

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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RESMED LIMITED, RESMED INC., AND  
RESMED CORP.,  
Petitioner,

v.

FISHER & PAYKEL HEALTHCARE LIMITED,  
Patent Owner.

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Case IPR2019-00173  
Patent 9,974,914 B2

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Before THOMAS L. GIANNETTI, MICHAEL L. WOODS, and  
AMANDA F. WIEKER, *Administrative Patent Judges*.

WIEKER, *Administrative Patent Judge*.

DECISION  
Institution of *Inter Partes* Review  
35 U.S.C. § 314

## I. INTRODUCTION

### A. *Background*

ResMed Limited, RedMed Inc., and ResMed Corp. (“Petitioner”) filed a Petition requesting an *inter partes* review of claims 9–28 (“challenged claims”) of U.S. Patent No. 9,974,914 B2 (Ex. 1001, “the ’914 patent”). Paper 1 (“Pet.”); *see also* Paper 8, 1 (informing that ResMed Limited has changed its corporate name to ResMed Pty Ltd.). Fisher & Paykel Healthcare Limited (“Patent Owner”) filed a Preliminary Response. Paper 10 (“Prelim. Resp.”). At our request (*see* Paper 11), Petitioner and Patent Owner each filed a brief addressing the appropriate claim construction of the phrases “curving inwardly . . .” and “curving inward . . .,” appearing in, *inter alia*, challenged claims 9 and 11, and submitted briefing and a hearing transcript on the issue, from related litigation. Paper 16 (“Pet. Claim Constr. Br.”); Paper 18 (“PO Claim Constr. Br.”); Papers 13, 14; Exs. 1018–1019; Exs. 2003–2004.

We have authority under 35 U.S.C. § 314 and 37 C.F.R. § 42.4. An *inter partes* review may not be instituted unless it is determined that “the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314; *see also* 37 C.F.R. § 42.4(a) (“The Board institutes the trial on behalf of the Director.”).

For the reasons provided below and based on the record before us, we determine that Petitioner has demonstrated a reasonable likelihood that Petitioner would prevail in showing the unpatentability of at least one of the

challenged claims. Accordingly, we institute an *inter partes* review on all grounds set forth in the Petition.

*B. Related Proceedings*

The parties represent that the '914 patent is involved in an International Trade Commission investigation titled: *In the Matter of Obstructive Sleep Apnea Treatment Mask Systems and Components Thereof*, Inv. No 337-TA-1136, (USITC, Sept. 7, 2018). Pet. 1–2; Paper 5, 1; *see also* Paper 11 (noting that the parties have settled their dispute). The parties also represent that the '914 patent is the subject of three additional *inter partes* review proceedings: IPR2019-00172, IPR2019-00177, and IPR2019-00178. Pet. 2; Paper 5, 1.

Additionally, the parties state that they are involved in district court litigation, *Fisher & Paykel Healthcare Ltd. v. ResMed Corp.*, No. 3:16-cv-02068 (S.D. Cal.), and other *inter partes* review proceedings, concerning other patents. Pet. 1–2; Paper 5, 1.

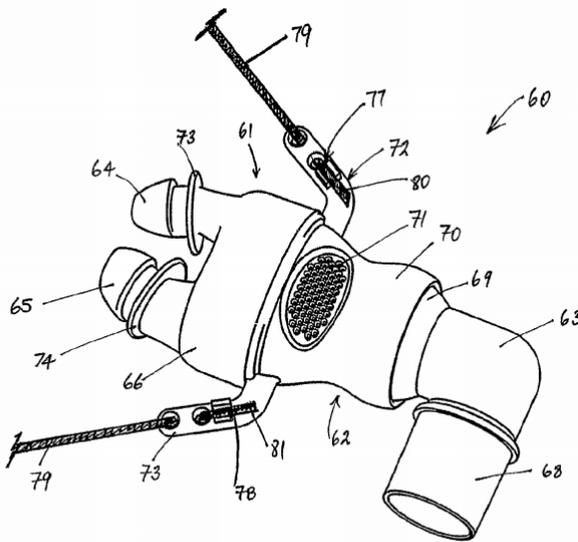
*C. The '914 Patent*

The '914 patent is titled “Breathing Assistance Apparatus” and issued on May 22, 2018, from U.S. Application No. 14/333,134, which was filed on July 16, 2014. Ex. 1001, (21), (22), (45), (54). Patent Owner does not dispute Petitioner’s contention that the effective filing date of the '914 patent is no earlier than August 6, 2004. *See generally* Prelim. Resp.; *see also* Pet. 9–12; Ex. 1001, (30); Ex. 1002, 301.

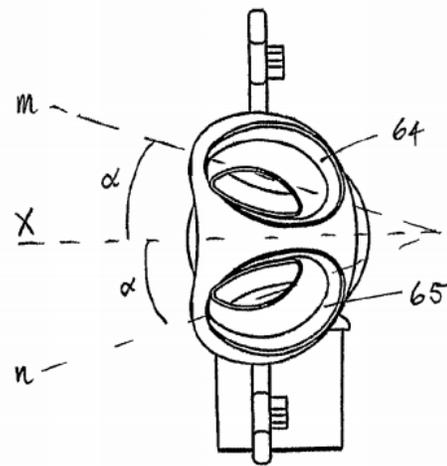
The '914 patent discloses a nasal cannula for use in a continuous positive airway pressure (CPAP) device that treats sleep apnea by supplying pressurized gases to a patient. Ex. 1001, 1:14–16, 1:29–36, 2:49–63, Fig. 1.

According to the '914 patent, CPAP nasal masks utilized in the prior art were uncomfortable, due to the headgear attaching the mask to the patient's face, and were noisy, due to air leaks at the interface between the mask and the face. *Id.* at 1:66–2:14. Such disadvantages led some patients to forgo treatment. *Id.* at 2:7–10. Thus, the '914 patent discloses a breathing assistance apparatus intended to avoid these disadvantages. *Id.* at 2:45–48.

Figures 9 and 12 of the '914 patent are reproduced below.



**Figure 9**



**Figure 12**

Figure 9 depicts a nasal cannula for use with a CPAP device (*see id.* at Fig. 1), and Figure 12 depicts a front view of the prong portion of such a cannula. *Id.* at 3:39–40, 3:44–45, 4:21–24. As shown in Figure 9, nasal cannula 60 includes three main components: prong part 61, body part 62, and ball jointed connector 63, which connects to a source of treatment gas. *Id.* at 6:66–7:2, 8:1–5.

Prong part 61 includes tubular body 66, from which nasal prongs 64, 65 extend at a proximal end. *Id.* at 7:7–14. Prongs 64, 65 are “shaped to follow the contours of the human nares.” *Id.* at 7:3–6. Thus, prongs 64, 65

are substantially oval, with their widths narrowing closer to the tip of each prong, and wherein the prongs “are angled toward one another (or toward the horizontal axis X),” as shown in Figure 12, such that “they are more ergonomically correct . . . and may assist in directing the gas[] flow from the prongs to the user’s nasal cavities.” *Id.* at 7:14–30.

The distal end of tubular body 66 of prong part 61 fits with body part 62. *Id.* at 7:7–10, Fig. 11. Body part 62 “is a tubular passageway” connecting prong part 61 and ball joint 69. *Id.* at 7:48–50. Body part 62 includes apertures 71, which vent gas exhaled by the patient, and shield 75, which prevents the mixing of supplied treatment gas and exhaled gas. *Id.* at 7:52–60, Fig. 10.

#### *D. Illustrative Claim*

The ’914 patent includes 28 claims, and claims 9–28 are challenged in this proceeding. Independent claim 9 is illustrative, and is reproduced below, with added paragraph numbers, as utilized by the parties. Pet. 15–31; Prelim. Resp. 3 n.1, 3–4.

- 9.P A nasal cannula configured to deliver humidified gases to a user, the nasal cannula comprising:
  - 9.1 a prong part comprising: a prong part body having a first end with two openings, a second end with a single opening, and an outer surface extending between the two openings of the first end and the single opening of the second end and having at least a *curved user-side portion* facing toward a user’s face in use, the user-side portion *curving inwardly toward an interior of the prong part body*; and
  - 9.2 two prongs extending from and integrally formed with the first end of the prong part body, the two prongs being angled toward each other,

- 9.3 each of the two prongs having a first side *adjacent* the user-side portion and a second side opposite the first side, the first sides of the two prongs being disposed *further apart* than the second sides of the two prongs,
- 9.4 the prongs being spaced from each other and being shaped to fit within corresponding nares of a user to deliver the gases thereto in use, and
- 9.5 the second end of the prong part body being disposed opposite to the first end and being configured to receive the humidified gases.

Ex. 1001, 10:4–27 (emphases added).

#### *E. Applied References*

Petitioner relies upon the following references (Pet. 3–4, 14, 78):

Thomlinson et al., U.S. Patent Application Publication No. 2005/0011524 A1, filed July 9, 2004, published January 20, 2005 (Ex. 1010, “Thomlinson”);

Gunaratnam et al., U.S. Patent Application Publication No. 2004/0226566 A1, filed February 20, 2004, published November 18, 2004 (Ex. 1011, “Gunaratnam”); and

Sleeper et al., U.S. Patent Application Publication No. 2005/0028822 A1, filed July 26, 2004, published February 10, 2005 (Ex. 1014, “Sleeper”).

Petitioner also relies upon the Declaration of Mr. Anthony Michael Ging (Ex. 1009).

Patent Owner supports its Preliminary Response with a Declaration of Mr. Patrick W. Truitt, Jr. (Ex. 2001).

*F. Asserted Grounds of Unpatentability*

Petitioner challenges the patentability of claims 9–28 of the ’914 patent based on the following grounds. Pet. 3–4.

<b>References</b>	<b>Basis</b>	<b>Claims</b>
Thomlinson and Gunaratnam	§ 103	9–28
Thomlinson, Gunaratnam, and Sleeper	§ 103	11–14

II. DISCUSSION

*A. Claim Construction*

The Petition was filed on November 7, 2018, prior to the effective date of the rule change that replaces the broadest reasonable interpretation standard. *See* Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340 (Oct. 11, 2018) (final rule) (“This rule is effective on November 13, 2018 and applies to all IPR, PGR and CBM petitions filed on or after the effective date.”). Neither party disputes the application of the broadest reasonable interpretation standard, and accordingly, we apply it in this proceeding. Pet. 13–14; Prelim. Resp. 5.

Under the broadest reasonable interpretation standard, claim terms in an unexpired patent are given their broadest reasonable interpretation in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b) (2017). Accordingly, under such a standard, “words of the claim must be given their plain meaning, unless such meaning is inconsistent with the specification and prosecution history.” *Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1062 (Fed. Cir. 2016).

Neither party proposed that any term or phrase of the ’914 patent claims be construed expressly. Pet. 13–14; Prelim. Resp. 4–5. However, the panel determined that additional briefing regarding the phrases “curving

inwardly toward an interior of the prong part body” and “curving inward toward an interior of the body part,” appearing in challenged claims 9 and 11, would be helpful in considering whether to institute *inter partes* review. Despite the variations in these limitations (“inwardly” or “inward”; limiting “the prong part body” or “the body part”), we refer to them all as the “curving inward” limitation(s). *See* Ex. 1001, 10:13–14, 10:41–42. Paper 11, 3. Accordingly, both parties submitted briefs setting forth their positions regarding the proper construction of these phrases. Pet. Claim Constr. Br.; PO Claim Constr. Br. The parties also submitted the claim construction briefing and the *Markman* hearing transcript from the related ITC investigation. Papers 13, 14; Exs. 1018–1019, Exs. 2003–2004; *see supra* Sections I.A.–B.

In its briefing in this proceeding, Petitioner argues that the broadest reasonable interpretation of these phrases is “having some inward curvature such that its center is close to the middle of the prong part body’s (or body part’s) interior.”<sup>1</sup> Pet. Claim Constr. Br. 2 (emphasis omitted). Petitioner contends that its proposed construction is supported by Figures 12 and 15 of the ’914 patent, as well as its prosecution history, but explains that the ’914 patent specification does not discuss these limitations. *Id.* at 1–2. According to Petitioner, its prior art contentions set forth in the Petition are consistent with its proposed construction. *Id.* at 3–5.

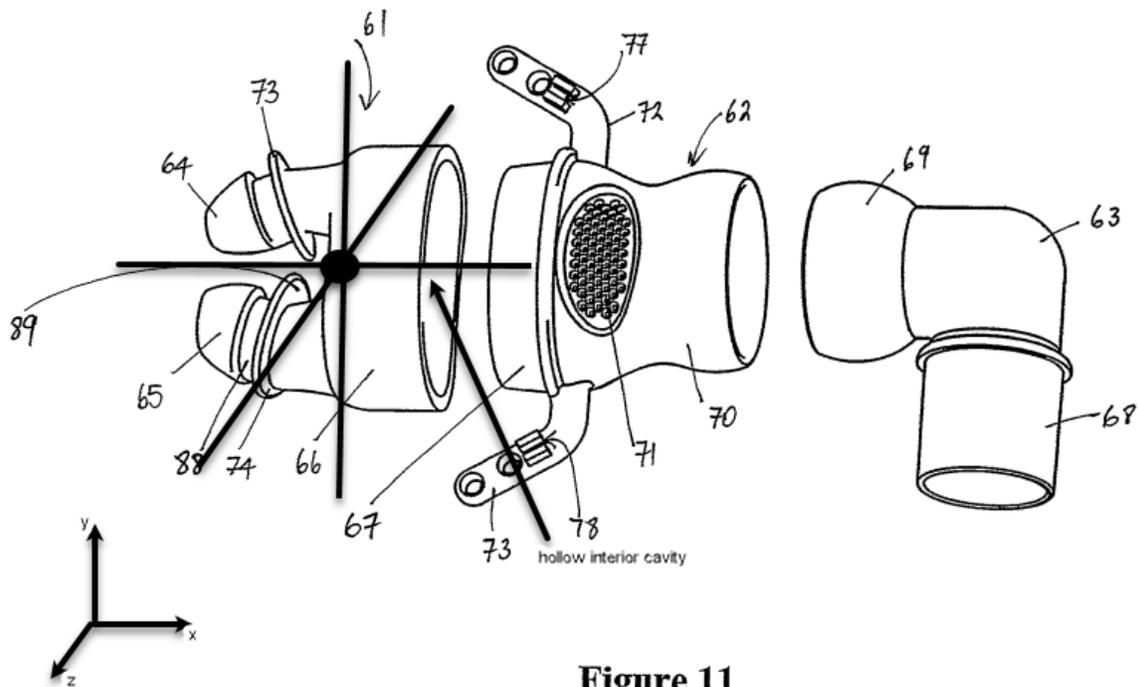
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<sup>1</sup> Petitioner contrasts this construction with that it proposed in the ITC Investigation: “inwardly bowed surface such that its center is closest to the middle of the prong part body’s ([or] the body part’s) interior.” Pet. Claim Constr. Br. 2.

In its briefing in this proceeding, Patent Owner argues that these phrases should be given their plain and ordinary meaning as “curving into and toward the interior of the prong part body [or body part].” PO Claim Constr. Br. 1. Patent Owner argues that “[n]othing in the surrounding claim language or the intrinsic record sets forth any unique meaning to any language recited by the phrases.” *Id.* at 2. Patent Owner also contends that its proposed construction is supported by Figures 12, 15, and 17 of the ’914 patent. *Id.* at 3.

We are not persuaded to adopt either of the constructions proposed by the parties for the reasons that follow. The “curving inward” limitations recite a curve that turns “toward *an* interior” of the recited part. The use of the word “an” suggests that this may encompass one, or more than one, interiors. *See KCJ Corp. v. Kinetic Concepts, Inc.*, 223 F.3d 1351, 1356 (Fed. Cir. 2000) (“‘[A]n’ in patent parlance carries the meaning of ‘one or more’ in open-ended claims.”) (citations omitted). However, both constructions proposed by the parties describe a curve that turns toward a *single* “interior” of the recited part. *See* Pet. Claim Constr. Br. 2 (“*the* middle of *the* prong part body’s . . . *interior*”) (emphases added); PO Claim Constr. Br. 1. (“*the interior* of the prong part body”) (emphasis added). Despite referencing a single “interior,” neither party identifies what that “interior” is, or identifies a reference point by which we could identify which of the several interiors of the recited part is intended.

For example, the parties’ constructions do not identify whether the referenced “interior” is the hollow interior cavity of the recited part, an axial interior along an x, y, or z axis of the part, or some other interior. Annotated Figure 11 is reproduced below, to illustrate this point.



**Figure 11**

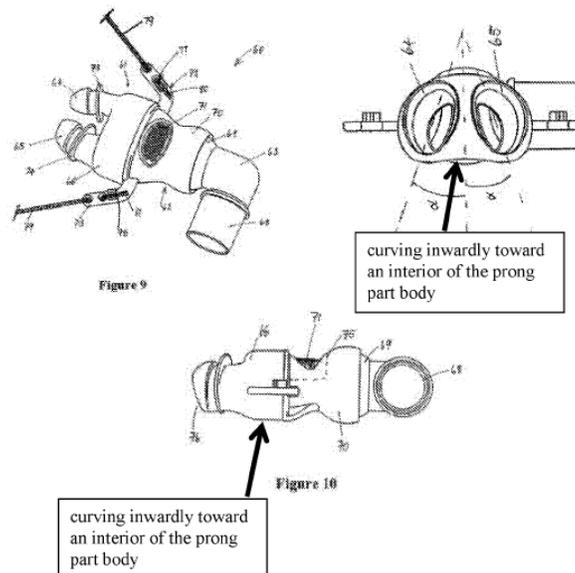
As shown above, Figure 11 has been annotated by the panel to identify several different “interior[s]” of prong part body 66. For example, the mid-point of the length of the x-axis of the prong part body, extending left-to-right in the figure, could be considered an “interior” of that part along the x-axis. Likewise, the mid-point of the length of the y-axis, extending top-to-bottom in the figure, could be considered an “interior” of the part along the y-axis. And the mid-point of the length of the z-axis, extending back-to-front (out of the paper) in the figure, could be considered an “interior” of the part along the z-axis.

Moreover, the figure depicts that prong part body 66 includes an at least partially hollow cavity within the part, through which gases travel to reach the user. The mid-point of that hollow cavity also could be considered an “interior” of the part. Indeed, during the *Markman* hearing in the ITC Investigation, the administrative law judge made a similar observation with respect to proposed Petitioner’s construction in that proceeding. Ex. 1019,

183–193. In response to an argument that the curve must turn toward “[t]he middle of the interior space,” the judge queried, “But that could be -- is it middle top to bottom, [middle] left to right, middle forward to back? There’s so many middles.” *Id.* at 188. Here, there are so many interiors.

Accordingly, at this stage of the proceeding, we consider the constructions advanced by both parties to be inconsistent and unsatisfactory, in that they fail to identify the “interior” toward which the recited curved portion and curved part turn. We provide our own construction of the “curving inward” limitations, which we apply in this Decision.

The claim terms “curving,” “inwardly,” “inward,” and “interior” are not used in the ’914 patent specification in relation to the disclosed invention, except in the claims. *See generally* Ex. 1001. Indeed, the curving inward limitations were added to the claims by amendment, during prosecution. *Compare* Ex. 1002, 421–422 (claims as filed), *with id.* at 278–280 (claim amendment); *see also id.* at 298–318 (interview discussing proposed amendment), 301. In advancing this amendment, the applicant annotated Figures 10 and 12 of the ’914 patent, reproduced below.



Annotated Figures 10 and 12 depict a nasal cannula, with arrows added by the applicant to indicate where the applicant contended that the prong part body curves inward. *Id.* at 285. The applicant described these as “[n]on-limiting embodiments.” *Id.*

In its annotation to Figure 12, the applicant provided an arrow pointing to an inwardly depressed area between prongs 64, 65, at which prong part body 66 curves inwardly, in a concave manner, toward the hollow interior cavity of that part. *Id.*; *see also id.* at 301 (reflecting the applicant’s contention that written description support is provided at Ex. 1001, 6:64–7:67, Figs. 12, 17). Thus, this portion of the prosecution history suggests that this curving inward limitation encompasses a concave curved area that turns *inward toward a hollow interior cavity* of the prong part body.<sup>2</sup> Both Petitioner and Patent Owner appear to agree that this curving inwardly limitation encompasses a concave curved area that turns inward toward a hollow interior cavity of the part, and their proposed constructions appear consistent with such an understanding. *See, e.g.*, Pet. 11 (identifying the same portion of Figure 12); Prelim. Resp. 9 (same); Pet. Claim Contr. Br. 3; PO Claim Constr. Br. 1; *see also* Ex. 1018, 618 (Petitioner’s ITC argument that “[t]he direction of curvature is ‘toward an interior,’ a direction that puts

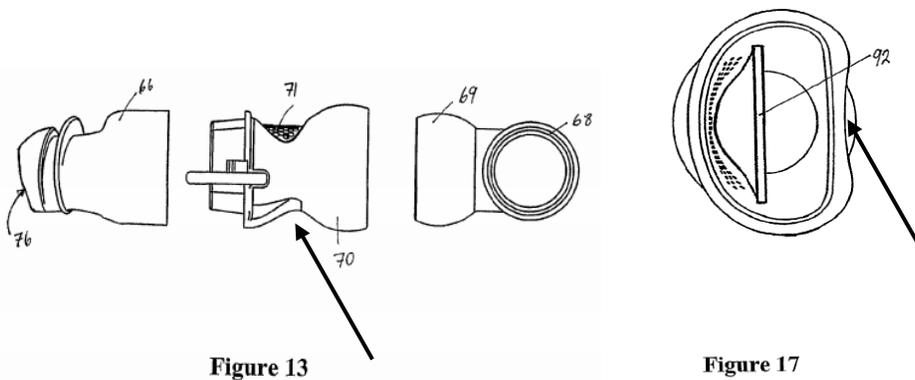
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<sup>2</sup> In its annotation to Figure 10, the applicant pointed to an area on the outer surface of the prong part body that appears substantially *flat and straight*, and contended that this area is “curving inwardly toward an interior of the prong part body.” Ex. 1002, 285. Because it identifies a straight segment of the prong part body, which does not appear to curve in any direction, this annotation does not provide useful guidance as to the curving inward limitation.

the curved surface's center closest to the middle of *the interior's open space.*") (emphasis added).

Claim 11 recites a curved part that curves inward toward an interior of "the body part," e.g., body part 62, not the prong part body (e.g., element 66) of the prong part (e.g., element 61). During prosecution, the applicant did not provide annotations or discussion with respect to the curving inward limitation as it relates to the body part. *See generally* Ex. 1002, 277–291, 298–318. Although the applicant did not discuss this limitation, in an interview summary, the Examiner conveyed the applicant's contention that written description support for the amendment was provided at, e.g., Figure 17. *Id.* at 301. Additionally, Figure 13 also may provide support.

Figures 13 and 17 are reproduced below, with annotations provided by the panel.



Annotated Figures 13 and 17 depict two different embodiments of a nasal cannula, with added arrows identifying areas of each body part that appear to curve inward. Ex. 1001, 3:46–47, 3:57–58, Figs. 11, 16. As seen in annotated Figure 13, the body part includes a curved area that appears to turn inward, in a concave manner, toward a hollow interior of the body part, in the region opposite apertures 71. Likewise, in the embodiment shown in Figure 17, in which the cannula does not include a prong part, body part 90

includes a curved area that appears to turn inward, in a concave manner, toward a hollow interior of the body part, in the region opposite expiratory vent shield 92. *Id.* at 7:61–67, Figs. 12, 17. Thus, these portions of the prosecution history and specification also suggest that this curving inward limitation encompasses a concave curved area that turns *inward toward a hollow interior cavity* of the body part.

Accordingly, for the foregoing reasons and on the record before us, we determine that each curving inward limitation includes an at least partially concave curved area that turns *inward toward an at least partially hollow interior cavity* of the claimed part, i.e., “the prong part body” or “the body part.”<sup>3</sup> The prosecution history and figures discussed above provide support for such a construction. We recognize, however, that the broadest reasonable interpretation of these phrases also may encompass other curves, although the parties have not provided a sufficient evidentiary basis to make such a determination, at this stage. *See, e.g.*, Ex. 1001, 3:15–17 (“The disclosures and the descriptions herein are purely illustrative and are not intended to be in any sense limiting.”); Ex. 1002, 285 (“[n]on-limiting embodiments”). At this stage of the proceeding, we determine that no further construction of these phrases is required. *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

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<sup>3</sup> We recognize that claim 1 does not recite expressly that the prong part body or the body part include a *hollow interior cavity*, however, we discern that these parts must include an at least partially hollow interior in order to “deliver humidified gases” or “supply humidified gases,” as claimed. *See* Ex. 1001, 9:6–7, 9:29–31, Figs. 1, 11.

*B. Principles of Law*

A claim is unpatentable under 35 U.S.C. § 103 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 said subject matter pertains.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). 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 non-obviousness.<sup>4</sup> *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). When evaluating a combination of teachings, we must also “determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.” *KSR*, 550 U.S. at 418 (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). Whether a combination of prior art elements would have produced a predictable result weighs in the ultimate determination of obviousness. *Id.* at 416–417.

“In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016). The burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

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<sup>4</sup> At this stage of the proceeding, Patent Owner has not presented objective evidence of non-obviousness.

We analyze the challenges presented in the Petition in accordance with the above-stated principles.

*C. Level of Ordinary Skill in the Art*

Petitioner contends that a person of ordinary skill in the art at the time of the effective filing date would have had “at least a bachelor’s degree in industrial design, mechanical engineering, biomedical engineering, or a similar technical field, with at least two years of relevant product design experience,” and that additional experience or education could compensate for a deficit of the other. Pet. 14 (citing Ex. 1009 ¶¶ 20–21). Patent Owner does not dispute Petitioner’s position. Prelim. Resp. 5.

For purposes of this Decision, we agree with and apply Petitioner’s identification of the qualifications of a person of ordinary skill, which is consistent with the testimony of each party’s declarant. Ex. 1009 ¶¶ 20–21; Ex. 2001 ¶¶ 25–26.

*D. Obviousness over the Combined Teachings of Thomlinson and Gunaratnam*

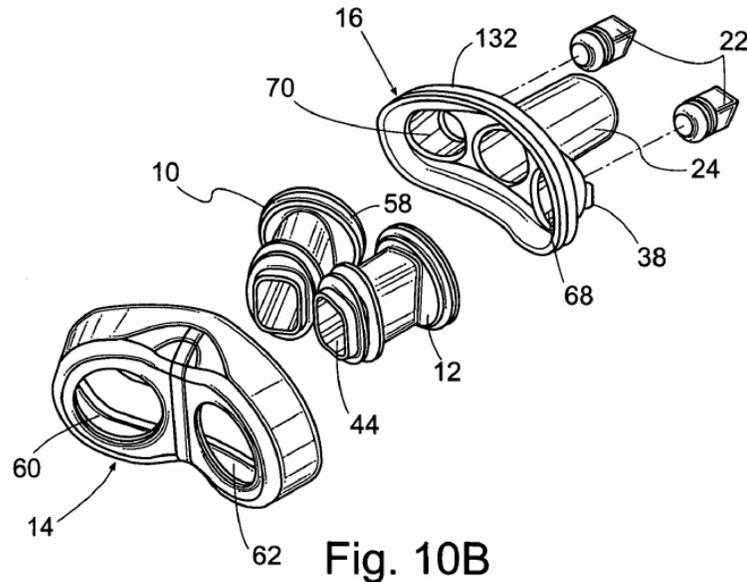
Petitioner contends that claims 9–28 of the ’914 patent would have been obvious over the combined teachings of Thomlinson and Gunaratnam. Pet. 14–77. Patent Owner disagrees. Prelim. Resp. 8–29. Patent Owner argues that Thomlinson fails to disclose the subject matter of claim limitation 9.1, and that both Thomlinson and Gunaratnam fail to disclose the subject matter of claim limitation 9.3. *Id.* at 8–28. Patent Owner also argues that a person of ordinary skill would not have had a reason to modify Thomlinson in light of Gunaratnam’s teachings. *Id.* at 28–29.

For reasons that follow, we determine Petitioner has demonstrated a reasonable likelihood of prevailing as to the challenged claims.

*1. Overview of Thomlinson (Ex. 1010)*

Thomlinson is a U.S. patent application publication titled “Nasal Interface Apparatus,” which discloses a nasal interface device for CPAP applications. Ex. 1010, (54), Abstract.

Thomlinson’s Figure 10B is reproduced below.



**Fig. 10B**

Figure 10B depicts an exploded view of a nasal interface. *Id.* ¶ 19. The nasal interface shown above includes gas inlet 24, distal portion 16, first nasal prong 10 joined to second nasal prong 12 by platform 58, and proximal portion 14. *Id.* ¶¶ 216–217. Thomlinson also explains that “nasal prongs 10 and 12 and proximal portion 14 can be combined to form part of a nasal interface of the present invention.” *Id.* ¶ 274; *see also id.* ¶¶ 299–300.

*2. Overview of Gunaratnam (Ex. 1011)*

Gunaratnam is a U.S. patent application publication titled “Nasal Assembly,” which discloses a nasal assembly for delivering breathable gas to a patient. Ex. 1011, (54), Abstract.

Gunaratnam's Figure 25 is reproduced below.

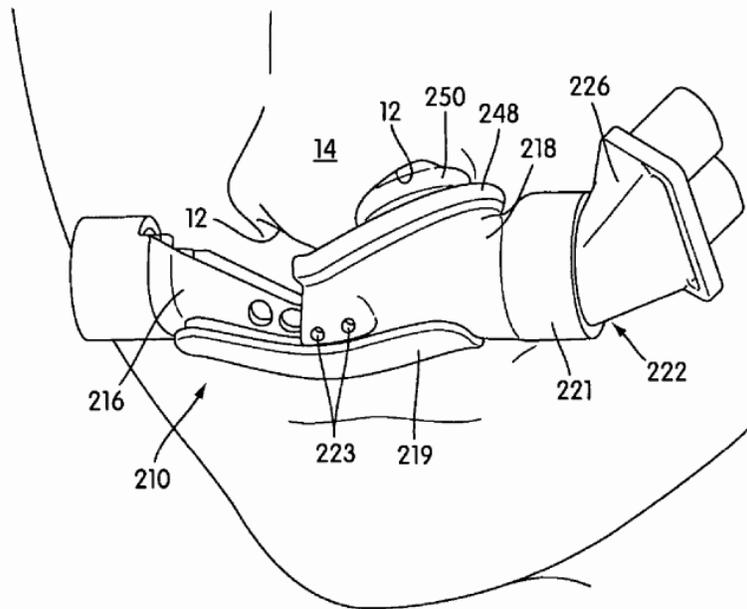


FIG. 25

Figure 25 depicts a nasal assembly engaged with a patient's nasal passages. *Id.* ¶ 53. As shown, nasal assembly 210 includes frame 216 and removable nozzle assembly 218, to which breathable gas is delivered. *Id.* ¶ 236. Nozzle assembly 218 also includes nozzles 250 for engagement with the patient's nasal passages. *Id.* ¶ 239, Fig. 25; *see also id.* ¶¶ 291 (sealing with nasal passages), 293 (asymmetric about central axis), Fig. 65A.

### 3. Analysis of Claim 9

We have considered the Petition and the Preliminary Response, and we determine that Petitioner's arguments and evidence are sufficient to establish a reasonable likelihood of prevailing with respect to challenged claim 9.

*i. Element 9.P: “A nasal cannula configured to deliver humidified gases to a user”*

On this record, the cited evidence supports Petitioner’s undisputed contention that Thomlinson teaches the subject matter of the claim preamble. *See, e.g.*, Pet. 15–16; Ex. 1010, Abstract, ¶ 325 (humidified), Figs. 10A–B.

*ii. Element 9.1: “the nasal cannula comprising: a prong part comprising: a prong part body having a first end with two openings, a second end with a single opening, and an outer surface extending between the two openings of the first end and the single opening of the second end and having at least a curved user-side portion facing toward a user’s face in use, the user-side portion curving inwardly toward an interior of the prong part body”*

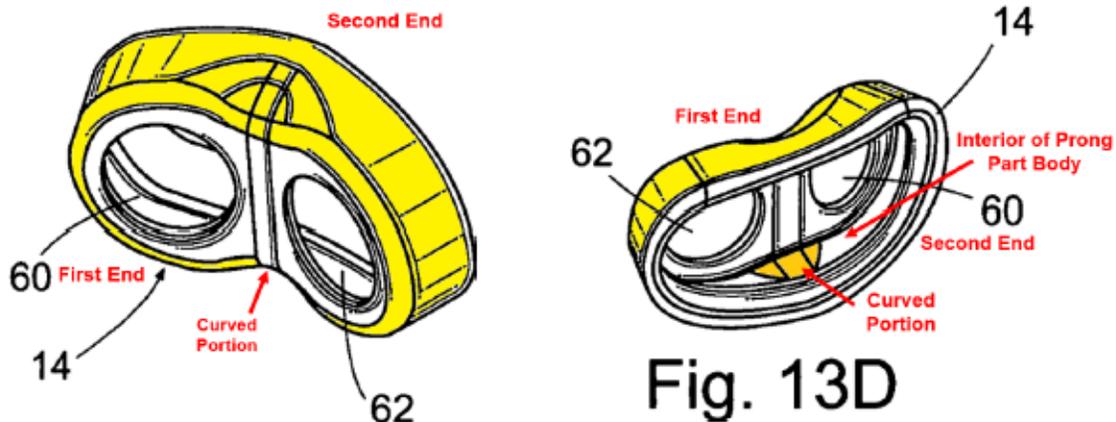
We treat this limitation in two parts. First, Petitioner contends that Thomlinson’s proximal portion 14 may be formed integrally with nasal prongs 10, 12, and constitutes a prong part as claimed. *Id.* at 16–17 (citing Ex. 1010 ¶¶ 216–217, 299–300, Fig. 10B). Petitioner contends that this prong body includes a first end with two openings, a second end with a single opening, and an outer surface that extends between the two openings and the single opening. *Id.* at 18–20 (citing Ex. 1009 ¶¶ 34–35, 58–61; Ex. 1010 ¶¶ 212, 216–217, 252–253, 274, 299–300, Figs. 10A–B, 13A–F, 18A–E, 13D–G, 18A–E).

In a footnote, Patent Owner argues that Thomlinson does not depict or describe expressly the embodiment in which proximal portion 14 and prongs 10, 12 are formed integrally and, thus, the Petition lacks support for its contention that this embodiment would include a single opening at the second end. Prelim. Resp. 16 n.3. Otherwise, Patent Owner does not dispute these contentions.

On this record, we disagree with Patent Owner’s argument regarding the “single opening.” Thomlinson explicitly discloses that proximal portion 14 and prongs 10, 12 may be formed integrally. Ex. 1010 ¶¶ 274 (“combined”), 299 (“integral”), 300 (“formed as integral bodies”). In these disclosures, Thomlinson does not suggest that any deviations are made to the basic structures of proximal portion 14 or prongs 10, 12, other than to disclose that these elements would be made integral by, e.g., “blow molding, injection molding, and/or overmolding.” *Id.* ¶ 300. Patent Owner has not presented any persuasive evidence or reasoning to suggest that these manufacturing methods would have required a modification to the single opening at the second end, as shown in, for example, Thomlinson’s Figure 10B. Accordingly, on this record, the cited evidence supports Petitioner’s contention that Thomlinson teaches these portions of this limitation. *See* Pet. 16–20; *see also id.* at 17 (modified and annotated Figure 10B, depicting integral proximal portion 14 and prongs 10, 12), 18 (modified and annotated Figure 10B, identifying first end toward figure left, second end toward figure right), 19 (modified and annotated Figure 10B, identifying the outer surface), 20 (annotated Figure 13B, identifying first end with two openings, and second end with a single opening); Ex. 1010 ¶¶ 216–217, 299–300 (integral); Ex. 1009 ¶¶ 34–35, 58–61, 65–66, 102–103.

Second, Petitioner also contends that the outer surface of Thomlinson’s proximal portion 14 includes a curved user-side portion facing toward a user’s face in use, which curves inwardly toward an interior of the prong part body as claimed. Pet. 20–21. In support of this contention, Petitioner cites Thomlinson’s paragraphs 216, 217, 227, 277, as well as Figures 10A–B, 13A, 13B, 13D, 13E, and 13I. *Id.* (also citing Ex. 1009

¶¶ 102–104, Fig. 5). Petitioner annotates Figures 10B and 13D, reproduced below, to identify the curved segment.

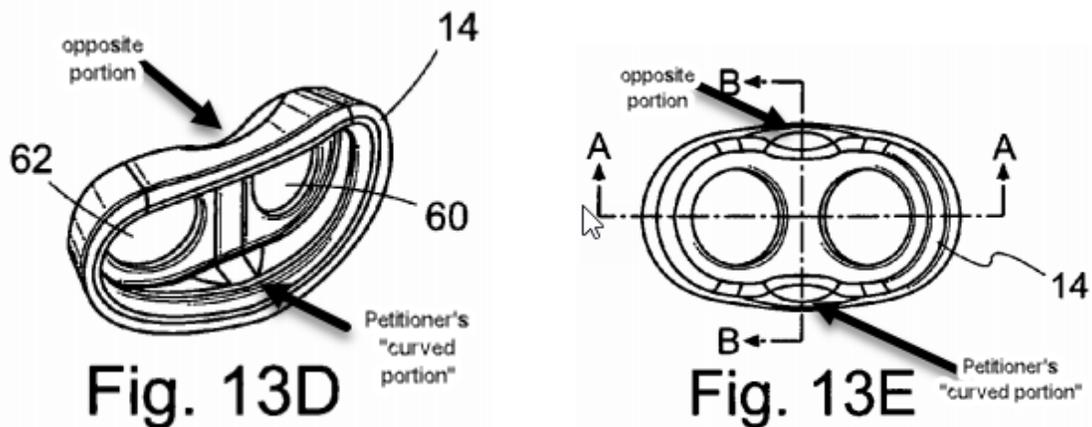


*Id.* at 21. Annotated Figures 10B and 13D depict proximal portion 14 with annotations added by Petitioner, identifying the lower portions of the figures as the “curved portion.” *Id.*

Patent Owner disputes Petitioner’s contentions. Prelim. Resp. 8–21. Specifically, Patent Owner argues that cited paragraphs 216, 217, and 277 do not discuss the outer surface that faces toward the user. *Id.* at 17–18; Ex. 2001 ¶¶ 54, 56, 58–59. Patent Owner also argues that although paragraph 227 refers to a curved portion of proximal portion 14, the paragraph relates to the curve shown in the top-down view of Figures 12B and 13B, which does not face toward the user, as required by the claim. *Id.* at 18–19. Additionally, Patent Owner argues that the cited figures also fail to depict a curve on a portion facing toward the user. *Id.* at 10–17. Specifically, Patent Owner argues that Figures 10A, 13A, and 13B present top-down views (*id.* at 11); Figures 13E and 13I present front views (*id.* at 12); although Figures 10B and 13D partially depict the inner surface of the part, i.e., the back-side of the claimed first portion, these views do not depict the first portion that actually faces toward the user and, if anything,

demonstrate that no curvature exists (*id.* at 12–14); and Figure 13G presents a back view which, if anything, demonstrates that any curvature curves away from the interior of the part (*id.* at 15).

As discussed above in Section II.A., we determine that this curving inward limitation at least includes a “concave curved area that turns *inward toward an at least partially hollow interior cavity* of the” prong part body. On this record, we determine that the cited evidence adequately supports Petitioner’s contention that Thomlinson teaches this limitation, as construed. Patent Owner is correct that the cited paragraphs of Thomlinson do not describe a curved segment as claimed. Moreover, many of Patent Owner’s criticisms of the views presented in the cited figures appear valid. However, Patent Owner’s arguments do not take account of the teachings of the cited figures taken as a whole. For example, cited Figures 13D and 13E, reproduced below with annotations added by the panel, reasonably depict a curved segment as claimed.



Annotated Figures 13D–E depict proximal portion 14 with arrows added by the panel at the bottoms of the figures, to indicate the structure identified by Petitioner as the “curved portion,” and arrows added at the tops of the figures, to indicate an “opposite portion.” Ex. 1010, Figs. 13D–E.

As shown in Annotated Figure 13E, the identified curved segment of the claimed first portion is depicted in an identical manner to the identified opposite portion, except that the opposite portion is located on the opposing surface, i.e., on the claimed second portion of the prong part body. As shown in Annotated Figure 13D, the identified opposite portion is a concave curved area that turns inward toward the hollow interior cavity of proximal portion 14. Thus, Patent Owner’s argument—that Figure 13D does not depict the first portion of the outer surface that faces toward the user—is not dispositive. Prelim. Resp. 12–14. We discern that, taking Figures 13D and 13E together, the identified curved segment of Figure 13D also appears to include a concave curved area that turns inward toward the hollow interior cavity of proximal portion 14, but simply from the opposing side of the proximal portion, because the curved segment is depicted in Figure 13E with an identical structure as the opposite portion of that figure, which clearly curves inward toward the hollow interior cavity. As discussed in Section II.A., the curving inward limitation encompasses a curved area that turns inward in this manner.

Accordingly, on this record, we find adequate support for Petitioner’s contention that Thomlinson teaches this limitation of claim 1.

*iii. Element 9.2: “two prongs extending from and integrally formed with the first end of the prong part body, the two prongs being angled toward each other”*

On this record, the cited evidence supports Petitioner’s undisputed contention that Thomlinson teaches this limitation. *See, e.g.*, Pet. 22–23; Ex. 1010 ¶¶ 274, 299–300 (prongs 10, 12 integrally formed with proximal portion 14), Figs. 1, 4, 6, 10A (angled prongs); Ex. 1009 ¶¶ 58–61, 105.

*iv. Element 9.3: “each of the two prongs having a first side adjacent the user-side portion and a second side opposite the first side, the first sides of the two prongs being disposed further apart than the second sides of the two prongs”*

Petitioner contends that Thomlinson’s prongs 10, 12 have a first side adjacent the user-side portion and a second side opposite the first side, and provides annotated Figure 10A, reproduced below, to support this contention.

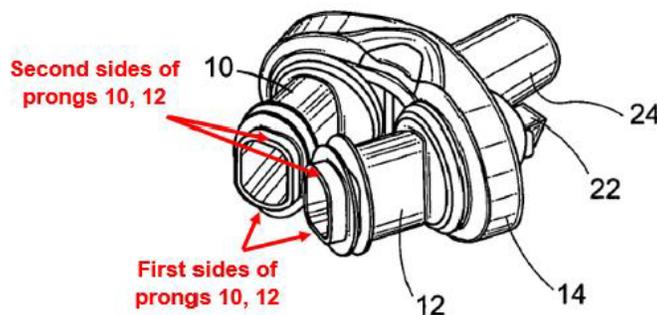


Fig. 10A

Annotated Figure 10A depicts a nasal interface with Petitioner’s added annotations identifying the first and second sides of the prongs. Pet. 23–24 (citing Ex. 1010, Fig. 10A; Ex. 1009 ¶¶ 76, 106–107).

Petitioner also contends that Thomlinson’s prongs may be rotatable, and cites Mr. Ging’s testimony that it was common knowledge that most patients’ nares are angled, back to front. Pet. 24 (citing Ex. 1010 ¶ 268; Ex. 1009 ¶¶ 78–79, 106–107). Thus, Petitioner contends that, in Thomlinson’s embodiment in which proximal portion 14 is integrally formed with prongs 10, 12, “a [person of ordinary skill] would have been prompted to mold the prongs 10/12 in a permanently rotated orientation with the first sides farther apart than the second sides so as to improve alignment between the prongs 10/12 and the nares of the patient.” *Id.* at 24–25 (also

contending this was “an ordinary feature commonly found in nasal interfaces before the ’914 patent”) (citing Ex. 1010 ¶¶ 274, 299–300; Ex. 1009 ¶¶ 83, 106–107; Exs. 1012–1013, 1015).

In addition, Petitioner contends that, to the extent Thomlinson does not disclose the “further apart” portion of this limitation, Gunaratnam confirms that this was a conventional option that provided known benefits. Pet. 25 (citing Ex. 1009 ¶¶ 79–80, 108). Petitioner cites to Gunaratnam’s Figure 65A, which Petitioner contends teaches nasal prongs rotated toward each other so that the first sides are further apart than the second sides. *Id.* at 25–27 (citing Ex. 1011 ¶¶ 189, 291, 293–297; Ex. 1009 ¶¶ 80, 108–109). In light of these teachings, Petitioner contends that a person of ordinary skill would have been prompted to modify Thomlinson’s prongs to orient them toward each other, with their first sides further apart than their second sides, to achieve known benefits such as: (1) to achieve an asymmetric orientation with a better fit that more closely aligns with the natural orientation of the user’s nares; (2) to achieve an improved seal between the prongs and nares; and (3) because such a modification would have been the mere application of a known technique to a known system to achieve predictable results. *Id.* at 27–28 (citing, e.g., Ex. 1009 ¶¶ 82–84, 108–109; Ex. 1011 ¶¶ 189, 291, 293, Fig. 23; Ex. 1010 ¶ 268).

Patent Owner makes several arguments, which we address in turn. Prelim. Resp. 21–29. First, Patent Owner argues that Petitioner’s identification of the claimed first and second sides, as shown in annotated Figure 10A, reproduced above, is deficient because Petitioner points to the tips of the prongs, which are not adjacent any surface on the prong part body. *Id.* at 21–23.

We disagree. Petitioner clearly identifies Thomlinson’s prongs 10, 12 as the claimed “two prongs extending from . . . the prong part body.” Pet. 22–23 (citing Ex. 1010, Fig. 10A). As the cited figure makes clear, these prongs extend outward from the openings of the prong part body to their terminal, proximal ends, at which location Petitioner included its arrows. Pet. 24 (citing Ex. 1010, Fig. 10A (annotated)). Thus, with respect to limitation 9.3, although Petitioner’s annotated Figure 10A includes arrows that point to the terminal, proximal ends of prongs 10, 12, *see id.*, when read in conjunction with the remainder of Petitioner’s contentions, we discern that the identified first and second sides of the prongs extend the entire length of the prongs, as reflected in the further annotated Figure 10A, shown below.

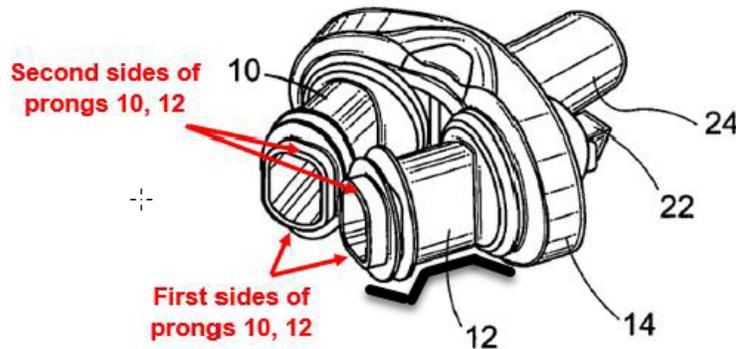


Fig. 10A

Further annotated Figure 10A depicts a nasal cannula with a line, added by the panel, extending along the entire length of the first side of prong 12. Pet. 22–24; *see also* Ex. 1009 ¶¶ 76 (“A [person of ordinary skill] would have recognized that nasal prongs 10 and 12 have a first side that is adjacent the curved segment of the prong part body . . . and a second side that is adjacent the second portion of the prong part body.”), 106–107.

Second, Patent Owner argues that it would have been infeasible simply to rotate Thomlinson's prongs 10, 12, as Petitioner contends, because rotation would have required that apertures 60, 62 and the base of prongs 10, 12 are both circular, in contrast to the claim requirement that the first sides of the prongs are further apart than the second sides, which would require a non-circular prong base. Prelim. Resp. 23–24 (citing Ex. 2001 ¶¶ 64–67).

We disagree, and find Patent Owner's argument to be misplaced. Petitioner contends that it would have been obvious to mold Thomlinson's prongs in a permanently rotated configuration, and that such a configuration would have aligned with a user's nares more appropriately. Pet. 24–25; Ex. 1009 ¶ 78. Thus, the proposed modification does not turn on the physical ability of Thomlinson's prongs to rotate, e.g., with a circular base and circular aperture, as Patent Owner's argument (and Mr. Truitt's cited testimony) presumes. Rather, the proposed modification requires directly molding the prongs in the proposed orientation, to mimic the natural orientation of most user's nares. Pet. 24–25. Thomlinson expressly discloses that the prongs may be positioned in varying configurations—including to correspond to the spacing of the user's nares—and may be molded. Ex. 1010 ¶¶ 268 (rotatable), 271 (correspond to spacing of patient's nares, even when prongs 10, 12 are joined by platform 58), 300 (blow molded, injection molded, or over molded); Ex. 1009 ¶¶ 77–78. Neither Patent Owner nor Mr. Pruitt provide sufficient evidence or reasoning to demonstrate that it would not have been obvious to a person of ordinary skill to mold Thomlinson's prongs in such an orientation, or that molding in this manner was not within the skill level of a person of ordinary skill. Prelim.

Resp. 23–24; Ex. 2001 ¶¶ 64–67. Thus, on this record, we disagree with Patent Owner’s argument.

Third, Patent Owner argues that a person of ordinary skill would not have been motivated to mold Thomlinson’s prongs in a rotated orientation because Thomlinson expressly discloses advantages associated with prong rotation, which requires separate, non-integrated components. Prelim. Resp. 25 (citing Ex. 2001 ¶ 68). Specifically, Patent Owner cites Thomlinson’s disclosure that independent and separately rotatable prongs allows individual adjustment of each prong, which improves patient comfort and sealing. *Id.* at 25–26 (citing Ex. 1010 ¶ 268); *see also id.* at 26–28 (citing Ex. 1010 ¶¶ 196 (ease of assembly; ease, cost of manufacturing), 262 (interchangeability), 267 (sealing and comfort), 274 (ease; reduced manufacturing cost); Ex. 2001 ¶¶ 72–74)). By contrast, Patent Owner argues that Thomlinson does not identify any advantages associated with use of integrated components. *Id.* at 28. Thus, Patent Owner contends Petitioner’s proposed modification would have been unnecessary, in light of Thomlinson’s disclosed rotation. *Id.* (citing Ex. 2001 ¶ 74).

We disagree. Although Thomlinson discloses advantages associated with the use of non-integrated components, e.g., individual adjustment of prongs and reduced manufacturing cost (*see* Ex. 1010 ¶¶ 268, 274), nonetheless, Thomlinson also plainly discloses that proximal portion 14 and prongs 10, 12 may be made integral (*id.* ¶¶ 274, 299–300). Petitioner provides evidence, in the form of Mr. Ging’s testimony, that a person of ordinary skill would have recognized advantages to the use of integrated components. *See* Pet. 24–25; *see also id.* at 18–29 (providing reasons to modify the orientation of Thomlinson’s prongs, including improved comfort

and sealing). For example, Mr. Ging opines that integrally forming these parts would have resulted in a one-piece construction that reduces the number of parts, thereby decreasing the amount of time required for assembly and cleaning. Ex. 1009 ¶ 35. Additionally, Mr. Ging testifies that a one-piece construction would have eliminated the risk of the prongs rotating out of position. *Id.* Mr. Ging also acknowledges that these realizing these benefits may result in “other possible tradeoffs.” *Id.* ¶ 60.

We recognize that Patent Owner provides evidence, in the form of Mr. Truitt’s testimony, that a person of ordinary skill would have found Petitioner’s proposed modification unnecessary, in view of the advantages associated with rotatable prongs, as disclosed by Thomlinson. However, neither Patent Owner nor Mr. Truitt addresses the purported advantages of integration, as identified by Mr. Ging, and neither Patent Owner nor Mr. Truitt weigh those advantages against any asserted disadvantages. As our reviewing court has explained, “[t]he fact that the motivating benefit comes at the expense of another benefit . . . should not nullify its use as a basis to modify the disclosure of one reference with the teachings of another. Instead, the benefits, both lost and gained, should be weighed against one another.” *Winner Int’l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349 n.8 (Fed. Cir. 2000); *see also In re Urbanski*, 809 F.3d 1237, 1244 (Fed. Cir. 2016); *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (citation omitted).

Likewise, although Mr. Truitt disputes the notion that a person of ordinary skill would have found it obvious “to mold the prongs 10/12 [of Thomlinson] in a permanently rotated orientation,” *see* Ex. 2001 ¶¶ 68–74 (citing Pet. 24–25), neither Patent Owner nor Mr. Truitt dispute the

underlying contention that the nares of most patients exhibit an angled orientation, and that orienting nasal prongs to match the orientation of the user's nares would have improved sealing and comfort. Ex. 1009 ¶¶ 38, 77–78, 106–109; Ex. 1011, Fig. 23. Moreover, although the Board considers testimonial evidence provided with Patent Owner's Preliminary Response, "a genuine issue of material fact created by such testimonial evidence will be viewed in the light most favorable to the petitioner solely for purposes of deciding whether to institute an *inter partes* review." See 37 C.F.R. § 42.108(c).

Finally, Patent Owner argues that Gunaratnam is irrelevant because a person of ordinary skill would have understood that "any advantage of the angled orientation of prong tips shown in Petitioner's additional references would be, at best, redundant of the advantages of Thomlinson's component prongs that can be rotatably adjusted in place." Prelim. Resp. 28–29 (citing Ex. 2001 ¶ 75). Thus, Patent Owner argues that a person of ordinary skill would have had no reason to modify Thomlinson as proposed. *Id.* at 29 (citing Ex. 2001 ¶ 76).

We disagree, for similar reasons as discussed above. Namely, Patent Owner does not address the purported advantages of integration, as presented by Petitioner and Mr. Ging. Additionally, Patent Owner does not dispute Petitioner's substantive contention that Gunaratnam teaches nasal prongs rotated toward each other so that the first sides are farther apart than the second sides. On this record, we find adequate support for Petitioner's contentions. Pet. 25–28; Ex. 1011 ¶¶ 189, 291, 293–297, Figs. 23, 65A; Ex. 1009 ¶¶ 80–84, 108–109.

Accordingly, at this stage of the proceeding, we are persuaded by Petitioner's contentions.

v. *Element 9.4: "the prongs being spaced from each other and being shaped to fit within corresponding nares of a user to deliver the gases thereto in use"*

On this record, the cited evidence supports Petitioner's undisputed contention that Thomlinson teaches this limitation. *See, e.g.*, Pet. 29–30; Ex. 1010 ¶¶ 251 (sizing), 271 (spacing), Figs. 5, 10A.

vi. *Element 9.5: "the second end of the prong part body being disposed opposite to the first end and being configured to receive the humidified gases."*

On this record, the cited evidence supports Petitioner's undisputed contention that Thomlinson teaches this limitation. *See, e.g.*, Pet. 30–31; Ex. 1010 ¶¶ 216–217, 274, 299, 318 ("tubing 90 directly connected to distal portion 16"), 323, 325–326, Figs. 10A–B, 30–31; Ex. 1009 ¶¶ 58–61, 68–70, 111–112.

#### *vii. Summary of Claim 9*

For the reasons detailed above, we are persuaded by Petitioner's contentions regarding independent claim 9.

#### *4. Dependent Claims 10–28*

Petitioner contends that Thomlinson teaches each additional limitation recited in dependent claims 10–28, or would have rendered obvious each limitation. Pet. 31–77. Patent Owner does not dispute Petitioner's contentions, apart from its arguments regarding independent claim 1. Prelim. Resp. 8, 20. On this record, we determine that the cited evidence supports Petitioner's undisputed contentions that Thomlinson teaches, or would have rendered obvious, each limitation of dependent claims 10–28.

*See, e.g.*, Pet. 43 (annotated figure identifying recessed surface), 57–58 (annotated figures identifying horizontal and vertical directions, right and left side curved portions/apexes), 73 (annotated figure identifying apex of curved portion); Ex. 1010 ¶¶ 216–217 (distal portion 16), 228 (silicone proximal portion 14), 237 (rigid plastic distal portion 16), 255 (silicone prongs 10, 12), 284 (exhalation ports 22, 68, 70), 318 (tubing 90), Fig. 10A (flaps 18, 20), Fig. 3 (exhalation ports 22), Fig. 8 (strap connections 28, 30), Fig. 10B (openings 68, 70), Fig. 30 (strap attachment plate 92), Fig. 17E–G (lip 132), Fig. 30 (connection to tubing), Fig. 60 (ball joint 225); Ex. 1011, Figs. 108–109 (headgear 602); Ex. 1009 ¶¶ 74 (lip 132), 90–91 (headgear extensions), 128–144 (combination with Gunaratnam’s headgear), 151–164 (same).

### 5. Conclusion

On the record before us and for the foregoing reasons, Petitioner has demonstrated a reasonable likelihood of success in demonstrating the unpatentability of challenged claims 9–28, over the combined teachings of Thomlinson and Gunaratnam.

#### *E. Obviousness over the Combined Teachings of Thomlinson, Gunaratnam, and Sleeper*

Petitioner contends that claims 11–14 of the ’914 patent also would have been obvious over the combined teachings of Thomlinson, Gunaratnam, and Sleeper. Pet. 78–81. Patent Owner does not address this ground. *See generally* Prelim. Resp.

On this record, we determine that the cited evidence supports Petitioner’s undisputed contentions that Thomlinson, Gunaratnam, and

Sleeper teaches, or would have rendered obvious, claims 11–14. Pet. 78–81; *see also* Ex. 1009 ¶¶ 181–235; Ex. 1014, Abstract, ¶¶ 34, 46–50, Figs. 6–10.

### III. CONCLUSION

On April 24, 2018, the Supreme Court held that a final written decision under 35 U.S.C. § 318(a) must decide the patentability of all claims challenged in the petition. *See SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348 (2018). After considering the evidence and arguments presented in the Petition and Preliminary Response, we determine that Petitioner has demonstrated a reasonable likelihood of success in proving that claims 9–28 of the '914 patent are unpatentable. Accordingly, we institute an *inter partes* review of all claims and all grounds set forth in the Petition.

At this stage of the proceeding, we have not made a final determination as to the patentability of any challenged claim or as to the construction of any claim term.

### IV. ORDER

Upon consideration of the record before us, it is:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 9–28 of the '914 patent is instituted with respect to all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), *inter partes* review of the '914 patent shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

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