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.: 36784-0042IP2
Issue Date:	May 21, 2013	
Appl. Serial No.:	12/307,993	
Filing Date:	June 17, 2009	
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 *Gunaratnam* et al. ("*Gunaratnam*")
RMD1005	U.S. Patent Application Publication No. 2003/0196658 to *Ging* et al. ("*Ging*")
RMD1006	[RESERVED]
RMD1007	U.S. Patent No. 6,691,707 to *Gunaratnam* et al. ("the *'707 patent*" or "*Gunaratnam II*")
RMD1008	Declaration of 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. ("*Lovell*")
RMD1013	[RESERVED]
RMD1014	Merriam-Webster's Collegiate Dictionary, Eleventh Edition (2004) (selected portions)
RMD1015	[RESERVED]
RMD1016	[RESERVED]
RMD1017	[RESERVED]
RMD1018	[RESERVED]

EXHIBIT LIST

RMD1019	U.S. Patent 4,782,832 to Trimble et al. ("*Trimble*" or "'832 Patent")
RMD1020	U.S. Patent 6,431,172 to Bordewick ("*Bordewick*")
RMD1021	[RESERVED]
RMD1022	U.S. Patent 6,581,594 to Drew et al. ("*Drew*")
RMD1023	PCT Pub. WO 2008/007985 A1 to *McAuley* et al., a publication of International Application No. PCT/NZ2007/000185.
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 *McAuley* et al. ("*McAuley*")
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.

EXHIBIT LIST

RMD1037	[RESERVED]
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	[RESERVED]
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 *Fisher & Paykel Healthcare Ltd. v. ResMed Corp.*, Case No. 3:16-cv-02068-GPC-WVG (S.D. Cal.)
RMD1044	Patent Owner's Complaint for *Fisher & Paykel Healthcare Ltd. v. ResMed Corp.*, Case No. 2:16-cv-06099-R-AJW (C.D. Cal.)
RMD1045	Patent Owner's Notice of Voluntary Dismissal Without Prejudice for *Fisher & Paykel Healthcare Ltd. v. ResMed Corp.*, Case No. 2:16-cv-06099-R-AJW (C.D. Cal.)
RMD1046	Petitioners' Complaint for *ResMed Inc., et al. v. Fisher & Paykel Healthcare Corp. Ltd., et al.*, Case No. 3:16-cv-02072-JAH-MDD (S.D. Cal.)
RMD1047	Petitioners' Notice of Voluntary Dismissal Without Prejudice for *ResMed Inc., et al. v. Fisher & Paykel Healthcare Corp. Ltd., et al.*, 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 8, 20, 21, 26, and 27 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 1-7, 17-19, 24, and 25 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 IPR36784-0042IP2@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 that 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 8, 20, 21, 26, and 27 of the '807 patent, and a finding of unpatentability as follows:

Ground	References
1	Claims 8, 20, 21, 26 and 27 are obvious under 35 U.S.C. § 103 over *Gunaratnam* (RMD1004) in view of *Ging* (RMD1005)
2	Claims 8, 20, 21, 26, and 27 are obvious under 35 U.S.C. § 103 over *Gunaratnam* in view of *Ging* and *McAuley* (RMD1034)
3	Claims 8, 20, 21, 26 and 27 are obvious under 35 U.S.C. § 103 over *Lovell* (RMD1012) in view of *Gunaratnam*

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:

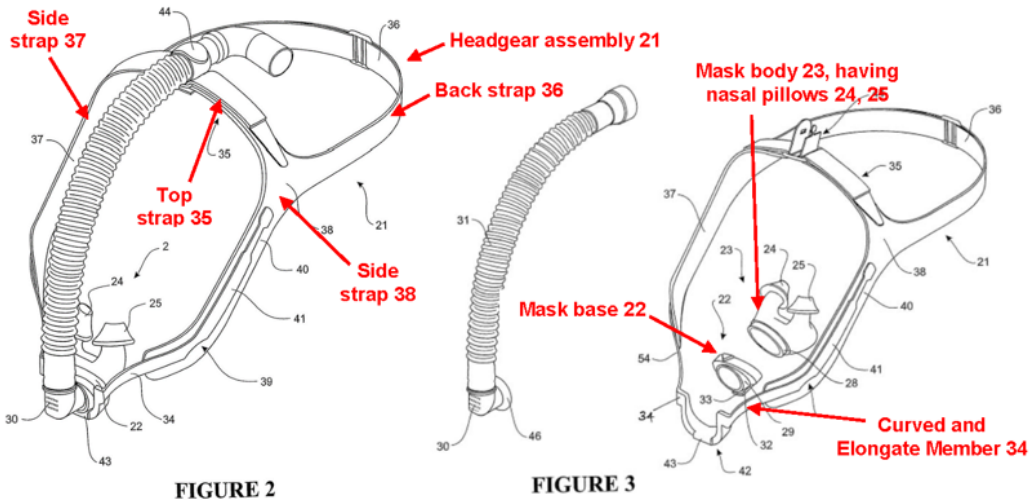

FIGURE 2 FIGURE 3

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 47 [issued claim 8], 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 infra* 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

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-like connector / connector end" (claim 8).

The claimed "ring-like connector" (and "ring-like connector end") is a structure with a generally circular inner passage to enable the claimed rotation of the elbow relative to the mask body when the ring-like connector is secured around an outer portion of the elbow, and does not require a particular outside shape for

the ring-like connector. *See generally* RMD1008, ¶¶ 40-41.

For the purposes of this Petition, the terms "ring-like connector" and "ring-like connector *end*" are treated as the same thing (*see* RMD1001, col. 12:30-31, 42-43, 45), despite that ambiguity making claim 8 vague. Indeed, the prosecution history seems to show that the two references to the "ring-like connector *end*" in the "tube assembly" claim element of claim 8 – as opposed to using the previously recited "ring-like connector" – was a drafting error. As originally presented, claim 47 (issued claim 8) included a "tube assembly" comprising an "elbow" with a "connector end" that is "ring-like," presumably describing in claim terms the flanged connector end 46 of elbow 30 shown in Figure 3. *See* RMD1009, p. 517. Claim 47 was later amended to recite a "ring-like connector" (not "connector end") as part of a "mask assembly" claim element, now presumably attempting to describe in claim terms a different structure from the specification, namely, mask base 22 shown in Figure 3. *See id.*, pp. 615-16. In the same amendment, the first reference to "ring-like connector end" in the "tube assembly" claim element was amended to include the definite article "the," which seems to indicate that the "ring-like connector end" was intended to refer back to the "ring-like connector" recited in the "mask assembly" claim element. *See id.*, pp. 615-16. As such, the failure to delete the "end" from the two instances of "ring-type connector" later in the claim seems to have been a drafting error.

The term "ring" or "ring-like connector" 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 8 for the claimed "ring like connector" is the following: (1) it is a component of the claimed "mask assembly" and not of the "tube assembly" that includes an "elbow," as discussed above; (2) it is "releasably connected to the mask body inlet" (e.g., inlet of body 23); (3) it is "secured around an outer portion of the elbow" (e.g., connector 30); and (4) "the elbow and the mask body [are] connected at least in part by the ring-like connector end." *See* RMD1001, col. 12:30-32, 43-44, 44-45. As such, the structure in the '807 specification that seems to correspond to the claimed "ring-like connector" is "mask base" 22. Indeed, mask base 22 is said to be "a *ring* or sleeve type attachment." *See id.* at col. 6:20 (emphasis added); *see also* col. 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 46 swivels). The ring-shaped mask base 22 is shown in FIGS. 3-5 copied below:

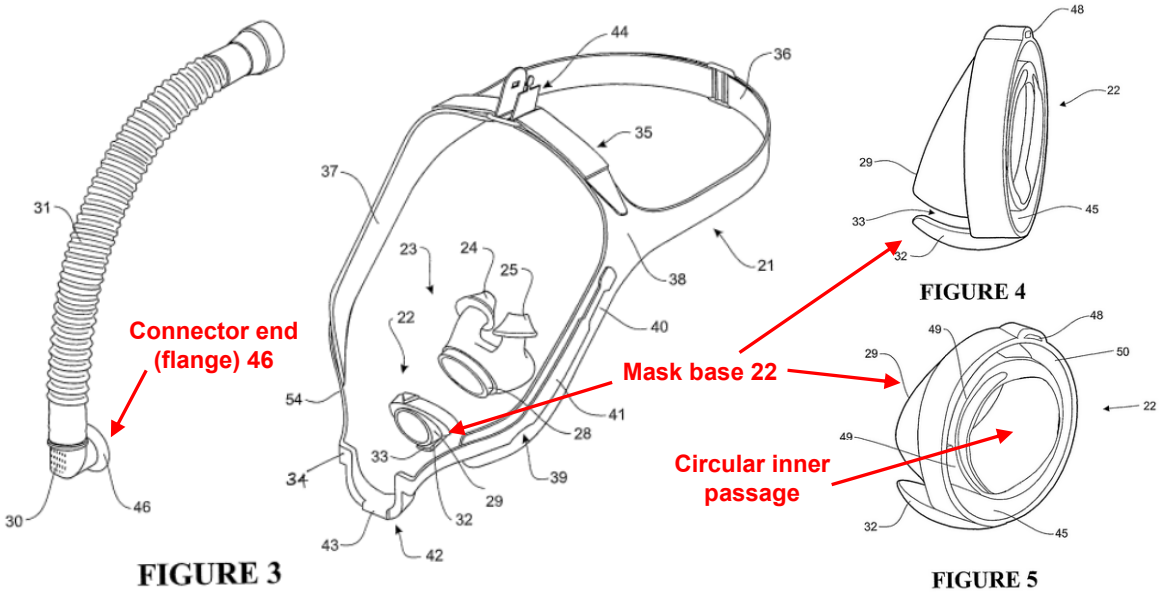

FIGURE 3

FIGURE 4

FIGURE 5

RMD1001, FIGS. 3, 4, 5. Note that the connector end 46 of elbow connector 30 has an annular flange that is also ring shaped, but that flange of connector end 46 does not correspond to the claimed "ring-like connector" because it is not part of the "mask assembly" as defined by claim 8, and that was made clear during prosecution as discussed above. Because claim 8 recites "the ring-like connector end [is] secured around an outer portion of the elbow," and "the elbow and the mask body [are] capable of rotating relative to each other," the context of claim 8 supports the ring-like connector having a generally circular inner passage.

Regarding the outer surface of the claimed "ring-like connector," however, nothing within the plain language of the claim or from the intrinsic record requires that the outer surface of the ring-like connector 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 "wherein a plane bisects the ring-like connector and the first nasal pillow is located on a side of the plane opposite the second nasal pillow" (claim 8).

This phrase requires that the "ring-like connector" (and "elbow" around which the rink-like connector is secured) 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-like connector 22 (as shown on the annotated figure below), that plane would extend between the two nasal pillows 24, 25, leaving one pillow on each side of the plane, as shown below:

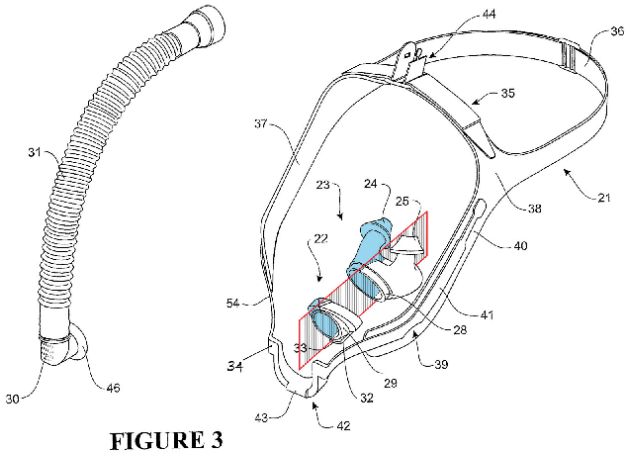

FIGURE 3

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 phrase "wherein the first side strap and the second side strap are configured to connect and disconnect with the mask assembly … wherein the mask assembly is configured to connect to only the two side straps" (claim 8).

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, these claim limitations set forth in independent claim 8 are the same as in claim 1, and the interpretation of these claim elements should be the same in claim 1 as in claim 8. Specifically regarding claim 1, 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, and thus independent claim 8 which is the same as claim 1 in these respects, necessarily covers an indirect connection.[1]

The second part of the construction requiring that *only* the two side straps

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[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 8.32; Ground 3, limitations 8.27-8.34.

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 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 8, 20, 21, 26, and 27 are unpatentable as obvious over *Gunaratnam* in view of *Ging*.

Gunaratnam discloses many designs of patient interfaces. 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) a nasal mask assembly that includes the claimed "ring-like connector" located at the front center of the mask assembly, (b) a tube assembly with an elbow, wherein the mask assembly's ring-like connector is secured around an outer portion of the elbow, and (c) headgear assembly for which only two side straps are connectable to the mask assembly, as

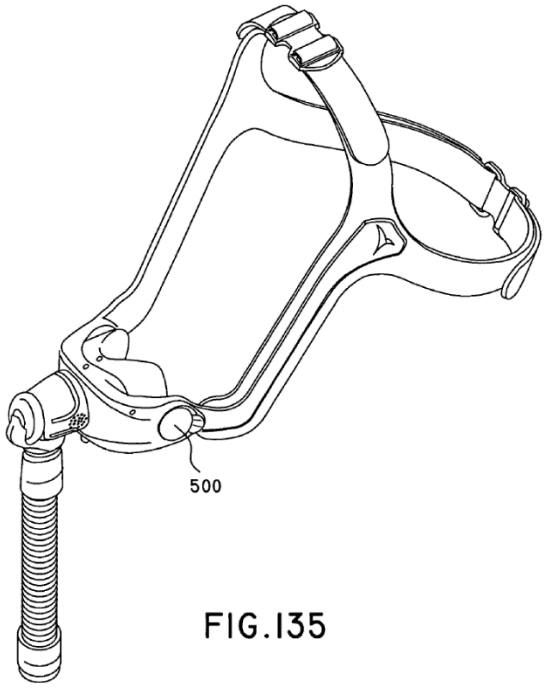


FIG.135

set forth in claim 8. *See* RMD1008, ¶¶ 44-48, 62-63. The Figure 135 patient interface includes all limitations of claim 8, except the nasal mask being a nasal *pillows* mask, and the details of the claimed "ring-like connector" and the ring-like connector being secured around an outer portion of the elbow, as claimed. 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, 61-65, 120-167, 175, 180.

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 8, limitation 8.5 (*see* claim charts, Section V.A.3 below) recites the mask body having "a first nasal pillow and a second nasal pillow." *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 in fact 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, ¶¶ 120-127.

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, ¶¶ 125-127. 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). Applying a known nasal pillows mask body to *Gunaratnam*'s Figure 135 patient interface yields a configuration shown below:

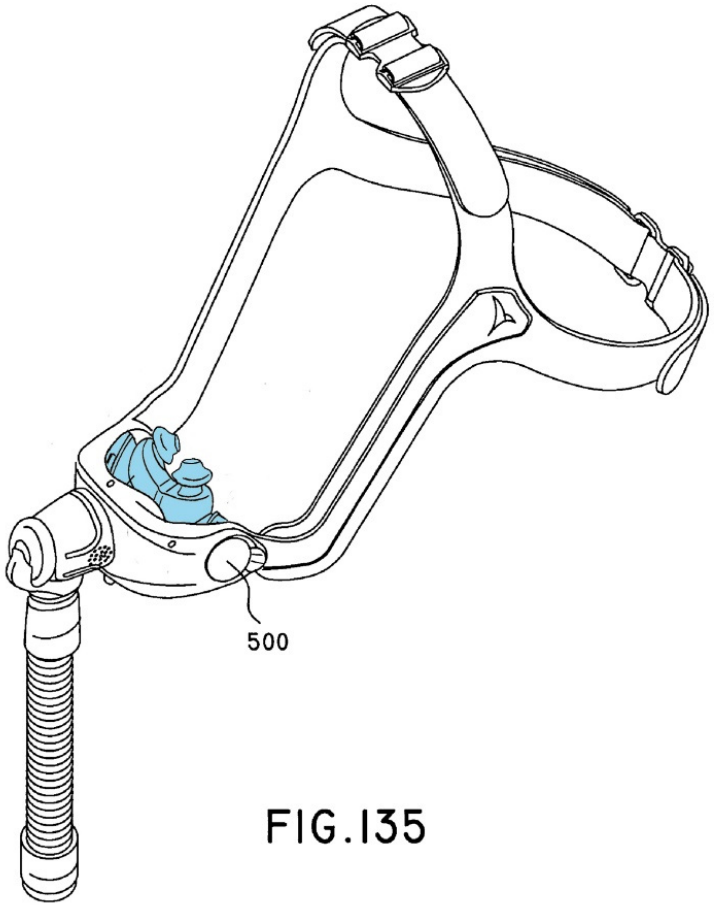


FIG.135

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, ¶ 127. 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, ¶

127. 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:

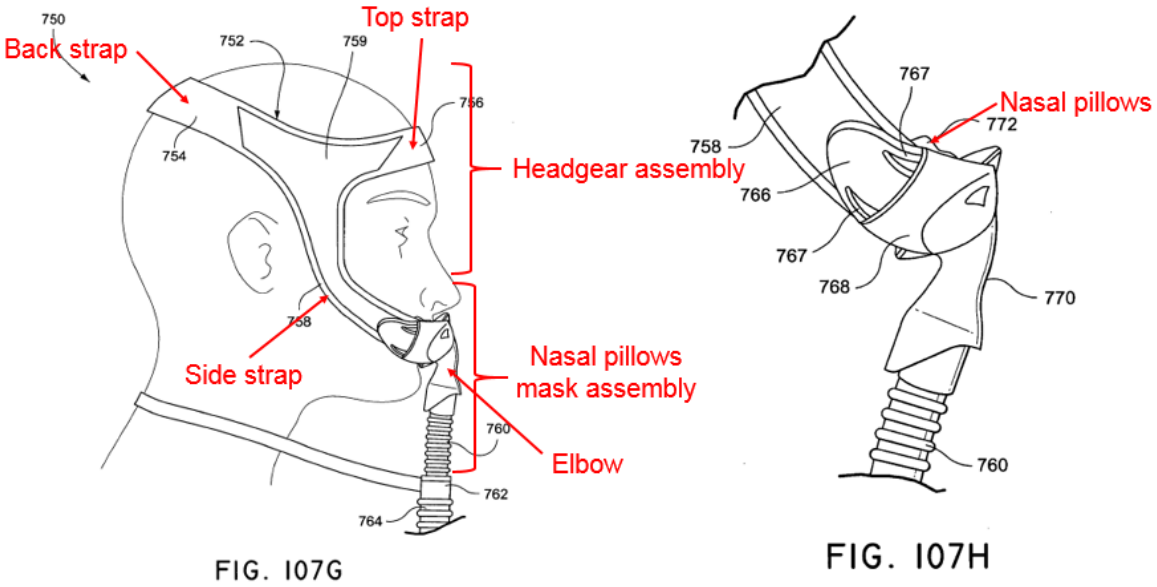


FIG. 107G FIG. 107H

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, ¶ 127; *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* disclose the claimed "ring-like connector" and the ring-like connector being "secured around an outer portion of the elbow," as claimed.

Limitations 8.14 and 8.24 (*see* claim charts, Section VII.A.3 below) require

(1) a "ring-like connector releasably connected to the mask body inlet," and (2) "the ring-like connector end [sic: ring-like connector] being secured around an outer portion of the elbow." Section VI.A provides a construction for "ring-like connector" and "ring-like connector end" – they are referring to the same thing, which is "a structure with a generally circular inner passage to enable the claimed rotation of the elbow relative to the mask body when the ring-like connector is secured around an outer portion of the elbow, and does not require a particular outside shape for the ring-like connector." Section V.B details the prosecution history relating to the "secured around" limitation.

Gunaratnam's Figure 135 discloses the claimed ring-like connector by virtue of its mask frame. The "mask frame" meets the claimed ring-like connector, in that it releasably connects with the mask "cushion" which serves as the claimed mask body, and has an opening in the front center of the mask frame into which a rotatable elbow fits, and thus the mask frame is a ring that is "secured around" an outer portion of the elbow" as claimed. *See* RMD1004, FIG. 135; *see generally* RMD1008, ¶¶ 142-

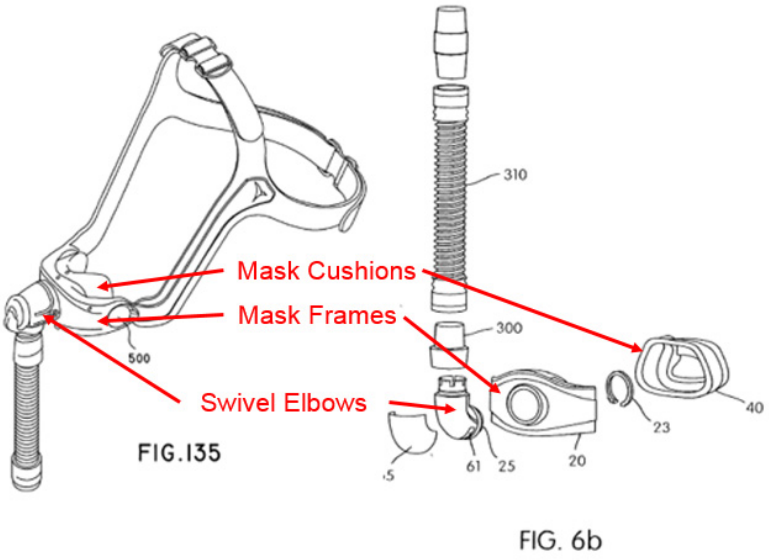
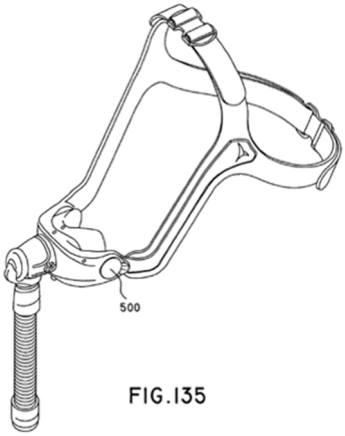


FIG.135

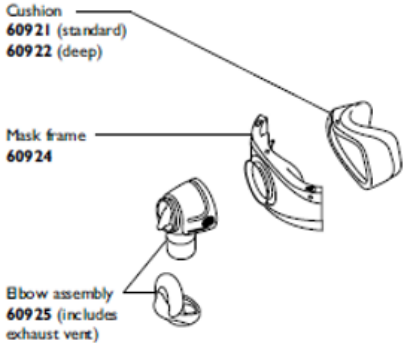
FIG. 6b

151, specifically ¶ 145, *see also* ¶ 35. 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).

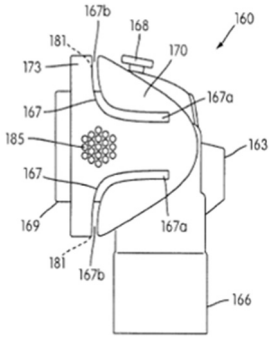
The applicability of *Ging's* details for a nasal mask frame and swivel elbow to *Gunaratnam's* Figure 135 is clear. *Gunaratnam* specifically refers to ResMed's Vista Mask (RMD1024), and it is the Vista mask that is disclosed in *Ging* (indeed, *Gunaratnam* incorporates by reference the provisional 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:



Gunaratnam's FIG. 135



ResMed's Mirage Vista Nasal Mask



Ging's FIG. 16b

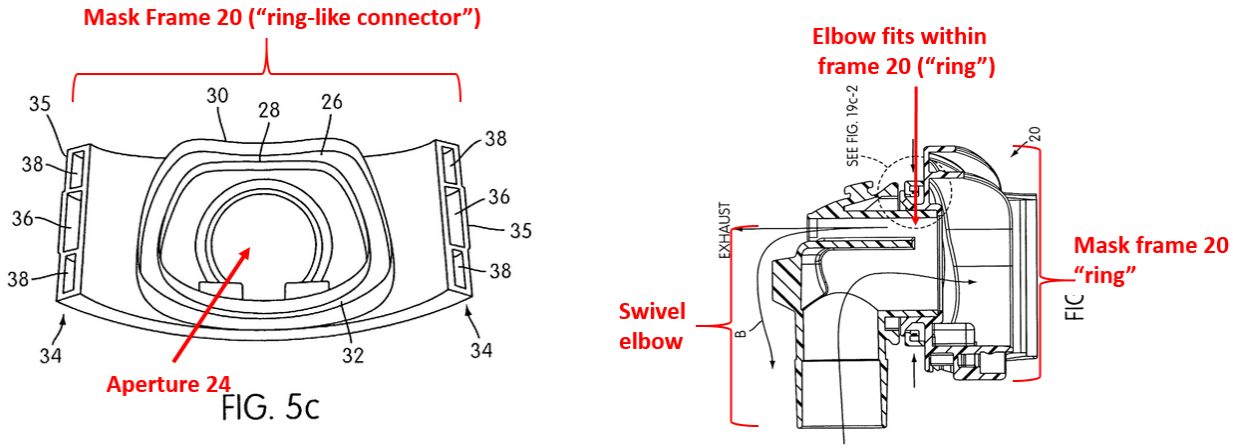
RMD1004 **RMD1024** **RMD1005**

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* Figure 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-like connector," despite not having a circular periphery, given the proper interpretation of "ring-like connector" discussed in Section VI.A. *See also* RMD1008, ¶¶ 150-151. Indeed, in the context of the '807 claims, the peripheral shape of the mask's ring-like connector has no criticality because the disclosed structure on the outside of that ring-like structure (the curved elongate member 34, FIG. 3) is unclaimed, as described above in Section V.A. *See* RMD1008, ¶ 41; and *generally* ¶¶ 77-85; *KSR*, 550 U.S. at 416. But even if the "ring-like connector" were read narrowly to require a more circular outer perimeter, that shape would nevertheless have been an obvious modification from the shape of *Gunaratnam* and *Ging*, as will be discussed in Ground 2. *See* RMD1008, ¶¶ 151, 181-185.

Regarding the ring-like connector being *secured around an outer portion of the elbow* as claimed (limitation 8.24), 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, and thus the mask frame secures around an outer portion of the swivel elbow:



RMD1005, FIG. 5c (above left, showing mask frame aperture 24); FIGS. 19c-1 (above right, showing mask frame secured around an outer portion of the elbow); *see also* RMD1005, FIGS. 1-6b, 19a-1 – 19c-2, ¶ 161; RMD1004, FIGS. 110-111 (mask frame secured around swivel elbow, albeit the swivel elbow fitting in 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 mask frame in *Gunaratnam's* Figure 135 patient interface to be secured around an outer portion of the elbow, as claimed. *See* RMD1008, ¶¶ 35, 89, 145.

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

The correspondence between claims 8, 20-21 and 26-27 and the teachings of

Gunaratnam and *Ging* is set forth below.

Claim 8 (Limitation 8.1): "A patient interface comprising: a mask assembly . . .; a tube 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* RMD1004, FIG. 135; *see also* ¶ 403; RMD1008, ¶¶ 44-48.

Limitation 8.2: "a mask assembly having:" *Gunaratnam's* Figure 135 patient interface has a nasal mask assembly, as does *Ging*. *See* RMD1004, FIG. 135, ¶ 403; RMD1005, ¶ 107; *see also* RMD1008, ¶ 42.

Limitations 8.3, 8.4, and 8.5: "a mask body," (8.3) "the mask body comprising a substantially flexible elastomeric material," (8.4), and "the mask body comprising a first nasal pillow and a second nasal pillow." (8.5) 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 design, 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, ¶¶ 120-127; *see also infra* Section VII.A.1. Doing so would yield a patient interface with a mask body having first and second nasal pillows, as claimed.

Regarding the limitation of "the mask body comprising a substantially flexible elastomeric material," *Gunaratnam* discloses a nasal pillows mask body (e.g., nozzle assembly 18 from FIGS. 1, 5, and 6) being made of a substantially flexible 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, ¶¶ 128-130. 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 substantially flexible elastomeric material, such as silicone, or that such a material selection would have been an obvious design choice. *See id.*

Limitation 8.6: "the first nasal pillow and the second nasal pillow being angled toward one another." *Gunaratnam* discloses that the first nasal pillow (first of the nozzles 50) and the second nasal pillow (second of the nozzles 50) of the mask body (nozzle assembly 18) are angled toward one another. This feature is clearly shown in Figures 1, 5, and 6 of *Gunaratnam*, for example, although other nasal pillows described throughout *Gunaratnam* also have this feature. *See, e.g.*, RMD1004, FIGS. 90, 92-93.

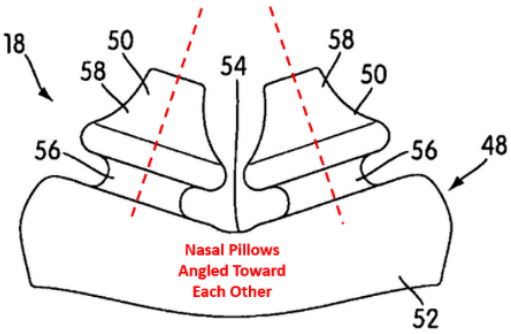


FIG. 5

Limitations 8.7, 8.8: "the first nasal pillow comprising a first generally conical portion and a first generally cylindrical portion" (8.7) and "the second nasal pillow comprising a second generally conical portion and a second generally cylindrical portion" (8.8). *Gunaratnam* discloses in one example that the first and second nasal pillows (e.g., nozzles 50 of nozzle assembly may each have a generally conical portion 58 and a generally 56 cylindrical portion. *See* RMD1004, FIGS. 1, 5-6, ¶¶ 185, 189-190. These features can be seen well in Figure 6 of *Gunaratnam*, copied and annotated

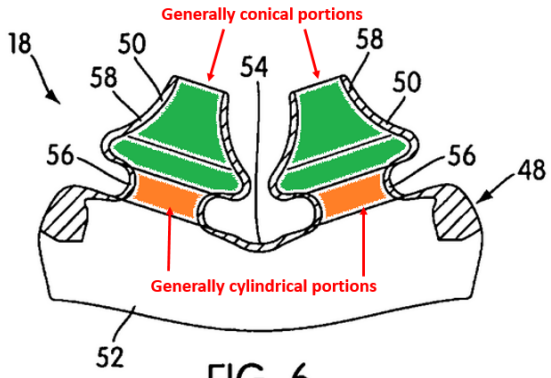


FIG. 6

above. *See also* RMD1009, p. 589 (Examiner reached same read); RMD1008, ¶¶ 131-132.

Gunaratnam further discloses an alternate nozzle structure in Figure 107N that would be applicable to nozzle assembly 18 or other nasal pillows mask bodies. The Figure 107N structure clearly has a generally conical portion and a generally cylindrical portion, as shown in the annotated Figure 107N at right. *Id.* at FIG. 107N, ¶ 374. *See also* RMD1008, ¶¶ 131-132.

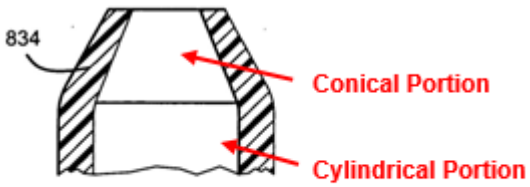


FIG. 107N

Limitations 8.9, 8.10, 8.11: "the first nasal pillow comprising a first outlet opening and the second nasal pillow comprising a second outlet opening" (8.9), "the mask body also comprising a mask body inlet opening" (8.10), and "the mask body inlet opening being spaced apart from the first outlet opening and the second outlet opening" (8.11): Regarding the two claimed "outlet openings" for the two pillows, that simply describes the known structure of a nasal pillow, as shown in *Gunaratnam* for example in Figure 6. *See also* RMD1008, FIGS. 1, 5-8, *see also id.* at ¶ 185 ("When the nozzle assembly 18 is attached to the frame 16, the nozzle assembly 18 and the frame 16 together form a conduit for directing

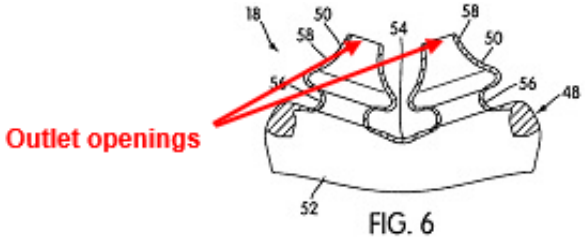


FIG. 6

breathable gas to the patient's nose through the pair of nozzles 50."); FIG. 31 (showing perspective view of a nozzle and its outlet opening); FIG. 107N (top); *see also* RMD1008, ¶¶ 133-134.

Next, regarding the "mask body inlet" (Limitation 8.10), as discussed under Limitations 8.3-8.5 the structure of *Gunaratnam* and *Ging* that aligns with the "mask body" as claimed is the nasal mask cushion of *Gunaratnam* Figure 135 (modified to be a nasal pillows mask cushion instead of a full nasal mask cushion as discussed in Section VII.A.1). *Gunaratnam* discloses the mask cushion (the claimed body) having an inlet opening as claimed, in that nozzle assembly 18 includes an opening on a side of nozzle assembly 18 that connects to frame 16. In particular, nozzle assembly 18 includes a base portion 48 having side walls 52 that define an inlet opening opposite the nozzles 50. In use, pressurized gas enters the nozzle assembly 18 through the inlet opening. *See* RMD1004, ¶¶ 184-188; *see also* RMD1008, ¶¶ 135-136.

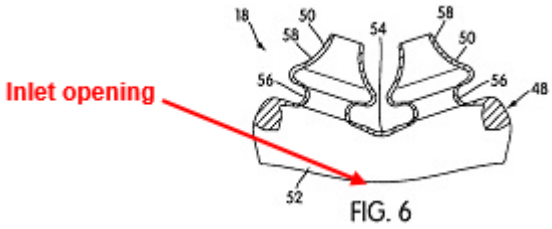


FIG. 6

Regarding the inlet opening being "spaced apart from" the two outlet openings of the pillows (Limitation 8.11), this limitation is met also. Considering the "mask body" to be the nozzle assembly 18 or cushion, the mask body inlet opening is

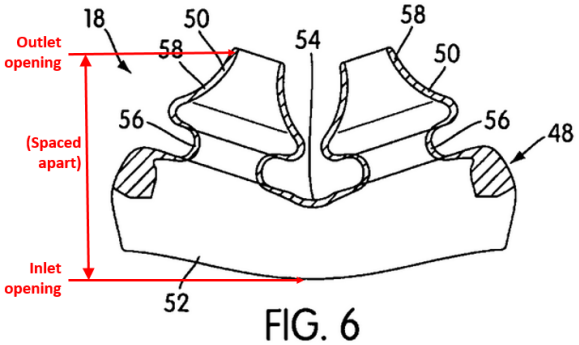


FIG. 6

spaced apart from the respective outlet openings, as shown for example in the annotation of *Gunaratnam* Figure 6 at right.

Limitation 8.12: "the mask body sized and shaped to leave the mouth of a 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, ¶ 138. 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, ¶¶ 137-138. Specifically regarding the example nasal pillows mask body shown in Figures 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 8.13: "the mask body inlet opening comprising a generally circular opening into the mask body." As discussed above, when *Gunaratnam's* Figure 135 interface is modified to include a nasal pillows mask body in place of the full nasal mask body shown in Figure 135, the mask body would be for example a nozzle assembly 18 of the type shown for example in Figure 6 of *Gunaratnam* (copied at right). As can be seen for example in Figure 1 of *Gunaratnam*, the base portion 48 of nozzle assembly 18 is generally circular (although referred to in the specification as a dog-bone shape), but *Gunaratnam* nevertheless discloses that the base portion 48 may have "any suitable shape." RMD1004, ¶ 188; *see also* RMD1008, ¶ 140. As such, the inlet opening where the nozzle assembly 18 would be attached to a mask frame (such as the mask frame in Figure 135) would similarly be any suitable shape, for example, generally circular. *See id.* Further illustrating the shape and configuration of a two-part mask assembly (with a mask frame and mask body that attach together to form a chamber through which air flows), *Gunaratnam* Figure 135 and *Ging* disclose a nasal mask body with an inlet opening corresponding in shape to a channel 26 formed in the mask frame 20. *See*

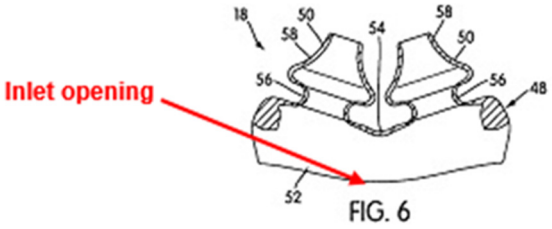


FIG. 6

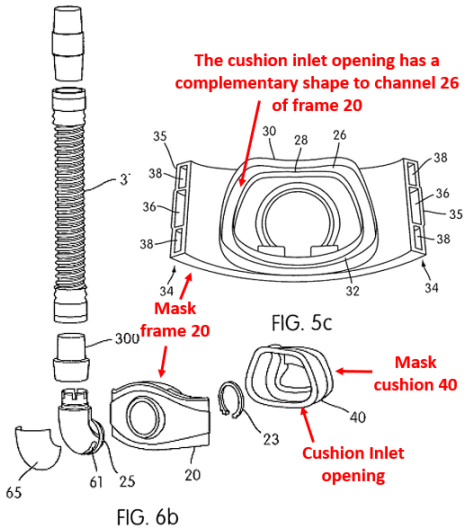


FIG. 6b

FIG. 5c

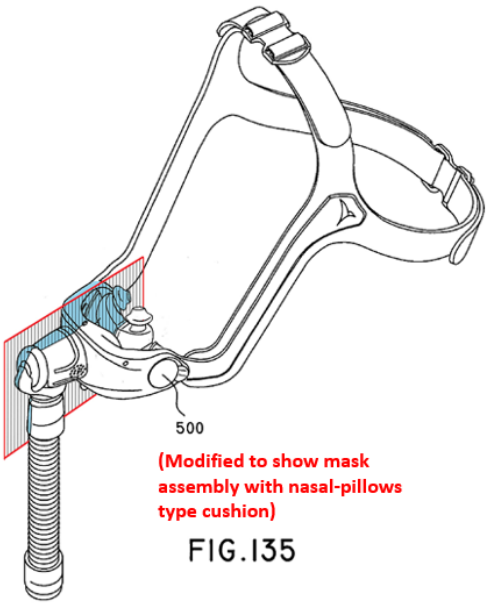
Gunaratnam, FIG. 135; *Ging*, FIG. 6b. As illustrated in Figures 5c and 6b of *Ging*, the shape of the opening into the nasal mask body is generally circular, and corresponds in shape with the channel 26 in the mask frame 20 to mate with that channel 26. *See* RMD1005, FIGS. 5c, 6b. *Ging* further discloses that the shape of that channel 26 in mask frame 20 may be any number of shapes, including a "circle." *See id.* at ¶ 115. Given that, *Ging* discloses the inlet to the mask body / cushion may similarly be circular. *See* RMD1008, ¶ 141. In addition, even though the mask body in *Gunaratnam* and *Ging* discloses a mask body / cushion that is full face as opposed to nasal pillows, one of skill in the art before the '807 patent would have understood that the shape options for an inlet opening to a nasal pillows mask body / cushion may be similarly shaped as described in *Ging* for the full nasal mask. *See id.*

Limitation 8.14: "the mask assembly having a ring-like connector releasably connected to the mask body inlet."[2] As discussed above in Section

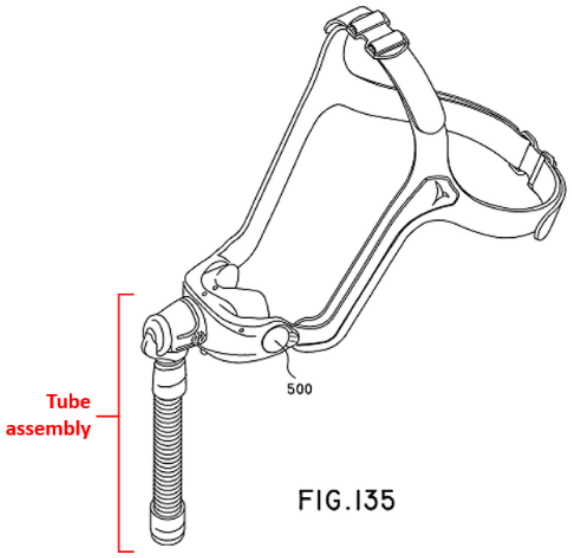
[2] There is no antecedent basis for "the mask body inlet" recited in Limitation 8.14. For the purpose of this IPR, Petitioners treat "mask body inlet" as referring to the "mask body inlet opening" recited in Limitation 8.10, but do not waive any argument regarding claim scope or arguments that may be made under 35 U.S.C. § 112 in other proceedings.

VII.A.2, *Gunaratnam/Ging* disclose a mask frame labeled 20 in *Ging*. As was conventional at the time 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 (the claimed ring-like connector) is releasably connected to the mask body inlet, as is also discussed above in Section VII.A.2. *See also* RMD1008, ¶¶ 142-151.

Limitation 8.15: "wherein a plane bisects the ring-like connector and the first nasal pillow is located on a side of the plane opposite the second nasal pillow." As explained in Section VI.B, this claim limitation requires that the ring-like connector 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, as shown at right. If one were to consider a plane that bisects the ring-like connector (mask frame) vertically as shown at right, 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, ¶¶ 152-154.



Limitation 8.16: "a tube assembly configured to deliver airflow to the mask body." *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 (annotated at right); RMD1005, FIG. 26, ¶ 153; *see also id.* at ¶ 111 and FIG. 1. As is well known, that tube assembly delivers airflow into a chamber formed by the mask frame and the mask body, and thus the tube delivers airflow to the mask body.



Limitations 8.17-8.20: "the tube assembly comprising a flexible conduit" (8.17), "the flexible conduit comprising a first end and a second end" (8.18), "the first end of the flexible conduit comprising a connector" (8.19), and "the second end of the flexible conduit comprising an elbow" (8.20): *Gunaratnam* and *Ging* both disclose the tube assembly having a flexible conduit comprising a connector at one end and an elbow at the other end, as shown in *Gunaratnam* Figure 135 and *Ging* Figures 6b and 26, copied below:

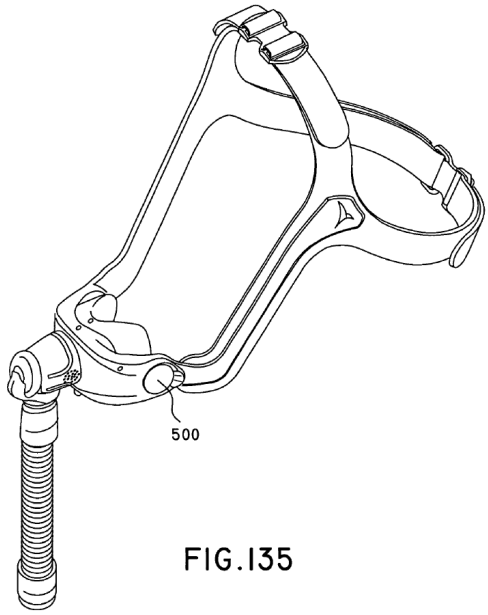


FIG.135

RMD1004

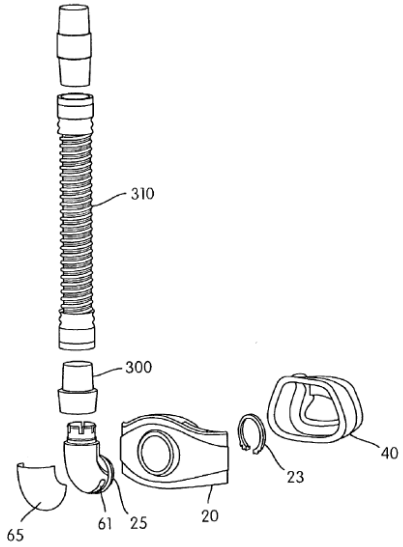


FIG. 6b

RMD1005

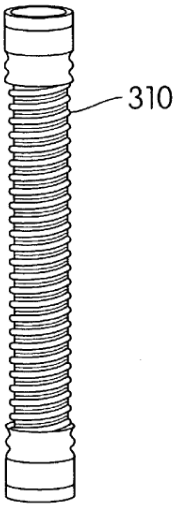


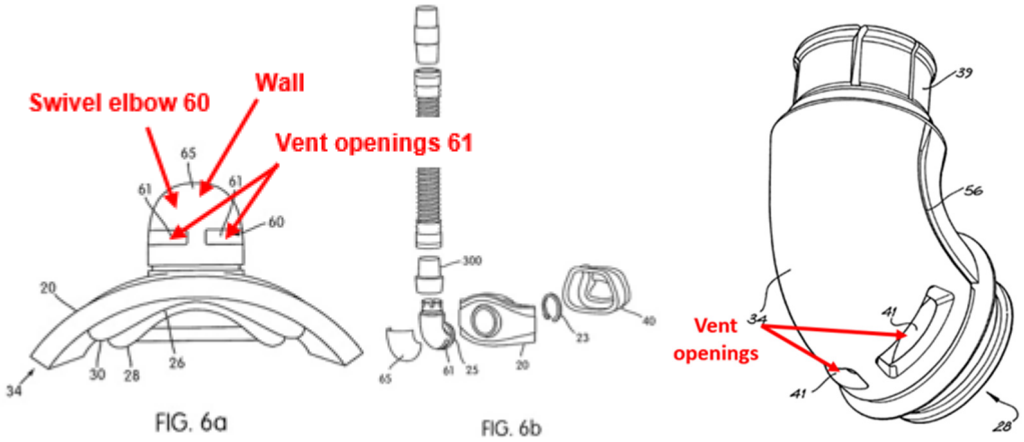
FIG. 26

RMD1005

See also RMD1005, FIG. 26 and ¶ 153, FIG. 1 and ¶ 111; *see also* RMD1008, ¶¶ 155-156. Referring specifically to Figure 6b of *Ging*, the claimed "flexible conduit" includes air tube 310 which one of skill in the art would understand to be flexible. *See* RMD1008, ¶ 156. The claimed "first end" of the conduit is the opening at the top of the figure in Figure 6b, which is a connection to a connector tube as shown. The claimed "second end" of the flexible conduit includes swivel elbow assembly 60 (not labeled in FIG. 6b, but labeled in FIGS. 2 and 3). *See generally* RMD1008, ¶¶ 155-156.

Limitations 8.21-8.23: "the elbow comprising a wall" (8.21), "the wall comprising a vent" (8.22), "the vent comprising a plurality of holes extending through the wall of the elbow" (8.23): Having vent holes in the elbow for

exhausting exhaled air was well known, and in fact *Gunaratnam* states 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, ¶¶ 157-161. *Ging* and *Gunaratnam II* both illustrate the vent holes as they would be in the Figure 135 elbow, as shown below:



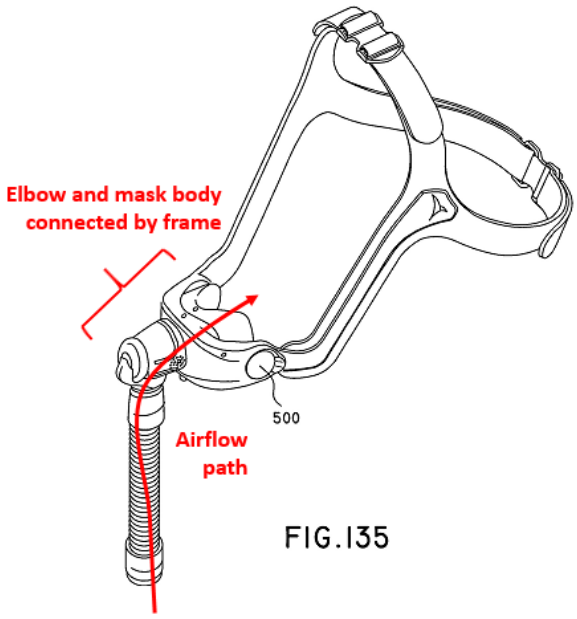
RMD1005, FIGS. 6a, 6b, and ¶ 113; RMD1007, FIG. 4 (above right).

Limitation 8.24: "the ring-like connector end being secured around an outer portion of the elbow." As discussed above in Section VII.A.2, *Gunaratnam* and *Ging* teach that the mask frame (ring-like connector)[3] of Gunaratnam's Figure 135 patent interface is secured around an outer portion of the elbow, or at a

[3] As discussed in Section VI.A, Petitioners assumes for purposes of this Petition that the "ring-like connector end" is referring to the previously recited "ring-like connector."

minimum that is one obvious way in which the Figure 135 interface would be implemented.

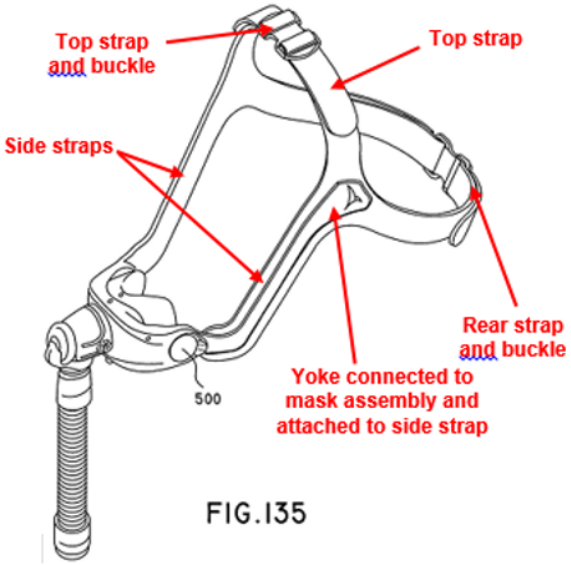
Limitation 8.25: "the elbow and the mask body being connected at least in part by the ring-like connector end such that airflow from the tube assembly can be directed from the elbow through the generally circular opening of the mask body and into the mask body." In *Gunaratnam's* Figure 135 patient interface, when read with further detail provided in *Ging*, has a ring-like connector (mask frame 20) that serves at least in part to connect the elbow with the mask body. *See* RMD1004, FIG. 135, ¶ 403; RMD1005, FIGS. 6b, 16a – 19c-2, ¶¶ 112-113, 149-162. In such a connected configuration as described, one of skill would understand that "airflow from the tube assembly is directed from the elbow through the generally circular opening of the mask body (the mask body inlet opening) and into the mask body," as claimed. *See* RMD1008, ¶¶ 162-163; *see also* RMD1005, ¶ 153.



Limitation 8.26: "the elbow and the mask body being capable of rotating relative to each other." *Gunaratnam* discloses a "swivel" elbow in its Figure 135

embodiment, which one of skill would understand provides for the elbow being rotatable relative to the mask frame, and because the mask frame is secured to the mask cushion, is rotatable relative to the mask cushion. *See* RMD1004, FIG. 135, ¶ 403; RMD1008, ¶¶ 109-110. *Ging* similarly discloses a swivel elbow 160 rotatably engaged with an opening in the mask frame 20, and thus there too the swivel elbow 160 is rotatable relative to the mask cushion. *See* RMD1005, *Ging*, ¶¶ 151-62 and FIGS. 16a – 16c-2, ¶ 113 and FIGS. 6a and 6b.

Limitation 8.27: "a headgear assembly configured to secure the mask body to a face of the user." *Gunaratnam* Figure 135 (annotated at right) shows a headgear assembly with all of the limitations 8.28-8.34 below, and *Gunaratnam's* Figures 107G-H and 180 show that same headgear assembly being used with a nasal pillows mask. *See* RMD1008, ¶¶ 164-167.



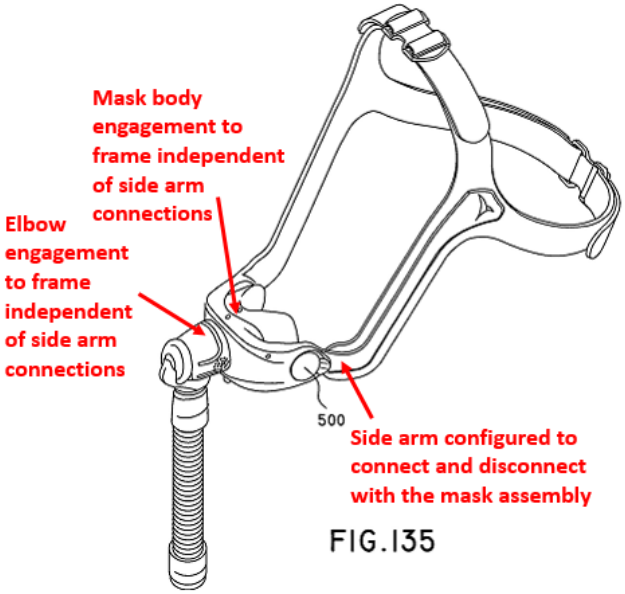
Limitation 8.28: "the headgear assembly comprising a first side strap and a second side strap." *Gunaratnam's* headgear assembly of Figures 135 and 107G-H has two side straps. *See* RMD1004, FIGS. 135 (annotated in limitation 8.27) 107G-H, 108; RMD1008, ¶ 95; RMD1035, p. 4 and RMD1036, p. 1 (ResMed nasal pillows masks with headgear similar to that in *Gunaratnam* Figure 135).

Limitation 8.29: "a top strap being connected to the first side strap and the second side strap." *Gunaratnam's* headgear assembly of Figures 135 and 107G-H includes a top strap connected to both side straps. *See* RMD1004, FIGS. 135 (annotated in limitation 8.27), 107G-H, 108.

Limitation 8.30: "the top strap including buckle configured to adjust a length of the top strap." The top strap in the headgear assembly in *Gunaratnam* Figures 135 107G-H includes a buckle on top, facilitating length adjustment of the top strap. *See* RMD1004, FIG. 135 (annotated in limitation 8.27); *see also id.* at FIGS. 18 & 83, ¶ 211.

Limitation 8.31 "and a back strap adjustably connected to at least one of the top strap, the first side strap, and the second side strap:" In the same manner as the disclosed '807 headgear assembly, *Gunaratnam's* headgear assembly of Figures 135 and 107G-H includes a back strap connected to the top strap and the side straps, and is adjustably connected to those other straps by virtue of having a back buckle. *See* RMD1004, FIG. 135 (annotated in limitation 8.27); *see also id.* at FIGS. 107G-H, 108, FIGS. 18, 83, ¶ 211; *compare with* RMD1001, FIG. 2 (showing the '807 disclosed back strap design is the same as *Gunaratnam's*).

Limitation 8.32: "wherein the first side strap and the second side strap are configured to connect and disconnect with the mask assembly while the elbow is connected with the mask body." *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, ¶¶ 164-165. As such, the side straps may be connected and disconnected with the mask assembly while the elbow remains engaged with the mask body. *See id.*; *see also* RMD1004, ¶¶ 403, 377-81, FIGS. 108-113, 135 (describing and illustrating the connection of the yokes to the mask assembly in various embodiments related 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.[4] Even if the

[4] 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,

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, ¶ 166. 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, ¶¶ 166-167.

Limitation 8.33: "wherein the mask assembly is configured to connect to only 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*

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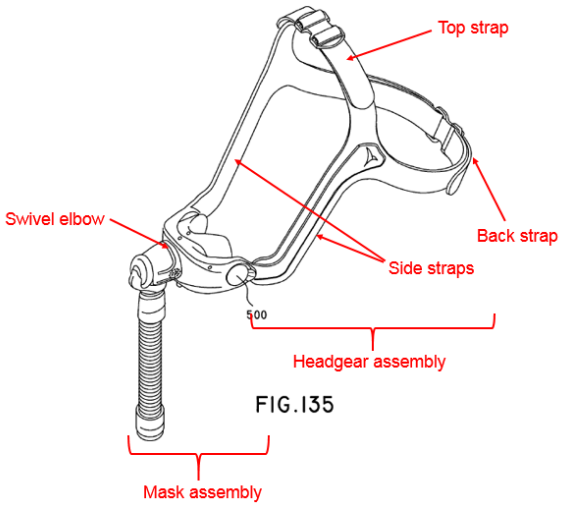
and side arms in *Gunaratnam* Figure 135 as shown above in the annotated Figure 135) are considered part of the claimed "mask assembly."

FIGS. 107G-H; RMD1008, ¶¶ 164-167; *see also* Section VI.C (claim construction for limitation 8.33); discussion under limitation 8.32 (discussing that even if claim 8 required a direct connection, which it does not, that would have been nothing more than an obvious design choice).

Limitation 8.34: "wherein top strap connects only with one or more of the first side strap, the second side strap, and the back strap." In *Gunaratnam's* Figure 135, the top strap (annotated in limitation 8.27) 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).

Claims 20, 21: "A patient interface as claimed in claim 8, wherein the top strap is integrally formed with one or more of the side straps and the back strap" (claim 20) and "A patient interface as claimed in claim 20, wherein the top strap is integrally formed with one or more of the side straps" (claim 21). *Gunaratnam's* Figure 135 top



strap being is shown integrally formed with the two side straps and with the back strap, and thus meets claims 20 and 21. *See* RMD1008, ¶¶ 172-175; *see also* RMD1004, FIGS. 107, 107-1, 107-2, 107G-H, (additionally integrally formed headgear configurations), ¶ 213 (disclosing the headgear assembly 20 in some embodiments "may be constructed as a one piece structure").

Claims 26, 27: "A patient interface as claimed in claim 8, wherein the top strap is releasably connected to one or more of the side straps and the back strap" (claim 26) and "A patient interface as claimed in claim 26, wherein the top strap is releasably connected to the back strap" (claim 27). To the extent claims 26 and 27 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 26 and 27. 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 26, 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 26 and 27. *See also* RMD1008, ¶¶ 176, 180. As such, the limitations of claims 26 and 27 are met by *Gunaratnam's* Figure 135 headgear assembly.

To the extent that claims 26 and 27 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, ¶¶ 176-180; *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, 180; RMD1005, FIGS. 1, 1b, ¶¶ 145-148 (top strap 140 releasably connected to side straps and rear strap); RMD1008, ¶¶ 178-179, 180; 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, 180. 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 26-27. *See* RMD1008, ¶¶ 176-180.

B. Ground 2: Claims 8, 20, 21, 26, and 27 are obvious over *Gunaratnam* in view of *Ging* and *McAuley*

In Ground 1, it is shown that *Gunaratnam* and *Ging* render obvious claims 8, 20, 21, 26, and 27 under Petitioners' proposed claim constructions. If the Board construes the claimed "ring-like connector" more narrowly than Petitioners propose in Section VI.A and require the ring-like connector 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.

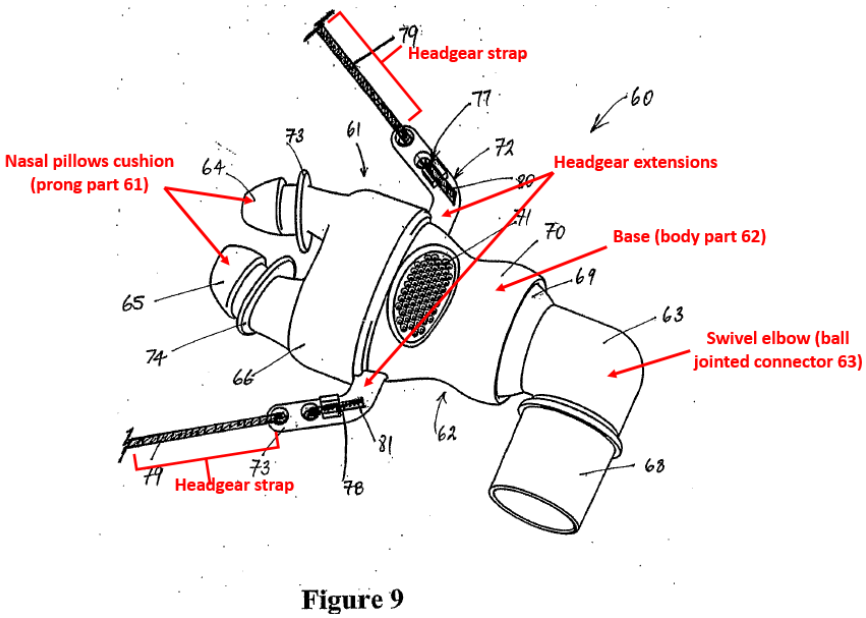


Figure 9

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., nasal pillows mask body), a rigid body part 62 (a "ring-like connector," 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 (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 nasal pillows mask body 61 connect. *Id.* at 7:5-10. The swivel elbow 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 ball-jointed connector [cross-section labeled 85] 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.

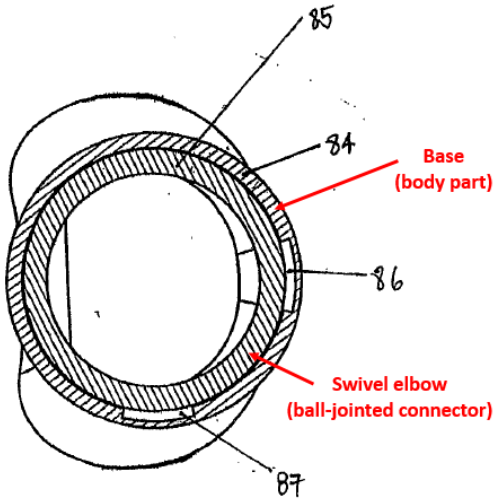


Figure 15

One of skill would have been motivated to use *McAuley's* teaching 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.*

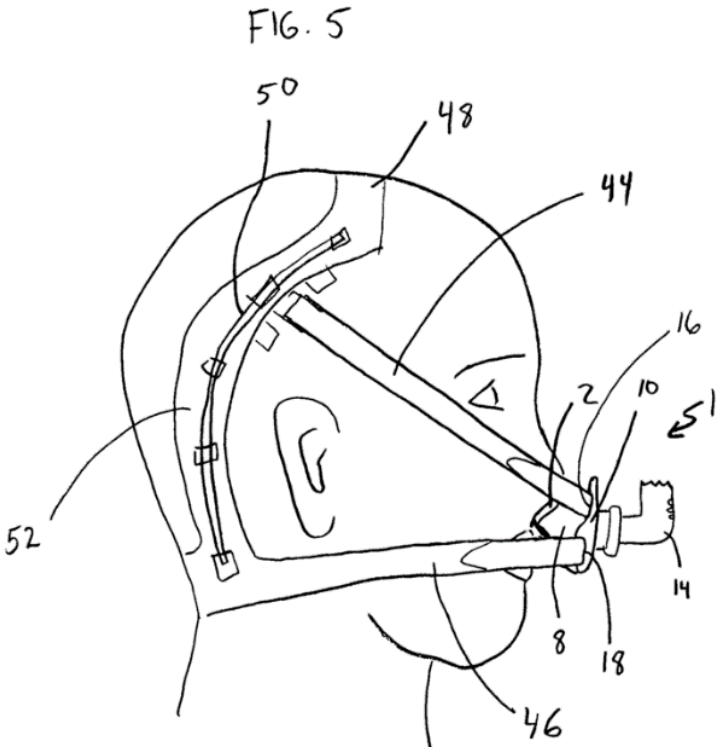
With the patient interface combination of *Gunaratnam* and *Ging* further modified in view of *McAuley*, the limitations of claim 8 and its dependent claims at issue are still taught. A full analysis is not required here, because the modification only affects the outer periphery of the "ring-like connector" and claim 8. 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.

Accordingly, claims 8, 20, 21, 26, and 27 are obvious over *Gunaratnam* in view of *Ging* and *McAuley*.

C. Ground 3: Claims 8, 20, 21, 26, and 27 are unpatentable as obvious over *Lovell* in view of *Gunaratnam*

1. The combined teachings of *Lovell* and *Gunaratnam*.

Lovell discloses a patient interface with a nasal pillows mask assembly and a headgear assembly. *Lovell* may be applied to the '807 claims in two ways. In one reading, *Lovell* meets all limitations of claim 8, except for the headgear assembly. *Gunaratnam* teaches the claimed headgear assembly as discussed under Ground 1, in Figure 135 and also in Figures 107G-H where the headgear assembly is specifically shown with a nasal pillows mask assembly. It would have been obvious to have modified the *Lovell* patient interface to include the two-point connection *Gunaratnam* headgear assembly in place of the four-point connection headgear assembly shown in *Lovell*, to provide an alternative and simplified headgear configuration. *See generally* RMD1008, ¶¶ 44-48, 58-60, 186-189, 209-225, 228-236.



Specifically regarding the "ring-like connector" claim limitation and the fact that the rotatable elbow must "fit into" the claimed ring-like connector, there are

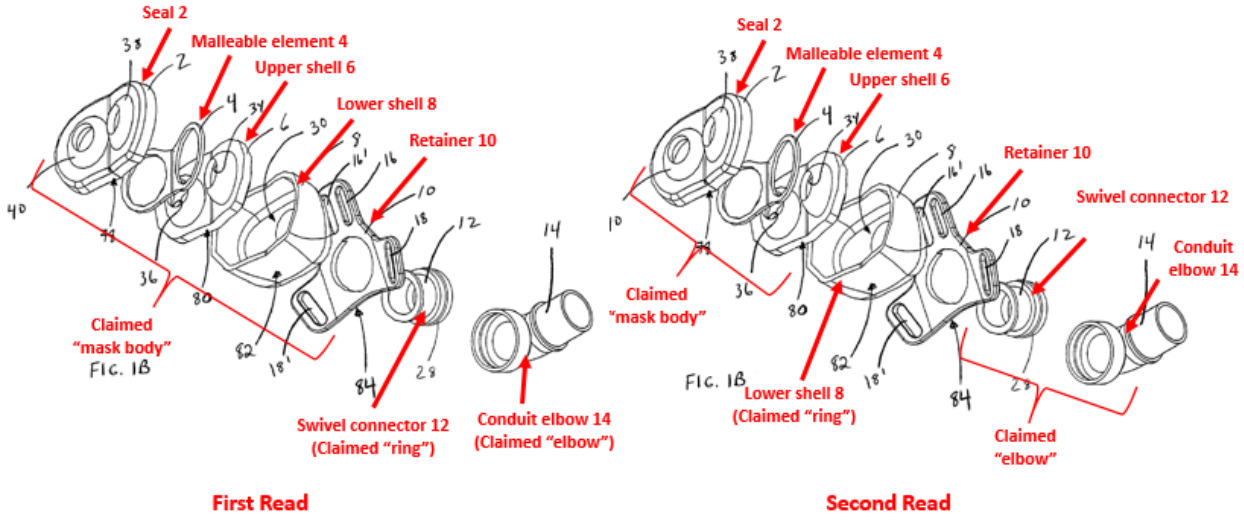
two structures in *Lovell* that read on the claimed ring-like connector – a swivel connector 12 and lower mask frame 8. *See* RMD1012, FIG. 1B, col. 4:20-5:67; *see also* limitations 8.14-8.15 and 8.24-8.25 discussed below. Under a reading where the lower mask frame 8 is the claimed ring-like connector, the claim limitation of requiring that the ring-like connector be "secured around an outer portion of the elbow" (limitation 8.24) is literally met. Under the second reading with the swivel connector 12 as the claimed ring-like connector, although the "secured around" 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 swivel connector is 12 "secured around" elbow 14 as claimed, as opposed to "fitting into" the elbow 14 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 8, 20, 21, 26 and 27 and the teachings of *Lovell* and *Gunaratnam* are discussed below.

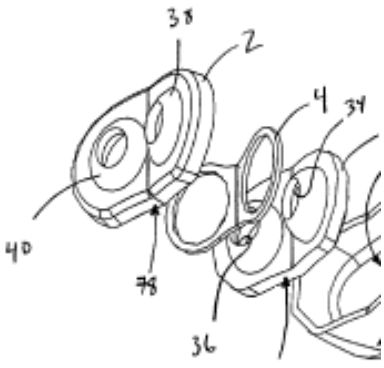
Claim 8 (Limitations 8.1 - 8.3): "A patient interface (8.1) comprising: a mask assembly (8.2) having a mask body (8.3)." *Lovell* discloses designs for a patient interface including a mask assembly having a mask body. *See, e.g.*, RMD1012, FIG. 5, col. 2:31-61 (mask assembly generally). Two different structures read on the mask body as claimed, depending on the structure constituting the claimed "ring-like connector" in limitation 8.14. **First**, with the swivel connector 12 as the claimed ring-like connector, 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-like connector, 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:



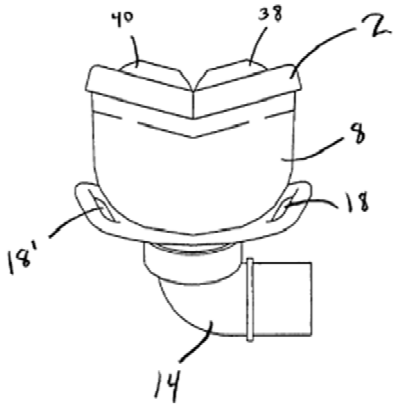
See also RMD1008, ¶¶ 191-192.

Limitation 8.4: "the mask body comprising a substantially flexible elastomeric material." *Lovell* discloses that the seal 2 of the mask body comprises silicone, which is a substantially flexible 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, ¶ 209. As such, the structures of *Lovell* corresponding to the claimed mask body comprise a substantially flexible elastomeric material.

Limitations 8.5 - 8.6: "the mask body comprising a first nasal pillow and a second nasal pillow (8.5), the first nasal pillow and the second nasal pillow being angled toward one another (8.6)." *Lovell's* mask body includes 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. The domes 38 and 40 (nasal pillows) are angled toward each other, as shown by Figure 2A copied at right. *See* RMD1008, ¶ 210.



Limitations 8.7, 8.8: "the first nasal pillow comprising a first generally conical portion and a first generally cylindrical portion" (8.7) and "the second nasal pillow comprising a second generally conical portion and a second generally cylindrical portion (8.8)." Each of *Lovell's* nasal pillows include a conical "dome 38" or "dome 40" and a corresponding portion of the "seal 2" that is generally cylindrical. *See* RMD1012, FIG. 1A-2B, 8A.

To the extent that *Lovell* does not show the required shape of the nasal pillows, CPAP masks with such pillow pillows were known in the art. For example, as described above for Ground 1, *Gunaratnam* discloses that nozzles 50 of nozzle assembly 18 each comprise a generally conical portion and a generally cylindrical portion.

A skilled artisan would have seen a reason to have modified *Lovell* to have pillow cushions with the shapes disclosed by the various pillow cushions in *Gunaratnam* because these designs provide a mechanism to "sealingly engage with

nasal passages 12 of the patient's nose 14." *See* RMD1004, ¶¶ 185, 190 ("the first portion 56 of the nozzles 50 have [sic] a reduced cross-section with respect to the second portion 58 to allow the nozzles 50 to move relative to the base portion 48, and hence the frame 16, for increased comfort and accommodation of variations in patient facial features."); *see also* RMD1008, ¶¶ 211-215. Indeed, because the '807 patent "simply arranges old elements with each performing the same function it had been known to perform, and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int'l v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) (*citing Sakraida*, 425 U.S. 273).

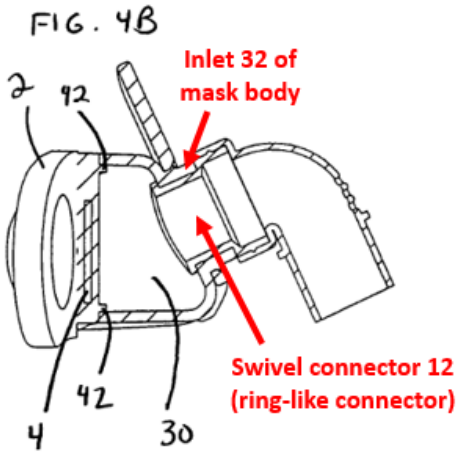
Limitations 8.9 - 8.11: "the first nasal pillow comprising a first outlet opening and the second nasal pillow comprising a second outlet opening (8.9), the mask body also comprising a mask body inlet opening (8.10), the mask body inlet opening being spaced apart from the first outlet opening and the second outlet opening (8.11)." The outlets of the nasal pillows are at the end of the conical portion of the nasal pillow that rests within a user's nares (with both the nasal pillows shown in *Lovell* or *Gunaratnam*). The mask body inlet opening (e.g., the inlet 32 of lower shell 8 into which air enters the mask body) is spaced apart from the nasal pillow outlets, as shown in FIG. 1B.

Limitation 8.12: "the mask body sized and shaped to leave the mouth of a user uncovered by the mask body when in use." As shown in Figure 5, *Lovell's*

mask body is sized and shaped to leave the mouth of the user uncovered by the mask body when in use. *See* RMD1012, col. 2:33-35 ("[D]evices of the invention seal with the external skin surrounding the nares at the base of the nose and/or along the inner rim of the nares of a user."); *id*. at col. 2:36-40; *see also* RMD1008, ¶¶ 216-217.

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

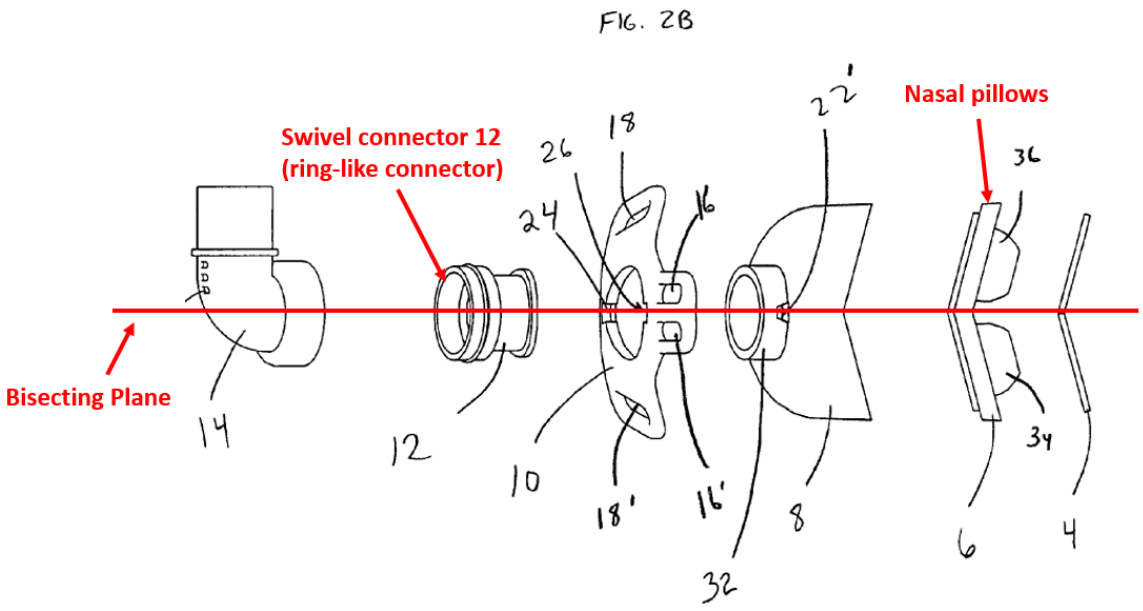
Limitation 8.14: "the mask assembly having a ring-like connector releasably connected to the mask body inlet." As mentioned, the claimed ring-like connector reads on *Lovell* in two respects. **First**, *Lovell* discloses a "ring-like connector" as swivel connector 12, and discloses that this ring-like connector (swivel connector 12) is releasably connected to an inlet of the mask body (the mask body including components 8, 6, 4 and 2). Specifically, a portion of the swivel connector 12 fits within an inlet 32 of the lower shell 8, as shown in FIG. 4B. *See also* RMD1012, col. 5:24-26 ("The nasal mask 1 includes an inlet 32 into which a swivel connector 12 fits. The swivel connector 12 has a slightly concave shape on the end that fits into the inlet 32.").



Second, *Lovell* discloses a ring-like connector as lower mask shell 8 (this structure meets the "ring-like connector" limitation as properly interpreted under Section VI.A), and discloses that this ring-like connector (lower shell 8) is engaged with an inlet of structure constituting a mask body (the mask body including components 6, 4 and 2). Specifically, the lower shell 8 engages with upper shell 6 of the mask body, as shown in FIG. 4B. *See also* RMD1012, col. 4:38-40. Although *Lovell* states that the two portion of the shell 6, 8 "can be heated and

welded together, welded together with a solvent and/or bonded together with a bonding agent" (col. 4:40-43), *Gunaratnam* teaches that two mask shells that form a chamber may alternatively be releasable and reattachable to facilitate cleaning the insides of the nasal mask assembly. *See* RMD1004, ¶ 186 (nozzle assembly 18 removably attachable to mask frame by rib / recess structures); *see also* RMD1008, ¶ 201; RMD 1041, ¶ 12.2; RMD1005, FIGS. 5c, 6b, 24, 27-29, ¶¶ 114-115. As such, it would have been obvious at the time to have made the two shells 6 and 8 of *Lovell* releasably connectable.

Limitation 8.15: "wherein a plane bisects the ring-like connector and the first nasal pillow is located on a side of the plane opposite the second nasal pillow." *Lovell's* ring-like connector (considering either the swivel connector 12 or the lower mask shell 8 as the ring-like connector) 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 the first nasal pillow would be located on a side of the plane opposite the second nasal pillow, as shown below:



See RMD 1008, ¶¶ 218-219; *see also* Section VI.B (showing location of the defined plane).

Limitation 8.16 – 8.18: "a tube assembly configured to deliver airflow to the mask body (8.16), the tube assembly comprising a flexible conduit (8.17), the flexible conduit comprising a first end and a second end (8.18)." To the extent that the claimed feature of "a tube or conduit extending from the elbow" is not explicitly shown in *Lovell*, this feature would have been implied or inherent, as a skilled artisan would have understood that a tube or conduit is needed to deliver pressurized air from a source (e.g., a CPAP machine) to the patient interface. *See* RMD1012, col. 1:12-20 ("In general, a supply of pressurized air or therapeutic gas is provided by a tube or conduit to a delivery apparatus designed to conform to particular body structure."); *see* RMD1008, ¶ 220. One of skill would understand

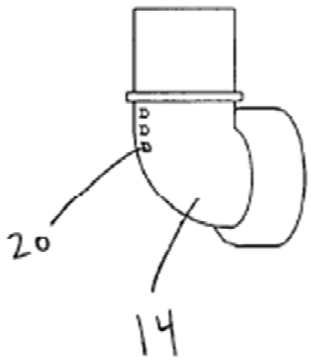
that the swivel elbow 14 would connect to a tube and would have looked to other references (such as *Gunararatnam*) to identify a suitable tube assembly. *Gunaratnam* at FIG. 135 shows that the tube attaches to the center of the mask frame for delivering air, that the tube has a first and a second end, and that the tube is flexible (as illustrated by the ridges in the tube). *See* RMD1004, FIG. 135, ¶¶ 3, 323, 340, 364.

Limitation 8.19: "the first end of the flexible conduit comprising a connector." As discussed under limitations 8.16-8.18, *Lovell* would necessarily have a flexible conduit, although the details of that are not shown, but they are well known in the art and shown in *Gunaratnam*. As shown in Figure 135 of *Gunaratnam*, a first end of the tube (the lower end of the tube in the figure) comprises a connector. Indeed, with respect to Figure 108, which shows a similar or identical tube, *Gunaratnam* discusses that "[t]he air delivery tube 606 may include a swivel connector 607 and includes an end 609 which also may be provided with a swivel connector. The end 609 is provided with a source of pressurized gas." *See* RMD1004, ¶ 377. Such connectors are disclosed throughout the rest of *Gunaratnam*, for example, at Figure 107A (item 660) and Figure 107D (item 704). *See* RMD1004, ¶¶ 364 and 366.

Limitation 8.20: "the second end of the flexible conduit comprising an elbow." *Lovell* discloses the conventional use of an elbow component labeled 14.

See RMD1012, FIGS. 1, 3A, 4B, 5, col. 5:26-34. In that the claimed "elbow" interacts with the claimed "ring-like structure" in limitation 8.24, two different structures are considered to be the claimed elbow – the elbow 14 by itself, and alternatively the combination of elbow 14 and swivel connector 12. Either way, the elbow would attach at the second end of the flexible conduit, as described above.

Limitations 8.21-8.23: "the elbow comprising a wall (8.21), the wall comprising a vent (8.22), the vent comprising a plurality of holes extending through the wall of the elbow (8.23)" 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 limitations 8.21-8.23 under Ground 1.



Limitation 8.24: "the ring-like connector end being secured around an outer portion of the elbow." **First**, regarding the swivel connector 12 as the claimed ring-like connector, *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 (in other words, so that the ring-like connector is "secured around an outer portion of the elbow"), 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, 221-222. Indeed, it was well known before the time of the '807 patent for elbows to fit into a mask assembly, to facilitate rotatable engagement of the elbow vis-à-vis the mask assembly. This is shown for example in *Gunaratnam* (RMD1004), in Figures 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

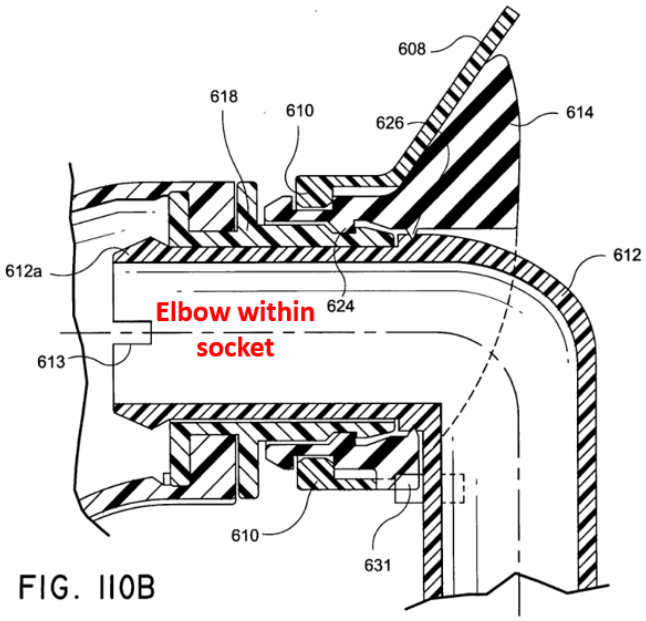


FIG. 110B

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); RMD1018, FIGS. 1-2 (swivel elbow fits into front of nasal mask frame).

Second, considering the lower mask shell 8 as the claimed ring-like connector, *Lovell* discloses swivel connector 12 fits into an inlet 32 of lower mask shell 8. *See* RMD1012, FIG. 4B. As such, shell 8 of *Lovell* is secured around an outer portion of the elbow (the elbow in *Lovell* being the combination of elbow 14 and connector 12). Here, the "secured around" limitation is met literally. *See* RMD1008, ¶ 222.

Limitation 8.25: "the elbow and the mask body being connected at least in part by the ring-like connector end such that airflow from the tube assembly can be directed from the elbow through the generally circular opening of the mask body and into the mask body." One of skill would understand that in use, a pressurized flow of gas applied to *Lovell*'s mask would follow a path from the tube

or conduit, through the elbow 14, the opening of the mask body, and into the mask body. *See, e.g.*, RMD1012, FIGS. 1B, 5, 10B; RMD1008, ¶ 223.

Limitation 8.26: "the elbow and the mask body being capable of rotating relative to each other." *Lovell* discloses that the elbow (conduit elbow 14 or alternatively the combination of elbow 14 and connector 12) is rotatably engaged with the ring (swivel connector 12 or lower mask shell 8). *See* RMD1012, FIGS. 1, 3A, 4B, 5, col. 5:26-34 ("A conduit elbow 14 fits onto the swivel connector 12 over a flange 28 on the swivel connector 12. . . . The swivel connector 12 produces a swivel mount connection between the conduit elbow 14 and the inlet 32 [of lower mask shell 8].").

Limitation 8.27 – 8.34 (Hedgear Assembly): "a headgear assembly configured to secure the mask body to a face of the user." Each of the additional headgear requirements in claim 8 are disclosed in *Gunaratnam*, as set forth in Ground 1. As discussed in Section VII.C.1, one of skill would have been motivated to apply *Gunaratnam's* headgear to *Lovell's* mask to reduce the number of connections between the headgear and mask. *See also* RMD1008, ¶¶ 224-225. For example, a two-strap connection would be less cumbersome for a patient than a four-strap connection and would result in a simpler design. *See id.* at 224. How to connect the two side straps from *Gunaratnam* to the mask assembly from *Lovell* would be well within the capabilities of a skilled artisan, and would be an obvious

implementation detail. *See id.* at 225. For example, the side arms could attach to connection points on *Lovell's* retaining structure 10 or directly to the retaining structure 10,[5] while side arms along the side straps provide added stability. *See id.*; RMD1004, ¶¶ 369-70, FIGS. 107G-H (nasal pillows mask where only two side straps connect to the mask frame via connector portions 766, 770).

One of skill would not have agreed with the applicant's argument during prosecution that modifying *Lovell's* mask to connect to only two side straps would "prevent[] the nasal mask from being securely positioned against the nares of a user." *See* RMD1008, ¶¶ 36-38; RMD1012, FIG. 5, FIG. 1B; RMD1009, pp. 615-616, 620-622; RMD1004, FIG. 135.

Claims 20, 21: "A patient interface as claimed in claim 8, wherein the top strap is integrally formed with one or more of the side straps and the back strap." (claim 20) and "A patient interface as claimed in claim 20, wherein the top strap is integrally formed with one or more of the side straps" (claim 21). These claim

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[5] Further, as discussed under Ground 1, limitation 8.32, 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 8.32 and 8.33).

limitations are present is present in *Guaratnam's* Figure 135 (and Figure 107G-H and 108) headgear assembly, as described with respect to Ground 1, claims 20, 21.

Claims 26, 27: "A patient interface as claimed in claim 8, wherein the top strap is releasably connected to one or more of the side straps and the back strap" (claim 26) and "A patient interface as claimed in claim 26, wherein the top strap is releasably connected to the back strap" (claim 27). These claim limitations are present is present in *Guaratnam's* Figure 135 (and Figure 107G-H and 108) headgear assembly, or are obvious design choices, as described with respect to Ground 1, claims 26, 27.

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 of claims 8, 20, 21, 26, and 27 of the '807 patent.

Respectfully submitted,

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(Trial No. IPR2016-01734)

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 12,985, which is less than the 14,000 allowed under 37 CFR § 42.24(a)(1(i).

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Date: September 7, 2016

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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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