

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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FISHER & PAYKEL HEALTHCARE LIMITED,  
Petitioner,

v.

RESMED LIMITED,  
Patent Owner.

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Case IPR2017-00634  
Patent 8,944,061 B2

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Before RICHARD E. RICE, BARRY L. GROSSMAN, and  
JAMES J. MAYBERRY, *Administrative Patent Judges*.

RICE, *Administrative Patent Judge*.

DECISION  
*Denying Inter Partes Review*  
*37 C.F.R. § 42.108*

## I. INTRODUCTION

### A. Background

Fisher & Paykel Healthcare Limited (“Petitioner”) filed a Petition (Paper 1, “Pet.”) requesting an *inter partes* review of claims 17, 18, 20–23, 26–30, 32, 33, 35–38, 41–46, 48–50, and 81–91 (the “challenged claims”) of U.S. Patent No. 8,944,061 B2 (Ex. 1101, “the ’061 Patent”). Petitioner supported the Petition with a declaration from Jason Eaton, P.E. (Ex. 1105). ResMed Limited (“Patent Owner”) filed a Preliminary Response to the Petition (Paper 7, “Prelim. Resp.”).

Under 35 U.S.C. § 314, an *inter partes* review may not be instituted “unless . . . 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). Upon considering the Petition, including the evidence filed therewith, and the Preliminary Response, we determine that Petitioner has not shown a reasonable likelihood that it would prevail with respect to any of the challenged claims.

Accordingly, we do not institute an *inter partes* review.

### B. Related Matters

The parties identify a related federal district court case involving the ’061 Patent: *Fisher & Paykel Healthcare Ltd. v. ResMed Corp.*, Case No. 3:16-cv-02068-DMS-WVG (S.D. Cal.). Pet. 8; Paper 4, 2. The parties also identify two additional petitions filed by Petitioner requesting *inter partes* review of the ’061 Patent. Pet. 8; Paper 4, 2; *see* IPR2017-00632, Paper 1; IPR2017-00635, Paper 1.

*C. The '061 Patent*

The '061 Patent, titled “Cushion to Frame Assembly Mechanism,” issued on February 3, 2015, and claims priority from an application filed on January 12, 2006, and two provisional applications filed on October 14 and November 9, 2005, respectively. Ex. 1101, (45), (54), (60), (63). The patent relates to a patient interface for use in treatment of sleep disordered breathing such as obstructive sleep apnea, and, in particular, to an apparatus for securing a face-contacting portion of a patient interface, such as a cushion, to a frame or shell of the patient interface. *Id.* at 1:17–23.

Petitioner provides the following annotated version of Figure 3 of the '061 Patent illustrating mask assembly 210:

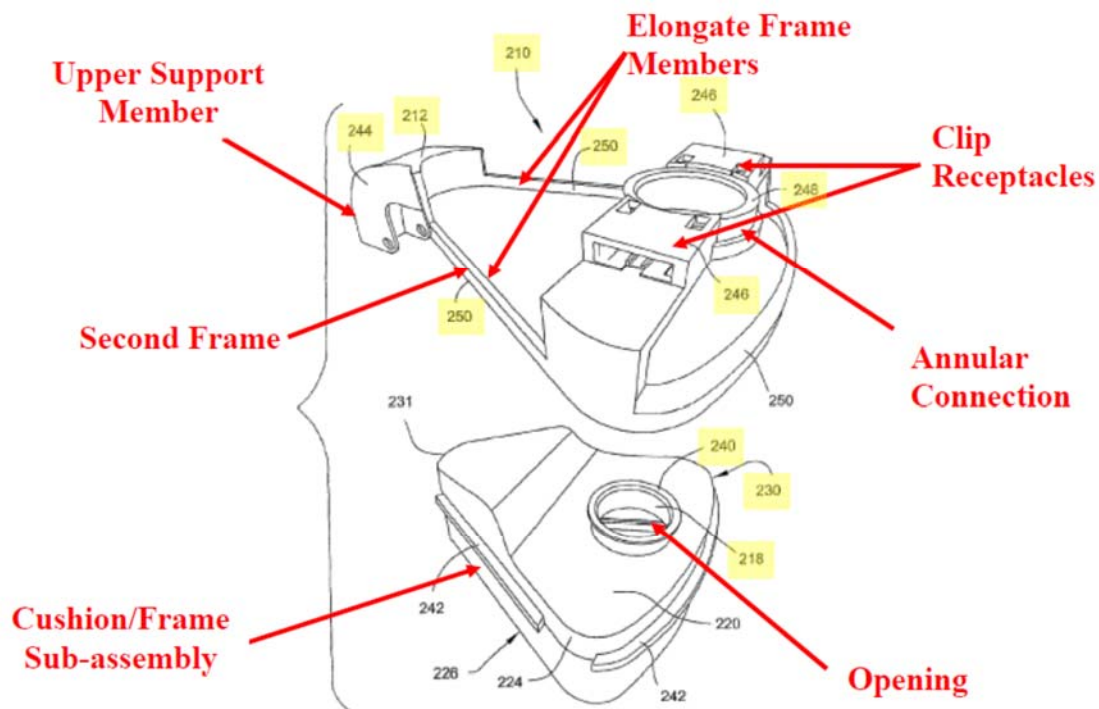


Fig. 3

Pet. 17; Ex. 1101, Fig. 3. As shown in annotated Figure 3 above, mask assembly 210 includes skeleton frame 212 (labeled “Second Frame”), which

is adapted to interlock removably with cushion/frame sub-assembly 230. Ex. 1101, 6:53–58. Cushion/frame sub-assembly 230 comprises an integrally molded frame and cushion. *Id.* at 6:59–60. The cushion/frame assembly includes opening 218, which is surrounded by annular wall 240. *Id.* at 6:64–67, 7:15–16, Fig. 3.

Petitioner’s annotated version of Figure 4 of the ’061 Patent, reproduced below, illustrates skeleton frame 212 engaged with cushion/frame sub-assembly 230:

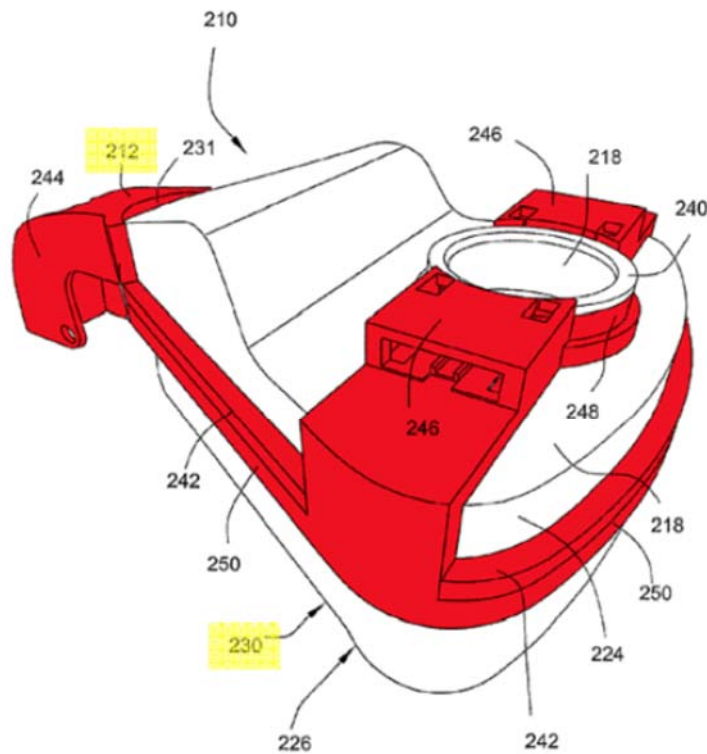


Fig. 4

Pet. 18; Ex. 1101, Fig. 4. As shown in the annotated Figure 4 above, annular wall 240 of the cushion/frame sub-assembly interlocks with annular elbow connection seal 248 of skeleton frame 212. Ex. 1101, 7:22–25, Fig. 4. The annular elbow connection seal of skeleton frame 212 is adapted to engage an

inlet conduit, e.g., an elbow. *Id.* at 7:15–16. Skeleton frame 212 includes upper support member 244 adapted to support a forehead support and lower headgear clip receptacles 246 adapted to engage clips on straps of a headgear assembly. *Id.* at 7:11–14.

The challenged claims include independent claims 17, 32, and 81. Each of these claims recites, *inter alia*, a “first frame” and a “second frame.” Claims 17 and 81 are illustrative of the claimed subject matter, and are reproduced below:

17. A mask assembly for treatment of sleep disorder breathing by delivering a flow of pressurized gas to a patient, the mask assembly comprising:

a first frame made of first material;

a cushion connected to the first frame, the cushion being adapted to form a seal around a patient’s nose and mouth and being made from a second material that is more flexible than the first material; and

a second frame adapted to constrain the first frame, the second frame comprising an upper support member that supports a forehead support, two lower headgear clip attachments engaged with clips provided to straps of a headgear assembly, an annular connection adapted to engage an elbow of an inlet conduit and an opening located between the annular connection and the upper support member, the opening providing access to the first frame.

Ex. 1101, 20:58–21:7.

81. A mask assembly for treatment of sleep disorder breathing by delivering a flow of pressurized gas to a patient, the mask assembly comprising:

a first frame made of first material;

a cushion connected to the first frame, the cushion being adapted to form a seal around the patient’s nose and mouth and being made from a second material that is more flexible than the first material, the first frame and the cushion together forming a breathing chamber; and

a second frame adapted to constrain the first frame, the second frame comprising an upper member, a lower member with an annular opening adapted to allow an inlet conduit to provide pressurized gas to the patient, 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.

*Id.* at 27:13–31.

#### *D. The Asserted Ground*

Petitioner challenges claims 17, 18, 20–23, 26–30, 32, 33, 35–38, 41–46, 48–50, and 81–91 under 35 U.S.C. § 103, as obvious over Lovell,<sup>1</sup> Gunaratnam,<sup>2</sup> and Gelinas.<sup>3</sup> Pet. 10.

## II. ANALYSIS

### *A. Level of Skill in the Art*

Petitioner asserts that a person of ordinary skill in the art at the time of the invention (“POSITA”) “would have at least a bachelor’s degree in mechanical engineering, biomedical engineering, or other similar type of engineering degree, combined with at least two years of experience in the field of masks, respiratory therapy, patient interfaces or relevant product design experience.” Pet. 21 (citing Ex. 1105 ¶¶ 24–26). Patent Owner does not dispute the level of skill in the art asserted by Petitioner. Based on the Petition and Preliminary Response, we are persuaded that the level of skill in the art asserted by Petitioner is reasonable, and we adopt it for purposes of this Decision.

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<sup>1</sup> US 6,631,718 B1, iss. Oct. 14, 2003 (Ex. 1102, “Lovell”).

<sup>2</sup> US 6,796,308 B2, iss. Sept. 28, 2004 (Ex. 1103, “Gunaratnam”).

<sup>3</sup> US 2003/0029454 A1, pub. Feb. 13, 2003 (Ex. 1104, “Gelinas”).

*B. Claim Construction*

In an *inter partes* review, the Board gives claim terms in an unexpired patent their broadest reasonable interpretation in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *see Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under that standard, a claim term generally is given its ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). While our claim interpretation “cannot be divorced from the specification and the record evidence,” *see Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015) (quoting *In re NTP, Inc.*, 654 F.3d 1279, 1288 (Fed. Cir. 2011)), we must be careful not to import limitations from the specification that are not part of the claim language, *see SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

The parties advance competing claim constructions for “engage” as used in the phrases “an annular connection adapted to engage an elbow of an inlet conduit” (claim 17), “the elbow engages the second frame” (claim 50), and “the inlet elbow engages the second frame” (claim 91). *See* Pet. 12–14; Prelim. Resp. 14–19. Petitioner also proposes an explicit construction for the term “sealingly connected” as used in the phrase “the annular opening and the elbow are sealingly connected” (claims 46 and 48). Pet. 14–16. We determine, however, that no explicit interpretation of any claim term is

required for the purposes of this Decision. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

### *C. Asserted Obviousness*

A claim is unpatentable for obviousness under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). In analyzing the obviousness of a combination of prior art elements, it can be important to identify a reason that would have prompted one of skill in the art to combine the elements in the way the claimed invention does. *Id.* The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness, i.e., secondary considerations, if in evidence. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

Petitioner challenges claims 17, 18, 20–23, 26–30, 32, 33, 35–38, 41–46, 48–50, and 81–91 under 35 U.S.C. § 103 as obvious over Lovell, Gunaratnam, and Gelinas. *See supra* Section I.D. For the reasons discussed below, Petitioner has not shown a reasonable likelihood that it would prevail with respect to any of the challenged claims.

#### *1. Overview of Lovell*

Petitioner's annotated version of Figure 10A of Lovell, reproduced below, depicts nasal mask 201 having retainer 212, which connects to inlet 208 of shell 204. Pet. 24; Ex. 1102, 9:34–39, Fig. 10A.



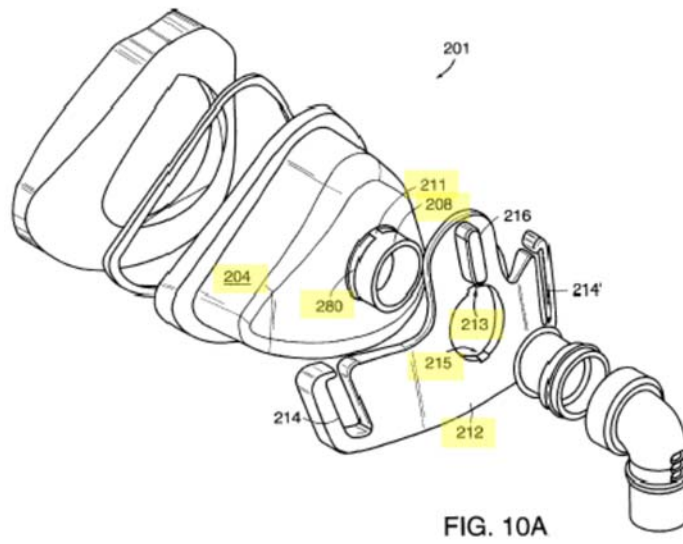


Figure 10A is a schematic exploded perspective view of the components of nasal mask 201. Ex. 1102, 4:3–4, 9:34–36. “The retainer 212 is disposed about the inlet 208 to facilitate retention of the mask 201 on a user.” *Id.* at 9:43–44. “The retainer aperture and the inlet 208 are generally sized in an interference fit so that the retainer 212 is properly retained by the cooperation of the tabs 211, 211', the slots 213, 215, and the depressed annular region 280 when fully seated against the shell 204.” *Id.* at 9:59–64.

## 2. Overview of Gunaratnam

Gunaratnam discloses nasal masks and full-face masks for delivering breathable gas to a patient. Ex. 1103, Figs. 5a, 5c, 15, 4:19–21, 6:3–4. Petitioner’s annotated versions of Figures 5a and 5c of Gunaratnam, depicting nasal mask frame 160, are reproduced below. Pet. 26; *see* Ex. 1103, 3:6–7, 3:10–12, 4:19–33.

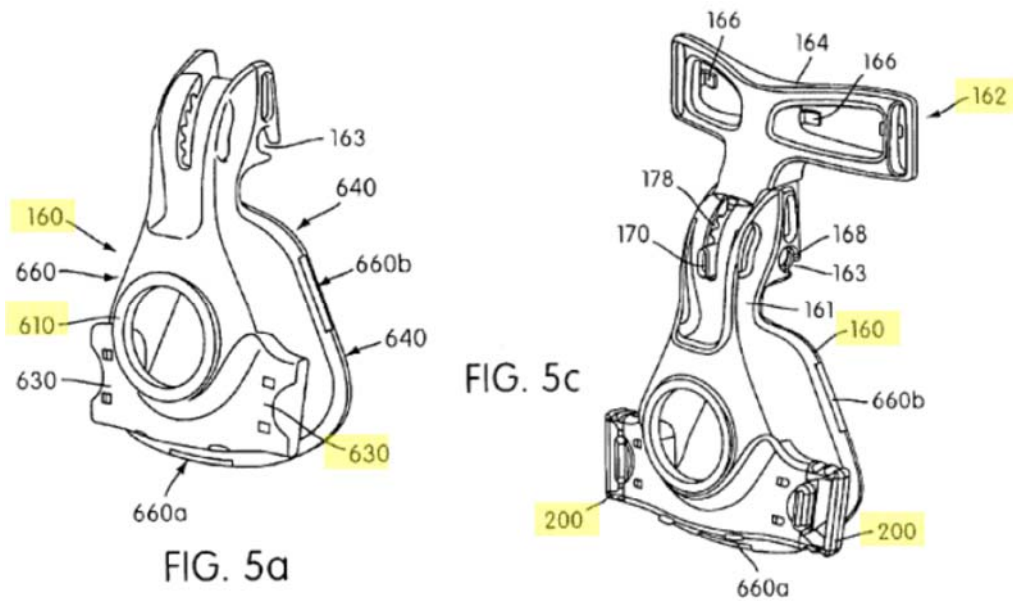


Figure 5a shows a front perspective view of nasal mask frame 160, and Figure 5c shows adjustable forehead support 162 connected to nasal mask frame 160. Ex. 1103, 3:6–9, 10–12, 4:46–48. Nasal mask frame 160 incorporates gas inlet aperture 610 for connection to a gas-delivery conduit (not shown in the figures above). *Id.* at 4:23–24.

Petitioner's annotated version of Figure 15 of Gunaratnam, which depicts a full-face mask, is reproduced below. Pet. 27; *see* Ex. 1103, 4:5–6, 6:3–4.

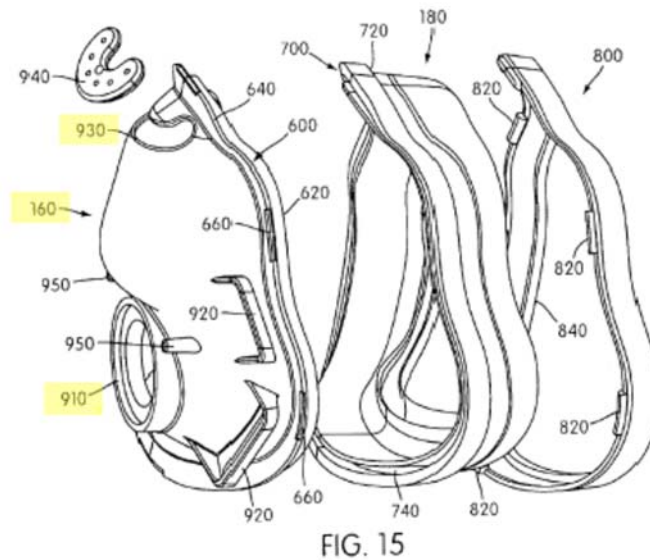
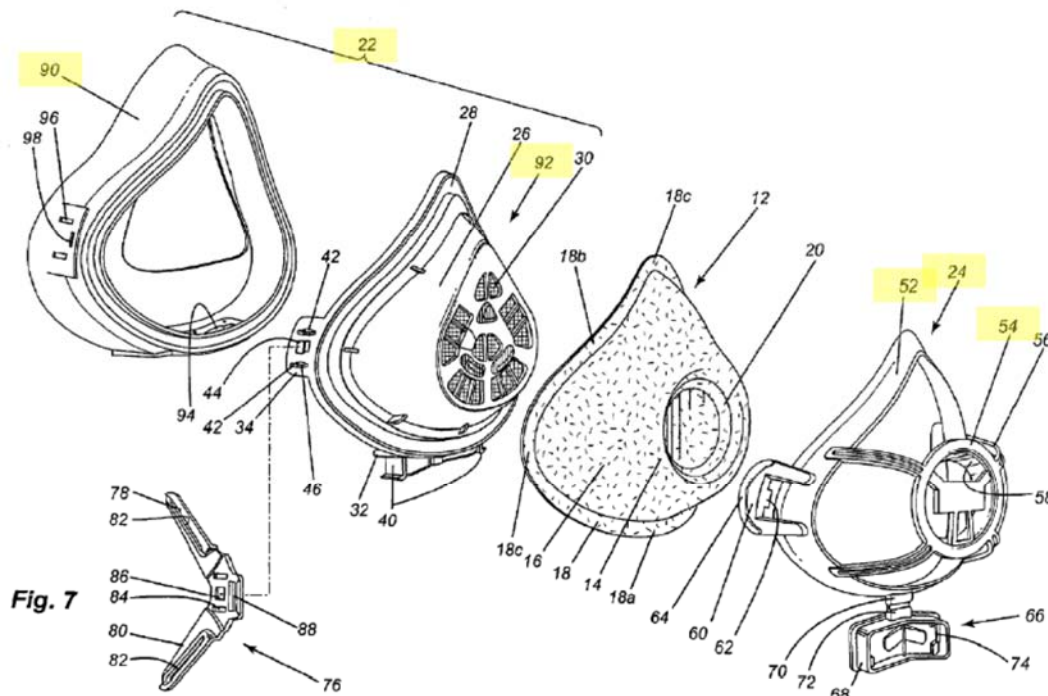


Figure 15 of Gunaratnam depicts full-face mask frame 160, which is adapted to cover both the mouth and nose regions of the patient's face. Ex. 1103, 6:25–26. As shown in the annotated figure above, mask frame 160 includes aperture 930 for receiving air vent 940. *Id.* at 6:25–29. Figure 15 also shows cushion 180 and clip 800. *Id.* at 6:6–7. Clip 800 overlies cushion 180, completely surrounds frame 160, and includes securing tabs 820, which mate with recesses 660 in frame 160. *Id.* at 6:12–13, 19–25.

### 3. Overview of Gelinas

Gelinas discloses full-face respirator 10 including face piece 22, filter 12, and cover 24. Ex. 1104 ¶¶ 24, 26, Fig. 7. Petitioner's annotated version of Figure 7 of Gelinas (*see* Pet. 28) is reproduced below.



As shown in annotated Figure 7 above, cover 24 and face piece 22 define a cup-shaped void area suitable to receive filter 12. Ex. 1104 ¶ 31. “Cover 24 is movable from a first position, in which the void area is opened allowing the installation or removal of filter 12, to a second position, in which cover 24 mates with facepiece 22 and filter 12 is received in the void area.” *Id.* Cover 24 includes peripheral portion 52 and ring 54, which are connected together by branches 56. *Id.* ¶ 32.

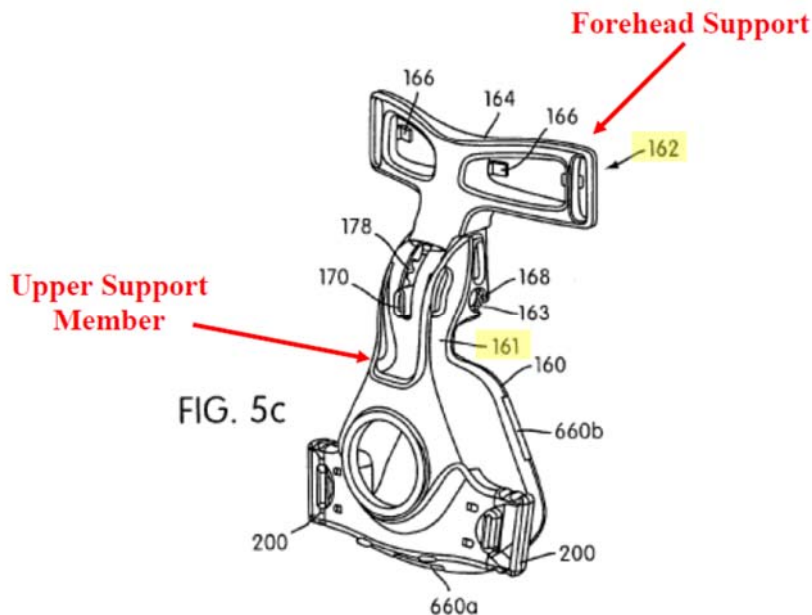
#### 4. Petitioner’s Contentions

Petitioner argues that Lovell teaches nearly all of the limitations of the challenged claims. Pet. 28. With respect to independent claim 17, for example, Petitioner contends that Lovell teaches a mask assembly having a first frame (shell 204) made of a first material; a cushion made from a second material that is more flexible than the first material; and a second frame (retainer 212) including an upper support member (216), two headgear

attachments (214, 214'), and an annular connection (aperture in retainer 212). *Id.* at 28–29. Petitioner concedes, however, that Lovell does not teach several of the claim limitations, which we discuss below.

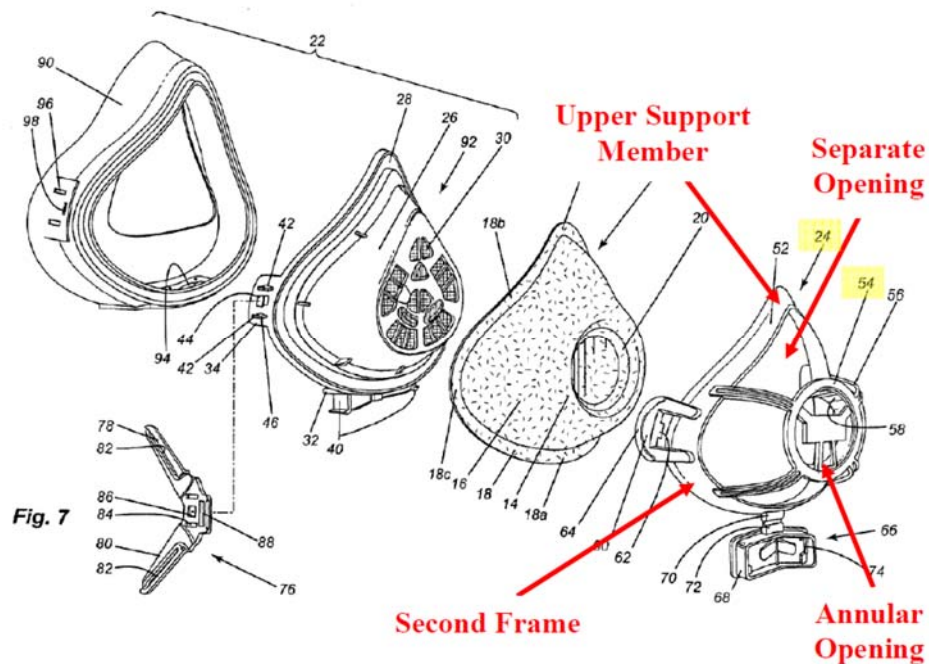
Petitioner concedes that Lovell’s cushion is not adapted to form a seal around the patient’s nose and mouth, as required by independent claim 17 (as well as independent claims 32 and 81). *Id.* at 31. Petitioner contends, however, that a POSITA would have been motivated to modify Lovell’s nasal mask to form a seal around the patient’s nose and mouth, as taught by Gunaratnam and Gelinas, in order to accommodate patients who breathe through their mouth during sleep. *Id.* at 31–33 (citing Ex. 1105 ¶ 64).

Petitioner also concedes that Lovell’s upper support member (216) is not configured to provide forehead support, as required by independent claims 17 and 32, but argues that Gunaratnam cures that deficiency. Pet. 35–36; *see supra* Section I.C. Petitioner provides an annotated version of Gunaratnam’s Figure 5c, reproduced below, to illustrate its argument. *Id.* at 36.



As indicated in annotated Figure 5C above, Petitioner contends that “Gunaratnam describes a frame with an upper support member 161 that supports a forehead support 162, and the forehead support 162 provides direct support to the forehead.” *Id.* at 35–36 (citing Ex. 1103, 4:47–52; Ex. 1105 ¶ 72). Petitioner argues that a POSITA would have been motivated to incorporate Gunaratnam’s forehead support into Lovell’s second frame 212 “to provide additional support in the forehead area and to keep the mask positioned properly on the face.” *Id.* at 36 (citing Ex. 1105 ¶ 75).

Further, Petitioner concedes that Lovell does not expressly disclose an opening/separate opening between the annular connection/annular opening and the upper support member, as required by each of the challenged independent claims. *Id.* at 45. Petitioner relies on Gelinas and Gunaratnam to cure that deficiency. *Id.* at 46–48. Petitioner’s annotated version of Gelinas’s Figure 7 is reproduced below. *See id.* at 46.



Referring to annotated Figure 7, Petitioner asserts that “Gelinas discloses a second frame 24 with a separate opening between an annular opening 54 and an upper support member of the second frame 24.” *Id.* (citing Ex. 1104 ¶¶ 26–32). Petitioner further asserts that a POSITA “would have been motivated to modify the nasal mask of Lovell to be a full-face mask” and that, in converting Lovell’s nasal mask to a full-face mask, “a person of skill would have recognized that the full-face mask would require a gas washout vent to enable CO<sub>2</sub> washout and vent the breathing chamber upon [over-pressurization].” *Id.* at 47 (citing Ex. 1102, 5:36–41; Ex. 1105 ¶¶ 96–97). Petitioner argues that Gunaratnam teaches providing the vent in the nasal bridge region of the mask assembly, and a POSITA “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.* at 48 (citing Ex. 1105 ¶ 98); *see* Ex. 1103, 6:28–29, Fig. 15. Additionally, Petitioner argues that “providing a second frame with a separate opening as in Gelinas would facilitate a more secure connection between the periphery of the second frame (surrounding the second opening) and the first frame, while also minimizing the amount of material in the second frame.” *Id.* (citing Ex. 1105 ¶ 98).

#### 5. Obviousness Analysis

Each of the challenged independent claims requires an opening in the second frame that provides access to the first frame. Independent claim 17 requires, *inter alia*, “a second frame . . . comprising an upper support member that supports a forehead support, . . . an annular connection adapted to engage an elbow of an inlet conduit and an opening located between the

annular connection and the upper support member, the opening providing access to the first frame.” Independent claim 32 requires, *inter alia*,

a second frame . . . comprising an upper support member adapted to assist with forehead support, . . . an annular opening adapted to allow an elbow to provide pressurized gas to the patient, and 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.

And independent claim 81 requires, *inter alia*,

a second frame . . . comprising an upper member, a lower member with an annular opening adapted to allow an inlet conduit to provide pressurized gas to the patient, and a separate opening located between the annular opening and the upper member, the separate opening providing access to the first frame while the mask assembly is fully assembled.

Petitioner has not persuaded us that a POSITA would have combined the teachings of Lovell, Gunaratnam, and Gelinas to achieve an opening in Lovell’s second frame that provides access to the first frame. *See In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (“[T]here must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”). For example, Petitioner has not persuaded us that, in Lovell’s two-frame mask system, adding a vent to the nasal bridge region of the *first* frame would have required forming an opening in the *second* frame for access to the vent through the second frame. Rather, we are persuaded that Lovell’s second frame does not cover the nose bridge region of Lovell’s first frame, and that an opening in the second frame would not have been required for access to a vent in the nasal bridge region of the first frame. *Compare* Pet. 48 (“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.” (citing



Ex. 1105 ¶ 98)), *with* Prelim. Resp. 40 (“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.”).

Patent Owner provides an annotated version of Lovell’s Figure 9, reproduced below, demonstrating persuasively that the nasal bridge region of Lovell’s shell 204 is *not* covered by retainer 212. Prelim. Resp. 39.

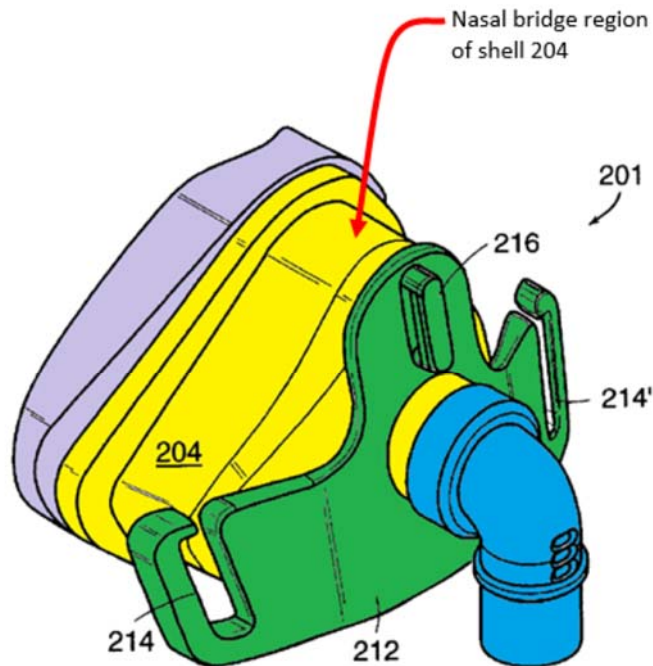


FIG. 9

Annotated Figure 9 above shows shell 204 in yellow and retainer 212 in green. As illustrated in the figure, the nasal bridge region of shell 204 is not covered by retainer 212. Referring to the figure, Patent Owner argues persuasively that a vent could be located in the nasal bridge region of shell 204 without forming a corresponding opening in retainer 212:

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."

*Id.*

Each of the challenged independent claims also requires the location of the opening in the second frame to be between the annular connection/annular opening and the upper support member. Even assuming that adding a gas washout vent to Lovell's first frame would have required forming a corresponding opening in the nasal bridge region of Lovell's second frame, Petitioner has not persuaded us that the combination of Lovell, Gunaratnam, and Gelinas teaches the required location of the opening, i.e., between the annular connection/annular opening and the upper support member.

As discussed above, Petitioner argues that Gunaratnam teaches providing a gas washout vent in the nasal bridge region of the mask assembly. Pet. 47–48. Petitioner does not contend, however, that Gunaratnam teaches an opening in the second frame between the annular connection/annular opening and the upper support member. Rather, Petitioner argues that Gelinas provides that teaching. *See id.* at 48 (arguing that a POSITA "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." (emphasis added)).

We are not persuaded that Gelinas teaches "a separate opening between the annular elbow connection and the upper support member of the second frame," as Petitioner contends. *See id.* Indeed, as discussed further

below, Gelinas does not disclose “an annular elbow connection,” much less teach “a separate opening between the annular elbow connection and the upper support member of the second frame.”

In an annotated version of Gelinas’s Figure 7 (reproduced above), Petitioner identifies the opening in Gelinas’s ring 54 as the “annular opening.” Pet. 46. Ring 54, however, is neither “an annular connection adapted to engage an elbow of an inlet conduit,” as required by claim 17, nor an annular opening adapted to allow an elbow/inlet conduit to provide pressurized gas to the patient, as required by claims 32 and 81. Petitioner’s argument that Gelinas, nevertheless, teaches “a separate opening between the annular elbow connection and the upper support member of the second frame” fails to analyze properly (1) the scope and content of the prior art and (2) any differences between the claimed subject matter and the prior art, as required to show obviousness. *See Graham*, 383 U.S. at 17–18.

Finally, Petitioner’s argument that “providing a second frame with a separate opening as in Gelinas would facilitate a more secure connection between the periphery of the second frame (surrounding the second opening) and the first frame, while also minimizing the amount of material in the second frame,” is conclusory and unpersuasive. *See* Pet. 48 (citing Ex. 1105 ¶ 98). Petitioner does not explain sufficiently why the separate opening would provide a more secure connection or use less material. *See* Prelim. Resp. 40–43.

After considering the Petition and the Preliminary Response, and for the reasons discussed above, we are not persuaded that Petitioner has established a reasonable likelihood of prevailing on its contention that independent claims 17, 32, and 81 would have been obvious over Lovell,

Gunaratnam, and Gelinas. We reach the same conclusion with respect to dependent claims 18, 20–23, 26–30, 33, 35–38, 41–46, 48–50, and 82–91, for the same reasons.

### III. CONCLUSION

For the reasons given, Petitioner has not shown a reasonable likelihood that it would prevail in establishing unpatentability of any of challenged claims 17, 18, 20–23, 26–30, 32, 33, 35–38, 41–46, 48–50, and 81–91.

### IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that that Petitioner's Petition for an *inter partes* review of claims 17, 18, 20–23, 26–30, 32, 33, 35–38, 41–46, 48–50, and 81–91 is denied.

IPR2017-00634  
Patent 8,944,061 B2

PETITIONER:

Brenton R. Babcock  
Benjamin J. Everton  
KNOBBE, MARTENS, OLSON & BEAR, LLP  
2brb@knobbe.com  
2bje@knobbe.com

PATENT OWNER:

Michael T. Hawkins  
Michael J. Kane  
Christopher C. Hoff  
Stephen R. Schaefer  
Andrew Dommer  
FISH & RICHARDSON P.C.  
hawkins@fr.com  
kane@fr.com  
hoff@fr.com  
schaefer@fr.com  
dommer@fr.com