emphasis added).
[8.14] the mask assembly having a ring-like connector releasably connected to the mask body inlet	Figure 135 includes a mask frame, which is a "ring-like connector" that defines a circular inner passage for receiving a portion of an elbow, and that allows the elbow to rotate. Thus the "ring-like connector" element as recited in claim 8 is present in *Gunaratnam*'s Figure 135 design, or is at most an obvious implementation detail of this design in view of the teachings of *Gunaratnam* and *Ging*. *Ging* discloses the details of a mask frame 20 (the claimed "ring-like connector") similar to the mask frame provided in  FIG.135 FIG. 6b the patient interface design depicted in *Gunaratnam* Figure 135 and shows how the ring-like connector is engaged with the mask body. *Ging* shows an exploded view in Figure 6b of a patient interface comprising a

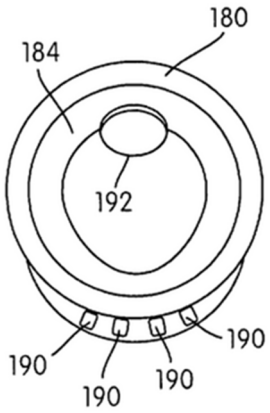
'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
	mask cushion 40 (the claimed "mask body"), a mask frame 20 (the claimed "ring-like connector"), and a swivel elbow, similar to *Gunaratnam*'s Figure 135 design, as shown in the figure above. The mask frame 20 in *Ging* is a "ring-like connector" because it has a circular inner passage that allows the elbow to rotate. *See, e.g.,* RMD1005, *Ging*, Figure 6b. Specifically, the central bore 24 (also referred to as aperture 24) of the mask frame 20 is the circular inner passage. *Ging* also discloses that the mask frame 20 is releasably connected to an inlet of the mask cushion 40. *See, e.g., Ging*, at ¶¶ 0115, 0196-223, Figs. 5, 5c (describing in detail how the mask frame 20 is releasably connected to the mask cushion 40) *see also id.* at 27a-28 and ¶¶ 0196-223 (describing a mask frame and cushion connection system with releasable connection). Figures 5c and 6b show that a lip of the mask cushion 40 is received by a channel 26 of the mask frame 20. RMD1005, *Ging*, Figs. 5c, 6b, 24, 27-29, ¶¶ 0114-15 (describing that channel 26 of the mask frame 20 receives and "edge of the side wall or central portion 215 (Figs. 24e and 27a) of the cushion 40").
[8.15] wherein a plane bisects the ring-like connector and the first nasal pillow is located on a side of the plane opposite the second nasal pillow	This claim limitation requires that the ring be located generally at the center of the mask. This feature would be present in the modified configuration of Gunaratnam's Figure 135 design if a nasal pillows-type cushion (e.g., like nozzle assembly 18 or the pillows in Figs. 107G-H) were substituted for the full nasal cushion of the original design. If one were to consider a plane that bisects the ring (e.g., mask frame) present in the Figure 135 mask assembly vertically, that plane

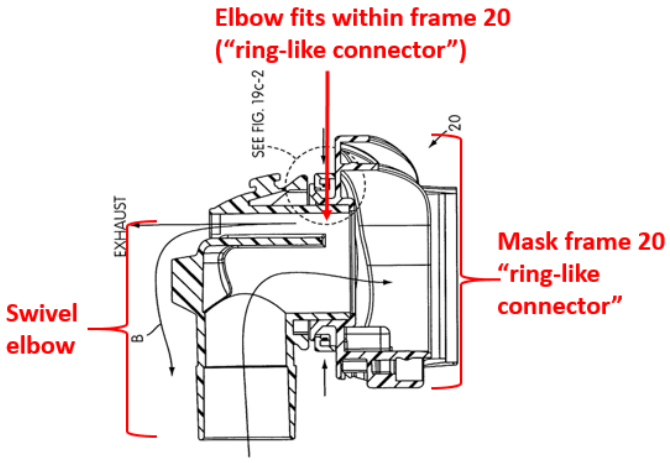
'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
	would bisect the nasal mask assembly vertically. Moreover, that plane would lie between each of the two nasal pillows, which would position each of the two nasal pillows on opposite sides of the plane. The figure illustrates a modified version of Figure 135 that shows one example of how a nasal pillows cushion could easily be implemented in the patient interface design of Figure 135.  (Modified to show mask assembly with nasal-pillows type cushion) FIG.135
[8.16] a tube assembly configured to deliver airflow to the mask body	Figure 135 of *Gunaratnam* discloses a tube assembly configured to deliver airflow to the mask body, as indicated by the figure at right. *See also* RMD1004, *Gunaratnam*, Figs. 45, 49, 76A-B, and 107-107J (additional figures showing patient interfaces with tube assemblies).  FIG.135

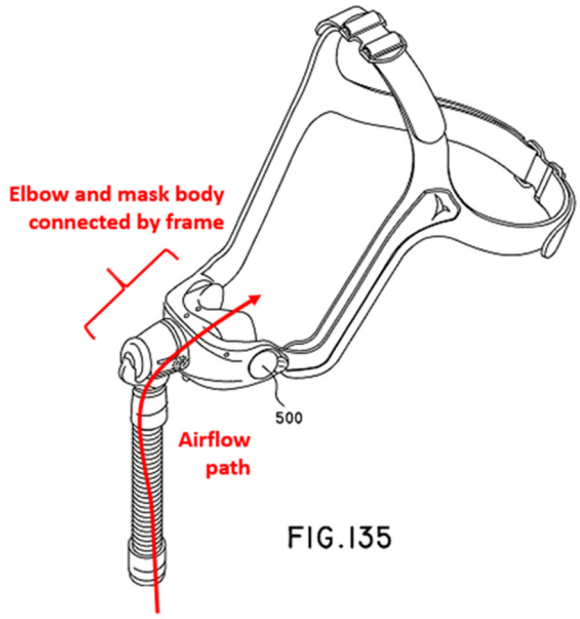
'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
	The details of a tube assembly and swivel elbow applied to a patient interface having a "ring-like connector" – in addition to being implied or inherent in *Gunaratnam*'s Fig. 135 design – are further described in *Ging*. For example, *Ging* shows a tube or conduit (air delivery tube 310) in Figure 26. RMD1005, *Ging*, Fig. 26, ¶ 0153 ("The air tube 310 (Fig. 26) is preferably directly connected to a stem 166 of swivel elbow 160 (without connector tube 300) to supply pressurized breathable air or gas from a pressurized supply through air tube 310, intake port 162 and into cushion 40 for breathing by the patient."); *see also id.* at ¶ 0111; *id.* at Fig. 1.  FIG. 26
[8.17] the tube assembly comprising a flexible conduit	*Ging* discloses this feature, in that the tube assembly includes a flexible conduit, namely gas delivery tube 310. In use, the gas delivery tube 310 connects directly to a portion of the swivel elbow 160. RMD1005, *Ging*, Fig. 26, ¶ 0153 ("The air tube 310 (Fig. 26) is preferably directly connected to a stem 166 of swivel elbow 160 (without connector tube 300) to supply pressurized breathable air or gas from a pressurized supply through air tube 310, intake port 162 and into cushion 40 for breathing by the patient."); *see also id.* at ¶ 0111; *id.* at Fig. 1.
[8.18] the flexible conduit comprising a first end and a second end	*Ging* discloses that the gas delivery conduit 310 includes a first end and a second end. *See* RMD1005, *Ging*, Figs. 1, 6b, 26.

'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
[8.19] the first end of the flexible conduit comprising a connector	The first end of the flexible conduit (gas delivery tube 310) in *Ging* comprises a connector, as shown in Figure 26. One of skill in the art would understand that the connector at the first end may be used to connect the flexible conduit to a pressurized gases supply, such as a CPAP machine. 
[8.20] the second end of the flexible conduit comprising an elbow	*Ging* discloses this feature, in that the second end of the gas delivery conduit 310 (the flexible conduit) connects to a swivel elbow 160 (or swivel elbow 60 in Figs. 1-3). RMD1005, *Ging*, Fig. 26, ¶ 0153 ("The air tube 310 (Fig. 26) is preferably directly connected to a stem 166 of swivel elbow 160 (without connector tube 300) to supply pressurized breathable air or gas from a pressurized supply through air tube 310, intake port 162 and into cushion 40 for breathing by the patient."); *see also id.* at ¶ 0111; *id.* at Figs. 1-3. Figure 2 of *Ging* is annotated here.  The second end of the gas delivery tube 310 "compris[es]" the swivel elbow 160 (or swivel elbow 60) because the swivel elbow 160 connects to, and can thus become part of, the second end of the tube 310 in the assembled patient interface.

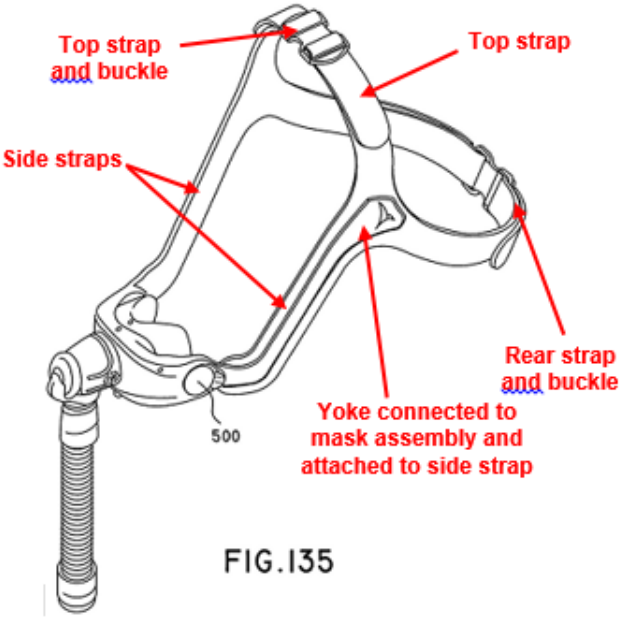
'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
[8.21] the elbow comprising a wall	*Ging* discloses several embodiments of swivel elbows, each embodiment including a wall in the swivel elbow. One of these embodiments is the swivel elbow 60, shown in Figures 6a and 6b of *Ging*, for example.  FIG. 6a FIG. 6b
[8.22] the wall comprising a vent	*Ging* discloses that the elbow assembly 60 includes vent openings 61. The vent openings 61 are located in the wall of the elbow assembly 60. RMD1005, *Ging*, Figs. 6a, 6b, ¶ 0113 (describing that "[t]he elbow assembly 60 may also include one or more vent openings 61 open to atmosphere, for example, for gas washout of exhaled carbon dioxide, among other things," and that "[t]he vent openings 61 are structured so that treatment pressure will be maintained within the nasal cavity"). *Ging* states that further details of the elbow assembly 60, including the vent openings 61 are disclosed in *Gunaratnam II* (RMD1007), which is incorporated by reference into *Ging's* disclosure. *See* RMD1005, *Ging*, ¶ 0113. The vent openings are clearly shown, for example in Figure 4 of *Gunaratnam II* (at right). RMD1007, Fig. 4. *See also* 

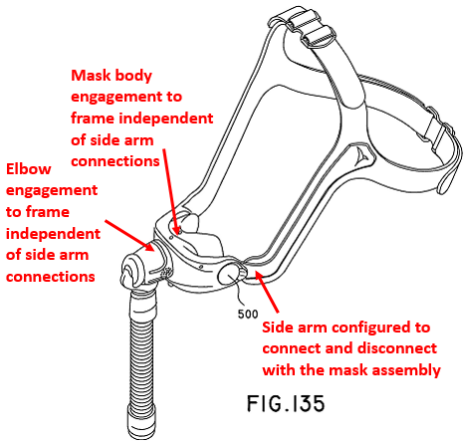
'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
	RMD1004, *Gunaratnam*, ¶ 0403 (explaining that the swivel elbow in any embodiment "may be provided with appropriate vents to exhaust gas from the breathing chamber").
[8.23] the vent comprising a plurality of holes extending through the wall of the elbow	*Ging* discloses that "[t]he elbow assembly 60 [Figs. 6a and 6b] may also include one or more vent openings 61 open to atmosphere, for example, for gas washout of exhaled carbon dioxide, among other things." RMD1005, *Ging*, Figs. 6a, 6b, and ¶ 0113. In another disclosed elbow design, *Ging* further describes a vent cover 180 that includes a plurality of holes (vents 190) for venting the patient's exhaled gases from the mask assembly. *Id.* at Fig. 22 (at left) and ¶¶ 0163-64. In view of the disclosure from *Ging*, and *Gunaratnam's* teaching that the swivel elbow "may be provided with appropriate vents to exhaust gas from the breathing chamber" (RMD1004, ¶ 0403), it would have been obvious for a skilled artisan to locate a plurality of vent holes in the elbow of *Gunaratnam's* Fig. 135 design, so as to ensure adequate ventilation of exhaled gases from the patient's breathing space.  ***Ging*, Fig. 22**
[8.24] the ring-like connector end being secured around an outer portion of the elbow	This feature is implied or inherent in *Gunaratnam's* Fig. 135 design, as the frame (ring-like connector [end]) is, in ResMed's VISTA mask design, secured around an outer portion of the elbow. *See* RMD1004, *Gunaratnam*, ¶ 0403. To the extent the details of the VISTA configuration are not explicitly shown in *Gunaratnam*, this feature is shown, for example, in

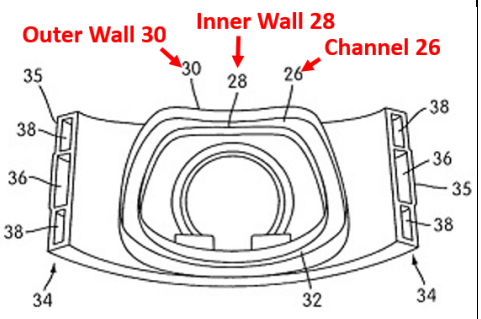
'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
	Figures 19a-1 through 19c-2 of *Ging*, which depict an end portion 169 of the swivel elbow 160 inserted within the aperture 25 of the mask frame 20 when the elbow 160 is rotatably engaged with the mask frame 20. In use, the mask frame 20 is thus secured around an outer portion (end portion 169) of the elbow (swivel elbow 160). RMD1005, *Ging*, Figs. 19a-1 – 19c-2, ¶ 0161. Figure 19c-1 is  annotated above. This feature is also disclosed in an alternative embodiment of *Ging*. In particular, Figures 6a and 6b show a distal end of the elbow assembly 60 projecting through the aperture 24 of the mask frame 20 when the patient interface is assembled. The mask frame 20 thus secures the elbow assembly 60 so that the elbow assembly 60 is rotatable relative to the mask frame 20. RMD1005, *Ging*, Figs. 6a, 6b, ¶ 0113.

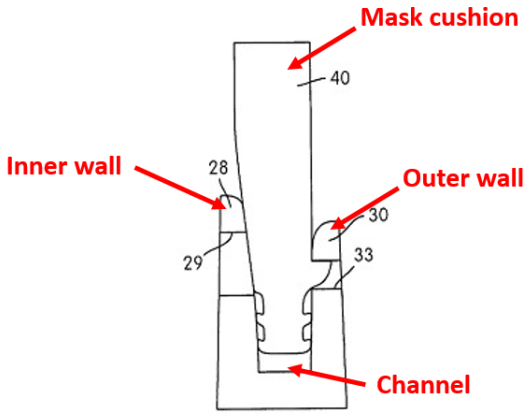
'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
[8.25] the elbow and the mask body being connected at least in part by the ring-like connector end such that airflow from the tube assembly can be directed from the elbow through the generally circular opening of the mask body and into the mask body	This feature is disclosed in both *Gunaratnam* and in *Ging*. First, *Gunaratnam*, in Figure 135, discloses a swivel elbow connected to the front center of a frame for a nasal mask. Figure 135 depicts the mask body as including a full nasal cushion that surrounds the patient's nose, but the nasal pillows-type cushions, such as nozzle assembly 18, would also be applicable to the mask assembly in Figure 135 rather than the full nasal cushion. One of skill in the art would recognize that this feature is implied or inherent in the disclosure of *Gunaratnam's* Figure 135 patient interface design, in that the swivel elbow and the nasal cushion in Figure 135 are connected at least in part by the frame such that airflow from the tube assembly can be directed from the elbow through the generally circular opening of the frame and into the nasal cushion.  FIG.135 Likewise, this feature is clearly present in *Ging*. For example, *Ging* discloses that, when assembled, swivel elbow 160 and mask cushion 40 (a "mask body") are connected at least in part by the mask frame 20 (the "ring-like connector"). This connection is made such that airflow from the tube assembly is directed from the swivel elbow 160 through the opening of mask cushion 40 (which may be generally circular, as discussed above) and into the cushion 40. RMD1005, *Ging*, Fig.

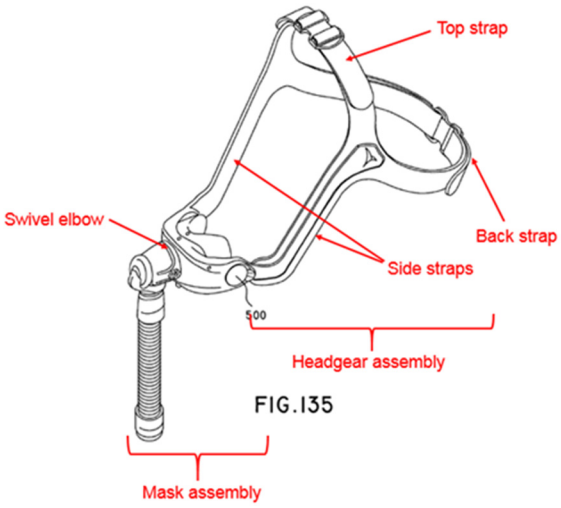
'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
	1; Figs. 16a – 19c-2, ¶ 0153 (describing how air from tube 310 flows through intake port 162 of the swivel elbow 160 "and into cushion 40 for breathing by the patient").
[8.26] the elbow and the mask body being capable of rotating relative to each other	This feature is disclosed in the patient interface shown in Figure 135 of *Gunaratnam*, which includes a "swivel elbow." RMD1004, *Gunaratnam*, Fig. 135, ¶ 0403 (referring to the elbow as a "swivel" elbow); *see also id.* at ¶ 0389 ([t]he swivel elbow 612, as shown in Fig. 10B, is able to fit and snap into mask frame 616" and "[t]his construction allows free swiveling within the frame 616, between a range of defined angles"). Furthermore, *Ging* discloses that the swivel elbow and mask cushion 40 are capable of being rotated relative to each other. RMD1005, *Ging*, ¶ 0151("Swivel elbow 60 is rotationally connected to frame 20."); *see also id.* at ¶¶ 0151-62, Figs. 16a – 10c-2 (describing details of the swivel elbow 160 and its engagement with mask frame 20).
[8.27] a headgear assembly configured to secure the mask body to a face of the user	The patient interfaces shown in *Gunaratnam*'s Figures 107, 107E, 107G-H, and 135 all include a headgear assembly, with 107, 107E, and 107G-H showing headgear assemblies used with nasal pillows type mask assemblies. *See* RMD1004, Figs. 107, 107G-H, 135. The patient interfaces shown in Ging similarly include headgear assemblies. See, e.g., RMD1005, *Ging*, Figs. 1-3.

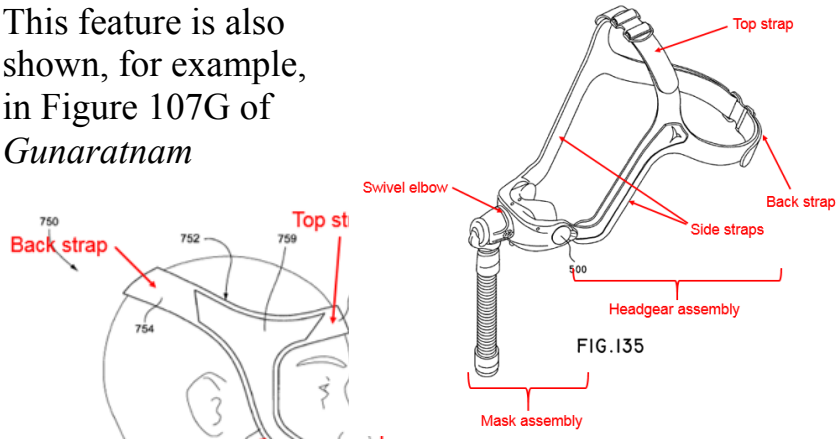
'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
	 Specifically regarding the design shown in Figure 135 of *Gunaratnam*, a headgear assembly having two side straps, a top strap with a buckle, and a back strap is disclosed. The general configuration of the headgear assembly is depicted in Figure 135 (annotated here).
[8.28] the headgear assembly comprising a first side strap and a second side strap	*Gunaratnam* in Figure 135 discloses that the headgear assembly includes a first side strap and a second side strap. *See* RMD1004, *Gunaratnam*, Fig. 135 (reproduced and annotated in for limitation 8.27 above).
[8.29] a top strap being connected to the first side strap and the second side strap	*Gunaratnam* in Figure 135 discloses that the headgear assembly includes a top strap being connected to the first side strap and the second side strap. *See* RMD1004, *Gunaratnam*, Fig. 135 (reproduced and annotated for limitation 8.27 above).
[8.30] the top strap including buckle configured to adjust a length of the top strap	*Gunaratnam* in Figure 135 discloses that the top strap of the headgear assembly includes a buckle. The buckle is configured to adjust a length of the top strap. *See* RMD1004, *Gunaratnam*, Fig. 135 (reproduced and annotated for limitation 8.27 above).

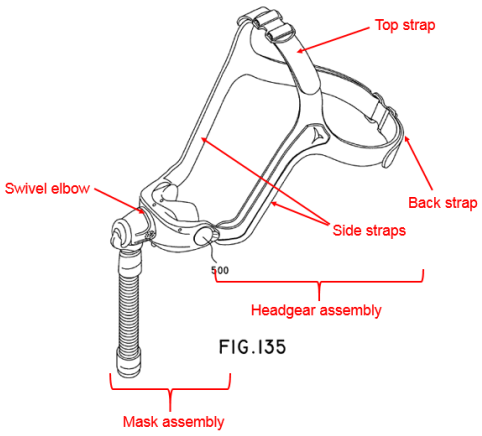
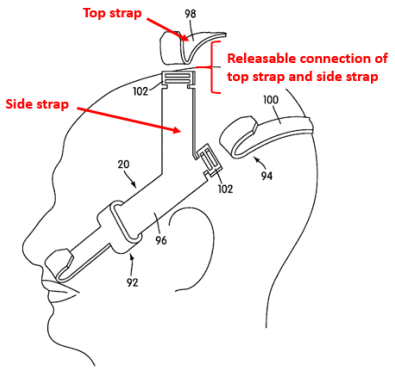
'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
[8.31] and a back strap adjustably connected to at least one of the top strap, the first side strap, and the second side strap	*Gunaratnam* in Figure 135 discloses that the headgear assembly includes a back strap adjustably connected to at least one of the top strap, the first side strap, and the second side strap. In particular, the back strap in Figure 135 also includes a buckle that facilitates the adjustable connection. *See* RMD1004, *Gunaratnam*, Fig. 135 (reproduced and annotated for limitation 8.27 above).
[8.32, 8.33] wherein the first side strap and the second side strap are configured to connect and disconnect with the mask assembly while the elbow is connected with the mask body, wherein the mask assembly is configured to connect to only two side straps	This feature is inherently present in the Figure 135 design of *Gunaratnam*, as evidenced by *Gunaratnam* and *Ging*.  FIG.135 Because the elbow in Figure 135 is located at the front center of the mask assembly, the two side straps are configured to connect and disconnect with the mask assembly while the elbow remains connected with the mask body via the frame. The connection between the side straps and the mask assembly are made indirectly via side arms, and this connection is independent of the connection between the elbow and mask body. *See* RMD1004, *Gunaratnam*, at ¶ 377-81, 0403, Figures 108-13, 135. Even assuming a direct connection of the straps to the mask assembly were required by the claims (which is not the case), it would have been an obvious design modification to *Gunaratnam* Figure 135 to allow the *side straps* to connect and disconnect directly from the mask assembly, rather than the *yokes* (side arms) as in Figure 135. The obviousness of the design modification is illustrated by *Gunaratnam* also disclosing such a direct connection configuration in the headgear assembly for a similar type of nasal interface

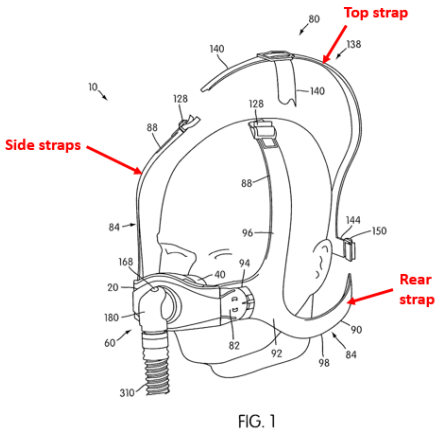
'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
	(having nasal pillows), namely in Figures 107G-H. In the embodiment of Figures 107G-H, the headgear assembly 752 includes a back strap 754, front strap 756, and pair of side straps 758. Here, the side straps 758 connect directly to the frame 768, rather than the yokes 759 connecting to the frame. The side straps 758 in this embodiment are configured to connect and disconnect with the mask assembly while the elbow 770 remains engaged with the frame 768 (or mask frame 20) and the frame 768 (or mask frame 20) remains engaged with the mask body (e.g., nozzle assembly 18) RMD1004, *Gunaratnam*, Figs. 107G-H, ¶¶ 0369-0370. One of ordinary skill in the art would have been motivated to apply the side strap connect and disconnect feature of Figs. 107G-H to the Figure 135 embodiment to provide any of the advantages resulting from such design, such as to allow a quick release of the straps from the headgear assembly.
[17] A patient interface as claimed in claim 1, wherein the ring comprises a first wall and a second wall defining a space therebetween, and wherein a portion of the mask body is configured to removably attach to the ring via friction within the space and with the first wall and the second wall	The additional features of claim 7 are clearly disclosed in *Ging* and are also taught in *Gunaratnam*. As mentioned above, the mask frame 20 (or a portion thereof) shown in Figures 1, 3, 5, 5a, and 5c of *Ging*, for example, is a "ring" as claimed. *Ging* discloses that the mask frame 20 has a first wall as inner wall 28, and a second wall as outer wall 30. The inner wall 28 and outer wall 30 of the mask frame 20 define a space therebetween, which *Ging* refers to as channel 26. RMD1005, *Ging*, ¶ 0111. Figure 5c is copied here for illustration. A portion of the mask body removably attaches to the ring (mask frame 20) via friction within the space between the first  FIG. 5c

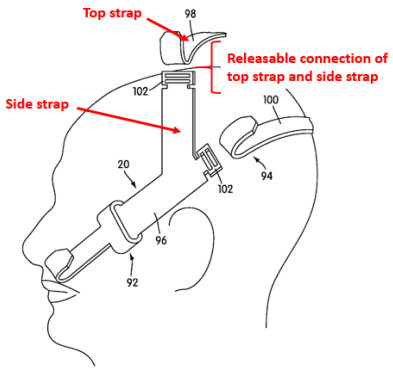
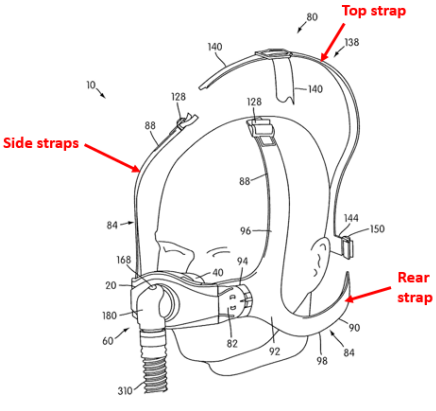
'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
	wall and the second wall and with the first wall and the second wall. Additionally, *Ging* discloses that a portion of the mask cushion 40 is configured to removably attach via friction to the mask frame 20 (ring) within the channel 26 (space between first and second walls) and with the inner wall 28 (inner wall) and the outer wall 30 (second wall). RMD1005, *Ging*, ¶¶ 0111, 0114-15, 0215 ("By control of this source of friction, it is possible to influence the engagement and disengagement forces, i.e., the forces required to engage and disengage the cushion and frame. The preferred aim being to have those forces remain with defined limits for the expected useful life of the cushion."), ¶ 0204-05 (describing in detail how a portion of mask cushion 40 fits within the channel 26 and with the inner wall 20 and outer wall 30), Figs. 27A-27E, 28, *generally* ¶ 0196-223 (describing various aspects of a mask frame and cushion connection system).  FIG. 28 In addition, *Gunaratnam* discloses that the nozzle assembly 18, which would be obvious to apply to the patient interface design of Figure 135, includes a portion that is configured to removably attach to a mask frame via a friction fit. RMD1004, *Gunaratnam*, ¶ 186 ("[T]he nozzle assembly 18 may be removably attached to the frame 16 in any other suitable manner, e.g., ***friction*** or interference fit and/or a tongue and

'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
	groove arrangement, as is known in the art.") (emphasis added). In view of the foregoing teachings of *Gunaratnam* and *Ging*, the additional feature of claim 7 would have been nothing more than an obvious design choice to a skilled artisan to apply to the design of *Gunaratnam* Figure 135.
[18, 19] A patient interface as claimed in claim 1, wherein the top strap is integrally formed with one or more of the side straps and the back strap (claim 18) A patient interface as claimed in claim 18, wherein the top strap is integrally formed with one or more of the side straps" (claim 19).	*Gunaratnam* discloses the additional feature of a top strap being integrally formed with one or more of the side straps and the back strap. In Figure 135 (copied and annotated at right), for example, respective sides of the top strap are integrally formed with one or more of the side straps and the back strap (claim 18), and meets the feature of the top strap being integrally formed with one or more of the side straps (claim 19). *See* RMD1004, *Gunaratnam*, Figs. 107, 107-1, 107-2, and 107G-F (showing additional integrally formed headgear configurations), ¶ 213 (noting that the headgear assembly 20 in some embodiments "may be constructed as a one piece structure"). It would have been obvious for a person of ordinary skill in the art to apply these various headgear designs to the Figure 135 design in *Gunaratnam* in order to reduce the effort required of the patient to make connections among the integral parts of the assembly. 
[20, 21] A patient interface as claimed in	*Gunaratnam* and *Ging* disclose the patient interface as claimed in claim 8. *Gunaratnam* discloses the

'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
claim 8, wherein the top strap is integrally formed with one or more of the side straps and the back strap (claim 20) A patient interface as claimed in claim 20, wherein the top strap is integrally formed with one or more of the side straps (claim 21)	additional feature of a top strap being integrally formed with one or more of the side straps and the back strap. In Figure 135 (annotated at right), for example, respective sides of the top strap are integrally formed with a side strap and the back strap. This feature is also shown, for example, in Figure 107G of *Gunaratnam*  FIG.135 FIG. 107G (annotated below). The top strap 756, back strap 754, and side straps 758 are shown as a unitary headgear structure, and are thus integrally formed. As such, the headgear meets the feature of having a top strap 756 that is integrally formed with one or more of the side straps 758 and the back strap 754 (claim 20), and meets the feature of the top strap being integrally formed with one or more of the side straps (claim 21). *See* RMD1004, *Gunaratnam*, Figs. 107, 107-1, 107-2, and 107F (showing additional integrally formed headgear configurations), ¶ 0213 (noting that the headgear assembly 20 in some embodiments "may be constructed as a one piece structure"). It would have been obvious for a person of ordinary skill in the art to apply these various headgear designs to the Figure 135 design in *Gunaratnam* to reduce the effort required to make connections among the integral parts of the assembly.

'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
[24, 25] A patient interface as claimed in claim 1, wherein the top strap is releasably connected to one or more of the side straps and the back strap (claim 24) A patient interface as claimed in claim 24, wherein the top strap is releasably connected to the back strap (claim 25).	*Gunaratnam* discloses certain configurations that meet the additional feature of a top strap being releasably connected to one or more of the side straps and the back strap. To begin, the patient interface design shown in Figure 135 of *Gunaratnam* includes a top strap having a first portion which is integrally formed with (i) a first of the pair of side straps and (ii) a portion of the back strap. A second portion of the top strap is integrally formed with (i) a second of the pair of side straps and (ii) a second portion of the back strap. A buckle connects the first and second portions of the top strap, so that at least a portion of the top strap is releasably connected to one or more of the side straps and the back strap, as claimed.  FIG.135 Additionally, *Gunaratnam* discloses many different headgear configurations. A number of these alternative embodiments include releasably connected straps consistent with claim 24. For example, Figure 18 (copied below) depicts a headgear assembly 20 having a top strap 98, a rear strap 100, and a pair of side straps 96. As shown in Fig. 18 (copied and annotated at right), the top strap 98 is releasably connected to the side straps 96. RMD1004,  FIG. 18

'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
	Gunaratnam, Fig. 18, ¶¶ 209-211. The Figure 18 embodiment thus discloses the releasable connection feature of claim 24.  FIG. 1 *Ging*, in Figure 1 (copied and annotated at left), also discloses a headgear assembly 80 having a top strap 140, side straps (the portion of front straps 84 that run from the top of the patient's head and down the cheeks), and a rear strap (the portions of front strap 84 that curve around the back of the user's head to connect to strap 142). RMD1005, *Ging*, Figs. 1, 1b, ¶¶ 0145-48. The top strap 140 is clearly releasably connected to the side straps and is also releasably connected to the rear strap (back strap), as required by claim 25. *Id.* In view of the teachings of *Gunarantam* and *Ging*, one of skill would have found it obvious to provide releasable connections among the top strap and the side straps or the top strap and the rear strap in order to allow the user more flexibility in sizing the headgear assembly and to allow the headgear to be more easily removed from the patient by the releasable connections.
[26, 27] A patient interface as claimed in claim 8, wherein the top strap is releasably connected to one or more of the side straps and the back strap (claim 26)	*Gunaratnam* and *Ging* disclose the patient interface as claimed in claim 8. *Gunaratnam* discloses certain configurations that meet the additional feature of a top strap being releasably connected to one or more of the side straps and the back strap. To begin, the patient interface design shown in Figure 135 of *Gunaratnam* includes a top strap having a first portion which is integrally formed with (i) a first of the pair of side straps and (ii) a portion of the back strap.

'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
A patient interface as claimed in claim 26, wherein the top strap is releasably connected to the back strap (claim 27)	A second portion of the top strap is integrally formed with (i) a second of the pair of side straps and (ii) a second portion of the back strap. A buckle connects the first and second portions of the top strap, so that at least a portion of the top strap is releasably connected to one or more of the side straps and the back strap, as claimed. Additionally, *Gunaratnam* discloses many different headgear configurations. A number of these alternative embodiments include releasably connected straps consistent with claim 26. For example, Figure 18 depicts a headgear assembly 20 having a top strap 98, a rear strap 100, and a pair of side straps 96. As shown in Fig. 18, the top strap 98 is releasably connected to the side straps 96. RMD1004, *Gunaratnam*, Fig. 18, ¶¶ 209-211. The Figure 18 embodiment thus discloses the releasable connection feature of claim 26.  FIG. 18  FIG. 1 *Ging*, in Figure 1 (annotated at left), also discloses a headgear assembly 80 having a top strap 140, side straps (the portion of front straps 84 that run from the top of the patient's head and down the cheeks), and a rear strap (the portions of front strap 84 that curve around the back of the user's head to connect to strap 142). RMD1005, *Ging*, Figs. 1, 1b,

'807 Claims	Exemplary Disclosures from *Ging* and *Gunaratnam*
	¶¶ 0145-148. The top strap 140 is clearly releasably connected to the side straps and is also releasably connected to the rear strap (back strap), as required by claim 27. *Id.* In view of the teachings of *Gunarantam* and *Ging*, one of skill would have found it obvious to provide releasable connections among the top strap and the side straps or the top strap and the rear strap in order to allow the user more flexibility in sizing the headgear assembly and to allow the headgear to be more easily removed from the patient by the releasable connections.

3. Supplemental Analysis Of Individual Claim Limitations

65. In addition to the analysis embodied in the claim chart shown in Section VIII.B.2 above, I offer the following observations regarding certain elements of the claims that supplement the analysis in the claim chart, and that support my opinion that the combination of *Gunaratnam* and *Ging* renders obvious each of claims 1-8, 17-21, and 24-27 of the '807 patent.

a) Claim Limitations 1.2 and 1.3

66. I understand that claim 1 recites the feature of "a mask assembly having: a mask body including two nasal pillows extending from it, which in use rest in a substantially sealed manner against the nares of a user." Figure 135 of *Gunaratnam* discloses a nasal mask assembly, but not one that is a nasal pillows

type mask assembly. As will be discussed below, however, nasal pillows type mask assemblies were well known in the art long before the '807 patent.

67. For example, nasal pillows type mask assemblies are shown in various configurations throughout *Gunaratnam*, in Figures 1-133. Figure 1, for example, shows a nasal assembly 10 that includes a mask frame 16 and a nozzle assembly 18. The nozzle assembly 18 in this embodiment of *Gunaratnam* discloses the claimed "mask body including two nasal pillows extending from it, which in use rest in a substantially sealed manner against the nares of a user." Figures 5 and 6 show the nozzle assembly 18 in greater detail. *See* RMD1004 at Figs. 1, 5, 6; *see also id.* at Figs. 7, 8, ¶¶ 185-96. *Gunaratnam* describes that the nozzle assembly 18 includes a pair of "nozzles 50" – a term for which one of ordinary skill in the art would have understood at the time of the '807 patent as referring "nasal pillows," as that term is used in the claims. These nasal pillows in *Gunaratnam* rest in use in a substantially sealed manner against the nares of a user. This is clearly shown in Figure 1, and also described in the text of *Gunaratnam*'s specification, which states that "[t]he nozzle assembly [18] is coupled with the main body of the frame [16] with the pair of nozzles structured to sealingly engage with nasal passages of a patient's nose in use." RMD1004 at ¶ 26.

68. Multiple other embodiments of *Gunaratnam* also employ a mask body having two nasal pillows extending from it, which in use rest in a substantially

sealed manner against the nares of a user, as claimed. For example, Figures 61-65 show a nasal mask having a nozzle assembly 518 and a pair of nozzles 550 (nasal pillows), which one of skill would understand rest in use in a substantially sealed manner against the nares of a user. *Id.* at Figs. 61-65, ¶¶ 291-94. The cushion assembly 604 in an embodiment illustrated by Figures 108-13 similarly includes nasal pillows in a mask body that would seal against the nares of a user in use. *Id.* at Figs. 108-13. The nozzle assembly 18 also includes a base portion 48 that includes structure for attaching to a mask frame 16.

69. The feature is additionally present in the patient interface embodiment shown in Figures 107G-H of *Gunaratnam*. Figure 107H depicts a portion of one nozzle 772 behind the mask frame 768 (although Figures 107G-H do not show the interface in use, which is why the mask is shown as being slightly dropped below the patient's nose). *See* RMD1004 at Figs. 107G-H, ¶¶ 369-70. In use, the mask would not cover the patient's mouth.

70. Not all of the patient interfaces disclosed in *Gunaratnam* are masks with nasal pillows, which include a mask body having a pair of nasal pillows extending from it, which in use rest in a substantially sealed manner against the nares of a user. The nasal mask depicted in Figure 135, for example, utilizes a full nasal cushion rather than nasal pillows. RMD1004 at Fig. 135, 403. The nasal cushion in Figure 135 is arranged in use to surround the breathing passages of the

patient's nose by forming a sealed space from above the patient's upper lip to a location atop the patient's nose (e.g., the bridge of the nose). The nasal cushion thus allows the patient to receive pressurized air for CPAP therapy from the sealed space surrounding the patient's nasal breathing passages, rather than from respective nozzles that rest against the nares.

71. Although the Figure 135 embodiment of *Gunaratnam* does not itself have nasal pillows, it is my opinion that one of ordinary skill in the art would have found it obvious to implement a mask body having a pair of nasal pillows, such as the nozzle assembly 18, in the Figure 135 embodiment. The motivation for modifying the nasal mask of Figure 135 in this manner would have been to achieve any of the benefits of nasal pillows that were well-known at the time of the ’807 patent. For example, nasal pillows masks are generally smaller and lighter than full nasal cushion masks. Many patients prefer nasal pillows due to their relatively smaller size, minimal surface area that contacts the patient’s skin, and their ability to relieve pressure on the bridge of the patient’s nose for increased comfort. Nasal pillows may also be less obstructive to a patient’s field of vision in use than other, larger types of masks. Ultimately, these benefits that many patients prefer in nasal pillows masks may result in greater patient compliance with prescribed CPAP treatment. *See, e.g.*, U.S. Pat. 4,782,832 to *Trimble* et al (RMD1019); U.S. Pat.

6,431,172 to Bordewick (RMD1020); U.S. Pat. 7,219,669 to *Lovell* et al. (RMD1012); *Gunaratnam* (RMD1004).

72. Some patients, however, do prefer full nasal masks over pillows, because the patient may find pillows to be uncomfortable in the nostrils. One of ordinary skill in the art would have understood at the time that full nasal masks and nasal pillows masks were two different, but well-known options. These two options – full nasal type mask assemblies and nasal pillows type mask assemblies – are substantially interchangeable from the standpoint of the headgear assembly design.

73. Finally, I note that the corresponding description of Figure 135 in *Gunaratnam* suggests that its full nasal cushion could be interchanged with a nasal pillows mask body. RMD1004 at ¶ 403 ("Further, the nozzle assembly and/or its associated cushion could be replaced with a nasal mask and/or nasal cushion."). This further confirms my analysis that it would have been obvious to implement nasal pillows in the nasal mask shown in Figure 135. Indeed, one of ordinary skill in the art would have understood from this statement in *Gunaratnam* that the patient interface design in Figure 135 could alternatively be made with nasal pillows, rather than the full nasal cushion that is shown in the drawing. This is especially clear given that the embodiment shown in Figures 107G-H of *Gunaratnam* is a nasal pillows type mask in which the elbow is connected to the

front center of the mask assembly. It is clear from *Gunaratnam* that it was known well before the time of the '807 patent that a patient interface having an elbow connected at the front center of the mask could be employed with a nasal pillows cushion (mask body).

b) Claim Limitation 1.4

74. I understand that claim 1 recites the feature of a "mask body sized and shaped to leave the mouth of the user uncovered by the mask body when in use." In my opinion, this feature is present in *Gunaratnam* (RMD1004) in the embodiment shown in Figure 135, and would also be present even if Figure 135 were modified to incorporate nasal pillows, like those taught by Figures 107G-H of *Gunaratnam*. *See also id.* at Figs. 1, 5, 6, and 61 (showing nasal pillows as nozzle assemblies 18, 518).

75. It was conventional at the time of the '807 patent for nasal pillows masks to leave the mouth of the patient uncovered when in use. *See, e.g.*, U.S. Pat. 4,782,832 to *Trimble* et al (RMD1019); U.S. Pat. 6,431,172 to Bordewick (RMD1020); U.S. Pat. 7,219,669 to *Lovell* et al. (RMD1012); *Gunaratnam* (RMD1004). This arrangement stands in contrast to another class of patient interfaces – namely, full face masks – which create a sealed space surrounding both the patient's mouth and nose in use.

76. Nasal masks deliver pressurized air to the patient's airways via the patient's nose only, whereas full face masks allow pressurized air to be delivered to the airways via both the patient's nose and mouth. Accordingly, regardless of whether the original nasal cushion in Figure 135, or a nasal pillows mask body were employed, the resulting patient interface would have "a mask body sized and shaped to leave the mouth of the user uncovered by the mask body when in use." Other nasal masks disclosed in *Gunaratnam* demonstrate this feature as well. *See* RMD1004 at Figs. 25, 36-38, 51-52, 59, 107G-H (examples of nasal pillows masks showing the user's mouth uncovered in use).

c) Claim Limitation 1.5

77. I understand that claim 1 recites the feature of a "ring engaged with the mask body." The "ring" structure in claim 1 is also referred to elsewhere in the claim. In particular, claim 1 recites that the "ring" is bisected by a plane such that each of the nasal pillows on the mask body are positioned on opposite sides of the plane; that "an elbow [is] rotatably engaged with the ring" such that "the ring form[s] a socket in to which a portion of the elbow fits to facilitate the rotatable engagement between the elbow and the ring"; and that "the two side straps are configured to connect and disconnect with the mask assembly while the elbow remains rotatably engaged with the ring and the ring remains engaged with the mask body." Moreover, I agree with Petitioners' proposed construction of the

claimed "ring" element as referring to a structure with a generally circular inner passage to enable the claimed rotatable engagement with an elbow that fits into the ring, and I agree that there is no requirement that the outside shape of the ring have any particular geometry.

78. I first note that the patient interface depicted in Figure 135 of *Gunaratnam* includes a mask frame, which is a "ring" that defines a circular inner passage for receiving a portion of an elbow, and that allows the elbow to rotate. Thus the "ring" element as recited in claim 1 is present in *Gunaratnam*'s Figure 135 design, or at most, I believe would have been an obvious implementation detail of this design to one of ordinary skill in the art in view of the teachings of *Gunaratnam* and *Ging*.

79. In my opinion, the "ring" element of claim 1 is disclosed in *Ging* by the mask frame 20. For example, the mask frame 20 is shown in an embodiment depicted in Figures 6a and 6b of *Ging*. RMD1005 at Figs. 6a, 6b; *see also id.* at Figs. 1-5c (showing the mask frame 20 in additional embodiments). I believe that the mask frame 20 meets each of the elements of claim 1 involving the claimed "ring," as set forth in the claim chart included above.

80. Moreover, *Ging* discloses the details of a mask frame 20 (a "ring") similar to the mask frame provided in the patient interface design depicted in *Gunaratnam* Figure 135 and shows how the ring is engaged with the mask body.

The mask frame 20 in *Ging* serves a number of purposes in the patient interface embodiment of Figures 6a and 6b, as would have been understood by a person of ordinary skill in the art. First, it acts as a rigid support structure for the mask cushion 40. *Ging* discloses that the mask cushion 40, which is made of a softer, flexible material such as silicone, includes a portion that connects with the mask frame 20. Mask frame 20 thus provides support to the mask cushion 40. In addition, the mask frame 20 forms a central bore 24 for connecting the swivel elbow assembly 60 to the mask frame 20. In particular, when the patient interface is assembled, a portion of the swivel elbow 60 protrudes through the central bore 24 of the mask frame 20. A C-clip 23 secures the elbow assembly 60 to the mask frame 20, such that the elbow 60 can freely rotate within the central bore 24 relative to the mask frame 20. This arrangement is shown in greater detail in U.S. Patent No. 6,691,707 (RMD1007) in Figures 2, 4, 6, 7, and 9, for example. *See* RMD1007 at Figs. 2, 4, 6, 7, 9; *see also* RMD1005 Figs. 5c, 6a, 6b, ¶ 113. The configuration of the nasal mask, including mask frame 20, in *Ging* thus allows pressurized air to be delivered through the front center of the mask, in contrast to some other configurations (e.g., RMD1004 at Fig. 1) where the pressurized air is delivered through a side end of a mask frame.

81. *Gunaratnam's* mask frame in Figure 135 and *Ging's* mask frame 20 are similar to the component in the '807 patent which, based on my review of the

'807 patent and file history (RMD1009), I believe the claimed "ring" structure is referring to mask base 22. *See, e.g.*, RMD1001 at Figs. 2-5, 6:19-56 (describing details of the mask base 22 and noting that the "mask base 22 is a ring or sleeve type attachment"). The mask base 22 in the '807 patent is a rigid frame structure that generally serves many of the same functions as the mask frame 20 in *Ging*. For example, the mask base 22 engages with a mask body 23 when an external lip 28 of the mask body 23 is received in a channel 45 of the mask base 22. Like *Ging's* mask frame 20, the mask base 20 thus serves as a rigid support structure for a softer, flexible mask body. The mask base 22 also forms a circular cavity, defined in part by semi-tubular projection 29, which is configured to allow the swivel elbow connector 30 to rotatably connect to the mask base 22. *See id.* at 6:19-56.

82. I believe that one of ordinary skill would have recognized that mask frames, like the mask base 22 in the '807 patent, were conventional components of a respiratory interface to connect between a swivel elbow and a mask cushion such as mask body 23. This is evidenced at least by the mask frame in Figure 135 of *Gunaratnam*, mask frame 20 in *Ging*, and the mask shell 15 in the '707 patent. *See* RMD1004 at Figs. 107G-H; RMD1005 at Figs. 5-6b; RMD1007 at Figs. 1-2.

83. The mask frame 20 from *Ging* includes a central bore 24 that forms a circular inner passage of the frame 20. Accordingly, the mask frame 20 meets the meaning of a "ring" in the context of the '807 patent.

84. As shown in Figures 5c and 6b of *Ging*, I recognize that the outer perimeter of the mask frame 20 has a generally rounded, rectangular geometry. But under the proper construction of "ring," its outer perimeter need not have a particular shape. Notably, although the '807 specification provides that the "mask base 22 is a ring or sleeve type attachment," nothing in the patent explains any particular benefit or significance to having a more circular outer geometry.

85. However, even if the term "ring" were to require a circularly shaped outer perimeter, I believe that one of ordinary skill in the art at the time of the '807 patent would have found it to be an obvious design choice to modify *Ging's* mask frame 20 to have such a circular outer perimeter. The modification could be achieved while maintaining the functions served by the mask frame 20 in its original shape as disclosed in *Ging*. For example, the mask frame 20 could be further rounded to make a generally circular outer perimeter without affecting how the swivel elbow assembly 60 connects to the mask frame 20, or how the mask cushion 40 fits into the channel 28 of the mask frame 20. The connections of the mask frame 20 to the headgear assembly could be easily adapted to accommodate the generally circular outer perimeter. Indeed, modifying *Ging's* mask frame 20 to

have a substantially circular shape would have been the application of a known teaching to yield predictable results.

d) Claim Limitation 1.6

86. I understand that claim 1 recites the feature of "a plane substantially bisecting the ring, each of the two nasal pillows positioned on opposite sides of the plane." In my opinion, this feature is met by the combined teachings of *Gunaratnam* and *Ging*. As previously noted, I agree with the Petitioners' proposed construction of this claim element as referring to a requirement that the ring be located generally at the front center of the mask.

87. The nasal mask in Figure 135 of *Gunaratnam* is arranged such that the swivel elbow connects to the front center of the mask frame. RMD1004 at Fig. 135, ¶ 403. Accordingly, a vertical plane bisecting the frame in the mask of Figure 135 would also bisect left and right sides of the full nasal cushion such that respective left and right halves of the cushion would be positioned on opposite sides of the plane.

88. If a mask body having two nasal pillows, such as nozzle assembly 18 or nozzle assembly 518, were applied to the nasal mask of Figure 135 (as would be obvious as discussed above with respect to claim element 1.3), the resulting mask would thus meet the claim limitation, as each of the two nasal pillows would be positioned on an opposite side of a plane substantially bisecting the mask frame.

Additionally, if the details of *Ging*'s ring (mask frame 20) were applied to the Figure 135 embodiment, the resulting mask would also meet the claim limitation, as each of the two nasal pillows would be positioned on an opposite side of a plane that substantially bisects the ring. This is conceptually illustrated in the following figure, which is a modified version of Figure 135 of *Gunaratnam*, in which the full nasal cushion has been replaced with a nasal pillows cushion. A bisecting plane is superimposed on the modified mask:

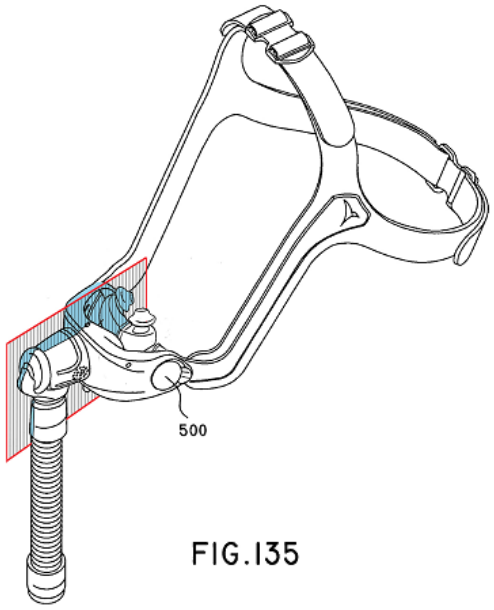


FIG.135

e) Claim Limitation 1.8

89. I understand that claim 1 recites that "the ring form[s] a socket into which a portion of the elbow fits to facilitate the rotatable engagement between the elbow and the ring." In my opinion, this feature is met by both *Gunaratnam* and *Ging*. For example, as I have discussed with respect to limitation 1.5, the mask

frame 20 in *Ging* is a structure that defines a circular inner passage that receives an elbow and allows the elbow to rotate within the circular passage. As such, one of ordinary skill in the art would have understood that *Ging's* mask frame 20 forms a socket into which a portion of the elbow fits to facilitate the rotatable engagement between the elbow and the ring. Moreover, although the Figure 135 embodiment does not explicitly show the mechanism by which its swivel elbow connects to the mask frame, a socket design would have been an obvious design choice to achieve such connection. Figure 110 of *Gunaratnam*, for example, shows a swivel elbow 612 rotatably engaged within a socket of a mask frame. RMD1004 at FIG. 110.

f) Claim Limitation 1.9

90. I understand that claim 1 recites that "the elbow compris[es] a plurality of vent holes." In my opinion, this feature would be present in the patient interface constructed following the combined teachings of *Gunaratnam* and *Ging*.

91. To begin, I note that it was well-known at the time of the '807 patent to provide a means of venting gases exhaled by the patient from a CPAP or other respiratory mask assembly. In order to administer pressurized gases in a clinically effective manner, it is critical that exhaled gases be removed from the patient's breathing space, in order to prevent carbon dioxide accumulation that could occur in a closed system. In some cases, carbon dioxide accumulation may place the

patient at risk of hypercapnia, symptoms of which include shortness of breath, increased heart rate and blood pressure, drowsiness, and even unconsciousness.

92. Therefore, an imperative design consideration for CPAP masks before the time of the '807 patent, and for respiratory masks more generally, was to provide a mechanism allowing for removal of exhaled gases from the patient's breathing space, so as to prevent the patient from continuously re-breathing exhaled air. For example, the mask in one embodiment of *Gunaratnam* includes a plurality of vent holes (vent apertures 619) in the nasal cushion 617, rather than the swivel elbow. RMD1004 at Fig. 110, ¶ 381.

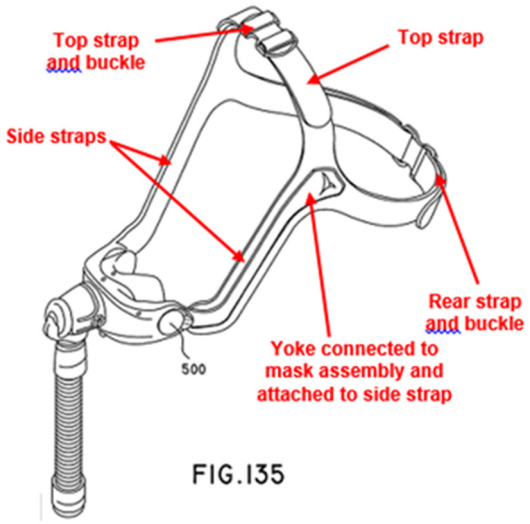
93. It is not necessary, however, that the vent holes be located in the mask cushion or mask body. For example, *Gunaratnam* states that the vent holes may be located on any appropriate component of the mask assembly, including the swivel elbow. *Id.* at ¶ 403 ("In FIG. 135, the elbow is provided to the front of the mask frame, like [ResMed's] VISTA mask, while both apertures/first connector portions are provided with plugged seal rings. ***Of course, in each embodiment, frame, elbow, and/or seal ring(s) may be provided with appropriate vents to exhaust exhaled gas from the breathing chamber***.") (emphasis added). In view of this teaching from *Gunaratnam*, it is my opinion that it would have been obvious that such vent holes as recited in limitation 1.9may include a plurality of vent holes.

94. Additionally, *Ging* and the '707 patent (RMD1007) disclose a plurality of vent holes located in a swivel elbow that would have been obvious to apply to *Gunaratnam*'s mask in Figure 135. For example, the cover of the elbow assembly 60 includes a plurality of holes 190 for venting exhaled gas to atmosphere, as shown in Figure 22. RMD1005 at Fig. 22; *see also id.* at Figs. 6a, 6b, ¶ 113 (describing a pair of vent openings 61 within an elbow assembly 60); RMD1007 at Fig. 4 (showing another view of an elbow like that shown as elbow assembly 60 in *Ging*). A person of ordinary skill in the art would have applied *Ging's* teaching of a plurality of holes extending through the wall of the elbow to the Figure 135 embodiment in *Gunaratnam*, in order to maximize the rate at which exhaled gases are vented from the mask assembly. Given that the elbow is located at the front of the mask, the patient's exhaled gas would be forced in the direction of the elbow during expiration. The location of the holes in the elbow would thus make them directly in the flow path of the exhaled gases, which would allow efficient venting of the gases.

g) Claim Limitation 1.12

95. I understand that claim 1 recites "a headgear assembly having: two side straps that pass down the cheeks of the user to secure the mask body to a face of the user." This feature is clearly shown in the Figure 135 embodiment of *Gunaratnam*, as illustrated below. Although the assembly in this view is not

depicted as being donned by a user, one of ordinary skill in the art at the time of the '807 patent would have recognized that the side straps in Figure 135 were arranged to help secure the mask body to the face of the user, and that when worn, the side straps would pass down the cheeks of the user.



h) Claim Limitation 1.15

96. I understand that claim 1 recites that "the two side straps are configured to connect and disconnect with the mask assembly while the elbow remains rotatably engaged with the ring and the ring remains engaged with the mask body." In my opinion, this feature would be present in the patient interface constructed following the combined teachings of *Gunaratnam* and *Ging*.

97. To begin, a person of ordinary skill in the art would have understood that the straps located on either side of the mask frame depicted in the patient interface in Figure 135 of *Gunaratnam* could be connected to and disconnected

from the mask assembly (indirectly, via the yokes (side arms)) while the swivel elbow remains rotatably engaged with the ring and the ring remains engaged with the mask body. The details of how the side arms could be connected and disconnected from the frame are shown and described with respect to Figs. 108-114 in *Gunaratnam*, for example. Of course, Figure 135 is different from Figs. 108-114 in that the elbow is located in front of the frame, rather than inserted from the side, but the manner in which the yokes connect to the frame would be substantially the same. It is clear, however, that the connection between the yokes and the mask assembly are independent of the connection between the elbow, ring, and mask in the Figure 135 embodiment.

98. Furthermore, to the extent that claim 1 requires a direct connection between the side straps and the mask assembly – which it does not (see *supra* ¶ 43) – this feature is also disclosed in the embodiment shown in Figures 107G-H of *Gunaratnam*. In particular, based on the depiction of the embodiment in Figures 107G-H and the discussion in paragraphs 369-70, a person of ordinary skill in the art would have understood that the side straps 758 were capable of being disconnected from the mask frame 768 directly while the elbow connector portion 770 remains engaged (e.g., rotatably engaged) with the mask frame 768 and while the mask frame 768 remains engaged with the mask body (e.g., nozzle assembly 18). RMD1004 at ¶ 370 ("As shown in FIG. 107H, each strap 758 includes a first

connector portion 766 having one or more arms 767 which can be resiliently flexed toward one another to insert and remove the connector portion 766 from a suitable recess in frame 768."). Even when applying the *Ging* elbow/mask connection mechanism including the claimed "ring" in the *Gunaratnam* mask assembly, connecting and disconnecting the straps from the mask would be possible "while the elbow remains rotatably engaged with the ring and the ring remains engaged with the mask body," as claimed. In my opinion, it would have been predictable, and indeed obvious to apply the strap connect and disconnect feature from Figures 107G-H of *Gunaratnam* into the Figure 135 embodiment (as modified by *Ging*). One of ordinary skill would have been motivated to apply the teachings from Figures 107G-H to allow patients to more readily connect and disconnect the mask assembly from the headgear assembly, thereby minimizing the effort required for a patient to don and remove the mask and headgear assemblies in use.

99. In contrast to Figures 135 and 107G-H, patient interface designs such as Figure 134 in *Gunaratnam*, locate the elbow on one of the sides of the mask where one of the side straps also connects to the mask. RMD1004 at ¶ 403. In such designs, the opening on the side of the mask assembly receives both the elbow and the side arm. *Id.* Therefore, the elbow must disengage from the mask assembly in order to disconnect the side arm. However, in Figure 135, the openings on the side of the mask assembly receive only the side arms, not the

elbow, and therefore the connection between the elbow and mask assembly is not affected by the side arms.

i) Claim Limitation 1.16

100. I understand that claim 1 recites that "the mask assembly is configured to connect to only the two side straps." The proper construction of this phrase is discussed in paragraph 43 above. For at least the reasons discussed with respect to claim limitation 1.15, I believe that one of ordinary skill in the art would have seen that the patient interface of *Gunaratnam*'s Figure 135 embodiment meets this feature. Furthermore, and as discussed with respect to claim limitation 1.15, to the extent a direct connection is required between the mask assembly and the side straps, I believe that one of ordinary skill in the art would have been prompted from *Gunaratnam*'s FIG. 107G-H embodiment to modify the Figure 135 design to employ a direct connection.

j) Claim 2

101. I understand that claim 2 depends from claim 1 and additionally recites the feature that "the mask body includes a lip and the ring includes a channel receiving the lip of the mask body." In other words, this claim recites a technique that was conventional before the '807 patent regarding how two-point mask assemblies were connected together.

102. As I previously explained with respect to claim 1, the *Gunaratnam* Figure 135 patient interface includes a ring as the mask frame of the nasal interface. *Ging* discloses the details of a mask frame 20 that meets the structure of the particular "ring" claimed in the '807 patent, which frame 20 is similar in many relevant aspects to the frame depicted in Figure 135. For example, the mask frames in both *Gunaratnam* Figure 135 and in *Ging* (e.g., Figs. 5, 5a, 5c, 6a) each includes a circular inner passage through which a portion a swivel elbow protrudes to facilitate a rotatable connection of the swivel elbow to the mask frame, and thus to the mask assembly as a whole. The frames also include structure to allow a mask body (e.g., cushion 40 in *Ging*) to engage with the mask frame.

103. *Ging* discloses that the mask frame 20 (ring) includes a channel 26 that receives a lip of a mask cushion 40 (mask body), and thus discloses the feature recited in claim 2. *See* RMD1005, *Ging*, Fig. 5c (depicting the rear side of mask frame 20 and showing a channel 26 that receives a lip of a mask cushion 40); Figs. 27a-28 (depicting close-up cross-sectional views of the engagement of a lip of the mask cushion 40 in the channel 26).

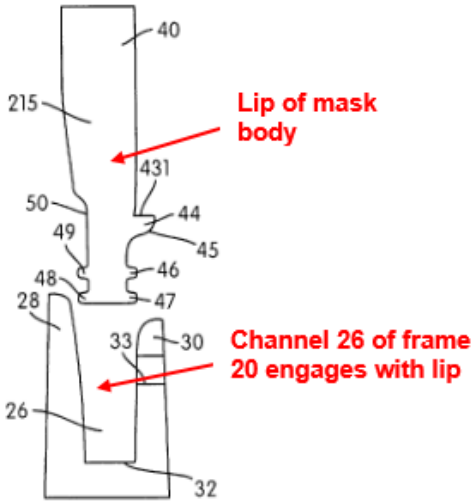


FIG. 27a

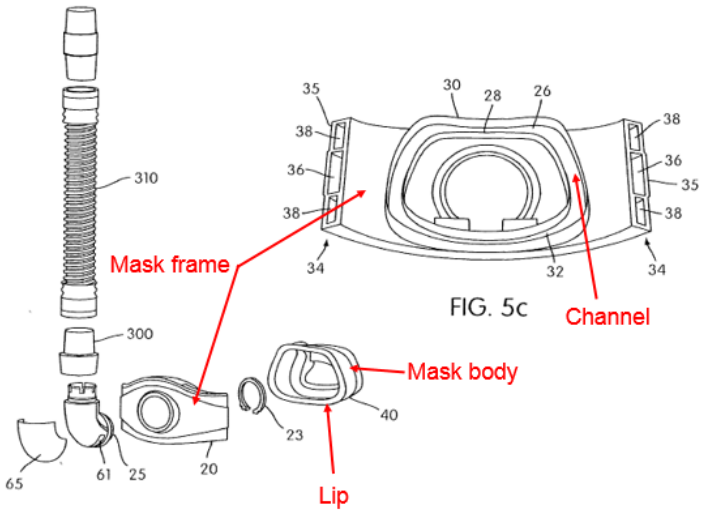


FIG. 6b

104. In my opinion, a person of ordinary skill in the art would have applied *Ging's* teaching of a channel in a mask frame (ring) that receives a lip of a mask cushion (mask body) to the nasal interface of *Gunaratnam* Figure 135 in order to provide a reliable structure for securing the mask cushion to the mask frame. Furthermore, the details of the connection between the mask frame and cushion as

depicted in Figs. 27a-28 of *Ging* would have been obvious to apply to *Gunaratnam* Figure 135 in order to achieve the benefits of such connection as described in *Ging*, including to reduce the force required for the patient to insert the cushion into the frame relative to the force required for removal of the cushion from the frame (thereby providing a more secure connection of the cushion to the frame while still allowing the patient to insert the cushion into the channel of the frame with relative ease). RMD1005 at ¶ 197-99.

k) Claim 3

105. I understand that claim 3 depends from claim 2, and recites the additional feature that the "mask body comprises a molded elastomeric material." In my opinion, this feature was conventional for CPAP masks before the '807 patent, and specifically is disclosed in both *Gunaratnam* and in *Ging*. *Gunaratnam* explains that nozzle assembly 18 (the claimed "mask body") can be constructed as a "one part molded silicone piece." RMD1004 at ¶ 182; *see also id.* at ¶¶ 191-92 (describing that "the nozzles are constructed from a substantially flexible polymer material, such as a silicone elastomer"). One of skill in the art would have understood that a molded silicone piece, as disclosed in *Gunaratnam*, is a molded elastomeric material as claimed. An elastomeric material generally refers to an elastic material that approximates the elastic qualities of rubber. Molded silicone is elastomeric in the sense that it is soft, flexible, and generally elastic. Indeed,

even the ’807 patent acknowledges that silicone is a substantially flexible material. RMD1001 at 5:36-40 (“The body and pillows are preferably integrally moulded in a substantially flexible plastics material. In the preferred form this material is silicone, but other appropriate materials, such as, rubber, thermoset elastomer or thermoplastic elastomer, such as Kraton™ may be used.”). Thus this feature would have been implied or inherent in *Gunaratnam*’s Figure 135 design.

106. *Ging* also discloses a mask body that is made of a molded elastomeric material. In particular, *Ging* provides that certain portions of the mask cushion 40 may be “formed, for example, in a one-shot injection molding process as is known in the art, using, e.g., silicone such as SILASTIC™ with 40 durometer of hardness.” RMD1005 at ¶ 174.

107. In my opinion, it would have been an obvious design choice to one skilled in the art to form the mask body of a patient interface using a molded elastomeric material, as claimed. Some reasons that would have prompted a person of skill in the art to do so before the time of the ’807 patent would be to maximize the comfort of the mask body when donned by the patient, and to allow the requisite flexibility to form a seal between the mask body and the perimeters of the patient’s nostrils that would be impervious to air other than what is fed to the patient from the CPAP machine. Indeed, mask cushions were conventionally made from elastomeric materials before the time of the ’807 patent for these reasons.

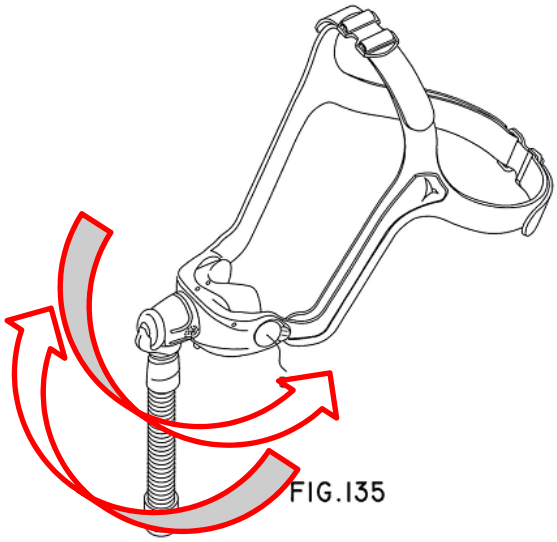
See, e.g., U.S. Pat. 4,782,832 to *Trimble* et al (RMD1019) at 2:42-45, 4:51-56, 5:6-10, 6:1-5; U.S. Pat. 6,431,172 to Bordewick (RMD1020) at 3:30-43, 3:54-58; U.S. Pat. 7,219,669 to *Lovell* et al. (RMD1012) at 2:48-55, 4:43-48; *Gunaratnam* (RMD1004) at ¶¶ 182, 191-92.

l) Claim 4

108. I understand that claim 4 depends from claim 1, and recites the additional feature that "the elbow is able to swivel in the ring such that the tubing is available to be adjacent to either side strap." Based on my review of the record, it is my opinion that this feature would be present in the combined patient interface of *Gunaratnam* and *Ging*.

109. A person of ordinary skill in the art would first recognize that this feature is present in the Figure 135 embodiment of *Gunaratnam*. In particular, given that the swivel elbow is located in the front center of the mask assembly, the tube would be available to be adjacent to either side strap on either side of the user's face when the swivel elbow is rotated by about 120-150 degrees in either direction from the orientation of the elbow shown in Figure 135. This is depicted in the annotated Figure 135 below. In contrast, I note that with the configuration of the elbow on the side of the mask assembly in the embodiment shown in Figure 108 of *Gunaratnam*, the tubing is most commonly positioned adjacent to one of the

side straps, but not the other, although even there it is likely capable of being positioned adjacent to either side strap.



110. One of skill would have understood that the swivel elbow could generally be rotated relative to the mask frame in Figure 135 in the directions shown in the above illustration, for example, to minimize hose strain as the patient moves about during sleep.

111. Additionally, *Ging* in the embodiment represented in Figures 6a and 6b discloses a mechanism by which a swivel elbow assembly 60 (the claimed "elbow") can connect to a mask frame 20 (the claimed "ring"). When connected, the elbow assembly 60 is secured to the frame 20, and can freely rotate within the central bore 24 of the mask frame 20. It would have been predictable for one of skill in the art to implement the connection of the elbow 60 to the mask frame 20

without restrictions that would prevent the elbow from rotating to any orientation relative to the mask frame 20.

112. Similarly, *Ging* discloses elsewhere that a swivel elbow 160 can be "rotationally connected" to the mask frame 20. RMD1005 at ¶ 0151. In the absence of restrictions to the swivel elbow's 160 range of motion, one of skill would understand that the swivel elbow 160 could rotate a sufficient amount such that the gas delivery tube 310 would be available to be adjacent to either side strap. Because the elbow 160 is provided in the center of the frame, and the elbow 160 can rotate in clockwise and counter-clockwise directions, it would be capable of swiveling by at least the amount necessary to achieve the feature recited in claim 4. RMD1005, *Ging*, ¶ 151, Figs. 1, 16a – 19c-2.

113. Accordingly, if this type of swivel elbow connection from *Ging* were to be applied to *Gunaratnam's* Figure 135 embodiment, the swivel elbow assembly 60 would be capable of swiveling in the ring such that the tubing would be available to be adjacent to either of the side straps of the headgear assembly. For example, rotating the elbow between 120 and 150 from an initial orientation in which the tubing points straight down would bring the tubing to be adjacent to one of the side straps that run along the cheeks of the patient. *See* RMD1004 at Fig. 135; RMD1005 at Figs. 6a-b, ¶¶ 113, 148-53; *see also* RMD1007 at 5:31-33 (disclosing in further detail a swivel elbow connection like that depicted in Figures

6a and 6b of *Ging*); RMD1005 at ¶ 151, Figs. 1, 16a – 19c-2 (showing a swivel elbow 160 "rotationally connected" to the mask frame 20, which one of skill would recognize is capable of rotating a sufficient amount such that the tubing 310 would be available next to be adjacent to either side strap); RMD1004 at ¶¶ 389 (providing that the "swivel elbow 612, as shown in FIG. 10B, is able to fit and snap into the mask frame 616," thereby "allow[ing] free swiveling within the frame 616, between a range of defined angles"); *id.* at Figs. 108A, 108B, ¶ 394 (disclosing a "tube retainer 900" for receiving and locating an air delivery tube 606 when the elbow and tube 606 are rotated so that the tubing is adjacent to a headgear strap).

m) Claim 5

114. I understand that claim 5 depends from claim 1, and recites the additional feature that "the ring comprises a hard plastic material." In my opinion, this feature was conventional for CPAP masks before the '807 patent and specifically is present at least inherently in both the *Gunaratnam* and *Ging* references. It was conventional at the time for mask frames in CPAP patient interfaces to be formed from a hard plastic material. For example, that the background discussion of *Ging* notes that "mask assembl[ies] typically include a ***rigid shell***." RMD1005 at 1:60-62 (emphasis added). Rigid / hard mask frames like those noted in *Ging* were conventional as they provided the structure required

to support a mask cushion on a patient-facing side of the interface and to support a connection to an air delivery tube on the opposite side of the interface. Plastics were among the most common classes of materials that mask frames were made of at the time of the '807 patent due, for example, to their ability to be molded into sophisticated shapes, while also being lightweight and cost-effective. A person of skill in the art would have found that constructing the ring using a hard plastic material in the manner of claim 5 would have been an obvious implementation detail yielding predictable results. *See also* RMD1004 at ¶¶ 4, 178, 255. Further, one of ordinary skill in the art would have recognized that designing the "ring" with a hard material would have been important to allow the elbow to swivel easily. If the "ring" were not a hard material, the purpose of the swivel would be defeated.

n) Claim 6

115. I understand that claim 6 depends from claim 1, and recites the additional feature that the patient interface "further compris[es] molded side arms extending away from the ring to connect with the side strap, the molded side arms connecting to the side straps that pass down the cheeks of the user." In my opinion, this feature would be present in the combined patient interface of *Gunaratnam* and *Ging*.

116. Specifically with respect to the portion of claim 6 that requires the side arms to be "molded," it is my opinion that this feature would have been obvious to one of ordinary skill in the art from the teachings of *Gunaratnam* and *Ging*. *Gunaratnam* discloses various designs that include "yokes" as side arms of a headgear assembly. For example, *Gunaratnam's* Figure 135 design includes yokes that attach on either side of the mask frame that extend away from the mask frame to connect with respective side straps on either side of the mask that pass down the cheeks of the user. *Id.* at Fig. 135; *see also* Figs. 110-114 (showing views of mask assemblies having similar configurations to Figure 135 in which a pair of yokes connects to either side of the mask assembly, but in which the swivel elbow connects from the side of the mask assembly rather than the front center as in Figure 135).

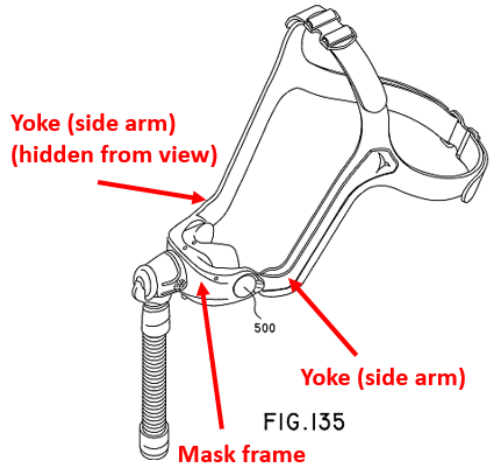


FIG.135

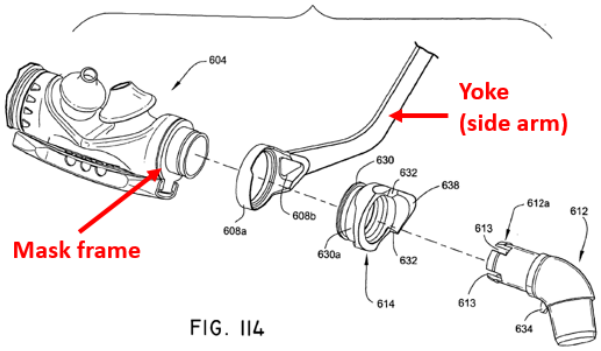


FIG. 114

117. Although *Gunaratnam* does not specifically mention that the yokes are molded, it does teach that the yokes can be made of a rigid plastic material.

See RMD1004 at ¶ 315 ("The headgear yoke 580 acts as a stiffener to add rigidity to the headgear assembly 520. . . . In FIG. 60, the yoke 580 is a semi-rigid layer, such as plastic, which is provided to, e.g., sewn onto, the headgear straps 598 and/or 599."); *see also id.* at ¶¶ 0376, 0379, 0390. Similarly, *Ging* teaches that its yokes may be "constructed of a somewhat rigid material, e.g., plastic," such as nylon or polypropylene. RMD1005 at ¶ 120; *generally id.* at ¶¶ 119-22. One of skill would have understood at the time of the '807 patent that molding was a conventional technique in manufacturing three-dimensional plastic components. In my opinion, molding the yokes disclosed in *Gunaratnam* and *Ging* would have been an obvious design choice to achieve predictable results, such as low-cost, highly replicable components capable of being manufactured at a high volume. Moreover, it was well-known at the time of the '807 patent, even for CPAP patient interfaces, to manufacture yokes in a headgear assembly from molded plastics. *See* RMD1037, *Lau*, 2:50-52 ("Preferably, the headgear yoke sections are molded from a single type of material . . . ."); *id.* at 3:9-11 (stating that the "yoke side sections" in a headgear assembly could be "molded from a semi-rigid plastic").

o) Claim 7

118. I understand that claim 7 depends from claim 1, and recites the additional feature that "in use, gases flow from the tube or conduit, through the elbow, through the ring, through the mask body and through the pillows." In my

opinion, this feature would clearly be present in the patient interface resulting from the combined teachings of *Gunaratnam* and *Ging*. As an initial matter, in the patient interface configuration shown in Figure 135 in *Gunaratnam*, one of skill in the art would have understood that in use, gases flow from the air delivery tube (which may be connected to a pressurized air source, such as a CPAP machine), through the swivel elbow, through the mask frame, through the mask body (e.g., the full nasal cushion as depicted or the nozzle assembly 18 if the nozzle assembly 18 were applied to the Fig. 135 embodiment), and finally through the nozzles 50 of the nozzle assembly 18. RMD1004 at Fig. 135; *see also id.* Figs. 1, 5, 6.

119. Similarly, in the patient interface configuration shown in Figure 6b of *Ging*, one of skill in the art would have understood that in use, gases would have flowed from the CPAP machine, through tube 310 and swivel connector 300, through the elbow assembly 60 / swivel elbow 160, through mask frame 20, and through the mask cushion 40. Thus, the airflow paths in both *Gunaratnam* and in *Ging* are substantially similar, and so when *Ging's* teachings are applied to *Gunaratnam*, the resulting patient interface would include the additional feature recited in claim 7.

p) Claim Limitations 8.3, 8.5

120. I understand that claim 8 recites the feature of a "mask body" (element 8.3) and further recites that the "mask body compris[es] a first nasal

pillow and a second nasal pillow" (element 8.5). Figure 135 of *Gunaratnam* discloses a nasal mask assembly, but not one that is a nasal pillows type mask assembly in which the mask body includes a pair of nasal pillows. As will be discussed below, however, nasal pillows type mask assemblies were well known in the art long before the '807 patent.

121. For example, nasal pillows type mask assemblies are shown in various configurations throughout *Gunaratnam*, in Figures 1-133. Figure 1, for example, shows a nasal assembly 10 that includes a mask frame 16 and a nozzle assembly 18. The nozzle assembly 18 in this embodiment of *Gunaratnam* discloses a "mask body" that includes first and second nasal pillows as recited in claim 8. Figures 5 and 6 show the nozzle assembly 18 in greater detail. *See* RMD1004 at Figs. 1, 5, 6; *see also id.* at Figs. 7, 8, ¶¶ 185-96. *Gunaratnam* describes that the nozzle assembly 18 includes a pair of nozzles 50, which one of ordinary skill in the art would have understood at the time of the '807 patent as being "nasal pillows," as that term is used in the claims. Unlike a full nasal cushion, these nasal pillows in *Gunaratnam* rest in use in a substantially sealed manner against the nares of a user. *See* RMD1004 at Fig. 1, ¶ 26. This is clearly shown in Figure 1, and also described in the text of *Gunaratnam*'s specification, which states that "[t]he nozzle assembly [18] is coupled with the main body of the frame [16] with the pair of

nozzles structured to sealingly engage with nasal passages of a patient's nose in use." RMD1004 at ¶ 26.

122. Multiple additional embodiments of *Gunaratnam* similarly employ mask bodies that have a pair of nasal pillows. For example, Figures 61-65 show a nasal mask having a nozzle assembly 518 and a pair of nozzles 550 (nasal pillows), which would rest in use in a substantially sealed manner against the nares of a user. *Id.* at Figs. 61-65, ¶¶ 291-94. The cushion assembly 604 in an embodiment illustrated by Figures 108-13 similarly includes nasal pillows in a mask body that would seal against the nares of a user in use. *Id.* at Figs. 108-13. The nozzle assembly 18 also includes a base portion 48 that includes structure for attaching to a mask frame 16.

123. The feature is additionally present in the patient interface embodiment shown in Figures 107G-H of *Gunaratnam*. Figure 107H depicts a portion of one nozzle 772 behind the mask frame 768 (although Figures 107G-H do not show the interface in use, which is why the mask is shown as being slightly dropped below the patient's nose). *See* RMD1004 at Figs. 107G-H, ¶¶ 0369-70. In use, the mask would not cover the patient's mouth.

124. Not all of the patient interfaces disclosed in *Gunaratnam* have nasal pillows type mask bodies, which in use rest in a substantially sealed manner against the nares of a user. The nasal mask depicted in Figure 135, for example,

utilizes a full nasal cushion rather than nasal pillows. RMD1004 at Fig. 135, ¶ 403. The nasal cushion in Figure 135 is arranged in use to surround the breathing passages of the patient's nose by forming a sealed space from above the patient's upper lip to a location atop the patient's nose (e.g., the bridge of the nose). The nasal cushion thus allows the patient to receive pressurized air for CPAP therapy from the sealed space surrounding the patient's nasal breathing passages, rather than from respective nozzles that rest against the nares.

125. Although the Figure 135 embodiment of *Gunaratnam* does not itself have nasal pillows, it is my opinion that one of ordinary skill in the art would have found it obvious to implement a mask body having a pair of nasal pillows, such as the nozzle assembly 18, in the Figure 135 embodiment. The motivation for modifying the nasal mask of Figure 135 in this manner would have been to achieve any of the benefits of nasal pillows that were well-known at the time of the '807 patent. For example, nasal pillows masks are generally smaller and lighter than full nasal cushion masks. Many patients prefer nasal pillows due to their relatively smaller size, minimal surface area that contacts the patient's skin, and their ability to relieve pressure on the bridge of the patient's nose for increased comfort. Nasal pillows may also be less obstructive to a patient's field of vision in use than other, larger types of masks. Ultimately, these benefits that many patients prefer in nasal

pillows masks may result in greater patient compliance with prescribed CPAP treatment.

126. Some patients, however, do prefer full nasal masks over pillows, because the patient may find pillows to be uncomfortable in the nostrils. One of ordinary skill in the art would have understood at the time that full nasal masks and nasal pillows masks were two different, but well-known options. These two options – full nasal type mask assemblies and nasal pillows type mask assemblies – are substantially interchangeable from the standpoint of the headgear assembly design.

127. Finally, I note that the corresponding description of Figure 135 in *Gunaratnam* suggests that its full nasal cushion could be interchanged with a nasal pillows mask body. RMD1004 at ¶ 403 ("Further, the nozzle assembly and/or its associated cushion could be replaced with a nasal mask and/or nasal cushion."). This further confirms my analysis that it would have been obvious to implement nasal pillows in the nasal mask shown in Figure 135. Indeed, one of ordinary skill in the art would have understood from this statement in *Gunaratnam* that the patient interface design in Figure 135 could alternatively be made with a mask body having nasal pillows, rather than the full nasal cushion that is shown in the drawing. This is especially clear given that the embodiment shown in Figures 107G-H of *Gunaratnam* is a nasal pillows type mask in which the elbow is

connected to the front center of the mask assembly. It is clear from *Gunaratnam* that it was known well before the time of the '807 patent that a patient interface having an elbow connected at the front center of the mask could be employed with a nasal pillows cushion (mask body).

q) Claim Limitation 8.4

128. I understand that claim 8 recites the feature of "the mask body comprising a substantially flexible elastomeric material." In my opinion, this feature was conventional for CPAP masks before the '807 patent, and specifically is disclosed in both *Gunaratnam* and in *Ging*. First, *Gunaratnam* explains that nozzle assembly 18, which may be applied as the claimed mask body (which would have been obvious), can be constructed as a "one part molded silicone piece." RMD1004 at ¶ 182; *see also id.* at ¶¶ 191-92 (describing that "the nozzles are constructed from a substantially flexible polymer material, such as a silicone elastomer"). One of skill in the art would have understood that molded silicone is an elastomeric material. An elastomeric material generally refers to an elastic material that approximates the elastic qualities of rubber. Molded silicone is elastomeric in the sense that it is soft, flexible, and generally elastic. Indeed, even the '807 patent acknowledges that silicone is a substantially flexible material. RMD1001 at 5:36-40 ("The body and pillows are preferably integrally moulded in a substantially flexible plastics material. In the preferred form this material is

silicone, but other appropriate materials, such as, rubber, thermoset elastomer or thermoplastic elastomer, such as Kraton™ may be used.").

129. Additionally, *Ging* discloses a mask body that comprises a substantially flexible elastomeric material. In particular, *Ging* provides that certain portions of the mask cushion 40 may be "formed, for example, in a one-shot injection molding process as is known in the art, using, e.g., silicone such as SILASTIC™ with 40 durometer of hardness." RMD1005 at ¶ 174.

130. In my opinion, it would have been an obvious design choice to one skilled in the art to form the mask body of a patient interface from a substantially flexible elastomeric material, as claimed. Some reasons for doing so would have been to maximize the comfort of the mask body when donned by the patient, and to allow the requisite flexibility to form a seal between the mask body and the perimeters of the patient's nostrils that would be impervious to air other than what is fed to the patient from the CPAP machine. It was conventional at the time of the '807 patent to make mask cushions out of substantially flexible elastomeric materials so that the cushion would be capable of serving as a perimeter seal while contouring to the patient's nasal passages. *See, e.g.*, U.S. Pat. 4,782,832 to *Trimble* et al (RMD1019) at 2:42-45, 4:51-56, 5:6-10, 6:1-5; U.S. Pat. 6,431,172 to Bordewick (RMD1020) at 3:30-43, 3:54-58; U.S. Pat. 7,219,669 to *Lovell* et al. (RMD1012) at 2:48-55, 4:43-48; *Gunaratnam* (RMD1004) at ¶¶ 182, 191-92.

r) Claim Limitations 8.7, 8.8

131. I understand that claim 8 recites the features of "the first nasal pillow comprising a first generally conical portion and a first generally cylindrical portion," and "the second nasal pillow comprising a second generally conical portion and a second generally cylindrical portion." Regarding the geometry of its nasal pillows, the '807 patent states that "[t]he nasal pillows 24, 25 are preferably frustoconical in shape and in use rest against a patient's nares, to substantially seal the patient's nares" and "[t]he nasal pillows 24, 25 are preferably an elliptical cone and as such are tubular and allow for a passage of gases to flow from the tubing 3 and through the mask body 23." RMD1001 at 5:29-31, 5:41-43. Although the text of the '807 patent does not specifically distinguish the conical and cylindrical portions of the nasal pillows 24, 25, claim 8 appears to refer to the following portions of the nasal pillows type mask body 23 as the "generally cylindrical" and "generally conical" portions, annotated in Fig. 7 below:

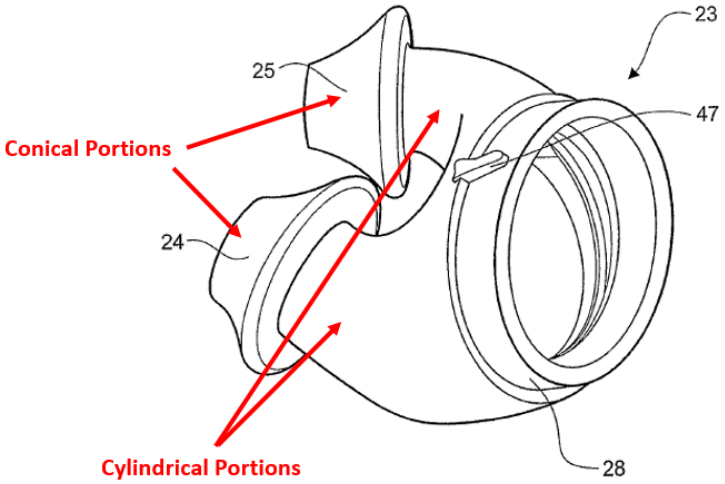


FIGURE 7

132. In my opinion, these features are present in *Gunaratnam's* nasal pillows mask, because the portion 58 of each nozzle 50 (see Fig. 5) is clearly conical (indeed, paragraph 189 describes them as "cone-shaped"), where the portion 56 of each nozzle 50 is generally cylindrical. Furthermore, *Gunaratnam* discloses an alternative nozzle structure in Fig. 107N that includes a proximal portion that is conical and a distal portion of the nozzle that is cylindrical. I believe that it would have been an obvious design modification for a person of ordinary skill in the art to have substituted the nozzle shown in Fig. 5 with the nozzle shown in Fig. 107N, because the nozzles were described in the same document with respect to similar products and would be understood to be suitable alternatives for each other.

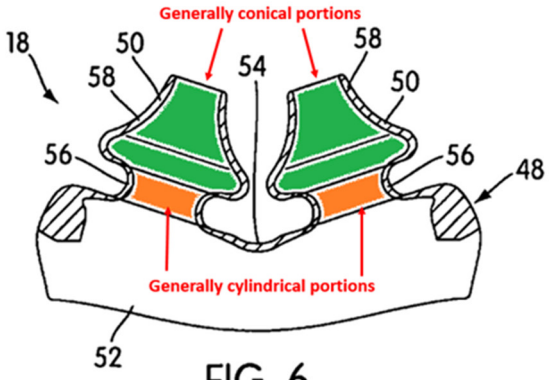


FIG. 6

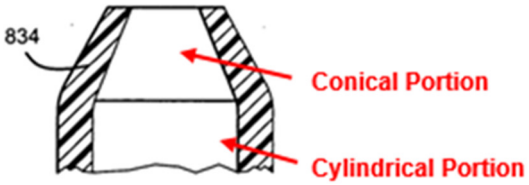


FIG. 107N

s) Claim Limitation 8.9

133. I understand that claim 8 recites the feature of "the first nasal pillow comprising a first outlet opening and the second nasal pillow comprising a second outlet opening." In my opinion, this feature would have been well understood from the teachings of *Gunaratnam* by a person of ordinary skill in the art. To the extent these features are not expressly disclosed, they are implied or inherent in *Gunaratnam's* nasal pillows designs.

134. For example, *Gunaratnam* suggests the first nasal pillow (first of the nozzles 50 of nozzle assembly 18) comprises a first outlet opening, and the second nasal pillow (second of the nozzles 50 of nozzle assembly 18) comprises a second outlet opening. Although the respective outlets of the pair of nozzles 50 are not specifically labeled in the figures, they are nonetheless represented at the tops of the truncated conical portions (second portions 58) of the nozzles 50 in Figures 5-8. RMD1004,

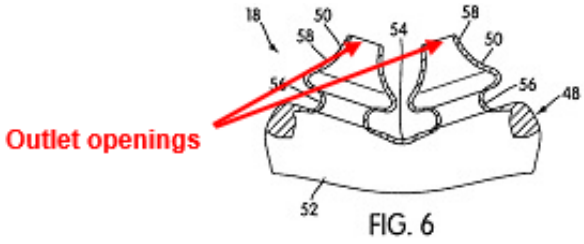


FIG. 6

Gunaratnam, Figs. 1, 5-8, *see also id.* at ¶ 0185 ("When the nozzle assembly 18 is attached to the frame 16, the nozzle assembly 18 and the frame 16 together form a conduit for directing breathable gas to the patient's nose through the pair of nozzles 50."); Fig. 31 (showing perspective view of a nozzle and its outlet opening); Fig. 107N (top). One of ordinary skill in the art would have understood that outlet openings are inherent or implied in all of the nasal pillows bodies described in *Gunaratnam*, as an outlet would be required for air to be delivered to the nasal passages of the patient.

t) Claim Limitation 8.10

135. I understand that claim 8 recites the feature of a "mask body also comprising a mask body inlet opening." One of skill would have understood that such a mask body inlet opening was conventional and would have been inherent in the design of many mask bodies, such as *Gunaratnam's* nozzle assembly 18, because gas must flow through the mask body to the nasal pillows in order for the patient interface to function. Therefore, such a "mask body inlet opening" as claimed would necessarily be present in the nozzle assembly 18 in *Gunaratnam*. One view of nozzle assembly 18 is shown in Figure 6, which is copied and annotated below. *See also* Ging (RMD1005) at Figs. 24A-25C (showing various views of a mask cushion for a nasal interface that includes a mask body inlet

opening, which may be received in the channel 26 of a frame 20 to engage the cushion to the frame 20).

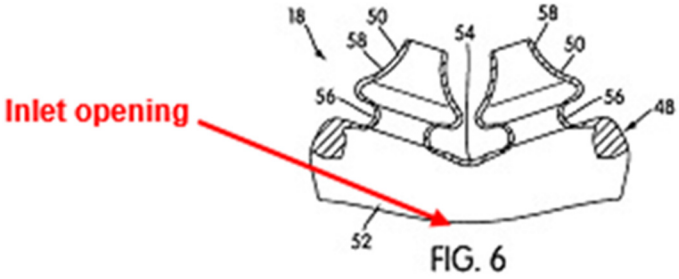


FIG. 6

136. As discussed in *Gunaratnam*,the nozzle assembly 18 includes an opening on a side of the nozzle assembly 18 that connects to the frame 16 (i.e., the bottom side of the nozzle assembly 18 to which the arrow points in annotated Figure 6 above). In particular, the nozzle assembly 18 includes a base portion 48 having side walls 52 that define an inlet opening opposite the nozzles 50. In use, pressurized gas enters the nozzle assembly 18 through the inlet opening. RMD1004, *Gunaratnam*, ¶¶ 0184-0188 (describing the attachment of nozzle assembly 18 to frame 16 and the structure of the nozzle assembly 18 so as to form the claimed mask body inlet opening). Additionally, one of ordinary skill in the art would have understood that a mask body inlet opening is inherent or implied in all of the nasal pillows bodies described in *Gunaratnam*, as an inlet would be required in order for air to be delivered through the body, the pillows, and to the patient.

u) Claim Limitation 8.12

137. I understand that claim 8 recites the feature of a "mask body sized and shaped to leave the mouth of a user uncovered by the mask body when in use." In my opinion, this feature is present in *Gunaratnam* (RMD1004) in the embodiment shown in Figure 135, and would also be present even if Figure 135 were modified to incorporate nasal pillows, like those taught by Figures 107G-H of *Gunaratnam*. *See also id.* at Figs. 1, 5, 6, and 61 (showing nasal pillows as nozzle assemblies 18, 518).

138. It was conventional at the time of the '807 patent for nasal pillows masks to leave the mouth of the patient uncovered when in use. *See, e.g.*, U.S. Pat. 4,782,832 to *Trimble* et al (RMD1019); U.S. Pat. 6,431,172 to Bordewick (RMD1020); U.S. Pat. 7,219,669 to *Lovell* et al. (RMD1012); *Gunaratnam* (RMD1004). This arrangement stands in contrast to another class of patient interfaces – namely, full face masks – which create a sealed space surrounding both the patient's mouth and nose in use. Nasal masks deliver pressurized air to the patient's airways via the patient's nose only, whereas full face masks allow pressurized air to be delivered to the airways via both the patient's nose and mouth. Accordingly, regardless of whether the original nasal cushion in Figure 135, or a nasal pillows mask body were employed, the resulting patient interface would have "a mask body sized and shaped to leave the mouth of the user uncovered by the

mask body when in use." Other nasal masks disclosed in *Gunaratnam* demonstrate this feature as well. *See* RMD1004 at Figs. 25, 36-38, 52-53, and 59 (examples of nasal pillows masks showing the user's mouth uncovered in use).

v) Claim Limitation 8.13

139. I understand that claim 8 recites the feature of a "mask body inlet opening comprising a generally circular opening into the mask body." In my opinion, this feature is taught both by *Gunaratnam* and *Ging*, and would be an obvious modification to the patient interface in Figure 135 of *Gunaratnam*.

140. The nozzle assembly 18 (which would be obvious to apply to *Gunaratnam's* Figure 135 embodiment) in *Gunaratnam* has a mask body inlet opening that is preferably made in a "dog-bone shape." RMD1004 at ¶ 188. However, *Gunaratnam* teaches that the inlet opening could nonetheless be "any suitable shape." *Id.* In my opinion, and in view of the teaching from *Gunaratnam* that the mask body inlet opening may be made in "any suitable shape," one of ordinary skill would have found that a "circular opening" as claimed would be a suitable shape for the inlet opening of nozzle assembly 18. A circular inlet opening would be equally capable as a dog-bone shaped opening, for example, of connecting to the mask frame 16 while ensuring a reliable seal between the nozzle assembly 18 and the frame 16. A suitable shape for the inlet opening may vary based on the geometry of the mask frame (mask base) to which it connects. If the

geometry of the mask frame dictated a circular shape for the inlet opening of the mask body, then it would have been obvious to provide a circular shaped inlet opening as appropriate. *Gunaratnam* thus suggests that the shape of the inlet opening is an implementation detail, and a circular inlet would have been an obvious design choice.

141. Additionally, *Ging's* mask cushion 40 has an inlet opening that is generally in the shape of a trapezoid. But *Ging* also teaches that the shape of the inlet opening to the cushion 40 is nothing more than a design choice, and even mentions that the inlet opening could be circular. *See* RMD1005 at ¶ 115 ("The shape of the channel 26, e.g., a generally trapezoid shape as seen in FIG. 5c, is selected so as to achieve guidance to correct cushion orientation relative to the channel 26 without the need for additional guide pieces as would be the case should the channel 26 have a more symmetrical shape such as an equilateral triangle, ***circle***, square, or rectangle. Nevertheless, the cushion channel 26 could adopt any of these shapes.") (emphasis added). By applying this teaching to a nasal pillows mask body in *Gunaratnam's* Figure 135 embodiment, I believe that a person of ordinary skill in the art would have found it to be an obvious design modification to make the inlet opening of the nasal pillows mask body circular in shape, such as to achieve a symmetrical fit of the mask body to the mask frame as described in *Ging*.

w) Claim Limitation 8.14

142. I understand that claim 8 recites the feature of a "mask assembly having a ring-like connector releasably connected to the mask body inlet." In my opinion, the "ring-like connector" element of claim 8 is taught by *Gunaratnam* and *Ging*.[2]

143. To begin, Figure 135 of *Gunaratnam* includes a mask frame, which is a "ring-like connector" that defines a circular inner passage for receiving a portion of an elbow, and that allows the elbow to rotate. Thus the "ring-like connector" element as recited in claim 8 is present in *Gunaratnam*'s Figure 135 design, or is at most an obvious implementation detail of this design in view of the teachings of *Gunaratnam* and *Ging*.

144. *Ging* discloses the details of a mask frame 20 (the claimed "ring-like connector") similar to the mask frame provided in the patient interface design depicted in *Gunaratnam* Figure 135. The mask frame 20 is shown in an embodiment depicted in Figures 6a and 6b of *Ging*, for example. RMD1005,

[2] Claim 8 recites both a "ring-like connector" and a "ring-like connector end." For the purpose of my analysis here, Petitioners have asked me to treat the terms interchangeably. I have therefore assumed that the "ring-like connector end" is referring to the "ring-like connector."

Ging, Figs. 6a, 6b; *see also id.* at Figs. 1-5c (showing the mask frame 20 in additional embodiments).

145. The mask frame 20 in *Ging* serves a number of purposes in the patient interface embodiment of Figures 6a and 6b, as would have been understood by a person of ordinary skill in the art. First, it acts as a rigid support structure for the mask cushion 40. *Ging* discloses that the mask cushion 40, which is made of a softer, flexible material such as silicone, includes a portion that connects with the mask frame 20. Mask frame 20 thus provides support to the mask cushion 40. In addition, the mask frame 20 forms a central bore 24 for connecting the swivel elbow assembly 60 to the mask frame 20. In particular, when the patient interface is assembled, a portion of the swivel elbow 60 protrudes through the central bore 24 of the mask frame 20. A C-clip 23 secures the elbow assembly 60 to the mask frame 20, such that the elbow 60 can freely rotate within the central bore 24 relative to the mask frame 20. This arrangement is shown in greater detail in U.S. Patent No. 6,691,707 in Figures 2, 4, 6, 7, and 9, for example. *See* RMD1007, '707 Patent (*Gunaratnam* II), Figs. 2, 4, 6, 7, 9; *see also* RMD1005, *Ging*, Figs. 5c, 6a, 6b, ¶ 113. The configuration of the nasal mask, including mask frame 20, in *Ging* thus allows pressurized air to be delivered through the front center of the mask, in contrast to some other configurations (e.g., RMD1004, *Gunaratnam*,

Figure 1) where the pressurized air is delivered through a side end of a mask frame.

146. Based on my review of the '807 patent and file history, I believe that the "ring-like connector" element in claim 8 refers to the mask base 22 that is depicted, for example, in Figures 2-5 of the patent. *See, e.g.*, RMD1001, '807 Patent, Figs. 2-5, 6:19-56 (describing details of the mask base 22 and noting that the "mask base 22 is a ring or sleeve type attachment"). The mask base 22 in the '807 patent is a rigid frame structure that generally serves many of the same functions as the mask frame 20 in *Ging*. For example, the mask base 22 engages with a mask body 23 when an external lip 28 of the mask body 23 is received in a channel 45 of the mask base 22. Like *Ging's* mask frame 20, the mask base 20 thus serves as a rigid support structure for a softer, flexible mask body. The mask base 22 also forms a circular cavity, defined in part by semi-tubular projection 29, which is configured to allow the swivel elbow connector 30 to rotatably connect to the mask base 22. *See id.* at 6:19-56.

147. *Gunaratnam's* mask frame in Figure 135 and *Ging's* mask frame 20 are similar to the component in the '807 patent which, based on my review of the '807 patent and file history (RMD1009), I believe the claimed "ring-like connector" structure is referring to, namely mask base 22. *See, e.g.*, RMD1001 at Figs. 2-5, 6:19-56 (describing details of the mask base 22 and noting that the

"mask base 22 is a ring or sleeve type attachment"). The mask base 22 in the '807 patent is a rigid frame structure that generally serves many of the same functions as the mask frame 20 in *Ging*. For example, the mask base 22 engages with a mask body 23 when an external lip 28 of the mask body 23 is received in a channel 45 of the mask base 22. Like *Ging's* mask frame 20, the mask base 20 thus serves as a rigid support structure for a softer, flexible mask body. The mask base 22 also forms a circular cavity, defined in part by semi-tubular projection 29, which is configured to allow the swivel elbow connector 30 to rotatably connect to the mask base 22. *See id.* at 6:19-56.

148. I believe that one of ordinary skill would have recognized that mask frames, like the mask base 22 in the '807 patent, were conventional components of a respiratory interface to connect between a swivel elbow and a mask cushion such as mask body 23. This is evidenced at least by the mask frame in Figure 135 of *Gunaratnam*, mask frame 20 in *Ging*, and the mask shell 15 in the '707 patent. *See* RMD1004 at Figs. 107G-H; RMD1005 at Figs. 5-6b; RMD1007 at Figs. 1-2.

149. The mask frame 20 from *Ging* includes a central bore 24 that forms a circular inner passage of the frame 20. Accordingly, the mask frame 20 meets the meaning of a "ring-like connector" in the context of the '807 patent.

150. As shown in Figures 5c and 6b of *Ging*, I recognize that the outer perimeter of the mask frame 20 has a generally rounded, rectangular geometry.

But under the proper construction of "ring-like connector," its outer perimeter need not have a particular shape. Notably, although the '807 specification provides that the "mask base 22 is a ring or sleeve type attachment," nothing in the patent explains any particular benefit or significance to having a more circular outer geometry.

151. However, even if the term "ring-like connector" were to require a circularly shaped outer perimeter, I believe that one of ordinary skill in the art at the time of the '807 patent would have found it to be an obvious design choice to modify *Ging's* mask frame 20 to have such a circular outer perimeter. The modification could be achieved while maintaining the functions served by the mask frame 20 in its original shape as disclosed in *Ging*. For example, the mask frame 20 could be further rounded to make a generally circular outer perimeter without affecting how the swivel elbow assembly 60 connects to the mask frame 20, or how the mask cushion 40 fits into the channel 28 of the mask frame 20. The connections of the mask frame 20 to the headgear assembly could be easily adapted to accommodate the generally circular outer perimeter. Indeed, modifying *Ging's* mask frame 20 to have a substantially circular shape would have been the application of a known teaching to yield predictable results.

x) Claim Limitation 8.15

152. I understand that claim 8 recites the feature of "a plane [that] bisects the ring-like connector and the first nasal pillow is located on a side of the plane opposite the second nasal pillow." As I have previously noted, I agree with Petitioners' proposed construction of this claim element as referring to the requirement that the ring-like connector be located generally at the front center of the mask. In my opinion, this feature is met by the combined teachings of *Gunaratnam* and *Ging*.

153. The nasal mask in Figure 135 of *Gunaratnam* is arranged such that the swivel elbow connects to the front center of the mask frame. RMD1004 at Fig. 135, ¶ 403. Accordingly, a vertical plane bisecting the frame in the mask of Figure 135 would also bisect left and right sides of the full nasal cushion such that respective left and right halves of the cushion would be positioned on opposite sides of the plane.

154. If a mask body having two nasal pillows, such as nozzle assembly 18 or nozzle assembly 518, were applied to the nasal mask of Figure 135 (as would be obvious as discussed above with respect to claim element 1.3), the resulting mask would thus meet the claim limitation, as each of the two nasal pillows would be positioned on an opposite side of a plane substantially bisecting the mask frame. Additionally, if the details of *Ging*'s ring (mask frame 20) were applied to the

Figure 135 embodiment, the resulting mask would also meet the claim limitation, as each of the two nasal pillows would be positioned on an opposite side of a plane that substantially bisects the ring. This is conceptually illustrated in the following figure, which is a modified version of Figure 135 of *Gunaratnam*, in which the full nasal cushion has been replaced with a nasal pillows cushion. A bisecting plane is superimposed on the modified mask:

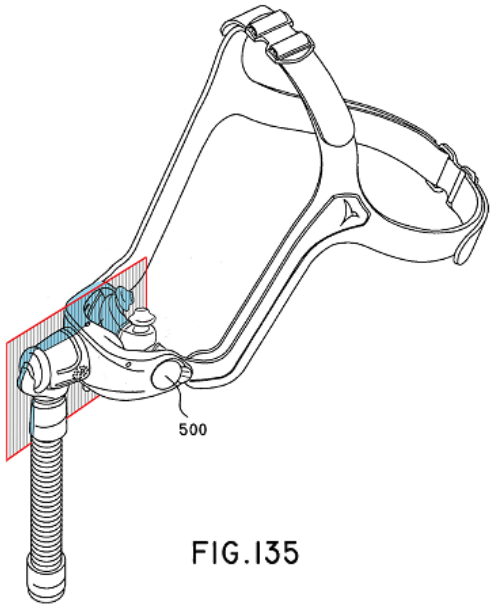


FIG.135

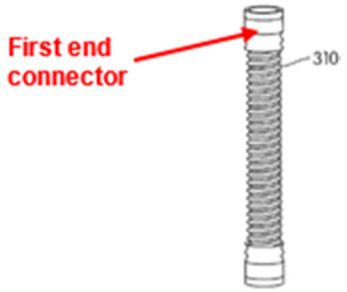
y) Claim Limitations 8.17, 8.19

155. I understand that claim 8 recites the feature of "the tube assembly comprising a flexible conduit." In my opinion, this feature is present in the patient interface embodiment of *Gunaratnam* depicted in Figure 135 and in *Ging*. First, the tube assembly is shown in Figure 135 as being connected to the front of the mask from the end of the swivel elbow opposite the end that is connected to the

mask frame. RMD1004, *Gunaratnam*, FIG. 135, ¶ 0403. *Gunaratnam* does not specifically mention what would have been understood by a person of ordinary skill in the art from Figure 135, namely that the tube assembly comprises a flexible conduit. It was conventional, and nearly universally adopted in CPAP and other respiratory systems, for gas delivery tubes in CPAP systems (and other positive pressure airflow systems) to be made of flexible conduits. These conduits would establish a gas flow path between an air flow generator (e.g., a CPAP machine) and the patient interface. The flexibility of the conduit affords the patient freedom to move while undergoing treatment (such as the ability to roll and move during sleep and the administration of CPAP therapy). The ribs shown on the gas delivery tube 310 in *Ging* (Fig. 6b) (RMD1005), and in Figure 135 of *Gunaratnam* (RMD1004) are common on flexible conduits used in CPAP systems.

156. Additionally, *Ging* discloses this feature, in that the tube assembly includes a flexible conduit, namely gas delivery tube 310. In use, the gas delivery tube 310 connects directly to a portion of the swivel elbow 160. RMD1005, *Ging*, Fig. 26, ¶ 153 ("The air tube 310 (Fig. 26) is preferably directly connected to a stem 166 of swivel elbow 160 (without connector tube 300) to supply pressurized breathable air or gas from a pressurized supply through air tube 310, intake port 162 and into cushion 40 for breathing by the patient."); *see also id.* at ¶ 111; *id.* at Fig. 1. The first end of the flexible conduit (gas delivery tube 310) in *Ging*

comprises a connector, as shown in Figure 26. One of skill in the art would understand that the connector at the first end may be used to connect the flexible conduit to a pressurized gases supply, such as a CPAP machine.



z) Claim Limitation 8.23

157. I understand that claim 8 recites that "the vent compris[es] a plurality of holes extending through the wall of the elbow." In my opinion, this feature is disclosed in both *Gunaratnam* and *Ging*, and would be present in a patient interface constructed according to the combined teachings of these references.

158. To begin, I note that it was well-known at the time of the '807 patent to provide a means of venting gases exhaled by the patient from a CPAP or other respiratory mask assembly. In order to administer pressurized gases in a clinically effective manner, it is critical that exhaled gases be removed from the patient's breathing space, in order to prevent carbon dioxide accumulation that could occur in a closed system. In some cases, carbon dioxide accumulation may place the patient at risk of hypercapnia, symptoms of which include shortness of breath, increased heart rate and blood pressure, drowsiness, and even unconsciousness.

159. Therefore, a common design consideration for CPAP masks, and respiratory masks more generally, is to provide a mechanism that allows for removal of exhaled gases from the patient's breathing space, so as to prevent the patient from continuously re-breathing exhaled air. For example, the mask in one embodiment of *Gunaratnam* includes a plurality of vent holes (vent apertures 619) in the nasal cushion 617, rather than in the swivel elbow. RMD1004, *Gunaratnam*, FIG. 110, ¶ 0381. It is not necessary, however, that the vent holes be located in the mask cushion or mask body. For example, *Gunaratnam* states that the vent holes may be located on any appropriate component of the mask assembly, including the swivel elbow. *Id.* at ¶ 0403 ("In FIG. 135, the elbow is provided to the front of the mask frame, like [ResMed's] VISTA mask, while both apertures/first connector portions are provided with plugged seal rings. ***Of course, in each embodiment, frame, elbow, and/or seal ring(s) may be provided with appropriate vents to exhaust exhaled gas from the breathing chamber***."). Accordingly, *Gunaratnam* expressly states that some implementations of the FIG. 135 embodiment may include vents on the elbow.

160. To the extent that this feature is not explicitly shown in the drawings of *Gunaratnam*, it is my opinion that including a plurality of vent holes extending through a wall of an elbow would have been obvious design choice. For example, the cover of the elbow assembly 60 in *Ging* includes a plurality of holes 190 for

venting exhaled gas to atmosphere, as shown in Figure 22. RMD1005, *Ging*, FIG. 22; *see also id.* at FIGs. 6a, 6b, ¶ 113 (describing a pair of vent openings 61 within an elbow assembly 60); RMD1007, '707 Patent (*Gunaratnam* II), FIG. 4 (showing another view of an elbow like that shown as elbow assembly 60 in *Ging*). *Ging* further discloses that "[t]he elbow assembly 60 [Figs. 6a and 6b] may also include one or more vent openings 61 open to atmosphere, for example, for gas washout of exhaled carbon dioxide, among other things." RMD1005, *Ging*, Figs. 6a, 6b, and ¶ 113.

161. A person of ordinary skill in the art would have applied *Ging's* teaching of a plurality of holes extending through the wall of the elbow to the Figure 135 embodiment in *Gunaratnam*, in order to maximize the rate at which exhaled gases are vented from the mask assembly. Given that the elbow is located at the front of the mask, the patient's exhaled gas would be forced in the direction of the elbow during expiration. The location of the holes in the elbow would thus make them directly in the flow path of the exhaled gases, which would allow efficient venting of the gases.

aa) Claim Limitation 8.25

162. I understand that claim 8 recites the feature of "the elbow and the mask body being connected at least in part by the ring-like connector end such that airflow from the tube assembly can be directed from the elbow through the

generally circular opening of the mask body and into the mask body." In my opinion, this feature is disclosed in both *Gunaratnam* and in *Ging*. First, *Gunaratnam*, in Figure 135, discloses a swivel elbow connected to the front center of a frame for a nasal mask. Figure 135 depicts the mask body as including a full nasal cushion that surrounds the patient's nose, but the nasal pillows-type cushions, such as nozzle assembly 18, would also be applicable to the mask assembly in Figure 135 rather than the full nasal cushion. One of skill in the art would recognize that this feature is implied or inherent in the disclosure of *Gunaratnam's* Figure 135 patient interface design, in that the swivel elbow and the nasal cushion in Figure 135 are connected at least in part by the frame such that airflow from the tube assembly can be directed from the elbow through the generally circular opening of the frame and into the nasal cushion.

163. Likewise, this feature is clearly present in *Ging*. For example, *Ging* discloses that, when assembled, swivel elbow 160 and mask cushion 40 (a "mask body") are connected at least in part by the mask frame 20 (the "ring-like connector"). This connection is made such that airflow from the tube assembly is directed from the swivel elbow 160 through the opening of mask cushion 40 (which may be generally circular, as discussed above) and into the cushion 40. RMD1005, *Ging*, Fig. 1; Figs. 16a – 19c-2, ¶ 153 (describing how air from tube

310 flows through intake port 162 of the swivel elbow 160 "and into cushion 40 for breathing by the patient").

bb) Claim Limitations 8.32, 8.33

164. I understand that claim 8 recites the features of "the first side strap and the second side strap [being] configured to connect and disconnect with the mask assembly while the elbow is connected with the mask body" (claim element 8.32) and "wherein the mask assembly is configured to connect to only two side straps" (claim element 8.33)." In my opinion, these features would be present in the patient interface constructed according to the combined teachings of *Gunaratnam* and *Ging*.

165. To begin, a person of ordinary skill in the art would have understood that the straps located on either side of the mask frame depicted in the patient interface in Figure 135 of *Gunaratnam* could be connected and disconnected (indirectly, via the yokes (side arms)) with the mask assembly while the swivel elbow remains rotatably engaged with the ring and the ring remains engaged with the mask body. Figure 135 thus shows an indirect connection of the mask assembly to only two side straps. The details of how the side arms, which are attached to the straps, could be connected and disconnected from the frame are shown and described with respect to FIGs. 108-114 in *Gunaratnam*, for example. RMD1004, ¶¶ 377-81. Of course, Figure 135 is different from FIGs. 108-114 in

that the elbow is located in front of the frame, rather than inserted from the side, but the manner in which the yokes connect to the frame would be substantially the same. It is clear, however, that the connection between the yokes and the mask assembly are independent of the connection between the elbow, ring, and mask in the Figure 135 embodiment.

166. Furthermore, to the extent that claim 8 requires a direct connection between the side straps and the mask assembly – which it does not (see *supra* ¶ 43) – this feature is also disclosed in the embodiment shown in Figures 107G-H of *Gunaratnam*. In particular, based on the depiction in Figures 107G-H and the discussion in paragraphs 0369-70, a person of ordinary skill in the art would have understood that the side straps 758 were capable of being disconnected from the mask frame 768 directly while the elbow connector portion 770 remains engaged (e.g., rotatably engaged) with the mask frame 768 and while the mask frame 768 remains engaged with the mask body (e.g., nozzle assembly 18). RMD1004, *Gunaratnam*, ¶ 0370 ("As shown in FIG. 107H, each strap 758 includes a first connector portion 766 having one or more arms 767 which can be resiliently flexed toward one another to insert and remove the connector portion 766 from a suitable recess in frame 768.").

167. In my opinion, it would have been predictable, and indeed obvious to apply the strap connect and disconnect feature from Figures 107G-H of

Gunaratnam into the Figure 135 embodiment (as modified by *Ging*). One of ordinary skill would have been motivated to apply the teachings from Figures 107G-H to allow patients to more readily connect and disconnect the mask assembly from the headgear assembly, thereby minimizing the effort required for a patient to don and remove the mask and headgear assemblies in use.

cc) Claim 17

168. I understand that claim 17 depends from claim 1, and recites the additional feature that "the ring comprises a first wall and a second wall defining a space therebetween, and wherein a portion of the mask body is configured to removably attach to the ring via friction within the space and with the first wall and the second wall." In my opinion, this feature is disclosed by the teachings of *Ging* and *Gunaratnam*.

169. Recall that Figure 135 of *Gunaratnam* discloses the claimed "ring" as the frame of the mask assembly shown therein. *Ging* teaches additional detail of a mask frame 20, which is comparable to the frame shown in Figure 135 of *Gunaratnam*. In particular, *Ging* discloses that the mask frame 20 has a first wall as inner wall 28, and a second wall as outer wall 30. The inner wall 28 and outer wall 30 of the mask frame 20 define a space therebetween, which *Ging* refers to as channel 26. RMD1005, *Ging*, ¶ 111, FIGs. 5, 5c, 6a, 6b. *Ging* includes extensive discussion of how the mask cushion 40 fits into the channel 26 of the mask frame

20. A person of ordinary skill in the art would have understood that the engagement of the cushion 40 to the mask frame 20 in *Ging* would have relied on a frictional fit. *See, e.g.*, RMD1005, *Ging*, ¶¶ 196-223 (discussing in detail a mask frame and cushion connection system).

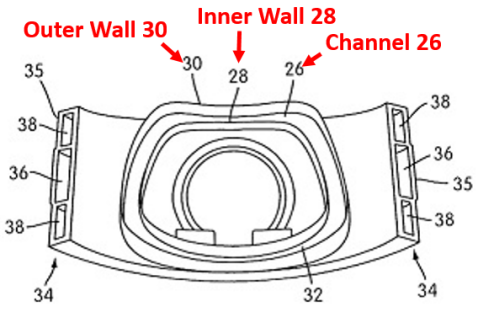


FIG. 5c

170. In particular, *Ging* discloses that the mask cushion 40 can include a plurality of finger-like projections, and the mask frame 20 can include a notch for receiving one of the projections. As the patient pushes the cushion 40 into the channel 26 of the mask frame, one of the projections locks into the notch of the mask frame 20 to secure the cushion 40 to the frame 20. The user receives tactile feedback from this configuration that indicates that the mask is secured. As *Ging* properly explains, this configuration allows for control of the frictional forces between the mask frame 20 and cushion 40, so that, for example, less force may be required to engage the cushion 40 to the frame 20 than the amount of force required to disengage the cushion 40 from the frame 20. *See* RMD1005, *Ging*, 27:65-28:46. A person of skill in the art before the time of the '807 patent would

have applied these teachings of *Ging* to *Gunaratnam* (e.g., in the Figure 135 embodiment) in order to achieve the benefits of such an arrangement that are mentioned in *Ging*, including allowing for control of the frictional forces between the mask frame and mask body (cushion), and to ensure a secure engagement where more force is required for removal of the body from the frame than is required to insert the body into the frame.

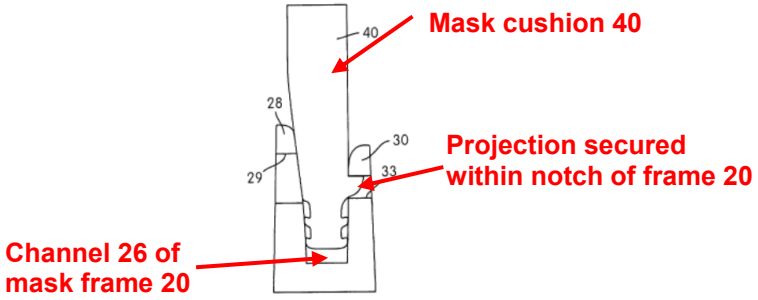
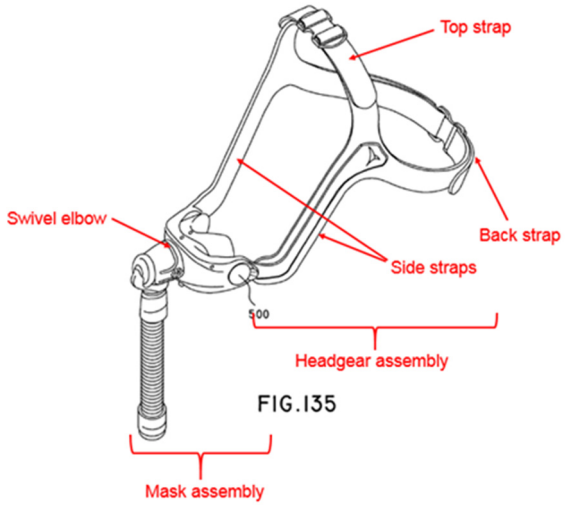


FIG. 28

171. Further, I note that *Gunaratnam* discloses that the nozzle assembly 18, which I have explained would have been obvious to apply to the patient interface design of Figure 135, includes a portion that is configured to removably attach to a mask frame via a friction fit. RMD1004, *Gunaratnam*, ¶ 186 ("[T]he nozzle assembly 18 may be removably attached to the frame 16 in any other suitable manner, e.g., ***friction*** or interference fit and/or a tongue and groove arrangement, as is known in the art.") (emphasis added). This further supports my opinion that claim 17 would have been obvious to one of ordinary skill in the art at the time of the '807 patent.

dd) Claims 18, 19

172. I understand that claim 18 depends from claim 1, and recites the additional feature that "the top strap is integrally formed with one or more of the side straps and the back strap." Claim 19 depends from claim 18, and more specifically adds the feature that the "top strap is integrally formed with one or more of the side straps." In my opinion, these features are disclosed in *Gunaratnam*. First, Figure 135 shows that respective sides of the top strap are integrally formed with one or more of the side straps and the back strap (claim 18), and meets the feature of the top strap being integrally formed with one or more of the side straps (claim 19).



173. Additionally, Figures 107G and 107H show a headgear assembly having side straps 758, a rear strap 754, and a top strap 756. RMD1004, *Gunaratnam*, FIGs. 107G-H. The headgear assembly in this embodiment is a

unitary headgear structure in which the side straps 758, rear strap 754, and top strap 756 all appear to be integrally formed. Although paragraphs 369 and 370 of *Gunaratnam's* disclosure do not expressly mention the headgear in this embodiment as being a unitary structure, this feature is taught elsewhere in *Gunaratnam*. *See* RMD1004, *Gunaratnam*, ¶ 0213 (describing that the headgear assembly 20 in some embodiments "may be constructed as a one piece structure"). This type of unitary structure appears to be what is depicted in Figure 107G.

174. Moreover, a person of skill in the art would have recognized at the time of the '807 patent that headgear assemblies having integrally formed straps were conventional. It would have been an obvious design choice to make the top strap integrally formed with one or more of the side straps and the back strap, as recited in claim 18. Integrally formed straps would have been beneficial, for example, to maintain the overall structure of the headgear assembly so that the user need not be concerned with making connections among various parts of the headgear assembly. Instead, the user could quickly, and with minimal burden, slip the headgear assembly with integrally formed straps onto his or her head.

ee) Claims 20, 21

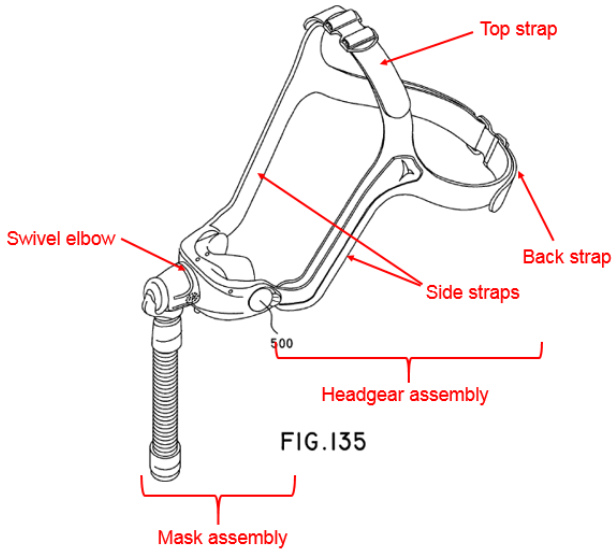
175. I understand that claim 20 depends from claim 8, and recites the additional feature of "the top strap [being] integrally formed with one or more of the side straps and the back strap." Claim 21 depends from claim 20, and more

specifically adds the feature that the "top strap is integrally formed with one or more of the side straps." For substantially the same reasons that I have discussed in connection with claims 18 and 19, it is my opinion that claims 20 and 21 each would have been obvious in view of the combined teachings of *Gunaratnam* and *Ging*.

ff) Claims 24, 25

176. I understand that claim 24 depends from claim 1, and recites the additional feature of a "top strap [that] is releasably connected to one or more of the side straps and the back strap." Claim 25, in turn, depends from claim 24 and recites the additional feature of "the top strap [being] releasably connected to the back strap." In my opinion, claims 24 and 25 each would have been obvious in view of the combined teachings of *Gunaratnam* and *Ging*.

First, the patient interface design shown in Figure 135 of *Gunaratnam* includes a top strap having a first portion which is integrally formed with (i) a first of the pair of side straps and (ii) a portion of the back strap. A second portion of the top strap is integrally formed with (i) a second of the pair of side straps and (ii) a second portion of the back strap. A buckle connects the first and second portions of the top strap, so that at least a portion of the top strap is releasably connected to one or more of the side straps and the back strap, as claimed.



177. Additionally, *Gunaratnam* discloses many different headgear configurations. A number of these alternative embodiments include releasably connected straps consistent with claim 24. For example, Figure 18 (copied below) shows a headgear assembly 20 comprised of a top strap 98, a back strap 100, and a pair of side straps 96. As shown in Figure 18, the top strap 98 is releasably connected to the side straps 96 via buckles 102 provided at the ends of the side straps 96. RMD1004, *Gunaratnam*, ¶ 0211. Figure 18 thus discloses the additional feature of claim 24. It would have been obvious to apply the releasable connections taught in Figure 18 to the patient interface depicted in the embodiment of Figure 135 so as to ease the removal and disassembly of the headgear.

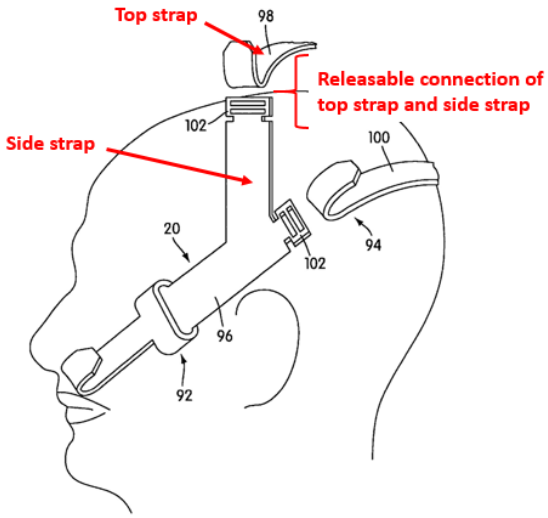


FIG. 18

178. Moreover, *Ging* discloses a headgear assembly having releasable strap connections that would meet the additional features recited in both of claims 24 and 25. Figure 1 in *Ging* discloses a headgear assembly 80 having a top strap 140, side straps (the portion of front straps 84 that run from the top of the patient's head and down the cheeks), and a rear strap (the portions of front strap 84 that curve around the back of the user's head to connect to strap 142). RMD1005, *Ging*, Figs. 1, 1b, ¶¶ 145-148. The top strap 140 is releasably connected to the side straps and is releasably connected to the rear strap. *Id.* Therefore, *Ging* discloses in this embodiment the claimed feature of a top strap that is releasably connected to a back strap.

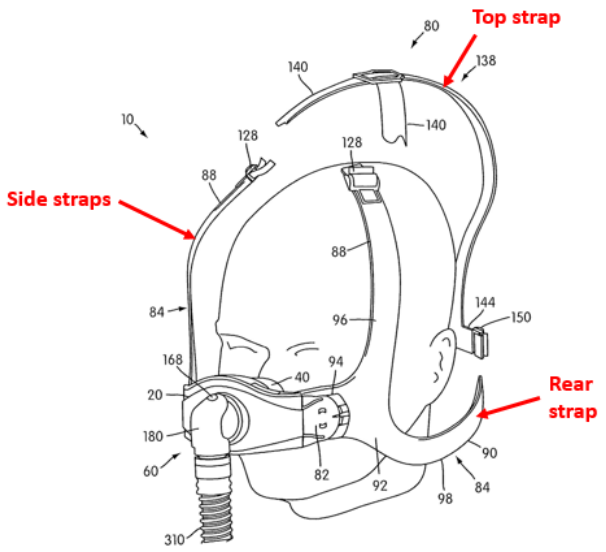


FIG. 1

179. In my opinion, it would have been an obvious design choice to one of skill in the art to modify the headgear assemblies depicted in the Figure 135 design to incorporate the teachings of a top strap releasably connected to a back strap. One of skill would have been motivated to modify *Gunaratnam's* headgear assembly in this manner, for example, to improve the ease of removal and disassembly of the headgear for the patient. Additionally, a person of ordinary skill in the art would have recognized that releasable connections would facilitate greater size adjustments than some designs with an integral formation. Releasable strap connections would thus have provided a different set of advantages than designs having integrally formed straps. If one of skill were more concerned with the adjustability of headgear assembly, then the releasable connections may have been preferable to the integrally formed straps that are shown in Figures 135 and

107G-H of *Gunaratnam*. Releasable connections would also allow the user to more easily remove the headgear assembly by breaking the releasable connections.

gg) Claims 26, 27

180. I understand that claim 26 depends from claim 8, and recites the additional feature of the "top strap [being] releasably connected to one or more of the side straps and the back strap." In addition, claim 27 depends from claim 26 and further specifies that "the top strap is releasably connected to the back strap." For substantially the same reasons that I have discussed in connection with claims 24 and 25, it is my opinion that claims 26 and 27 each would have been obvious in view of the combined teachings of *Gunaratnam* and *Ging*.

C. Ground 2: *Gunaratnam* in view of *Ging* and *McAuley*

181. Based on my knowledge and experience in the field, and my review of the documents listed in Section V above, it is my opinion that a person of ordinary skill in the art would have combined *Gunaratnam* with *Ging* and *McAuley* to arrive at the patient interfaces of claims 1-8, 17-21, and 24-27 of the '807 patent.

182. As noted in Section VII.B above (Ground 1), *Gunaratnum* in view of *Ging* discloses all of the limitations of claims 1-8, 17-21, and 24-27 of the '807 patent. But to the extent that the Board construes the claimed "ring" to require a generally circular outer periphery, and find that neither *Gunaratnam* nor *Ging* teach as much, I believe that skilled artisans would have seen reason to have

designed the *Ganaratnum* and *Ging* mask frame to have a circular outer periphery as taught by *McAuley*.

183. As previously mentioned above, McCauley's patient interface includes a "body part 62" that has a generally-circular exterior and serves as a frame or base to which a swivel elbow, headgear straps, and a nasal pillows cushion attach.

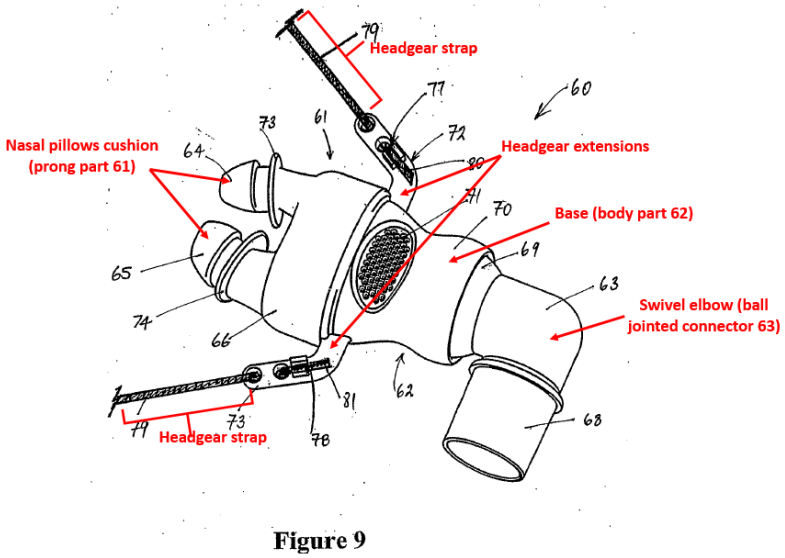


Figure 9

184. With McAuley's teachings in mind, I believe that persons of ordinary skill in the art would have seen reason to have modified the combination of *Gunaratnam* and *Ging* (i.e., the Figure 135 embodiment from *Gunaratnum* modified to include nasal pillows and additional detail of certain features shown by *Ging*) to make the exterior of *Gunaratnam's* frame generally circular. I believe this, because skilled artisans would have understood that the circular configuration would have been smaller and therefore would have reduced the weight of the mask, which would have increased patient comfort when wearing the mask. Another reason that skilled artisans would have seen a reason to have designed the *Gunaratnam* frame to be circular was that the circular frame would

have been more compact and therefore users would have had a view that was less obstructed by the patient interface. And even further, a modification to make *Gunaratnam's* frame circular would have required less material and therefore would have reduced the material costs in manufacturing. In a patient interface that has been modified to have a generally circular frame, I believe that *Gunaratnam's* headgear straps could connect to structures that project from the sides of the generally-circular frame, like *McAuley's* extension members 72 and 73, or could connect directly to attachment points on the surface of the rounded frame, without extensions 72 and 73. In some instances, connecting the headgear straps to extension members 72 or 73 would serve to provide additional stability of the mask assembly on the patient's face due to the connection points being further outward from the center of the patient's face in use.

185. In addition to the reasons I have articulated in Section VIII.B above (Ground 1), along with the additional modification taught by *McAuley* of making the frame to have a circular outer periphery, I believe that the combination of *Gunaratnam*, *Ging*, and *McAuley* renders obvious each of claims 1-8, 17-21, and 24-27 of the '807 patent.

D. Ground 3: *Lovell* in view of *Gunaratnam*

1. Motivation to Combine *Lovell and Gunaratnam* as Proposed by Petitioners

186. Based on my knowledge and experience in the field, and my review of the documents listed in Section V above, it is my opinion that a person of ordinary skill in the art would have combined *Lovell* and *Gunaratnam* to arrive at the patient interfaces of claims 1-8, 17-21, and 24-27 of the '807 patent. I recognize that the combination of *Lovell* and *Gunaratnam* was applied in an obviousness rejection that was overcome by the applicant during original examination. *See* RMD1009 at pp. 585-90 (office action rejecting certain claims over *Lovell* and *Gunaratnam*) and 613-23 (applicant's response to office action) However, as discussed above in paragraphs 30-39, I disagree with the arguments made by the applicant to overcome the rejection.

187. As noted in greater detail below, *Lovell* discloses most of the features of independent claims 1 and 8, including the recited mask body, ring, and an elbow rotatably engaged with the ring. Although *Lovell* does not disclose thatits "mask assembly is configured to connect to only the two side straps," this feature was disclosed by *Gunaratnum* and I believe that skilled artisans would have seen reason to have designed *Lovell's* mask to use a two-strap headgear assembly, as disclosed by *Gunaratnum*. Indeed, *Gunaratnam* discloses numerous nasal pillows

masks in which the mask assembly connects to only two side straps, whether directly or indirectly, such as in Figures 107G-H and 135. *See* RMD1004 at FIGS. 107G-H and 135. Additionally, as explained in paragraphs 30-39 above, I believe that the feature of an elbow that fits *into* the ring would have been obvious to one of ordinary skill in the art before the time of the '807 patent.

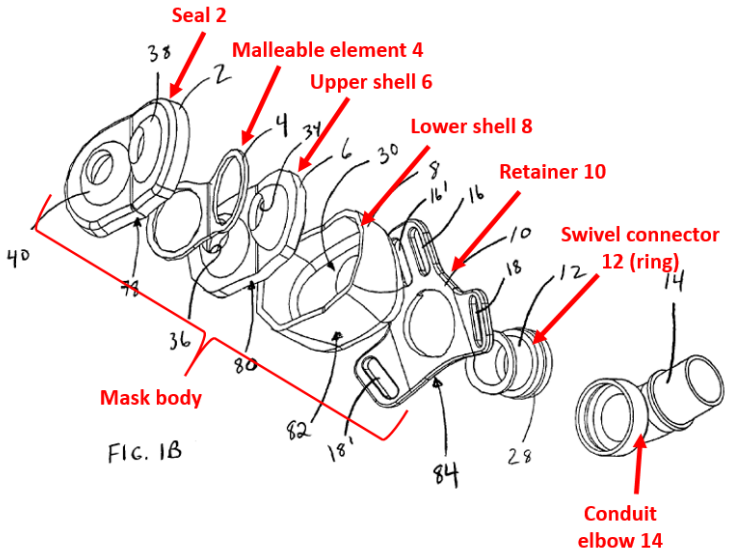
188. I believe that a skilled artisan would have been motivated to apply *Gunaratnam's* headgear design to *Lovell's* mask assembly because doing so would reduce the number of connections between the headgear and mask assembly, which would result in a simpler design that was less cumbersome for a patient. *Gunaratnam* teaches that rigid side arms (yokes) extending along the side straps provide any additional stability needed to compensate for the use of only two straps.

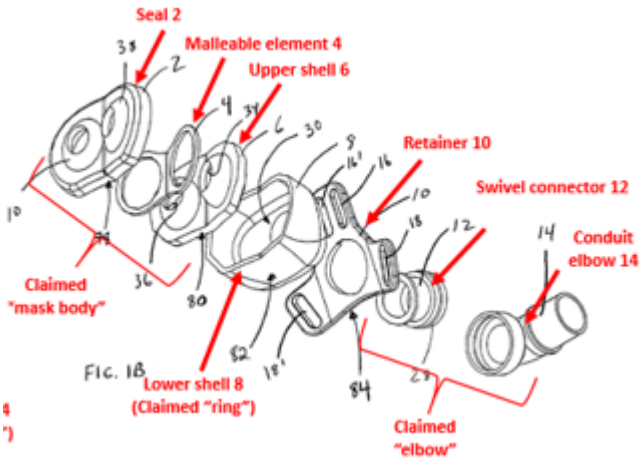
2. Claim Chart Showing Corresponding Disclosure in *Lovell* and *Gunaratnam* For Each Element of Claims 1-8, 17-21, and 25-27 of the '807 Patent

189. ResMed's counsel prepared the following claim charts for claims 1-8, 17-21, and 24-27 of the '807 patent, which is based on the invalidity grounds provided in ResMed's Petitions for *inter partes* review. The claim charts incorporate my analysis of where the respective elements of these claims are disclosed or suggested in the prior art references, *Lovell* (RMD1012) and *Gunaratnam* (RMD1004), or in related references as noted in the charts. Based on

my review of these prior art references, and the ’807 patent and file history, I agree that each element of claims 1-8, 17-21, and 24-27 of the ’807 patent is disclosed or suggested by *Lovell*, *Gunaratnam*, or both references, or would have been obvious to one of skill in the art in view of the teachings of *Lovell* and *Gunaratnam*. I further agree that the following claim charts accurately demonstrate the correspondence between the elements of the ’807 claims at issue and exemplary disclosure from *Lovell* and *Gunaratnam*. As demonstrated by the claim chart, and my analysis in Section VIII.D.3 below, it is my opinion that claims 1-8, 17-21, and 24-27 of the ’807 patent are obvious over *Lovell* in view of *Gunaratnam*.

'807 Claims	**Exemplary Disclosures from *Lovell* and *Gunaratnam***

[1.1, 1.2] A patient interface comprising: a mask assembly having . . . and a headgear assembly	*Lovell* discloses a patient interface as nasal mask 1. *Lovell*'s nasal mask 1 includes a mask assembly having a number of components, including a swivel connector 12 for connecting to a conduit elbow 14, a retaining structure 10, a lower shell 8, an upper shell 6, a malleable element 4, and a nasal pillows seal 2. *See* RMD1012, Fig. 1B. As noted below under Limitations 1.5, 1.7 and 1.8 regarding the claimed "ring" being engaged with the claimed "mask body," different structures may constitute the mask body as claimed, depending on the structures constituting the claimed ring. For example, if considering the swivel connector 12 as the claimed "ring," then all of components 2, 4, 6 and 8 (and optionally also 10) constitute the mask body. If considering the lower mask shell 8 as the claimed "ring," then components 2, 4 and 6 constitute the mask body. Either way, the structures constitute a mask body, as illustrated below: **First Reading of "Mask Body"**  **Second Reading of "Mask Body"**

	
[1.3, 1.4] a mask body including two nasal pillows extending from it, which in use rest in a substantially sealed manner against the nares of a user the mask body sized and shaped to leave the mouth of the user uncovered by the mask body when in use	*Lovell's* mask body includes two nasal pillows as domes 38, 40 on seal 2, or as domes 38, 40 together with the two outlets 34, 36 on the upper shell 6 extending from the mask body. RMD1012, 8:51-52 ("[T]he seal 2 has two domes 38, 40 that cover the two outlets 34, 36."). *Lovell's* nasal pillows in use rest in a substantially sealed manner against the nares of a user, and the mask body sized and shaped to leave the mouth of the user uncovered by the mask body when in use. *See* RMD1012, 2:33-35 ("[D]evices of the invention seal with the external skin surrounding the nares at the base of the nose and/or along the inner rim of the nares of a user.."); *id.* at 8:59-61 ("The contact, between the seal 2 and the external skin surrounding the nares at the base of the nose and/or the inner rim of the nares is minimal."); *id.* at Fig. 5 (showing the user's mouth uncovered while donning the nasal mask).

[1.5] a ring engaged with the mask body	The claimed ring reads on *Lovell* in two respects. First, *Lovell* discloses a "ring" as swivel connector 12, and discloses that this ring (swivel connector 12) is engaged with structure constituting a mask body. Specifically, a portion of the swivel connector 12 fits within an inlet 32 of the lower shell 8, as shown in Fig. 4B. *See also* RMD1012, col. 5:24-26 ("The nasal mask 1 includes an inlet 32 into which a swivel connector 12 fits. The swivel connector 12 has a slightly concave shape on the end that fits into the inlet 32."). Second, *Lovell* discloses a ring as lower mask shell 8 (this structure meets the "ring" limitation as properly interpreted under Section VI.A), and discloses that this ring (lower shell 8) is engaged with structure constituting a mask body. Specifically, the lower shell 8 engages with upper shell 6 of the mask body, as shown in Fig. 4B. *See also* RMD1012, col. 4:38-40.
[1.6] a plane substantially bisecting the ring, each of the two nasal pillows positioned on opposite sides of the plane	The ring (swivel connector 12) is generally located at the center of the mask in *Lovell*'s design. Therefore, if one were to consider a vertical plane that bisected the ring (swivel connector 12), that plane would lie between each of the two nasal pillows such that the two pillows would be located on opposite sides of the planes.

[1.7] an elbow rotatably engaged with the ring	*Lovell* discloses that the swivel connector 12 produces a swivel mount connection between the elbow 14 and an inlet 32 to lower mask shell 8. *See* RMD1012, col. 5:32-34, and Fig. 4B shown at right. Referring to Figure 2B, one of skill in the art would have understood the swivel connection could be achieved by making the swivel connector 12 rotatable vis-à-vis the lower mask inlet 32, by making the elbow 14 rotatable vis-à-vis the swivel connector 12, or both. As such, considering the lower mask shell 8 as the claimed "ring" (as discussed under Limitation 1.5 above), the elbow (made collectively of elbow 14 and swivel connector 12) would be rotatably engaged with the ring (lower mask shell 8). Alternatively, considering the swivel connector 12 as the claimed "ring" (as discussed under Limitation 1.5 above), the elbow 14 would be rotatably engaged with the ring (swivel connector 12). RMD1012, Figs. 1, 3A, 4B, 5, col. 5:26-34.

[1.8] the ring forming a socket into which a portion of the elbow fits to facilitate the rotatable engagement between the elbow and the ring	First, regarding the swivel connector 12 as the claimed ring, *Lovell* discloses a different configuration in which the elbow fits over the ring (swivel connector 12), but one of skill would have seen the choice of which component fits over the other to be an obvious design choice. Indeed, it was well known at the time of the '807 patent for elbows to fit *within* a socket of a mask assembly, to facilitate rotatable engagement of the elbow. This feature is present in an embodiment of *Gunaratnam* (RMD1004), depicted in Figs. 110B and 111, for example. The modification would simply involve making the elbow 14 a male connector, and the swivel connector 12 a female connector, rather than the reverse as in *Lovell*'s preferred embodiment. Absent special considerations not applicable to *Lovell*'s design, one of skill in the art would have recognized that switching the location of the male and female components would be predictable and routine, and would have seen *Gunaratnam's* design in which the elbow fits within a socket to be a predictable alternative to *Lovell*'s design. Second, regarding the lower mask shell 8 as the claimed ring, *Lovell* discloses swivel connector 12 fits into an inlet 32 of lower mask shell 8. *See* RMD1012, Fig. 4B. As such, shell shell 8 of *Lovell* forms a socket into which a portion of an elbow (elbow 14 plus connector 12) fits to facilitate rotatable engagement between the elbow and the ring, as claimed.

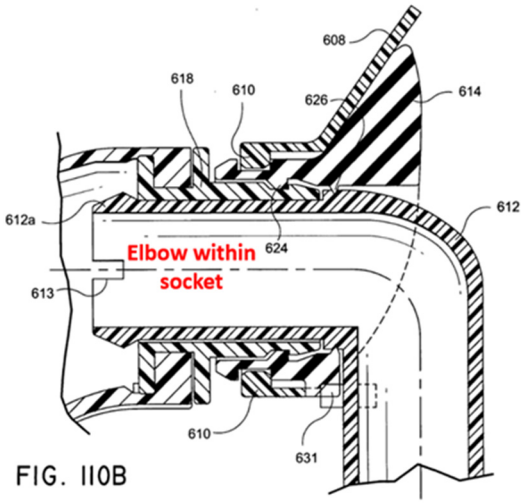
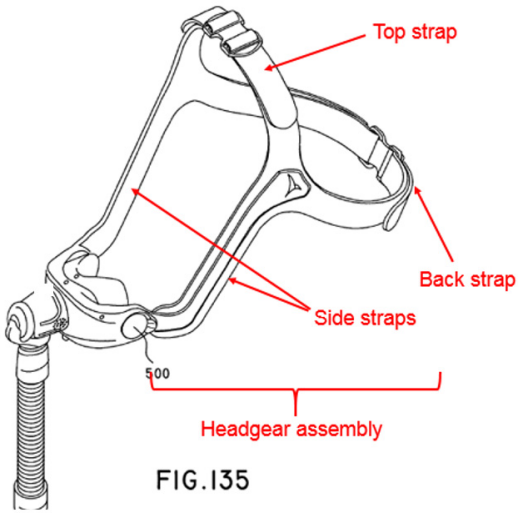
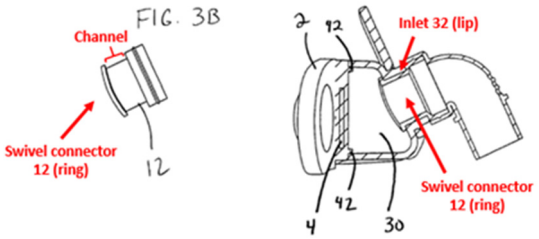


FIG. 110B

[1.9] the elbow comprising a plurality of vent holes	*Lovell* discloses that the elbow 14 comprises a plurality of vent holes, namely apertures 20. *See* RMD1012, Fig. 2B, 5:46-50 ("The conduit elbow 14 is shown with an angled portion of about ninety degrees, as well as apertures 20 as seen in FIG. 2B, only one aperture being labeled for the sake
[1.10] a tube or conduit extending from the elbow	To the extent that the claimed feature of "a tube or conduit extending from the elbow" is not explicitly described in *Lovell*, this feature would have been implied or inherent in the design of *Lovell's* nasal mask, as a tube or conduit is generally required to deliver pressurized air from a source (e.g., a CPAP machine) to the patient interface. *See* RMD1012, 1:17-20 ("In general, a supply of pressurized air or therapeutic gas is provided by a tube or conduit to a delivery apparatus designed to conform to particular body structure."). Such a tube or conduit as claimed is further disclosed in *Gunaratnam* Fig. 135. *See, e.g.*, RMD1004, Fig. 135.

[1.11–1.17] (Headgear Assembly)	Claim 1 further requires a headgear assembly that includes two side straps, a top strap, and a back strap, which have particular features set forth in limitations 1.11-1.17. Each of these features is disclosed in *Gunaratnam*, as set forth above in Ground 1 of the Petition. During prosecution, claim 1 (application claim 37) was amended to add the requirement that "the mask assembly is configured to connect to *only* the two side straps," (limitation 1.16) in order to distinguish *Lovell's* design in which the mask assembly connects to four straps. *See, e.g.,* RMD1012, Fig. 5, Fig. 1B (showing four strap connection points 16, 16', 18, and 18' on retainer 10); RMD1009, pp. 585-90, 613-23.  FIG.135 One of skill would not have agreed with the applicant's argument during prosecution that modifying *Lovell's* mask to connect to only two side straps would "prevent[] the nasal mask from being securely positioned against the nares of a user." To the contrary, *Gunaratnam* discloses numerous nasal pillows masks in which the mask assembly connects to only two side straps, while the mask is still capable of being securely positioned on the patient's face. *See, e.g.*, RMD1004, Figs. 108, 135 (mask assembly connected to only two side arms); *id.* at Figs. 107G-H (mask assembly having only two headgear connections). For example, *Gunaratnam*'s Figure 135 design shows only two side straps connected to a mask

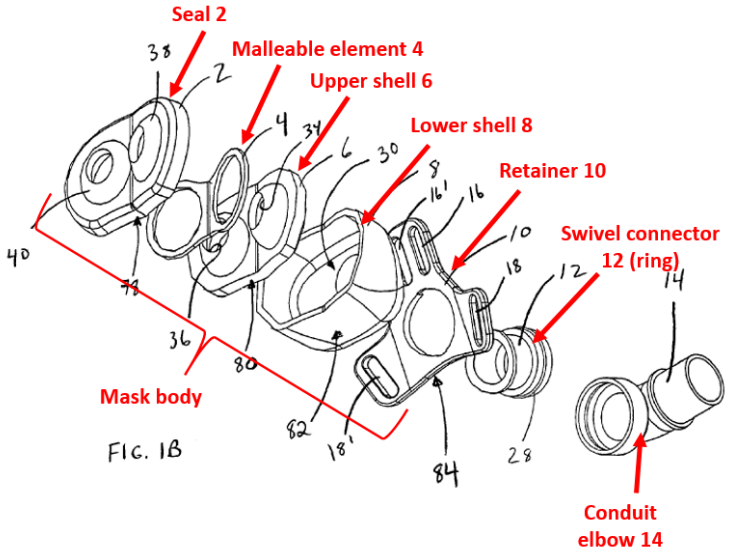
	assembly by side arms (yokes) on either side of the mask. RMD1004, Fig. 135. One of skill would have been motivated to apply *Gunaratnam's* headgear design to *Lovell's* mask assembly in order to reduce the number of connections between the headgear and mask assembly. For example, a two-strap connection would be less cumbersome for a patient than a four-strap connection and would generally result in a simpler design. Additionally, *Gunaratnam* teaches that rigid side arms (yokes) extending along the side straps provide any additional stability needed to compensate for the use of only two straps connected to the mask assembly, rather than four. The particular manner in which the two side straps from *Gunaratnam* connect to the mask assembly from *Lovell* would be well within the capabilities of a skilled artisan to determine, and would be an obvious implementation detail. For example, the side arms could attach directly to a pair of connection points on *Lovell's* retaining structure 10. Alternatively, the two side straps could connect directly to the retaining structure 10, while side arms run along the side straps for added stability. RMD1004, ¶¶ 0369-70, Figs. 107G-H (showing a nasal pillows mask in which only two side straps connect directly to the mask frame via connector portions 766, 770).

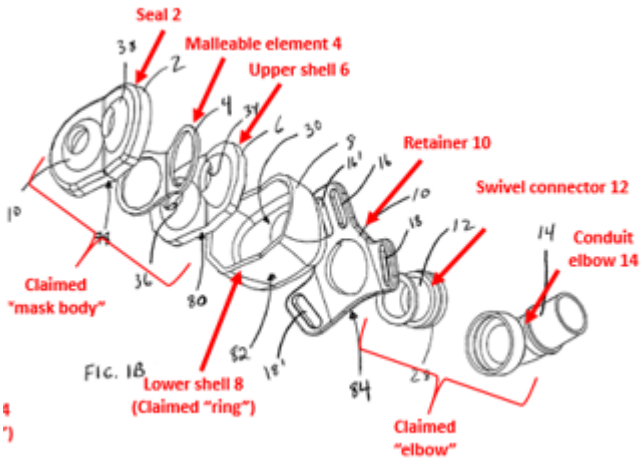
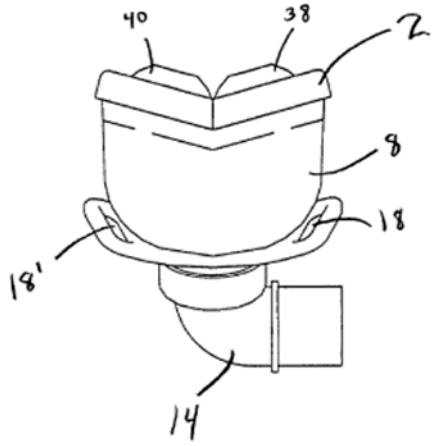
[2] A patient interface as claimed in claim 1, wherein the mask body includes a lip and the ring includes a channel receiving the lip of the mask body	First regarding the swivel connector 12 as the claimed "ring," the inlet 32 of *Lovell's* lower shell 8 forms the claimed "lip" of the mask body (shown above for Limitations 1.1-1.2). The central section of the ring (swivel connector 12) forms the claimed "channel" of the ring. When *Lovell's* nasal mask is assembled, the channel of the ring (swivel connector 12) receives the lip (inlet 32) of the mask body. This feature is represented in Figs. 3B and 4B of *Lovell* (RMD1012).  Even if the ring (swivel connector 12) were modified to form a socket that receives a portion of the elbow 14 *within* the ring, the ring would still include a channel for the lip of the mask body to go into. Second regarding lower mask shell 8 as the claimed "ring," *Lovell* discloses the upper mask shell 6 (i.e., the part of the mask body to which shell 8 is engaged) having a lip or flange 42 (*see* Fig. 4B), which flange 42 allows the lower mask shell 8 to seat the upper mask shell 6 so the two parts can be affixed together. *See* RMD1012, Fig. 4B and col. 4:38-52. One of skill at a time before the '807 patent would have understood that the lip and channel arrangement in *Lovell* may be modified so that the lip of the upper mask shell 6 fits into a channel of the lower mask shell 10 (ring), to provide an arrangement wherein the two parts can be connectable and disconnectable by friction fit, to provide for ease of user cleaning the insides of the mask components between uses. Such a configuration of two mask components is disclosed, for example, in *Gunaratnam* when read in view of further detail provided in *Ging*. *See* Discussion of claim 2 under Ground 1.

[3] A patient interface as claimed in claim 2, wherein the mask body comprises a molded elastomeric material	*Lovell* discloses that the seal 2 of the mask body comprises silicone, which one of skill in the art would recognize is an elastomeric material. RMD1012, 7:35-45 (the seal 2 may be a "bladder . . . that is filled with a soft material 62" such as "molded silicone.")
[4] A patient interface as claimed in claim 1, wherein the elbow is able to swivel in the ring such that the tubing is available to be adjacent to either side strap	*Lovell* discloses that "the conduit elbow 14 is capable of being rotated 360 degrees about an axis extending through the center of the inlet 32." RMD1012, 5:35-37. Given that the elbow 14 is located at the front, center of the mask, and that the elbow is capable of swiveling in the ring 360 degrees, the tubing connected to the elbow would be available to be adjacent to any of *Lovell*'s straps. Similarly, in the modified patient interface of claim 1, in which the headgear assembly from *Gunaratnam* Fig. 135 is applied to *Lovell*'s mask assembly, the elbow 14 would be capable of swiveling in the ring such that the tubing would be available to be adjacent to either side strap.

[5] A patient interface as claimed in claim 1, wherein the ring comprises a hard plastic material	First regarding the swivel connector 12 as the claimed "ring," the ring (swivel connector 12) of *Lovell* would necessarily comprise a hard material in order to provide the structural support required to facilitate the swivel connection between the elbow 14 and the mask body. Also, the choice of a hard ***plastic*** material, as required by claim 5, would have been an obvious material selection for one of skill in the art. For example, *Gunaratnam* teaches that components of a mask assembly may be made from rigid polymer materials, which one of skill would understand to include hard plastics. *See* RMD1004, ¶¶ 0004, 0255. Second regarding the lower mask shell 8 as the claimed "ring," *Lovell* discloses that the mask shell 8 is "manufactured from a flexible material, for example, but without limitation, by a molding process using a compliant polymer," for example, "a thermopolymer elastomer." *See* RMD1012, col. 4:43-48. One of skill in the art would understand that a thermoplastic elastomer is a plastic material. Regarding the plastic material being "hard" as claimed, *Lovell* discloses that the connection between the swivel connector 12 and the inlet 32 of lower mask shell 8 can be "permanent and inseparable." RMD1012, 5:28-32. One of skill in the art would understand that, to achieve this inseparable connection, both the inlet 32 of lower mask shell 8 and swivel connector 12 would be made of a hard material. Moreover, one of skill in the art would have seen, for example from *Gunaratnam*, that it was known to make a mask out of a hard or rigid lower mask shell and a more flexible upper mask shell, and that configuration facilitates a user being able put the two parts back together by a friction fit after taking them apart to clean them between uses. *See* RMD1004, ¶ 0004, 0178, 0186, 0191-0192. By contrast, with both mask shells being flexible, it would be difficult for a user to put the two mask shells back together.

[6] A patient interface as claimed in claim 1 further comprising molded side arms extending away from the ring to connect with the side strap, the molded side arms connecting to the side straps that pass down the cheeks of the user	The additional feature of claim 6 would be present in the patient interface disclosed in *Lovell* as modified by *Gunaratnam*. For example, the side arms (yokes) from *Gunaratnam* would connect to the mask body in *Lovell*, and would extend away from the ring (swivel connector 12) to connect with the side straps. Moreover, one of skill would have understood that the side arms (yokes) being molded would have been an implied or inherent feature of the yokes 608 in *Gunaratnam*, or at a minimum would have been an obvious design choice. For example, many different embodiments including similar yoke structures are described throughout *Gunaratnam*, which make clear that the yoke members can be constructed from molded plastic material. *See* RMD1004, *Gunaratnam*, ¶ 0315 ("The headgear yoke 580 acts as a stiffener to add rigidity to the headgear assembly 520. . . . In Fig. 60, the yoke 580 is a semi-rigid layer, such as plastic, which is provided to, e.g., sewn onto, the headgear straps 598 and/or 599."); *see also id.* at ¶¶ 0376, 0379, 0390.
[7] A patient interface as claimed in claim 1, wherein, in use, gases flow from the tube or conduit, through the elbow, through the ring, through the mask body and through the pillows	The additional feature recited in claim 7 is present in the patient interface disclosed in *Lovell*, including if modified by *Gunaratnam*. One of skill would understand that in use, a pressurized flow of gas applied to *Lovell*'s mask would follow a path from the tube or conduit, through the elbow 14, through the ring (swivel connector 12), through the mask body, and through the pillows (nasal pillows seal 2). *See, e.g.*, RMD1012, *Lovell*, Figs. 1B, 5, 10B.

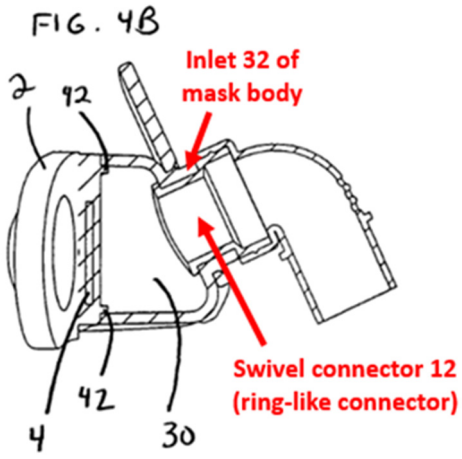
[8.1–8.3] A patient interface (8.1) comprising: a mask assembly (8.2) having a mask body (8.3)	*Lovell* discloses a patient interface as nasal mask 1. *Lovell*'s nasal mask 1 includes a mask assembly having a number of components, including a swivel connector 12 for connecting to a conduit elbow 14, a retaining structure 10, a lower shell 8, an upper shell 6, a malleable element 4, and a nasal pillows seal 2. *See* RMD1012, Fig. 1B. As noted below under Limitations 1.5, 1.7 and 1.8 regarding the claimed "ring" being engaged with the claimed "mask body," different structures may constitute the mask body as claimed, depending on the structures constituting the claimed ring. For example, if considering the swivel connector 12 as the claimed "ring," then all of components 2, 4, 6 and 8 (and optionally also 10) constitute the mask body. If considering the lower mask shell 8 as the claimed "ring," then components 2, 4 and 6 constitute the mask body. Either way, the structures constitute a mask body, as illustrated below: **First Reading of "Mask Body"**  **Second Reading of "Mask Body"**

	
[8.4] the mask body comprising a substantially flexible elastomeric material	*Lovell* discloses that the seal 2 of the mask body comprises silicone, which one of skill in the art would recognize is a substantially flexible elastomeric material. RMD1012, 7:35-45 (the seal 2 may be a "bladder . . . that is filled with a soft material 62" such as "molded silicone.").
[8.5, 8.6] the mask body comprising a first nasal pillow and a second nasal pillow (8.5), the first nasal pillow and the second nasal pillow being angled toward one another (8.6)	*Lovell's* mask body includes (i) two nasal pillows as domes 38, 40 on seal 2, or (ii) as domes 38, 40 on seal 2 together with the two outlets 34, 36 on the upper shell 6 extending from the mask body. RMD1012, 8:51-54 ("[T]he seal 2 has two domes 38, 40 that cover the two outlets 34, 36."). The domes 38 and 40 are angled toward each other, as shown by Figure 2A (below). 

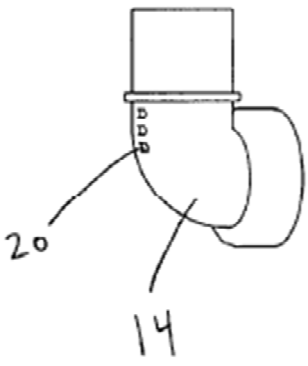
[8.7, 8.8] the first nasal pillow comprising a first generally conical portion and a first generally cylindrical portion (8.7) the second nasal pillow comprising a second generally conical portion and a second generally cylindrical portion (8.8)	Each of *Lovell's* nasal pillows include a conical "dome 38" or "dome 40" and a corresponding portion of the "seal 2" that is generally cylindrical. *See* RMD1012, Figures 1A-2B and 8A. To the extent that *Lovell* does not show the required shape of the nasal pillows, CPAP masks with such pillow pillows were known in the art. For example, as described above for Ground 1, *Gunaratnam* discloses that nozzles 50 of nozzle assembly 18 each comprise a generally conical portion and a generally cylindrical portion. A skilled artisan would have seen a reason to have modified *Lovell* to have pillow cushions with the shapes disclosed by the various pillow cushions in *Gunaratnam* because these designs provide a mechanism to "sealingly engage with nasal passages 12 of the patient's nose 14." RMD1004 at ¶ 0185, 0190 ("the first portion 56 of the nozzles 50 have [sic] a reduced cross-section with respect to the second portion 58 to allow the nozzles 50 to move relative to the base portion 48, and hence the frame 16, for increased comfort and accommodation of variations in patient facial features.")

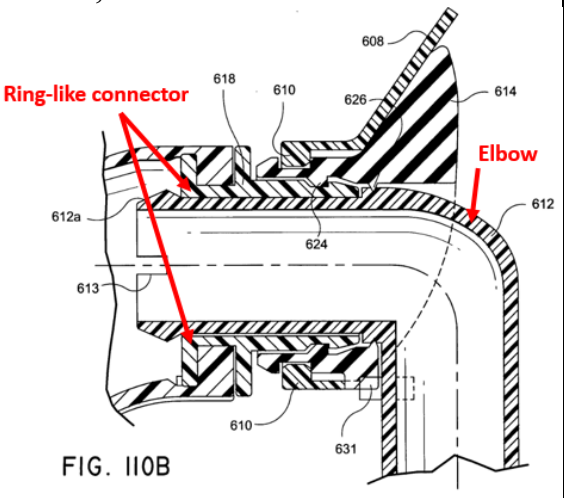
[8.9– 8.11] the first nasal pillow comprising a first outlet opening and the second nasal pillow comprising a second outlet opening (8.9) the mask body also comprising a mask body inlet opening (8.10) the mask body inlet opening being spaced apart from the first outlet opening and the second outlet opening (8.11)	The outlets of the nasal pillows are at the end of the conical portion of the nasal pillow that rests within a user's nares (with both the nasal pillows shown in *Lovell* or *Gunaratnam*). The mask body inlet opening (e.g., the inlet 32 of lower shell 8 into which air enters the mask body) is spaced apart from the nasal pillow outlets, as shown in Fig. 1B.
[8.12] the mask body sized and shaped to leave the mouth of a user uncovered by the mask body when in use	As shown in Figure 5, *Lovell's* mask body is sized and shaped to leave the mouth of the user uncovered by the mask body when in use. *See* RMD1012, 2:33-35 ("[D]evices of the invention seal with the external skin surrounding the nares at the base of the nose and/or along the inner rim of the nares of a user."); *id*. at 2:36-40.

[8.13] the mask body inlet opening comprising a generally circular opening into the mask body	First referring first to the reading where *Lovell's* swivel connector 12 is the claimed ring-like connector and thus the claimed mask body is the combination of *Lovell's* retainer 10, lower shell 8, upper shell 6, malleable element 4 and seal 2, the *Lovell* mask body has a generally circular inlet as inlet 32 of lower shell 8 (*see* Fig. 2B). That inlet 32 is a generally circular opening into the mask body. Second referring to the reading where *Lovell's* lower shell 8 is the claimed ring-like connector and thus the claimed mask body is the combination of *Lovell's* upper shell 6, malleable element 4 and seal 2, the *Lovell* mask body has a generally circular perimeter around an opening for air to enter into the mask body and from there out the nasal pillows. *See* RMD1012, Fig. 1A.

[8.14] the mask assembly having a ring-like connector releasably connected to the mask body inlet	As mentioned, the claimed ring-like connector reads on *Lovell* in two respects. First, *Lovell* discloses a "ring-like connector" as swivel connector 12, and the ring-like connector (swivel connector 12) is releasably connected with the mask body inlet. Specifically, a portion of the swivel connector 12 fits within an inlet 32 of the lower shell 8, as shown in Fig. 4B. *See also* RMD1012, 5:24-32 ("The nasal mask 1 includes an inlet 32 into which a swivel connector 12 fits. The swivel connector 12 has a slightly concave shape on the end that fits into the inlet 32. . . . The connection between the inlet 32 and the swivel connector 12 . . . can be a selectively removable connection.").  Second, *Lovell* discloses a ring as lower mask shell 8 (this structure meets the "ring" limitation as properly interpreted under Section VI.A), and discloses that this ring (lower shell 8) is engaged with an inlet of structure constituting a mask body. Specifically, the lower shell 8 engages with upper shell 6 of the mask body, as shown in Fig. 4B. *See also* RMD1012, col. 4:38-40. *Lovell* further discloses a "ring-like connector" as swivel connector 12, and the ring-like connector (swivel connector 12) is releasably connected with the mask body inlet. Specifically, a portion of the swivel connector 12 fits within an inlet 32 of the lower shell 8, as shown in Fig. 4B. *See also* RMD1012, col. 5:24-32 ("The nasal mask 1 includes an inlet 32 into which a swivel connector 12 fits. The swivel connector 12 has a slightly concave shape on the end that fits into the inlet 32. . . . The connection between the inlet 32 and

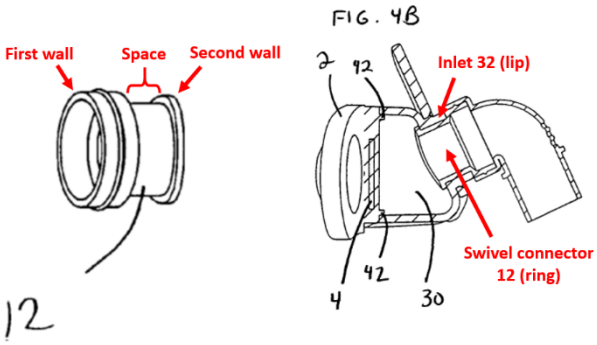
	the swivel connector 12 . . . can be a selectively removable connection.").
[8.15] wherein a plane bisects the ring-like connector and the first nasal pillow is located on a side of the plane opposite the second nasal pillow	The ring-like connector (swivel connector 12 or lower mask shell 8) is generally located at the center of the mask in *Lovell*'s design. Therefore, if one were to consider a vertical plane that bisected the ring-like connector (swivel connector 12), that plane would lie between each of the two nasal pillows such that the two pillows would be located on opposite sides of the plane.
[8.16–8.18] a tube assembly configured to deliver airflow to the mask body (8.16) the tube assembly comprising a flexible conduit (8.17) the flexible conduit comprising a first end and a second end (8.18)	To the extent that the claimed feature of "a tube or conduit extending from the elbow" is not explicitly shown in *Lovell*, this feature would have been implied or inherent, as a skilled artisan would have understood that a tube or conduit is needed to deliver pressurized air from a source (e.g., a CPAP machine) to the patient interface. *See* RMD1012, 1:12-20 ("In general, a supply of pressurized air or therapeutic gas is provided by a tube or conduit to a delivery apparatus designed to conform to particular body structure."). One of skill would understand that the swivel elbow 14 would connect to a tube and would have looked to other references (such as *Gunararatnam*) to identify a suitable tube assembly. *Gunaratnam* at Fig. 135 shows that the tube attaches to the center of the mask frame for delivering air, that the tube has a first and a second end, and that the tube is flexible (as illustrated by the ridges in the tube). *See* RMD1004 at Figure 135; ¶¶ 0003, 0323, 0340, 0364.

[8.19] the first end of the flexible conduit comprising a connector	As shown in Figure 135 of *Gunaratnam*, a first end of the tube (the lower end of the tube in the figure) comprises a connector. Indeed, with respect to Figure 108, which shows a similar or identical tube, *Gunaratnam* discusses that "[t]he air delivery tube 606 may include a swivel connector 607 and includes an end 609 which also may be provided with a swivel connector. The end 609 is provided with a source of pressurized gas." RMD1004 at ¶ 0377. Such connectors are disclosed throughout the rest of *Gunaratnam*, for example, at Figure 107A (item 660) and Figure 107D (item 704). *See* RMD1004 at ¶¶ 0364 and 0366.
[8.20] the second end of the flexible conduit comprising an elbow	Lovell discloses an elbow (conduit elbow 14) to which the flexible conduit would attach, as described above. Indeed, Lovell names its elbow a "conduit" elbow. RMD1012, Figs. 1, 3A, 4B, 5, 5:26-34 ("A conduit elbow 14 fits onto the swivel connector 12 over a flange 28 on the swivel connector 12. . . . The swivel connector 12 produces a swivel mount connection between the conduit elbow 14 and the inlet 32.").
[8.21–8.23] the elbow comprising a wall (8.21) the wall comprising a vent (8.22) the vent comprising a plurality of holes extending through the wall of the elbow (8.23)	*Lovell* discloses that a wall in elbow 14 comprises a plurality of vent holes, namely apertures 20 that extend through the wall of the elbow. *See Lovell*, Fig. 2B, 5:46-50 ("The conduit elbow 14 is shown with an angled portion of about ninety degrees, as well as apertures 20 as seen in FIG. 2B, only one aperture being labeled for the sake of clarity. These apertures 20 allow the release of gases exhaled by the user."). 

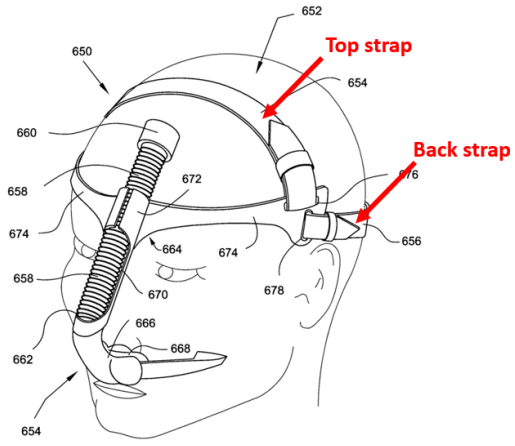
[8.24] the ring-like connector end being secured around an outer portion of the elbow	As mentioned above, the claimed "ring-like connector" in *Lovell* may be the swivel connector 12 or the lower mask shell 8. First, regarding the swivel connector 12 as the ring-like connector, *Lovell* discloses a different configuration in which the conduit elbow 14 fits over the ring-like connector (swivel connector 12), rather than the ring-like connector fitting over the elbow.  FIG. 110B However, one of skill would have seen the choice of which component fits over the other to be an obvious design choice. Indeed, it was well known at the time of the '807 patent for a ring-like connector to be secured around an outer portion of an elbow in order to facilitate rotatable engagement of the elbow. This feature is present in an embodiment of *Gunaratnam* (RMD1004), depicted in Figs. 110B and 111, for example. The modification would simply involve making the elbow 14 a male connector, and the swivel connector 12 a female connector, rather than the reverse as in *Lovell*. One of skill in the art would have recognized that switching the location of the male and female components would be predictable and routine, and would have seen *Gunaratnam's* design in which the ring-like connector is secured around an outer portion of the elbow to be a predictable alternative to *Lovell*'s design. Second, regarding the lower mask shell 8 as the claimed ring-like connector, *Lovell* discloses swivel connector 12 fits into an inlet 32 of lower mask shell 8. *See* RMD1012, Fig. 4B. As such, shell 8 of *Lovell* is

	secured around an outer portion of the elbow (the elbow in *Lovell* being the combination of elbow 14 and connector 12).
[8.25] the elbow and the mask body being connected at least in part by the ring-like connector end such that airflow from the tube assembly can be directed from the elbow through the generally circular opening of the mask body and into the mask body	One of skill would understand that in use, a pressurized flow of gas applied to Lovell's mask would follow a path from the tube or conduit, through the elbow 14, the opening of the mask body, and into the mask body. See, e.g., RMD1012, Lovell, Figs. 1B, 5, 10B.
[8.26] the elbow and the mask body being capable of rotating relative to each other	*Lovell* discloses that the elbow (conduit elbow 14 or alternatively the combination of elbow 14 and connector 12) is rotatably engaged with the ring (swivel connector 12 or lower mask shell 8). RMD1012, Figs. 1, 3A, 4B, 5, 5:26-34 ("A conduit elbow 14 fits onto the swivel connector 12 over a flange 28 on the swivel connector 12. . . . The swivel connector 12 produces a swivel mount connection between the conduit elbow 14 and the inlet 32 [of lower mask shell 8].").

[8.27–8.34] (Headgear Assembly) a headgear assembly configured to secure the mask body to a face of the user	Each of the additional headgear requirements in claim 8 are disclosed in *Gunaratnam*, as set forth in Ground 1. One of skill would have been motivated to apply *Gunaratnam's* headgear to *Lovell's* mask to reduce the number of connections between the headgear and mask. For example, a two-strap connection would be less cumbersome for a patient than a four-strap connection and would result in a simpler design. How to connect the two side straps from *Gunaratnam* to the mask assembly from *Lovell* would be well within the capabilities of a skilled artisan, and would be an obvious implementation detail. For example, the side arms could attach to connection points on *Lovell's* retaining structure 10 or directly to the retaining structure 10, while side arms along the side straps provide added stability. RMD1004, ¶¶ 0369-70, Figs. 107G-H (nasal pillows mask where only two side straps connect to the mask frame via connector portions 766, 770). One of skill would not have agreed with the applicant's argument during prosecution that modifying *Lovell's* mask to connect to only two side straps would "prevent[] the nasal mask from being securely positioned against the nares of a user." RMD1012, Fig. 5, Fig. 1B; RMD1009, pp. 615-616, 620-622; RMD1004, Fig. 135.

[17] A patient interface as claimed in claim 1, wherein the ring comprises a first wall and a second wall defining a space therebetween, and wherein a portion of the mask body is configured to removably attach to the ring via friction within the space and with the first wall and the second wall	 First considering *Lovell's* swivel connector as the claimed ring and that the claimed mask body in *Lovell* includes lower shell 8, *Lovell's* swivel connector 12 includes a first flange 28 on a first side of the connector 12 and a second flange on the opposite side of the connector 12. These flanges are a "first wall" and a "second wall," respectively, which define a space therebetween. *See* RMD1012, Fig. 2B (excerpt of swivel connector 12 copied and annotated below). The portion of the mask body (inlet 32) removably attaches to the ring (swivel connector 12) via friction within the space between the first and second walls (first and second flanges). RMD1012, Fig. 4B (copied and annotated below); 5:24-45. One of skill in the art would have recognized that because the inlet 32 the swivel connector 12 when engaged, friction would necessarily occur between the inlet 32 and swivel connector 12. Even if the ring (swivel connector 12) were modified to form a socket that receives a portion of the elbow 14 *within* the ring, the ring would still include a two walls with a space therebetween. Alternatively considering *Lovell's* lower mask shell 8 to be the claimed ring and that the claimed maks body in *Lovell* includes upper shell 6, *Lovell* discloses the upper mask shell 6 (i.e., the part of the mask body to which shell 8 is engaged) having a flange 42 (*see* Fig. 4B), which flange 42 allows the lower mask shell 8 to seat the upper mask shell 6 so the two parts can be affixed together. *See* RMD1012, Fig. 4B and col. 4:38-

	52. One of skill at a time before the '807 patent would have understood that the lip and channel arrangement in *Lovell* may be modified so that the lip of the upper mask shell 6 fits into a channel or "open space" of two walls provided in the lower mask shell 8 (ring), to provide an arrangement wherein the two parts (lower mask shell 8 and upper mask shell 8) can be connectable and disconnectable by friction fit, to provide for ease of user cleaning the mask components between uses. Such a configuration of two mask components is disclosed, for example, in *Gunaratnam* when read in view of further detail provided in *Ging*. *See* Discussion of claims 2 and 17 under Ground 1.
[18, 19] A patient interface as claimed in claim 1, wherein the top strap is integrally formed with one or more of the side straps and the back strap" (claim 18) A patient interface as claimed in claim 18, wherein the top strap is integrally formed with one or more of the side straps (claim 19)	The patient interface disclosed in *Lovell* as modified to include the headgear assembly of *Gunaratnam*'s Fig. 135 design would include the features of claims 18 and 19. *Gunaratnam* discloses the additional feature of a top strap being integrally formed with one or more of the side straps and the back strap. In Figure 135 for example, respective sides of the top strap are integrally formed with one or more of the side straps and the back strap (claim 18), and meets the feature of the top strap being integrally formed with one or more of the side straps (claim 19). *See* RMD1004, *Gunaratnam*, Figs. 107, 107-1, 107-2, and 107G-F (showing additional integrally formed headgear configurations), ¶ 213 (noting that the headgear assembly 20 in some embodiments "may be constructed as a one piece structure"). It would have been obvious for a person of ordinary skill in the art to apply these various headgear designs to the Figure 135 design in *Gunaratnam* to reduce the effort required of the patient to make connections between the headgear and mask.

[20, 21] A patient interface as claimed in claim 8, wherein the top strap is integrally formed with one or more of the side straps and the back strap (claim 20) A patient interface as claimed in claim 20, wherein the top strap is integrally formed with one or more of the side straps (claim 21)	This feature is disclosed by *Gunaratnam's* headgear, as described with respect to Ground 1.
[24, 25] A patient interface as claimed in claim 1, wherein the top strap is releasably connected to one or more of the side straps and the back strap (claim 24) A patient interface as claimed in claim 24, wherein the top strap is releasably connected to the back strap (claim 25)	The patient interface disclosed in *Lovell* as modified by *Gunaratnam* would include the features recited in claims 24 and 25. The feature of claim 24 is disclosed in *Gunaratnam*, as explained in Ground 1. Moreover, *Gunaratnam* discloses the top strap being releasably connected to the back strap, as recited in claim 25, in the headgear design depicted in Fig. 107A (copied and annotated at right). Fig. 107A shows the top strap 654 being releasably connected to the back strap 656 through a support arm 675. *See* RMD1004, Fig. 107A. One of skill would have found it obvious to provide releasable connections among the top strap and the side straps or the top strap and the rear strap to allow the user more flexibility in sizing the headgear assembly and for the headgear to be more easily removed by the releasable connections.  FIG. 107A

[26, 27] A patient interface as claimed in claim 8, wherein the top strap is releasably connected to one or more of the side straps and the back strap (claim 26) A patient interface as claimed in claim 26, wherein the top strap is releasably connected to the back strap (claim 27)	The patient interface disclosed in *Lovell* as modified by *Gunaratnam* would include the features recited in claims 26 and 27. The feature of claims 26 and 27 is disclosed in *Gunaratnam*, as explained in Ground 1. Fig. 107A of *Gunaratnam* also shows the top strap 654 being releasably connected to the back strap 656 through a support arm 675. *See* RMD1004, Fig. 107A. One of skill would have found it obvious to provide releasable connections between the top strap and the rear strap to allow the user flexibility in sizing the headgear and for the headgear to be more easily removed by the releasable connections.

3. Supplemental Analysis Of Individual Claim Limitations

190. In addition to the analysis embodied in the claim chart shown in Section VIII.D.262 above, I offer the following observations regarding certain elements of the claims that supplement the analysis in the claim chart, and that support my opinion that the combination of *Lovell* and *Gunaratnam* renders obvious each of claims 1-8, 17-21, and 24-27 of the '807 patent.

a) Limitations 1.3-1.4

191. I understand that claim 1 recites "a mask body including two nasal pillows extending from it, which in use rest in a substantially sealed manner against the nares of a user," and "the mask body sized and shaped to leave the mouth of the user uncovered by the mask body when in use."

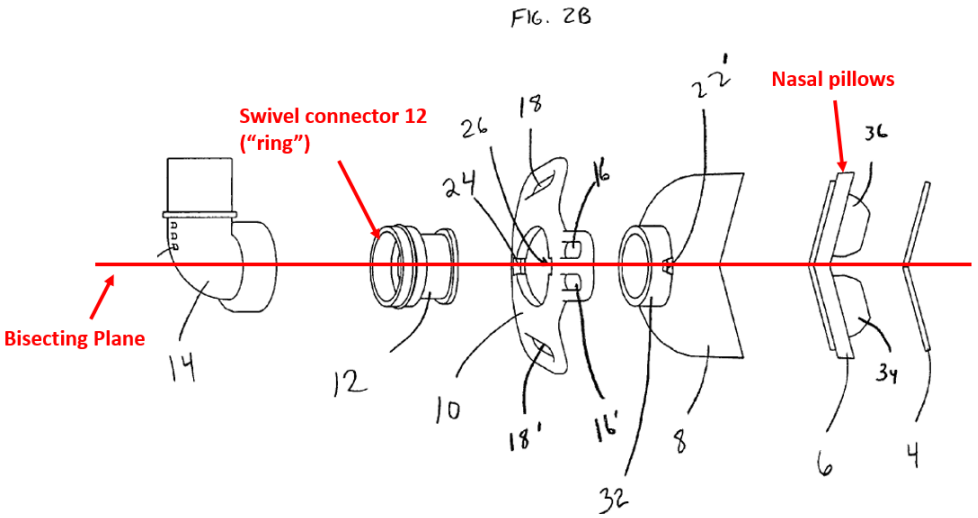
192. *Lovell's* mask body (whether considering the mask body to be the combination of lower shell 8, upper shell 6, element 4 and seal 2, or alternatively just shell 6, element 4 and seal 2) includes two nasal pillows as domes 38, 40 on seal 2, or as domes 38, 40 together with the two outlets 34, 36 on the upper shell 6 extending from the mask body. RMD1012, 8:51-54 ("[T]he seal 2 has two domes 38, 40 that cover the two outlets 34, 36."). In my opinion, one of ordinary skill in the art would have understood that *Lovell's* nasal pillows rest, in use, in a substantially sealed manner against the nares of a user. One of ordinary skill also would have understood that the mask body is sized and shaped to leave the mouth of the user uncovered by the mask body when in use. *See* RMD1012, 2:33-35 ("[D]evices of the invention seal with the external skin surrounding the nares at the base of the nose and/or along the inner rim of the nares of a user.."); *id.* at 8:59-61 ("The contact, between the seal 2 and the external skin surrounding the nares at the base of the nose and/or the inner rim of the nares is minimal."); *id.* at Fig. 5 (showing the user's mouth uncovered while donning the nasal mask).

b) Limitation 1.6

193. I understand that claim 1 recites "a plane substantially bisecting the ring, each of the two nasal pillows positioned on opposite sides of the plane." As I have previously noted, I agree with Petitioners' proposed construction of this claim

element as referring to the requirement that the ring be located generally at the front center of the mask.

194. In my opinion, this feature is met by the patient interface disclosed in *Lovell*. In particular, the ring (swivel connector 12 or alternatively lower shell 8) is generally located at the front center of the mask in *Lovell*'s design. Therefore, if one were to consider a vertical plane that bisected the ring-like connector (swivel connector 12), that plane would lie between each of the two nasal pillows such that the two pillows would be located on opposite sides of the plane. This would have been apparent to one of ordinary skill in the art at the time of the '807 patent, and is conceptually illustrated in annotated Figure 2b from *Lovell*, copied below:



c) Limitation 1.8

195. I understand that claim 1 recites "the ring forming a socket into which a portion of the elbow fits to facilitate the rotatable engagement between the elbow and the ring."

196. First considering *Lovell's* elbow 14 as the claimed elbow and swivel connector 12 as the claimed "ring," *Lovell* does not expressly disclose this feature because elbow 14 fits over connector 12 instead of into connector 12. But in my opinion, such a configuration would have been obvious to one of ordinary skill in the art in light of the teachings of *Gunaratnam* (RMD1004). In particular, *Lovell* discloses a configuration in which the elbow fits *over* the ring (swivel connector 12), rather than within it. However, one of skill would have seen the choice of which component fits over the other to be an obvious design choice. As evidenced by *Gunaratnam*, it was well known at the time of the '807 patent for elbows to fit *within* a socket of a mask assembly, to facilitate rotatable engagement of the elbow. For example, the design depicted in Figs. 110B (copied and annotated below) and 111, show that the modification would simply involve making the elbow 14 a male connector, and the swivel connector 12 a female connector, rather than the reverse as in *Lovell*'s preferred embodiment. Absent special considerations not applicable to *Lovell*'s design, one of skill in the art would have recognized that switching the location of the male and female components would

be predictable and routine, and would have seen *Gunaratnam's* design in which the elbow fits within a socket to be a predictable alternative to *Lovell*'s design. *See also supra* at ¶¶ 33-35.

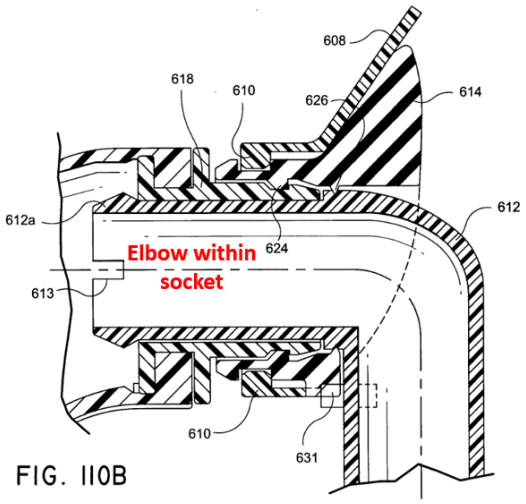


FIG. 110B

Alternatively considering *Lovell's* elbow 14 and swivel connector 12 as the claimed elbow and the lower shell 8 as the claimed "ring," the "fits into" limitation is met, because swivel connector fits into lower shell 8.

d) Limitation 1.10

197. I understand that claim 1 recites "a tube or conduit extending from the elbow." One of ordinary skill in the art would have recognized this feature as being disclosed expressly or at least inherently in the design of *Lovell's* nasal mask, as a tube or conduit is generally required to deliver pressurized air from a source (e.g., a CPAP machine) to the patient interface. *See* RMD1012, 1:18-20 ("In general, a supply of pressurized air or therapeutic gas is provided by a tube or

conduit to a delivery apparatus designed to conform to particular body structure."). Such a tube or conduit as claimed is further disclosed in *Gunaratnam's* Fig. 135 design. *See, e.g.*, RMD1004, Fig. 135 (showing a tube or conduit connected to the front of the mask assembly, extending from the swivel elbow).

e) Limitations 1.11-1.17

198. I understand that claim 1 further requires a headgear assembly that includes two side straps, a top strap, and a back strap, which have particular features set forth in limitations 1.11-1.17. The particular language of the respective limitations is mentioned in Section VIII.B above (Ground 1). In my opinion, each of these features is disclosed in *Gunaratnam*, as explained in Section VIII.B above (Ground 1). Moreover, I believe that an ordinary skilled artisan would have found it predictable to apply *Gunaratnam's* headgear designs (e.g., the headgear assembly shown in Fig. 135 of *Gunaratnam*) to *Lovell*'s patient interface, and would have seen reason to do so to enhance the comfort and fit of *Lovell's* mask and to reduce the burdens of donning and removing the mask. *See supra* ¶¶ 36-38.

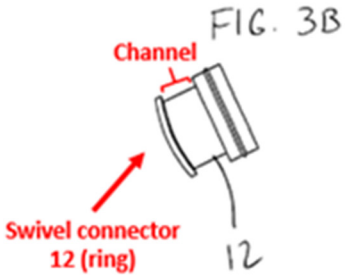
199. In my opinion, the particular manner in which the two side straps from *Gunaratnam* connect to the mask assembly from *Lovell* would be well within the capabilities of one of ordinary skill in the art to determine, and would have been an obvious implementation detail. For example, the side arms could attach

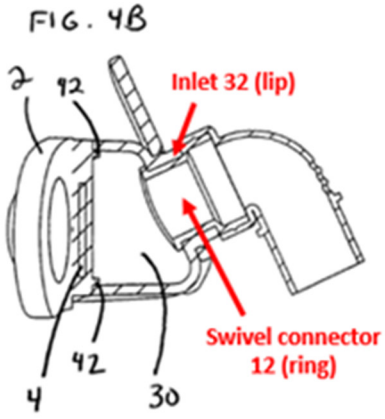
directly to a pair of connection points on *Lovell's* retaining structure 10. Alternatively, the two side straps could connect directly to the retaining structure 10, while side arms run along the side straps for added stability. RMD1004, ¶¶ 0369-70, Figs. 107G-H (showing a nasal pillows mask in which only two side straps connect directly to the mask frame via connector portions 766, 770).

f) Claim 2

200. I understand that claim 2 depends from claim 1 and further recites "wherein the mask body includes a lip and the ring includes a channel receiving the lip of the mask body." In other words, this claim recites a technique that was conventional before the '807 patent regarding how two-point mask assemblies were connected together.

201. First considering the reading wherein *Lovell's* swivel elbow 12 is the claimed ring and *Lovell's* lower shell 8 is part of the claimed mask body, the inlet 32 of *Lovell's* lower shell 8 forms the claimed "lip" of the mask body. The central section of the ring (swivel connector 12) forms the claimed "channel" of the ring. When *Lovell's* nasal mask is assembled, the channel of the ring (swivel connector 12) receives the lip (inlet 32) of the mask body. This feature is represented in Figs. 3B and 4B of *Lovell* (RMD1012).





Second considering the reading wherein *Lovell's* lower shell 8 is the claimed ring and *Lovell's* upper shell 6, malleable element 4 and seal 2 are the claimed mask body, the lower shell 8 (the ring) has a lip (the perimeter of the shell 6 facing upper shell 6 as shown in Figure 1B) and the upper shell 6 would have a channel into which the lip of lower shell would fit. As I have testified elsewhere, lip and channel connection configurations were well known in this art, and it would have been obvious to put the lip and channel on either of these two components to be able to allow a user to take then apart, for example to clean them.

202. One of skill would have recognized that, even if the swivel connector 12 were modified to form a socket that receives a portion of elbow 14 *within* the connector 12 instead of over it, the swivel connector 12 would still include a channel for the lip of the mask body to go into.

g) Claim 3

203. I understand that claim 3 depends from claim 2 and further recites "wherein the mask body comprises a molded elastomeric material." *Lovell* discloses that the seal 2 of the mask body comprises silicone, which one of skill in the art would have understood is a molded elastomeric material. RMD1012, 7:35-45 (the seal 2 may be a "bladder . . . that is filled with a soft material 62" such as "molded silicone."). Indeed, silicone is used in many applications due to its elastomeric qualities that provide a durable, flexible material. An elastomeric material generally refers to material that approximates the elastic qualities of rubber. Silicone is elastomeric in the sense that it is soft, flexible, and generally elastic. Indeed, even the '807 patent acknowledges that silicone is a substantially flexible material. RMD1001 at 5:36-40 ("The body and pillows are preferably integrally moulded in a substantially flexible plastics material. In the preferred form this material is silicone, but other appropriate materials, such as, rubber, thermoset elastomer or thermoplastic elastomer, such as Kraton™ may be used."). Thus this feature from claim 3 would have been implied or inherent in *Lovell*'s design. *See, e.g.*, U.S. Pat. 4,782,832 to *Trimble* et al (RMD1019) at 2:42-45, 4:51-56, 5:6-10, 6:1-5; U.S. Pat. 6,431,172 to Bordewick (RMD1020) at 3:30-43, 3:54-58; U.S. Pat. 7,219,669 to *Lovell* et al. (RMD1012) at 2:48-55, 4:43-48; *Gunaratnam* (RMD1004) at ¶¶ 182, 191-92.

h) Claim 4

204. I understand that claim 4 depends from claim 1 and further recites "wherein the elbow is able to swivel in the ring such that the tubing is available to be adjacent to either side strap." In *Lovell's* design, "the conduit elbow 14 is capable of being rotated 360 degrees about an axis extending through the center of the inlet 32." RMD1012, 5:34-37. Given that the elbow 14 is located at the front, center of the mask, and that the elbow is capable of swiveling in the ring 360 degrees, one of ordinary skill would have recognized that the tubing connected to the elbow in *Lovell's* design would be available to be adjacent to any of the straps, including a side strap. Moreover, if the modified patient interface of claim 1, in which the headgear assembly from *Gunaratnam* Fig. 135 is applied to *Lovell*'s mask assembly, it is my opinion that the elbow 14 would be capable of swiveling in the ring such that the tubing would be available to be adjacent to either side strap. *See also supra* discussion of claim 4 at paragraphs 109-110 (explaining that *Gunaratnam's* design in Figure 135 also meets the additional limitation of claim 4).

i) Claim 5

205. I understand that claim 5 depends from claim 1 and further recites "wherein the ring comprises a hard plastic material." Although *Lovell* does not expressly disclose the material of the ring (swivel connector 12) as a hard plastic,

one of ordinary skill in the art would have recognized that such a material choice would have been obvious in the context of *Lovell*'s design. For example, the ring (swivel connector 12) would necessarily be "hard" in order to provide the structural support required to facilitate the swivel connection between the elbow 14 and the mask body. With respect to the requirement that the ring be made of a plastic material, this would too was a conventional material choice at the time of the '807 patent. For example, *Gunaratnam* teaches that components of a mask assembly may be made from rigid polymer materials, which one of ordinary skill would understand to include hard plastics. *See* RMD1004, ¶¶ 0004, 0255. Plastics were beneficial due to their ability to be molded and extruded into particular shapes and to be mass-produced in a cost-effective manner.

j) Claim 6

206. I understand that claim 6 depends from claim 1 and further recites "further comprising molded side arms extending away from the ring to connect with the side strap, the molded side arms connecting to the side straps that pass down the cheeks of the user." In my opinion, this feature would have been present in the patient interface design disclosed in *Lovell* as modified by *Gunaratnam*. For example, the side arms (yokes) from *Gunaratnam's* Figure 135 design would connect to the mask body in *Lovell*, and would extend away from the ring (swivel connector 12) to connect with the side straps. Regarding the requirement that the

side arms be "molded," such feature would have been an implied or inherent feature of the yokes 608 in *Gunaratnam*, or at a minimum would have been an obvious design choice.

207. For example, *Gunaratnam* teaches that the yokes can be made of a rigid plastic material. *See* RMD1004 at ¶ 315 ("The headgear yoke 580 acts as a stiffener to add rigidity to the headgear assembly 520. . . . In FIG. 60, the yoke 580 is a semi-rigid layer, such as plastic, which is provided to, e.g., sewn onto, the headgear straps 598 and/or 599."); *see also id.* at ¶¶ 0376, 0379, 0390. One of skill would have understood at the time of the '807 patent that molding was a conventional technique in manufacturing three-dimensional plastic components. In my opinion, molding the yokes disclosed in *Gunaratnam* and *Ging* would have been an obvious design choice to achieve predictable results, such as low-cost, highly replicable components capable of being manufactured at a high volume. Moreover, it was well-known at the time of the '807 patent, even for CPAP patient interfaces, to manufacture yokes in a headgear assembly from molded plastics. *See* RMD1037, *Lau*, 2:50-52 ("Preferably, the headgear yoke sections are molded from a single type of material . . . ."); *id.* at 3:9-11 (stating that the "yoke side sections" in a headgear assembly could be "molded from a semi-rigid plastic").

k) Claim 7

208. I understand that claim 7 depends from claim 1 and further recites "wherein, in use, gases flow from the tube or conduit, through the elbow, through the ring, through the mask body and through the pillows." In my opinion, one of ordinary skill in the art would have understood that in use, a pressurized flow of gas applied to *Lovell*'s mask would follow a path from the tube or conduit, through the elbow 14, through the ring (swivel connector 12), through the mask body, and through the pillows (nasal pillows seal 2). *See, e.g.*, RMD1012, *Lovell*, Figs. 1B, 5, 10B.

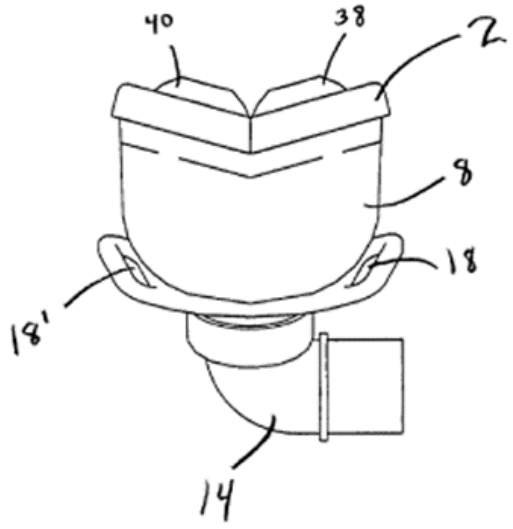
l) Claim Limitation 8.4

209. I understand that claim 8 recites "the mask body comprising a substantially flexible elastomeric material." *Lovell* discloses that the seal 2 of the mask body comprises silicone, which one of skill in the art would have understood is a substantially flexible elastomeric material. RMD1012, 7:35-45 (the seal 2 may be a "bladder . . . that is filled with a soft material 62" such as "molded silicone."). Indeed, silicone is used in many applications due to its elastomeric qualities that provide a durable, flexible material. An elastomeric material generally refers to an elastic material that approximates the elastic qualities of rubber. Silicone is elastomeric in the sense that it is soft, flexible, and generally elastic. Indeed, even the '807 patent acknowledges that silicone is a substantially flexible material.

RMD1001 at 5:36-40 ("The body and pillows are preferably integrally moulded in a substantially flexible plastics material. In the preferred form this material is silicone, but other appropriate materials, such as, rubber, thermoset elastomer or thermoplastic elastomer, such as Kraton™ may be used."). Thus this feature from claim 8 would have been implied or inherent in *Lovell*'s design. *See, e.g.*, U.S. Pat. 4,782,832 to *Trimble* et al (RMD1019) at 2:42-45, 4:51-56, 5:6-10, 6:1-5; U.S. Pat. 6,431,172 to Bordewick (RMD1020) at 3:30-43, 3:54-58; U.S. Pat. 7,219,669 to *Lovell* et al. (RMD1012) at 2:48-55, 4:43-48; *Gunaratnam* (RMD1004) at ¶¶ 182, 191-92.

m) Claim Limitations 8.5, 8.6

210. I understand that claim 8 recites "the mask body comprising a first nasal pillow and a second nasal pillow (8.5), the first nasal pillow and the second nasal pillow being angled toward one another (8.6)." In my opinion, this feature is taught by *Lovell*. *Lovell's* mask body includes (i) two nasal pillows as domes 38, 40 on seal 2, or (ii) as domes 38, 40 on seal 2 together with the two outlets 34, 36 on the upper shell 6 extending from the mask body. RMD1012, 8:51-52 ("[T]he seal 2 has two domes 38, 40 that cover the two outlets 34, 36."). The domes 38 and 40 are angled toward each other, as clearly shown by Figure 2A (copied below).



n) Claim Limitations 8.7, 8.8

211. I understand that claim 8 recites "the first nasal pillow comprising a first generally conical portion and a first generally cylindrical portion" (8.7) and "the second nasal pillow comprising a second generally conical portion and a second generally cylindrical portion (8.8)." Regarding the geometry of its nasal pillows, the '807 patent states that "[t]he nasal pillows 24, 25 are preferably frustoconical in shape and in use rest against a patient's nares, to substantially seal the patient's nares" and "[t]he nasal pillows 24, 25 are preferably an elliptical cone and as such are tubular and allow for a passage of gases to flow from the tubing 3 and through the mask body 23." RMD1001 at 5:29-31, 5:41-43. Although the text of the '807 patent does not specifically distinguish the conical and cylindrical portions of the nasal pillows 24, 25, claim 8 appears to refer to the following

portions of the nasal pillows type mask body 23 as the "generally cylindrical" and "generally conical" portions, annotated in Fig. 7 below:

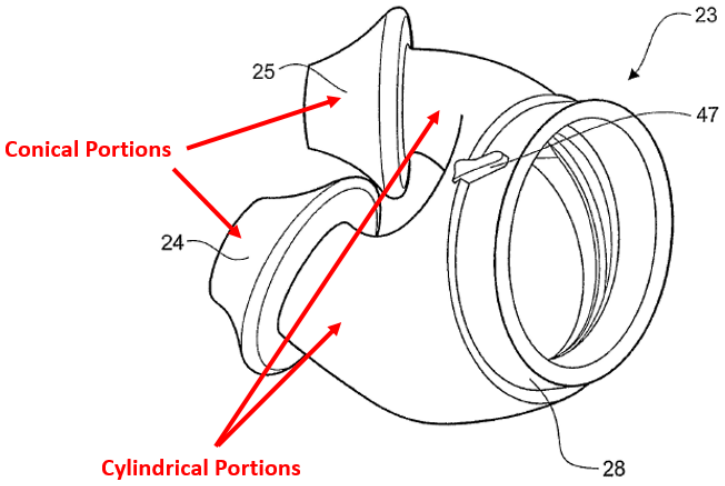
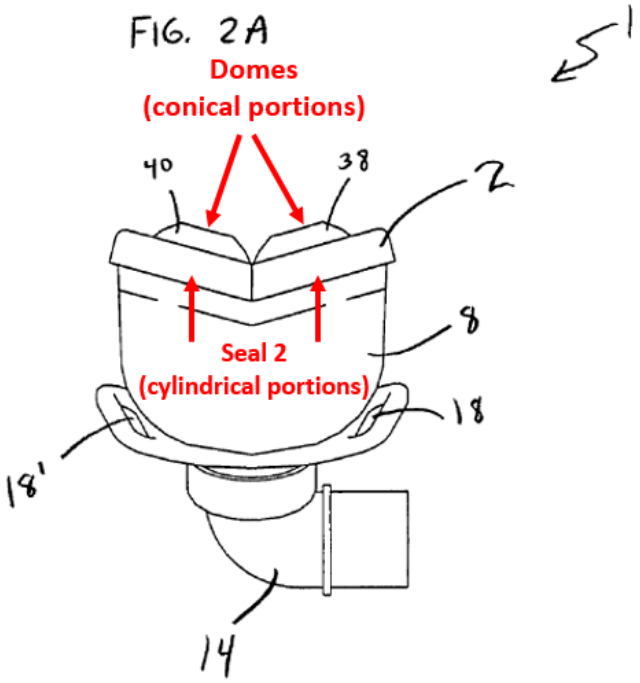


FIGURE 7

212. In my opinion, each of *Lovell's* nasal pillows includes a conical "dome 38" or "dome 40" and a corresponding portion of the "seal 2" that is generally cylindrical. *See* RMD1012, Figures 1A-2B and 8A. Figure 2A is copied and annotated below for reference.



213. Moreover, CPAP masks with pillows having the claimed geometries were well known in the art at the time of the '807 patent. For example, *Gunaratnam* discloses that the first and second nasal pillows (e.g., nozzles 50 of nozzle assembly 18, depicted in FIGs. 5 and 6) each comprise a generally conical portion and a generally cylindrical portion. In particular, *Gunaratnam* describes that each of the nozzles 50 has a first portion 56 and a second portion 58. The first portion 56 of each nozzle 50 is generally cylindrical, while the second portion 58 of each nozzle is generally conical. *See* RMD1004, *Gunaratnam*, Figs. 1, 5-6, ¶¶ 0185, 189-90. These features are shown in Figure 6 of *Gunaratnam*, which is copied and annotated below. *See also* RMD1009, p. 589 (Examiner reached same read).

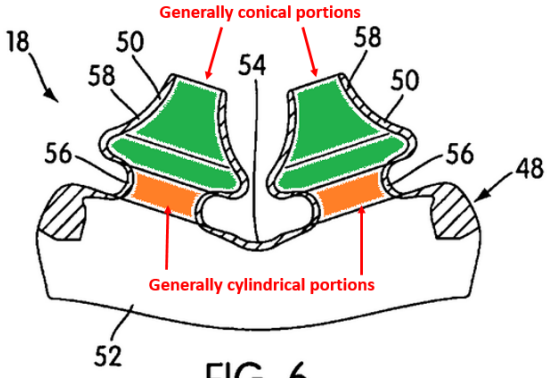


FIG. 6

214. *Gunaratnam* further discloses an alternate nozzle structure in Figure 107N that would be applicable to nozzle assembly 18 or other nasal pillows mask bodies. The Figure 107N structure clearly has a generally conical portion and a generally cylindrical portion, as shown in the annotated Figure 107N at right.

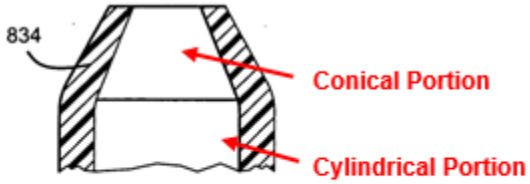


FIG. 107N

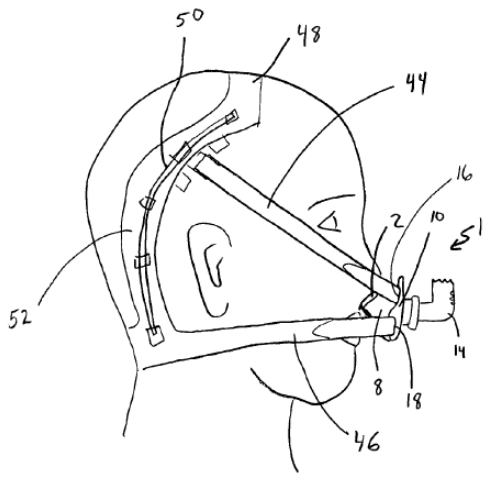
215. A skilled artisan would have seen reason to modify *Lovell* to have pillow cushions with the shapes disclosed by the various pillow cushions in *Gunaratnam* because these designs provided a mechanism to "sealingly engage with nasal passages 12 of the patient's nose 14." RMD1004 at ¶ 185, 190 ("the first portion 56 of the nozzles 50 have [sic] a reduced cross-section with respect to the second portion 58 to allow the nozzles 50 to move relative to the base portion 48, and hence the frame 16, for increased comfort and accommodation of

variations in patient facial features."). The modification of *Lovell* by *Gunaratnam* in this regard would thus have been a predictable choice yielding predictable results.

o) Claim Limitation 8.12

216. I understand that claim 8 recites "the mask body sized and shaped to leave the mouth of a user uncovered by the mask body when in use." In my opinion, this feature is taught by *Lovell*. In particular, *Lovell*'s patient interface employs a nasal pillows design. One of ordinary skill would have understood that nasal pillows designs generally, including the design disclosed in *Lovell*, were configured with mask bodies that rested in or against the nares of the user, but left the mouth of the user uncovered while in use. In this way, patients could breathe through their mouths at appropriate times, and nasal pillows provided a lightweight alternative to full face masks for patients that breathed through their nose during sleep. Figure 5 of *Lovell* (copied below) shows the patient interface and mask body in use, where the mouth of the user is uncovered by the mask body.

FIG. 5



217. To the extent that *Lovell* does not expressly discuss this feature (e.g., because it is implied or inherent in the design), *Gunaratnam* also discloses, for example, in Figure 135 a nasal cushion that is sized and shaped to cover only the nose of the user, and to leave the mouth of the user uncovered by the cushion. In addition, if the nasal cushion shown in Figure 135 of *Gunaratnam* was replaced with a nasal pillows cushion shown in other patient interface designs of *Gunaratnam*, such as in Figure 1 (as would have been obvious, as discussed above), the nasal pillows cushion in the resulting patient interface would also leave the mouth of the user uncovered when in use. To the extent that the view shown in Fig. 1 of *Gunaratnam* does not explicitly show the mouth uncovered, *Gunaratnam* further shows this feature, for example, in Figures 25, 36-38, 51-52 and 59, examples of which are copied below:

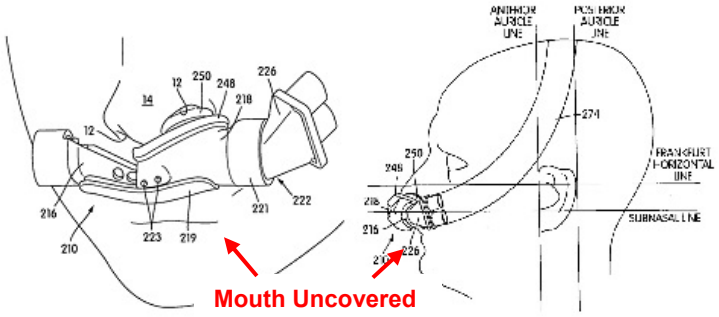
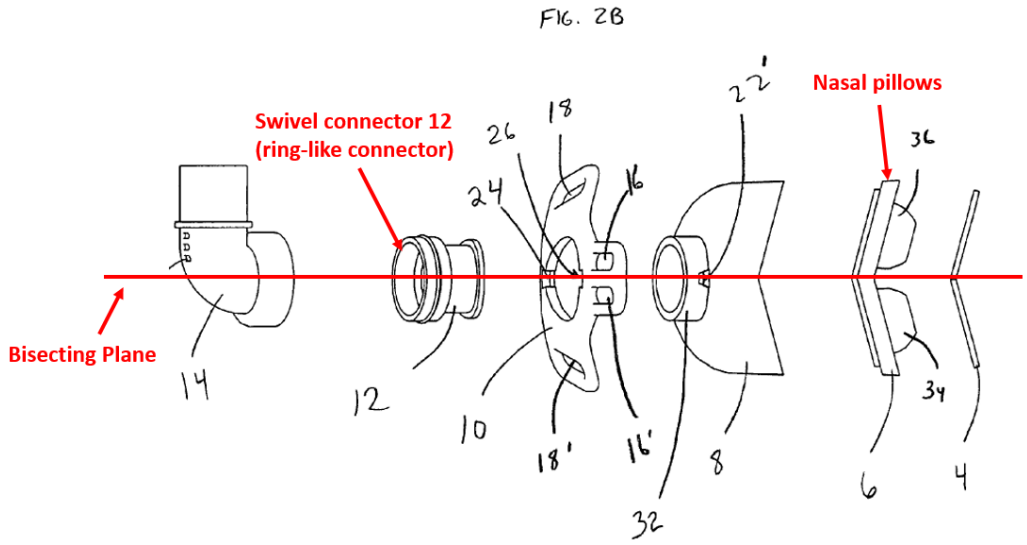


FIG. 25 FIG. 36

p) Claim Limitation 8.15

218. I understand that claim 8 recites "wherein a plane bisects the ring-like connector and the first nasal pillow is located on a side of the plane opposite the second nasal pillow." As I have previously noted, I agree with Petitioners' proposed construction of this claim element as referring to the requirement that the ring-like connector be located generally at the front center of the mask.

219. In my opinion, this feature is met by the patient interface disclosed in *Lovell*. In particular, the ring-like connector (swivel connector 12) is generally located at the front center of the mask in *Lovell*'s design. Therefore, if one were to consider a vertical plane that bisected the ring-like connector (swivel connector 12), that plane would lie between each of the two nasal pillows such that the two pillows would be located on opposite sides of the plane. This would have been apparent to one of ordinary skill in the art at the time of the '807 patent, and is conceptually illustrated in annotated Figure 2b from *Lovell*, copied below:



q) Claim Limitations 8.16-8.18

220. I understand that claim 8 recites "a tube assembly configured to deliver airflow to the mask body (8.16), the tube assembly comprising a flexible conduit (8.17), the flexible conduit comprising a first end and a second end (8.18)." In my opinion, to the extent that these features are not expressly described in *Lovell*, one of ordinary skill in the art would have understood that these features were implied or inherent in *Lovell's* patient interface, as it was widely recognized that a tube or conduit is needed to deliver pressurized air from a source (e.g., a CPAP machine) to the patient interface. *See* RMD1012, 1:12-20("In general, a supply of pressurized air or therapeutic gas is provided by a tube or conduit to a delivery apparatus designed to conform to particular body structure."). One of ordinary skill would have understood that the swivel elbow 14 in *Lovell*, in practice, would connect to an air delivery tube and would have looked to other

references (such as *Gunararatnam*) to identify a suitable tube assembly. *Gunaratnam* at Fig. 135, for example, shows that the tube attaches to the front center of the mask frame for delivering air, that the tube has a first and a second end, and that the tube is flexible (as illustrated by the ridges in the tube). *See* RMD1004 at Figure 135; ¶¶ 3, 323, 340, 364. The modification of *Lovell*'s design to incorporate a tube assembly like that shown in Fig. 135 of *Gunaratnam* would have been no more than an obvious design choice to achieve a well understood and common function of transporting air from a blower apparatus to a mask assembly.

r) Claim Limitation 8.24

221. I understand that claim 8 recites "the ring-like connector end being secured around an outer portion of the elbow."

222. First referring to the reading where *Lovell's* swivel connector 12 is the claimed ring-like connector (or ring-like connector end), *Lovell* does not expressly disclose this feature because the swivel connector 12 is secured within the outer portion of the elbow 14 instead of around it as claimed, but in my opinion such a configuration would have been obvious to one of ordinary skill in the art in light of the teachings of *Gunaratnam* (RMD1004). In particular, *Lovell* discloses a configuration in which the elbow fits *over* the ring-like connector (swivel connector 12), rather than the ring-like connector being secured around an outer portion of the elbow. However, one of skill would have seen the choice of which

component fits over the other to be an obvious design choice. As evidenced by *Gunaratnam*, it was well known at the time of the '807 patent for elbows to fit *within* a ring-like connector of a mask assembly, to facilitate rotatable engagement of the elbow. For example, the design depicted in Figs. 110B (copied and annotated below) and 111, show that the modification would simply involve making the elbow 14 a male connector, and the swivel connector 12 a female connector, rather than the reverse as in *Lovell*'s preferred embodiment. Absent special considerations not applicable to *Lovell*'s design, one of skill in the art would have recognized that switching the location of the male and female components would be predictable and routine, and would have seen *Gunaratnam's* design in which the elbow fits within a socket to be a predictable alternative to *Lovell*'s design.

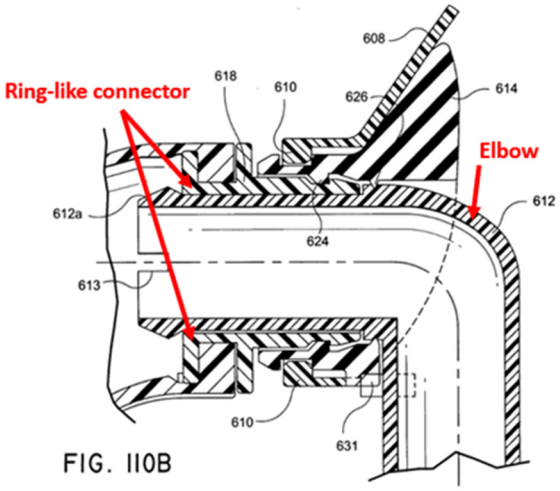
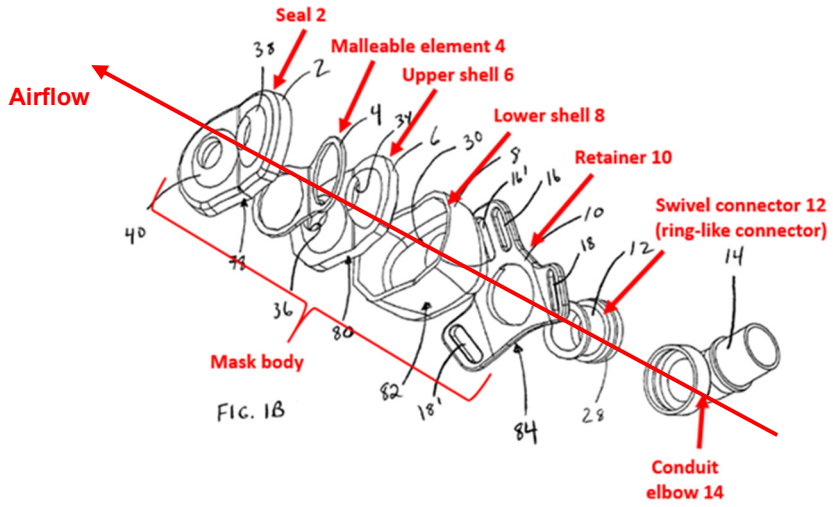


FIG. 110B

Alternatively regarding the lower mask shell 8 as the claimed ring-like connector, Lovell discloses that swivel connector 12 fits into an inlet 32 of lower mask shell 8. See RMD1012, Fig. 4B. As such, shell 8 of Lovell is secured around an outer portion of the elbow (the elbow in Lovell being the combination of elbow 14 and connector 12).

s) Claim Limitation 8.25

223. I understand that claim 8 recites "the elbow and the mask body being connected at least in part by the ring-like connector end such that airflow from the tube assembly can be directed from the elbow through the generally circular opening of the mask body and into the mask body." In my opinion, this feature is taught at least by *Lovell*. One of skill would understand that in use, a pressurized flow of gas applied to *Lovell*'s mask would follow a path from the tube or conduit, through the elbow 14, the opening of the mask body, and into the mask body. *See, e.g.*, RMD1012, *Lovell*, Figs. 1B, 5, 10B.



t) Claim Limitations 8.27-8.34

224. I understand that claim 1 further requires a headgear assembly that includes two side straps, a top strap, and a back strap, which have particular features set forth in limitations 8.27-8.34. The particular language of the respective limitations is mentioned in Section VIII.B above (Ground 1). In my opinion, each of these features is disclosed in *Gunaratnam*, as explained in Section VIII.B above (Ground 1). Moreover, I believe that an ordinary skilled artisan would have found it predictable to apply *Gunaratnam's* headgear designs (e.g., the headgear assembly shown in Fig. 135 of *Gunaratnam*) to *Lovell*'s patient interface, and would have seen reason to do so to enhance the comfort and fit of *Lovell's* mask and to reduce the burdens of donning and removing the mask. *See supra* ¶¶ 36-38.

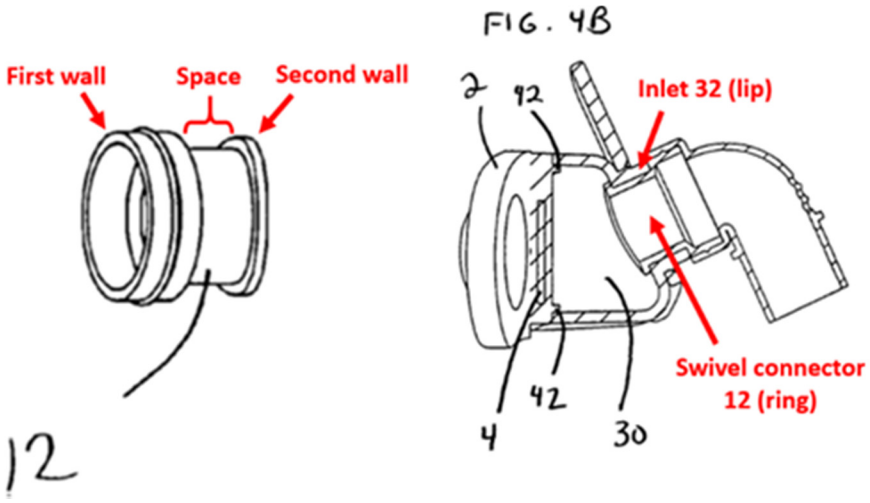
225. In my opinion, the particular manner in which the two side straps from *Gunaratnam* connect to the mask assembly from *Lovell* would be well within the capabilities of one of ordinary skill in the art to determine, and would have been an obvious implementation detail. For example, the side arms could attach directly to a pair of connection points on *Lovell's* retaining structure 10. Alternatively, the two side straps could connect directly to the retaining structure 10, while side arms run along the side straps for added stability. RMD1004, ¶¶ 0369-70, Figs. 107G-H (showing a nasal pillows mask in which only two side straps connect directly to the mask frame via connector portions 766, 770).

u) Claim 17

226. I understand that claim 17 depends from claim 1 and further recites "wherein the ring comprises a first wall and a second wall defining a space therebetween, and wherein a portion of the mask body is configured to removably attach to the ring via friction within the space and with the first wall and the second wall." First considering *Lovell's* swivel connector as the claimed ring and that the claimed mask body in *Lovell* includes lower shell 8, *Lovell's* swivel connector 12 (ring) includes a first flange 28 on a first side of the connector 12 and a second flange on the opposite side of the connector 12. These flanges are a "first wall" and a "second wall," respectively, which define a space therebetween. *See* RMD1012, Fig. 2B (excerpt of swivel connector 12 copied and annotated below).

The portion of the mask body (inlet 32) removably attaches to the ring (swivel connector 12) via friction within the space between the first and second walls (first and second flanges). RMD1012, Fig. 4B (copied and annotated below); 5:24-45. One of skill in the art would have recognized that because the inlet 32 contacts the swivel connector 12 when engaged, friction would result from the contact and rotation between the inlet 32 and swivel connector 12. Alternatively considering *Lovell's* lower mask shell 8 to be the claimed ring and that the claimed maks body in *Lovell* includes upper shell 6, *Lovell* discloses the upper mask shell 6 (i.e., the part of the mask body to which shell 8 is engaged) having a flange 42 (*see* Fig. 4B), which flange 42 allows the lower mask shell 8 to seat the upper mask shell 6 so the two parts can be affixed together. *See* RMD1012, Fig. 4B and col. 4:38-52. One of skill at a time before the '807 patent would have understood that the lip and channel arrangement in *Lovell* may be modified so that the lip of the upper mask shell 6 fits into a channel or "open space" of two walls provided in the lower mask shell 8 (ring), to provide an arrangement wherein the two parts (lower mask shell 8 and upper mask shell 8) can be connectable and disconnectable by friction fit, to provide for ease of user cleaning the mask components between uses. Such a configuration of two mask components is disclosed, for example, in *Gunaratnam* when read in view of further detail provided in *Ging*. *See* Discussion of claims 2 and 17 under Ground 1.

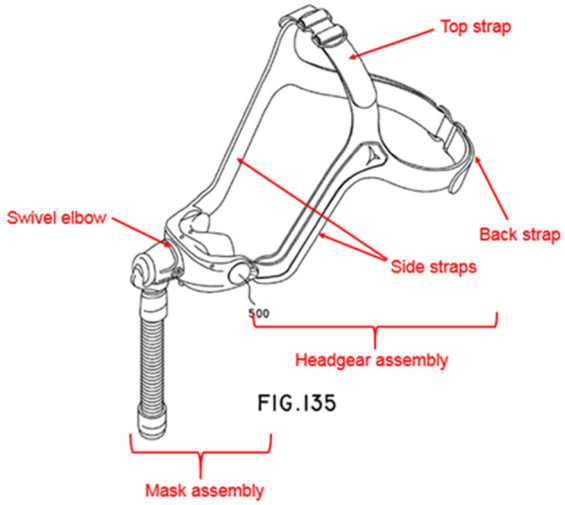
227. One of ordinary skill in the art would have recognized that even if the swivel connector 12 in *Lovell* were modified to form a socket that receives a portion of the elbow 14 *within* the ring, such modification would not change the fact that the ring would still include two walls with a space therebetween, albeit in a slightly different configuration.



v) Claims 18-21

228. I understand that claim 18 (which depends from claim 1) and claim 20 (which depends from claim 8) further recite "wherein the top strap is integrally formed with one or more of the side straps and the back strap." Moreover, claim 19 (which depends from claim 18) and claim 21 (which depends from claim 20) further recite "wherein the top strap is integrally formed with one or more of the side straps." In my opinion, the patient interface disclosed in *Lovell* as modified to include headgear assembly from *Gunaratnam*'s designs would include the features of each of claims 18-21.

229. For example, *Gunaratnam's* Figure 135 shows that respective sides of the top strap are integrally formed with one or more of the side straps and the back strap (claims 18, 20), and further shows the top strap being integrally formed with one or more of the side straps (claims 19, 21).



230. Additionally, Figures 107G and 107H of *Gunaratnam* show a headgear assembly having side straps 758, a rear strap 754, and a top strap 756. RMD1004 FIGs. 107G-H. The headgear assembly in this embodiment is a unitary headgear structure in which the side straps 758, rear strap 754, and top strap 756 all appear to be integrally formed. Although paragraphs 369 and 370 of *Gunaratnam's* disclosure do not expressly mention the headgear in this embodiment as being a unitary structure, this feature is taught elsewhere in *Gunaratnam*. *See* RMD1004, *Gunaratnam*, ¶ 0213 (describing that the headgear

assembly 20 in some embodiments "may be constructed as a one piece structure"). This type of unitary structure appears to be what is depicted in Figure 107G.

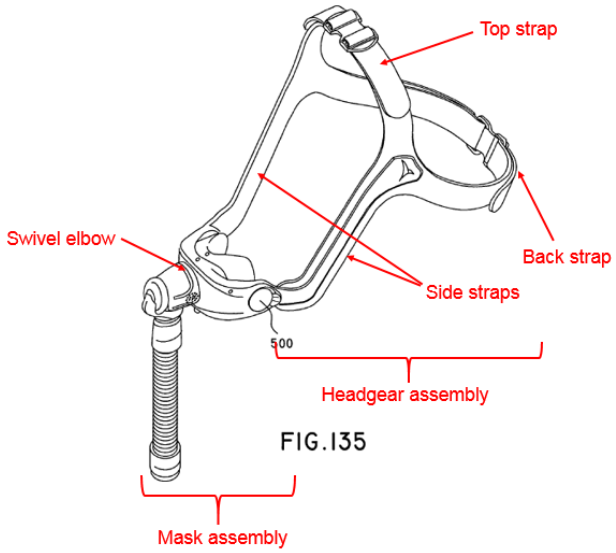
231. Moreover, a person of skill in the art would have recognized at the time of the '807 patent that headgear assemblies having integrally formed straps were conventional. It would have been an obvious design choice to make the top strap integrally formed with one or more of the side straps and the back strap. One of ordinary skill would have recognized that integrally formed straps would have been beneficial, for example, to maintain the overall structure of the headgear assembly so that the user need not be concerned with making connections among various parts of the headgear assembly. Instead, the user could quickly, and with minimal burden, slip the headgear assembly with integrally formed straps onto his or her head.

w) Claims 24-27

232. I understand that claim 24 (which depends from claim 1) and claim 26 (which depends from claim 8) further recite "wherein the top strap is releasably connected to one or more of the side straps and the back strap." Moreover, claim 25 (which depends from claim 24) and claim 27 (which depends from claim 26) further recite "wherein the top strap is releasably connected to the back strap." In my opinion, the patient interface disclosed in *Lovell* as modified to include

headgear assembly from *Gunaratnam*'s designs would include the features of each of claims 24-27.

233. For example, the patient interface design shown in Figure 135 of *Gunaratnam* includes a top strap having a first portion which is integrally formed with (i) a first of the pair of side straps and (ii) a portion of the back strap. A second portion of the top strap is integrally formed with (i) a second of the pair of side straps and (ii) a second portion of the back strap. A buckle connects the first and second portions of the top strap, so that at least a portion of the top strap is releasably connected to one or more of the side straps and the back strap, as claimed.



234. Additionally, *Gunaratnam* discloses many different headgear configurations. A number of these alternative embodiments include releasably connected straps consistent with claims 24 and 26. For example, Figure 18 (copied

below) shows a headgear assembly 20 comprised of a top strap 98, a back strap 100, and a pair of side straps 96. As shown in Figure 18, the top strap 98 is releasably connected to the side straps 96 via buckles 102 provided at the ends of the side straps 96. RMD1004, *Gunaratnam*, ¶ 0211. Figure 18 thus discloses the additional feature of claims 24 and 26. It would have been obvious to apply the releasable connections taught in Figure 18 to *Lovell*'s design so as to ease the removal and disassembly of the headgear.

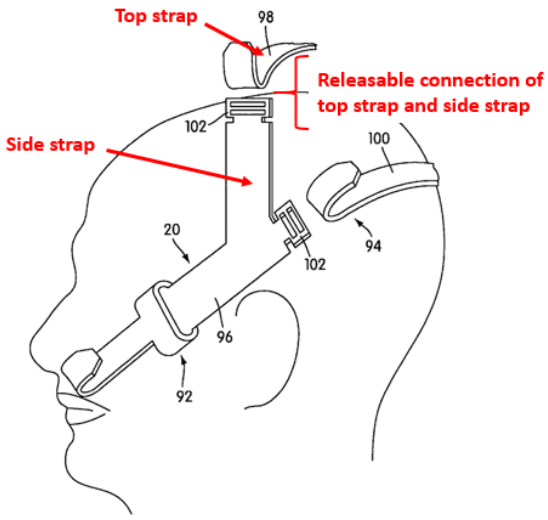


FIG. 18

235. Moreover, *Gunaratnam* discloses the top strap being releasably connected to the back strap, as recited in claims 25 and 27, in the headgear design depicted in Fig. 107A (copied and annotated below). Fig. 107A shows the top strap 654 being releasably connected to the back strap 656 through a support arm 675. *See* RMD1004, Fig. 107A. One of skill would have found it obvious to

provide releasable connections among the top strap and the side straps or the top strap and the rear strap to allow the user more flexibility in sizing the headgear assembly and for the headgear to be more easily removed by the releasable connections.

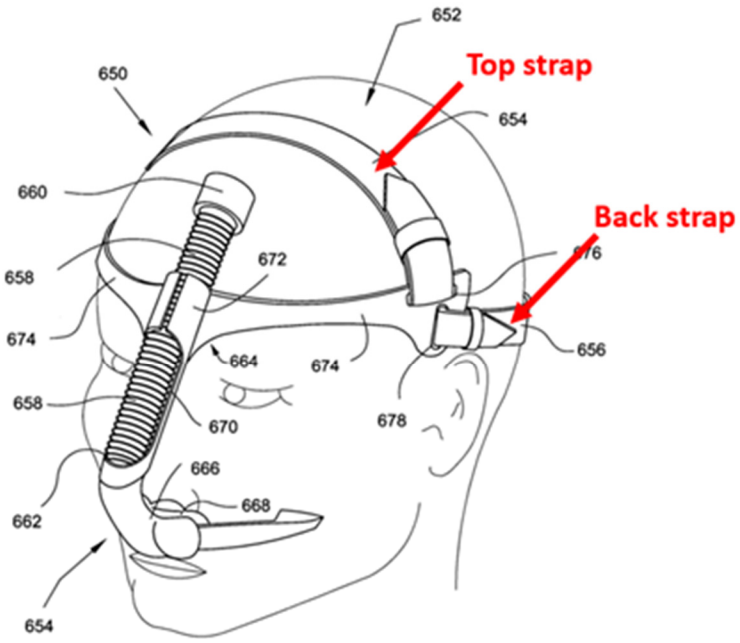


FIG. 107A

236. In my opinion, it would have been an obvious design choice to one of skill in the art to modify *Lovell*'s design to incorporate the teachings of a top strap releasably connected to a back strap as taught by *Gunaratnam*. One of skill would have been prompted to do so, for example, to improve the ease of removal and disassembly of the headgear for the patient. Additionally, one of skill have recognized that releasable connections would facilitate the ability to make greater size adjustments than some designs with an integral formation. Releasable strap

connections would thus have provided a different set of advantages than designs having integrally formed straps. Releasable connections in some examples would allow the user to more easily remove the headgear assembly by breaking the releasable connections.

IX. CONCLUSION

237. I currently hold the opinions expressed in this declaration. However, my analysis may continue after the signing of this declaration. If and as my analysis continues, I may acquire additional information and/or obtain supplemental insights that result in added observations. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. I hereby 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.

Respectfully submitted,

Date: September 7, 2016 /John I. Izuchukwu/

Appendix A

Curriculum Vitae of
John I. Izuchukwu, PhD, MBA, PE

JOHN I. IZUCHUKWU, PH.D., MBA, PE

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EXPERTISE SUMMARY

Consultant Specializing in Medical Device Product Development, Endoscopic Surgical Devices, Respiratory Devices, Drug Delivery Devices, Manufacturing Process Design, Design Verification and Validation, FDA and CE Quality Systems Regulations and Regulatory Approval Process, Product Liability, Failure and Root Cause Analysis, Forensic Investigation, and Patent Valuation.

EDUCATION

MBA Kellogg School of Management, Northwestern University, Evanston, IL, 2002
Ph.D. Industrial & Mechanical Engineering, Northeastern University, Boston, MA, 1994
MS Mechanical Engineering, University of Portland, Portland, OR, 1984
BS Industrial & Mechanical Engineering, University of Portland, Portland, OR, 1980

Certifications, Awards, Honors and Recognitions

- Registered Professional Engineer
- Certificate New Product Development, Harvard Business School
- Certificate European Medical Device Directives for Product Safety and Testing
- Johnson & Johnson Achievement Award for Design Quality Assurance
- Ethicon Endo-Surgery Innovation Award for Inventions and Invention Disclosures
- UMR Faculty Recognition for contribution to Engineering Education Center
- DEC 100 and DECathalon Awards for impact on revenue growth
- Marquis Who's who in Science & Engineering,
- Marquis Who's Who in The World
- Marquis Who's Who in America
- 2000 Outstanding Scientists of the 20th Century, Int'l Biographical Center Cambridge, England.

AREAS OF EXPERTISE

- New product and process development
- Design and development of respiratory devices
- Diagnostic, monitoring, sedative and therapeutic drug delivery devices
- Laparoscopic and endoscopic surgical devices
- Medical device design verification and validation
- Quality Systems Regulations - 21 CFR Part 820 QSR, ISO 9000 / ISO 9001 / ISO 13485
- Regulatory approval process for Class I and Class II medical devices
- Surgical staplers, skin stapling devices
- Oxygen Concentrators
- Oxygen Conserving Devices
- Sleep Apnea and CPAP devices
- Spirometry, Spirometers and Flow Sensors
- Compressed Medical Gas Storage and Delivery
- Failure mode effect and criticality analysis
- Incident Investigation and Root Cause Analysis
- Failure analysis
- Forensic Engineering

- Forensics Investigation Support
- Quality Function Deployment
- Conjoint Analysis
- Project Management
- Patent evaluation and valuation
- Financial Engineering
- Reliability Engineering
- Statistical Quality Control
- Concurrent Engineering
- Design for manufacturing and assembly
- Manufacturing process planning
- Capacity Planning
- Operations Management

PROFESSIONAL EXPERIENCE

Core Devices Inc., Saint Louis, MO **2001 – Present**
President/CEO

- Chief Executive Officer (CEO) and Chief Technical Officer (CTO) of Core Devices, a biomedical research and development company.
- Founded company, to address unmet needs for technologies to enable surgical procedure in the field.
- Established vision and direction, led funding efforts, appointed board members, recruited management team, developed business, strategic and operational plans, conducted market research, defined target markets and competitive strategies.
- Led research and development activities, providing technical direction for new product development and process.
- Developed R&D strategy that leverages academia for basic research, design firms and original equipment manufacturers for system and component level design, in order to reduce product development cycle time and cost.
- Invented and secured 3 utility patents for an oxygen conserving device, a conformal oxygen system for persons with respiratory disability, and a backpack-able field anesthesia machine for surgical care on battlefields, disaster locations and rural hospital settings.
- Validated market need through target customers, scientific presentations and independent research.
- Awarded multiple grants by the National Institutes of Health (NIH) for proof of concept and prototype development of an ambulatory oxygen device and a portable anesthesia machine.
- Served as an expert witness on several patent litigation and product liability cases.

Nellcor Puritan Bennett – A Mallinckrodt Co., Saint Louis, MO 1998 – 2001
Sr. Director Global R&D

- Led global R&D and engineering for the Alternate Care Segment; a $400 business unit within the Respiratory Group.
- Managed product development, sustaining engineering and regulatory activities across sites in the United States, France and Canada with a $20 million R&D budget.
- Built R&D from scratch to over 100 engineers and scientists, equipped with standardized design tools, laboratories and test engineering facilities.
- Established a common product development process, to accelerate screening, adoption, development and commercialization of inventions.

- Established development and career plans for managerial and individual contributors.
- Unified cross-functional teams with a common product development process, performance metric and reward system.
- Developed diagnostic and therapeutic devices for respiratory care, including chronic obstructive pulmonary disease (COPD) and sleep apnea disorder.
- Brought to market more than a dozen new products, contributing over $200 million in revenue and average of 50% gross margin. This includes the Renaissance II spirometer for diagnosis of respiratory disorder, Puritan Bennett OxiClip (an oxygen conserving device), Aeris590 oxygen concentrator, HeLIOS (high efficiency liquid oxygen system), GK418, GK420 CPAP devices and sleep masks for treatment of sleep apnea, KS330 and KS325 bi-level ventilator for respiratory support. These products are helping to advance patient care in acute, sub-acute and alternate care settings.
- Prosecuted and was awarded 13 utility patents for novel oxygen delivery devices.
- Established a global advisory board of thought leaders in medicine, to provide clinical guidance to R&D advances into emerging market areas.

Ethicon Endo-Surgery, Inc. A Johnson & Johnson, Co., Blue Ash, OH 1994-1998
Team Leader, Research and Development, Endo-mechanical Devices

- Led R&D for a $200 million business unit focused on endoscopic surgical devices.
- Led parallel projects and cross-functional teams of design, manufacturing, reliability and quality engineers, marketing, regulatory and clinical personnel, to develop, test, validate and bring to market a family of handheld instruments for general, gynecologic and thoracic surgery, including skin staplers, graspers, dissectors, and scissors in accordance with FDA/GMP guidelines.
- Translated customer needs into key product attributes and technical specifications using QFD and ConJoint techniques, resulting in positive customer ratings and 100% new product success rate. Introduced a platform strategy that emphasizes interchangeable parts, to consolidate suppliers, reduce material cost by $1.6 million and cycle time by 12 months.
- Prosecuted and received three surgical skin stapler patents.
- Relocated assembly from Peterboro, Canada to Juarez Mexico - reducing labor cost by $1.2MM
- Earned Johnson & Johnson Achievement Award for design quality assurance on the Proximate-Plus-MD family of skin stapler projects.
- Received Ethicon-Endo Surgery Innovation Award for contributions to patent estate.

Digital Equipment Corporation, Marlboro, MA 1983 - 1994
Worldwide Strategy Manager Product Development, Engineering Systems Group

- Led worldwide product development strategy for a $400 million business unit.
- Managed strategic joint ventures for engineering and manufacturing automation technologies targeted at Digital's VAX/VMS and ULTRIX platforms.
- Negotiated technology licensing and strategic agreements to close portfolio gaps, reduce product development cycle-time and cost of goods.
- Established the simultaneous product development process; a unique approach to product development, which establishes operational guidelines for managing products throughout their life cycles.

Manager Aerospace Strategy and Data Integration Products, Engineering Systems Group

- Responsible for worldwide Aerospace business strategy and development of industry specific design and manufacturing automation solutions.
- Developed strategy to grow revenue from $500 million to $1.0 billion in five years.

- Developed products for concurrent engineering and legacy CAD/CAM data integration based on IGES and Standard for The Exchange of Product Data (STEP) translators.
- Harmonized strategy with CALS (Computer-Aided Acquisition and Logistics Support) - initiative for digital interchange of technical information among computer systems.
- Represented DEC on the External Research Board investigating and proposing joint ventures.

Manager Manufacturing and Application Center for Technology

- Managed a $20 million consulting practice targeted at Fortune 100 Aerospace and Defense Electronics manufactures.
- Developed and delivered consulting modules on engineering and manufacturing process automation, concurrent engineering, product data management, Computer-Aided Design and Manufacturing (CAD/CAM), Computer-Aided Engineering (CAE), Deming, Juran, Ishikawa, Taguchi, Quality Function Deployment (QFD), Design-for-Manufacturing (DFM), Total Quality Management (TQM) and operations management principles.
- Managed delivery of multi-million dollars process re-engineering projects at Raytheon, Lockheed, GE, Grumman, Allied Signal, Sikorsky, Ford and General Motors.
- Grew revenue by 50% to $30 million during a two year window.

Manager Mechanical Design Automation, Engineering Systems Group

- Managed application engineering responsible for mechanical design automation tools, which were optimized to run on Digital's computers, operating systems, and database management systems, including competitive migrations.

Strategic Alliance Mgr, Computer-Aided Software Engineering

- Managed strategic alliances for computer-aided software engineering solutions
- Developed strategic plans, performed portfolio gap analysis and negotiated joint ventures for a family of software design automation tools that fulfilled global customer needs.
- Recruited and migrated Cadre and IDE's SA/SD tools to Digital's platforms

Tektronix, Test & Measurements Group, Beaverton, OR 1980 - 1983
Industrial & Mechanical Design Engineer; Sr. Mechanical Design Engineer

- Responsible for mechanical design, simulation, testing and manufacturing process planning. Designed adjustable work dispensers and automated assembly systems. Led project on numerical control and distributed intelligence.

ACADEMIC AND PROFESSIONAL AFFILIATIONS

- Adjunct Professor Missouri University of Science & Technology
- Adjunct Professor Saint Louis University
- Adjunct Professor University of Maryland University College
- Adjunct Professor Fontbonne University
- Adjunct Professor Babson College
- Adjunct Professor Framingham State College

PUBLICATIONS AND PATENTS (19 patents, selected publications and citations)
Issued Patents:

1. *Skin Stapler with Multi-directional Release Mechanism*, U.S. Patent No. 5908149, June 1, 1999.
2. *Skin Stapler with Rack and Pinion Staple Feed Mechanism*, U.S. Patent No. 5937951, August 17, 1999.

3. *Skin Stapler with Movable Anvil*, U.S. Patent No. 5938101, August 17, 1999.
4. *Adhesively Connected Polymeric Pressure Chambers and Method for Making the Same*, U.S. Patent No. 6,412,484, July 2, 2002.
5. *Fluid Control Valve for Pressure Vessel*, U.S. Patent No. 6412484, July 2, 2002.
6. *Wheeled Personal Transport Device Incorporating Gas Storage Vessel Comprising A Polymeric Container System For Pressurized Fluids*, U.S. Patent No. 6412801, July 2, 2002.
7. *Walking Assistance Device Incorporating Gas Storage Vessel Comprising a Polymeric Container System For Pressurized Fluids*, U.S. Patent No. 6453920, Sept. 24, 2002.
8. *High Pressure Fitting With Dual Locking Swaging Mechanism*, U.S. Patent No. 6502571, Jan. 7, 2003.
9. *Polymeric Container System for Pressurized Fluids,* U.S. Patent No. 6510849, Jan. 28, 2003.
10. *Emergency Breathing Apparatus Incorporating Gas Storage Vessel Comprising A Polymeric Container System For Pressurized Fluids,* U.S. Patent No. 6510850, Jan. 28, 2003.
11. *Wearable Storage System for Pressurized Fluids,* U.S. Patent No. 6,513,522, February 4, 2003.
12. *Wearable Belt Incorporating Gas Storage Vessel Comprising A Polymeric Container System for Pressurized Fluids,* U.S. Patent No. 6,513,523, February 4, 2003.
13. *Utility Belt Incorporating Gas Storage Vessel,* U.S. Patent No. 6,526,968, March 4, 2003.
14. *Vehicle Incorporating Gas Storage Vessel Comprising A Polymeric Container System For Pressurized Fluids,* U.S. Patent No. 6,527,075, March 4, 2003.
15. *Litter Incorporating Gas Storage Vessel Comprising A Polymeric Container System For Pressurized Fluids,* U. S. Patent No. 6,536,425, March 25, 2003.
16. *Method For Forming A Polymeric Container System For Pressurized Fluids, U.S. Patent No. 6,579,401, June 17, 2003.*
17. *Ambulatory Storage System for Pressurized Gases*, US Patent No. 6,651,659, Nov. 22, 2003.
18. *Conserver for Pressurized Gas Tank*, United States Patent No. 6866042, March 15, 2005
19. *Portable Field Anesthesia Machine and Control Therefore*, United States Patent No. 7,438,072 B2, October 21, 2008.

Funded Research/Grants:

- Oxygen Device for Persons With Respiratory Disability, NIH Grant No. 1 R43 HL072675-01A1, 06/18/2004 – 12/18/2005
- Portable Field Anesthesia Machine, NIH Grant No. 1 R43 GM073235-01, 03/01/2005 – 08/31/2006

Book/Book Chapters:

- J. I. Izuchukwu and C. A. Dyer. “Evolution of Legacy Software Using Declarative Programming,” *in Intelligent Engineering Systems Through Artificial Neural Networks: Smart Engineering System Design: Neural Networks, Evolutionary Programming And Artificial Life*, vol. 15. C. H. Dagli, A. L. Buczak, E. L. Enke, M. J. Embrechts, O. Ersoy (Eds.). New York: ASME Press, 2005, pp. 265-273.
- J. I. Izuchukwu and C. A. Dyer. "Derivation of Design and Manufacturing Solutions by Means of Decision Pruning and Evolutionary Programming," *in Intelligent Engineering Through Artificial Neural Networks: Smart Engineering Systems: Neural Networks, Fussy Logic, Data Mining, and Evolutionary Programming*, vol. 7. C. H. Dagli, M. Akay, O. Ersoy, B. R. Fernadez, A. Smith (Eds.). New York: ASME Press, 1997, pp. 759-770.
- J. I. Izuchukwu. *A Hybrid Quality Control Approach to Minimizing Defect Propagation: With Application to VLSI Systems*. Ph.D. Diss. Boston: Northeastern University, 1994.

Journal Articles:

- J. I. Izuchukwu. “Effect of Pressurization and Volume - Temperature Change on Gas Diffusion in a Semi-Impervious Polymeric and Spherical Oxygen Storage Chamber.” NIH Sponsored Research 1R44372675-01A1 (in-progress*, J. Heat Transfer)*
- J. I. Izuchukwu. “Conformal Oxygen Device for Persons with Respiratory Disability.” NIH Sponsored Research 1R44372675-01A1 (in-progress, *J. Biomedical Engineering*)
- J. I. Izuchukwu. “Heating Power Requirement for a Thermally Compensated Anesthetic Vaporizer.” NIH Sponsored Research 1R43GM073235-01 (in-progress, *J. Heat Transfer*)
- J. I. Izuchukwu. “Control of Anesthetic Temperature and Insulation to Thermal Decay by Means of Heat Transfer from a By-pass Gas Stream in a Variable By-pass Gas Vaporizer.” NIH Sponsored Research 1R43GM073235-01 (in-progress, *J. Heat Transfer*)
- J. I. Izuchukwu. “Portable Field Anesthesia Machine.” NIH Sponsored Research 1R43GM073235-01 (in-progress, *J. Biomedical Engineering Technology*).
- J. I. Izuchukwu. “Automatically Controlled Portable Anesthesia Machine for Mass Casualty Care (in-progress, *J. Biomedical Engineering Technology*).”
- J. Izuchukwu. “Benefit of Oxygen Saturation Monitoring At Home for Patients with Lung or Heart Disease, or Sleep Apnea Syndrome (in-progress, *J. of Biomedical Engineering Technology*).”
- J. I. Izuchukwu. "Process and Technical Perspectives on Integrated Product Development." *J. Manufacturing Science and Eng.* 118 (3), pp. 117-118, Aug. 1996.
- J. I. Izuchukwu. "Architecture and Process: The Role of Integrated Systems in Concurrent Engineering." *Industrial Management.* 34(2):19-23, Mar. 1992.
- J. I. Izuchukwu. "Artificial Intelligence Can Reduce Product Cost by Optimizing Design Decisions." *Industrial Engineering.* 23 (8):42-46, Aug. 1991.
- J. I. Izuchukwu. "Intelligent Foundation for Product Design Reduces Cost and Time-to-Market." *Industrial Engineering.* 23 (7):29-34, Jul. 1991.
- J. I. Izuchukwu. "Design Team Approach to ‘Class A’ Engineering", *Industrial Engineering.* 37-39, Jan. 1991.
- J. I. Izuchukwu. "Sharing Product Data in CAD Applications." *Mechanical Engineering Systems.* 1(1): 24-26, Jul. 1990.
- J. I. Izuchukwu. "Project Management: Shortening the Critical Path.” *Mechanical Engineering*. 112(2): 59-60, Feb. 1990.
- J. I. Izuchukwu. “Tracking Operator Assembly Performance By Means of a Rotational Assignment Algorithm.” (in-progress, *J. Manuf. Science & Engineering*)
- J. I. Izuchukwu. "A Structured Approach to Business Process Re-engineering Using IDEF (in review, *J. Management Science*)."
- J. I. Izuchukwu. "The Utility of Critical Dimensional Analysis in Supplier Process Capability Investigation." (in-review, *International J. Production Research*).
- J. I. Izuchukwu. "Using Long Run Steady State AOQ to Estimate Warranty Cost (in-review, *Journal of Manuf. Science and Engineering*)."
- J. I. Izuchukwu. “Post-Mortem on Balance Sheet Based Corporate Downsizing (in-progress, *J. Management*).”
- J. I. Izuchukwu. “When Balance sheet Myopia Leads to Procedural Injustice in Corporate Acquisition” (in-progress, *J. Management*).”
- J. I. Izuchukwu. “Influence of Cognitive Bias and Innovation Phobia on Strategic Planning” (in-progress, J. Management).”
- J. I. Izuchukwu. “The Challenge of Corporate Goal Attainment When Metric and Compensation Plans Are Misaligned” (in-progress*, J. Management*).”

Proceedings:

- J. I. Izuchukwu. "Integrated Product Development: Process and Technology Perspectives." *PROCEEDINGS: 5th Annual Process Analysis Symposium for Competitiveness.* Shrewsbury, Massachusetts. 1994.
- J. I. Izuchukwu. "Implementing Concurrent Engineering." *PROCEEDINGS: Institute for International Research.* Chicago, Illinois. 1990.

Researchers and Inventors Citing My Work:

- Dana P. Nickerson, Introduction to Concurrent Engineering, PROCEEDINGS, Electro '90 Conference, Boston, Massachusetts.
- Stephen Evanczuk, "Concurrent Engineering: The New Look of Design." *High Performance Systems*, April 1990.
- Vandita Bharwaj. "An Enhanced New Product Development (NPD) Model and the Application of Taguchi Methods in Upstream NPD Activities." MS Eng. Thesis, Memorial University of Newfoundland, Aug. 2000.
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- Lt. Col. R. N. Gamache. "The Defense Acquisition Challenge: A Strategy for Improving Weapon System Affordability." *Executive Research Project*, U. S. Air Force, The National College of The Armed Forces, National Defense University, 1993.
- H. K. Bowen and R. N. Longuemare. *Defense Task Force Study on Engineering in the Manufacturing Process.* Office of the Secretary of Defense, March 1993.
- Stuart Bretschneider. "Operational Research Contributions to Evaluation of R&D Projects," in Evaluating R&D Impacts: Methods and Practice, B. Bozeman and J. Melkes (Eds.). New York: Kluwer Academic Publishers, 1993, p. 146.
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- Dennis E. Kroll. Class Lecture, Topic: "Artificial Intelligence in Manufacturing." MFE 555, Bradley University, 1996.
- Dennis E. Kroll. Class Lecture, Topic: "Introduction to Engineering Expert Systems." IE588/CIS588, Bradley University, 1996.
- Adedeji B. Badiru, *Project Management in Manufacturing and High Technology Operations*, 1996, Wiley-IEEE.
- I. C. Gregory. "The Transfer of 'Best Practice' Knowledge into Manufacturing Companies." Engineering Doctorate, University of Warwick, UK 1997.
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1997.
- Method - Itoh, et al. “Method of Generating An Image And An Apparatus For Carrying Out Such A.” U. S. Patent 5692115, 1997.
- Sebastian, et al. “Concurrent Engineering Design Tool and Method.” U. S. Patent 5822206, 1998.
- J. J. Donald. “Evaluation and Assessment of Variation Risk Management and the Supporting Tools and Techniques.” MS Diss., Massachusetts Inst. of Technology, 1998.
- Robert Wyant, *Concurrent Engineering*, Pennsylvania Sate University.
- Role Change of Engineers in Integrated Product Development, Paul Hong, University of Toledo, Mark A. Vonderembse, University of Toledo, William J. Doll, University of Toledo, Abraham Y. Nahm, University of Wisconson, *Decision Sciences Institute 2002 Annual Meeting Proceedings*.
- Mandar Chincholkar, Design for Production: Using Manufacturing Cycle Time Information to Improve Product Development, Ph.D. Thesis 2002, Institue for Systems Research, University of Maryland.
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- Lavagnon A. Ika, Godbout Martin Godbout et Associes, Sebastien H. Azondekon, *Les Faiblesses de l’Analyse de la Valeur Acquise en Mesure de la Performance de Projet*, Universite du Quebec a Hull.
- Lavagnon A. Ika, *Analyse De La Valeur Acquise En Contexe D’ Interdependence Des Chemise: La Solution PNET*, Universite du Quebec a Montreal, ASAC Conference 2005.
- Doll, W. J, “OEM new product development practices: the case of the automotive industry,” *Journal of Supply Chain Management*, Jun 22, 2006.