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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED LIMITED, RESMED INC., and RESMED CORP.
Petitioners,

v.

FISHER & PAYKEL HEALTHCARE LIMITED,
Patent Owner.

Case No. IPR2016-01726
U.S. Patent No. 8,443,807

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TABLE OF EXHIBITS

Exhibit No.	Description
2001	The Oxford American College Dictionary (2002) (definition of "ring")
2002	U.S. Patent No. 4,782,832 to Trimble et. al.
2003	Webster's New World College Dictionary (5th ed. 2014) (definition of "ring")
2004	FPH Opus 360 Brochure
2005	U.S. Pat. No. 6,907,882 to Ging

I. INTRODUCTION AND SUMMARY OF ARGUMENT

Patent Owner Fisher & Paykel Healthcare Limited ("FPH") is a world leader and innovator in respiratory therapy devices for critical care and home care use. U.S. Patent No. 8,443,807 ("the '807 Patent") at issue in this IPR claims an innovative respiratory mask that may be used with Continuous Positive Airway Pressure (CPAP) machines to treat sleep apnea.

FPH and Petitioners ResMed Inc., ResMed Corp, and ResMed Limited are presently engaged in a global patent dispute relating to CPAP machines and related masks. As part of that dispute, Petitioners seek *inter partes* review of Claims 1-7, 17-19, and 24-25 of the '807 Patent. Before filing the present IPR petition, however, Petitioners filed a declaratory judgment action in district court challenging the validity of the '807 Patent. Petitioners' request to institute an IPR is therefore statutorily barred by 35 U.S.C. § 315(a).

In the event that the Board determines that this IPR is not barred by statute, an IPR should not be instituted as to any of the challenged claims because Petitioners have not met their burden of demonstrating a reasonable likelihood that the claims are invalid under 35 U.S.C. § 314(a) for several reasons.

Petitioners' primary prior art reference — Gunaratnam (Ex. 1004) — was considered by the PTO during prosecution. The PTO addressed the very figure in Gunaratnam (Figure 135) that Petitioners rely upon in Grounds 1-3. Ex. 1009 at

588. The PTO also relied upon Figure 135 of Gunaratnam in combination with another reference — Lovell (Ex. 1012) — as a basis for rejecting some of the pending claims. *Id.* at 588-89. That is the same combination that Petitioners rely upon in Ground 3. FPH overcame the PTO's rejections and the claims were allowed. Consequently, the Board should exercise its discretion and decline institution pursuant to 35 U.S.C. § 325(d).

Ground 1 also relies upon an overbroad construction of the "ring" recited in Claim 1 of the '807 Patent. According to Petitioners, virtually any structure with an opening through it is a "ring." However, under the proper construction of ring — "a generally circular band of material" — neither Gunaratnam nor Ging (Ex. 1005) disclose a "ring." Ground 1 of the Petition fails for this reason.

Claim 1 also requires a mask body that includes "two nasal pillows." Figure 2 (below) of the '807 Patent illustrates an embodiment that includes nasal pillows 24, 25.

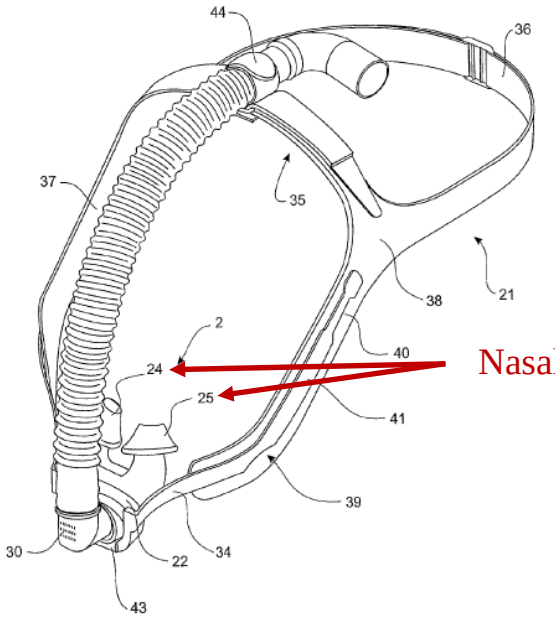


FIGURE 2

Ex. 1001 at Fig. 2 (annotations added). In use, the nasal pillows are located beneath the patient's nose and extend partially within and separately form a seal with each of the patient's nares. *Id.* at 5:29-33. Figure 20 (below) shows an example of nasal pillows 306, 307 sealing with a patient's nares.

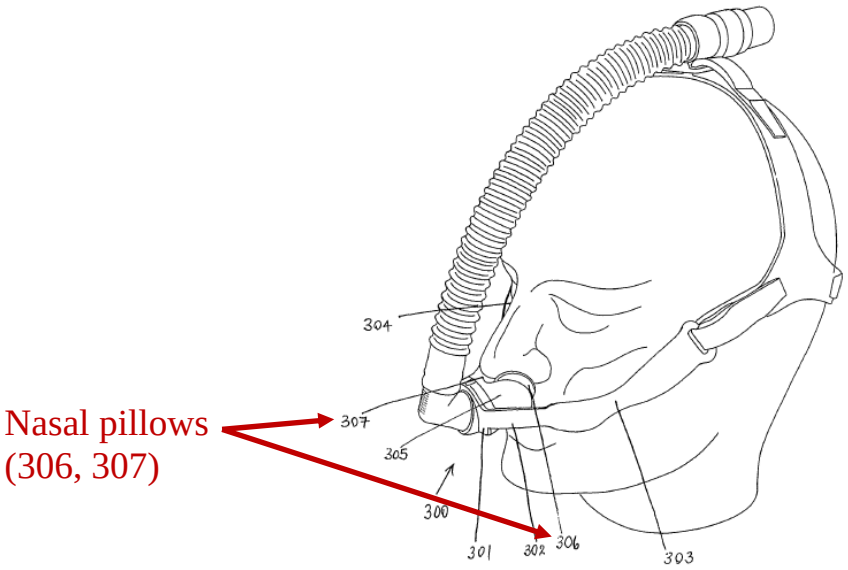
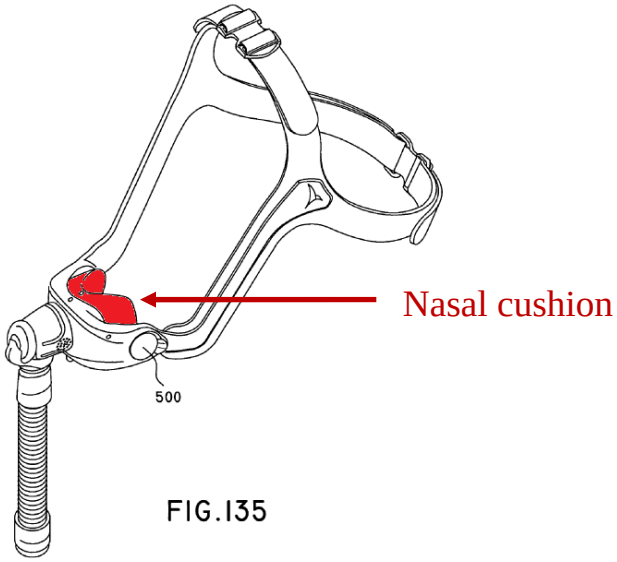


FIGURE 20

Id. at Fig. 20 (annotations added). As is evident from the figure above, a force component that is generally parallel to the patient's face and directed upwardly underneath the patient's nose is required to position the nasal pillows against the nares and form a seal.

Grounds 1 and 2 hinge upon the alleged obviousness of incorporating a nasal pillows assembly into the mask shown in Gunaratnam Figure 135 (below).



Ex. 1004 at Fig. 135 (annotations and color added). The mask shown in Figure 135 of Gunaratnam does not have nasal pillows. It instead includes a nasal cushion, which is an entirely different type of mask and which uses entirely different forces to properly seal to the face. *Id.* ¶ [0403] (identifying Figure 135 as including a nasal cushion).

A nasal cushion is designed to fit *over* the nose and form a seal around the outside of the nose. *See, e.g.*, Ex. 1005 (Ging) ¶¶ [0169, 0172, 0174, 0176] (describing nasal cushion); Ex. 1008 ¶ 70. Figure 1 of Ging (below) shows an example of a nasal cushion mask and illustrates how the cushion 40 is held against the patient's face and forms a seal around the nose.

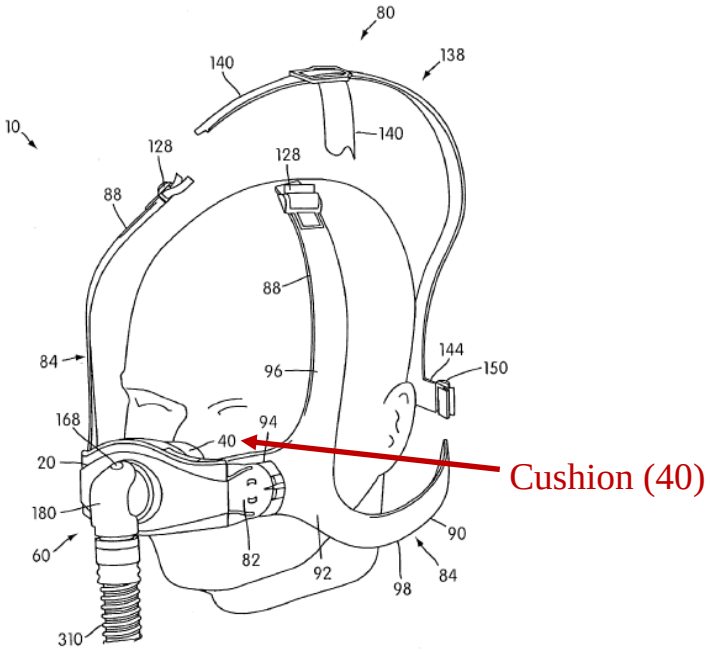


FIG. 1

Ex. 1005 at Fig. 1 (annotations added), ¶ [0107]. With nasal cushions, a force component that is generally perpendicular to the patient's face is required to hold the nasal cushion against the face and form a seal.

Petitioners have not shown that it would have been obvious to modify Gunaratnam Figure 135 by replacing the nasal cushion with nasal pillows. Petitioners propose removing the nasal cushion from Gunaratnam Figure 135 and replacing it with nozzle assemblies from other embodiments in Gunaratnam. But the nozzle assemblies, such as shown in Figure 1 of Gunaratnam (below), are significantly and fundamentally different from the nasal cushion of Gunaratnam Figure 135.

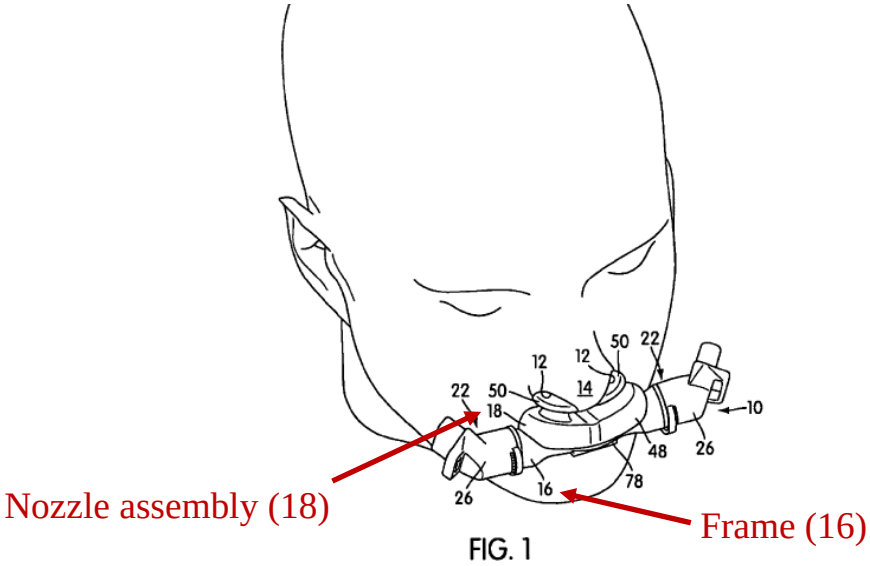


FIG. 1

Ex. 1004 at Fig. 1 (annotations added), ¶ [0177]. Petitioners do not provide sufficient rationale for their proposed redesign of Gunaratnam.

Gunaratnam does not teach that the nasal cushion shown in Figure 135 could be replaced with nasal pillows. Petitioners also do not provide any reasonable explanation as to how the substitution could be made with a reasonable expectation of success. Due to the substantial differences between cushion masks and nasal pillows masks, including the different forces required for the masks to achieve a proper seal, Petitioners have not shown that it is possible to swap out a nasal cushion in a particular mask design with nasal pillows as they contend with a reasonable expectation of success. Given the significant differences between the embodiments Petitioners seek to combine, it is plain that their picking and

choosing features from one embodiment and inserting them into another is motivated by improper hindsight.

Ground 2 also fails. Undoubtedly recognizing that their proposed construction of "ring" is overbroad and unsupported, Petitioners add yet another reference, McAuley (Ex. 1034), in Ground 2. Petitioners assert that McAuley discloses a "ring" and attempt to combine it with Gunaratnam and Ging. However, Petitioners do not explain how the frame shown in Gunaratnam Figure 135 could be redesigned as a ring while still maintaining its functionality. Petitioners also do not provide sufficient reasons why a person of ordinary skill in the art ("POSITA") would modify Gunaratnam's horseshoe-shaped frame to make it a ring.

Finally, Ground 3 relies upon the same prior art combination — Lovell and Gunaratnam — that was applied by the PTO and overcome by FPH during prosecution of the '807 Patent. Claim 1 of the '807 Patent requires that "the mask assembly is configured to connect to only two side straps." Lovell discloses a mask frame that is connected to four straps — two lower straps and two upper straps. Ex. 1012 at 6:44-7:4. Petitioners contend that it would have been obvious in view of Gunaratnam to remove two of the straps from Lovell. However, as FPH successfully argued during prosecution, removing two of the straps from the Lovell mask assembly would fundamentally alter the way in which the mask functions and it would not have been obvious to do so.

II. THE STATUTE BARS INSTITUTION OF AN INTER PARTES REVIEW

Petitioners' requested IPR may not be instituted because it is barred by statute. The statute is unequivocal:

> An inter partes review may not be instituted if, before the date on which the petition for such a review is filed, the petitioner or real party in interest filed a civil action challenging the validity of a claim of the patent.

35 U.S.C. § 315(a)(1). Before Petitioners filed the instant Petition, they filed a civil action in the United States District Court for the Southern District of California challenging the validity of the '807 Patent. Ex. 1046 (complaint filed August 16, 2016). The plain language of the statute bars the Petition.

The Board should not construe Section 315 in a manner contrary to its plain meaning. As the Supreme Court has explained:

> If the statute is clear and unambiguous "that is the end of the matter, for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress."

Sullivan v. Stroop, 496 U.S. 478, 482 (1990) (quoting *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 291-92 (1988)); *accord Carcieri v. Salazar*, 555 U.S. 379, 387 (2009) (collecting cases). Here, Section 315 leaves no wiggle room. Petitioners are barred.

A. Petitioners' Contrary Construction of Section 315 Is Meritless

Petitioners briefly acknowledge they had previously filed an action challenging the validity of the '807 Patent, and then note they dismissed the action without prejudice. Pet. at 1-2; *see also* Ex. 1046. Petitioners then argue that their "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." Pet. at 2.

Petitioners filed their declaratory judgment action apparently to ensure their home forum, the Southern District of California, would be the selected venue for the parties' U.S. patent dispute. Petitioners only dismissed their action after learning they obtained the desired forum because FPH also filed in that forum. Petitioners should not be permitted to escape the consequences of Section 315 flowing from their procedural maneuvering.

Petitioners apparently contend Section 315(a)(1) includes an implicit, unstated exception for complaints that are dismissed without prejudice. This, however, is directly contrary to *Sullivan*, 496 U.S. at 482, *Carcieri*, 555 U.S. at 387, and a long line of Supreme Court cases holding that the unambiguous language of a statute must be faithfully applied. Indeed, Petitioners seek to completely rewrite Section 315(a)(1) under the apparent guise of interpretation. The plain language of Section 315(a)(1) unambiguously bars an IPR if the

Petitioners previously "filed a civil action challenging the validity of a claim of the patent." 35 U.S.C. § 315(a)(1). Petitioners seek to rewrite this statute to declare that an IPR is barred if the Petitioners previously "filed a civil action challenging the validity of a claim of the patent, unless that civil action was dismissed without prejudice." There is no legal basis for adding this non-statutory exception to the unambiguous language of the statute.

B. Petitioners' Cited Authorities Are Contrary to Two Lines of Supreme Court Precedents

In support of their strained statutory construction, Petitioners cite two unpublished, non-precedential Board decisions. *See* Pet. at 2 (citing *Macuato U.S.A. v. BOS GmbH & KG*, IPR2012-00004, Paper No. 18 at 15-16 (P.T.A.B. Jan. 24, 2013), and *Oracle Corp. v. Click-to-Call Techs. LP*, IPR2013-00312, Paper No. 52 at 12-13 (P.T.A.B. Oct. 28, 2014)). These decisions reason that the Federal Rules of Civil Procedure and court precedent "treat a dismissal without prejudice as something that, *de jure*, never existed." *Oracle*, IPR2013-00312, Paper No. 52 at 12.[1] Thus, these decisions conclude, a dismissal without prejudice "leav[es] the parties in the same legal position as if the underlying complaint had never been

[1] Following this reasoning, the district court in the parties' pending litigation also granted Petitioners' motion to stay over FHP's objection that the case should not be stayed because the IPR petitions were barred under 35 U.S.C. § 315(a)(1).

served." *Id*. at 13; *see also Macuato*, IPR2012-00004, Paper No. 18 at 15-16.

These two non-precedential decisions are unpersuasive for at least two significant reasons. First, of course, they are both contrary to cases like *Sullivan*, 496 U.S. at 482, and *Carcieri*, 555 U.S. at 387, which hold that the plain language of statutory text must be followed by courts and agencies. The Board in *Oracle* and *Macuato* did not even address the statutory text, much less follow it.

Second, *Oracle* and *Macuato* err in assessing the significance of a dismissal without prejudice under Federal Rule of Civil Procedure 41(a). The Supreme Court clearly explained the effect of a Rule 41(a) dismissal without prejudice in *Semtek Int'l, Inc. v. Lockheed Martin Corp.*, 531 U.S. 497, 505 (2001), stating:

> The primary meaning of "dismissal without prejudice," we think, is dismissal without barring the plaintiff from returning later, to the same court, with the same underlying claim.

Id. The Court also quoted favorably the definition of "dismissal without prejudice" in Black's Law Dictionary – "removed from the court's docket in such a way that the plaintiff may refile the same suit on the same claim." *Id*.

In short, by designating their dismissal as being "without prejudice" under Rule 41(a), Petitioners merely reserved the right to refile the same claim in the same court at a later date. Petitioners did not and could not nullify the statutory right that had already accrued to FPH to be free from subsequent petitions for IPR.

It is true that some lower court decisions have loosely described the effect of a dismissal without prejudice as to "leave the parties as if the action had never been brought." *Bonneville Assocs. v. Barram*, 165 F.3d 1360, 1364 (Fed. Cir. 1999). This dicta, however, if construed as broadly as Petitioners would do, is inconsistent with the Supreme Court's decision in *Semtek.* Moreover, *Bonneville* and the other courts employing this dicta were all merely addressing the procedural effect of a dismissal without prejudice within the federal court system. None of them was addressing the effect or lack of effect of a dismissal without prejudice on a substantive statutory right, such as FPH's rights under 35 U.S.C. § 315(a).

In addition, the broad dicta of *Bonneville*, if read in the sweeping fashion that Petitioners desire, would be plainly wrong on its face. Rule 41(a) itself provides that a dismissal without prejudice does ***not*** "leave the parties as if the action had never been brought." Rule 41(a) states that a party who dismisses a claim without prejudice once may not thereafter dismiss the same claim without prejudice again. Fed. R. Civ. P. 41(a)(1)(B). Thus, the loose language of *Bonneville* cannot be taken to mean that a dismissal without prejudice leaves the parties as if the action had never been brought ***for all purposes***. Rather, consistent with *Semtek*, the language of *Bonneville* means only that a plaintiff is free to refile a claim that has been dismissed without prejudice. Indeed, the holding of *Bonneville* is that a dismissal without prejudice has no effect beyond this and thus

does not operate to toll the time for refiling an action or an appeal. *Bonneville*, 165 F.3d at 1364-65.

Finally, the plain language of Rule 41(a) is about dismissal, not filing. Rule 41(a) declares that the ***dismissal*** of a complaint is without prejudice under some circumstances. It does not say that the filing of a complaint is ever without prejudice. To determine the effect of the ***filing*** of a complaint, one must look elsewhere, in this case to 35 U.S.C. § 315(a).

C. Petitioners' Cited Authorities Are Also Contrary to the Rules Enabling Act

The two lines of Supreme Court precedents cited above provided reason enough to reject *Oracle* and *Macuato.* Another cardinal principle of federal law, however, provides an additional reason not to follow these non-precedential decisions. The Rules Enabling Act declares that the Federal Rules "shall not abridge, enlarge or modify any substantive right." 28 U.S.C. § 2072(b). Thus, any interpretation of the phrase "dismissal without prejudice" in Rule 41(a) to defeat a substantive right would violate the Rules Enabling Act.

Yet, that is precisely how *Oracle* and *Macuato* construe Rule 41(a). *Oracle* and *Macuato* both hold that the purported right of a plaintiff to dismiss its complaint without any consequence under Rule 41(a) trumps the substantive right of a patentee under 35 U.S.C. § 315(a) to be free from subsequent petitions for

inter partes Review. Such an interpretation of Rule 41(a) would abridge a substantive right of patentees under Section 315(a) and thus violate the Rules Enabling Act.

This is confirmed by the cases interpreting the Rules Enabling Act. For example, in *Semtek*, 531 U.S. 497, the issue was whether a Rule 41 dismissal "with prejudice" had *res judicata* effect. The defendant argued that the issue was governed by Rule 41, which specified that the dismissal "operates as an adjudication upon the merits." *Id*. at 501. Thus, the defendant argued, the dismissal was entitled to *res judicata* effect. The Supreme Court unanimously rejected this argument. *Id*. at 503. The Court concluded that the *res judicata* effect of a judgment was a substantive right, and that the defendant's interpretation of Rule 41 therefore "would arguably violate the jurisdictional limitation of the Rules Enabling Act: that the Rules 'shall not abridge, enlarge or modify any substantive right.'" *Id*. (quoting 28 U.S.C. § 2072(b)). In short, Rule 41(a) did not trump substantive law regarding the *res judicata* effect of judgments.

Brennan v. Silvergate District Lodge No. 50, 503 F.2d 800 (9th Cir. 1974), is to the same effect. There, the Secretary of Labor brought an action to set aside a union election in which Baffone had been elected union president. *Id.* at 802-03. Baffone sought to intervene under Rule 23 [now Rule 24] of the Federal Rules of Civil Procedure. *Id*. Baffone met the standard for intervention as of right under

the Federal Rules. *Id*. at 804. However, a substantive labor law statute generally barred intervention on the side of a union in suits brought by the Secretary of Labor. *Id*. (citing 29 U.S.C. § 482(b)). Quoting the Rules Enabling Act, the Ninth Circuit held that Rule 23 [now Rule 24] could not trump the rights created by substantive federal labor law. *Id*. Accordingly, Baffone could not intervene unless he met the statutory labor law requirements. *Id*. at 805. *See also John Hancock Life Ins. Co. v. J.P. Morgan Chase & Co.*, 938 F. Supp. 2d 440, 448 (S.D.N.Y. 2013) (under the Rules Enabling Act, Rule 23's equitable tolling principles are trumped by the statute of repose of the Securities Act of 1933).

In sum, the instant Petition is barred under the plain and unambiguous text of 35 U.S.C. § 315(a)(1).

III. BACKGROUND

A. Overview of the '807 Patent

The '807 Patent describes masks designed to improve patient comfort and compliance with CPAP treatment by overcoming disadvantages associated with conventional nasal masks that were "uncomfortable and cumbersome." Ex. 1001 at 2:23-27, 2:59-61. One embodiment of the patent is shown in Figure 2 (below).

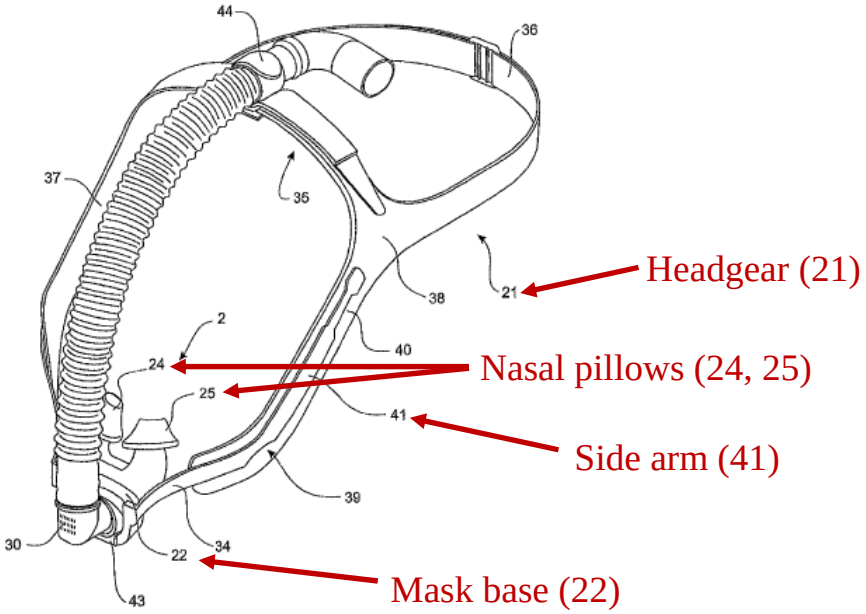


FIGURE 2

Id. at Fig. 2 (annotations added).

The patent describes that the mask includes a mask base 22. *Id.* at 5:25-40. In one embodiment, the patent describes the mask base 22 as "a ring or sleeve type attachment." *Id.* at 6:19-23. Figure 5 (below) shows further details of the mask base 22.

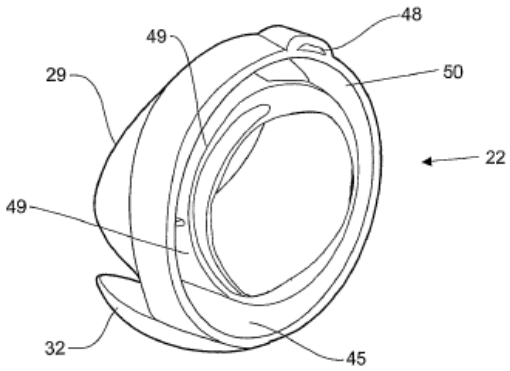


FIGURE 5

Id. at Fig. 5. As shown in Figure 2, the mask base attaches to a mask body 23 and to a connector 30 that is attached to a tube that provides gas to the mask. *Id.* at 6:19-45. Figure 7 of the patent further illustrates a mask body 23 and associated nasal pillows 24, 25.

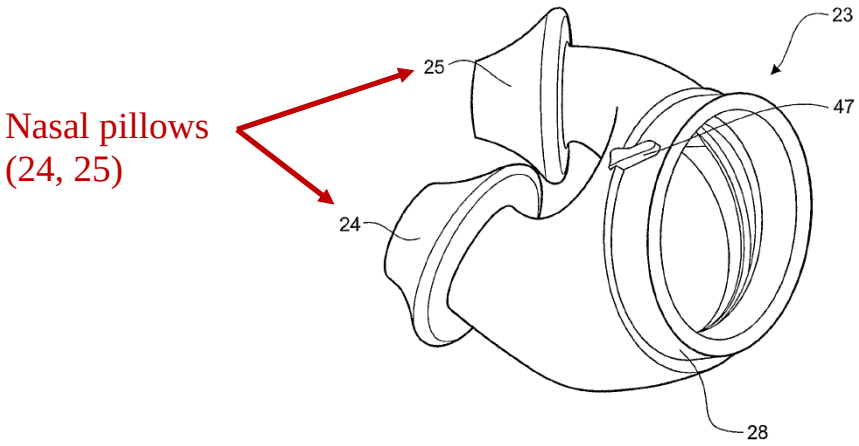


FIGURE 7

Id. at Fig. 7 (annotations added). The mask body 23 includes a lip 28 that is inserted into the channel 45 of the mask base 22 to connect the two components. *Id.* at 6:26-31. In use, the mask body is located beneath the patient's nose and the nasal pillows 24, 25 rest against the patient's nares to seal with the nares. *Id.* at 5:29-31, *see also* Fig. 20 (nasal pillows 306, 308 sealing with the nares).

As illustrated in the figures above, the configuration of the mask base 22 as a ring provides it with a compact profile. This allows the mask to be less obtrusive to the patient when the mask is worn, thereby improving comfort. FPH has manufactured and sold a mask under the name OPUS that includes a ring shaped

base. *See*, *e.g.*, Ex. 2004. The marketed benefits of that mask include its small size and slim-line design, which provide increased patient comfort. *Id.*

In the embodiment shown in Figure 3 (below), the mask also includes a substantially curved and elongate member 34 that has a central section 42 that supports the mask base 22 and contoured side arms 41, 54 that overlap and are attached to the side straps 37, 38, respectively.

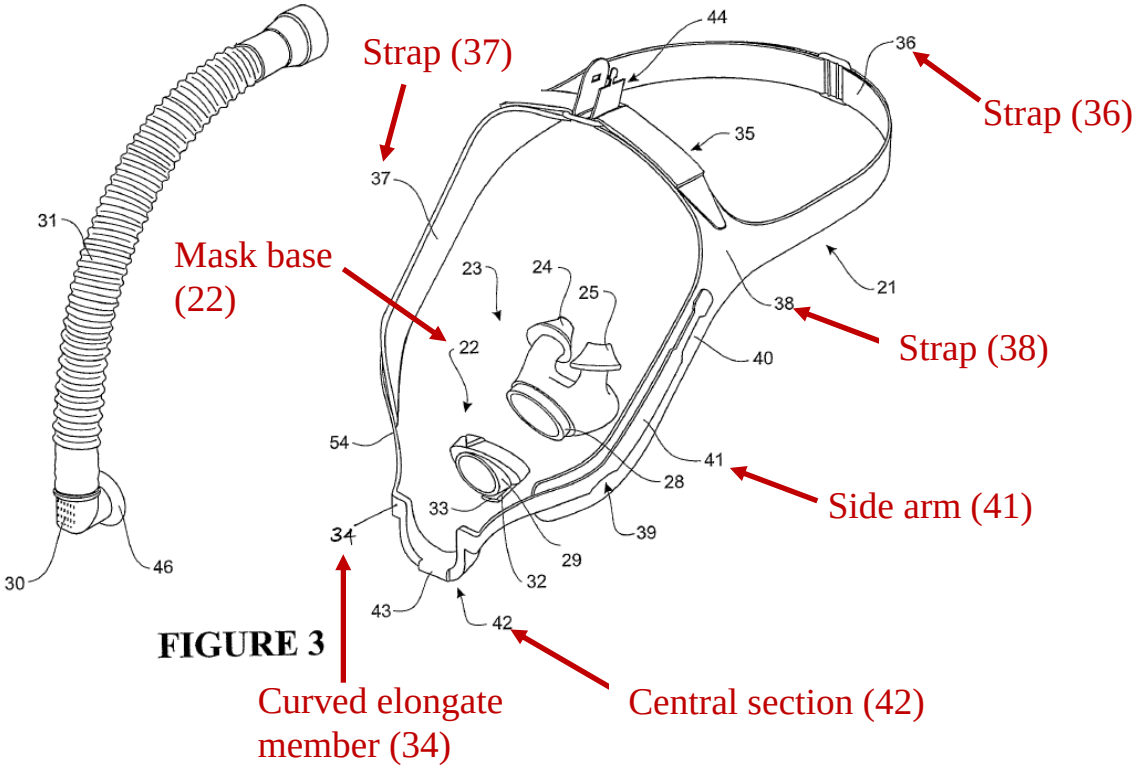


FIGURE 3

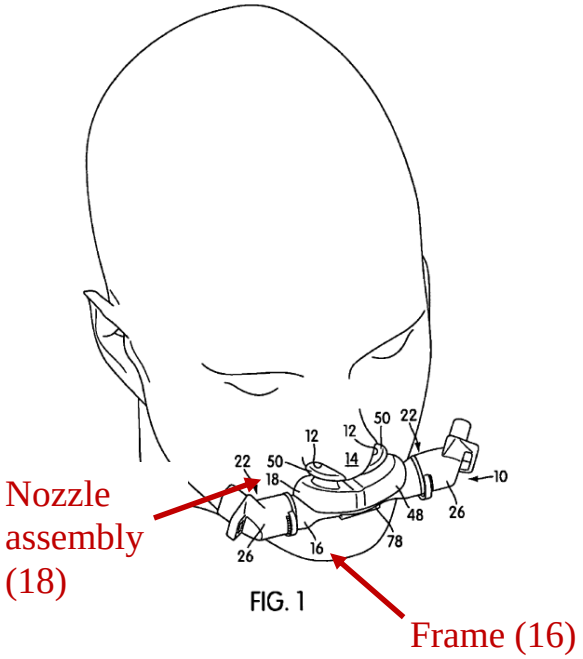
Id. at Fig. 3 (annotations added), 7:4-16. Alternatively, each of the "[side] arms may be attached one to each side of the [mask] base 22." *Id.* at 8:26-30. Headgear

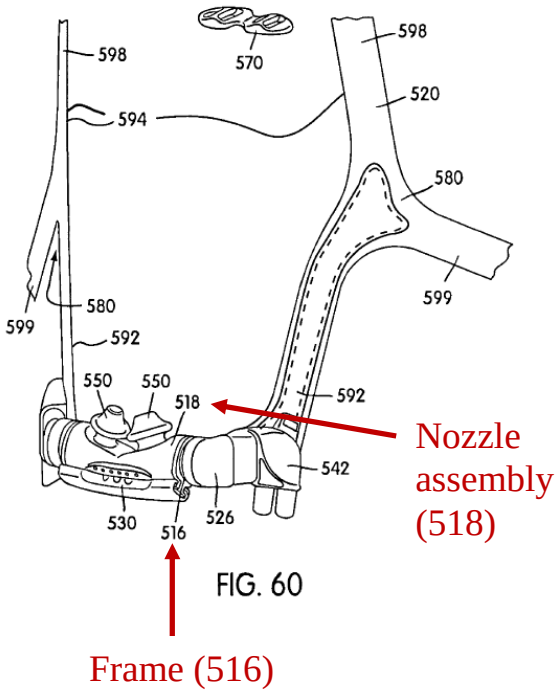
21 may also include a strap 35 that extends over the forehead or top front area of the patient's head and a strap 36 that extends around the back of the patient's head. *Id.* at 6:65-67.

B. Overview of the Alleged Prior Art

1. U.S. Patent Pub. No. 2004/0226566 ("Gunaratnam")

Gunaratnam was cited and considered by the Examiner during prosecution of the '807 Patent. Ex. 1009 at 585-91. The vast majority of the embodiments disclosed in Gunaratnam include a nozzle assembly extending from a tubular-style mask frame, such as shown in Figures 1 and 60 (below).





Ex. 1004 at Figs. 1 and 60 (annotations added), *see also, e.g.*, Figs. 25, 26, 38, 39, 51, 52, 59, 76A, 108, 109. Headgear attaches to each end of the tubular-style frame to hold the frame against the patient's upper lip. *See, e.g., id.* ¶¶ [0177], [0229–30], [0266].

Gunaratnam describes that the tubular mask assemblies provide separate or decoupled stability and sealing forces. *Id.* ¶¶ [0024, 0219, 0229-30, 0396]. The stability force secures the mask to the patient's face and the sealing force creates a seal with the patient's airways. *Id.* Because the stability force with nozzle style masks is generally much higher than the sealing force, Gunaratnam teaches that it is more desirable and comfortable for the patient if the forces are separated. *Id.* ¶ [0229]. Gunaratnam describes directing the stability force against the less sensitive regions of the face, such as the upper lip and cheeks, and directing the sealing force against the more sensitive areas, such as the nares. *Id.*

Gunaratnam explains that the sealing force may be created by a "spring-load[]" of the nozzles or by the expansion of a gusset portion of the nozzle assembly that inflates when filled with air to seal the nozzles against the nares. *Id.* ¶¶ [0218, 0232, 0251, 0286, 0321]. Gunaratnam further explains that modifying the tension on the headgear does not modify the sealing force because the forces are effectively "decoupled." *Id.* ¶¶ [0020, 0024, 0230].

Gunaratnam also discloses other mask embodiments in Figures 107G-H and 134-135, but provides little detail on their actual structure. Figures 107G-H (below) show a mask assembly 750 with headgear 752 having a yoke member 759, "nozzles" 772, and an air supply tube 760 connected to a frame 768.

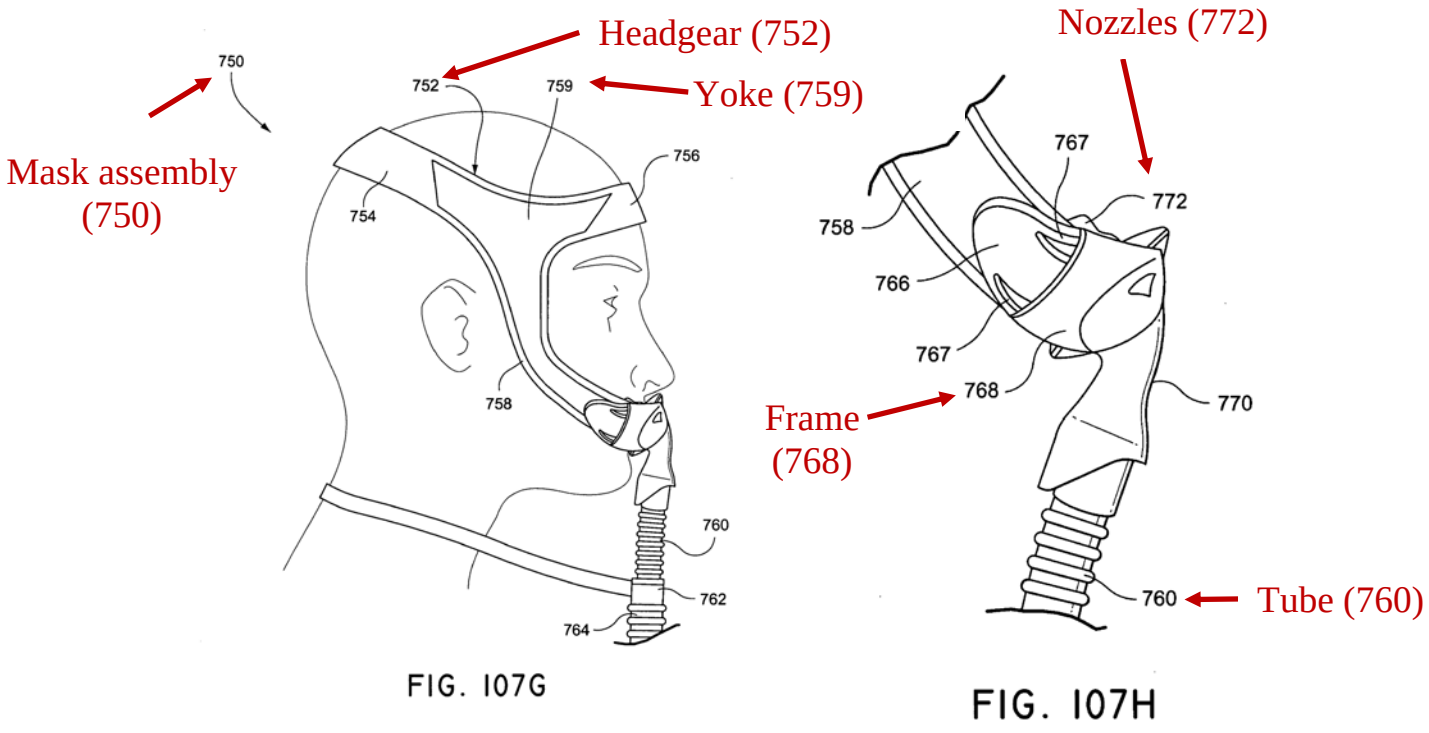


FIG. 107G

FIG. 107H

Id. at Figs. 107G and 107H (annotations added), *see also* ¶¶ [0369-70].

As shown in Figure 107G, the mask is positioned over the mouth and appears to deliver air through the mouth instead of through the nose. Gunaratnam does not describe the structure or function of the nozzles or how the nozzles interface with the frame, which is shaped like a football helmet chin strap.

Figures 134 and 135 (below) are stand-alone embodiments of Gunaratnam that include a nasal cushion (shown in red) that fits over the nose.

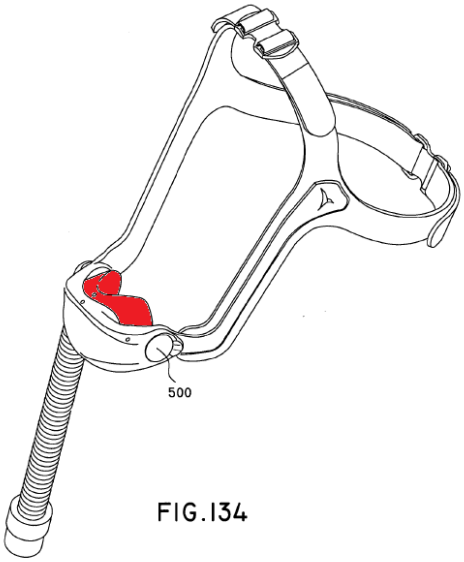


FIG.134

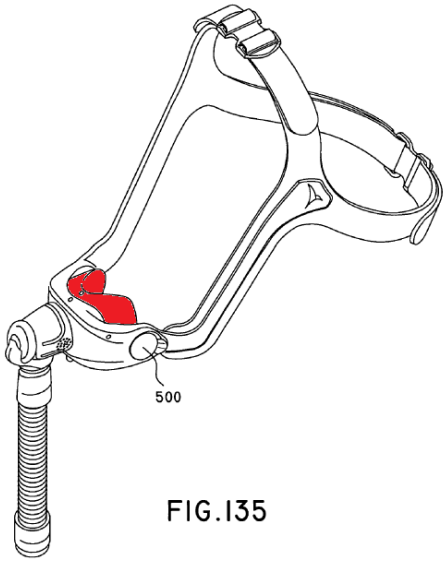


FIG.135

Id. at Figs. 134 and 135 (color added), *see also* ¶ [0403]. Gunaratnam includes a single paragraph describing these figures and provides very little structural detail. *Id.* ¶ [0403]. As shown above, the masks include a horseshoe-shaped frame and a headgear with yokes. Gunaratnam does not describe the connection of the headgear with the horseshoe-shaped frame, the inner structure of the horseshoe-shaped frame, or how the nasal cushion attaches to the mask.

2. U.S. Patent Pub. No. 2003/0196658 ("Ging")

A patent corresponding to Ging and having a nearly identical disclosure — U.S. Pat. No. 6,907,882 — is cited in the specification of the '807 Patent and is identified on the face of the patent as a cited reference. *See* Ex. 1001 at p. 2 and 2:50-54; Ex. 2005. Ging discloses designs for nasal cushion masks that surround the patient's nose. *See, e.g.*, Ex. 1005 ¶ [0107]. Ging does not disclose any masks having nasal pillows. As illustrated in Figure 6b (below), the mask assembly

includes a nasal cushion 40 connected to a curved, generally rectangular shaped frame 20.

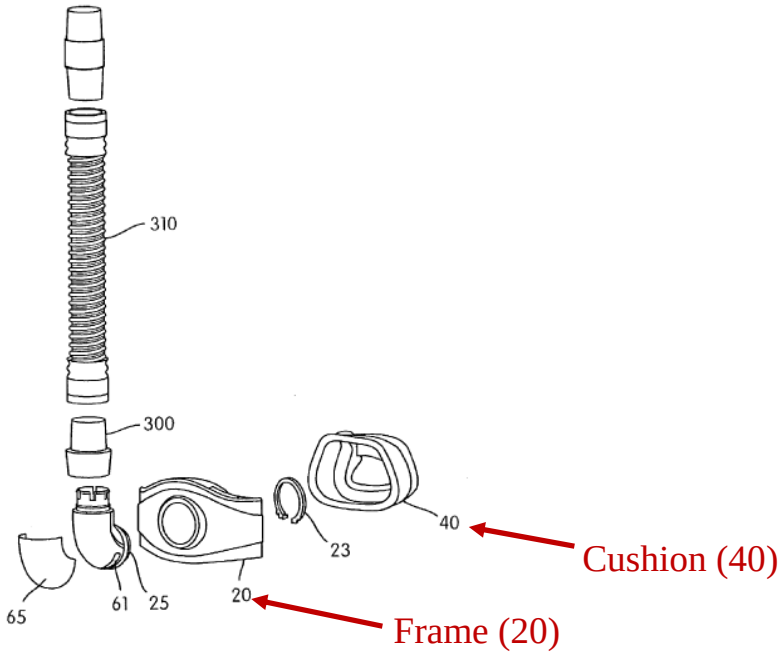


FIG. 6b

Id. at Fig. 6b (annotations added).

The curved, rectangular frame 20 is designed to follow the contours of the patient's cheeks along both sides of the nose but not contact the cheeks. *Id.* ¶¶ [0109, 0172]. The cushion 40 contacts and seals with the patient's face and distributes the force applied to the face from the headgear. *Id.* ¶¶ [0111, 0172]. This force is distributed around the perimeter of the cushion and against the upper lip and cheeks, minimizing excess force on the nasal bridge. *Id.* An example of the mask positioned on the patient's face is shown in Figure 1 (below).

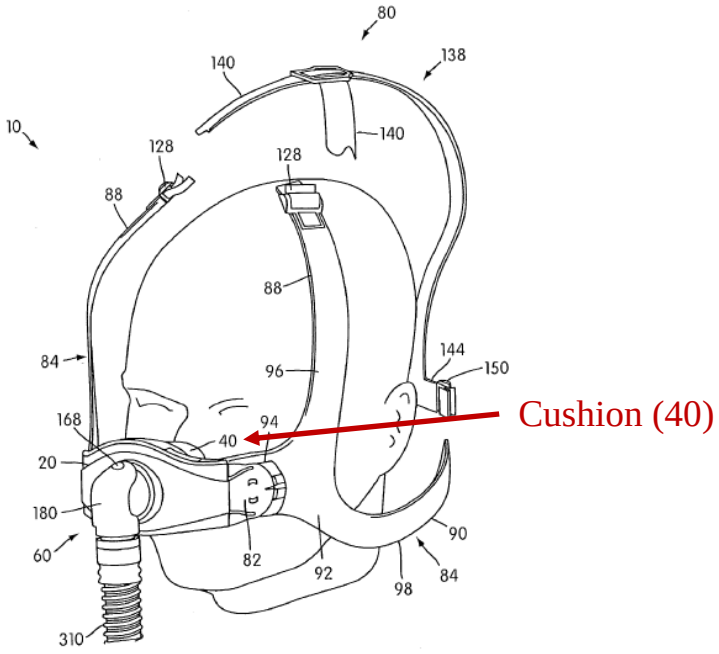


FIG. 1

Id. at Fig. 1 (annotations added).

3. PCT Pub. No. 2005/079726 ("McAuley")

McAuley discloses a nasal cannula 60 with two prongs 64, 65 that are inserted inside the nares to deliver a supply of air. Ex. 1034 at p. 8, lines 14-17; p. 10, line 31 to p. 11, line 3.[2] As shown in Figure 9 (below), prongs 64, 65 extend from a "tubular body" 66 that in use fits to another body component 62.

[2] Citations to exhibit page numbers are to the page numbers that have been added to the exhibits by the parties and not to original page numbers.

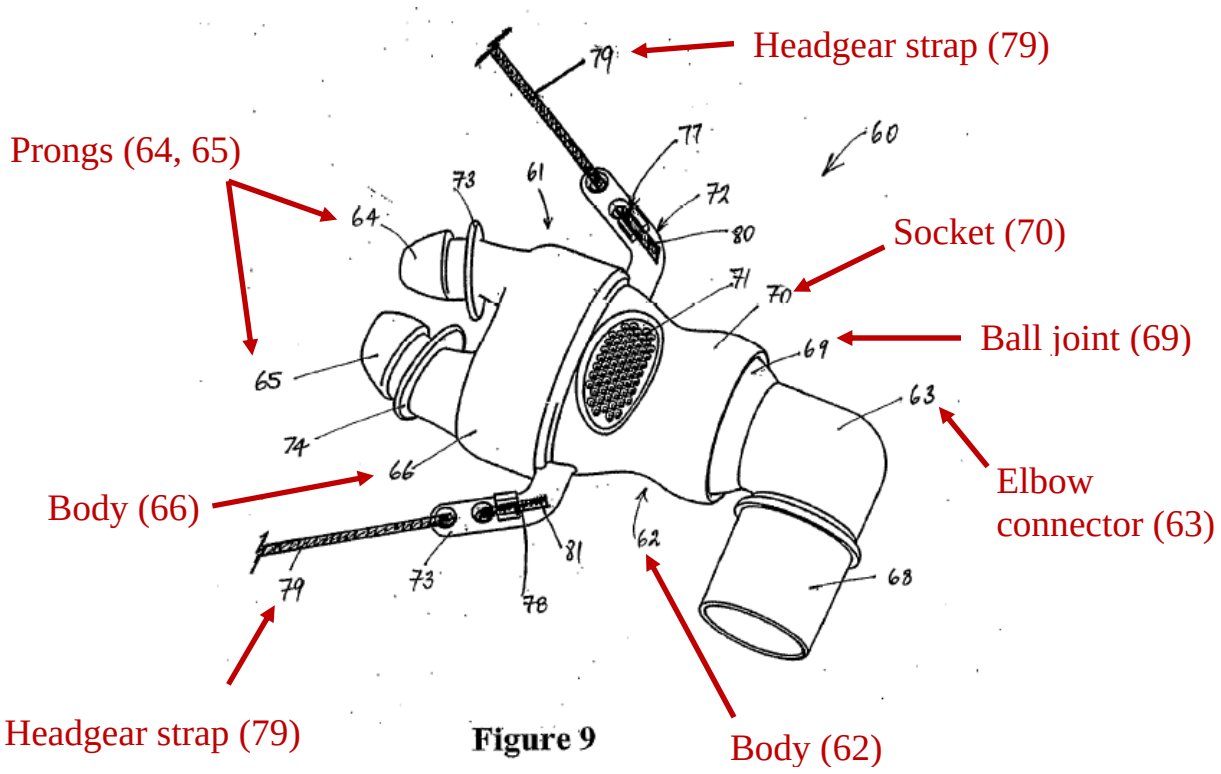
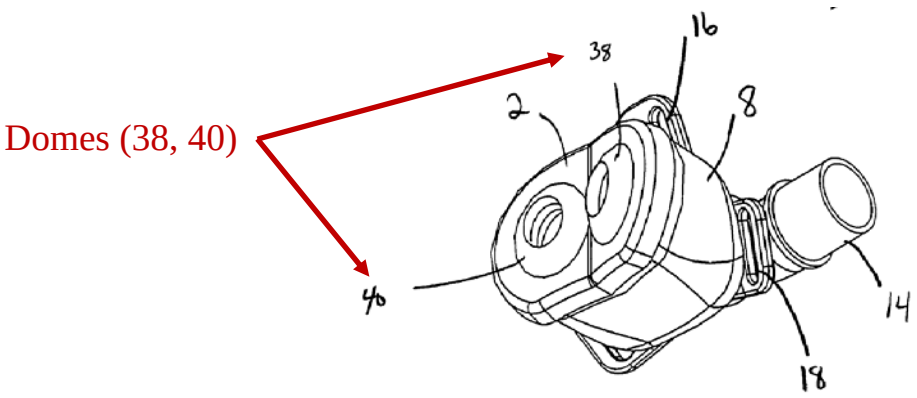


Figure 9

Id. at Fig. 9 (annotations added), *see also* p. 11, lines 3-6. As show above, body 62 includes a socket 70 for receiving an elbow connector 63 having a ball joint 69. *Id.* at p. 11, line 32 to p. 12, line 1. A flexible headgear strap 79 maintains the nasal cannula inside the nares during use. *Id.* at p. 13, lines 13-23. This headgear strap connects with headgear extensions 72, 73 that extend from body 62. *Id.*

4. U.S. Patent No. 7,219,669 ("Lovell")

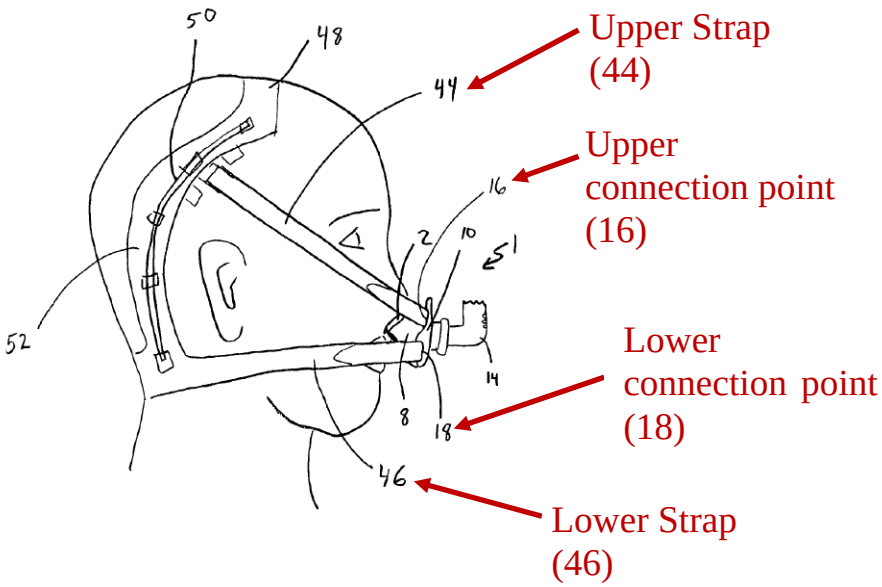
Lovell was also cited and considered by the Examiner during prosecution of the '807 Patent. Ex. 1009 at 585-91. Lovell discloses a nasal mask 1 having two domes 38, 40 that seal against a patient's nares as shown in Figure 1 (below).



Ex. 1012 at Fig. 1 (annotations added), *see also* 4:35-5:23, 6:44-7:4.

Four headgear straps – two upper straps 44 and two lower straps 46 – attach to upper and lower connection points 16, 18 and hold the mask assembly in place. *Id.* at 6:18-22, 6:44-7:4. Figure 5 (below) shows the straps on one side of the mask.

FIG. 5



Id. at Fig. 5 (annotations added). Lovell states that this "four point restraining system allows for the nasal mask 1 to be securely positioned against the nares of a user." *Id.* at 6:58-59. Lovell explains that the upper retention straps 44 and lower retention straps 46 each have different functions. *Id.* at 6:60-67. Specifically, the "lower connection points 18, 18', in concert with the lower retention straps 46, generally maintain the nasal mask 1 against a user's face" and the "upper connection points 16, 16' in concert with the upper retention straps 44 provide additional retention force on the upper portion of the nasal mask 1, closest to a user's eyes." *Id.* Lovell explains that this additional retention force provided by the upper connection points 16, 16' and the upper retention straps 44 retains the "nasal mask 1 securely against the external skin surrounding the nares at the base of a user's nose and/or along the rim of a user's nares." *Id.* at 6:67-7:3.

C. Overview of the Prosecution History of the '807 Patent

The primary references relied upon by Petitioners, Gunaratnam and Lovell, were expressly considered by the PTO during prosecution of the '807 Patent. Ex. 1009 at 585-91. During prosecution, pending Claims 38, 39, 41, 42, and 46 (which ultimately issued as independent Claim 1 and dependent Claims 2, 4, 5, and 7 respectively) were rejected under 35 U.S.C. § 102(e) over Lovell. *Id.* at 587. Pending Claim 40 (which ultimately issued as dependent claim 3) was rejected under 35 U.S.C. § 103(a) over Lovell, and pending Claims 45 and 47 (which

ultimately issued as dependent claim 6 and independent Claim 8, respectively) were rejected under 35 U.S.C. § 103(a) over Lovell in view of Gunaratnam.[3] *Id.* at 588-89.

The Examiner identified Lovell as disclosing "a nasal mask comprising a mask body 2 including two nasal pillows (38, 40), a ring 12, an elbow 14 including vents 20, a tube or conduit (not shown) connected to the free end of the elbow, and side straps (44, 46)." *Id.* at 587. These elements as identified by the Examiner are illustrated in Figures 1B, 2B and 5 of Lovell (below).

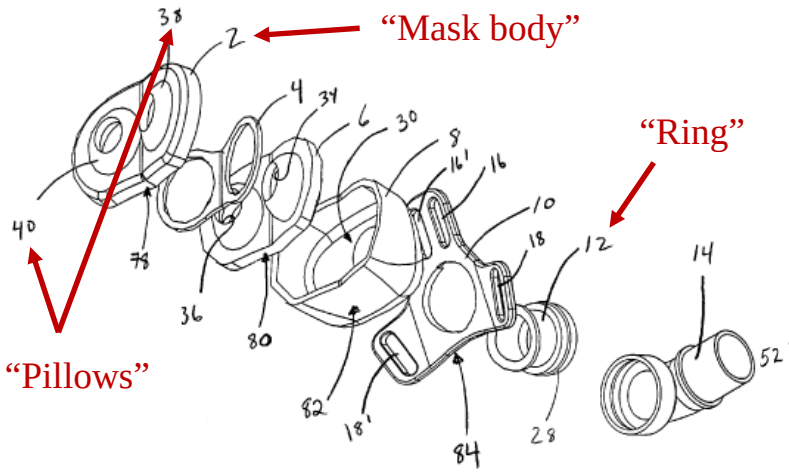


Figure 1B

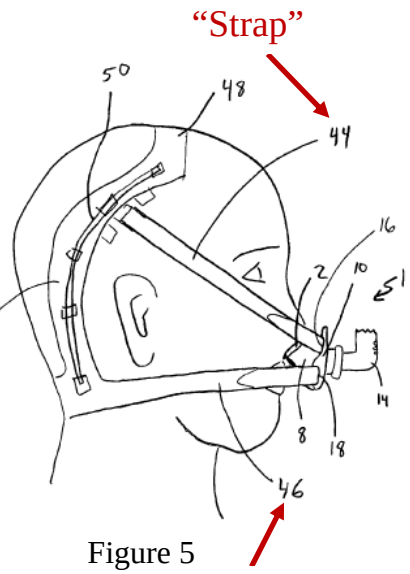
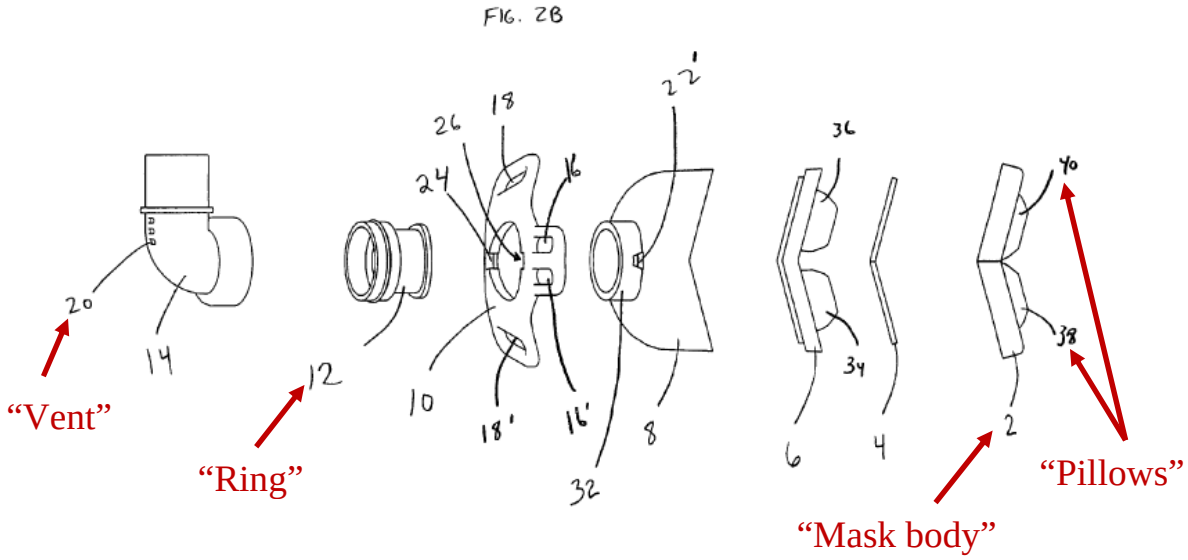


Figure 5

[3] A discussion of the prosecution of claims that are not the subject of Petitioners' IPR petitions for the '807 Patent has not been included.



Ex. 1012 at Figs. 1B, 2B, and 5 (annotations added). Notably, Petitioners rely in part in Ground 3 on the same reading of Lovell applied by the Examiner. Pet. at 47.

The Examiner acknowledged that Lovell "fails to disclose a pair of molded side arms" as required by pending Claim 45 (which issued as Claim 6). Ex. 1009 at 588. The Examiner instead cited to the "elements 608 and the unnumbered arms in Figure 135" of Gunaratnam and argued that it would have been obvious to modify the nasal mask of Lovell to "to have a pair of molded side arms in view of the teachings of Gunaratnam." *Id.* Petitioners repeat this same combination and argument in Ground 3. Pet. at 54.

The Examiner also noted that Lovell "fails to disclose the nasal pillows as comprising conical portion and cylindrical portion" as recited by pending Claim 47 (which issued as Claim 8). Ex. 1009 at 589. However, the Examiner argued that it

would have been obvious to combine the "conical portions 58 and cylindrical portions 56" of Figures 5-8 of Gunaratnam with the mask body of Lovell. *Id.* Petitioners also repeat this same combination and argument in connection with Ground 3. *See, e.g.*, Ex. 1008 ¶ 214.

In response to the Office Action, FPH amended pending independent Claims 38 and 47 (which issued as Claims 1 and 8) to include additional distinguishing limitations, including adding a limitation: "wherein the mask assembly is configured to connect to only [the] two side straps." Ex. 1009 at 614-615.

FPH also presented arguments in response to the rejections. *Id*. at 620-622. In response to the section 102 rejection, FPH argued, *inter alia*, that Lovell did not disclose the element of pending Claim 48 requiring that "the mask assembly is configured to connect to only two side straps" because Lovell discloses "a nasal mask 1 connected to a headgear apparatus 48 having two upper retention straps 44 and two lower retention straps 46 (total of 4 straps)." *Id.* at 620. In response to the section 103 rejection, FPH argued that it would not have been obvious to eliminate two straps from the four strap configuration disclosed in Lovell because doing so "'would require a substantial reconstruction of the elements shown in [Lovell] as well as a change in the basic principle under which the 'Lovell' construction was designed to operate.'" *Id.* at 621-22 (citing to M.P.E.P. § 2143.01 and *In Re Ratti*,

270 F.2d 810, 813 (CCPA 1959)). The Examiner thereafter issued a Notice of Allowance that allowed all of the pending claims. *Id*. at 629.

IV. CLAIM CONSTRUCTION

A. Legal Standard

In an IPR, the Patent Office applies the broadest-reasonable-interpretation standard to construe claims. *See* 37 C.F.R. § 42.100(b). The broadest reasonable interpretation does not mean the broadest possible interpretation. *Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1289 (Fed. Cir. 2015). Rather, this standard "applies … the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification." *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

B. Identification of a Person of Ordinary Skill In the Art

Petitioners provide a definition of a POSITA. Pet. at 7. This Preliminary Response applies Petitioners' definition in the interest of streamlining factual disputes at this stage of the proceeding. FPH believes the Board can resolve this IPR at the preliminary stage and deny institution applying Petitioners' definition. FPH reserves the right to propose its own definition of a POSITA should the Board institute trial.

C. Construction of "Ring"

Petitioners propose constructions for various claim terms. FPH responds to one proposed construction – for the term "ring" – below.[4]

Petitioners argue that the term "ring" in Claim 1 should be construed as "a structure with a generally circular inner passage to enable the claimed rotatable engagement with an elbow that fits into the ring, and does not require a particular outside shape for the ring." Pet. at 7-8. Petitioners' proposed construction is divorced from the plain and ordinary meaning of "ring" and should be rejected. Instead, the term ring should be given its ordinary meaning, namely "a generally circular band of material."

FPH's proposed construction is consistent with the meaning of "ring" as used in the '807 Patent. The patent states, in describing the mask base 22 shown in Figures 4 and 5, that "[t]he mask base 22 is a ring or sleeve like type attachment."

[4] Only those terms in controversy must be construed, and then only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999). FPH does not address all of Petitioners' proposed constructions because it is not necessary to construe those terms to resolve the IPR at this time. FPH reserves the right to revisit claim construction should the Board institute trial.

Ex. 1001 at 6:23. As shown in those figures (below), the mask base 22 is a generally circular band of material.

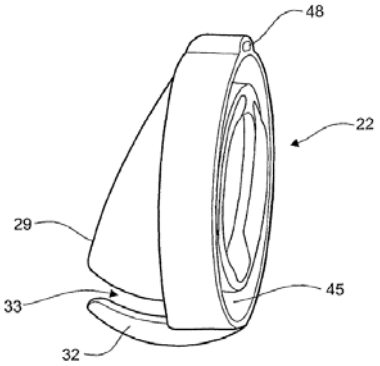


FIGURE 4

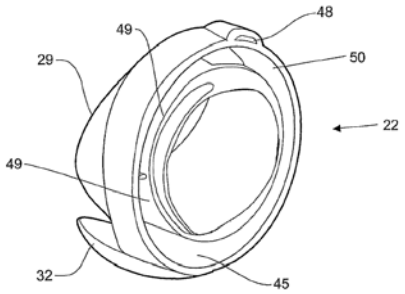


FIGURE 5

Id. at Figs. 4 and 5.

FPH's proposed construction is also supported by standard dictionary definitions. The first definition of "ring" in the Oxford-American Dictionary is: "a circular band of any material." Ex. 2001 at 3.[5] The definition also includes an example of a "fried onion ring." A fried onion ring is not perfectly circular, but it is generally circular. Similarly, the mask base 22 shown in Figures 4 and 5 of the '807 Patent is not perfectly circular, but it is generally circular. It is also the only structure described as a ring in the patent.

[5] *See also* Ex. 2003 at 3 defining "ring" as "2. a circular band of metal, plastic, etc., used to connect, hang, seal, decorate, etc. a thing or things [a key ring, a napkin ring]."

The definitions of "ring" in the dictionary relied upon by Petitioners also support FPH's proposed construction. The first definition of "ring" in the Merriam-Webster's Collegiate Dictionary cited by Petitioners is "a circular band for holding, connecting, hanging, pulling, packing, or sealing <a key ~> <a towel ~>." Ex. 1014 at 5. That definition more closely comports with FPH's construction than it does with Petitioners' construction. Petitioners ignore this first definition of "ring" and instead skip to and rely upon definition 3(b) — "an encircling arrangement <a ~ of suburbs>." *Id.*; *see also* Pet. at 10. That usage of "ring" is inapplicable here. For example, a "ring of suburbs" is not a structural component and also does not even contain "a generally circular inner passage" as required by Petitioners' proffered construction. Moreover, the word "encircling" in the definition implies a generally circular shape, consistent with FPH's construction.

Petitioners seek to define "ring" in a manner that does not require the outer surface of the ring to be of any particular shape. Pet. at 9. Petitioners' construction is therefore overly broad and goes well beyond the broadest reasonable interpretation. Virtually any structure, regardless of its shape, that includes "a generally circular inner passage" could be a "ring" according to Petitioners. For example, a large, square sheet of plastic with a hole through it

could be a "ring." However, as discussed above, the ordinary meaning of "ring" connotes a structure that is generally circular.

Petitioners acknowledge that the '807 Patent describes the mask base 22 as a ring. Pet. at 8. Petitioners then argue that the mask base 22 shown in Figures 3-5 is not circular. *Id.* at 10. However, the mask base 22 shown in those figures has an outer surface that is generally circular in shape, which is consistent with FPH's proposed construction.[6]

Petitioners further argue that Claim 1 does not recite how the outer surface of the claimed "ring" interacts with any particular component. Pet. at 9-10. However, even accepting that assertion as true *arguendo*, it does not change the ordinary meaning of "ring" and does not justify construing the term inconsistently with its ordinary meaning.

Petitioners' construction also erroneously seeks to read into the definition of "ring" other elements of Claim 1. Petitioners seek to define "ring" in terms of the functionality of "enabl[ing] the claimed rotatable engagement with an elbow that

[6] Petitioners also cite to Figures 20-22, which Petitioners characterize as illustrating a mask base 301 that is integrally formed with two curved members 302 extending to the side of the mask base. Pet. at 10. Petitioners do not explain how those figures allegedly support their proposed construction of "ring."

fits into the ring." Pet. at 7-8. However, Claim 1 elsewhere includes the element of "an elbow rotatably engaged with the ring." This claim language would be rendered superfluous if the limitation of enabling the rotatable engagement with an elbow is imported into the construction of "ring." Such a construction would be inconsistent with the presumption that all words in a claim have meaning and that claim terms should not be interpreted so as to render other terms superfluous. *See Digital-Vending Servs. Int'l, LLC v. Univ. of Phoenix, Inc.*, 672 F.3d 1270, 1275 (Fed. Cir. 2012) (declining to read limitation into claim term that appeared elsewhere in the claim in part because doing so would make the other claim language reciting the limitation superfluous); *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005) ("A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so.").

Finally, the examples of purported "rings" relied upon by Petitioners — a piece of jewelry, a "nut ring," and a "triangular-shaped ring" — do not support their proposed construction. Pet. at 10-11. "Ring" has a particular meaning with respect to jewelry. *See, e.g.*, Ex. 1014 at 5 (defining "ring" in definition 2 as "a circlet, usu. of precious metal worn esp. on the finger"). The claims of the '807 Patent do not relate to jewelry, and that jewelry rings may have different shapes yet still be generally referred to as "rings" does not support Petitioners' construction.

Petitioners also show an image of what they identify as a "nut ring." Pet. at 10. However, in the exhibit cited by Petitioners, the structure is nowhere referred to as a "nut ring." It is referred to as a "hex nut." Ex. 1039. And while Petitioners' declarant, Dr. Izuchukwu, states that the item is commonly referred to as a "nut ring," he provides no support other than citing to the exhibit that identifies the item as a "hex nut." Ex. 1008 ¶ 41. A hex nut by definition has a particular outer shape, namely six sides.

Petitioners also cite to a declaration submitted in an Australian patent proceeding that referred to a "triangular shaped ring." Pet. at 11 (citing Ex. 1041 ¶ 12.4). However, that reference to a "ring" also contained a specific qualifier as to the outer shape of the ring. The term "ring" as used in Claim 1 does not contain a unique qualifier such as "triangular" or "hex." In the absence of such qualifying language, "ring" should be given its customary meaning, which includes having a generally circular shape.

V. ARGUMENT

A. Legal Standard

The following statutory threshold that must be met to institute an IPR:

> (a) Threshold — The Director ***may not authorize*** an inter partes review to be instituted ***unless*** the Director determines that the ***information presented in the petition*** filed under section 311 and any response filed under section 313 ***shows*** that there is a reasonable

> likelihood that the Petitioners would prevail with respect to at least 1 of the claims challenged in the petition.

35 U.S.C. § 314(a) (emphasis added); *accord* 37 C.F.R. § 42.108(c).

All grounds of the IPR rely upon obviousness. For any IPR ground to prevail based on obviousness, it is not enough to simply show that a combination of references disclose the claim limitations; in addition, a reason to modify and combine the reference must be provided. *See, e.g.*, *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418-19 (2007) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. . . . [I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.") (internal quotation marks and citations omitted). Moreover, Petitioners cannot rely on conclusory attorney argument and expert testimony to establish a reason to combine the prior art. *See, e.g.*, *In re: Nuvasive, Inc*., No. 2015-1670, 2016 WL 7118526, at *4, *6 (Fed. Cir. Dec. 7, 2016) (vacating Board's finding of a motivation to combine prior art references that "relied on one conclusory statement by [Petitioner]'s expert" and "conclusory statements" by Petitioner's attorneys).

Several principles also signal when a motivation to make a proposed combination is lacking. *See, e.g.*, M.P.E.P. § 2143.01. For example, "[i]f [the] proposed modification would render the prior art invention being modified ***unsatisfactory for its intended purpose***, then there is no suggestion or motivation to make the proposed modification." *Id.* (*citing In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984) (explaining that if a reference's device "were turned upside down, it would be rendered inoperable for its intended purpose.")). Likewise, "[i]f the proposed modification or combination of the prior art would ***change the principle of operation*** of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." *Id.* (*citing In re Ratti*, 270 F.2d 810, 813 (CCPA 1959). Moreover, "when the prior art ***teaches away*** from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." *KSR*, 550 U.S. at 416 (*citing United States v. Adams*, 383 U.S. 39, 51-52 (1966)).

B. Institution Should Be Denied Because Both Gunaratnam and Lovell Were Expressly Considered by the PTO During Prosecution of the '807 Patent

The Board has discretion under 35 U.S.C. § 325(d) to decline institution on grounds that rely on "the same or substantially the same prior art or arguments previously [ ] presented to the PTO." Grounds 1 and 2 primarily rely upon modifying the nasal cushion mask of Gunaratnam Figure 135 to add nasal pillows.

The PTO, however, already considered and applied Gunaratnam — including Figure 135 specifically — during prosecution of the '807 Patent to reject (in combination with Lovell) what ultimately issued as independent Claim 8. Ex. 1009 at 588-89. After considering FPH's responsive arguments and claim amendments, the PTO allowed the claims. *Id.* at 613-23, 629. Ground 3 relies on Lovell in view of Gunaratnam. That same combination was cited by the Examiner during prosecution. *Id.* at 588-89. The Examiner also relied upon Lovell alone to reject what ultimately issued as Claim 1. *Id.* at 588. Because the PTO already considered and allowed the '807 Patent claims over these references, the Board should exercise its discretion to decline institution of Grounds 1-3. *See, e.g., Funai Elec. Co., Ltd. v. Gold Charm Ltd.*, No. IPR2015-01491, Paper No. 15, 19-20 (P.T.A.B. Dec. 28, 2015) (denying institution on one ground because petitioners failed to "present any persuasive evidence to supplement the record that was in front of the Office during the original prosecution").

Petitioners' argument that the "original examination does not diminish the merit of Ground [3]" is unavailing. Pet. at 45. Petitioners argue that "the prosecution history record does not indicate Gunaratnam's headgear assembly teachings were considered . . . ." *Id.* However, the Examiner specifically considered the headgear assembly of Gunaratnam, including as shown in Figure

135. Ex. 1009 at 588 (referring to "the unnumbered arms in Figure 135" of Gunaratnam).

Petitioners further argue that the Examiner did not consider "an alternative reading of Lovell in which the lower mask shell 8 is the claimed ring." Pet. at 45. The Examiner identified the swivel connector 12 shown in Lovell as corresponding to the claimed "ring," which is consistent with the "first read" of Lovell presented in the Petition. Ex. 1009 at 587; Pet. at 47. It is immaterial that the Examiner did not also present a far less reasonable alternate reading of Lovell that identified the oblong, lower mask shell 8 as the claimed "ring."

C. The Claim Charts In the Declaration of Petitioners' Declarant, Dr. Izuchukwu, Should Be Given Little or No Weight

Petitioners rely upon a declaration from John Izuchukwu. Ex. 1008. Dr. Izuchukwu's declaration includes claim charts purporting to show the alleged obviousness of the challenged claims. *Id.* at pp. 44-86, 161-190. However, Dr. Izuchukwu admits that he did not prepare these claim charts; Petitioners did. *Id.* ¶¶ 64, 189 (each stating in part: "ResMed's counsel prepared the following claim charts ….").

"Merely repeating an argument from the Petition in the declaration of a proposed expert does not give that argument enhanced probative value." *Kinetic Techs., Inc. v. Skyworks Solutions, Inc.*, IPR2014-00529, Paper No. 8 at 15

(P.T.A.B. Sept. 23, 2014); *see also InfoBionic, Inc. v. Braemer Mfg., LLC*, IPR2015-01704, Paper No. 11 at 6 (P.T.A.B. Feb. 16, 2016) (finding expert declaration unpersuasive when it "repeats the Petitioner's arguments and offers little or no elaboration"). The claim charts added by Petitioners' counsel into Dr. Izuchukwu's declaration do not provide additional, independent support for the arguments contained in the Petition and the Board should accord the claim charts little, if any, probative weight.

D. Petitioners Have Not Established a Reasonable Likelihood of Prevailing on Ground 1 (Alleged Obviousness of Claims 1-7, 17-19, 24, and 25 over Gunaratnam and Ging)

Ground 1 hinges upon an overly broad construction of "ring." Petitioners have not established a reasonable likelihood of success because neither Gunaratnam nor Ging teach or make obvious a "ring" as required by Claim 1 under the correct claim construction.

Ground 1 also primarily rests on a "photoshopped" version of the mask of Gunaratnam Figure 135 with the original nasal cushion replaced by a nasal pillow assembly. *See, e.g.*, Pet. at 16. Petitioners provide almost no structural details for this new proposed mask design and do not sufficiently explain how the modified design would be operable. Petitioners also ignore fundamental structural and functional differences between nasal pillow type masks and nasal cushion type

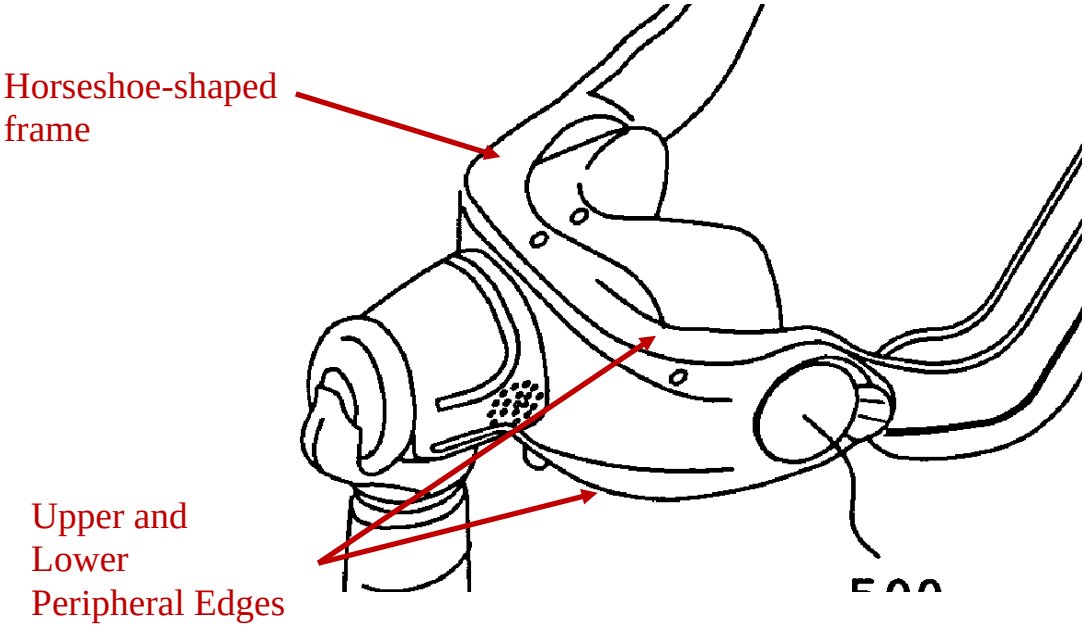
masks that preclude merely swapping out the nasal cushion shown in Gunaratnam Figure 135 for nasal pillows.

1. Gunaratnam and Ging Do Not Teach or Make Obvious "a ring" as Required by Claim 1

Claim 1 recites "a ring engaged with the mask body." Under its proper construction, a "ring" is "a generally circular band of material." *See* Section IV.C *supra*. Ground 1 fails because neither Gunaratnam nor Ging disclose or make obvious the claimed "ring."

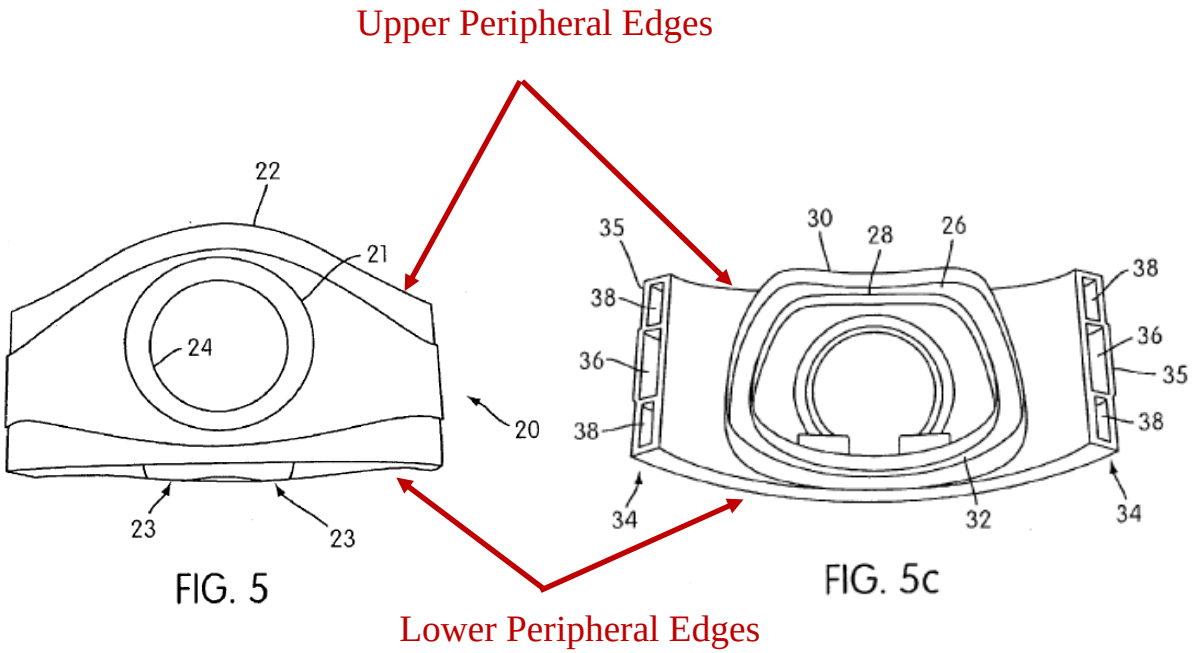
Petitioners identify both the horseshoe-shaped frame in Gunaratnam Figure 135 and the frame 20 in Ging as structure allegedly corresponding to the "ring" of Claim 1. Pet. at 18-19. However, the identified structures are not a generally circular band of material and thus are not a ring.

The horseshoe-shaped frame in Gunaratnam Figure 135 (excerpt shown below) includes upper and lower peripheral edges that form two surfaces that are generally parallel with each other across the length of the frame.



Ex. 1004 at Fig. 135 (annotations added). The oblong, horseshoe-shaped frame is not a generally circular band of material and thus is not a ring.

The frame 20 described in Ging also includes upper and lower peripheral edges that are generally parallel with each other as shown in Figures 5 and 5c (below).



Ex. 1005 at Figs. 5 and 5c (annotations added). As is evident from the figures above, the frame is a generally rectangular shape. *See also* Ex. 1008 ¶ 84 (characterizing the frame as having a "generally rounded, rectangular geometry"). The frame 20 is not a generally circular band of material, and is not a ring.

Petitioners do not identify any structure in Gunaratnam or Ging that corresponds to the "ring" of Claim 1 under the proper construction of that term. Petitioners also do not provide any reason or explanation in Ground 1 for modifying the frames described in Gunaratnam and Ging to make the frames generally circular in shape. Dr. Izuchukwu states in his analysis of Ground 1 that it would have been obvious to make the rectangular frame of Ging circular in shape. Ex. 1008 ¶ 85. However, Dr. Izuchukwu provides no reason why a POSITA

would make that modification in view of Gunaratnam or Ging, and his conclusory opinion is insufficient to demonstrate the modification would have been obvious. *See Nuvasive*, 2016 WL 7118526, at *6. Thus, Ground 1 of the Petition fails for this reason.

2. Petitioners Have Not Shown that it Would Have Been Obvious to Modify the Nasal Cushion Mask of Gunaratnam Figure 135 to Include a Nasal Pillow Assembly

Petitioners identify two primary reasons why a POSITA would have replaced the nasal cushion of Gunaratnam Figure 135 with nasal pillows: (1) Gunaratnam allegedly suggests it, and (2) the alleged interchangeability is purportedly supported by the designs shown in Figures 107G-H and other embodiments of Gunaratnam. Pet. at 16-17. However, neither supports replacing the nasal cushion of Figure 135 with nasal pillows.

a. Gunaratnam Does Not Teach or Suggest that Nasal Cushions May Be Replaced with Nasal Pillows

Petitioners argue that Paragraph 0403 of Gunaratnam suggests that nasal cushion and nasal pillow assemblies are interchangeable. Pet. at 16. However, Gunaratnam contains no such teaching or suggestion. Gunaratnam states that "the nozzle assembly and/or its associated cushion could be replaced with a nasal mask and/or nasal cushion." Ex. 1004 ¶ [0403]. It does not teach the opposite substitution could also be made — *i.e.* replacing a nasal cushion with a nozzle assembly. If anything, that Gunaratnam mentions only potentially replacing a

nozzle assembly with a nasal cushion, but does not also mention the reverse substitution, shows that it was not obvious to replace a nasal cushion (such as shown in Figure 135) with a nasal pillows assembly.

b. The Nozzle Embodiments of Gunaratnam Do Not Teach or Make Obvious the Interchangeability of Nozzles and Nasal Cushions

Petitioners' argument relies on cherry picking from among different mask components described in Gunaratnam without regard to their structural differences and whether they are actually interchangeable components. Given the fundamental differences between the mask assemblies that Petitioners seek to combine, it would not have been obvious to replace the nasal cushion shown in Figure 135 with any of the nozzle assemblies shown elsewhere in Gunaratnam.

i. The Mask Design Shown in Figure 135 Is Fundamentally Different from and Incompatible with the Other Embodiments of Gunaratnam Relied Upon by Petitioners

Petitioners argue that alleged similarities between the mask shown in Gunaratnam Figures 107G-H (below), which Petitioners characterize as including a centrally located elbow and a "four-strap headgear," and the mask shown in Figure 135 somehow supports the interchangeability of nasal pillows and nasal cushions. Pet. at 17.

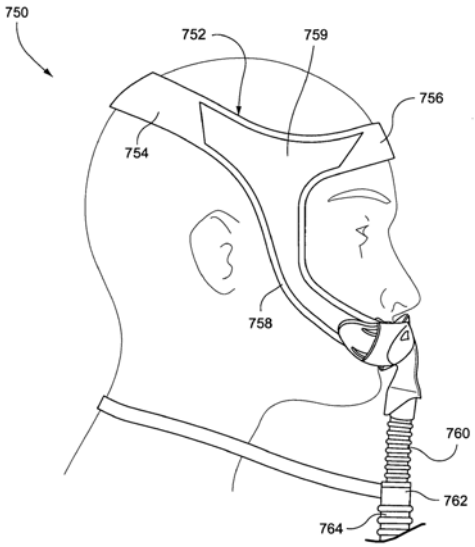


FIG. 107G

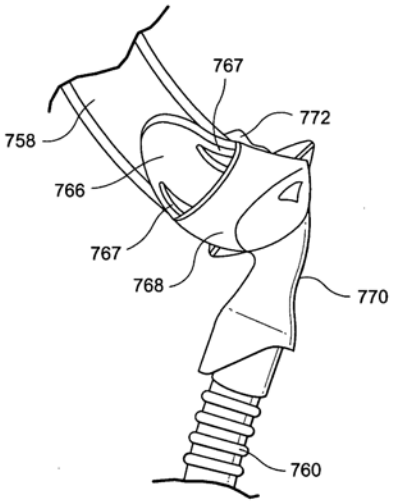


FIG. 107H

Ex. 1004 at Figs. 107G and 107H, *see also* ¶¶ [0369-70]. However, Petitioners ignore fundamental differences between the masks that do not support their interchangeability.

As a preliminary matter, Figures 107G-H appear to illustrate an oral mask with nozzles for delivering air to a patient's mouth. The mask shown in Figure 107G is positioned over the mouth and is not in contact with the patient's nose. Consequently, the mask does not teach or suggest that nasal cushions and nasal pillows are interchangeable. Petitioners assert that Figure 107G illustrates a nasal mask that is not "in use." *See*, *e.g.*, Pet. at 23. However, Gunaratnam does not describe the mask in that manner. Ex. 1004 ¶ [0369]. Nevertheless, given Petitioners' arguments to the contrary, the arguments below assume, *arguendo*, that the mask in Figures 107G-H is, in fact, a nasal mask.

The mask shown in Figures 107G-H includes a frame 768 set at an angle in relation to the patient's face. Nozzles 772 extend upward from the frame 768. The frame is also set in close proximity to the patient's face and located underneath the patient's nose. Because of this proximity with the face, the nozzles 772 necessarily extend only a short distance from the frame 768. Indeed, only a small portion of a nozzle 772 is visible extending from the frame in Figure 107H.

The horseshoe-shaped frame shown in Gunaratnam Figure 135 is substantially different in structure and shape from the mask shown in Figures 107G-H. As is apparent from Figure 135, the horseshoe-shaped frame would be offset a distance away from the patient's face when the mask is worn and the frame is generally maintained parallel to the patient's face in a vertical orientation. In order to work as a nasal cushion mask, the horseshoe-shaped frame must center on the patient's nose and position the nasal cushion to surround the nose and seal against the nasal bridge, cheeks and upper lip. *See, e.g.*, Ex. 1008 ¶ 70; Ex. 1005 ¶¶ [0178-79] (Ging – describing the operation of a nasal cushion).

Furthermore, replacing the nasal cushion in the mask of Figure 135 with a nasal pillow assembly would result in a mask where the nasal pillows are located in the area where the patient's nose previously entered the nasal cushion. The nasal pillows would be above the line of the patient's nares and thus could not seal with the nares.

In sum, there are numerous structural and fundamental differences between the masks shown in Figures 107G-H and Figure 135 that Petitioners fail to account for or recognize. In view of those differences, Petitioners' argument that alleged similarities in the figures between the centrally mounted elbows and the four strap headgear support "interchangeability" is unfounded.

ii. Petitioners Have Not Shown that Nasal Pillows Could Be Incorporated into Gunaratnam Figure 135 with a Reasonable Expectation of Success

To establish a *prima facie* case of obviousness. Petitioners have the "burden to demonstrate both that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367-68 (Fed. Cir. 2016). The legal requirement of a reasonable expectation of success is a separate requirement from a motivation or reason to combine. *Id*. at 1367.

Petitioners do not provide any detailed explanation as to how the nozzles included in Figures 107G-H or in other embodiments described in Gunaratnam could be incorporated with a reasonable expectation of success into the mask frame shown in Figure 135 or as modified in view of Ging. Dr. Izuchukwu similarly fails to provide any detailed explanation. Ex. 1008 ¶¶ 67-71. He merely asserts in a conclusory fashion that nasal cushions and nasal pillows are interchangeable and

that the substitution could be made, which is insufficient. *See, e.g.*, *id.* ¶¶ 46, 72; *Nuvasive*, 2016 WL 7118526, at *6 (vacating obviousness determination because motivation to combine finding improperly "relied on one conclusory statement by [Petitioner]'s expert").

Petitioners rely upon a photoshopped version of Figure 135 that includes a nozzle assembly. *See, e.g.*, Pet. at 16. The nozzle assembly illustrated by Petitioners appears to be based on the nozzle assembly shown in Figure 1 of Gunaratnam. Figure 1 (below) depicts a mask having a tubular style frame 16 that rests underneath the nares and against the patient's upper lip.

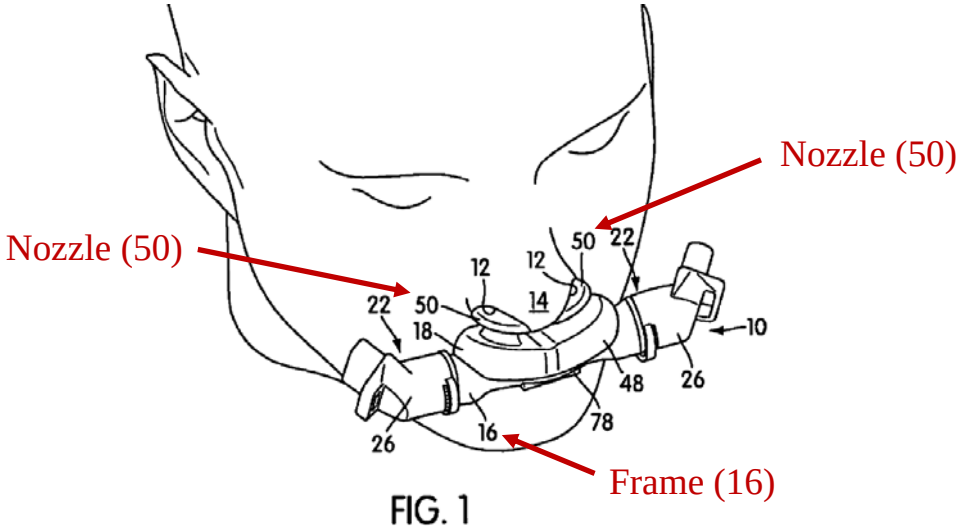
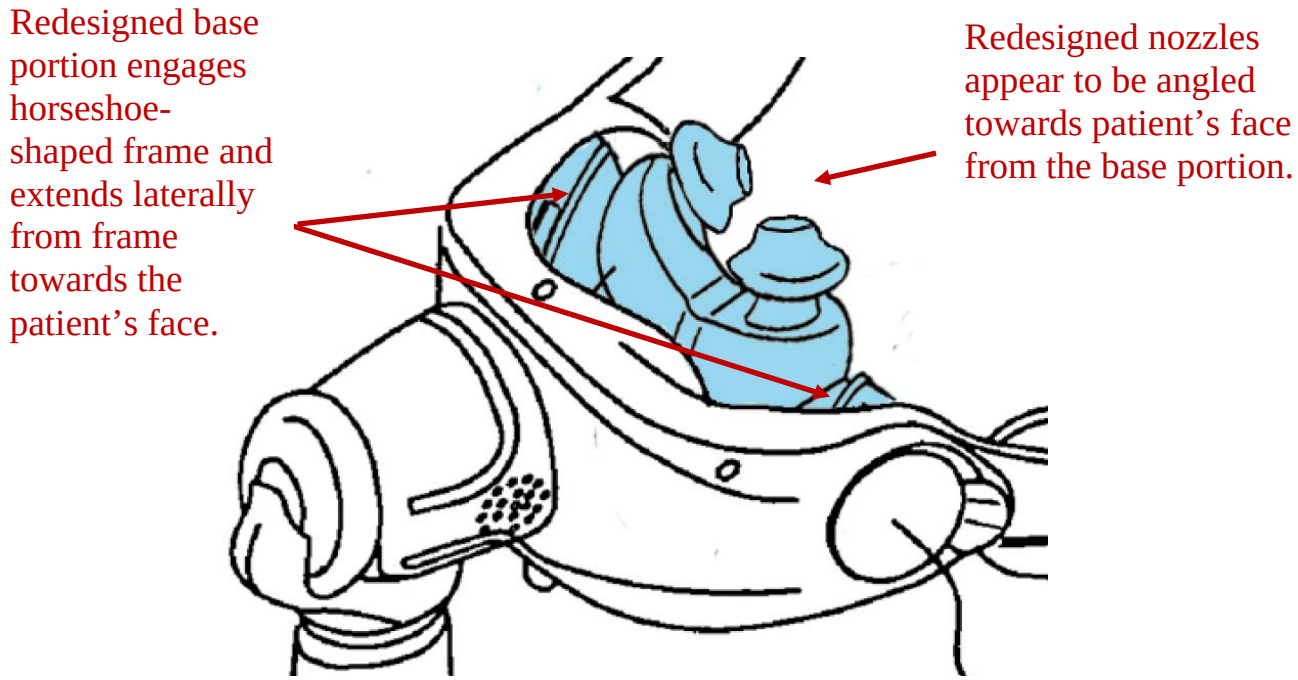


FIG. 1

Ex. 1004 at Fig. 1 (annotations added), *see also* ¶ [0177]. The tubular frame 16 supports a pair of nozzles 50 that seal with the nares. *Id.* ¶ [0185]. The nozzles 50 extend from a base portion that may be expandable when filled with air to move the nozzles towards the patient's nose. *Id.* ¶ [0187]. Other figures within

Gunaratnam disclose similar tubular style frames and associated nozzles. *See*, *e.g.*, *id.* at Figs. 25, 52, 60, 86, and 108.

Petitioners have constructed an entirely new nozzle assembly and inserted it into the frame shown in Figure 135. Petitioners have, without explanation, added a redesigned base portion to the nozzles and somehow attached the base portion to the vertically oriented interior of the horseshoe-shaped frame. A close up of this new nozzle assembly from the Petition, with annotations added by FPH, is shown below.



Pet. at 16 (annotations added).

Petitioners provide virtually no detail about how this new nozzle assembly interfaces with the horseshoe-shaped frame or how it would be operable.

Gunaratnam also does not support Petitioners' new design. None of the nozzle assemblies described in Gunaratnam include both a base portion that extends laterally from a frame towards the patient's face and nozzles that are angled towards the nares from the base portion as created by Petitioners in modified Figure 135 above. Also, none of the nozzle assemblies in Gunaratnam interface with a vertical surface like shown in Petitioners' modified Figure 135.

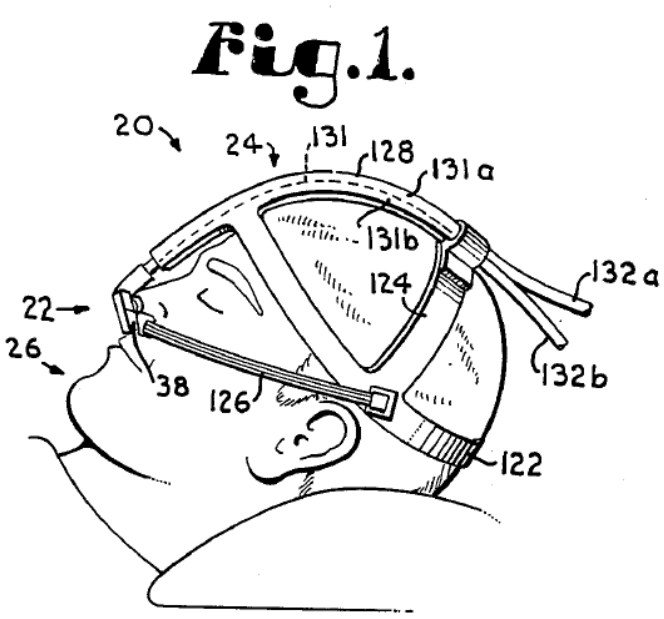
Petitioners also ignore that fundamental differences in the forces required for the sealing of nasal pillows and a nasal cushion prevent replacing the nasal cushion of Figure 135 with nasal pillows as Petitioners suggest. Nasal pillows are located beneath the nose and extend generally upward to seal with the patient's nares. Consequently, a force component that is generally parallel to the patient's face is required to hold the nasal pillows in sealing engagement with the nares. For example, Gunaratnam describes mechanisms for moving nozzles upward toward the patient's nose to seal with the nares. Ex. 1004 ¶[214-219].

In contrast, a nasal cushion is designed to fit over the nose and form a seal around the nose. *See*, *e.g.*, Ex. 1005 (Ging) at ¶ [169] (describing nasal cushion), Fig. 1; Ex. 1008 ¶ 70 (describing the nasal cushion mask shown in Gunaratnam Figure 135 as "arranged in use to surround the breathing passages of the patient's nose by forming a sealed space from above the patient's upper lip to a location atop the patient's nose (e.g., the bridge of the nose)."). A force component that is

generally perpendicular to the patient's face is required to hold the nasal cushion against the face and form a seal. Petitioners do not explain how the headgear shown in Gunaratnam Figure 135, which is designed to hold a nasal cushion in sealing engagement with the patient's face, could be operable to provide the forces required to work with nasal pillows.

iii. Gunaratnam Teaches Against Petitioners' Proposed Modification

Gunaratnam teaches that nasal masks that align sealing and stability forces can adversely affect patient comfort and teaches the importance of separating those forces. *Id.* ¶¶ [0017], [0024]. [0229]. Gunaratnam identifies and criticizes a counter-example of a prior art nasal mask — U.S. Patent No. 4,782,832 ("Trimble") — that aligns the sealing and stability forces. *Id.* ¶¶ [0005-0006]. As shown in Figure 1 (below), Trimble discloses a nasal puff assembly 20 that includes a nasal puff 22 positioned against the patient's nose and a harness assembly 24 worn over the head.



Ex. 2002 at Fig. 1, *see also* 3:51-58.

The harness assembly 24 holds puff 22 adjacent and partially within the patient's nasal passages. *Id.* A flexible mask-retaining strap 126 connects between the main harness strap 122 and the nasal puff 22. *Id.* at 6:60-66. Gunaratnam explains that because in the Trimble mask the force required to maintain a seal is directly associated with the force required to maintain the desired fit, the adjustment of the fit directly affects the seal and may adversely affect patient comfort. Ex. 1004 ¶ [0006].

Modifying the mask design of Gunaratnam Figure 135 to include nasal pillows would result in a mask where the forces holding the mask against the patient and the forces holding the nasal pillows against the patient's nares are aligned. Gunaratnam teaches away from aligning such forces. *Id.*; *see also* ¶¶

[0017, 0024, 0229]. A POSITA therefore would not have been motivated to make such a design. *See KSR*, 550 U.S. at 416 (explaining that "when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious").

iv. Petitioners' Reliance on Ging Shows It Would Not Have Been Obvious to Incorporate Nasal Pillows into Gunaratnam Figure 135

Petitioners' reliance on Ging further shows that it would not have been obvious to modify the cushion mask design shown in Gunaratnam Figure 135 to include a nozzle assembly. Ging discloses mask assemblies that include a nasal cushion. Ex. 1005 at, *e.g.*, Abstract, Figs. 1 and 6b. Petitioners thus seek to combine two nasal cushion mask designs – Gunaratnam Figure 135 and disclosure from Ging. To the extent that a POSITA would have been motivated to combine the two cushion mask designs, a POSITA would not then be further motivated to fundamentally alter the combined cushion mask design to include nasal pillows, *e.g.* apple plus apple does not equal an orange.

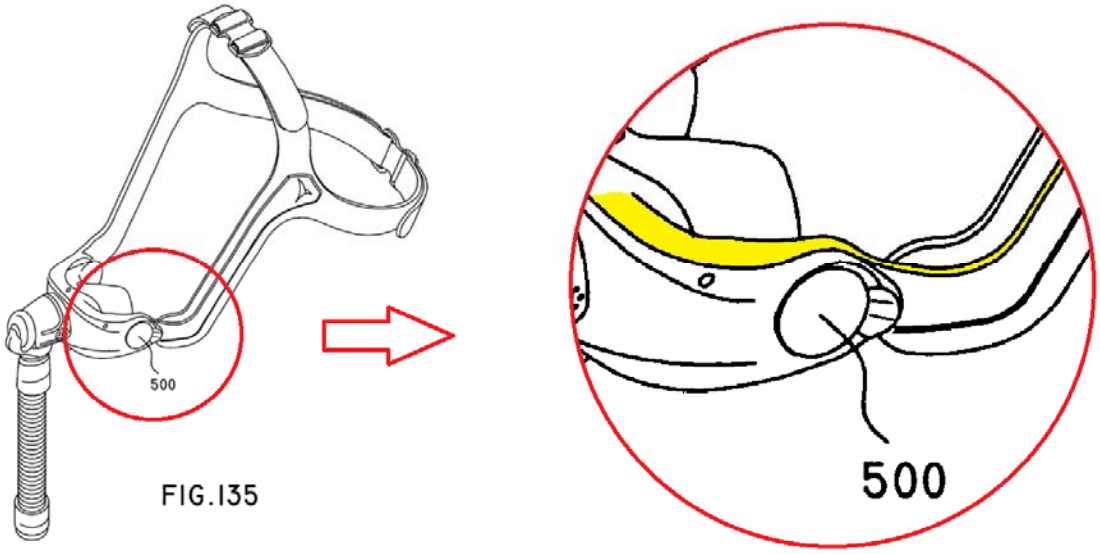
c. The Other Reasons Identified By Dr. Izuchukwu Do Not Provide a Reason to Replace the Nasal Cushion of Gunaratnam Figure 135 with Nasal Pillows

Dr. Izuchukwu opines that a POSITA would have been motivated to replace the nasal cushion of Figure 135 with nasal pillows to obtain the benefits associated with nasal pillows because many patients prefer nasal pillows for various stated

reasons. Ex. 1008 ¶ 71. However, he provides no supporting evidence showing that patients, in fact, prefer nasal pillows. Thus, Petitioners have not provided a sufficient reason to incorporate nasal pillows into Gunaratnam Figure 135. *See Nuvasive*, 2016 WL 7118526, at *6 (vacating obviousness determination because motivation to combine finding improperly "relied on one conclusory statement by [Petitioner]'s expert"). And in any event, as explained above, Petitioners have not explained with any particularity how nasal pillows could be incorporated into Gunaratnam Figure 135 (or the frame of Ging) with a reasonable expectation of success.

3. Gunaratnam and Ging Do Not Teach or Make Obvious "wherein the two side straps are configured to connect and disconnect with the mask assembly" as Required by Claim 1

Petitioners assert that the side straps shown in Gunaratnam Figure 135 satisfy the "wherein the two side straps are configured to connect and disconnect with the mask assembly" limitation of Claim 1. Pet. at 27-28. However, Gunaratnam does not describe that the yokes of Figure 135 are removable from the frame. Instead, Gunaratnam Figure 135 shows that the side yokes are formed as a single piece with the frame. A portion of Figure 135, highlighting the juncture of one of the side yokes with the frame, is shown below.



Ex. 1004 at Fig. 135 (highlighting added). Because the yokes are formed as a single piece with the frame, there is nothing to support Petitioners' conclusory assertion that the yokes are configured to connect and disconnect with the frame.

Petitioners assert that the side yokes of Figure 135 attach to the frame in a similar manner to Figures 108-113 of Gunaratnam. Pet. at 28. But Figures 108-113 depict a nozzle assembly that is affixed to a tubular shaped frame. Gunaratnam does not describe that the tubular frame is present in Figure 135. Further, Petitioners' modified Figure 135 also does not appear to include the tubular frame of Figures 108-113. Petitioners also provide no explanation why it would have been obvious to further alter Petitioners' already modified Figure 135 to add a removable connection for the yokes. Thus, for this additional reason, Petitioners have not shown that Claim 1 would have been obvious.

E. Petitioners Have Not Established a Reasonable Likelihood of Prevailing on Ground 2 (Alleged Obviousness of Claims 1-7, 17-19, 24, and 25 over Gunaratnam, Ging, and McAuley)

Petitioners add to their Ground 1 combination another reference — McAuley — which they assert discloses a "ring" under a narrower reading of that limitation. However, the combination does not render obvious any of the challenged claims.

1. Ground 2 Should Not Be Instituted for at Least the Reasons Provided for Ground 1

Petitioners acknowledge that their further proposed modification in view of McAuley "only affects the outer periphery of the 'ring' and claim 1." Pet. at 43. Ground 2 thus rests upon the same arguments presented by Petitioners in Ground 1 as to why a POSITA would have modified Gunaratnam Figure 135 to include nasal pillows. For all of the reasons provided above in connection with Ground 1, that modification would not have been obvious. Thus, Ground 2 should not be instituted.

2. It Would Not Have Been Obvious to Further Modify Gunaratnam Figure 135 to Include a "Ring" as Required by Claim 1

Modifying the oblong, horseshoe shaped frame of Gunaratnam Figure 135 to make it a ring would require substantial modifications to the frame. Petitioners provide almost no details as to how the mask frame of McAuley could be combined with a reasonable expectation of success with the frame shown in

Gunaratnam Figure 135 (as already modified by Petitioners in view of Ging). Petitioners also do not give any supported reasons why a POSITA would modify the frame shown in Gunaratnam Figure 135 to make it generally circular in shape. Accordingly, Petitioners have not established that the proposed combination would have been obvious.

The design of McAuley differs substantially from the design shown in Gunaratnam Figure 135; the components of the masks are far from interchangeable. For example, in McAuley, nasal prongs 64, 65 are inserted into the patient's nares. Ex. 1034 at p. 9, lines 1-3. The prongs extend from a tubular body 66 that fits onto another body 62, which Petitioners assert is a "ring." *Id.* at page 11, lines 3-6. This arrangement is illustrated, for example, in Figures 9 and 10 of McAuley (below) (Figure 10 is a side view of Figure 9).

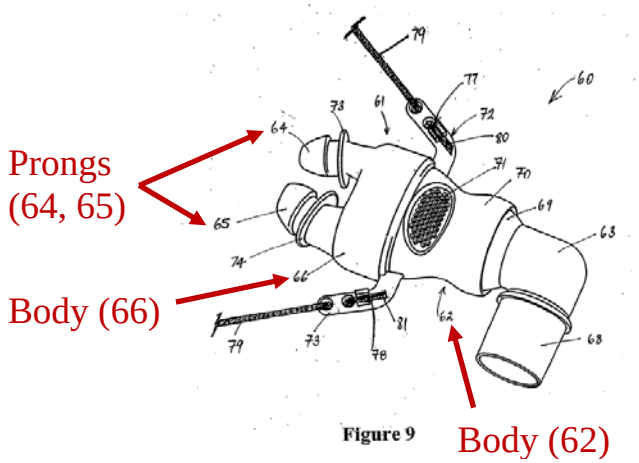


Figure 9

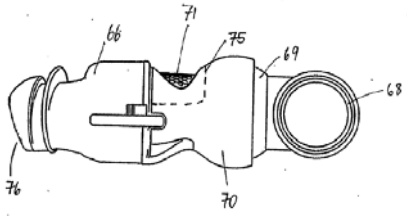
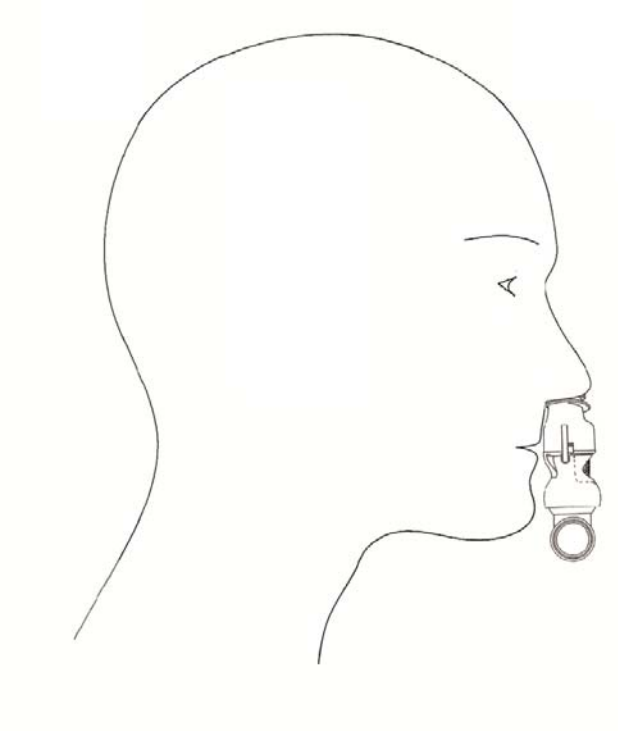


Figure 10

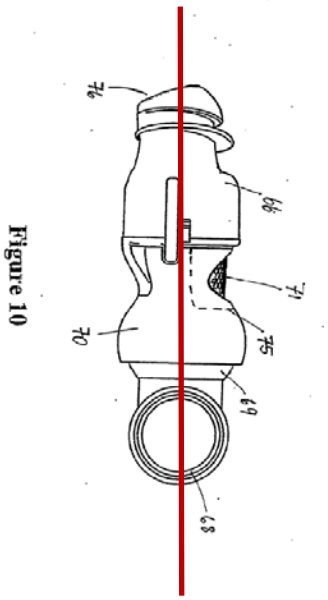
Id. at Figs. 9 and 10 (annotations added). An illustration below shows how the nasal cannula in Figure 10 would be positioned when used by a patient (straps have been omitted).



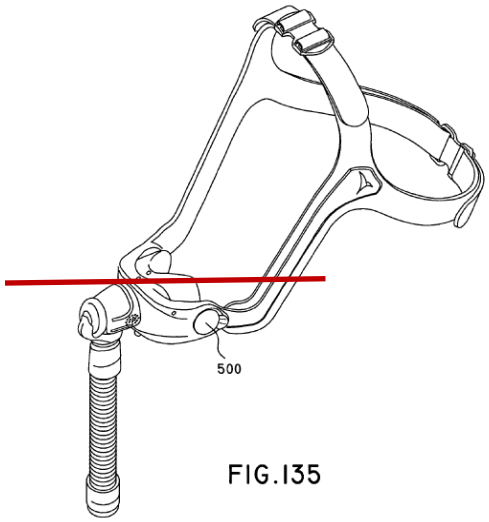
Petitioners provide almost no explanation about how the horseshoe-shaped frame of Gunaratnam Figure 135 could be converted into a ring based on McAuley or what the resulting structure would look like. For example, Petitioners do not explain how the nozzle assembly would attach or interface with the proposed ring or explain how the device could operate with a reasonable expectation of success.

Based on the proposed modification shown by Petitioners in Ground 1, Petitioners appear to propose modifying Figure 135 so that the added nozzle assembly attaches to a vertically oriented surface of the mask frame and thus has a

horizontal attachment orientation. *See, e.g.*, Pet. at 16. That is substantially different from the arrangement shown in McAuley, in which the nasal prongs 64, 65 and associated body 66 are located on top of body 62 and have a vertical attachment orientation. This difference is illustrated in the figures below.



Vertically oriented attachment



Horizontally oriented attachment

Ex. 1034 at Fig. 10; Ex. 1004 at Fig. 135 (annotations added). Petitioners do not explain why it would have been obvious to change the attachment orientation.

Moreover, while Gunaratnam discloses very little detail about the horseshoe shaped frame shown in Figures 134 and 135, it does note in describing Figure 134 that the frame "includes opposite apertures or first connector portions (e.g., tubular

extensions), each of which is provided with a seal ring ….." Ex. 1004 ¶ [0403]. Figure 134 is shown below.

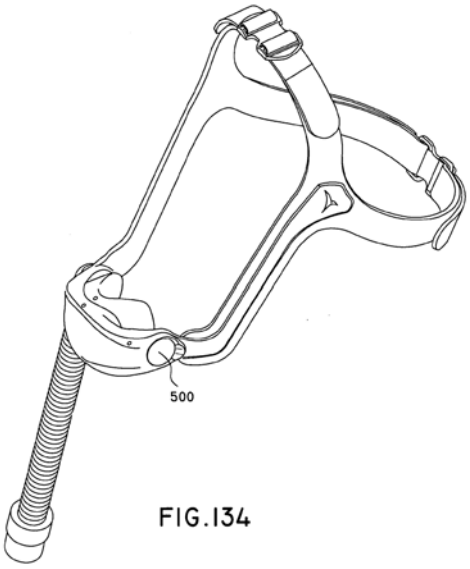


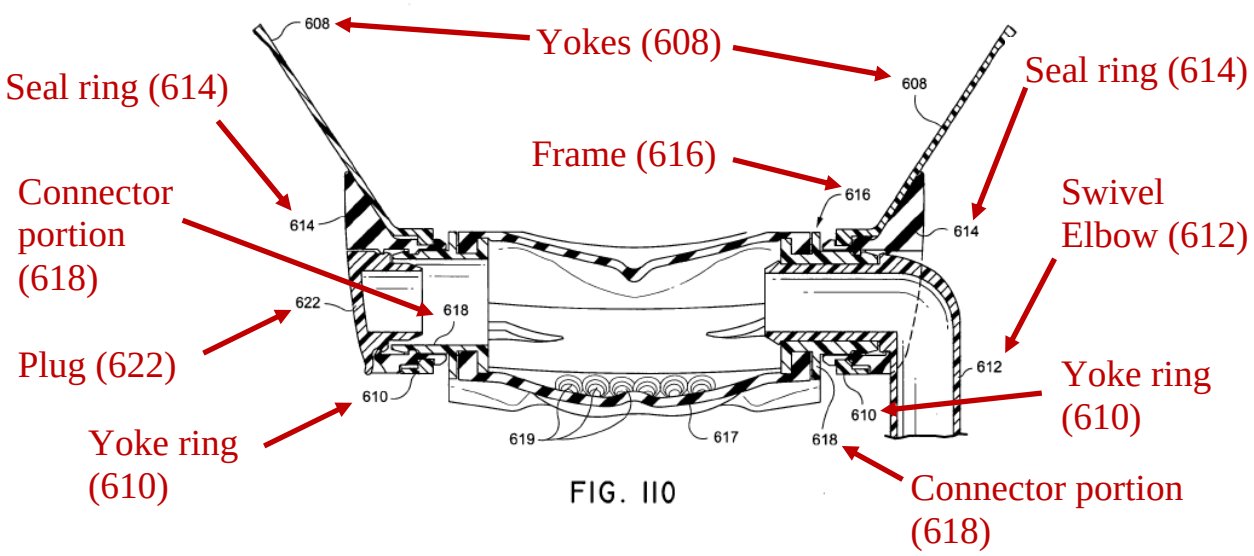
FIG.134

Gunaratnam further explains that one "seal ring 500 is adapted to include a separate or integral plug to close one aperture or first connector portion of the frame, while another seal ring is adapted to engage with the other frame aperture/first connector portion, and to receive the swivel elbow." *Id.* The "positions of the elbow and plug may be interchanged, depending on patient preference." *Id.* The horseshoe-shaped frame shown in Figure 135 has the elbow "provided to the front of the mask frame" while "both apertures/first connector portions are provided with plugged seal rings." *Id.*

Petitioners do not take into account the two apertures/connector portions located at either end of the frame in Figure 135 in their proposed modification. Petitioners have not explained how the frame could be modified to be made

circular while retaining the disclosed apertures/connector portions. Nor have Petitioners addressed why a POSITA would have been willing to eliminate the features in order to make the frame a ring.

In addition, modifying the horseshoe-shaped frame to be generally circular would substantially change the connection of the horseshoe-shaped frame with the yokes. Gunaratnam does not explain how the yokes are attached to the horseshoe shaped frame shown in Figure 135 beyond what is illustrated in the figure itself. However, as discussed above, Petitioners assert that the yokes in Figure 135 are connected to the frame like the yokes 608 in Figures 108-113 of Gunaratnam. Pet. at 28. Figure 110 of Gunaratnam is shown below.



Ex. 1004 at Fig. 110 (annotations added). Figure 110 shows a tubular-style mask frame 616 and connector portions 618 located at each end of the frame. *Id.* ¶

[0380]. A seal ring 614 connects at each connector portion 618 and a ring 610 of the yoke 608 attaches to the seal ring 614. *Id.* ¶¶ [0379-0380]. A plug 622 can be removably inserted into the seal ring 614 and a swivel elbow 612 can be attached to either of the left and right sides of the tubular-style frame 616 opposite the plug 622. *Id.* ¶ [0380].

Once the horseshoe-shaped frame of Figure 135 is modified to be generally circular as Petitioners propose, the attachment points of the yokes to the previously horseshoe-shaped frame presumably would be missing. Petitioners argue that the headgear straps of Gunaratnam "could simply connect to structures that project from the side of the generally-circular portion of the frame, like extension members 72 and 73 (taught by McAuley in Figure 9)" or "could connect directly to attachment points on the surface of the rounded frame, without extensions 72 and 73." Pet. at 54. However, McAuley does not disclose any yoke structures like those shown in Gunaratnam, let alone yoke structures attached with either of the extension members 72, 73 or directly with the body part 62. The headgear strap 79 in McAuley is made of a flexible material like silicon or rubber that is held in place by friction within channels 77, 78 on the extension member 72, 72. Ex. 1034 at p. 13, line 13-23. Nothing in McAuley discloses or suggests attaching a yoke with either of the extension members 72, 73 or directly with the frame.

Petitioners further argue that it would have been obvious to modify the frame shown in Gunaratnam Figure 135 to make it generally circular in order to reduce the weight of the frame, make the frame more compact, and reduce material costs. Pet. at 43. However, Petitioners do not explain how or why a generally circular frame (about which Petitioners have provided virtually no detail) would be lighter, more compact, or be less expensive to manufacture than the frame shown in Gunaratnam Figure 135. Dr. Izuchukwu similarly does not give any reasoned explanation. Ex. 1008 ¶ 184 (stating, without further elaboration, "the circular configuration would have been smaller and therefore would have reduced the weight of the mask"; "the circular frame would have been more compact and therefore users would have had a view that was less obstructed by the patient interface"; and "[making the frame] circular would have required less material and therefore would have reduced the material costs in manufacturing"). Petitioners' conclusory assertions are insufficient to demonstrate any reason why a POSITA would have replaced the frame of Gunaratnam Figure 135 with a ring. *See Nuvasive*, 2016 WL 7118526, at *6 (rejecting as insufficient Petitioner's "arguments amount[ing] to nothing more than conclusory statements that a PHOSITA would have been motivated to combine the prior art references").

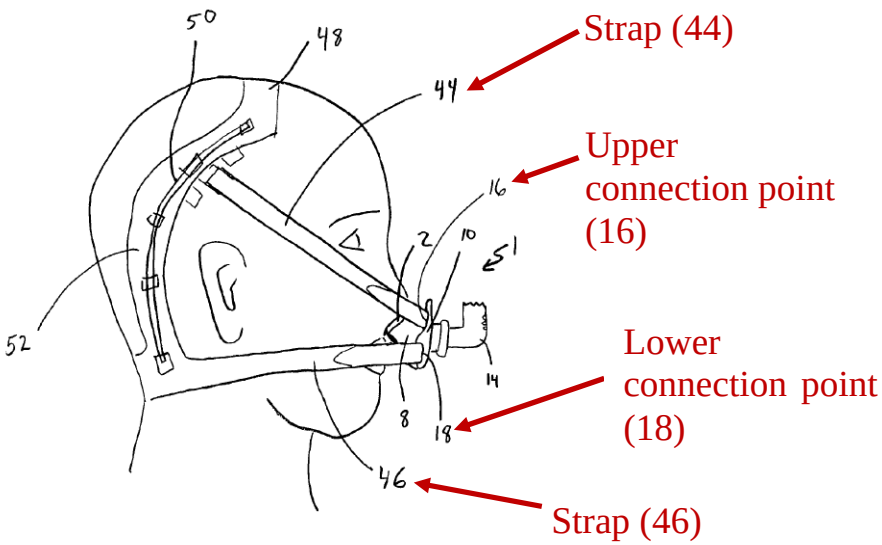
F. Petitioners Have Not Established a Reasonable Likelihood of Prevailing on Ground 3 (Alleged Obviousness of Claims 1-7, 17-19, 24, and 25 over Lovell and Gunaratnam)

Ground 3 relies upon the alleged obviousness of eliminating two of the straps from the four point connection system described in Lovell. However, as FPH argued during prosecution of the '807 Patent, removing two of the straps would fundamentally alter the way in which the Lovell mask functions and it would not have been obvious to do so. Ex. 1009 at 621-22. Thus, Ground 3 of the Petition also fails.

1. Petitioners' Proposed Replacement of the "Four Point Restraining System" of Lovell with the Headgear Described in Gunaratnam Would Change the Basic Principle of the Restraining System and Would Not Have Been Obvious

Lovell describes a nasal mask 1 with a "four point restraining system" which includes both upper 44 and lower 46 retention straps. Ex. 1012 at 6:44-7:4. Figure 5 of Lovell is shown below.

FIG. 5



Id. at Fig. 5 (annotations added)

The upper and lower retention straps 44, 46 serve distinct functions. *Id.* at 6:58-67. The lower retention straps 46 connect with the lower connection points 18, 18' on the retainer 10 and "generally maintain the nasal mask 1 against a user's face." *Id.* The upper retention straps 44 connect with the upper connection points 16, 16' on the retainer 10 and "provide additional retention force on the upper portion of the nasal mask 1, closest to a user's eyes." *Id.* Lovell explains that this "additional retention force" maintains the "nasal mask 1 securely against the external skin surrounding the nares at the base of a user's nose and/or along the rim of a user's nares." *Id.* at 6:69-7:3.

Thus, the basic operating principle of the four point restraining system is that the lower retentions straps 46 maintain the mask against the patient's face and the upper retention straps 44 provide additional force for sealing the domes of the mask against the patient's nares. Removing two of the strap connections would eliminate the functionality of those straps as described in Lovell and, as a result, the mask could not function as described. Consequently, as FPH successfully argued during prosecution, it would not have been obvious to remove two of the straps. Ex. 1009 at 622 (citing M.P.E.P. § 2143.01 and *In re Ratti*, 270 F.2d 810, 813 (CCPA 1959)).

Petitioners essentially ignore the function of the four point restraining system described in Lovell and focus exclusively on the modified design they propose. *See* Pet. at 53-55 (discussing the connection of the yokes and straps with the nasal mask of Lovell); Ex. 1008 ¶¶ 36-38, 198-99. By not considering the function of the headgear as described in Lovell, Petitioners have not established that their proposed combination, which eliminates two of the necessary connection points, would operate under the same basic principle as the four point restraining system or function for its intended purpose, or that the modification would have been obvious.

2. The Reasons Identified by Petitioners for Replacing the Four Point Restraining System of Lovell with the Headgear Designs of Gunaratnam Are Conclusory and Insufficient

Petitioners rely primarily on Gunaratnam Figure 135 in support of their proposed modification of Lovell. Pet. at 54. However, Figure 135 shows a nasal cushion design. The headgear in Figure 135 is designed to maintain the nasal cushion against the outer periphery of the patient's nose rather than seal against the patient's nares. *See, e.g.,* Ex. 1008 ¶ 124. In order to function, the headgear must create a force component generally perpendicular to the patient's face to position and maintain the nasal cushion against the face. In contrast, the mask described in Lovell requires a force component that is generally parallel to the patient's face in order to maintain the domes 38, 40 is sealing engagement with the patient's nares. *See, e.g.*, Ex. 1012 at 6:64-7:3 (explaining that the upper straps provide additional retention force that "retains the nasal mask 1 securely against the external skin surrounding the nares at the base of a user's nose and/or along the rim of a user's nares.").

Thus, the headgear in Gunaratnam Figure 135 operates on a different basic principal (maintaining a seal around the nose) than the four point restraining system in Lovell, which functions to maintain a seal between domes 38, 40 and the patient's nares. Gunaratnam does not teach that the headgear shown in Figure 135

could be used in a mask that includes nasal pillows or that the headgear provides the necessary forces required to be operable with nasal pillows.

Petitioners do not account for the fundamental differences in the forces required for the operation of nasal pillows masks and nasal cushion masks, and do not explain how Lovell would be operable if two of the straps from its design were removed. Instead, Petitioners assert in an insufficient and conclusory manner that a POSITA would have found it "predicable" to apply the headgear of Gunaratnam to the mask design described in Lovell. *See, e.g.*, Ex. 1008 ¶ 198.

Petitioners also rely upon Figures 107G-H in Gunaratnam in support of their proposed modification of Lovell. *See, e.g.*, Pet. at 44, 54. Gunaratnam provides very little structural detail of the mask shown in Figures 107G-H. Ex. 1004 ¶¶ [0369-0370]. However, the frame shown in Figures 107G-H differs in structure from the mask frame described in Lovell. In addition, the frame shown in Figure 107G of Gunaratnam is located in close proximity to the patient's face, while the mask shown in Lovell extends further outward from the patient's face. *Id.* at Fig. 107G; Ex. 1012 at Fig. 5. Petitioners do not account for these differences and have not demonstrated that the headgear shown in Figure 107G of Gunaratnam could be combined with Lovell with a reasonable expectation of success. Gunaratnam also does not describe how the headgear of Figures 107G-H purportedly functions (if at all) to maintain a seal between the mask and the patient's nares. Ex. 1004 ¶¶

[0369-0370]. In fact, Figure 107G depicts the mask positioned over the patient's mouth. Thus, Figures 107G-H do not support Petitioners' proposed modification of Lovell to somehow arrive at the invention of the challenged claims.

Gunaratnam also teaches that nasal masks that align the sealing and stability force can adversely affect patient comfort and criticizes a counter-example of a prior art nasal mask (Trimble), as discussed above. *Id.* ¶¶ [0005-0006]. Petitioners' proposed modification of Lovell to include only two straps, like Trimble, runs contrary to this teaching of Gunaratnam. Thus, a POSITA would not have been motivated to modify Lovell as proposed by Petitioners for this additional reason. *KSR*, 550 U.S. at 416.

Petitioners also rely on Figure 108 of Gunaratnam, and purported commercial devices shown in Ex. 1035 and Ex. 1036. Pet. at 54. However, those designs do not support the proposed modification of Lovell because they include a tubular-style frame that stabilizes against the patient's upper lip. *See*, *e.g.*, Ex. 1004 at ¶¶ [0229-30, 0266]. The headgear in that tubular-style frame mask is designed to direct the stability force against the less sensitive regions of the face, such as the upper lip and cheeks, through the frame. *Id.* The nasal mask in Lovell lacks any similar frame structure. *See*, *e.g.*, Ex. 1012 at Figure 5. Thus, Gunaratnam Figure 108 also does support Petitioners' proposed modification of Lovell.

Petitioners also contend that a POSITA would have been motivated to apply the headgear shown in Gunaratnam to the nasal mask of Lovell because "a two-strap connection would be less cumbersome for a patient than a four-strap connection." Pet. at 54; *see also* Ex. 1008 ¶¶ 36, 198. However, as explained above, modifying Lovell to eliminate two of the strap connection points would fundamentally alter the manner in which the headgear design operates, would eliminate functionality described by Lovell that is necessary for the mask to operate, and would not have been obvious.

Dr. Izuchukwu further declares that a POSITA would have been motivated to make the proposed modification "to reduce the cost of manufacturing the headgear," "to reduce the burdens of donning and removing the mask," and to "enhance the comfort and fit of *Lovell's* mask." Ex. 1008 ¶¶ 38, 198. However, Dr. Izuchukwu provides no evidence supporting any of those assertions and his conclusory assertions do not show that the proposed modification to the Lovell headgear design would have been obvious.

VI. CONCLUSION

For all these reasons, the Petition fails to establish a reasonable likelihood that any claim of the '807 Patent is unpatentable. The Board therefore should not institute trial in this proceeding.

Respectfully submitted,

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Dated: December 13, 2016

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CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that foregoing Patent Owner's Preliminary Response, exclusive of the parts exempted as provided in 37 C.F.R. § 42.24(b), contains 13,194 words and therefore complies with the type-volume limitations of 37 C.F.R. § 42.24(b).

KNOBBE, MARTENS, OLSON & BEAR, LLP

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CERTIFICATE OF SERVICE

I hereby certify that, pursuant to 37 C.F.R. § 42.6(e) and with the agreement of counsel for the Petitioner, a true and correct copy of **PATENT OWNER'S PRELIMINARY RESPONSE and EXHIBITS 2001-2005** are being served electronically on December 13, 2016, to the email addresses below:

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