

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: McAuley, et al.
U.S. Patent No.: 8,443,807 Attorney Docket No.: 36784-0042IP1
Issue Date: May 21, 2013
Appl. Serial No.: 12/307,993
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Title: BREATHING ASSISTANCE APPARATUS

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PETITION FOR *INTER PARTES* REVIEW
OF UNITED STATES PATENT NO. 8,443,807
PURSUANT TO 35 U.S.C. §§ 311–19, 37 C.F.R. § 42

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EXHIBIT LIST

EX. #	Exhibit Description
RMD1001	U.S. Patent No. 8,443,807 to McAuley et al. (“the ’807 patent”)
RMD1002	[RESERVED]
RMD1003	[RESERVED]
RMD1004	U.S. Patent Application Publication No. 2004/0226566 to <i>Gunaratnam</i> et al. (“ <i>Gunaratnam</i> ”)
RMD1005	U.S. Patent Application Publication No. 2003/0196658 to <i>Ging</i> et al. (“ <i>Ging</i> ”)
RMD1006	[RESERVED]
RMD1007	U.S. Patent No. 6,691,707 to <i>Gunaratnam</i> et al. (“the ’707 patent” or “ <i>Gunaratnam II</i> ”)
RMD1008	Declaration of Dr. John Izuchukwu, Ph.D., P.E. (“Izuchukwu Decl.”)
RMD1009	File History of U.S. Patent No. 8,443,807 to McAuley et al.
RMD1010	[RESERVED]
RMD1011	[RESERVED]
RMD1012	U.S. Patent No. 7,219,669 to Lovell et al. (“ <i>Lovell</i> ”)
RMD1013	[RESERVED]
RMD1014	Merriam-Webster’s Collegiate Dictionary, Eleventh Edition (2004) (selected portions)
RMD1015	[RESERVED]
RMD1016	U.S. Patent No. 4,676,241 to Webb et al. (“ <i>Webb</i> ”)
RMD1017	[RESERVED]
RMD1018	PCT Publication No. WO 2004/022147 to Drew (“ <i>Drew</i> ”)

RMD1019	U.S. Patent 4,782,832 to Trimble et al. (“ <i>Trimble</i> ” or “’832 Patent”)
RMD1020	U.S. Patent 6,431,172 to Bordewick (“ <i>Bordewick</i> ”)
RMD1021	U.S. Patent 6,192,886 to Rudolph (“ <i>Rudolph</i> ”)
RMD1022	U.S. Patent 6,581,594 to Drew et al. (“ <i>Drew</i> ”)
RMD1023	[RESERVED]
RMD1024	ResMed “Mirage Vista™ Nasal Mask: Components Card” publication, ©2005 ResMed Ltd.
RMD1025	[RESERVED]
RMD1026	[RESERVED]
RMD1027	[RESERVED]
RMD1028	[RESERVED]
RMD1029	[RESERVED]
RMD1030	[RESERVED]
RMD1031	[RESERVED]
RMD1032	[RESERVED]
RMD1033	[RESERVED]
RMD1034	PCT Publication No. WO 2005/079726 to <i>McAuley</i> et al. (“ <i>McAuley</i> ”)
RMD1035	ResMed “Mirage Swift™ Nasal Pillows System from ResMed” publication, ©2004 ResMed Ltd.
RMD1036	ResMed “Mirage Swift™ Nasal Pillows System: User’s Guide” publication, ©2004 ResMed Ltd.
RMD1037	U.S. Patent No. 7,178,528 (“ <i>Lau</i> ”)

RMD1038	WeddingBands.com – Men’s Wedding Ring Shopping Page (Retrieved October 16, 2015 from http://www.weddingbands.com/ProductPop_wedding_bands_metal/48214W.html)
RMD1039	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)
RMD1040	ResMed Origins Brochure (Retrieved April 17, 2016 from http://www.resmed.com/us/dam/documents/articles/resmed-origins.pdf)
RMD1041	Statutory Declaration made by Alistair Edwin McAuley, Apr. 9, 2015, in the matter of an Opposition by Fisher & Paykel Healthcare Limited of Australian patent application 2009221630 in the name of ResMed Limited
RMD1042	U.S. Patent No. 6,119,694 to Correa et al. (“Correa”)
RMD1043	Patent Owner’s Complaint for <i>Fisher & Paykel Healthcare Ltd. v. ResMed Corp.</i> , Case No. 3:16-cv-02068-GPC-WVG (S.D. Cal.)
RMD1044	Patent Owner’s Complaint for <i>Fisher & Paykel Healthcare Ltd. v. ResMed Corp.</i> , Case No. 2:16-cv-06099-R-AJW (C.D. Cal.)
RMD1045	Patent Owner’s Notice of Voluntary Dismissal Without Prejudice for <i>Fisher & Paykel Healthcare Ltd. v. ResMed Corp.</i> , Case No. 2:16-cv-06099-R-AJW (C.D. Cal.)
RMD1046	Petitioners’ Complaint for <i>ResMed Inc., et al. v. Fisher & Paykel Healthcare Corp. Ltd., et al.</i> , Case No. 3:16-cv-02072-JAH-MDD (S.D. Cal.)
RMD1047	Petitioners’ Notice of Voluntary Dismissal Without Prejudice for <i>ResMed Inc., et al. v. Fisher & Paykel Healthcare Corp. Ltd., et al.</i> , Case No. 3:16-cv-02072-JAH-MDD (S.D. Cal.)

I. INTRODUCTION

ResMed Limited, ResMed Inc., and ResMed Corp (collectively “ResMed” or “Petitioners”) petition for *inter partes* review (“IPR”) of claims 1-7, 17-19, 24, and 25 of U.S. Patent No. 8,443,807, assigned to Fisher & Paykel Healthcare Limited (“F&P”).

II. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8

A. Real Party-In-Interest under 37 C.F.R. § 42.8(b)(1)

ResMed Limited, ResMed Inc., and ResMed Corp are the Real Parties-in-Interest.

B. Related matters under 37 C.F.R. § 42.8(b)(2)

ResMed Corp is currently a defendant in a pending litigation in the Southern District of California involving the ’807 patent. *See Fisher & Paykel Healthcare Ltd. v. ResMed Corp.*, Case No. 3:16-cv-02068-GPC-WVG (S.D. Cal.). Patent Owner filed the complaint in this case on August 16, 2016, and alleges that ResMed infringes the ’807 patent. RMD1043.

On August 15, 2016, Patent Owner both filed and dismissed (without prejudice) a complaint in the Central District of California also alleging that ResMed infringes the ’807 patent. RMD1044; RMD1045.

Petitioners have also filed and dismissed (without prejudice) a complaint related to the ’807 patent. On August 16, 2016, Petitioners filed a complaint in the

Southern District of California alleging infringement of several patents held by Petitioners, and seeking declaratory judgment on non-infringement and invalidity of the '807 patent. RMD1046. Petitioners voluntarily dismissed this complaint without prejudice on August 18, 2016. RMD1047.

Petitioners' withdrawn action for declaratory judgment regarding the invalidity of the '807 patent has no effect under 35 U.S.C. § 315(a) because it was voluntarily dismissed without prejudice. *See Macuato U.S.A. v. BOS GmbH & KG*, IPR2012-00004, Paper No. 18 at pp. 15-16 (PTAB Jan. 24, 2013); *see also Oracle Corp., et al. v. Click-to-Call Techs. LP*, IPR2013-00312, Paper No. 52 at pp. 12-13 (PTAB Oct. 28, 2014). Additionally, Patent Owner's pending suit against Petitioners regarding the '807 patent has no effect under 35 U.S.C. § 315(b) since it was filed less than a year ago.

By separate petition, Petitioner seeks IPR of claims 8, 20, 21, 26, and 27 of the '807 patent, and also separately petitions for IPR of the '741 patent. The '741 patent issued from a continuation application to the '807 patent.

C. Lead and Back-Up Counsel under 37 C.F.R. § 42.8(b)(3)

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D. Service Information

Petitioners consent to electronic service by email at IPR36784-0042IP1@fr.com and PTABInbound@fr.com (cc'ing schaefer@fr.com and kane@fr.com).

III. PAYMENT OF FEES – 37 C.F.R. § 42.103

Petitioners authorize charging Deposit Account 06-1050 for the petition fee specified in 37 C.F.R. § 42.15(a) and for any other required fees.

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

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

Petitioners certify the '807 patent is available for IPR and that Petitioners are not barred or estopped from requesting IPR.

B. Challenge under 37 C.F.R. § 42.104(b) and relief requested

Petitioners request IPR of claims 1-7, 17-19, 24, and 25 of the '807 patent, and a finding of unpatentability as follows:

Ground	References
1	Claims 1-7, 17-19, 24, and 25 are obvious under 35 U.S.C. § 103 over <i>Gunaratnam</i> (RMD1004) in view of <i>Ging</i> (RMD1005)
2	Claims 1-7, 17-19, 24, and 25 are obvious under 35 U.S.C. § 103 over <i>Gunaratnam</i> in view of <i>Ging</i> and <i>McAuley</i> (RMD1034)
3	Claims 1-7, 17-19, 24, and 25 are obvious under 35 U.S.C. § 103 over <i>Lovell</i> (RMD1012) in view of <i>Gunaratnam</i>

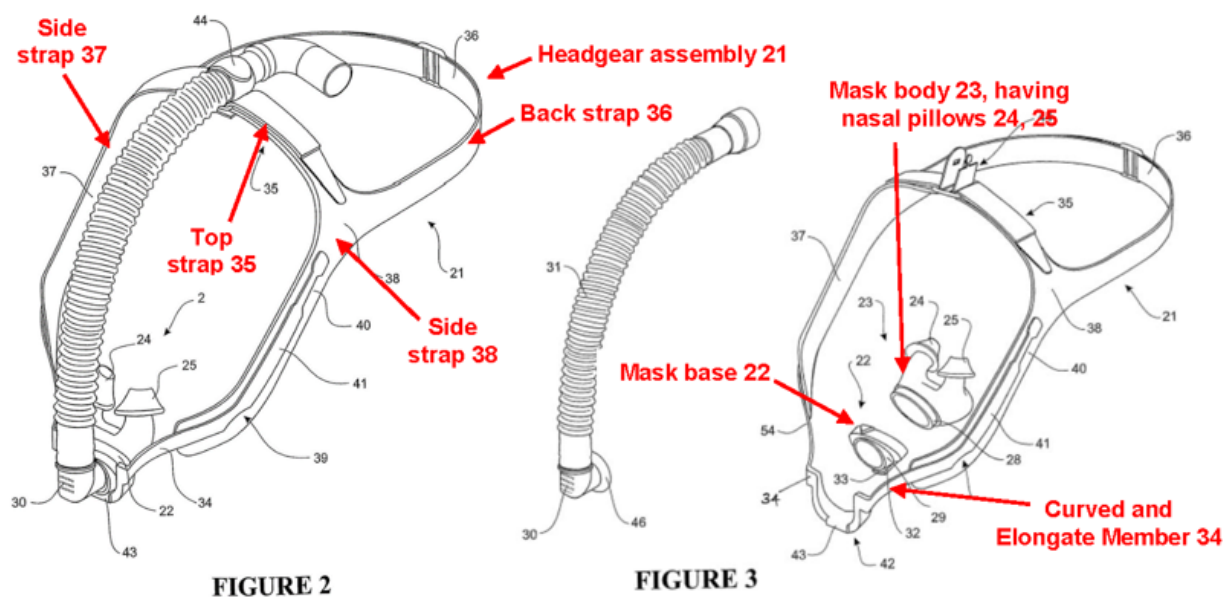
All of these references are prior art printed publications under pre-AIA 35 U.S.C. § 102(b), even assuming the '807 claims are entitled to the earliest claimed priority,

July 14, 2006. Specifically with respect to *McAuley*, its publication was Sep. 1, 2005, which is more than one year before the filing in the United States (i.e., the PCT filing designating the United States made on July 13, 2007), therefore making *McAuley* prior art under pre-AIA 35 U.S.C. § 102(b). The unpatentability of the claims is supported by the references and other evidence referenced in this Petition, including testimony of expert Dr. John Izuchukwu, Ph.D., P.E. (RMD1008).

V. THE '807 PATENT AND ITS PROSECUTION

A. The '807 patent's disclosure

The '807 patent relates to a particular patient interface design for systems that supply pressurized air to a person's airway, used for example by people suffering from sleep apnea. *See, e.g.*, RMD1001, col. 1:10-13, 1:24-55, 1:56-2:32, 2:58-3:30; *see also* RMD1008, ¶¶ 24-29; RMD1040 (discussing history of field); RMD1008, ¶¶ 24-27. Figures 2 and 3 illustrate the claimed subject matter:



RMD1001, FIGS. 2, 3. The patient interface shown here includes a “mask assembly” defined in the claims to include: (a) a nasal pillows type mask 2 including (i) a mask body 23 with nasal pillows 24, 25, and (ii) a mask base or “ring” 22; and (b) a swivel elbow connector 30 that connects at the front center of mask 2. *See id.* at col. 5:25-47, 6:38-45, 8:38-52. Headgear assembly 21 secures the mask assembly on the face of the user. *See id.* at col. 6:57-7:3; *see also* RMD1008, ¶¶ 28-29.

The ‘807 specification features the headgear having “a continuous and substantially curved elongate member [34] extending in use below a user’s nose.” *See, e.g.*, RMD1001, Abstract, FIGS. 2-3, col. 2:62-65, 3:11-17, 6:57-61, 7:4-8:6; *but see* RMD1042 (disclosing such an elongate member). But before prosecution on the merits, limitations directed to that feature were dropped. *See* RMD1009, pp. 3-8, 515-519. The claims as issued are simply an obvious collection of patient interface features.

B. The ‘807 patent’s prosecution history.

During prosecution after a rejection based on *Lovell* (RMD1012) – at issue in Ground 3 – applicants amended independent application claim 38 [issued claim 1], and argued two distinctions. *See* RMD1009, pp. 587, 614, 620-21, 629-33; RMD1012, FIGS. 1B, 2B, 5; RMD1008, ¶¶ 30-39.

First, as claimed the rotatable elbow *fits into* the claimed ring, as opposed to

fitting over the ring in *Lovell* (i.e., elbow 14 fits over swivel connector 12, identified by the examiner as a ring). See RMD1009, pp. 614, 620-621. But before the ‘807 patent, that difference would have been considered an obvious design choice, and in fact it was well known at the time that elbow connectors *fit into* masks. See RMD1008, ¶¶ 33-35. And regardless, *Lovell* discloses alternative structure (namely, lower mask shell 8), that meets all limitations of the claimed ring, and an elbow “fits into” the mask shell 8. See *supra* Section VII.C.

Second, as claimed the mask assembly connects to the headgear assembly *only by two side straps*, in contrast to *four side straps* in *Lovell*. See RMD1009, p. 614, 620-622; *see also* RMD1012, FIG. 5, col. 6:18-48. But the headgear assembly as claimed was already known, and indeed already known in connection with nasal pillows masks. See ResMed’s 2004 prior art Swift™ nasal pillows patient interface (RMD1035, RMD1036); ResMed’s 2004 *Gunaratnam* patent filing (RMD1004, *see especially* FIGS. 107G-H, *see also, e.g.*, FIGS. 18, 37-39, 52-56, 59-60, 76A-D, 84, 107, 107-1 to 107-2, 107D-E, 107I, 108). Thus, the second distinction over *Lovell* cannot support patentability. See RMD1008, ¶¶ 37-38.

Despite the flawed arguments, the examiner allowed the claims, giving no reasons for allowance. See RMD1009, pp. 629-33.

C. Person of ordinary skill in the art.

In view of the subject matter of the '807 patent, a person of ordinary skill in the art as of any of the claimed priority dates (as early as July 2006) 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. *See* RMD1008, ¶ 21. This level of knowledge and skill is applied throughout the Petition.

VI. CLAIM CONSTRUCTION UNDER 37 C.F.R. § 42.104(B)(3)

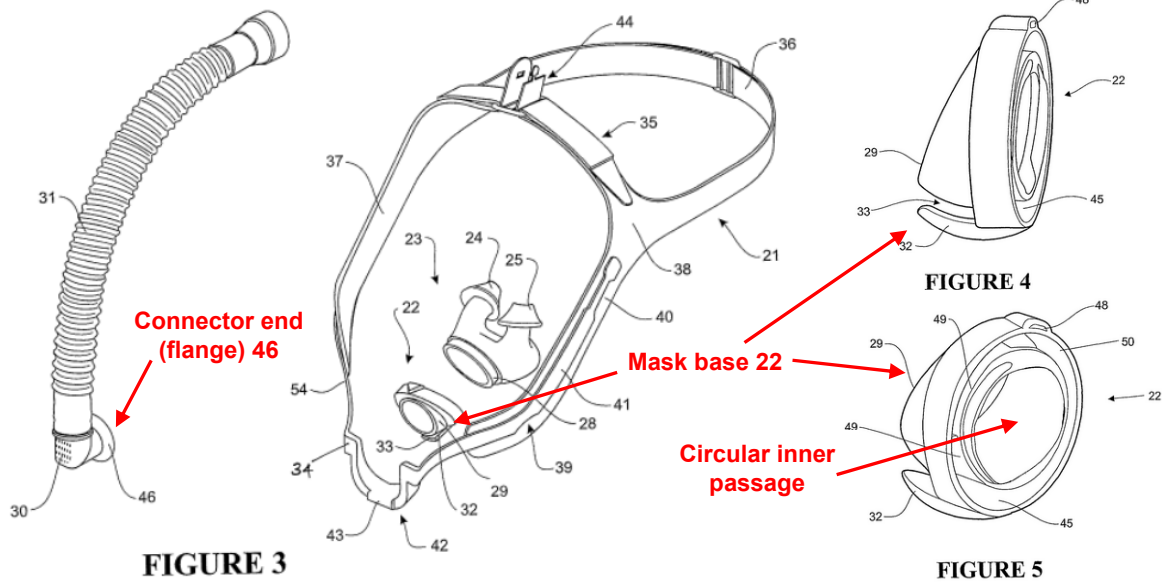
For *inter partes* review, a claim in an unexpired patent is given its broadest reasonable construction in light of the specification in which it appears. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142-46 (2016). Claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). The constructions offered below are intended to aid this proceeding, and do not waive any arguments concerning indefiniteness or claim breadth in proceedings applying different construction standards.

A. The claimed “ring” (claim 1).

The claimed “ring” is 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. *See generally* RMD1008, ¶¶ 40-41.

The term “ring” does not have a special meaning in the applicable field of the ’807 patent, and is not defined in the ’807 specification. *See* RMD1008, ¶ 41. The context in claim 1 for the claimed “ring” is that it is engaged with a “mask body” (e.g., body 23), and an elbow (e.g., “connector” 30) is “rotatably engaged with,” and “fits into,” the ring. *See* RMD1001, col. 11:35, 39-42, 5:31-33. As such, the structure in the ’807 specification corresponding to the “ring” is “mask base” 22; indeed, mask base 22 is said to be “a *ring* or sleeve type attachment.” *Id.*, col. 6:20 (emphasis added); *see also* 6:46-48 and 8:38-40 (focusing on curved inner surface of the mask base 22 for forming a socket in which the connector end 46 of elbow 30 swivels). The ring-shaped mask base 22 is shown in FIGS. 3-5 copied below:



RMD1001, FIGS. 3, 4, 5. Note that connector end 46 of elbow connector 30 has an annular flange that is also ring shaped, but that flange of end 46 does not correspond to the claimed “ring” because it is not described as being “rotatably engaged with” an elbow, as required by claim 1. Because claim 1 recites the elbow fitting into, and rotatably engaging, the ring, the context of claim 1 supports the ring having a generally circular inner passage.

Regarding the outer surface of the claimed “ring,” however, nothing within the plain language of the term “ring” or from the intrinsic record requires that the outer surface of the ring be of a particular shape. In the ‘807 specification, an outer surface of the ring (mask base 22) complements a central section 42 of a separate curved elongate member 34, *see, e.g., id.*, FIG. 3, col. 7:46-55, but in the claims of the ‘807 patent that elongate member 34 component or any other

component that interacts with the outer surface of the claimed ring is unclaimed. In addition, in an alternative embodiment shown in Figures 20-22, an alternative design for a mask base 301 is shown that is integrally formed with two curved members 302 extending to the side of mask base 301 and attaching to respective headgear straps. *See id.*, FIGS. 20-22 and col. 7:62-8:6. Indeed, the outside shape of the ‘807 patent’s mask base or ring 22 is not circular. *See, e.g.*, RMD1001 at Figs. 3-5. This is important because the “ring” feature is not recited in the original patent claims, and was only introduced by the preliminary amendment and thus draws its support from the original disclosure. More specifically, the rings in Figures 3-5 include projections on their top and lower portions (the lower portion projection best seen in Figure 3). RMD1001 at Figs. 3-5.

Also, dictionary definitions for “ring” do not impose a limitation on the shape of the outside surface of a “ring.” *See, e.g.*, RMD1014, p. 1074 (“an encircling arrangement”). Indeed, many structures are considered “rings” yet do not have a circular outside shape. For example, a “ring” for one’s finger may have an outer periphery that is square or rectangular, or that includes a setting with prongs and a stone. *See* RMD1038 (showing a non-circular finger ring, copied below at left). Also, a “nut ring” is hexagonal. *See* RMD1008, ¶ 41; RMD1039 (showing a galvanized nut ring, copied below at right):



RMD1038



RMD1039

In addition, the first named inventor McAuley of the '807 patent has referred to a triangle structure in a different mask (specifically, the ResMed Mirage Quattro full face mask) as a “triangular shaped ring.” *See* RMD1041, ¶ 12.4. As such, a construction that the periphery of the claimed ring need not be generally circular is well supported. *See also* RMD1008, ¶ 41.

B. The phrase “a plane substantially bisecting the ring, each of the two nasal pillows positioned on opposite sides of the plane” (claim 1).

This phrase requires that the “ring” (and elbow rotatably engaged therewith) be located generally at the mask’s front center. *See* RMD1008, ¶ 42. Referring to Figure 3 of the '807 patent, if a vertical plane were defined to bisect an opening in the ring 22 (as shown below), that plane would extend between the two nasal pillows 24, 25, leaving one pillow on each side of the plane, as shown below:

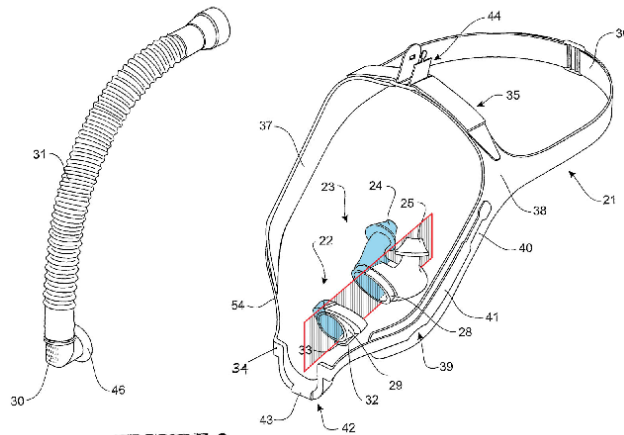


FIGURE 3

RMD1001, FIG. 3. This differs from some prior art configurations in which an elbow fits into a ring located *at the side* of the mask. *See, e.g.*, RMD1004, FIGS. 108-114 (depicting a nasal pillows-type mask having a swivel elbow that connects to a side of the mask assembly).

C. The phrases “wherein the two side straps are configured to connect and disconnect with the mask assembly” and “wherein the mask assembly is configured to connect to only the two side straps” (claim 1).

These clauses 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. *See* RMD1008, ¶ 43.

The first part of the construction not requiring a direct connection is supported by the '807 specification, which discloses only *indirect* connections between straps and mask assemblies. In Figures 2-3 for example, side straps 38

connect to a *rigid side arm* 41 (part of member 34), which in turn connects to the mask assembly 2. *See* RMD1001, col. 6:57-61, 7:4-55. Other embodiments in Figures 8-16 are similar. And in Figures 20-23, side straps 308 (or straps 411, 415 in FIG. 23) similarly connect to a curved elongate member 302 (405 in FIG. 23) and not to the mask assembly directly. Further, dependent claim 6 adds that “molded side arms extend away from the ring to connect with the side strap,” (*see, e.g.,* side arms 41 in Figure 3), and thus *requires an indirect connection* between the mask assembly and the side straps, the premise of that being claim 1 necessarily covers an indirect connection.¹

The second part of the construction requiring that *only* the two side straps and no other strap of the headgear assembly be connectable to the mask assembly is supported by the prosecution history as discussed above in Section V.B, in which the “four strap” connection to the mask assembly of *Lovell* was

¹ If the molded side arms 41 of the ‘807 patent are considered to be part of the claimed “mask assembly,” then it may be argued that the ‘807 specification does disclose a direct connection, but in that case similar side arm structures in the prior art would be part of the claimed “mask assembly” and there would be a direct connection in the prior art also. *See* Discussion under Ground 1, limitation 1.15; Ground 3, limitations 1.11-1.17.

distinguished. *See* RMD1012, FIG. 5; RMD1009, pp. 585-90, 613-23; RMD1008, ¶¶ 36-38.

VII. THE CHALLENGED CLAIMS ARE UNPATENTABLE AS OBVIOUS

A. Ground 1: Claims 1-7, 17-19, 24, and 25 are unpatentable as obvious over *Gunaratnam* in view of *Ging*.

Gunaratnam discloses numerous patient interface designs. The design shown in Figure 135 and described in *Gunaratnam* (¶ 403) serves as the starting point for the Ground 1 obviousness

analysis. The Figure 135 patient interface

includes a nasal mask assembly and an

elbow rotatably connected at the front

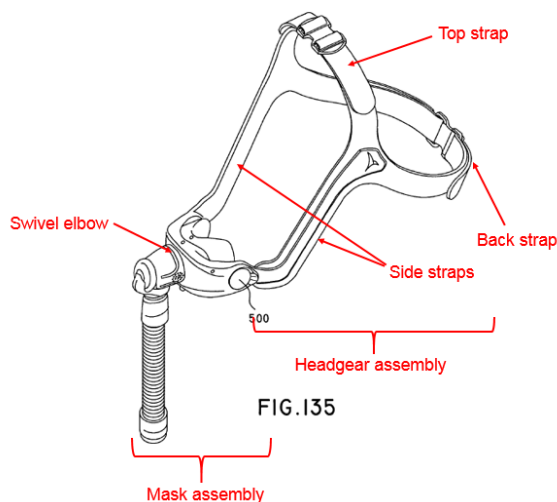
center of the mask, and includes a

headgear assembly where only two side

straps are connectable to the mask assembly. *See* RMD1008, ¶¶ 44-48, 62-63.

The Figure 135 interface includes all limitations of claim 1, except the nasal mask being a nasal *pillows* mask, and detail of the claimed “ring” and the elbow fitting into the ring. Those features are taught elsewhere in *Gunaratnam* and in *Ging*, and it would have been obvious to have applied those teachings to *Gunaratnam*’s

Figure 135 patient interface, as discussed below. *See generally* RMD1008, ¶¶ 44-54, 61-119, 168-174, 176-179.



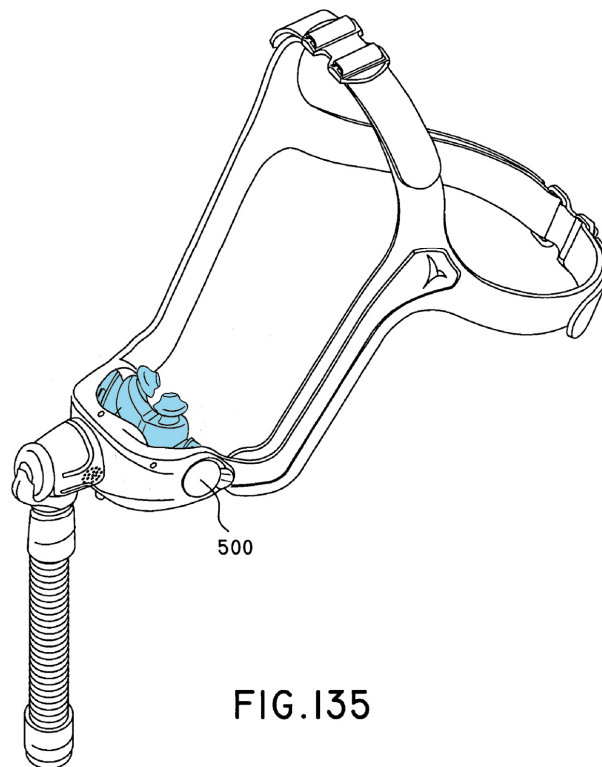
1. Obviousness of substituting a nasal pillows mask body as disclosed elsewhere in *Gunaratnam* for the full nasal mask body in *Gunaratnam*'s Figure 135 patient interface

Claim 1, limitation 1.3 (*see* claim charts, Section V.A.3 below) recites the mask body having “two nasal pillows.” *Gunaratnam*'s Figure 135 patient interface includes a full nasal mask covering the nose entirely, not nasal pillows. Long before the '807 patent though, nasal pillows masks were well-known alternatives to full nasal masks. *See, e.g.*, RMD1019; RMD1020; RMD1012; RMD1004, ¶¶ 4-9; *see also* RMD1008, ¶¶ 66-73. *Gunaratnam* also discloses patient interfaces using nasal pillows masks in Figures 1-133, and that is its primary focus. *See* RMD1004, FIGS. 1-133, ¶ 403, including FIGS. 1, 5-6, ¶¶ 185-93 (details of an example nasal pillows mask, which includes a frame and a “nozzle assembly” or mask body with two “nozzles” or pillows); *see also* RMD1035 and RMD1036 (ResMed's prior art “Mirage Swift™” Nasal Pillows patient interface from 2004); RMD1008, ¶¶ 66-73.

It would have been obvious before the '807 patent to have substituted, into the *Gunaratnam* Figure 135 patient interface, a nasal pillows mask body in place of the full nasal mask body, in view of the knowledge in the field at the time about nasal pillows masks including the teachings in *Gunaratnam*. *See* RMD1008, ¶¶ 71-73. Doing so would have been nothing more than applying known teachings in a known way to achieve a predictable result. *See id.*; *see also* *KSR Int'l Co. v.*

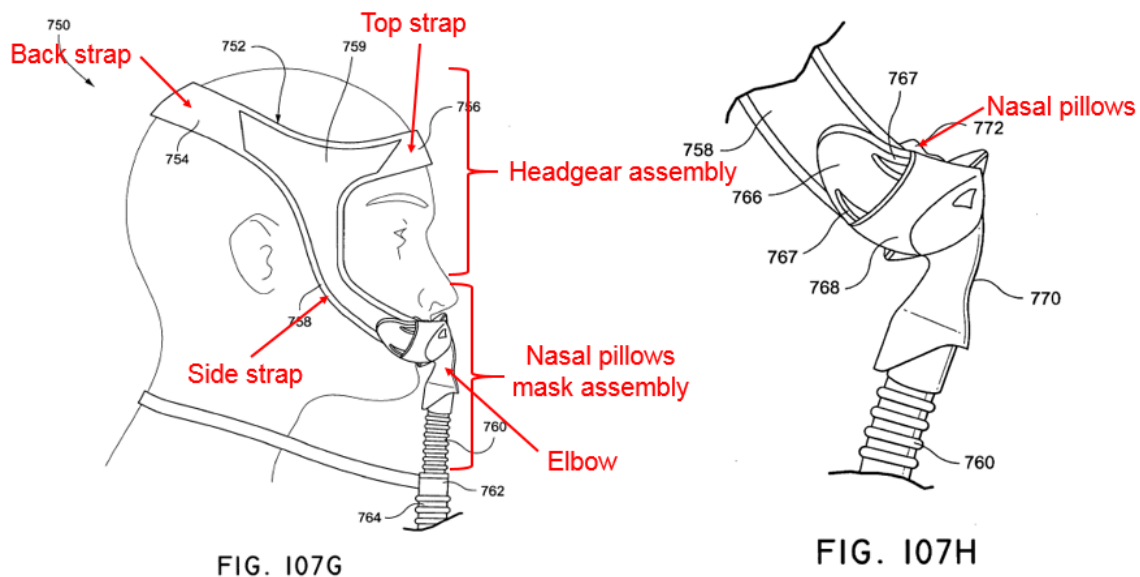
Teleflex Inc, 550 U.S. 398, 416 (2007). Moreover, *Gunaratnam* teaches that the claimed headgear is adaptable to be used with either a full nasal mask (FIG. 135) or a nasal pillows mask (FIGS. 107G-H, 108).

Applying a known nasal pillows mask body to *Gunaratnam*'s Figure 135 patient interface yields a configuration shown below:



RMD1004, FIG. 135. The obviousness of applying a known nasal pillows mask body to *Gunaratnam*'s Figure 135 patient interface is well supported. Indeed, *Gunaratnam* suggests it, in describing Figure 135, stating “the nozzle assembly and/or its associated cushion [i.e., the nasal pillows masks shown in Figures 1-133] could be replaced with a nasal mask and/or nasal cushion [i.e., the full nasal mask

of Figure 135].” *Gunaratnam*, ¶ 403; *see also* RMD1008, ¶ 73. One of skill in the art would have understood the converse is also true, namely, the full nasal mask of Figure 135 could be replaced with a nasal pillows mask. *See* RMD1008, ¶ 73. Moreover, *Gunaratnam* specifically teaches a nasal pillows mask specifically in combination with the elbow being connected at the front center of the mask as claimed, and with the same four-strap headgear as claimed. *See* RMD1004, FIGS. 107G-H, copied and annotated below:



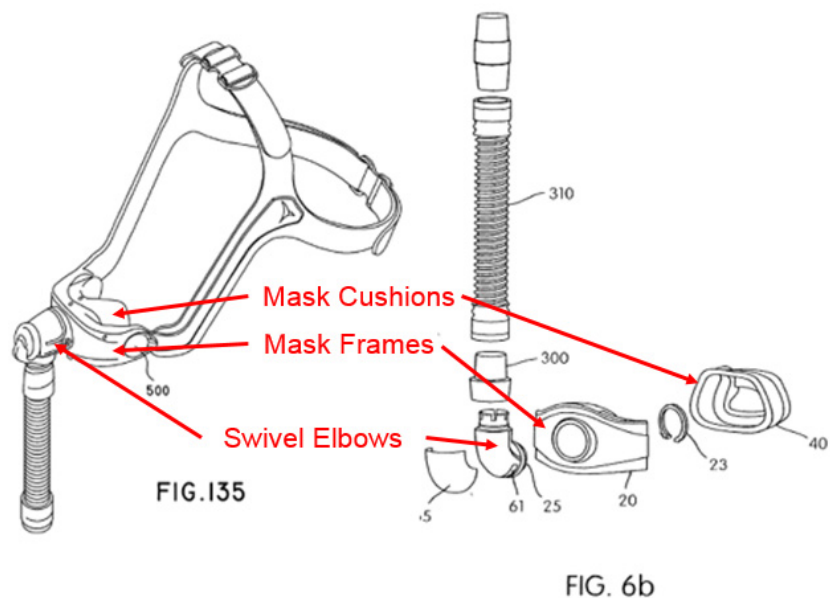
RMD1004, FIGS. 107G, 107H. The similarity of these aspects of the patient interface to the Figure 135 patient interface suggests the interchangeability of a full nasal mask and a nasal pillows mask in *Gunaratnam* Figure 135. *See* RMD1008, ¶ 73; *see also* RMD1004, FIG. 108; RMD1035, p. 4 and RMD1036, p. 1 (nasal pillows masks with headgear similar to *Gunaratnam* Figure 135).

2. *Gunaratnam*'s Figure 135 patient interface and further detail regarding that patient interface disclosed in *Ging* teach the claimed “ring” and ring “socket,” and an elbow “fitting into” the ring and socket, as claimed.

Limitations 1.5, 1.7, and 1.8 (*see* claim charts, Section VII.A.3 below)

require (1) a “ring” engaged with the mask body, and (2) a rotatable elbow that *fits into* a socket formed by the ring. Section VI.A provides a construction for “ring” – “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.” Section V.B details the prosecution history relating to the “fits into” limitation.

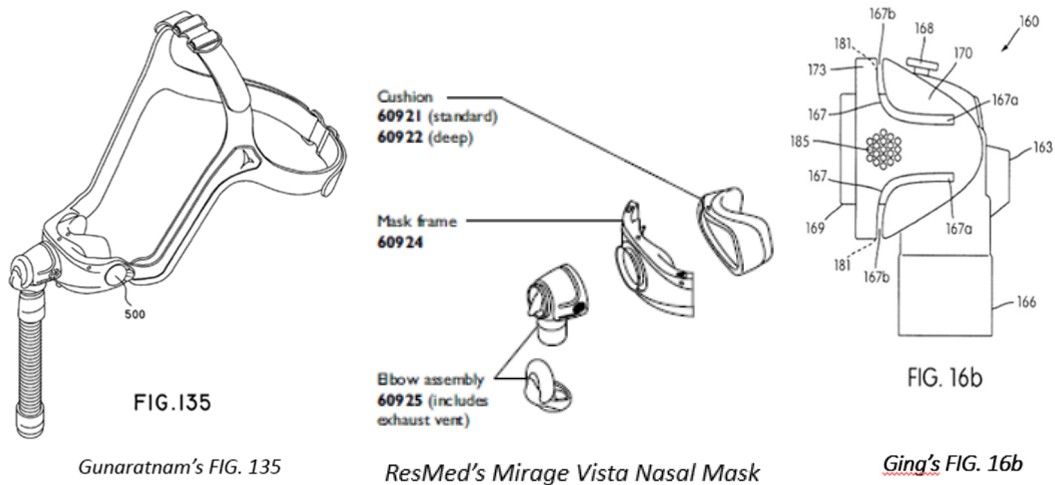
Gunaratnam's Figure 135 discloses the claimed ring by virtue of its mask frame. The “mask frame” meets the claimed ring, in that it engages with a mask “cushion” serving as the claimed mask body, and has an opening in the front center of the mask frame into which a rotatable elbow fits and through which air flows.



See RMD1004, FIG. 135; *see generally* RMD1008, ¶¶ 77-85, 89. The same nasal mask structure shown in *Gunaratnam* Figure 135, including the nasal mask frame,

is shown in more detail in another ResMed patent filing, *Ging*, for example Figure 6b of *Ging* shown above at right, with the mask frame referenced as 20. Compare RMD1004, FIG. 135, ¶ 403 with RMD1005, FIGS. 1, 2-6B, ¶¶ 108-116; see also RMD1005, FIGS. 5, 5c, 6b, 24, 27-29, ¶¶ 114-115, 195-223 (describing mask frame 20 engaged with mask cushion 40).

The applicability of *Ging*'s details for a nasal mask frame and swivel elbow to *Gunaratnam*'s Figure 135 is clear. *Gunaratnam* specifically refers to ResMed's Vista Mask (RMD1024), and it is the Vista mask that is disclosed in *Ging* (indeed, *Gunaratnam* incorporates by reference the provisional applications that form the basis of *Ging*). See RMD1004, ¶ 341, 403; see also RMD1008, ¶¶ 47-48, 51, 61-63. The similarity of the designs in these three documents is illustrated below:



RMD1004

RMD1024

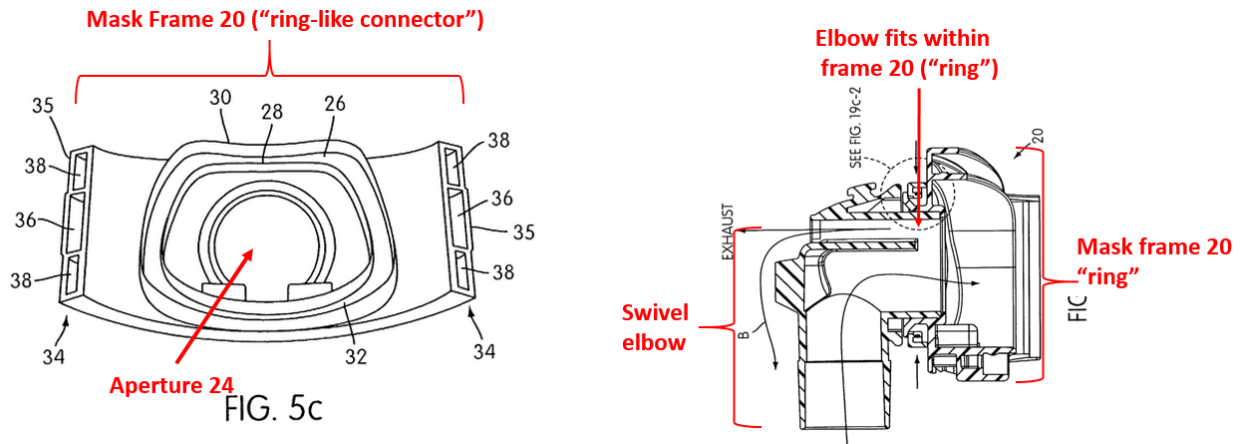
RMD1005

Note the identical design of the forwardly protruding flange on the mask frame, and the design detail of the swivel elbow (160 in *Ging*) including textured

protrusions 185 on the side and groove 167. Note also that the swivel elbow 160 design shown in *Ging*'s Figure 16b is said to be an alternative for the swivel elbow shown in *Ging*'s FIG. 6b, and thus would be used with same mask 20 shown in *Ging*'s FIG. 6b. *See* RMD1005, ¶¶ 151-162.

The *Gunaratnam/Ging* mask frame 20 meets the claimed “ring,” despite not having a circular periphery, given the proper interpretation of “ring” discussed in Section VI.A. *See also* RMD1008, ¶¶ 77-85. Indeed, in the context of the ‘807 claims, the shape of the mask ring’s periphery has no criticality because the disclosed structure on the outside of that ring (the curved elongate member 34, FIG. 3) is unclaimed, as described above in Section V.A. *See* RMD1008, ¶ 41; *KSR*, 550 U.S. at 416. But even if “ring” were read narrowly to require that the ring have a more circular perimeter, that shape would nevertheless have been an obvious, as will be discussed in Ground 2. *See* RMD1008, ¶¶ 85, 181-185.

Regarding the elbow *fitting into a socket* formed by the ring (mask frame) as claimed, it was well known at the time for elbows to fit into an aperture in a mask frame, and indeed *Ging* expressly shows a swivel elbow’s end portion 169 that is “fit into” a mask frame aperture 24:



RMD1005, FIG. 5c (above left, showing mask frame aperture 24), FIG. 19c-1 (above right, showing elbow fit into mask frame); *see also* RMD1005, FIGS. 1-6b, 19a-1 – 19c-2, ¶ 161; RMD1004, FIGS. 110-111 (swivel elbow fits into mask frame, albeit at the side of the mask frame); RMD1021, FIGS. 2, 7, col. 5:36-50 (elbow’s swivel connector 6 fits into front of nasal mask 5); RMD1018, FIGS. 1-2 (swivel elbow fits into front of nasal mask frame). As such, it would have been an obvious implementation detail for the elbow in *Gunaratnam*’s Figure 135 patient interface to “fit into” a socket formed by the mask frame. *See* RMD1008, ¶ 89.

3. Correspondence between the ‘807 patent claims and the teachings of *Gunaratnam* and *Ging*.

The correspondence between claims 1-7, 17-19, 24, and 25 and the teachings of *Gunaratnam* and *Ging* is set forth below.

Claim 1 (Limitation 1.1): “A patient interface comprising: a mask assembly . . . ; and a headgear assembly.” *Gunaratnam*’s Figure 135 shows a patient interface including a mask assembly and a headgear assembly that secures

the mask assembly to the user's face. *See* annotated RMD1004, FIG. 135 above; *see also* ¶ 403; RMD1008, ¶¶ 44-48.

Limitation 1.2: “a mask assembly having:” *Gunaratnam's* Figure 135 includes a nasal mask assembly, as does *Ging*. *See* annotated FIG. 135 above; RMD1004, FIG. 135, ¶ 403; RMD1005, ¶ 107; *see also* RMD1008, ¶ 42..

Limitation 1.3: “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.” As discussed in Section VII.A.1, it would have been obvious to a person of skill in the art before the '807 patent to have substituted, into *Gunaratnam's* Figure 135 patient interface, a nasal pillows mask body or cushion in place of the full nasal mask body or cushion shown in Figure 135, in view of known teachings at the time about nasal pillows masks for example in *Gunaratnam*. *See* RMD1008, ¶¶ 66-73; *see also infra* Section VII.A.1. Doing so would yield a patient interface with a mask body having two nasal pillows, as claimed.

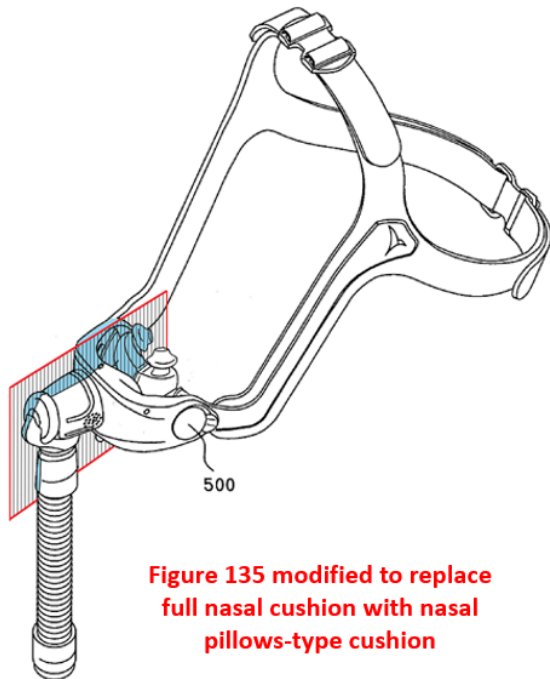
Regarding the “sealing in use” claim limitation, this is what nasal pillows masks are designed to do, and indeed *Gunaratnam* states that the “nozzles” (i.e., pillows) “sealingly engage with nasal passages [nares] ... in use.” *See* RMD1004, ¶ 26 (emphasis added); *see also id.* at FIGS. 5-8, ¶ 185.

Limitation 1.4: “the mask body sized and shaped to leave the mouth of the user uncovered by the mask body when in use.” Full nasal masks and nasal

pillows masks – as disclosed in *Gunaratnam, Ging* and elsewhere – are by design sized and shaped to leave the mouth uncovered when in use. *See* RMD1008, ¶ 75. As such, the Figure 135 patient interface of *Gunaratnam*, modified to have a nasal pillows mask body instead of a full nasal mask body as shown, would leave the mouth uncovered when in use. *See* RMD1004, FIGS. 107G-H, as well as FIGS. 25, 36-38, 51-52 and 59; *see also* RMD1008, ¶¶ 74-76. Specifically regarding the example nasal pillows mask body shown in FIGS. 107G-H of *Gunaratnam*, the fact that Figure 107G seems to show the nasal pillows cushion mask body covering the user’s mouth is irrelevant with respect to the claim limitation, because the mask body as shown in Figure 107G is not “in use” with the pillows inserted into the nares of the user. *See* RMD1008, ¶ 46.

Limitation 1.5: “a ring engaged with the mask body.” As discussed in Section VII.A.2, *Gunaratnam/Ging* disclose a mask frame labeled 20 in *Ging*. As was conventional in a two-part mask assembly where a mask body or cushion can be attached to a frame and taken apart for cleaning, the *Gunaratnam/Ging* mask frame is “engaged with” a mask cushion (the claimed mask body), as is also discussed above in Section VII.A.2. *See also* RMD1008, ¶¶ 77-85.

Limitation 1.6: “a plane substantially bisecting the ring, each of the two nasal pillows positioned on opposite sides of the plane.” As explained in Section VI.B, this claim limitation requires that the ring be located generally at the front center of the mask. *See also* RMD1008, ¶ 42. This feature would be present in



Gunaratnam’s Figure 135 design when a nasal pillows-type cushion is substituted in place of the full nasal cushion of Figure 135. If one were to consider a plane that bisects the ring (e.g., mask frame) vertically as shown at left, that plane would bisect the nasal mask body vertically and would lie between each of the two nasal pillows,

thereby leaving the pillows on opposite sides of the plane. *See* RMD1008, ¶¶ 86-88.

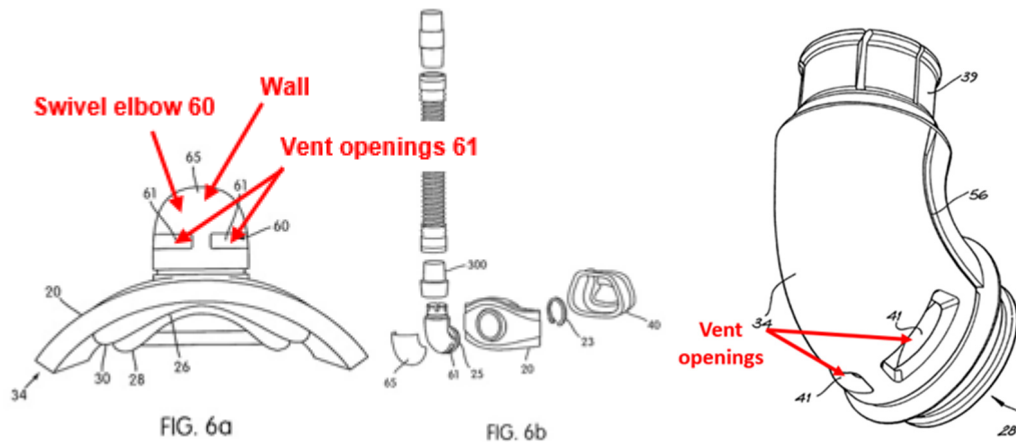
Limitation 1.7: “an elbow rotatably engaged with the ring.” *Gunaratnam* discloses a conventional “swivel” elbow in its Figure 135 design (*see* ¶ 403), and hence the elbow is rotatably engaged with the mask frame (ring). *See* RMD1004, FIG. 135, ¶ 403; RMD1008, ¶¶ 109-110. *Ging* similarly discloses a swivel elbow 160 rotatably engaged with the mask frame 20. *See* RMD1005, ¶¶ 151-62 and FIGS. 16a – 16c-2, ¶ 113 and FIGS. 6a and 6b. Indeed, swivel elbows were well

known well before the '807 patent. *See* RMD1021, FIGS. 2, 7, col. 36-50; RMD1018, FIGS. 1-2; RMD1016, FIGS. 1-3; RMD1022, FIGS. 1-2; *infra* Section V.A.2.

Limitation 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.”

As discussed above in Section VII.A.2, *Gunaratnam* and *Ging* teach that the mask frame (ring) of *Gunaratnam*'s Figure 135 patient interface forms a socket into which a swivel elbow fits, or at a minimum that is one obvious way in which the Figure 135 interface would be implemented.

Limitation 1.9: “the elbow comprising a plurality of vent holes.” Having vent holes in the elbow for exhausting exhaled air was well known, and in fact *Gunaratnam* states that the swivel elbow in FIG. 135 “may be provided with appropriate vents to exhaust exhaled gas from the breathing chamber.” RMD1004, ¶ 403; *see also* RMD1008, ¶¶ 90-94. *Ging* and *Gunaratnam II* both illustrate the vent holes as they would be in the FIG. 135 elbow, as shown below:

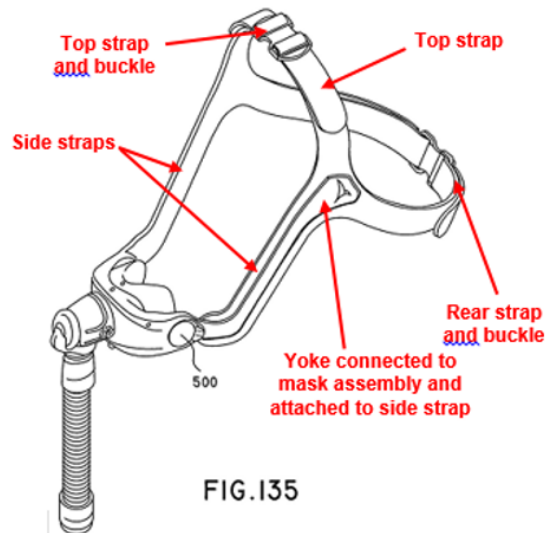


RMD1005, FIGS. 6a, 6b, and ¶ 113; RMD1007, FIG. 4 (above right).

Limitation 1.10: “a tube or conduit extending from the elbow.”

Gunaratnam’s Figure 135 design includes a tube or conduit extending from the swivel elbow, as is also taught by *Ging*. See RMD1004, FIG. 135; RMD1005, FIG. 26, ¶ 153, *see also id.* at ¶ 111 and FIG. 1.

Limitation 1.11: “a headgear assembly having:” *Gunaratnam* Figure 135 (annotated at right) shows a headgear assembly with all of the limitations 1.12-1.17 below, and *Gunaratnam*’s Figures 107G-H and 108 show that same headgear assembly being used with a nasal pillows mask. See RMD1008, ¶¶ 95-100.



Limitation 1.12: “two side straps that pass down the cheeks of the user to

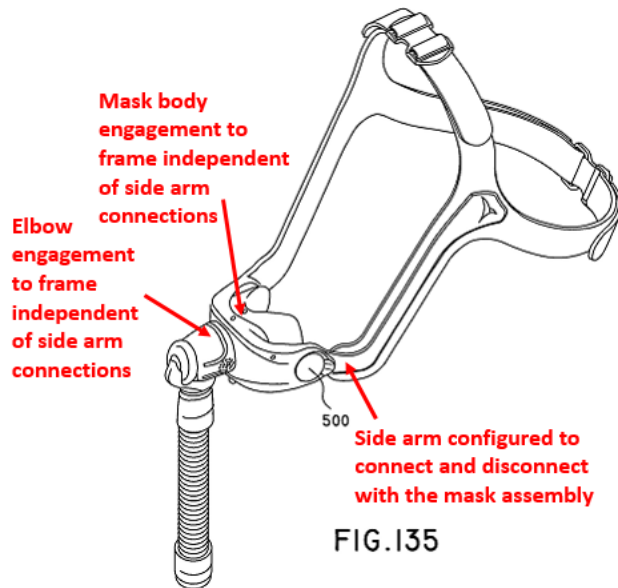
secure the mask body to a face of the user.” Gunaratnam’s headgear assembly of Figures 135 and 107G-H has two side straps that would pass down the cheeks of a user when worn, to secure the mask body to the user’s face. See RMD1004, FIGS. 135 (annotated in limitation 1.11); see also FIGS. 107G-H and 108; RMD1008, ¶ 95; RMD1035, p. 4 and RMD1036, p. 1 (ResMed nasal pillows masks with headgear similar to that in Gunaratnam Figure 135).

Limitation 1.13: “a top strap including a buckle configured to facilitate length adjustment of the top strap.” Gunaratnam’s headgear assembly of Figures 135 and 107G-H includes a top strap with a buckle, facilitating length adjustment of the top strap. See RMD1004, FIG. 135 (annotated in limitation 1.11); see also FIGS. 18 and 83, ¶ 211.

Limitation 1.14: “a back strap adjustably connected to at least one of the top strap and the two side straps.” In the same manner as the ‘807 headgear assembly, Gunaratnam’s headgear assembly of Figures 135 and 107G-H includes a back strap connected to both the top strap and both side straps, and is adjustably connected to those other straps by virtue of having a back buckle. See RMD1004, FIG. 135 (annotated in limitation 1.11); see also *id.* at FIGS. 18, 83, 107G-H, 108; ¶ 211; compare with RMD1001, FIG. 2 (showing the ‘807 disclosed back strap design is the same as Gunaratnam’s).

Limitation 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.”



Gunaratnam’s Figure 135 side straps are so configured, because the elbow is connected at the front center of the mask assembly, and the two side straps independently connect and disconnect at the sides. *See* RMD1008, ¶¶ 96-99. As such, the side straps may be connected

and disconnected with the mask assembly while the elbow remains engaged with the mask frame (ring) and the mask frame remains engaged with the mask body.

See id.; *see also* RMD1004, ¶¶ 403, 377-81, Figures 108-13, 135 (yokes connected to mask assembly in embodiments similar to Figure 135).

The side straps in Figure 135 do not connect directly to the mask assembly, but the claims do not require a direct connection. *See* Section VI.C.² Even if the

² As discussed in Section VI.C, footnote 1, there is a direct connection between the side straps and the mask assembly if side arms (side arms 41 in the ‘807 patent, and side arms in *Gunaratnam* Figure 135 as shown above in the annotated Figure 135) are considered part of the claimed “mask assembly.”

claims were construed to require a direct connection (which is incorrect, and indeed not disclosed in the ‘807 specification), it would nevertheless have been an obvious modification for the *Gunaratnam* Figure 135 headgear assembly to have the *side straps* connect *directly* to the mask assembly, rather than connecting via *yokes* as in Figure 135. See RMD1008, ¶ 98. The obviousness of this design modification is illustrated by *Gunaratnam* also disclosing such a direct connection in the headgear assembly for a similar type of nasal interface (having nasal pillows), namely in FIGS. 107G-H. In FIGS. 107G-H, side straps 758 connect directly to mask frame 768, rather than yokes 759 connecting directly to the frame. See RMD1004, FIGS. 107G-H and ¶¶ 369-370. One of ordinary skill in the art would have understood, in view of *Gunaratnam* for example, that direct and indirect connection of two side straps to the mask frame were two obvious design choices. See RMD1008, ¶ 98.

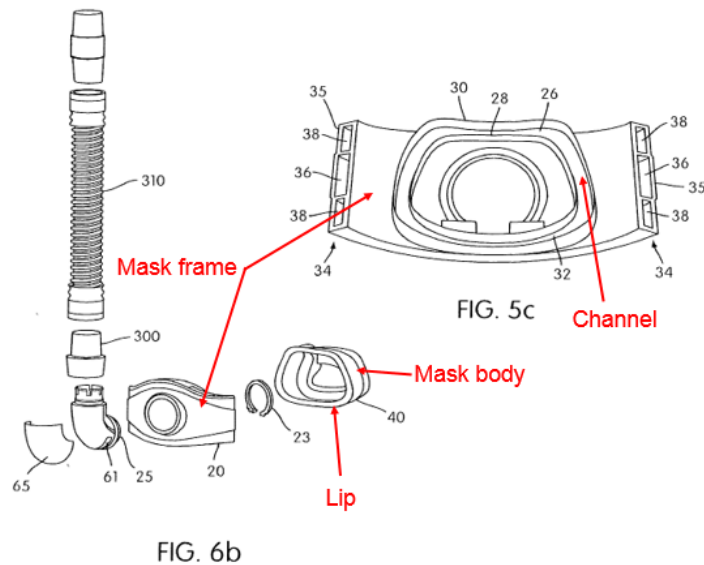
Limitation 1.16: “wherein the mask assembly is configured to connect to only the two side straps.” In *Gunaratnam*’s Figure 135, the mask assembly is configured to connect to *only* the two side straps, and is not configured to connect to any other strap of the headgear assembly. See RMD1004, FIG. 135; *see also* FIGS. 107G-H; RMD1008, ¶¶ 96-100; *see also* Section VI.C (claim construction for limitation 1.16); discussion under limitation 1.15 (discussing that even if claim 1 required a direct connection, which it does not, that would have been nothing

more than an obvious design choice).

Limitation 1.17: “wherein the top strap connects only with one or more of the side straps and the back strap.” In *Gunaratnam*’s Figure 135, the top strap (annotated in limitation 1.11) connects only with the side straps and the back strap, and therefore meets this claim limitation of connecting “only with one or more of the side straps and the back strap.” See RMD1004, FIG. 135; *see also* FIGS. 107G-H. The top strap in *Gunaratnam* Figure 135 is not, for example, configured to connect also with the tube or conduit, as in other prior art designs and in unclaimed designs in the ‘807 specification (*e.g.*, RMD1001, FIG. 9).

Claim 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.” Well before the ‘807 patent, the idea of mask components being supplied in multiple parts, for example to facilitate a user taking the parts apart to clean the insides of them, and also the idea of connecting the mask parts together by a “friction fit” or “tongue and groove” technique, with one part having a “lip” and the other having a “channel,” were well known in the art of patient interfaces, and indeed are taught by *Gunaratnam* and *Ging*. See RMD1041, ¶ 12.2; RMD1004, ¶ 186 (nozzle assembly removably attachable to mask frame by rib/recess structures); RMD1005, FIGS. 5c, 6b, 24, 27-29, ¶¶ 114-15; RMD1008, ¶¶ 101-104.

Ging teaches how the mask frame in Figure 135 of *Gunaratnam* would be connectable to a mask body by a lip and channel arrangement. *Ging* at FIGS. 5c and 6b, for example (copied and annotated at right), show how the mask frame 20 (the claimed ring) includes a channel 28 that receives a lip of the mask body 40. See RMD1005, FIGS. 5c, 6b, 24, 27-29, ¶¶ 111, 114-115, also



generally ¶¶ 195-223. *Gunaratnam* further discloses masks in which a mask frame is connectable to a nasal pillows mask body by a lip and channel arrangement. Specifically, the nasal pillows mask assembly 10 in Figures 1-8 has a mask frame 16 and a separate nozzle assembly 18 with pillows 18. *Gunaratnam* discloses that these two parts are connectable together in various ways, one being to have “a rib or groove/recess” (i.e., a lip and channel) in each of the two parts to interlock the two pieces together with a snap fit. See RMD1004, ¶ 186, see also FIGS. 7-8. Applying a nasal pillows mask body as disclosed throughout *Gunaratnam* to *Gunaratnam* Figure 135 would yield a mask body with a lip that is received in a channel of a ring (mask frame), or at a minimum that would have been an obvious way to connect the two mask pieces to facilitate a user being able

to disassemble the parts for cleaning the insides. *See* RMD1008, ¶¶ 101-104.

Claim 3: “A patient interface as claimed in claim 2, wherein the mask body comprises a molded elastomeric material.” *Gunaratnam* discloses a nasal pillows mask body (e.g., nozzle assembly 18 from FIGS. 1, 5, and 6) being made of a molded elastomeric material, such as silicone. *See* RMD1004, ¶ 182 (“[N]ozzle assembly 18 is formed from a one part molded silicone piece”); *see also id.* at ¶¶ 191-192 (“nozzles are constructed from a substantially flexible polymer material, such as a silicone elastomer”); *id.* at ¶¶ 266, 332, 334, 357; RMD1005, ¶ 182 (mask frame 200 and membrane 205 making up 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”); *id.* at ¶ 174; *see also* RMD1008, ¶ 107. One of skill in the art at the time 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. *See id.* at ¶¶ 105-107.

Claim 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.” In *Gunaratnam*’s Figure 135 patient interface – given the use of a “swivel” elbow (“rotatable” vis-à-vis the ring as discussed in Section VII.A.2 and

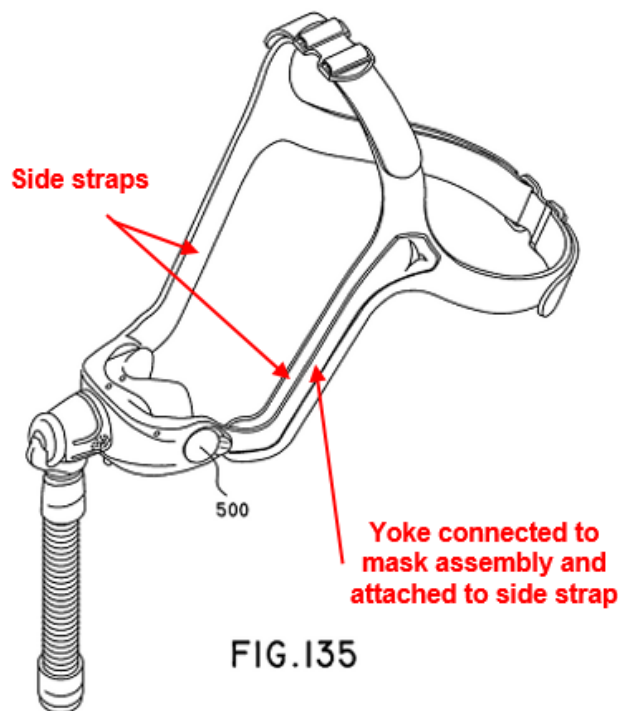
limitations 1.7 and 1.8) and the length and flexibility of the tube or conduit that attaches to the swivel elbow – the elbow is able to swivel in the mask frame (the claimed ring) such that the tubing is available to be adjacent to either side strap. *See* RMD1004, FIG. 135, ¶ 403; RMD1008, ¶¶ 108-113; *see also* RMD1004, FIGS. 108A, 108B, ¶ 394 (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). The same would be true of *Ging*. *See* RMD1005, ¶ 151, FIGS. 1, 16a – 19c-2; RMD1008, ¶¶ 111-112. For example, the swivel elbow 60 in Figures 6a-b of *Ging* is capable of freely rotating 360 degrees relative to the mask so the tube can be positioned adjacent either side strap. *See* RMD1005, FIGS. 6a, 6b, ¶¶ 113, 148-53; *see also* RMD1008, ¶¶ 108-113.

Claim 5: “A patient interface as claimed in claim 1, wherein the ring comprises a hard plastic material.” *Gunaratnam* and *Ging* both disclose that it was conventional for a mask assembly to include a *rigid* shell or mask frame. *See* RMD1004, ¶¶ 4, 255; RMD1005, ¶ 5; *id.* at claim 59 (claiming “[a] frame for a respiratory mask assembly” that includes “a substantially rigid main body”). The selection of a hard plastic material for such rigidity would have been an obvious design choice for one of skill in the art, and in fact *Gunaratnam* suggests the use of a hard plastic material. *See* RMD1004, ¶ 178 (describing a mask frame 16 that “*is a rigid or semi-rigid structure formed from a polymer material*”) (emphasis

added); *see also* RMD1008, ¶ 114. As such, *Gunaratnam* and *Ging* both teach the mask frame (the claimed ring) being made of hard plastic material.

Claim 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.” *Gunaratnam*’s Figure

135 patient interface includes a pair of yokes (the claimed “molded side arms”) that respectively connect to opposite sides of the mask frame (the claimed ring). *See* RMD1004, FIG. 135. The yokes extend away from the mask frame 20 and connect with the side straps as



shown in Figure 135, and pass down the cheeks of a user in use. *See* Discussion under Limitation 1.12. Figures 108-13 of *Gunaratnam* further illustrate the connection of yokes 608 to a mask frame 616, which is similar to how the yokes 608 are connected to the mask frame in Figure 135. In particular, yokes 608 include end rings 610 secured around a portion of the tubular frame 616, and extending from the frame 616 to connect with one of the side straps. *See*

RMD1004, FIGS. 108-110b, 135, ¶¶ 375-84; *see also* RMD1008, ¶ 116.

Regarding the yokes (side arms) being molded, one of skill would have understood that to be an obvious way to make the yokes given they are taught to be rigid and made for example of plastic, which would involve a molding process. *See* RMD1004, ¶ 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 ¶¶ 376, 379, 390; *see also generally* RMD1005, ¶¶ 119-22, and particularly ¶ 120 (yokes “constructed of a somewhat rigid material, e.g., plastic” such as nylon or polypropylene); *see also* RMD1008, ¶¶ 115-117.

Claim 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 flow of gases as set forth in claim 7 is simply how such patient interfaces work. The claimed flow of gases would be present in the patient interface of *Gunaratnam* Figure 135 modified to include a nasal pillows mask body as discussed in connection with claim 1. *See* RMD1004, FIG. 135, ¶ 403; RMD1008, ¶¶ 118-119.

Claim 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.” This

claim is similar to

dependent claim 2

discussed above. As

discussed above in

connection with claim

2, well before the ‘807

patent the idea of mask

components being

supplied in multiple

parts, for example to facilitate cleaning, and the idea of connecting together parts

of a mask by a “friction fit” or “tongue and groove” technique, with one part

having a space between two walls and the other part being attached via a friction fit

within that space, were well known. *See, e.g.*, RMD1041, ¶ 12.2; RMD1004, ¶

186. For example, *Ging* in FIG. 5c discloses a mask frame 20 that includes an

inner wall 26, outer wall 28, and channel 28 as a space therebetween into which a

lip of cushion 40 fits via friction. RMD1005, FIGS. 5c, 6b, 24, 27-29, ¶¶ 114-15,

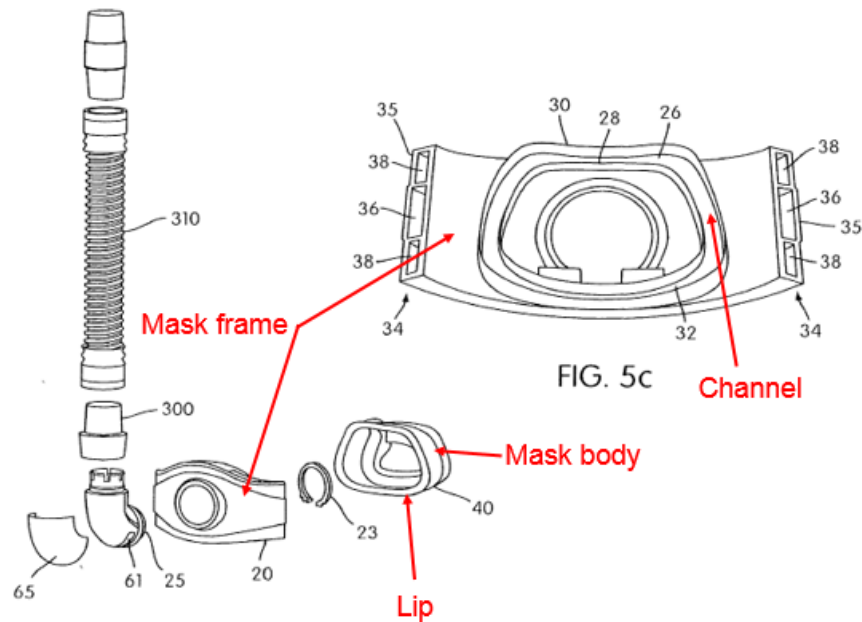
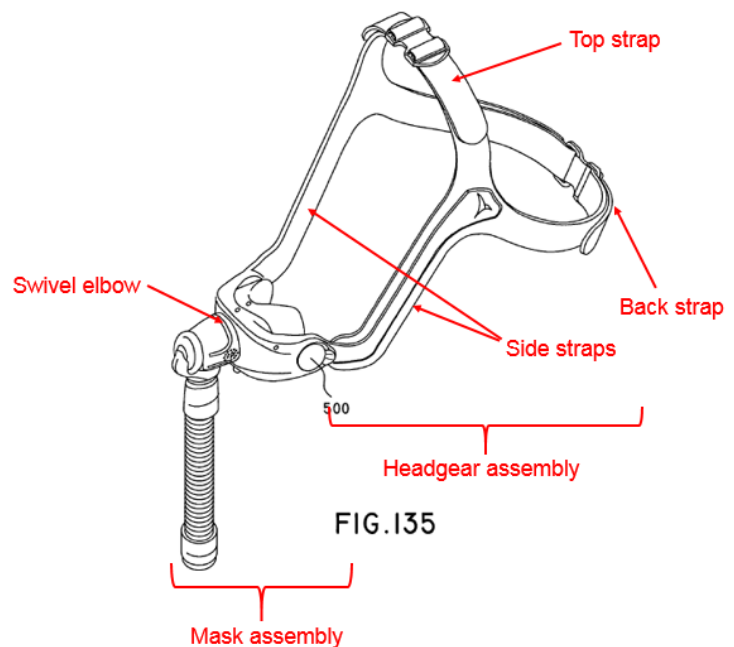


FIG. 6b

also generally ¶¶ 195-223. As Figures 1-8 of *Gunaratnam* disclose a frame and a nasal pillows body connectable via a similar mechanism, the details of *Ging*'s design would be applicable as a means to connect *Gunarantam* Figure 135's mask frame to a nasal pillows mask body. See also RMD1008, ¶¶ 169-171.

Claims 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) and “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's Figure 135 top strap is shown integrally formed with the two side straps and with the back strap, and thus meets claims 18 and 19. See RMD1008, ¶¶ 172-174; see also RMD1004, FIGS. 107, 107-1, 107-2, and 107F-G (additional integrally formed headgear configurations), ¶ 213 (disclosing the headgear assembly 20 in some embodiments “may be constructed as a one piece structure”).



Claims 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) and “A patient interface as claimed in claim 24, wherein the top strap is releasably connected to the back strap” (claim 25). To the extent claims 24 and 25 describe what is disclosed in the ‘807 specification (which does not show the *entire* top strap being releasably connected to either of the side straps or to the back strap), *Gunaratnam*’s Figure 135 headgear assembly meets claims 24 and 25. Indeed, *Gunaratnam*’s Figure 135 headgear assembly is the same in relevant respects to the headgear assembly disclosed in the ‘807 specification. Compare RMD1004, FIG. 135 with RMD1001, FIG. 2. Specifically, in *Gunaratnam*’s Figure 135 headgear assembly, one may consider each half of the “top strap” to be a “top strap,” and each half of the entire “back strap” to be a “back strap.” As such, the top strap on one side can be disconnected (by undoing the top buckle) from the top strap on the opposite side, and thus disconnected from the side strap on that opposite side. As such, that top strap is releasably connected to one of the side straps. That alone is sufficient to meet claim 24, which requires that the top strap be “releasably connected to *one or more* of the side straps and the back strap.” In addition, unbuckling the top buckle and the back buckle disconnects the top strap on one side from the back strap on the opposite side, and thus that top strap is releasably connected to a back strap also. That alone is sufficient to meet both claims 24 and 25. *See also* RMD1008, ¶ 176. As such, the limitations of claims 24 and 25 are met by *Gunaratnam*’s Figure 135 headgear

assembly.

To the extent that claims 24 and 25 are claiming the *entire* top strap be releasably connected to one or more of the other straps recited in the claim (even though the ‘807 specification does not seem to disclose that), modifying *Gunaratnam*’s Figure 135 headgear assembly so that would be the case would have been nothing more than an obvious design choice at the time. *See* RMD1008, ¶¶ 176-179; *see also* RMD1004, FIG. 18 and ¶ 211 (single top strap 98 releasably connected to side straps 96 via buckles 102 at the ends of the side straps 96); RMD1008, ¶ 177; RMD1005, FIGS. 1, 1b, ¶¶ 145-148 (top strap 140 releasably connected to side straps and rear strap); RMD1008, ¶¶ 178-179; RMD1037 (headgear with single releasable top member).

Given these and many other options known in the art at the time, one way in which *Gunaratnam*’s Figure 135 headgear assembly could have been modified in an obvious way is to have a single top strap, replacing the one buckle in the middle of dual top straps with a buckle at each end of the single top strap, and having each of those buckles connect with a small strap extending from the juncture of the side straps and the back strap, as shown in *Gunartnam* in Figure 18. *See* RMD 1008, ¶ 177. Such a modification may be made for patient comfort of not having a buckle at the top of the head, for example, if the patient is bald on top of the head. Such a modification may also be done in a manner that does not complicate manufacturing

or complicate donning and removing the headgear assembly, in that the headgear assembly still may be manufactured of two straps (namely, one long strap constituting the two side straps and the back strap, and one strap for the top strap) and of two buckles (the two being provided at the ends of the top straps as described above), instead of having one top buckle between the two top strap pieces and one back buckle between the two back strap pieces, as in *Gunaratnam* Figure 135 and in the '807 patent). *See also* RMD1037, FIG. 1 and col. 4:24-5:21 (headgear assembly with top portion 21 being releasably connected to side portions 22 and back strap 36). Such a design modification would have been well within the knowledge of a skilled person at the time, and no criticality is described in the '807 patent for the features in claims 24-25. *See* RMD1008, ¶¶ 176-179.

B. Ground 2: Claims 1-7, 17-19, 24, and 25 are unpatentable as obvious over *Gunaratnam* in view of *Ging* and *McAuley*.

In Ground 1, it is shown that *Gunaratnam* and *Ging* render obvious claims 1-7, 17-19, 24, and 25 under Petitioners' proposed claim constructions. If the Board construes the claimed "ring" more narrowly than Petitioners propose in Section VI.A and require the ring to have a generally circular periphery, which it should not, the prior art nevertheless teaches mask frames, and indeed nasal pillows mask frames, with generally circular peripheries for example in *McAuley* (RMD1034). And *McAuley* was not alone in this teaching. *Lovell* (RMD1012) similarly teaches a mask assembly wherein a lower shell 8 (analogous to a mask

frame) has a generally circular periphery. *See* RMD1012, FIGS. 1B, 2B. It would have been obvious at the time to have applied the knowledge in the art from *McAuley* for example of more circular mask frames to the *Gunaratnam* patient interface modified as discussed under Ground 1, for the purpose of providing a smaller and more streamlined patient interface, as discussed below. In addition, that modification is especially appropriate given one of the modifications under Ground 1 is to modify the Figure 135 patient interface to have a smaller nasal pillows mask body as opposed to the larger full nasal mask shown in Figure 135. *See generally* RMD1008, ¶¶ 55-57, 181-185.

Like *Gunaratnam* and the '807 patent, *McAuley* discloses a type of nasal pillows patient interface for the delivery of pressurized gas to the nares of a patient.

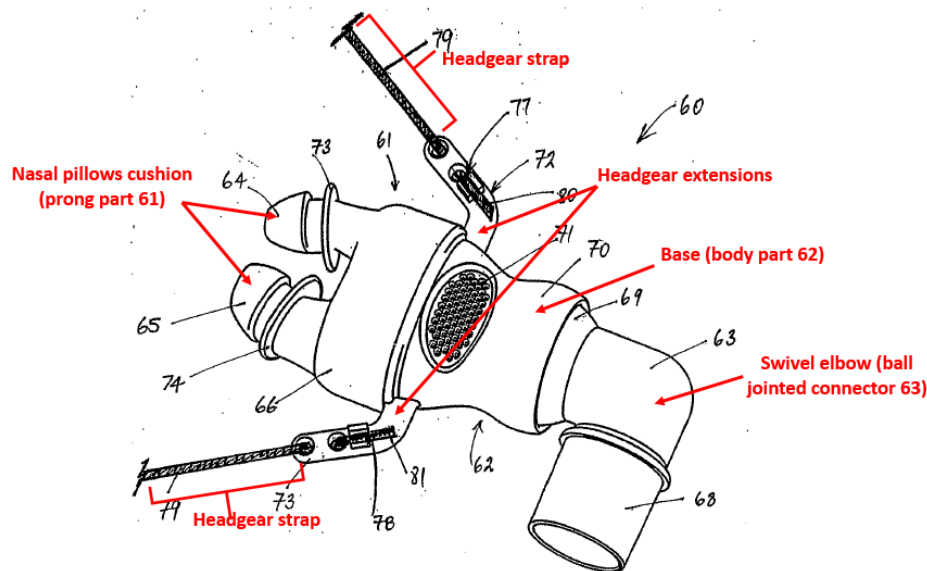


Figure 9

See RMD1034, Abstract; *see also* RMD1008, ¶¶ 55-57. *McAuley's* patient interface (referred to as a “nasal cannula”) includes three

principal components: a flexible prong part 61 (i.e., a nasal pillows mask body), a

rigid body part 62 (a “ring” as claimed), and a ball jointed connector 63 (swivel elbow). *See* RMD1034, col. 6:11-7:26. These components and others are illustrated, for example, in Figure 9 (reproduced and annotated above).

As shown in Figure 9, body part 62 has a generally-circular exterior and serves as a frame or base to which the swivel elbow 63 and the nasal pillows mask body 61 connect. *Id.* at 7:5-10. The swivel tube 63 includes on one side a ball joint 69 that fits within a half-spherical socket end 70 of the body part 62, and on the other side a swivel connector 68, which attaches to an inspiratory conduit (not shown in Figure 9). *See id.* at col. 9:32-10:3. Figure 15 (reproduced and annotated at right) is a cross-sectional view of the body part [cross-section labeled 84] with the swivel elbow [cross-section labeled 85]

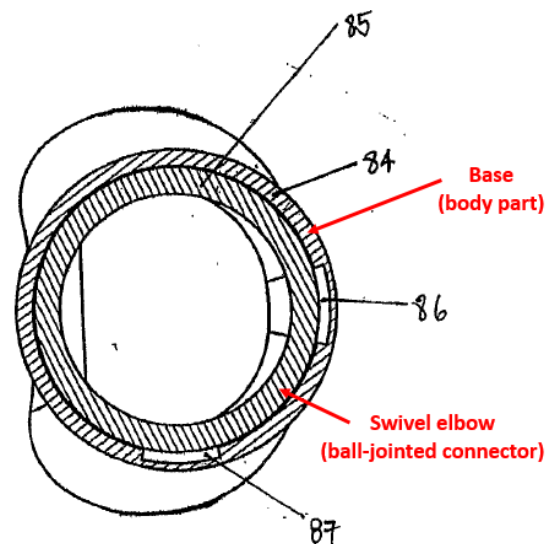


Figure 15

secured therein. The cannula assembly in *McAuley* is capable of attaching to a headgear assembly from just two attachment points (namely body part 62 connects to the headgear assembly with a pair of extensions 72, 73). *See id.* at col. 11:12-23.

One of skill would have been motivated to use *McAuley*’s teachings to modify the *Gunaratnam/Ging* patient interface described under Ground 1, because

doing so would reduce the weight of the mask on the patient's face, make the frame more compact (and therefore less obstructive to the patient's view), and reduce material costs in manufacturing the frame. *See* RMD1008, ¶¶ 181-185. Further, one of skill would also understand that making this combination would allow two side straps to connect to the frame, as taught by *McAuley* (Figure 9). That is, in the modified patient interface with the generally circular frame, one of skill would have understood that the headgear side straps from *Gunaratnam*'s Figure 135 design could simply connect to structures that project from the side of the generally-circular portion of the frame, like the extension members 72 and 73 (taught by *McAuley* in Figure 9). *See* RMD1008, ¶ 184. Alternatively, the headgear side straps could connect directly to attachment points on the surface of the rounded frame, without extensions 72 and 73. *See id.*

With the patient interface combination of *Gunaratnam* and *Ging* further modified in view of *McAuley*, the limitations of claim 1 and its dependent claims at issue are still taught. A full analysis is not required here, because the modification only affects the outer periphery of the "ring" and claim 1. The fact that any significance to the shape of the outer periphery of the ring is unclaimed – and is not described anywhere in the specification – shows that the choice of a circular outer periphery for the ring would have been no more than an obvious design choice. *See* RMD1008, ¶¶ 85, 181-185.

Specifically regarding the “ring” claim limitation and the fact that the rotatable elbow must “fit into” the claimed ring, there are two structures in *Lovell* that read on the claimed ring – a swivel connector 12 and lower mask frame 8. *See* RMD1012, FIG. 1B, col. 4:20-5:67; *see also* limitations 1.5-1.8 discussed below. Under a reading where the lower mask frame 8 is the claimed ring, the claim limitation of requiring that the elbow “fit into” the ring (limitation 1.8) is literally met. Under the second reading with the swivel connector 12 as the claimed ring, although the “fits into” limitation is not met, it would have been a matter of routine skill in the art (and further is taught by *Gunaratnam*) to modify *Lovell* so its elbow 14 “fits into” the swivel connector 12 as claimed, as opposed to “fitting over” the connector 12 as shown.

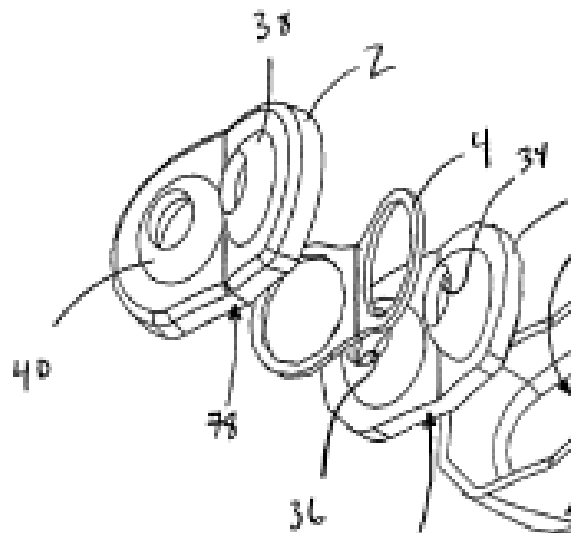
The fact that both *Lovell* and *Gunaratnam* were addressed during the original examination does not diminish the merit of Ground 2. The distinctions applicants drew between the ‘807 claims and *Lovell* amount to nothing more than obvious modifications to *Lovell*’s patient interface design. *See* RMD1008, ¶¶ 30-39; Section V.B above. Moreover, the prosecution history record does not indicate *Gunaratnam*’s headgear assembly teachings were considered; nor does it indicate the examiner considered an alternative reading of *Lovell* in which the lower mask shell 8 is the claimed ring.

2. Correspondence between the '807 patent claims and the teachings of *Lovell* and *Gunaratnam*.

The correspondence between claims 1-7, 17-19, 24 and 25 and the teachings of *Lovell* and *Gunaratnam* are discussed below.

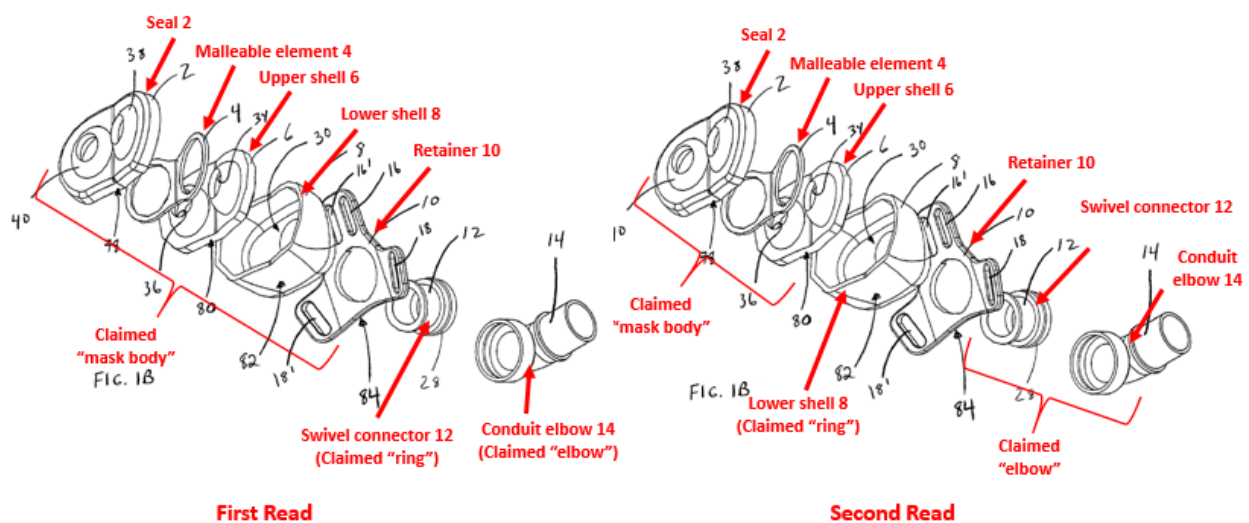
Claim 1 (Limitations 1.1-1.2): “A patient interface comprising: a mask assembly having . . . and a headgear assembly.” *Lovell* discloses designs for a patient interface including a mask assembly and a headgear assembly. *See, e.g.*, RMD1012, FIG. 5, col. 2:31-61 (mask assembly generally), 2:62-67 (headgear assembly generally).

Limitations 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 assembly includes a mask body with two nasal pillows. As shown in a portion of Figure 1B copied at right, the 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. *See* RMD1012, FIG. 1B, col. 8:51-52.



Lovell's nasal pillows in use rest in a substantially sealed manner against the nares of a user, and the mask body is sized and shaped to leave the mouth of the user uncovered by the mask body when in use. *See* RMD1012, col. 2:33-35 (“seal with the external skin surrounding the nares at the base of the nose and/or along the inner rim of the nares”), *see also* col. 8:59-61, FIG. 5 (showing the user’s mouth uncovered while donning the nasal mask); RMD1008, ¶¶ 191-192.

Two different structures read on the mask body as claimed, depending on the structure constituting the claimed “ring” in limitation 1.5. **First**, with the swivel connector 12 as the claimed ring, all of components 2, 4, 6 and 8 (and optionally also 10) constitute the claimed mask body. **Second**, with the lower mask shell 8 as the claimed ring, then only components 2, 4 and 6 constitute the claimed mask body. Either way, these structures constitute a mask body, as illustrated in the annotations of *Lovell's* Figure 1B below:

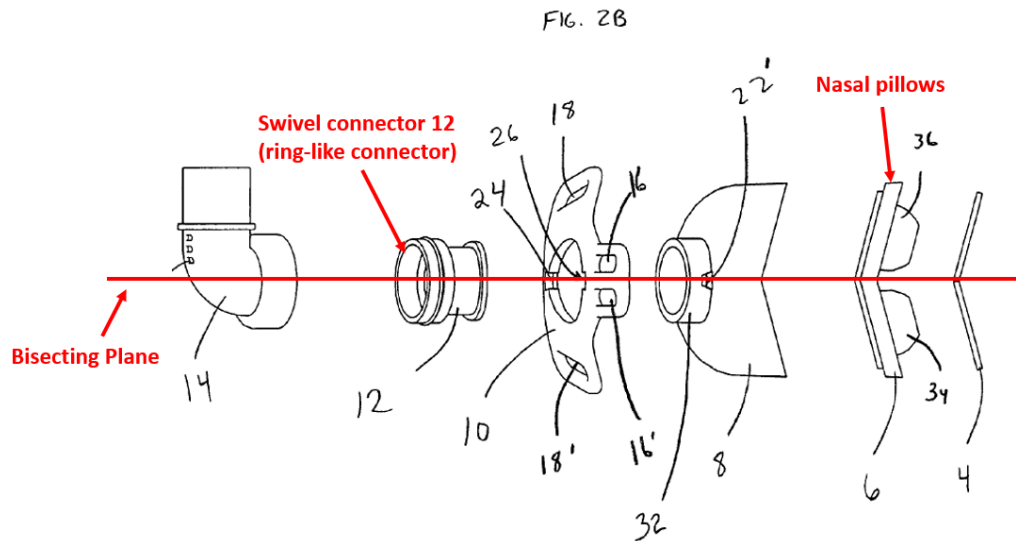


See also RMD1008, ¶¶ 191-192.

Limitation 1.5: “a ring engaged with the mask body.” The claimed “ring” reads on *Lovell* in two ways. **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 (components 2, 4, 6 and 8). Specifically, a portion of swivel connector 12 fits within an inlet 32 of the lower shell 8, as shown in Figure 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, and discloses that the lower shell 8 is engaged with structure constituting a mask body (components 2, 4 and 6). Specifically, the lower mask shell 8 engages with upper shell 6 of the mask body, as shown in FIG. 4B. *See also* RMD1012, col. 4:38-40.

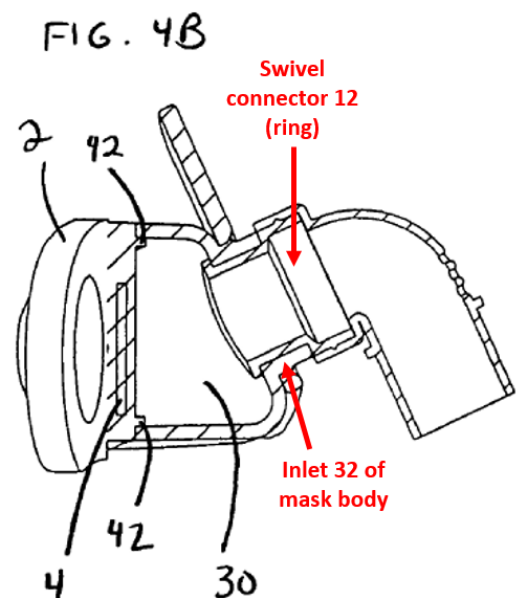
Limitation 1.6: “a plane substantially bisecting the ring, each of the two nasal pillows positioned on opposite sides of the plane.” *Lovell*’s ring (considering either the swivel connector 12 or the lower mask shell 8 as the ring) is generally located at the front center of the mask, and meets this claim limitation. *See* Section VI.B (claim construction for “bisecting” claim limitation). For example, if one were to consider a vertical plane that bisects the two ring structures in *Lovell* (swivel connector 12 and lower shell 8), that plane would lie between the

two nasal pillows such that the pillows would be located on opposite sides of the plane, as shown below in the annotation of *Lovell's* Figure 2B:



See RMD 1008, ¶¶ 193-94; see also Section VI.B (showing location of the defined plane).

Limitation 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. As such, the swivel connection is achieved by the swivel connector 12 being rotatable vis-à-vis the lower mask inlet 32, by the elbow 14 being rotatable vis-à-vis the swivel



connector 12, or both. **First**, considering the swivel connector 12 as the claimed “ring,” elbow 14 is rotatable vis-à-vis the ring (swivel connector 12). *See* RMD1012, FIGS. 1, 3A, 4B, 5, col. 5:26-34. *See id.* **Second**, considering the lower mask shell 8 as the claimed “ring” (as discussed under limitation 1.5), an elbow (specifically, the combined structure of elbow 14 and swivel connector 12) is also rotatable with the ring (lower mask shell 8). *See id.*

Limitation 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 that the elbow 14 fits over swivel connector 12, instead of into it as claimed. *See, e.g.,* RMD1012, FIGS. 2B, 4B, col. 5:26-28. That said, modifying the *Lovell* configuration so that the elbow 14 *fits into* the swivel connector 14, instead of *over* the swivel connector 14 as shown in *Lovell*, would have been nothing more than an obvious design choice at the time.

See RMD1008, ¶¶ 33-35, 195-196.

Indeed, it was well known before the time of the ’807 patent for elbows to *fit into* a socket of a mask assembly, and rotate within that socket. This is shown for example in *Gunaratnam*

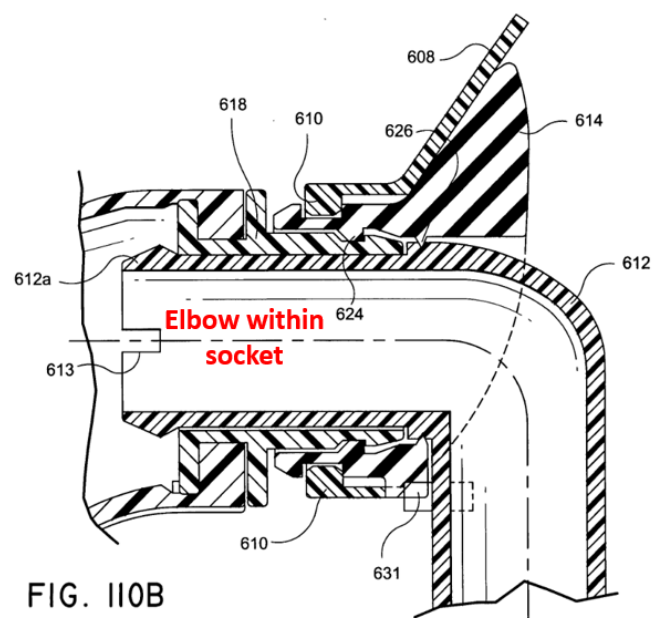
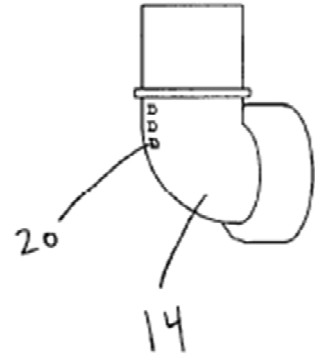


FIG. 110B

(RMD1004), in FIGS. 110B and 111 (FIG. 110B copied and labeled above). The modification would simply involve making *Lovell's* elbow 14 a male connector and swivel connector 12 a female connector, rather than the other way around. 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 RMD1008, ¶¶ 33-35, 195-196; see also RMD1005, FIG. 5c (showing mask frame aperture 24 through middle of mask frame), FIG. 19c-1 (elbow fitting into the mask frame aperture); see also FIGS. 1-6b, 19a-1 – 19c-2, ¶ 161 (also showing elbow fitting into the front of the mask frame); RMD1021, FIGS. 2, 7, col. 5:36-50 (elbow's swivel connector 6 fits into front of nasal mask 5); RMD1018, FIGS. 1-2 (swivel elbow fits into front of nasal mask frame).

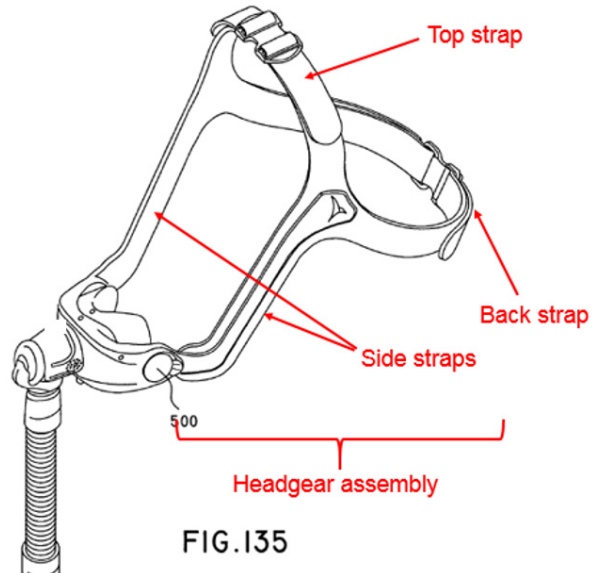
Second, considering the lower mask shell 8 as the claimed ring, *Lovell* discloses swivel connector 12 fits into an inlet 32 of lower mask shell 8. See RMD1012, FIG. 4B. As such, shell 8 of *Lovell* forms a socket into which a portion of an elbow (elbow 14 plus connector 12) fits to facilitate rotatable engagement between the elbow and the ring, as claimed. Here, the “fits into” limitation is met literally. See RMD1008, ¶ 196.

Limitation 1.9: “the elbow comprising a plurality of vent holes.” Having vent holes in the elbow for exhausting exhaled air was well known, and in fact *Lovell* discloses that elbow 14 has a plurality of vent holes (apertures 20). See RMD1012, FIG. 2B, col. 5:46-50 (“The conduit elbow 14 is shown with ... 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.”); see also discussion of limitation 1.9 under Ground 1.



Limitation 1.10: “a tube or conduit extending from the elbow.” Although not shown in figures, *Lovell* discloses that a tube or conduit delivers pressurized air from a source (e.g., a CPAP machine) to the patient interface. See RMD1012, col. 1:17-20; RMD1008, ¶ 197. The tube or conduit would connect to the elbow 14, as is conventional. Such a tube or conduit is also shown in *Gunaratnam*’s Figure 135.

Limitations 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 is also discussed above in Ground 1 of the Petition which shows the specific correspondence between the headgear assembly in *Gunaratnam* Figure 135 and



all of the headgear assembly limitations of claim 1. *See also* RMD1004, FIGS. 107G-H, and 108 (same headgear assembly used with nasal pillows mask assembly).

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 (office action), 613-23 (applicant’s response); *see also infra* Section V.B.

One of skill would have disagreed 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.” See RMD1008, ¶¶ 36-38. 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. 107G-H and 108, 135; see also RMD1035 and RMD1036 (same for ResMed’s Swift nasal pillows mask from 2004); RMD1008, ¶¶ 36-38, 198-199. 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.

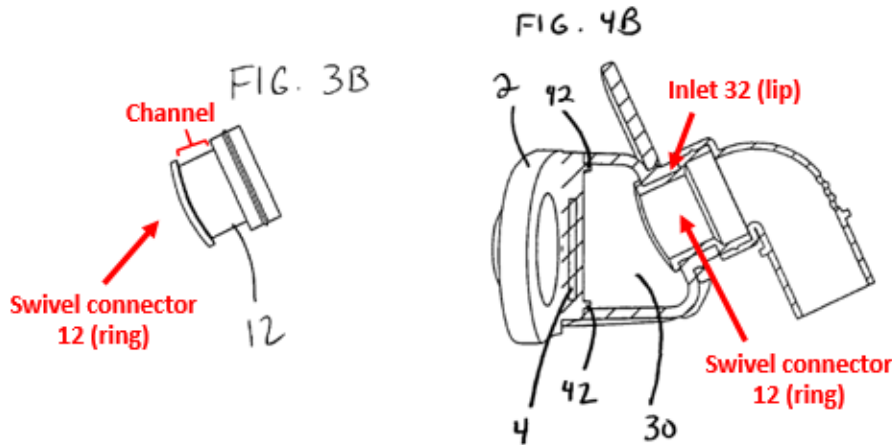
One of skill would have been motivated to apply *Gunaratnam*’s headgear design to *Lovell*’s mask assembly in order to reduce the number of connections between the headgear and mask assembly. See RMD1008, ¶¶ 36-38, 199. For example, a two-strap connection would be less cumbersome for a patient than a 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. See RMD1004, ¶ 376 (“Yokes provide stability to the sides. Yokes retain at least a partial portion of the basic shape of headgear, which facilitates donning of the headgear.”), ¶ 396 (“The

headgear provides stability, e.g., the yokes help maintain the mask assembly's position on the face.”).

The manner in which the two side straps from *Gunaratnam* would connect to the mask assembly from *Lovell* would be well within the capabilities of a skilled artisan, 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 10.³ Alternatively, the two side straps could be directly and releasably connected to the retaining structure 10, while side arms run along the side straps for added stability. *See* RMD1008, ¶ 199; *see also id.* at ¶¶ 186-188; RMD1004, ¶¶ 369-70, 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). Further, as discussed in Ground 1, limitation 1.15, a modification wherein there would be a direct connection would have been an obvious implementation detail well within the scope of knowledge of a skill artisan.

³ Further, as discussed under Ground 1, limitation 1.15, footnote 2, there is a direct connection between the side straps and the mask assembly if side arms (side arms 41 in the '807 patent, and side arms in *Gunaratnam* Figure 135 as shown above in the annotated Figure 135) are considered part of the claimed “mask assembly.” *See also* Section VI.C. (claim construction of limitations 1.15 and 1.16).

Claim 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 (part of the claimed “mask body”) forms the claimed



“lip,” and the swivel connector 12 has an annular “channel” that receives the inlet lip when assembled, as shown in Figures

3B and 4B. See RMD1012, FIGS. 3B, 4B; RMD1008, ¶ 201. 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 engagement with the lip of the mask body. See RMD1008, ¶ 202.

Second regarding the 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. *See* RMD1008, ¶ 201; *see also* RMD 1041, ¶ 12.2; RMD1004, ¶ 186 (nozzle assembly 18 removably attachable to mask frame by rib / recess structures); RMD1005, FIGS. 5c, 6b, 24, 27-29, ¶¶ 114-115; discussion of claim 2 under Ground 1.

Claim 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 is an elastomeric material. *See* RMD1012, col. 7:35-45 (the seal 2 may be a “bladder . . . that is filled with a soft material 62” such as “molded silicone.”); *see also* RMD1008, ¶ 203. As such, the structures of *Lovell* corresponding to the claimed mask body comprise a molded elastomeric material.

Claim 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 limitation regarding the elbow in *Lovell* being able to swivel in the ring is addressed in Limitation 1.7 above. Given the use of a “swivel” elbow that is able to swivel 360 degrees as noted in *Lovell* (*see* RMD1012, col. 5:35-37), the fact that the swivel elbow is located at the front center of the mask assembly,

and the length and flexibility of conventional tubes or conduits that would attach to *Lovell*'s swivel elbow, it is clear that the elbow 14 would be able to swivel such that the tubing is available to be adjacent to either side strap. *See* RMD1008, ¶ 204. The same would be true of *Gunaratnam* and *Ging*. *See* RMD1004, FIG. 135 and ¶ 403; RMD1008, ¶¶ 108-113; *see also* RMD1004, FIGS. 108A, 108B, ¶ 394 (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); RMD1005, FIGS. 1, 6a, 6b, FIGS. 16a – 19c-2, ¶¶ 113, 148-53; RMD1008, ¶¶ 108-113.

Claim 5: “A patient interface as claimed in claim 1, wherein the ring comprises a hard plastic material.” **First** regarding the swivel connector 12 of *Lovell* as the claimed “ring,” that connector 12 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. *See* RMD1008, ¶ 205. Also, the choice that the material be *plastic*, as required by claim 5, would have been an obvious material selection for one of skill in the art, given for example *Gunaratnam*'s teaching 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, ¶¶ 4, 255; RMD1008, ¶ 205.

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 of lower mask shell 8 being “hard” as claimed, *Gunaratnam* teaches 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 together by a friction fit after taking them apart to clean them between uses. See RMD1004, ¶¶ 4, 178, 186, 191-192. As such, *Gunaratnam* teaches that the lower mask shell 8 of *Lovell* may be made of a hard plastic material, as claimed.

Claim 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* as set forth above in connection with claim 1. For example, the side arms (yokes) from *Gunaratnam* would connect to the mask assembly in *Lovell*, and would extend away from the ring (that is, away from swivel connector 12 or alternatively mask shell 8) to connect with the side straps. See RMD1008, ¶¶ 206-207. 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. *See id.* 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, ¶ 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 ¶¶ 376, 379, 390.

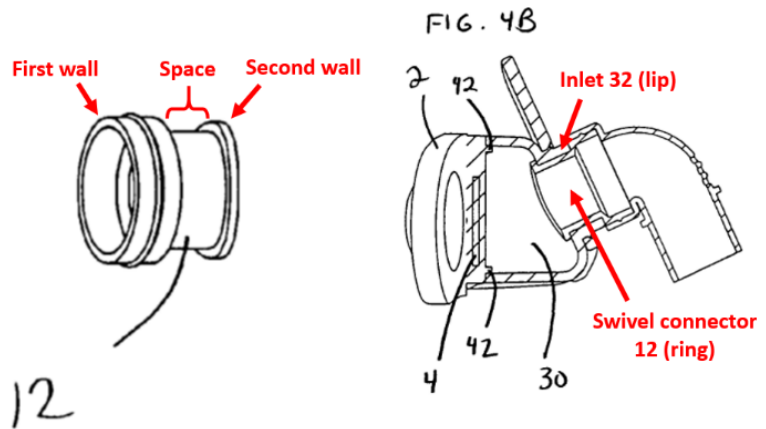
Claim 7: “A patient interface as claimed in claim 1, wherein, in use, gases flow from the tube or conduit, through the elbow, through the ring, through the mask body and through the pillows.” The flow of gases as set forth in claim 7 is simply how such patient interface systems work, and such flow of gases would be present in the patient interface of *Lovell* modified in view of *Gunaratnam* as described in connection with claim 1. *See, e.g.*, RMD1012, FIGS. 1B, 5, 10B; RMD1008, ¶ 208; *see also* RMD1004, FIG. 135, ¶ 403; RMD1008, ¶¶ 118-119.

Claim 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.”* This

claim is similar to dependent claim 2 discussed above. **First** regarding the swivel connector 12 as the claimed

“ring,” 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, and define a space therebetween, as shown in the annotation of the swivel connector 12 above. See RMD1012, FIGS. 2B and 4B (annotated above). 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. See RMD1008, ¶ 227. Regarding the limitation that the mask body be “configured to removably attach to the ring via friction within the space and with the first wall and the second wall,” Lovell discloses that connection between the inlet 32 and connector 12 “can be a selectively removable connection.” See RMD1012, col. 5:28-32. One of skill in

the art would understand the fit of the annular protrusion of the inlet 32 within the ring's "space" would be made via friction within the space and with the first wall and the second wall. *See* RMD1008, ¶ 226.

Second regarding the 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 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 "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. *See* RMD 1041, ¶ 12.2; RMD1004, ¶ 186 (nozzle assembly 18 removably attachable to mask frame by rib / recess structures); RMD1005, FIGS. 5c, 6b, 24, 27-29, ¶¶ 114-115; discussion of claim 2 under Grounds 1 and 3.

Claims 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) and "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). In the *Gunaratnam* headgear assembly (Figure 135 and also Figures 107G-H and 108), the top strap is shown to be integrally formed with the two side straps and with the back strap, and thus meets the limitations of claims 18 and 19. *See* RMD1008, ¶¶ 228-231; *see also* RMD1004, FIGS. 107, 107-1, 107-2, and 107G-F (showing additional integrally formed headgear configurations used with nasal pillows masks), ¶ 213 (noting that the headgear assembly 20 in some embodiments “may be constructed as a one piece structure”).

Claims 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) and “A patient interface as claimed in claim 24, wherein the top strap is releasably connected to the back strap” (claim 25). As explained under Ground 1, to the extent that claims 24 and 25 describe what is disclosed in the ‘807 specification (which does not show the *entire* top strap being releasably connected to either of the side straps or to the back strap), *Gunaratnam*’s Figure 135 headgear assembly meets claims 24 and 25. Indeed, *Gunaratnam*’s Figure 135 headgear assembly is the same in relevant respects to the headgear assembly disclosed in the ‘807 patent. *Compare* RMD1008, FIG. 135 *with* RMD1001, FIG. 2. Specifically, in the *Gunaratnam* Figure 135 headgear assembly, one may consider each half of the “top strap” to be a “top strap.” As such, the top strap on

one side can be disconnected (by undoing the top buckle) from the top strap on the opposite side of the headgear assembly, and thus disconnected from the side strop on that opposite side. As such, that top strap is releasably connected to one of the side straps. Similarly, unbuckling the top buckle and the back buckle disconnects the top strap on one side from the back strap on the opposite side, and thus the top strap is releasably connected to a back strap also. As such, the limitations of claims 24 and 25 are met.

To the extent that claims 24 and 25 are claiming the *entire* top strap be releasably connected to the other straps recited in the claim (even though the ‘807 specification does not seem to disclose that), modifying the *Gunaratnam* Figure 135 headgear assembly so that is true would have been nothing more than an obvious design choice at the time. *See* RMD1008, ¶ 176-179; *see also* RMD1037 (disclosing headgear with single top member). One way in which the headgear assembly could have been modified in an obvious way is to have a single top strap, replace the one buckle in the middle of the two top straps with a buckle at each end of the top strap, and have each of those buckles connect with a small strap extending from the juncture of the side straps and the back strap. Such a modification may be made for patient comfort of not having a buckle at the top of the head, for example, if the patient is bald on top of the head. Such a modification may also be done in a manner that does not complicate manufacturing or putting

the headgear assembly on and off, in that the headgear assembly still may be made of two straps (namely, one long strap constituting the two side straps and the back strap, and one strap for the top strap) and of two buckles (the two being provided at the ends of the top straps as described above, instead of having one top buckle between the two top strap pieces and one back buckle between the two back strap pieces, as in *Gunaratnam* Figure 135). See RMD1004, FIG. 18 (a variation of the Figure 135 headgear assembly in which buckle 102 is not positioned to be at the top of the patient's head, but instead is located more to the side); RMD1037, FIG. 1 and col. 4:24-5:21 (headgear assembly with top portion 21 being releasably connected to side portions 22 and back strap 36). Such a design modification would have been well within the knowledge of a skilled person at the time, and no criticality is described in the '807 patent for the features in claims 24-25.

VIII. GROUNDS 1, 2, AND 3 ARE NOT REDUNDANT

Petitioners submit Grounds 1, 2 and, 3 are not redundant of one another. Regarding Ground 1 versus Ground 2, Ground 2 is an alternative ground in the event the Board construes the claimed "ring" in claim 1 narrowly so as to distinguish the "ring" in the prior art under Ground 1. Regarding Grounds 1 and 2 versus Ground 3, the primary reference for Grounds 1 and 2 (*Gunaratnam*) is missing claim limitations that differ from those missing from the primary reference for Ground 3 (*Lovell*). Also, *Lovell* has a structure identified by the examiner

during prosecution as the claimed “ring,” and applicants did not dispute that labeling of *Lovell*, nor can it reasonably be disputed. For at least these reasons, Ground 3 presents issues that are substantively different from those in Grounds 1 and 2, and IPR should be instituted on all three Grounds.

IX. CONCLUSION

Petitioners request *inter partes* review and findings of unpatentability for claims 1-7, 17-19, 24, and 25 of the '807 patent.

Respectfully submitted,

Dated: September 7, 2016

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CERTIFICATION UNDER 37 CFR § 42.24(d)

Under the provisions of 37 CFR § 42.24(d), the undersigned hereby certifies that the word count for the foregoing Petition for Inter Partes Review totals 13,670, which is less than the 14,000 allowed under 37 CFR § 42.24(a)(1)(i).

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CERTIFICATE OF SERVICE

Pursuant to 37 CFR §§ 42.6(e)(1) and 42.105, the undersigned certifies that on September 7, 2016, a complete and entire copy of this Petition for *Inter Partes* Review, and all supporting exhibits, were provided via FedEx to the Patent Owner by serving the correspondence address of record as follows:

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