

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Fisher & Paykel Healthcare Limited,
Petitioner

v.

ResMed Limited
Patent Owner

Case IPR2017-00634
Patent 8,944,061

**PATENT OWNER RESMED LIMITED'S
PRELIMINARY RESPONSE**

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EXHIBITS

Exhibit No.	Description
EX. 2101	The American Heritage College Dictionary (3rd ed. 1993)
EX. 2102	MacMillan English Dictionary (2002)

I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.107(a), patent owner ResMed Limited (“Patent Owner”), submits this Preliminary Response to the Petition for *Inter Partes* Review of U.S. Patent No. 8,944,061 (“the ’061 patent”) filed by Fisher & Paykel Healthcare Limited (“Petitioner”). The Petition challenges claims 17, 18, 20-23, 26-30, 32, 33, 35-38, 41-46, 48-50, and 81-91 as purportedly being unpatentable over a single ground of rejection—obviousness over Lovell in view of Gunaratnam and Gelinas. The proposed rejection fails due to at least four main reasons.

First, Petitioner erroneously assumes Lovell discloses that the elbow that supplies air to the mask assembly “engages” a frame of that mask assembly. In order to rely on Lovell, Petitioner proposes a construction for the term “engage” that is not only conclusory and without supporting analysis, but is so all encompassing that it would render all components of Lovell’s mask assembly “engaged” to each other. Petitioner fails to contemplate any reasonable construction for “engage” that is consistent with the ’061 patent specification or other documentary evidence. *Infra*, Sections V and VI.A.

Second, Petitioner proposes modifying Lovell to add an extra opening in Lovell’s “retainer” and to place a vent in Lovell’s underlying “shell” at a location that corresponds to the newly-formed opening, but the Petition merely assumes—without support—that placing an opening and a vent at such locations would be

advantageous. The references on which Petitioner relies explain that a vent could be located at any one of at least three different locations, none of which correspond to the position suggested by Petitioner, and none of which suggest placing a vent within an opening of an overlying structure. The modification proposed by Petitioner is unsupported by evidence and would render Lovell's mask frame unsatisfactory for its intended use. *Infra*, Section VI.B.

Third, Petitioner contends that adding an opening to Lovell's "retainer" would form the "elongated members" that some claims recite, but even if one modified Lovell as Petitioner suggests, the purported elongated members would not contact Lovell's underlying "shell" to prevent rotation, as certain dependent claims require. This feature is wholly missing from both the secondary references on which Petitioner relies and from Lovell's modified mask. *Infra*, Section VI.C.

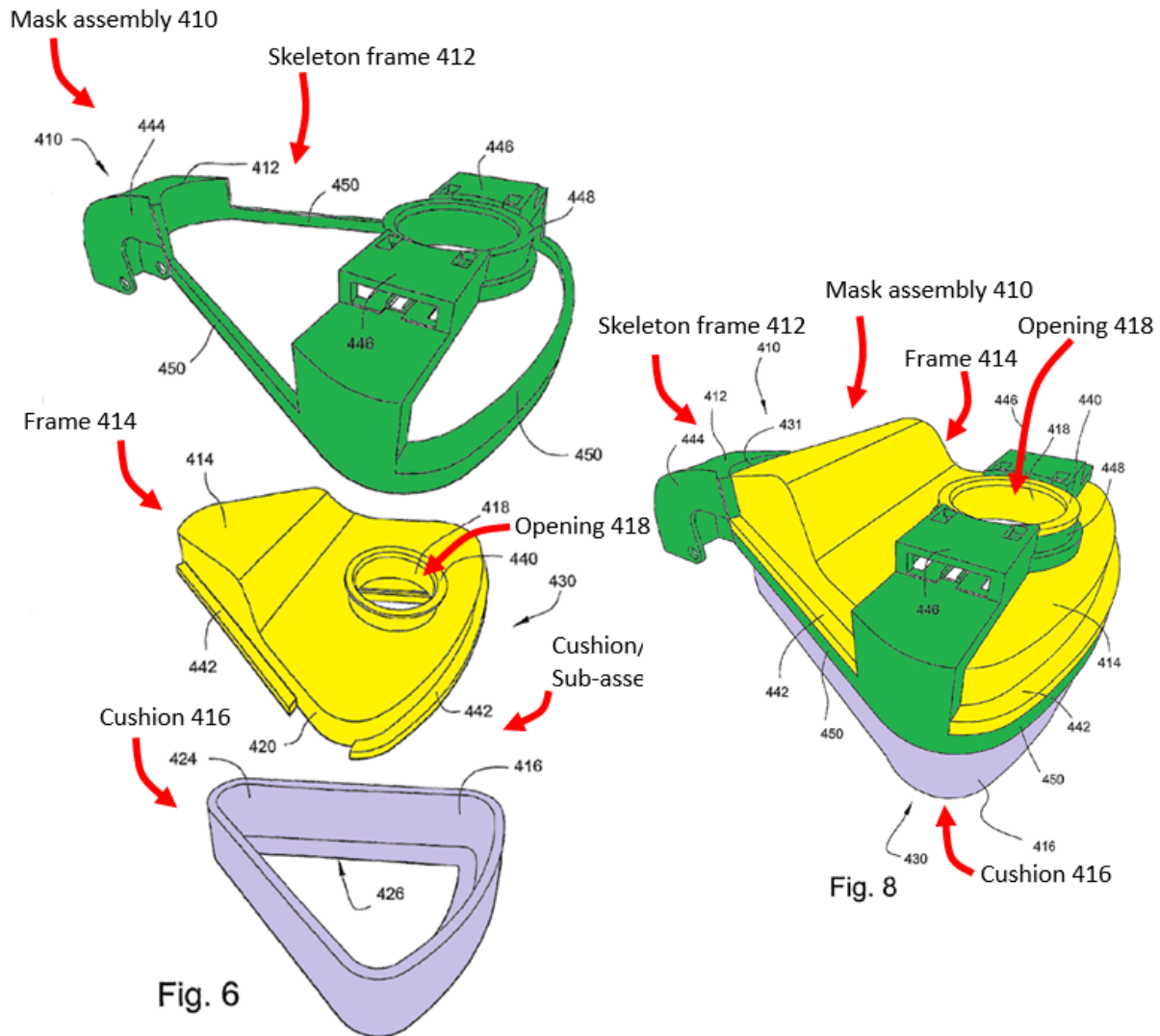
Fourth, Petitioner relies on the secondary Gelinas reference for certain features, but Gelinas discloses masks that filter contaminants out of the air, not masks that form a pressurized breathing chamber to treat sleeping disorders. For this and related reasons, Gelinas is a non-analogous reference that was grafted to Petitioner's primary reference in hindsight. *Infra*, Section VII.

For at least these reasons and the additional reasons described below, Patent Owner respectfully requests that the Board decline to institute *inter partes* review of the '061 patent.

II. BACKGROUND OF THE '061 PATENT

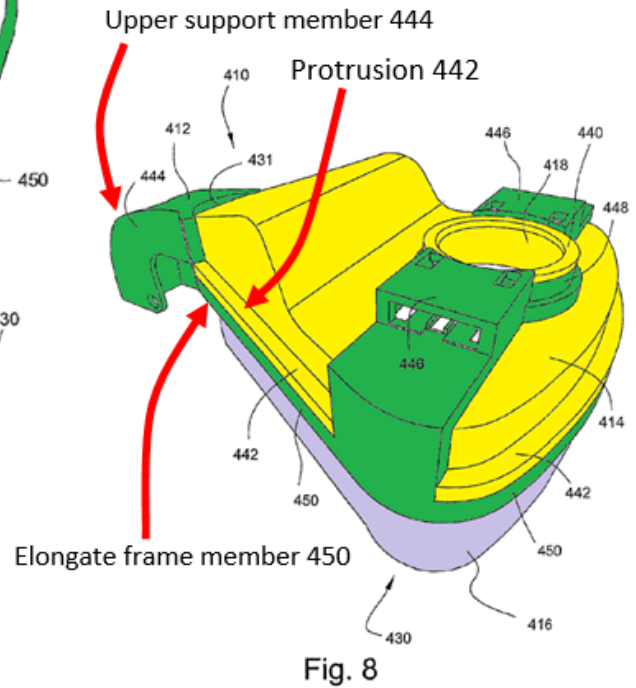
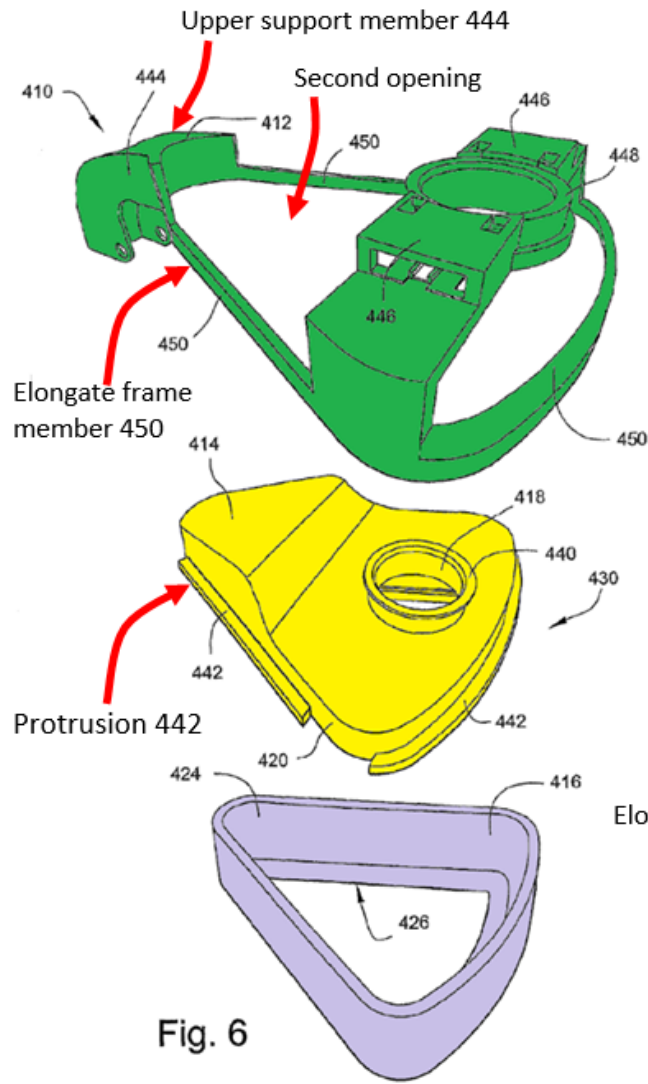
A. Patent Overview

The '061 patent is generally directed to mask assemblies for treating sleep disordered breathing. Ex. 1101, 1:15-33. The mask assemblies provide pressurized gas to breathing chambers of the mask assemblies, to maintain open airways as patients sleep. *Id.* Example embodiments of the challenged claims are illustrated in Figures 3, 4, and 6-8 of the '061 patent:



Ex. 1101, FIGS. 6 and 8 (annotated). These figures (and the accompanying description at column 6, line 51 through column 8, line 48) show a mask assembly that includes a skeleton frame that removably interlocks with a cushion/frame sub-assembly. In the embodiment of Figures 3 and 4, the cushion and frame are integrally molded as one piece to provide cushion/frame sub-assembly 230. In the embodiment shown in Figures 6-8, the cushion 416 and frame 414 are formed separately from one another and then interlocked to form cushion/frame sub-assembly 430. The frame 414 includes annular wall 440 that surrounds an opening 418. When the mask is assembled, the annular wall 440 protrudes through a circular opening in skeleton frame 412. Also when assembled, a portion of frame 414 protrudes through a different, triangular-shaped opening in skeleton frame 412. This triangular-shaped opening is surrounded by elongated frame members 450 that connect upper and lower portions of the mask frame. *Id.*, FIGS. 6 and 8; 8:34-36.

Frame 414 includes protrusions 442 that are designed to interlock with the skeleton frame's elongated frame members 450 when assembled, as shown in the annotated figures below:



Ex. 1101, Figs. 6 and 8 (annotated); *see id.*, 8:38-46 (explaining that “elongated frame members 450 interlock with respective protrusions 442”). As a point of clarification, the Petition mistakenly shaded protrusions 242 as being part of skeleton frame 212 (see below), but protrusions 242 are actually part of the cushion/frame sub-assembly 230 (see above). The erroneous images from the Petition are shown below (with annotations added to identify the error):

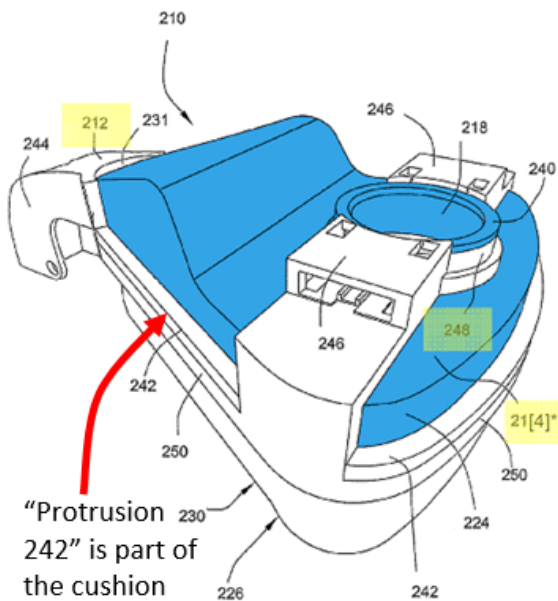


Fig. 4

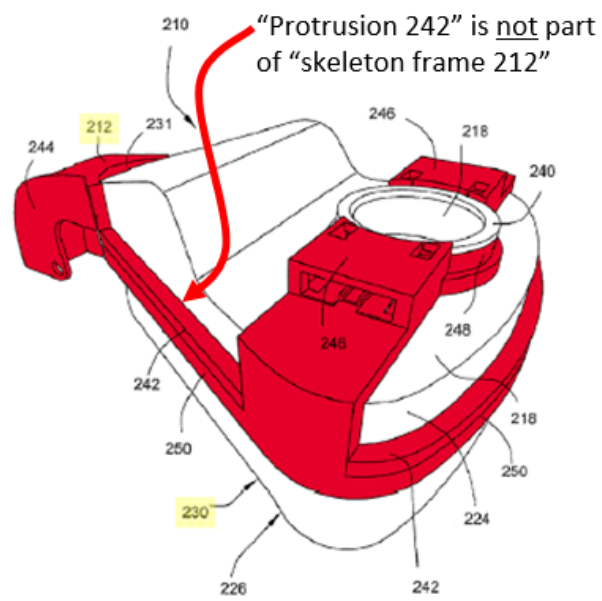


Fig. 4

Petition, pp. 13 and 18 (Petitioner's annotations removed).

B. Prosecution History

The '061 patent issued from U.S. Patent App. No. 13/834,189, which was filed on March 15, 2013. Ex. 1101, 1. Original claim 30 was directed to a mask assembly that comprised "a frame," "a cushion provided to the frame," and a "skeleton frame," similar to the claims that eventually issued. Ex. 1107, 12-13. Patent Owner filed a preliminary amendment, which cancelled all pending claims except for independent claim 30 and its dependent claims 31-34. *Id.*

The first Office action, dated February 26, 2014, rejected independent claim 30 as allegedly being anticipated by the Gunaratnam reference on which the Petition now relies as a secondary reference. *Id.*, 219-225. Patent Owner

responded to the Office action on March 15, 2013, by cancelling the pending claims and adding new claims 39-70. *Id.*, 280-289. The Office mailed a Notice of Allowance on September 9, 2014, which included Examiner's amendments that reflected agreements made during interviews between the Examiner and Patent Owner on June 17, 2014 and August 19, 2014. *Id.*, 295-302, 304, 357. Patent Owner filed an RCE on October 16, 2014, accompanied by claim amendments that corrected two typographical errors and that added new claims 71-130. *Id.*, 373-393. The Office then mailed a second Notice of Allowance on December 12, 2014. Ex. 1107, 399-400. The '061 patent issued February 3, 2015. Ex. 1101, 1; Ex. 1107, 437.

III. SUMMARY OF CITED REFERENCES

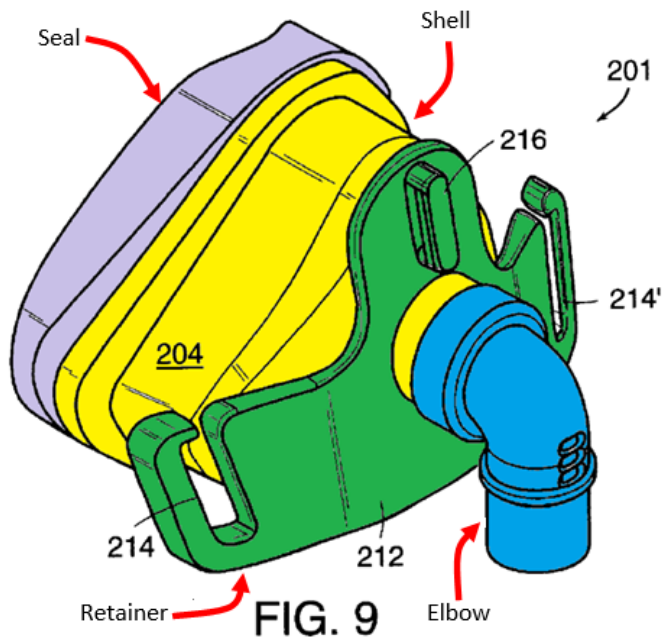
The Petition contends that all of the challenged claims are rendered obvious by the same combination of references—Lovell (Ex. 1102) in view of Gunaratnam (Ex. 1103) and Ging (Ex. 1104). An overview of these references follows.

A. Lovell (Ex. 1102)

Lovell relates to a nasal mask used to provide pressurized gases to a patient that suffers from a respiratory ailment. Ex. 1102, 1:5-8. Lovell's mask includes a seal that is designed to conform to a user's face (*Id.*, 4:55-58), a shell that is bonded to the seal and that forms a pressurized breathing chamber into which a user's nose is received (*Id.*, 4:34-58), and a retainer that includes connection points

(e.g., 214, 214', 216, and 216' in the below figure) to which headgear is connected.

Id., 5:62-19.



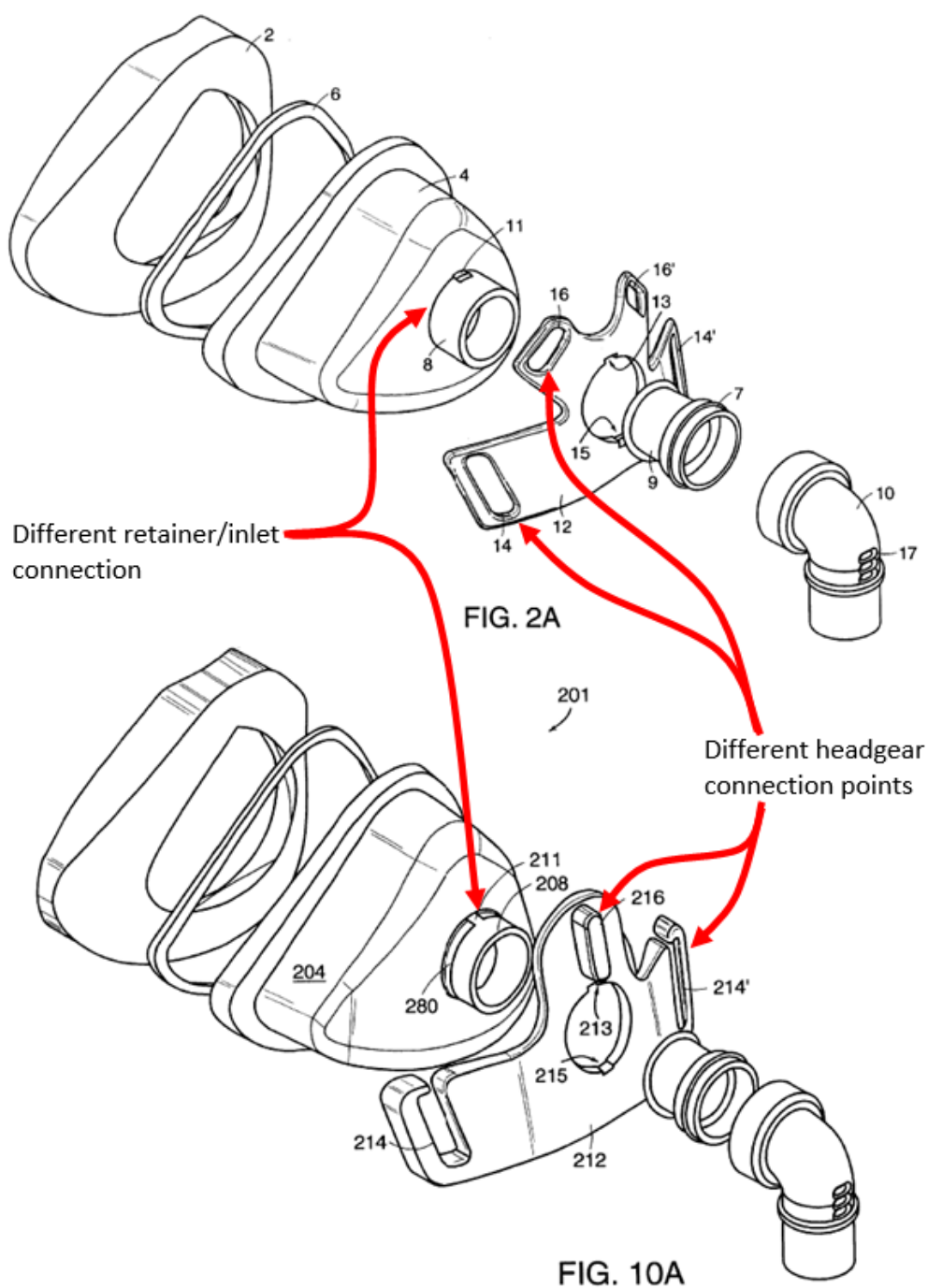
Id., FIG. 9 (annotated).

Lovell describes two primary embodiments, which are illustrated by Figures 1-8 and Figures 9-11, respectively. The embodiments are largely the same, but there are at least two main differences. *Id.*, 9:34-36.

First, retainer 12 of the Figure 1-8 Embodiment connects to inlet 8 in a different manner than how retainer 212 of the Figure 9-11 Embodiment connects to inlet 208. *Id.*, 9:36-67. Second, the Figure 1-8 Embodiment includes four headgear connection points 14, 14', 16, 16' that are different than the three

headgear connection points 214, 214', and 216 of the Figure 9-11 Embodiment.

Id., 6:2-13, 10:1-44. Lovell's FIGS. 2A and 10A illustrate these two differences:

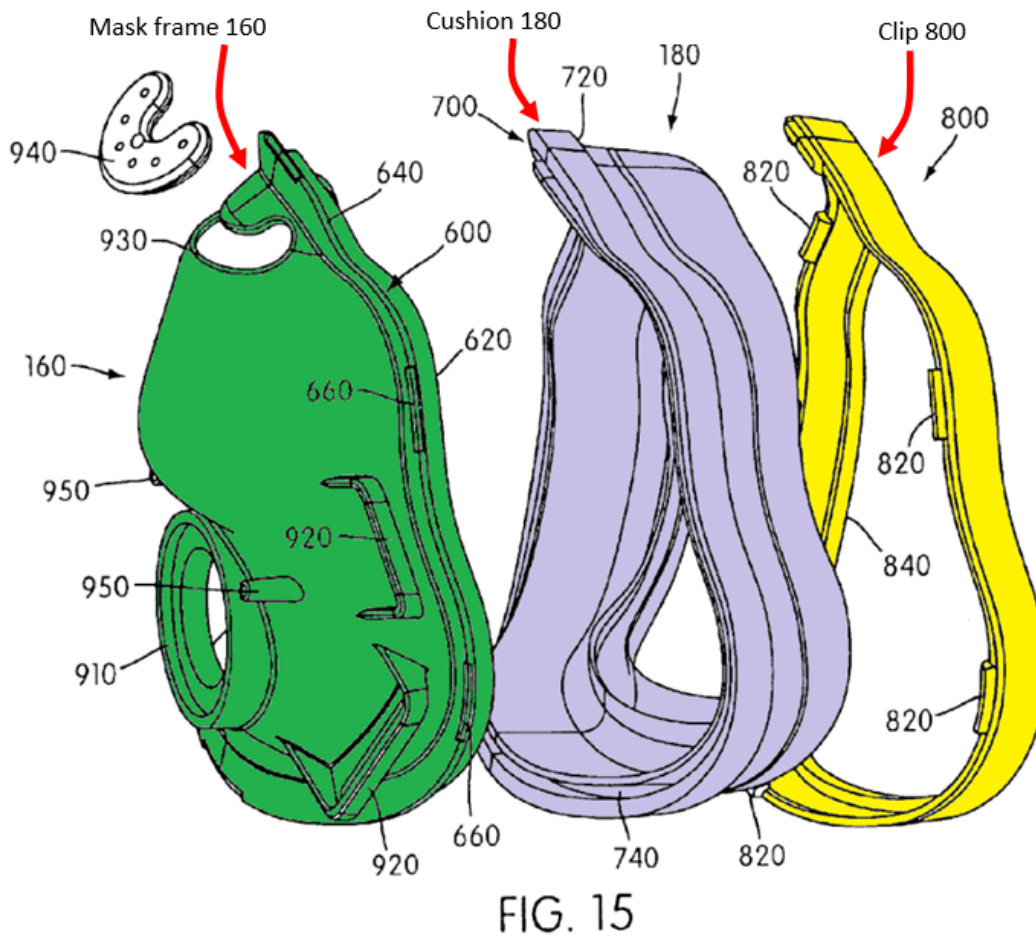


Id., FIGS. 2A and 10A (annotated).

Even though the Petition relies primarily on the Figure 9-11 Embodiment, this paper sometimes refers to the features of the Figure 1-8 Embodiment because the two embodiments are identical in many ways and Lovell includes additional description and figures for the Figure 1-8 Embodiment.

B. Gunaratnam (Ex. 1103)

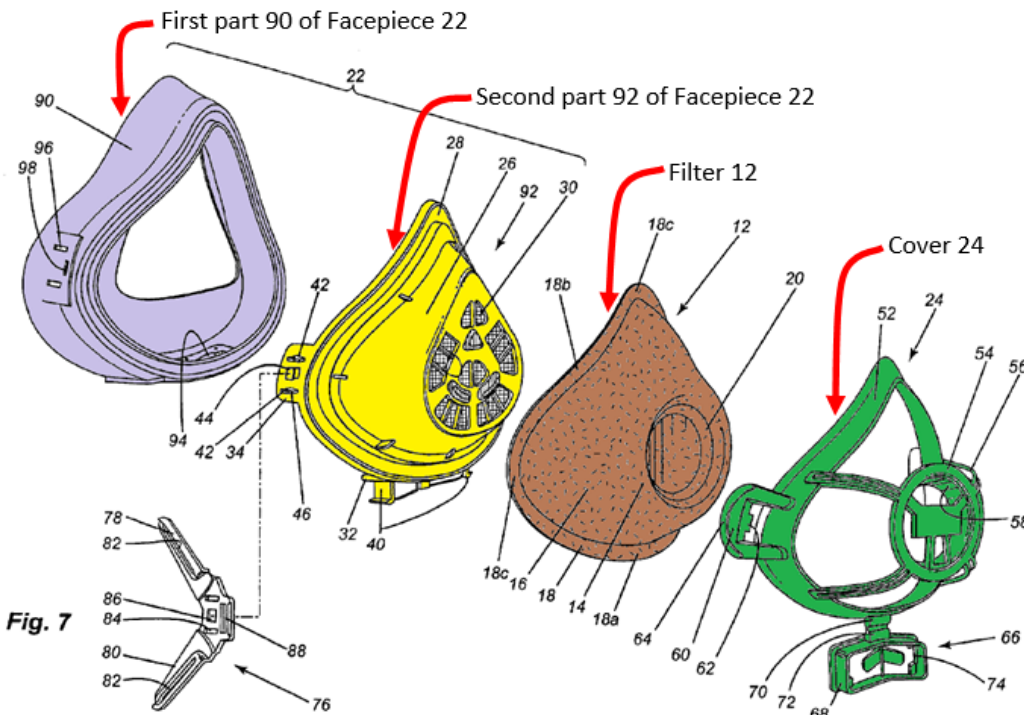
Gunaratnam discloses different embodiments of nasal masks and full-face masks that are used to deliver breathable gases to treat a patient with sleep disordered breathing (SDB). Ex. 1103, 1:20-25. The main embodiment in Gunaratnam on which Petitioner relies is the embodiment shown in Figures 8a-15, which includes a mask frame 160, a cushion 180, and a clip 800. *Id.*, 6:3-41. The clip 800 is adapted to “overlie the cushion (180)” to secure the cushion 180 to the mask frame 160. *Id.*, 6:13-15. Mask frame 160 includes an aperture 930 for receiving an air vent 940:



Id., FIG. 15 (annotated).

C. Gelinas (Ex. 1104)

Gelinas is directed to a “respirator” that “is adapted to receive and maintain a disposable filter that may be designed to protector a wearer from particulate, dust, smoke, oil, fumes and/or gases or vapors.” Ex. 1104, ¶23. The respirator includes facepiece 22 that includes a first part 90 and second part 92, a filter 12, and a cover 24:



Id., FIG. 7 (annotated), ¶26. The first part 90 of facepiece 22 surrounds the nose and mouth of the wearer “in an attempt to prevent the wearer from inhaling the substances that respirator 10 aims to filter.” *Id.*, ¶27. The second part 92 of facepiece 22 includes “openings 30 through which the breath of the wearer can be inhaled.” *Id.*, ¶28. The bottom of the second part 92 includes “openings 38 through which the breath of the wearer can be exhaled.” *Id.*, ¶29. A “filter 12 can be mounted on facepiece 22” to cover openings 30. *Id.*, ¶28. Cover 24 detachably mates with facepiece 22 “to define with facepiece 22 a void area therebetween that is also cup-shaped and suitable to receive filter 12.” *Id.*, ¶31. Gelinas is not related to, and does not provide a breathing chamber that remains pressurized.

Gelinas has no conduit, has no elbow, and doesn't have a single opening for receiving any such pressurized gases from a remote source. To the contrary, Gelinas is designed to filter contaminated air directly from a dirty environment that surrounds the mask and therefore includes multiple openings (at least 16) that are spread over a wide portion of the front of the mask to maximize air intake. Ex. 1104, ¶23, FIG. 7.

IV. STANDARD FOR GRANTING *INTER PARTES* REVIEW

The Board may grant a petition for *inter partes* review only where “the information presented in the petition ... shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a); 37 C.F.R. § 42.108(c). Petitioner bears the burden of showing that this statutory threshold has been met. *See* Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756 (Aug. 14, 2012).

Moreover, Petitioner must establish a *prima facie* case of obviousness with regard to its proposed combinations of references. It is well settled that “rejections on obviousness 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.” *KSR Intn'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). As shown below, Petitioner has not established a *prima facie* case of obviousness, with

respect to the sole ground of unpatentability presented in this Petition. As such, the Board should decline to institute review of the '061 patent.

V. CLAIM CONSTRUCTION

For the purposes of IPR, each claim of the '061 patent is to be “given its broadest reasonable construction in light of the specification of the patent in which it appears.” 37 C.F.R. § 42.100(b). Critically, this construction “cannot be divorced from the specification and the record evidence.” *In re NTP, Inc.*, 654 F.3d 1279, 1288 (Fed. Cir. 2011). Federal Circuit precedent requires that this construction must be not “the broadest construction” available, “but rather the broadest reasonable construction in light of the specification.” *In re Man Mach. Interface Techs. LLC*, 822 F.3d 1282, 1287 (Fed. Cir. 2016).

A. “annular connection adapted to engage an elbow” and “elbow engages the second frame”

Independent claim 17 recites that a second frame of a mask assembly comprises an “annular connection adapted to engage an elbow of an inlet conduit.” Dependent claims 50 and 91 similarly recite that an “elbow engages the second frame.” Petitioner contends that “[t]he term ‘engage’ in these phrases should be construed in a way that would not require direct contact or coupling between the second frame and the elbow.” Petition, pp. 12-14. Patent Owner does not dispute that “direct contact” should not be required under the construction standard in this

proceeding, but disagrees with Petitioner’s additional contention that “engage” should be construed to encompass the vast category of all “arrangements that support in an operable position relative to, either directly or in cooperation with other components.” *Id.*

Petitioner proposes its construction without setting forth any analysis that would support the breadth of its construction, other than to note that skeleton frame 412 in Figure 4 of the ’061 patent would “engage” an elbow under Petitioner’s absurdly broad construction. While true, skeleton frame 412 would also “engage” every structural element of the mask assembly in Figures 6-8 (below), because every mask feature would be supported “in an operable position relative to [the skeleton frame], either directly or in cooperation with other components.”

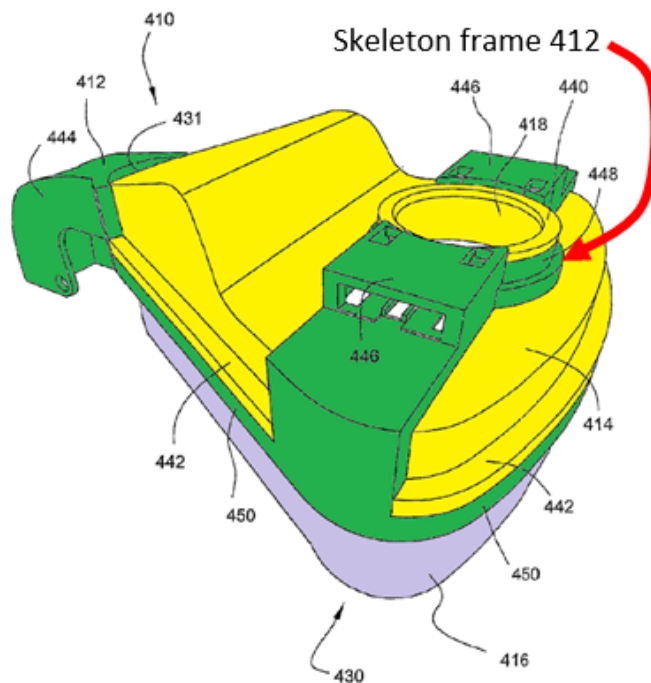


Fig. 8

The '061 patent specification never uses the term “engage” in such an all-encompassing manner; Petitioner ignored this fact.

Likewise, Mr. Eaton’s declaration includes no analysis that supports the outer boundaries of Petitioner’s absurdly broad construction. Paragraphs 32-36 of his declaration discuss this issue, but all of that discussion focuses on how skeleton frame 412 would not directly contact an elbow, followed by his unsupported assumption in paragraph 36, which simply concludes that the term “engage” must encompass the vast category of anything that “support[s] in an operable position relative to, either directly or in cooperation with other components.” Ex. 1105, ¶36. Even though Mr. Eaton’s assumption in paragraph 36 purports to be based upon the “description in the specification,” Mr. Eaton never points to any portion of the '061 patent specification that equates the outer boundaries of the scope of “engage” with such an undue breadth.

To the contrary, the '061 patent specification always uses the term “engage” in a manner that is more finely tailored than Petitioner’s vast category. Specifically, the '061 patent explains that parts “engage” when they “interlock” with each other:

As shown in FIG. 8, the skeleton frame 412 is engaged with the cushion/frame sub-assembly 430 such that the annular elbow connection seal 448 interlocks with the annular wall 440 of the

cushion/frame sub-assembly 430....

Ex. 1101, 8:38-48 (emphasis added). This ordinary usage of the term “engage” in the intrinsic record was never considered by Petitioner.

Further, this evidence in the intrinsic record is fully supported by the ordinary understanding of the term “engage” in dictionary definitions, which indicate that features “engage” if they “interlock” or if one part “fits into another part so that they work together”:

en•gage (ĕn-gáj') *v.*, **-gaged**, **-gag•ing**, **-gag•es**. – *tr.* **1.** To obtain the services of; employ. **2.** To arrange for the use of; reserve. **3.** To pledge or promise, esp. to marry. **4.** To attract and hold the attention of; engross. **5.** To win over or attract. **6.** To draw into; involve. **7.** To require the use of; occupy. **8.** To enter or bring into conflict with. **9.** **To interlock or cause to interlock**; mesh: *engage the clutch*. **10.** To give or take as security. – *intr.* **1.** To involve oneself or become occupied; participate. **2.** To assume an obligation; agree. **3.** To enter into conflict or battle. **4.** To become meshed or interlocked. [ME *engagen*, to pledge something as security for repayment of debt < OFr. *engagier* : *en-*, in; see EN-¹ + *gage*, pledge, of Gmc. orig.] – **en•gag'er** *n.*

Ex. 2101, 3-4 (emphasis added).

engage / in'geɪdʒ/ verb ★★

1 [T] *formal* to attract and keep someone’s interest or attention: *A good radio script should be able to engage the listener.* 1a. to start to employ someone or use their services: *The company is to engage a new sales director.* ♦ **engage sb to do sth** *A magician has been engaged to provide entertainment.*

2 [I/T] if a part of a machine engages, or you engage it, **it fits into another part so that they work together**: *A microswitch in the gear stick automatically engages and disengages the clutch.* ♦ *The mechanism failed to engage, causing a fault.* – opposite DISENGAGE

3 [I/T] *formal* to start to fight with an enemy in battle.

Ex. 2102, 3-4 (emphasis added). Here again, neither the Petition nor Mr. Eaton contemplate the usage of term “engage” in the intrinsic record and its consistency with extrinsic documentary evidence (cited above).

Simply put, Petitioner’s proposed construction is absurdly broad in that it would effectively eviscerate the term and replace it with a vast category of arrangements that do not necessarily “engage” one another—especially as the term “engage” is used in over ninety instances throughout in the ’061 patent specification. Construing this term in such broad strokes is unreasonable when the specification describes the term using language that both covers the disclosed embodiments and is consistent with dictionary definitions. *NTP*, 654 F.3d at 1288; *Man Mach. Interface*, 822 F.3d at 1287. For at least these reasons, the phrases

“annular connection adapted to engage an elbow” and “inlet elbow engages the second frame” should be construed to mean that the elbow and the second frame (for claims 50 and 91), or the elbow and the annular connection of the second frame (for claim 17), interlock or fit within one another, even if those components do not directly contact each other. *See, e.g.*, Ex. 1101, 8:38-48; Ex. 2101, 3-4; Ex. 2102, 3-4.

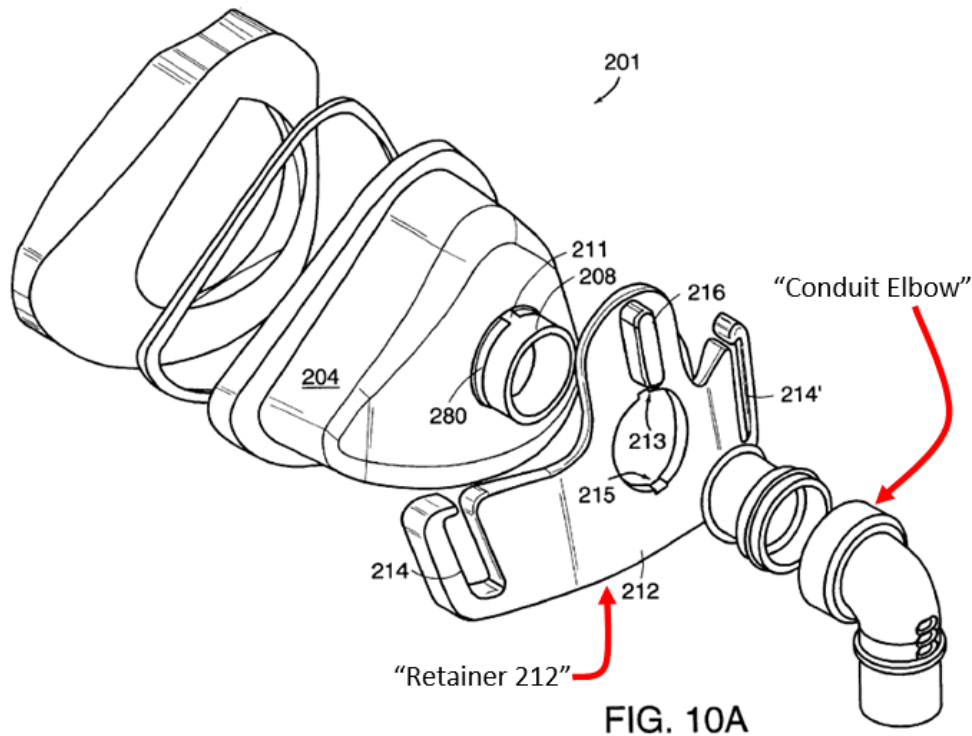
VI. THE PROPOSED COMBINATION OF LOVELL, GUNARATNAM, AND GELINAS DOES NOT DISCLOSE THE CHALLENGED CLAIMS

The Board should deny institution of the only ground presented in the petition—that claims 17, 18, 20-23, 26-30, 32, 33, 35-38, 41-46, 48-50, and 81-91 are purportedly unpatentable under 35 U.S.C. § 103 as obvious over Lovell in view of Gunaratnam and Gelinas. The proposed rejection fails due to multiple reasons which are detailed below.

A. “annular connection adapted to engage an elbow” and “elbow engages the second frame”

The Petition contends that Lovell discloses an “*annular connection adapted to engage an elbow*” (independent claim 17) and an “*elbow engages the second frame*” (dependent claims 50 and 91), because Lovell’s “conduit elbow” and “retainer 212” purportedly “engage” each other under Petitioner’s proposed construction. Petition, pp. 40-44. But as explained in Section V (*supra*), the

proper question is not whether both components fall into the vast category of any “arrangements that support in an operable position relative to, either directly or in cooperation with other components,” as contended by Petitioner. Petition, p. 14. Instead, the proper question is whether the components “interlock or fit within one another, even if those components do not directly contact each other.” *Supra*, Section V (citing to Ex. 1101, 8:38-48; Ex. 2101, 3-4; Ex. 2102, 3-4). Under the proper construction of “engage,” Lovell’s “retainer” does not “engage” its “conduit elbow” (as required by each of claims 17, 50, and 91):



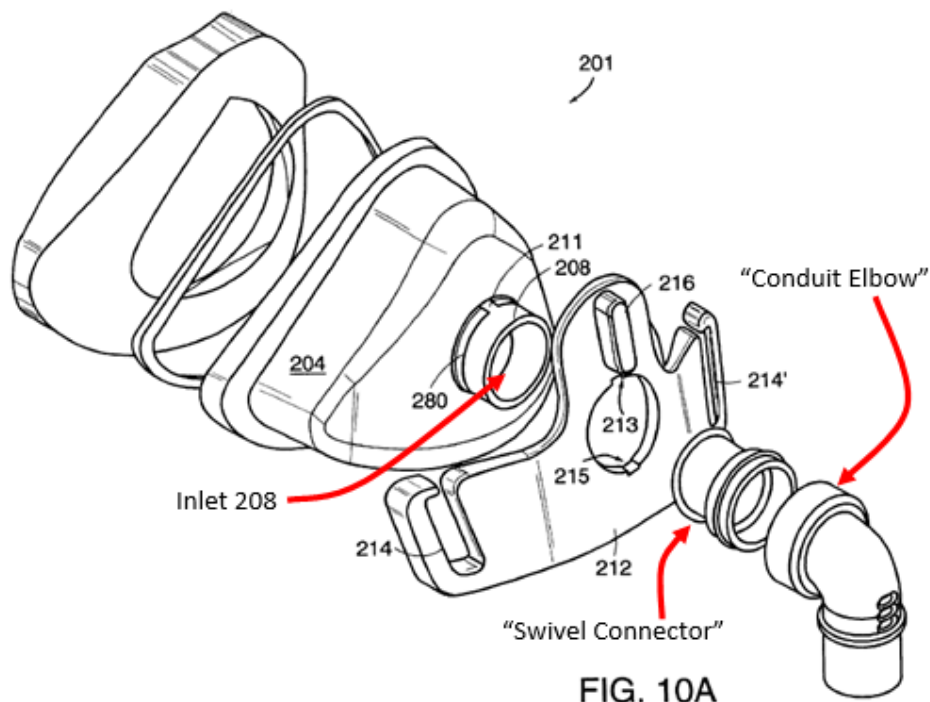
Ex. 1102, FIG. 10A (annotated).

As an initial point, the Petition appears to be mistaken when it states that

Lovell's elbow "directly contacts" the inlet 208 of shell 204 (the purported "first frame"):

Lovell shows an inlet 208 on the first frame 204 that extends through an annular connection (surrounding the unnumbered opening) on the second frame 212, such that the elbow of the inlet conduit directly contacts the inlet 208 on the first frame 204. Ex. 1102 at col. 9:43-48; Ex. 1105 ¶ 85. Thus, Lovell teaches an annular connection on the second frame adapted to engage an elbow. Ex. 1105 ¶ 85.

Petition, p. 40 (emphasis added). As shown below in Figure 10A, Lovell's "conduit elbow" does not directly contact inlet 208. Rather, the elbow directly contacts the "swivel connector," and the swivel connector then directly contacts the inlet:



Ex. 1102, FIG. 10A (annotated). The interconnection between these parts is illustrated in additional detail in Figures 8 and 10B, shown below:

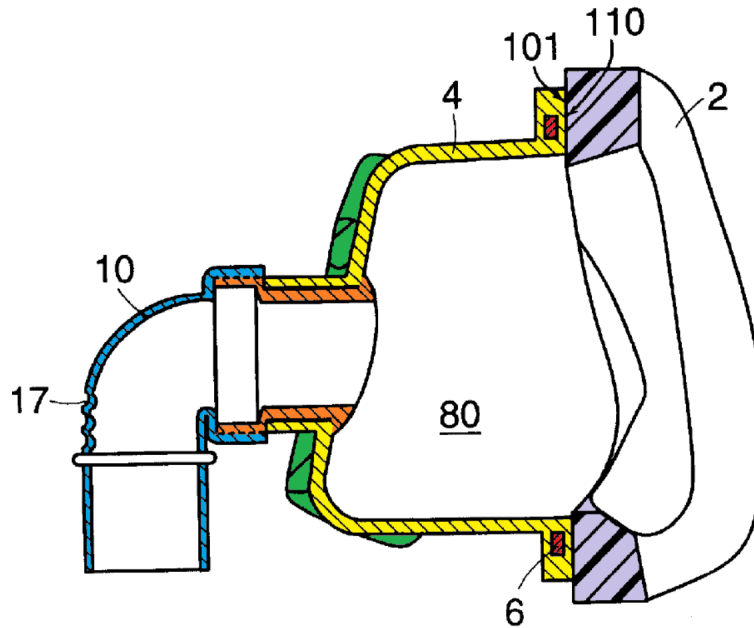


FIG. 8

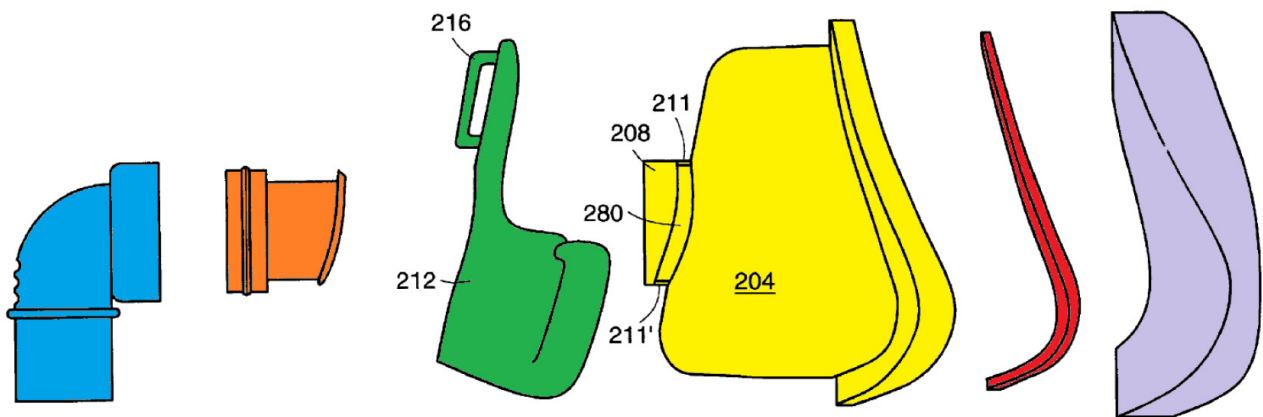


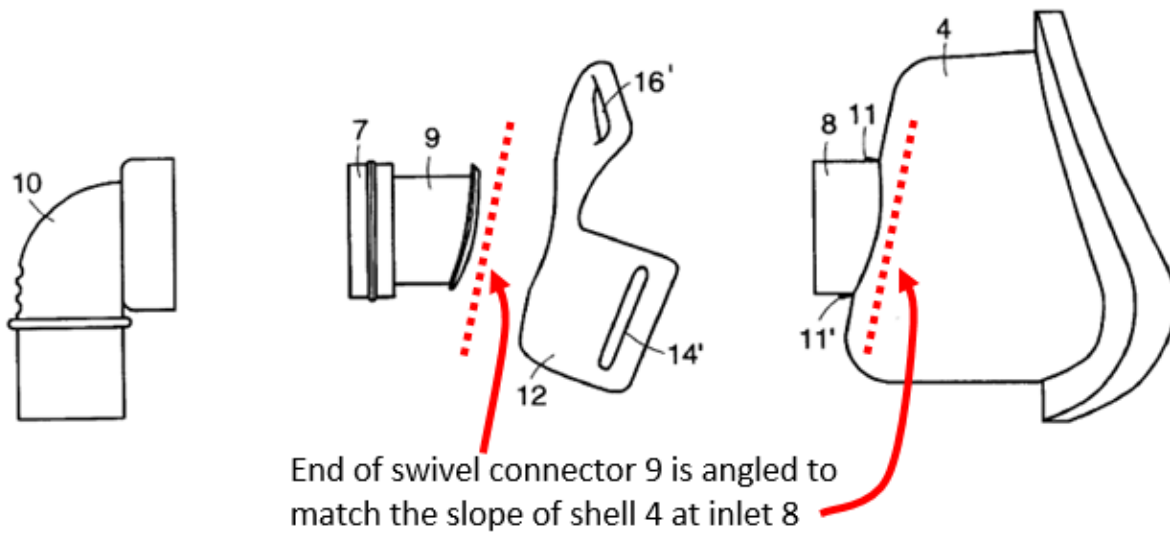
FIG. 10B

Ex. 1102, FIGS. 8, 9, and 10B. These figures demonstrate how Lovell's swivel connector (orange) is fitted through the shell inlet (yellow) so that flanges on either end of the swivel connector cover the ends of the shell inlet. *See Id.*, 5:9-16. The

elbow (blue) then fits over the outward end of the swivel connector (orange) to seal with the swivel connector, without contacting the shell inlet. *Id.*

Regardless, what should be plainly clear from these figures is that Lovell's elbow (blue) does not "interlock" or "fit within" the opening defined by Lovell's retainer (green). Instead, it is the swivel connector (orange) that interlocks and fits within the opening defined by Lovell's retainer (green). The elbow (blue) remains offset from Lovell's retainer by a substantial gap. *Id.* at FIGS. 8, 9, and 10B. For at least these reasons, Lovell does not disclose that its elbow engages its retainer (the purported "second frame") or the opening in that retainer (the purported "annular connection") in the manner specified by independent claim 17 (and dependent claims 50 and 91).

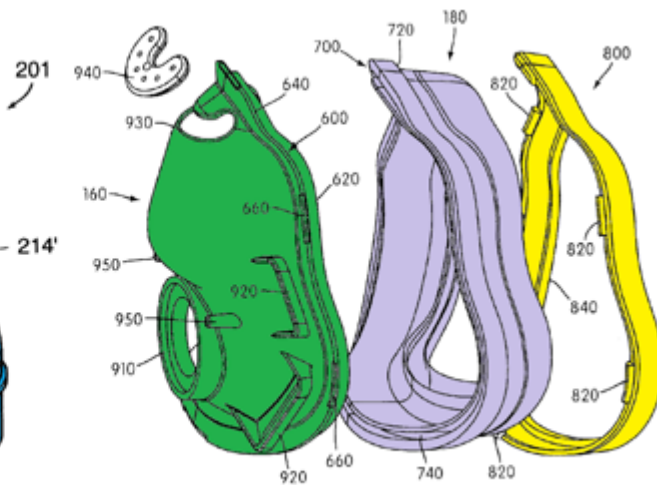
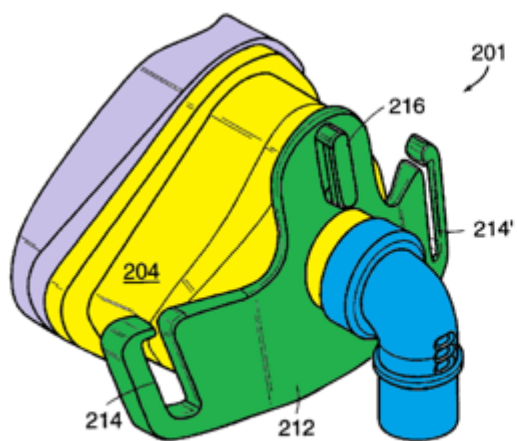
Moreover, it is worth noting the Petition never contends that Lovell's swivel connector (orange) is merely an extension to the elbow, which is due to the fact that Lovell's swivel connector is distinct and serves a separate function. In particular, Lovell's swivel connector is configured to remain fixed relative to the retainer to provide the surface on which the elbow swivels. For example, Lovell explains that "[t]he end of the swivel connector 9 that mates with the inlet 8 may be angled ... in order to match a slope of the shell 4 at the inlet 8, as best seen in FIG. 2B." Ex. 1102, 5:11-14. This is plainly illustrated by Lovell:



Ex. 1102, FIG. 2B (annotated). The complimentary angled surfaces indicate that swivel connector 9 would be fixed with respect to Lovell's shell 4 and retainer 12, because the angled engagement would make rotating swivel connector 9 difficult, if not impossible, when the mask is assembled. If one was able to turn swivel connector 9, the angled flange at the end of the connector closest to the user's face would push off shell 4 as it turned, disrupting the seal at the front of the mask.

The Petition recognized its flawed, overly broad construction for "engage," and thereafter provided an alternative argument that also fails. Namely, the Petition alternatively proposed that Lovell should be modified to implement Gunaratnam's two-seal configuration in the event that the Board construed "engage" to require the second frame to directly contact the elbow. Petition, pp. 42-43. As explained in Section V (*supra*), Patent Owner does not dispute that "engage" may not necessarily require direct contact, and it is therefore unnecessary

for the Board to proceed down the path of this alternative theory. Nevertheless, even if the Board considered Petitioner's alternative theory, the argument is unconvincing and requires tremendous hindsight because the proposed modification to Lovell (into a two-seal configuration) would have required a complete redesign of all of Lovell's mask elements. Not surprisingly, none of the requisite analysis and supporting facts/data for this backup proposal is provided in the Petition. In particular, the Petition and Mr. Eaton's declaration fail to discuss how a POSITA would have had to modify Lovell (shown below at left) to add Gunaratnam's two-seal design (shown below at right), and why a POSTIA would have considered each of these design modifications to be beneficial given that Lovell's mask already provided a solution for achieving the desired seal:



Ex. 1102, FIG. 9; Ex. 1103, FIG. 15. The Petition never contemplates that modifying Lovell's mask to implement Gunaratnam's two-seal configuration would have required (in hindsight) at least:

- 1) Adding an outwardly-protruding tube to the central opening in Lovell's retainer (green, see Gunaratnam's gas inlet aperture 910);
- 2) Modifying Lovell's conduit elbow (blue) to attach and seal to Lovell's newly-added outwardly-protruding tube, rather than Lovell's swivel connector (orange, see figures 8 and 10B on preceding pages);
- 3) Discarding the swivel connector (orange) as no longer necessary;
- 4) Expanding the periphery of Lovell's retainer (green) so that its periphery corresponds to the shape of Lovell's seal (purple), so that the retainer can contact and seal to Lovell's seal (purple) rather than Lovell's shell (yellow); and
- 5) Transforming Lovell's shell (yellow) from a frame that forms a significant part of Lovell's breathing chamber to a clip (see Gunaratnam's clip 800, in yellow) that instead connects the exterior of Lovell's seal (purple) to Lovell's newly-expanded retainer (green).

The Petition (at pages 42-44) and Mr. Eaton's declaration (at paragraphs 86-91) do not explain the significance of the redesign required to implement a "two-seal" device, other than assuming (without the support of underlying facts/data) that a

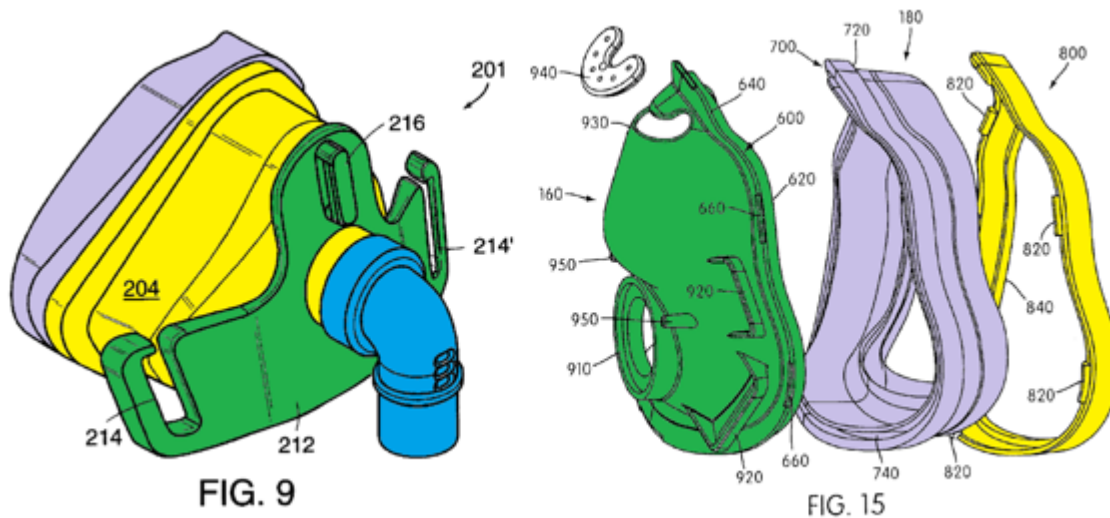
two-seal design is a “design choice,” and listing a few purported features.

Federal Circuit precedent plainly shows that such conclusory testimony without the requisite underlying facts/data is simply not enough to establish a *prima facie* case of obviousness. *In re Nuvasive*, 842 F.3d 1376, 1382-83 (Fed. Cir. 2016) (holding that an alleged motivation to modify a primary reference must not consist of mere “conclusory statements,” and instead “must be supported by a reasoned explanation”); *see also Microsoft v. Enfish*, 662 Fed. Appx. 981, 989-90 (Fed. Cir. 2016) (non-precedential); *Cutsforth v. Motivepower*, 636 Fed. Appx. 575, 577-78 (Fed. Cir. 2016) (non-precedential); *TRW Auto.*, IPR2014-01499, Paper No. 7 at p. 26; *Seabery N. Am.*, IPR2016-00905, Paper No. 12 at pp. 13-14; 37 C.F.R. § 42.65(a). Indeed, modifying Lovell’s shell into a “clip” is similar to what Petitioner proposed in a different IPR petition, and the Board declined to institute IPR in that proceeding because the modification was so outlandish and hindsight-based. *See* IPR2017-00057, Paper No. 7. In that proceeding, Petitioner proposed modifying the opposite of what it suggests here—by modifying Gunaratnam’s clip 800 from being an exterior clip to taking the shape of a frame that forms at least part of the breathing chamber, as shown by Lovell’s shell 4—but the Board in that other proceeding noted that Petitioner “fail[ed] to provide a persuasive rational underpinning to support its argument”:

We find that Fisher fails to provide a persuasive rational underpinning to support its argument that an artisan of ordinary skill would have been motivated to modify clip 800 to include additional structure that closes the large opening of clip 800 to form a bore, with that bore including Lovell's cylindrical structure to attach frame 160 at the bore.

IPR2017-00057, Paper No. 7, page 22. For at least these reasons, Petitioner's alternative argument is based on flawed assumptions, a failure to acknowledge all of the structural modifications actually proposed, and the same shortcoming recently repudiated by the Federal Circuit. *Nuvasive*, 842 F.3d at 1382-83; *Microsoft*, 662 Fed. Appx. at 989-90; *Cutsforth*, 636 Fed. Appx. at 577-78.

Finally, even if a POSITA was prompted to modify Lovell to have two seals, as proposed by Petitioner's alternative argument, doing so would have resulted in a mask that fails to provide other claim elements. Specifically, independent claims 32 and 81, and dependent claims 23 and 31, recite that "the first frame and the cushion together form a breathing chamber," or variations thereof. But while the breathing chamber in Lovell's unmodified design is formed by its cushion (purple) and shell (yellow), Petitioner's proposed modification would have resulted in a mask with the breathing chamber being formed by its cushion (purple) and retainer (green):



Ex. 1102, FIG. 9; Ex. 1103, FIG. 15. In Petitioner's proposed design, Lovell's purported first frame (i.e., its shell (yellow)) would be have been transformed from part of the breathing chamber into a clip that attached the cushion (purple) to the retainer (green) on the exterior of those components (in accordance with Gunaratnam's teachings cited by Petitioner), and therefore would not form part of the breathing chamber. Indeed, FIG. 15 of Gunaratnam shows that clip 800 connects the exterior of cushion 180 to the exterior of Gunaratnam's frame 600.

Ex. 1103, FIG. 15.

For at least these reasons, Petitioner has not met its burden of showing a reasonable likelihood of the unpatentability of claims 17, 18, 20-23, 26-30, 32, 50, and 91 of the '061 patent, and the Board should deny *inter partes* review of these claims under the only proposed ground of unpatentability presented in the petition.

B. “separate opening”

Even beyond any claim construction issue, Petitioner's proposed Ground fails because the Petition proposed a resulting combination that does not provide the second "opening" required for all of the challenged claims. For example, independent claims 17, 32, and 81 all recite some form of second "opening":

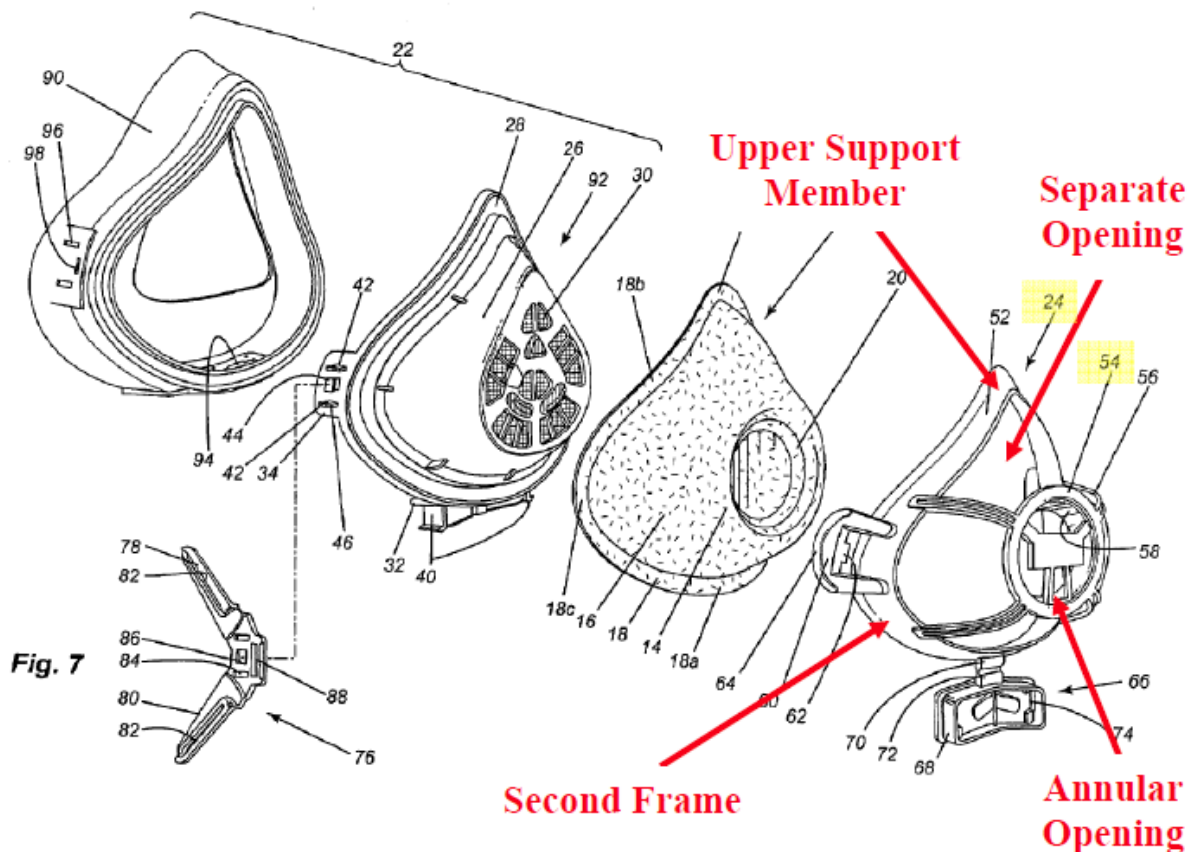
- "***an opening*** located between the annular connection and the upper support member, the opening providing access to the first frame" (claim 17);
- "***a separate opening*** located between the annular opening and the upper support member, the separate opening providing access to the first frame while the mask assembly is fully assembled" (claim 32); and
- "***a separate opening*** located between the annular opening and the upper member, the separate opening providing access to the first frame when the mask assembly is fully assembled" (claim 81).

The Petition ignored the fact that the proposed combination of Lovell, Gunaratnam, and Gelinas would not provide such a second "opening" for multiple reasons.

First, Petitioner admits (at page 45) that "Lovell does not expressly disclose an opening or separate opening between the annular opening and the upper support member" and instead relies on Gelinas, but Gelinas is woefully unrelated to Lovell and/or the claimed solution for the reasons discussed in additional detail below in

Section VII (*infra*), and therefore is improper for the proposed combination. *In re Biago*, 381 F.3d at 1325 (Fed. Cir. 2004).

Second, even if a POSITA would have been motivated to look to Gelinas, it does not disclose the feature that is missing from Lovell. The Petition erroneously relies on Gelinas's opening at the top portion of cover 24 as disclosing the recited "opening" or "separate opening," as Petitioner demonstrated in its annotated version of Figure 7 (shown below):



Petition, p. 46. Gelinas, however, does not disclose "the separate opening providing access to the first frame while the mask assembly is fully assembled"

(independent claim 17) or the other above-quoted “opening” requirements as recited in independent claims 32 and 81. Rather, Gelinas’s opening provides access to filter 12, not the alleged first frame, as shown below in Figure 4.

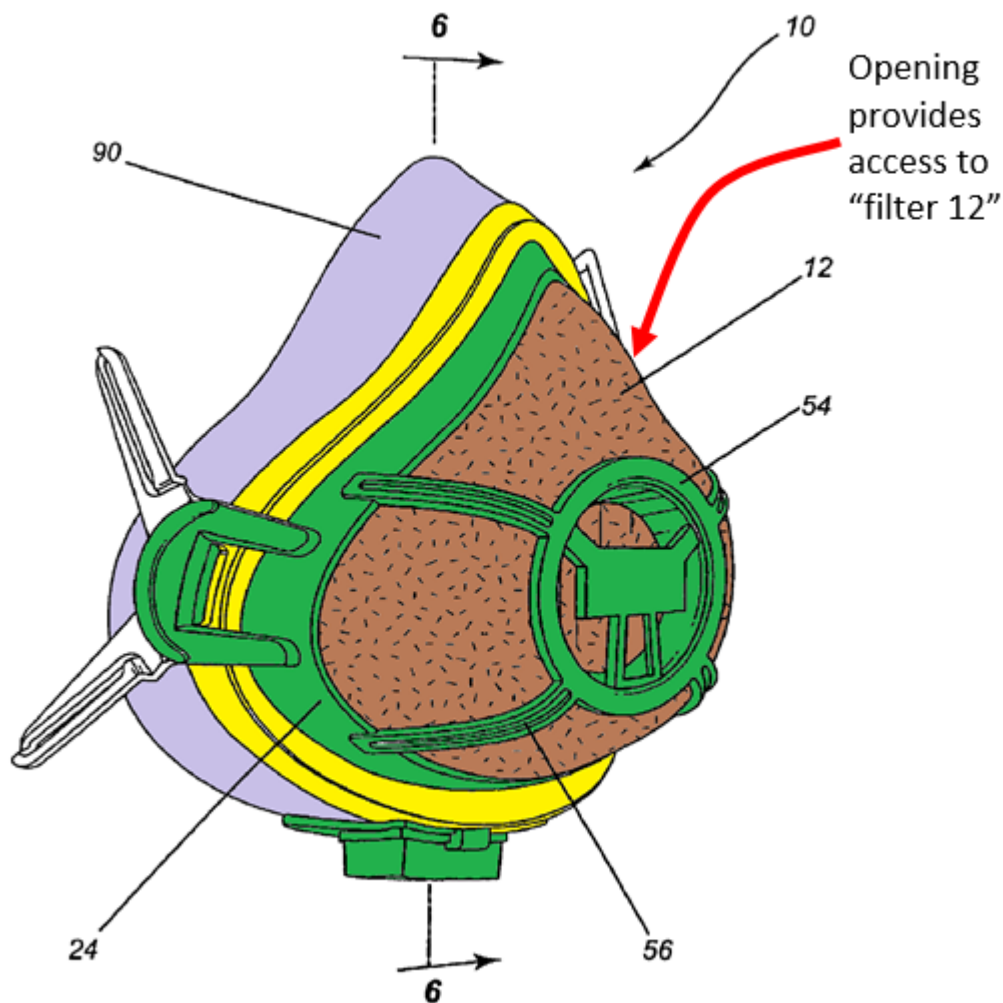


Fig. 4

Ex. 1102, FIG. 4 (annotated). There is simply no reference cited in the Petition that discloses a “separate opening” that provides access to a “first frame,” as

recited by the claims.

Third, even if a POSITA contemplated modifying Lovell (based on Petitioner's hindsight selection of Gelinas), a skilled artisan would not have incorporated Gelinas's opening into Lovell. The opening in Gelinas to which Petitioner points is not an opening in isolation from other features of the mask, but is the outermost-portion of an environmental air intake that allows air to pass through filter 12 and then through openings 30 in facepiece 22 on the back side of filter 12. Ex. 1104, ¶¶ 28-32. The Petition ignores that this type of environmental air intake is contrary to Lovell's intended purpose because including such an air intake would reduce or eliminate Lovell's ability to maintain a pressurized breathing chamber. *In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984); MPEP 2143.01(V) ("The proposed modification cannot render the prior art unsatisfactory for its intended purpose."). Petitioner ignored that the modifications of Lovell in view of the teachings of Gelinas would detrimentally affect the integrity/clinical effectiveness of the seal during Lovell's intended use. *Tec Air, Inc. v. Denso Mfg. Michigan Inc.*, 192 F.3d 1353, 1360 (Fed. Cir. 1999) (finding "no suggestion to modify a prior art device where the modification would render the device inoperable for its intended purpose"); *In re Fritch*, 972 F.2d 1260, 1266, footnote 12 (Fed. Cir. 1992). Petitioner never addresses why, in spite of this clearly divergent purpose of Lovell's sealed mask, a POSITA would have been prompted

to incorporate these features from Gelinas's type of environmental air intake. Moreover, the Petition ignores that the particular "opening" of Gelinas cited by Petitioner never serves as the entire air intake. Rather, there are four large openings covering the entire face of Gelinas's mask (and at least sixteen corresponding "openings 30" behind the filter), and Petitioner identifies no reason why a POSITA that was somehow motivated by Gelinas's environmental air intake would stop at implementing just one opening. Covering the entire front of Lovell's mask with environmental air intakes (which is what Gelinas teaches as desirable) would certainly exacerbate the depressurization Lovell sought to avoid and would render Lovell's mask unsuitable for its purpose of creating a pressurized breathing chamber to treat OSA. *Tec Air*, 192 F.3d at 1360. For at least this reason, Petitioner has not met its burden to demonstrate why a POSITA would have been prompted to modify Lovell's mask to incorporate the openings suggested from Gelinas's type of environmental air intake. *Cutsforth*, 636 Fed. Appx. at 577-78; *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1362 (Fed. Cir. 2016); *Ariosa Diagnostics*, 805 F.3d 1359, 1366 (Fed. Cir. 2015).

Fourth, Petitioner appears to recognize that a POSITA would not have added the opening in Gelinas's cover 24 to Lovell's mask absent a good reason (and adding an environmental air intake to Lovell's mask is not a good reason). As such, the Petition contends that Lovell's mask would need a vent to expel CO₂, and

that a POSITA would position the vent above the inlet in Lovell's retainer (at a position otherwise covered by Lovell's retainer), and then would form a hole in Lovell's retainer to expose the vent. Petition, pp. 46-47. The evidence of record, however, does not support such an illogical, hindsight-based modification for several reasons. As an initial point, Lovell's mask assembly already includes a "vent 17" on "elbow 10" in order "to allow the release of gases exhaled by the user, as well as preferentially vent the chamber 80 upon pressurization." Ex. 1102, 5:36-41; FIG. 1 (below, annotated).

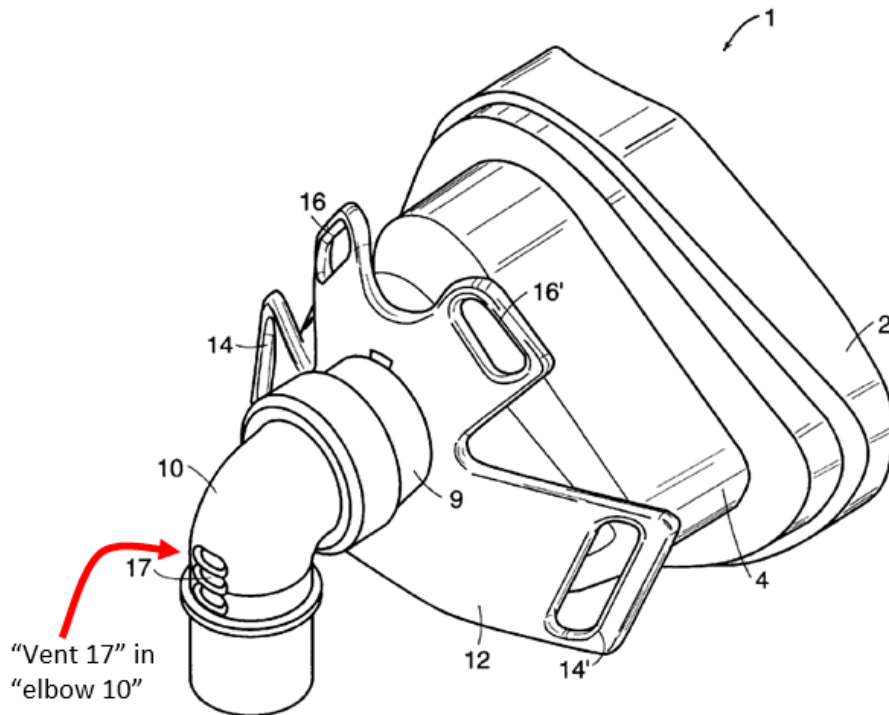


FIG. 1

Lovell explains that locating the vent on the elbow far away from the user's face is advantageous, for example, to "prevent escaping gases from disturbing a user due

to noise.” Ex. 1102, 5:44-47. Despite Lovell’s express teaching of a beneficial vent on an elbow and the corresponding advantages to locating the vent on the elbow, the Petition blindly proposes adding a vent on Lovell’s shell 4.¹ Petition, pp. 47-48. Such hindsight-based additions without meaningful reasons/benefits are insufficient to establish a *prima facie* case of obviousness. *Nuvasive*, 842 F.3d at 1382-83.

Still, even if there was a motivation to implement a vent on Lovell’s shell (which there was not for reasons described above), the art cited by Petitioner already explained exactly where such a vent would be located. For example, Lovell explains that “one or more outlets can be included, optionally, in a lower portion of the shell 4 to allow for drainage of any condensation formed within the chamber 80 of the shell 4” Ex. 1102, 5:54-61 (emphasis added). Moreover, Gelinas—to which Petitioner assumes a POSITA would have plucked from the sea of prior art in a pursuit for an alternative vent arrangement—also has its vent arrangement at the bottom of its mask assembly.

As shown in FIG. 6, bottom wall 32 comprises openings 38 through which the breath of the wearer can be exhaled and two spaced

¹ The Petition does not specify whether Lovell’s vent would be moved or whether a second vent would be added.

apart L-shaped proturbances 40. Each side walls [sic] 34- and 36 comprises two spaced apart posts 42 and a L-shaped proturberance 44, each post 42 having a notch 46.

As shown in FIG. 6, respirator 10 further comprises an inhalation valve 50 that recovers openings 30 and an exhalation value 48 that recovers openings 38. Inhalation valve 48 is designed to open in response to pressure from air inhaled by the wearer while exhalation valve 50 is designed to open in response to pressure from exhaled air and to ensure that the exhaled air does not pass back through filter 12 thereby preventing rebreathing of the exhlaed air.

Ex. 1104, ¶¶29-30 (emphasis added).

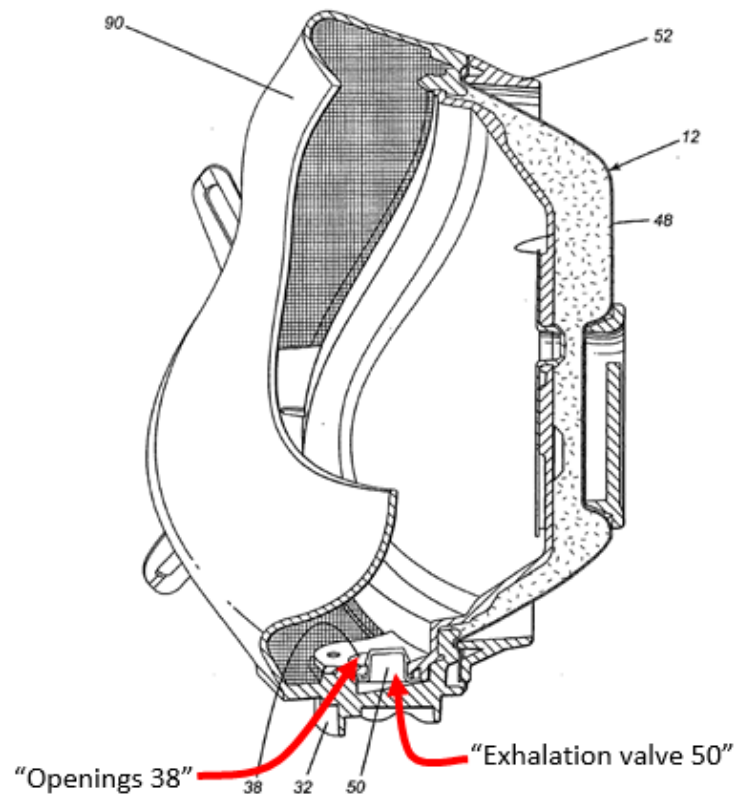


Fig. 6

Id., FIG. 6 (annotated). Thus, even if there was a motivation to implement a vent on Lovell's shell (which there was not for reasons described above), such a vent would not have been implemented at the location proposed in Petitioner's hindsight-based proposal.

Still, Petitioner then goes beyond Lovell and Gelinas to contend that Gunaratnam teaches providing the vent at "the well-known position" in the nasal bridge region of the mask assembly. Petition, 47-48 ("common and well-known"). First, such bald assumptions of mere common knowledge are not enough under Federal Circuit precedent. *Arendi*, 832 F.3d at 1362. Second, even if a POSITA ignored the unambiguous teachings in Lovell and Gelinas that vents should be placed on the conduit elbow or at the bottom of the mask, and was convinced by Gunaratnam and purportedly "common and well-known" knowledge that vents should be located at the "nasal bridge region of the mask assembly," Petitioner's proposed modification would still not result in a mask assembly that provided the claimed subject matter. Indeed, the Petition proposed adding a vent to the nasal bridge region of Lovell's shell 204 (yellow), but Petitioner overlooks the fact that such a location does not result in adding the claimed "opening" to Lovell's retainer 212 (green):

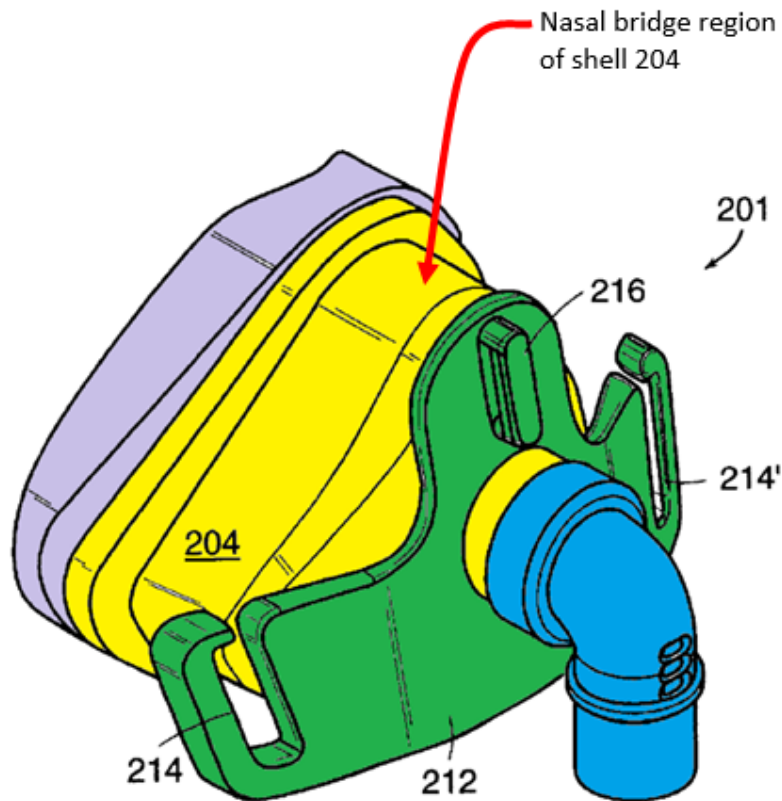


FIG. 9

Ex. 1102, FIG. 9 (annotated). Despite the illustration of Lovell's shell (above) having its nasal bridge region plainly uncovered by a frame and Petitioner's alleged reliance on Gunaratnam's vent location (upwardly-facing and proximate a user's face), the Petition takes an unreasoned leap and wrongly assumes that adding a vent to Lovell's nasal bridge region "would require access to the vent through the second frame:"

A person of skill in the art would have recognized that providing a vent on the first frame of a two-frame mask system would require access to the vent through the second frame. Ex. 1105 ¶ 98.

As such, a person of skill would have been motivated to modify the second frame to include a separate opening between the annular elbow connection and the upper support member of the second frame, as taught by Gelinas, to provide access to a vent in the nasal bridge region of the first frame. *Id.*

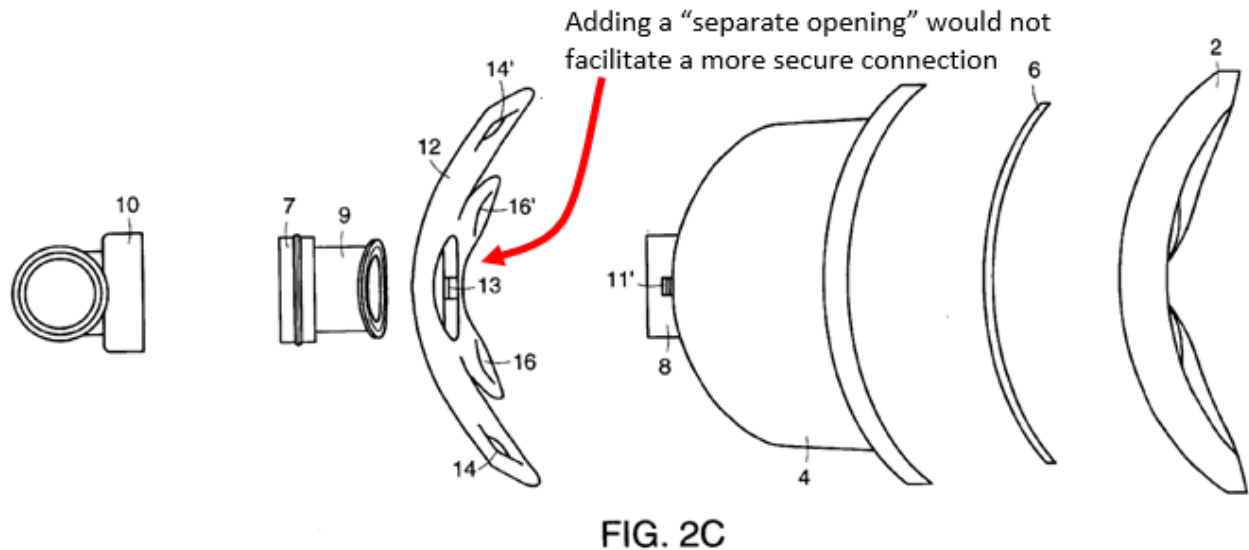
Petition, p. 48 (emphasis added). This statement is simply not true, as the above-annotated version of Lovell's Figure 9 shows. The Petition provides no reason why the proposed vent would be "required" at a position obscured by Lovell's retainer 212 rather than unobstructed locations. Worse yet, this unsupported assumption from the Petition is blindly parroted in Mr. Eaton's declaration without any additional analysis or underlying facts/data. Again, this is not enough.

Nuvasive, 842 F.3d at 1382-83; *Microsoft*, 662 Fed. Appx. at 989-90; *Cutsforth*, 636 Fed. Appx. at 577-78; *TRW*, IPR2014-01499, Paper No. 7 at p. 26; *Seabery*, IPR2016-00905, Paper No. 12 at pp. 13-14; 37 C.F.R. § 42.65(a).

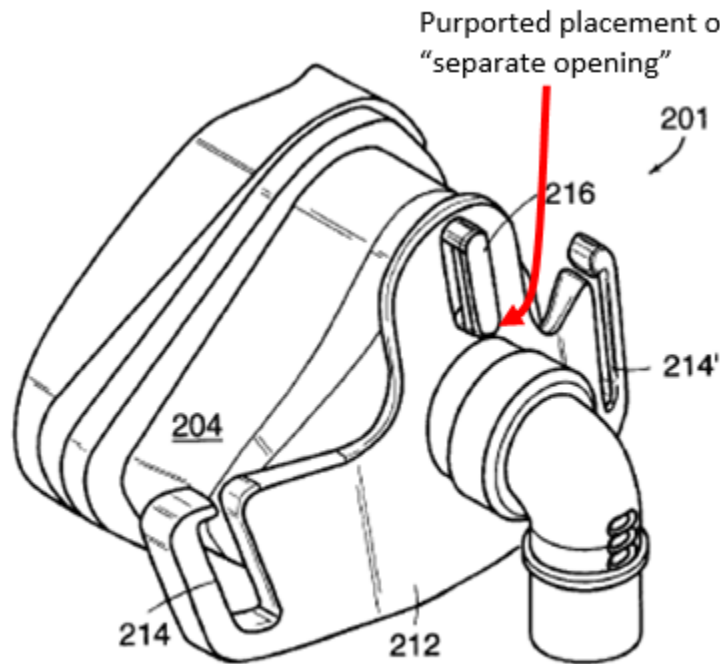
The last assumption that the Petition makes on this topic adds that the proposed additional opening would purportedly "facilitate a more secure connection between the periphery of the second frame (surrounding the second opening) and the first frame." Petition, p. 48. Yet again, the Petition fails to establish how such an opening would achieve a more secure connection between the two components absent some additional interlocking mechanism between the opening and Lovell's shell 4, which the Petition does not contemplate or propose

in its haste. *See* Petition, p. 48. Indeed, Lovell’s teaching does not support

Petitioner’s bald allegation:



Ex. 1102, FIG. 2C (annotated). That same last assumption in the Petition also contends that adding the proposed separate opening would “minimiz[e] the amount of material in the second frame,” but the Petition does not explain why minimizing the amount of material would be beneficial. Federal Circuit precedent explains that such reasoning falls short. *Nuvasive*, 842 F.3d at 1382-83. Moreover, even if the Petition explained why minimizing the amount of material was beneficial, adding the opening that proposed by Petitioner would actually require adding material to Lovell’s retainer. Specifically, even if Petitioner assumed that the proposed opening would be located between Lovell’s central swivel connector and its headgear slot 216, such a modification would logically require increasing the size of Lovell’s retainer:



Ex. 1102, FIG. 9 (annotated). Namely, adding a separate opening at this location would have required extending the top of Lovell's retainer 216 upwards (including headgear slot 216), and doing so would add material, not minimize it as Petitioner assumes. Furthermore, extending the top portion of Lovell's retainer 212 upward would further obscure a patient's vision, thereby running contrary to Lovell's intended purposes for the mask to "not to block the vision of a user." Ex. 1102, 6:64-66 (discussing the orientation of the upper retention straps 59).

Put simply, Petitioner has proposed a hindsight-based solution in search of a non-existent problem. Petitioner's proposal is to add a hole above a central air intake opening, but Petitioner has not articulated a single rational reason that would

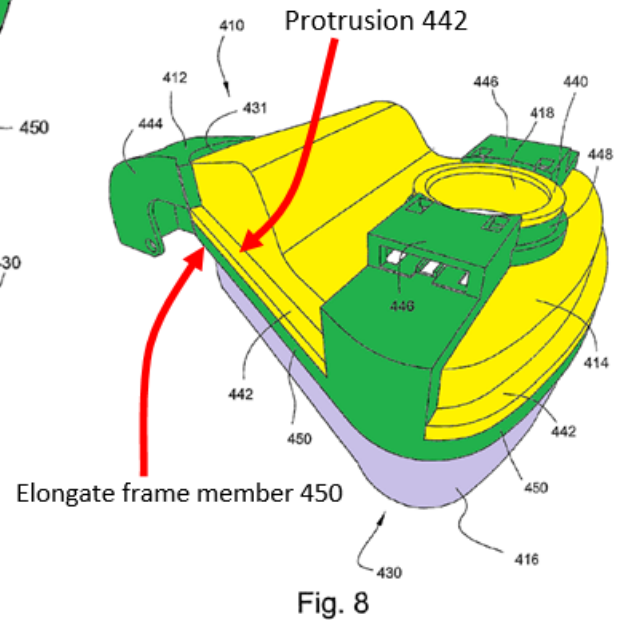
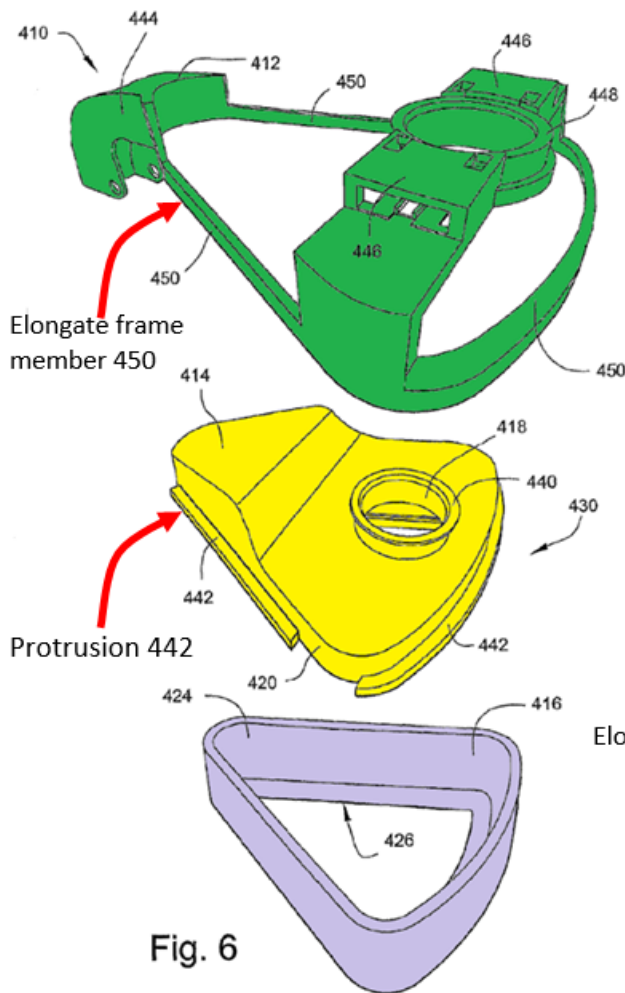
have motivated a POSITA to modify Lovell as suggested. Petitioner's arguments are a textbook example of improper hindsight reasoning. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983) (“a hindsight syndrome wherein that which only the inventor taught is used against its teacher”).

For these reasons, Petitioner has not met its burden of showing a reasonable likelihood of the unpatentability of claims 17, 18, 20-23, 26-30, 32, 33, 35-38, 41-46, 48-50, and 81-91 of the '061 patent, and the Board should deny *inter partes* review of these claims under the only proposed ground of unpatentability presented in the petition.

C. “the elongate frame members include contact points with the first frame to prevent rotation of the first frame with respect to the second frame” (dependent claims 83 and 89)

Dependent claims 83 and 89 recite that “*the elongate frame members include contact points with the first frame to prevent rotation of the first frame with respect to the second frame,*” but this feature does not appear in Gelinas, on which Petitioner relies, or even in Lovell's modified mask.

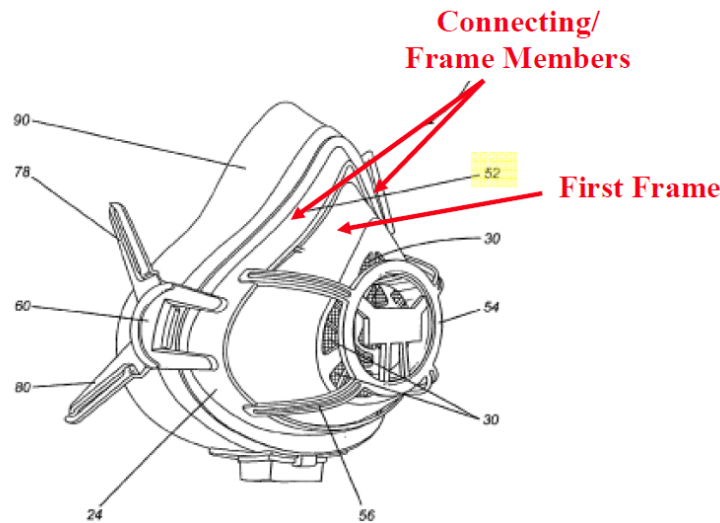
An example of this feature is illustrated in Figures 6 and 8 of the '061 patent, which show how elongate frame members 450 interlock with protrusions 442 and enclose frame 414 to prevent rotation:



Ex. 1101, Figs. 6 and 8 (annotated); *see id.*, 8:38-46 (explaining that “elongated frame members 450 interlock with respective protrusions 442”). As noted in Section II.A (*supra*), the Petition mistakenly shaded protrusions 442 as being part of skeleton frame 212, when protrusions 242 are actually part of the cushion/frame sub-assembly 230, as shown above. *See* Petition, pp. 13 and 18.

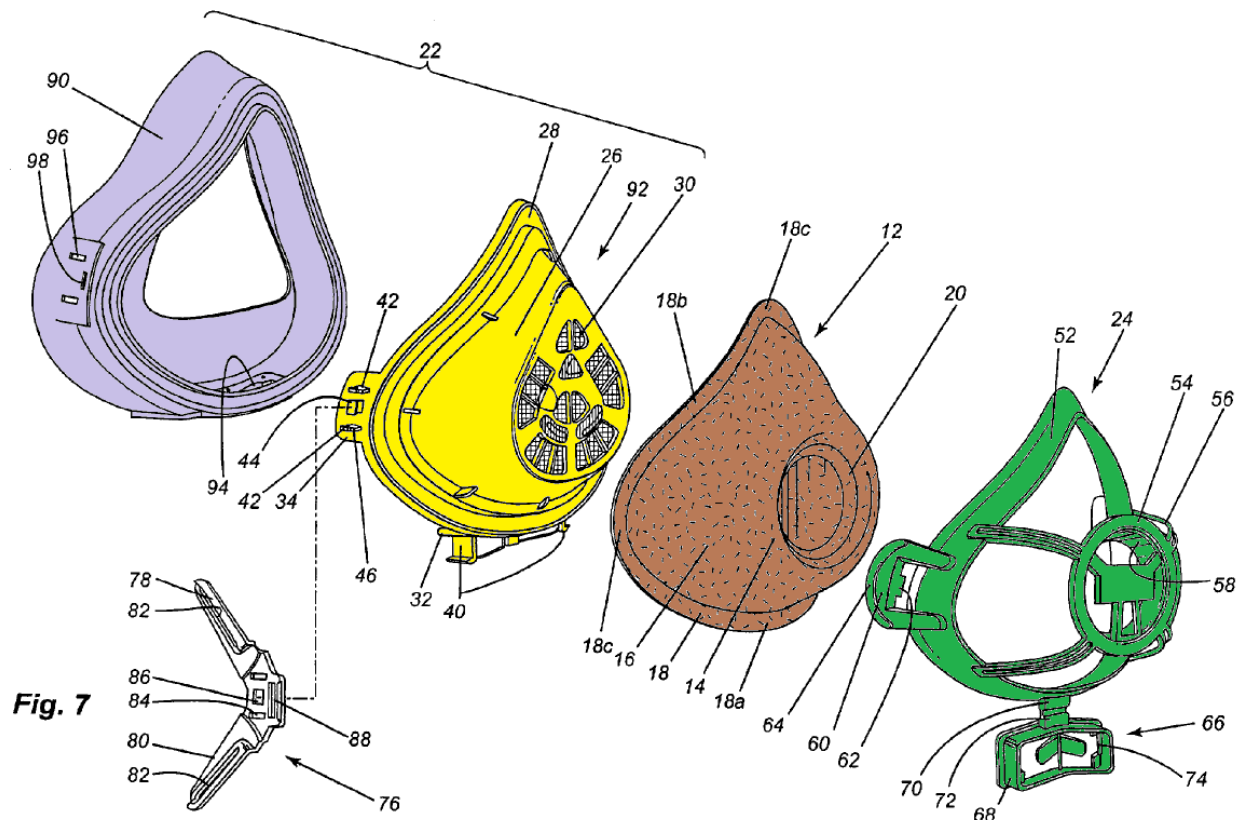
In any event, the Petition concedes that “Lovell ... does not expressly disclose the connecting members or elongated frame members” because the claims recite the elongated frame members “at least partially bounding the separate

opening,” and Lovell does not have a “separate opening.” Petition, p. 51. Instead, the Petition erroneously relies on Gelinas as purportedly disclosing a separate opening and its associated elongated frame members, as shown below in an annotated figure copied from the Petition.



Annotated Figure 2 of Gelinas (from page 52 of Petition)

Petition, p. 52. Gelinas’s purported “elongate frame members,” however do not disclose the feature that is missing from Lovell. Specifically, the claims require that the elongated frame members “include contact points with the first frame to prevent rotation of the first frame with respect to the second frame” (see claims 83 and 89) (emphasis added), but as shown below, Gelinas’s purported elongated frame members (upper portions of green cover 24) do not contact the purported first frame (yellow):



Ex. 1104, FIG. 7. Instead, the purported frame members contact the flange portion 18 of filter 12 (brown), as explained by Gelinas at paragraph 39:

In the second position, continuous surface 28 of facepiece 22 is complimentary with continuous surface 53 of cover 24 for sealingly engaging therebetween flange portion 18 of filter 12. In fact, flange portion 18 of filter 12 is compressed against continuous surface 28 of facepiece 22 by cover 24 thereby forming an airtight seal between facepiece 22 and filter 12.

Ex 1104, ¶39.

The only portions of cover 24 that appear to contact the purported first frame (yellow) are Gelinas's latches 60 and the securing member 66, but the Petition did

not identify these elements as disclosing elongated frame members and did not propose that Lovell's mask be modified to include the features. Moreover, the latches 60 and securing member 66 do not disclose "elongated frame members" because they are not "connecting the upper member and lower member and at least partially bounding the separate opening," as required by claims 82 and 89.

Importantly, regardless of Gelinas's teaching, the primary reference (Lovell) is inconsistent with Petitioner's theory. Even if one modified Lovell as Petitioner proposes to place a "separate opening located between the annular opening and the upper member" to purportedly form "elongated frame members" at the sides of the separate opening, the modified mask would still not include elongated frame members that include "contact points with the first frame to prevent rotation of the first frame with respect to the second frame" (as required by claims 83 and 89):

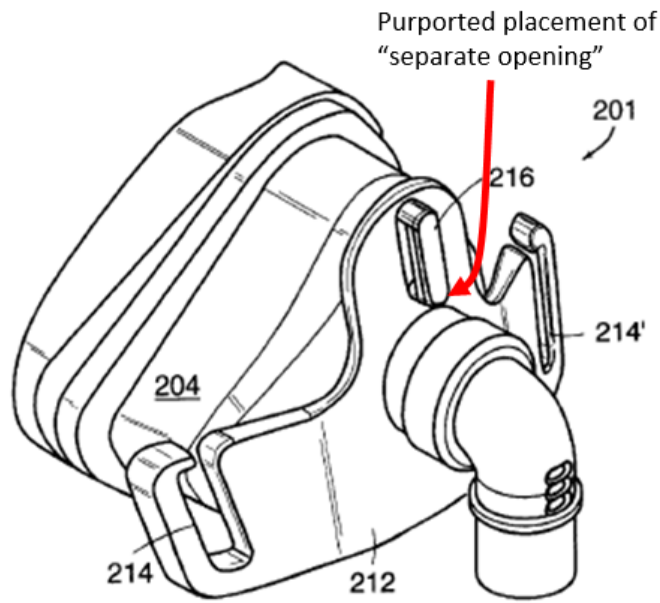


FIG. 9

Ex. 1102, FIG. 9 (annotated). Indeed, an exploded view (below) of Lovell's mask assembly shows how Lovell's "retainer 12 is contoured such that it approximately matches the external curvature of the contoured shell 4." *Id.*, 5:65-66, 9:44-46.

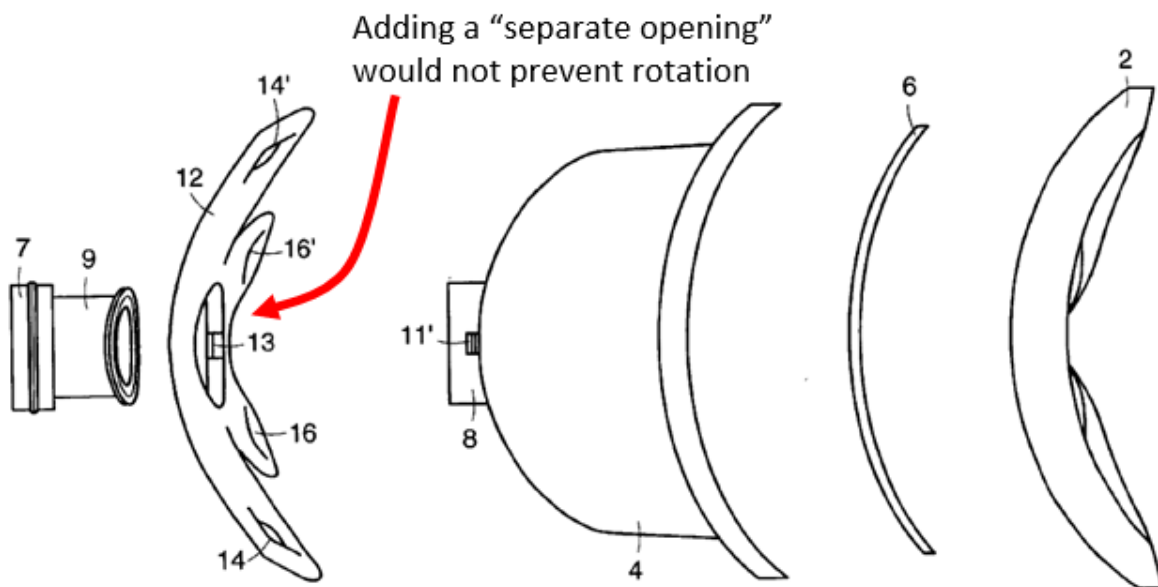


FIG. 2C

Id., FIG. 2C (annotated). But for the presence of outwardly protruding inlet 8, the convex surface of Lovell's retainer and the corresponding concave surface of Lovell's shell would move freely over each other like a ball and socket, and adding an opening to Lovell's retainer would not somehow "prevent rotation" of Lovell's retainer and shell. Rather, Lovell explains that the "particular angular orientation" between the two components is maintained by "two tabs 211, 211' included on the inlet 208 [that] mate with two slots 213, 215 formed in the retainer 212." *Id.*, 9:43-46, Figures 10A-B; *see also* FIG. 2C.

In summary, Gelinas's purported "elongated frame members" do not include "contact points with the first frame" as claims 83 and 89 require, and the features of Gelinas's mask that do prevent rotation are not "elongated frame members" (and the Petition never proposed that the rotation-prevention features be added to Lovell's mask). And even if Lovell's mask assembly were modified as Petitioner proposed by adding a separate opening in Lovell's retainer, the elongated frame members purportedly created by adding the separate opening would still not prevent rotation of the purported first and second frames, as claims 83 and 89 require.

For these reasons, Petitioner has not met its burden of showing a reasonable likelihood of the unpatentability of claims 83 and 89, and the Board should deny

inter partes review of these claims under the only proposed ground of unpatentability presented in the petition.

VII. A PERSON OF ORDINARY SKILL WOULD NOT HAVE BEEN MOTIVATED TO LOOK TO GELINAS TO MAKE A COMBINATION WITH LOVELL

As previously described, the Petition relies upon a proposed modification of Lovell based upon a disclosure in Gelinas, but the Petition assumes without any explanation that a POSITA would have already been aware of Gelinas when contemplating Lovell's mask for positive airway pressure therapy. Federal Circuit precedent explains that this threshold issue cannot be ignored, and Petitioner had a burden to show why a POSITA would have been motivated to even look to Gelinas's teaching given that Lovell's mask was directed to the distinct task of delivering pressurized gas to a patient for the treatment of a sleep disorder. *See WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1337 (Fed. Cir. 2016). Indeed, in *WBIP*, the court identified this same flaw:

[T]oo often the obviousness analysis is framed as an inquiry into whether a person of skill, with two (and only two) references sitting on the table in front of him, would have been motivated to combine (or, in [challenger's] view, could have combined) the references in a way that renders the claimed invention obvious. The real question is whether that skilled artisan would have plucked one reference out of the sea of prior art [] and combined it with conventional [] elements to address some need present in the field. Whether a skilled artisan

would be motivated to make a combination includes whether he would select particular references in order to combine their elements.

Id.

Contrary to the requirements of *WBIP*, the Petition did not identify any need present in Lovell's mask, let alone rationale that would have motivated a POSITA to look to Gelinas's device, which is plainly unrelated to delivering pressurized gas to a patient for the treatment of a sleep disorder. For at least this reason, the Petition failed to set forth a *prima facie* case of obviousness.

Furthermore, the Petition ignores the unrelated nature of Gelinas's device as compared to the subject matter of the '061 patent. The '061 patent is directed to various types of masks that are used to deliver pressurized gas to a patient for the treatment of a sleep disorder, and a POSITA would not have considered Gelinas, which is directed to masks that filter dust and other air contaminants from a work environment. Federal Circuit precedent explains that two tests separately qualify a secondary reference as being analogous and therefore permissible in an obviousness determination:

- (1) Whether the art is from the same field of endeavor, regardless of the problem addressed, or
- (2) If the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved.

Biago, 381 F.3d at 1325 (“References within the statutory terms of 35 U.S.C. § 102 qualify as prior art for an obviousness determination only when analogous to the claimed invention.”). Gelinas fails both of these tests.

Regarding the first test (i.e., whether or not Gelinas is “from the same field of endeavor”), Petitioner suggests that the relevant field is “facial breathing masks,” but Petitioner selected this field by mere conclusion without any supporting evidence, and the selected field is unjustifiably broad. Indeed, the Petition appears to define the field of endeavor as an afterthought, after having asserted that Gelinas falls within the same field of endeavor as the ’061 patent:

Moreover, a person of skill also would have looked at prior art respirator masks, such as Gelinas, when designing a CPAP mask. *Id.* ¶¶ 58-59. Gelinas is from the same field of endeavor, namely facial breathing masks, and was submitted as relevant prior art during the prosecution of the ’061 patent. *See* Ex. 1101 at 1-12. Even if it were determined that Gelinas is not from the same field of endeavor, the second frame 24 disclosed in Gelinas is pertinent to the same problem of providing access to an underlying frame in a two-frame arrangement, as explained further below.

Petition, p. 30 (emphasis added). The Petition provides no analysis regarding how Petitioner selected “facial breathing masks” as the field of endeavor, and Mr. Eaton’s testimony does not provide the requisite underlying facts or data.

This selection of “facial breathing masks” as the field of endeavor for the ’061 patent is peculiar and inconsistent with the intrinsic evidence, especially because the ’061 patent explicitly states that its “FIELD OF THE INVENTION” is a patient interface for treating sleep disordered breathing (SDB):

The present invention relates to a method and apparatus for assembling a patient interface for use in treatment of sleep disordered breathing (SDB) such as obstructive sleep apnea (OSA). In particular, the present invention relates to a method and apparatus for securing a face-contacting portion of a patient interface, such as a cushion, to a frame or shell of the patient interface.

Ex. 1101, 1:15-24. Indeed, not only is the ’061 patent’s FIELD OF THE INVENTION directed to patient interfaces for treating SDB, but the preamble of every single independent claim of the ’061 patent recites “A mask assembly for treatment of sleep disordered breathing by delivering a flow of pressured gas to a patient, the mask assembly comprising:” Ex. 1101, claims 1, 9, 17, 32, 51, 58, 65, 74, 81. The ’061 patent claim preambles are particularly relevant because *In re Biago* construed a claim preamble in a patent to determine whether a prior art reference was directed to the same field of endeavor and therefore would be analogous. *In re Biago*, at 1325 (construing a preamble that recites “A hair brush”

and determining whether a document disclosing a prior art toothbrush would be a “hair brush” and therefore analogous art).

And it is not as if Petitioner considers that all CPAP masks belong to the field of “breathing apparatuses and interface masks” under which the ’061 patent purportedly falls, because Mr. Eaton’s declaration admits that “Lovell and Gunaratnam are from the same field of CPAP breathing masks.” Ex. 1106, ¶58 (emphasis added). If the field of endeavor for Lovell and Gunaratnam should be “CPAP breathing masks,” then the ’061 patent would also have that same field of endeavor. Indeed, similar to the ’061 patent’s field of invention (quoted above), Lovell and Gunaratnam identify masks for treating OSA in their technical field statements:

The present invention relates to respiratory apparatus and more specifically to nasal masks useful for providing pressurized air or therapeutic gas to a patient suffering from an airflow limitation or other respiratory ailment.

Ex. 1102 (“Lovell”), 1:4-9.

The invention relates to a method and apparatus for connecting a nasal or full-face mask cushion to a mask frame, where the mask is suitable for the delivery of breathable gases to a patient for the treatment of sleep disordered breathing (SDB).

Ex. 1103 (“Gunaratnam”), 1:20-25

For all of these reasons, Petitioner’s characterization that the ’061 patent disclosure is directed to a “field” that involves all breathing apparatuses and interface masks (e.g., swimming snorkles, firemen masks, etc.) is not credible and is not supported by the intrinsic evidence. The ’061 patent specification provides a straightforward explanation that the proper field of invention here is masks for providing pressurized air to a patient to treat OSA. Gelinas is not analogous, and Petitioner fails to explain why a POSITA would have been motivated to even look to Gelinas for a proposed combination with any mask that already provided pressurized air to a patient to treat OSA.

Also, an additional approach to determine whether a patent and reference are from the same field of endeavor is whether the reference describes technology that has “the same function and structure” as the technology in the patent. MPEP 2141.01(a)(II); *Biago*, 381 F.3d at 1324 (“This test for analogous art requires the PTO to determine the appropriate field of endeavor by reference to ... the embodiments, function, and structure of the claimed invention.”); *see In re Deminski*, 796 F.2d 436, 442 (Fed. Cir. 1986); *In re Ellis*, 476 F.2d 1370, 1372 (C.C.P.A. 1973) (discussing the “structural similarities and the functional overlap” between the devices) (emphasis added). This additional approach further shows that Gelinas is not analogous art.

Regarding functional similarities, the '061 patent and Gelinas are plainly directed to different functions. As discussed above, the function of the '061 patent is to create a pressurized breathing chamber for treating “sleep disordered breathing (SDB) such as obstructive sleep apnea (OSA).” Ex. 1101, 1:16-24. On the other hand, the function of Gelinas is to provide a “safety device [to be] used by people working in air contaminated environments,” in order “to protect a wearer from particulate, dust, smoke, oil, fumes and/or gases or vapors.” Ex. 1104, ¶¶2-3.

Regarding structural similarities, the '061 patent and Gelinas have significantly different mask structures, stemming from their different functions. Both describe masks that have a face-contacting material and some sort of structure to hold that material to the face, but most everything forward in the masks differs, and it is these differing features on which Petitioner relies. The fundamental differences in these masks arises from different air supplies and different multi-part structures, as explained below.

Conduit air supply vs. Environmental air supply: Pressurized air must be supplied to the '061 patent's mask assembly to maintain a pressurized breathing chamber, which is provided through a singular annular opening by an elbow that is connected to a conduit supplying gas from a remote source. These components must seal at the opening to ensure that the breathing chamber remains pressurized. Gelinas, on the other hand, has no conduit, has no elbow, and doesn't have a single

opening for receiving any such pressurized air from a remote source. Rather, Gelinas is designed to filter contaminated air directly from a dirty environment that surrounds the mask and therefore includes multiple openings (at least 16) that are spread over a wide portion of the front of the mask to maximize air intake. Moreover, there is no seal at these openings as there is at the '061 patent's air intake

Different multi-part structures: Gelinas discloses a filter 12 that covers the entire surface of the mask in order to filter air, and a cover 24 that overlies the filter to hold the filter in place. Headgear is attached to the facepiece 22 that is on the side of the filter 12 that is closest to the user. The mask in the '061 patent, on the other hand, includes no filter (let alone one that covers the entire surface of the mask). Moreover, the '061 patent's mask includes its headgear attachment points on its skeleton frame 212, which is the portion of the mask furthest from the user, not closest. Further, the cushion/frame sub-assembly 230 in the '061 patent includes an annular wall 240 that protrudes through an aperture in the skeleton frame 212, while Gelinas has no such portion of its mask that protrudes through any other portion. And finally, the headgears are different between the two devices. Gelinas has a structure in which the headgear connects only to the sides of the mask, while the '061 patent's mask includes not only side attachments

(again, connected to a different part of the mask) but also provides attachment points for forehead support. Ex. 1101, 7:30-33; Ex. 1104, Fig. 1.

Regarding the second test (i.e., whether the reference is “reasonably pertinent to the particular problem with which the inventor is involved”), the Petition contends that Gelinas is pertinent to the same problem as the ’061 patent, but never explains how it determined that the problem was one “with which the inventor is involved,” as required by *In re Biago*. 381 F.3d at 1325. The Federal Circuit has explained that a reference is reasonable pertinent to the problem with which the inventor is involved if it “would have commended itself to an inventor’s attention in considering his problem” and “has the same purpose as the claimed invention”:

A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor’s endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem. Thus, the purposes of both the invention and the prior art are important in determining whether the reference is reasonably pertinent to the problem the invention attempts to solve. If a reference disclosure has the same purpose as the claimed invention, the reference relates to the same problem, and that fact supports use of that reference in an obviousness rejection. An inventor may well have been motivated to consider the reference when making his invention.

If it is directed to a different purpose, the inventor would accordingly have had less motivation or occasion to consider it.

In re Clay, 966 F.2d 656, 659 (Fed. Cir. 1992) (emphasis added); *see In re Klein*, 647 F.3d 1343, 1348 (Fed. Cir. 2011). The Petition (at page 30) contends that “Gelinas is pertinent to the same problem of providing access to an underlying frame in a two-frame arrangement,” but the Petition selected this “problem” by mere assumption without providing any underlying facts or data in support. Mr. Eaton similarly concludes that “Gelinas is pertinent to the same problem of providing access to an underlying frame in a two-frame arrangement,” without explaining why this purported problem would be that “with which the inventor is involved.” Ex. 1105, ¶58; *Clay*, 966 F.2d at 659.

The “particular problem with which the inventor is involved,” however, does not need to be formed by mere conclusion, and can be determined by reading the ’061 patent, which expressly mentions multiple “problems”:

- “difficulty with alignment and assembly,”
- “difficulty with adhesive, e.g., gluing, that does not allow disassembly for cleaning,”
- “over molded [sic, molded] parts that can have points of ingress that cannot be easily cleaned,”
- “interface methods that can be difficult to use on large frames, e.g. full-face mask, and can have misalignment issues.”

Ex. 1101, 1:52-64. None of these problems specify “providing access to an underlying frame,” as Petitioner suggests. Moreover, Petitioner used Gelinas not for any feature related to alignment/assembly/disassembly/cleaning/misalignment, but for an opening in a frame to provide access to an underlying vent.

In summary, for art to be analogous, it must either be from the same “field of endeavor,” or must be “reasonably pertinent to the particular problem with which the inventor is involved,” and Gelinas fails both these tests. The ’061 patent repeatedly explains how its field of endeavor relates to pressurized masks for treating Sleep Disordered Breathing (SDB), and Petitioner provides no analysis to reinforce its contention that the field of endeavor is “breathing apparatuses and interface masks.” Moreover, the ’061 patent mask and Gelinas have different functions (treating SDB vs. filtering particles out of the air) and different structures reflecting those very different functions. And finally, Petitioner never explained how it established that the problem that the inventor of the ’061 patent was trying to address was “providing access to an underlying frame.” For at least these reasons, the Petitioner failed to establish a *prima facie* case of obviousness. *Clay*, 966 F.2d at 659-60.

VIII. CONCLUSION

For the foregoing reasons, Petitioner has not met its burden of showing a reasonable likelihood of the unpatentability of claims 17, 18, 20–23, 26–30, 32, 33,

35–38, 41–46, 48–50, and 81–91, and the Board should deny *inter partes* review of these claims under the only proposed ground of unpatentability.

Respectfully submitted,

Date: April 27, 2017

/Michael T. Hawkins/
Michael T. Hawkins, Reg. No. 57,867
Attorney for Patent Owner,
ResMed Limited

Customer Number 26191
Fish & Richardson P.C.
Telephone: (612) 337-2569
Facsimile: (612) 288-9696

CERTIFICATION UNDER 37 C.F.R. § 42.24(d)

Under the provisions of 37 C.F.R. § 42.24(d), the undersigned hereby certifies that the word count for the foregoing Patent Owner Preliminary Response to Petition totals 10,649, which is less than the 14,000 allowed under C.F.R. § 42.24(b)(1).

Respectfully submitted,

Date: April 27, 2017

/Michael T. Hawkins/
Michael T. Hawkins, Reg. No. 57,867
Attorney for Patent Owner,
ResMed Limited

Customer Number 26191
Fish & Richardson P.C.
Telephone: (612) 337-2569
Facsimile: (612) 288-9696

CERTIFICATE OF SERVICE

Pursuant to 37 CFR §§ 42.6(e)(4) and 42.205(b), the undersigned certifies that on April 27, 2017, a complete and entire copy of this Patent Owner's Preliminary Response was provided via email to the Petitioner by serving the correspondence email address of record as follows:

Brenton R. Babcock
Benjamin J. Everton
Knobbe, Martens, Olson & Bear, LLP
2040 Main Street, 14th Floor
Irvine, CA 92614

Email: BoxFPH538-2@knobbe.com

 /Jessica K. Detko/
Jessica K. Detko
Fish & Richardson P.C.
60 South Sixth Street, Suite 3200
Minneapolis, MN 55402
(612) 337-2516