

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED LIMITED, RESMED INC., AND RESMED CORP,
Petitioner,
v.
FISHER & PAYKEL HEALTHCARE LIMITED,
Patent Owner.

Case IPR2016-01726
Patent 8,443,807 B2

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

RICE, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Background

ResMed Limited, ResMed Inc., and ResMed Corp (collectively, “Petitioner”) filed a Petition (Paper 4, “Pet.”) requesting an *inter partes* review of claims 1–7, 17–19, 24, and 25 of U.S. Patent No. 8,443,807 B2 (Ex. 1001, “the ’807 Patent”). Petitioner supported the Petition with a declaration from John Izuchukwu, Ph.D., P.E. (Ex. 1008). Fisher & Paykel Healthcare Limited (“Patent Owner”) filed a Preliminary Response (Paper 8, “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 and the Preliminary Response, we determine that Petitioner has not shown a reasonable likelihood that it would prevail with respect to at least one of the challenged claims. Accordingly, we do not institute an *inter partes* review.

B. Related Proceedings

The parties identify a related federal district court case involving the ’807 Patent: *Fisher & Paykel Healthcare Ltd. v. ResMed Corp.*, Case No. 3:16-cv-02068-GPC-WVG (S.D. Cal.). Pet. 1; Paper 6, 1–2.

Petitioner has filed a second petition for *inter partes* review of the ’807 Patent (*see* IPR2016-01734), as well as two petitions for *inter partes* review of U.S. Patent No. 8,479,471 B2, which is related to the ’807 Patent (*see* IPR2016-01714, IPR2016-01718).

The parties inform us that Petitioner filed and then voluntarily dismissed, without prejudice, a declaratory judgment action challenging the

validity of the '807 Patent (*ResMed Inc. v. Fisher & Paykel Healthcare Corporation Limited*, Case No. 3:16-cv-02072-JAH-MDD (S.D. Cal.)).
Pet. 1–2; Prelim. Resp. 9–10.

C. Statutory Bar Under 35 U.S.C. § 315(a)(1)

Patent Owner argues that the Petition is barred under 35 U.S.C. § 315(a)(1) because Petitioner filed a declaratory judgment action for invalidity of the '807 Patent on August 16, 2016, and before filing the instant Petition. Prelim. Resp. 9–16. That action, however, was voluntarily dismissed without prejudice on August 18, 2016, well before the instant Petition was filed. Pet. 2. As such, Patent Owner's argument fails because prior Board decisions have consistently interpreted 35 U.S.C. § 315(a)(1) as not barring *inter partes* review if the previously filed civil action was dismissed without prejudice, which is the case here. *See, e.g., Microsoft Corp. v. Parallel Networks Licensing, LLC*, Case IPR2015-00486, slip op. at 6–7 (PTAB Jul. 15, 2015) (Paper 10); *Oracle Corp. v. Click-to-Call Techs. LP*, Case IPR2013-00312, slip op. at 12–13 (PTAB Oct. 28, 2014) (Paper 52).

Patent Owner now challenges the Board's consistent interpretation of 35 U.S.C. § 315(a)(1). But Patent's Owner's arguments are in direct contrast to a decision in the related district court action, which relied upon the Board's consistent interpretation of 35 U.S.C. § 315(a)(1) in deciding whether to impose a stay pending our resolution of this proceeding. Ex. 3001. There, Patent Owner argued the statutory bar as a reason the court should not impose a stay. *Id.* at 3. The district court, noting that Petitioner's declaratory judgment action was voluntarily dismissed "without prejudice" prior to the instant Petition being filed, held that "the effect of a voluntary

dismissal w/out prejudice is to render the prior action a nullity” such that it is “treated as if it was not ‘filed’ at all” and thus “cannot give rise to a statutory bar under 35 U.S.C. § 315(a)(1).” *Id.* at 4. In doing so, the district court relied upon, and expressly adopted, the reasoning of prior Board decisions that came to a similar conclusion.¹ *Id.* Moreover, the district court noted that “at least eight Circuits had likewise determined that a dismissal without prejudice makes the situation as if the action had never been filed.”² *Id.*

We see no reason to deviate from our prior decisions interpreting 35 U.S.C. § 315(a)(1) or the district court’s concurring analysis of this issue, and Patent Owner’s arguments to the contrary do not persuade us otherwise. As such, we hold that the Petition is not barred by 35 U.S.C. § 315(a)(1).

D. The ’807 Patent

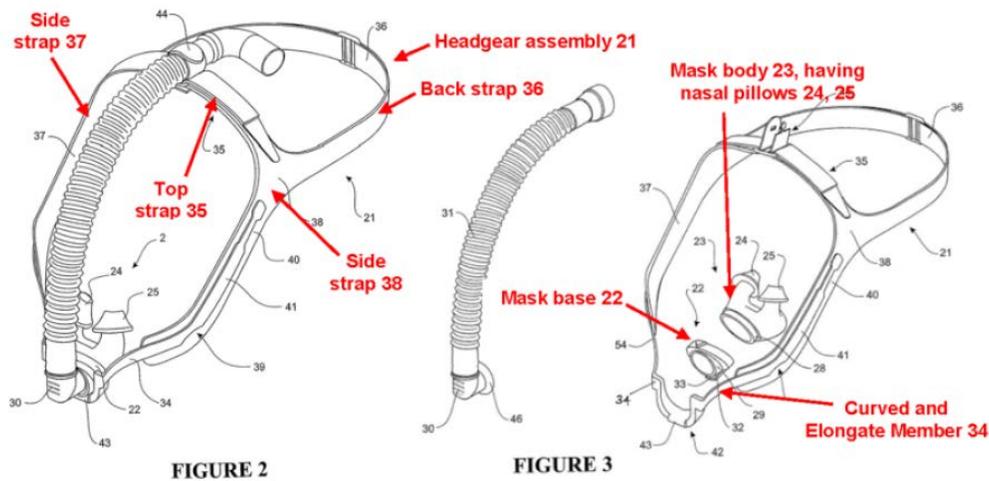
The ’807 Patent, titled “Breathing Assistance Apparatus,” issued on May 21, 2013, and claims priority from applications filed in New Zealand on July 14 and November 6, 2006. Ex. 1001, 1. The ’807 Patent relates to a

¹ The district court may have recognized that “an agency’s interpretation of the statute under which it operates is entitled to some deference.” *Southeastern Community College v. Davis*, 442 U.S. 397, 411 (1979).

² *See, e.g., Holloway v. U.S.*, 60 Fed. Cl. 254, 261 (2004), *aff’d* 143 F. App’x 313 (Fed. Cir. 2005) (treating civil action dismissed without prejudice “as if it never existed.”); *Bonneville Assoc., Ltd. P’ship v. Barram*, 165 F.3d 1360, 1364 (Fed. Cir. 1999) (“The rule in the federal courts is that ‘[t]he effect of a voluntary dismissal without prejudice pursuant to Rule 41(a) is to render the proceedings a nullity and leave the parties as if the action had never been brought.”) (citations and some internal quotations omitted).

nasal interface for the supply of positive pressure respiratory gases to a person suffering from obstructive sleep apnea. *See, e.g.*, Pet. 4 (citing Ex. 1001, 1:10–13, 1:24–2:32, 2:58–3:30; Ex. 1008 ¶¶ 24–29; Ex. 1040).

Figures 2 and 3 of the '807 Patent as annotated by Petitioner are reproduced below.



Id. at 4. The annotated figures above depict a patient interface embodiment including nasal mask 2, mask body 23 with nasal pillows 24, 25, mask base 22, swivel elbow connector 30, contoured side arms 41, 54, headgear assembly 21, and side straps 37, 38. *See id.* at 5 (citing Ex. 1001, 5:25–47, 6:38–45, 6:57–7:3, 8:38–52; Ex. 1008 ¶¶ 28–29). “The nasal pillows 24, 25 are preferably frustoconical in shape and in use rest against a patient’s nares,³ to substantially seal the patient’s nares.” Ex. 1001, 5:29–31. As described in the Specification, “mask base 22 is a ring or sleeve type attachment.” *Id.* at 6:19–20. The side straps extend underneath the side arms, to which they are glued or otherwise attached as shown in Figure 2,

³ “Nares” as used in the Specification is interchangeable with “nostrils.” *See* Ex. 1001, 2:4–10, 5:29–31, 6:9–12.

but in an alternative embodiment, the distal ends of the side straps are connected to the side arms, for example, by hook and loop material. *Id.* at 7:4–16, 38–45.

Of the challenged claims, claim 1 is the only independent claim, and claims 2–7, 17–19, 24, and 25 depend, directly or indirectly, from claim 1.

Claim 1 is reproduced below:

1. A patient interface comprising:
 - a mask assembly having:
 - a mask body including two nasal pillows extending from it, which in use rest in a substantially sealed manner against the nares of a user, the mask body sized and shaped to leave the mouth of the user uncovered by the mask body when in use;
 - a ring engaged with the mask body;
 - a plane substantially bisecting the ring, each of the two nasal pillows positioned on opposite sides of the plane;
 - an elbow rotatably engaged with the ring, the ring forming a socket into which a portion of the elbow fits to facilitate the rotatable engagement between the elbow and the ring, the elbow comprising a plurality of vent holes; and
 - a tube or conduit extending from the elbow;
 - and
 - a headgear assembly having:
 - two side straps that pass down the cheeks of the user to secure the mask body to a face of the user;
 - a top strap including a buckle configured to facilitate length adjustment of the top strap; and
 - a back strap adjustably connected to at least one of the top strap and the two side straps;
- wherein the two side straps are configured to connect and disconnect with the mask assembly while the elbow remains rotatably engaged with the

ring and the ring remains engaged with the mask body wherein the mask assembly is configured to connect to only the two side straps; and
wherein the top strap connects only with one or more of the side straps and the back strap.

Id. at 11:28–59.

E. Prosecution History

During prosecution, the Examiner rejected application claims 45, 47, 51, 52, 54 and 55 under 35 U.S.C. §103 as unpatentable over U.S. Patent No. 7,219,669 B1 (Ex. 1012, “Lovell”) and Figure 135 of U.S. Patent Publication No. 2004/0226566 A1 (Ex. 1004, “Gunaratnam”). Ex. 1009, 588–89. To overcome that rejection, Applicants amended the independent claims, including application claim 38 (patent claim 1), to recite that the mask assembly is configured to connect to only two side straps, and argued that removing two of the four side straps from Lovell’s mask would change the principle of operation of Lovell’s four point restraining system for securely positioning the mask against the nares of a user. *Id.* at 614–22. The Examiner then allowed the claims. *Id.* at 633.

F. The Asserted Grounds

Petitioner challenges claims 1–7, 17–19, 24, and 25 on the following grounds (Pet. 3):

Reference(s)	Basis	Claims Challenged
Gunaratnam and Ging ⁴	§ 103(a)	1–7, 17–19, 24, and 25

⁴ U.S. Patent Publication No. 2003/0196658 A1, pub. Oct. 23, 2003 (Ex. 1005, “Ging”).

Reference(s)	Basis	Claims Challenged
Gunaratnam, Ging, and McAuley ⁵	§ 103(a)	1–7, 17–19, 24, and 25
Lovell and Gunaratnam	§ 103(a)	1–7, 17–19, 24, and 25

II. ANALYSIS

A. *Level of Skill in the Art*

Petitioner asserts that a person of ordinary skill in the art (“POSITA”) “would have had a bachelor’s degree in mechanical engineering, biomedical engineering, or a related discipline, and at least five years of relevant product design experience in the field of medical devices or respiratory therapy, or an equivalent advanced education.” Pet. 7 (citing Ex. 1008 ¶ 21). As Patent Owner does not dispute Petitioner’s definition at this stage of the proceeding (Prelim. Resp. 32), we adopt it for the purposes of our Decision.

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*,

⁵ International Publication No. WO 2005/079726 A1, pub. Sept. 1, 2005 (Ex. 1034, “McAuley”).

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. DirectTV 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).

1. “ring”

Claim 1 recites “a *ring* engaged with the mask body” (emphasis added). Petitioner contends that the term “ring” requires “a structure with a generally circular inner passage to enable the claimed rotatable engagement with an elbow that fits into the ring, and does not require a particular outside shape for the ring.” Pet. 7–8; Ex. 1008 ¶¶ 40–41. Petitioner argues that “nothing within the plain language of the term ‘ring’ or from the intrinsic record requires that the outer surface of the ring be of a particular shape.” Pet. 9.

Patent Owner disagrees with Petitioner’s construction, and argues that “the term ring should be given its ordinary meaning, namely ‘a generally circular band of material.’” Prelim. Resp. 33. Patent Owner asserts that its proposed construction is consistent with the description in the Specification of mask base 22 as “a ring or sleeve like type attachment” (*id.* at 33–34 (citing Ex. 1001, 6:23, Figs. 4, 5)), and supported by standard dictionary definitions (*id.* at 34–35 (citing Ex. 1014, 5; Ex. 2001, 3; Ex. 2003, 3)). Patent Owner further argues that Petitioner’s construction is overly broad because it encompasses “[v]irtually any structure, regardless of its shape, that includes ‘a generally circular inner passage.’” *Id.* at 35.

We agree with, and adopt, Patent Owner's arguments. For the purposes of this Decision, we determine that the broadest reasonable interpretation consistent with the Specification of the term "ring" is a generally circular band of material.

2. *Other Claim Terms*

We determine that no other explicit claim interpretation 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).

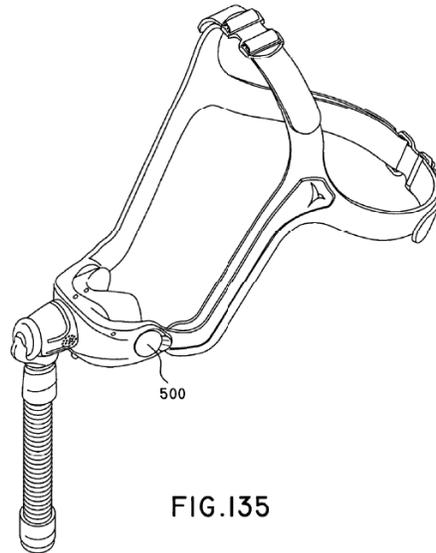
C. Asserted Obviousness

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).

*1. Asserted Obviousness over
Gunaratnam and Ging*

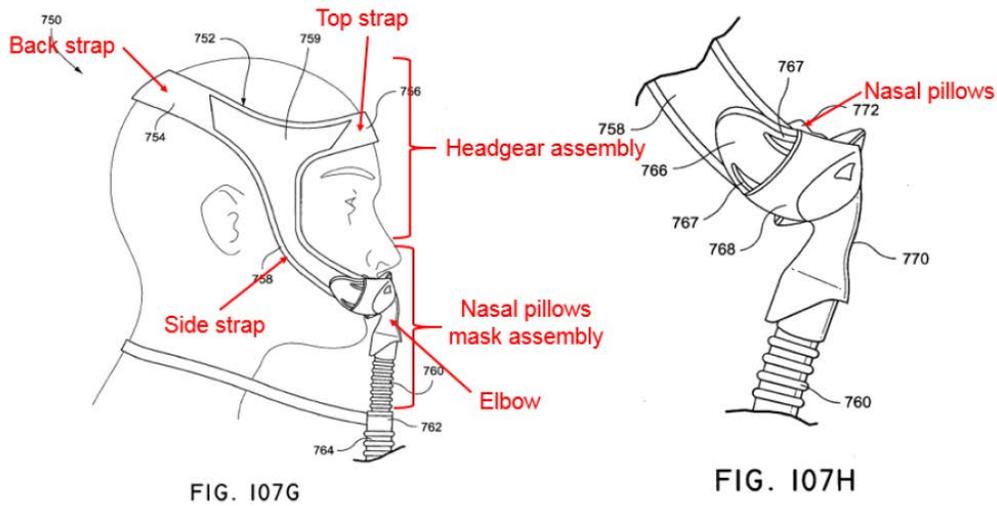
a. Overview of Gunaratnam

Figure 135 of Gunaratnam is reproduced below.



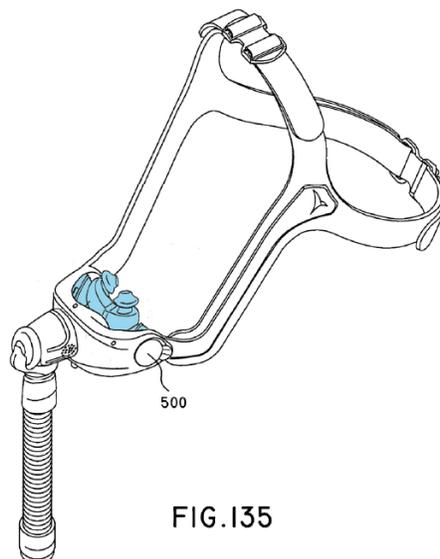
Ex. 1004, Fig. 135. Figure 135 of Gunaratnam depicts a mask having an elbow “provided to the front of the mask frame, like [ResMed’s] VISTA mask.” *Id.* ¶ 403. Petitioner asserts that “it is the Vista mask [specifically referenced in Gunaratnam] that is disclosed in *Ging*.” Pet. 19 (citing Ex. 1004 ¶¶ 341, 403; Ex. 1008 ¶¶ 47–48, 51, 61–63).

Petitioner acknowledges that Gunaratnam’s Figure 135 discloses “a full mask covering the nose entirely, not nasal pillows,” but asserts that Gunaratnam also discloses patient interfaces that use nasal pillows masks. *Id.* at 15 (citing Ex. 1004, Figs. 1–133; Ex. 1035; Ex. 1036; Ex. 1008 ¶¶ 66–73). Petitioner provides annotated versions of the nasal pillows masks depicted in Gunaratnam’s Figures 107G and 107H, which are reproduced below.



Id. at 17 (citing Ex. 1004, Figs. 107G, 107H). According to Petitioner, annotated Figures 107G and 107H illustrate “a nasal pillows mask specifically in combination with the elbow being connected at the front center of the mask as claimed, and with the same four-strap headgear as claimed.” *Id.*

Petitioner provides an annotated figure, reproduced below, to illustrate the asserted configuration achieved by “[a]pplying a known nasal pillows mask body to Gunaratnam’s Figure 135 patient interface”:



Id. at 16 (citing Ex. 1004, Fig. 135). Petitioner asserts that the similarly configured Gunaratnam embodiments “suggest[] the interchangeability of a full nasal mask and a nasal pillows mask in *Gunaratnam* Figure 135.” *Id.* at 17 (citing Ex. 1008 ¶ 73; Ex. 1004, Fig. 108; Ex. 1035, 4; Ex. 1036, 1).

b. Overview of Ging

Petitioner asserts that “[t]he same nasal mask structure shown in *Gunaratnam* Figure 135, including the nasal mask frame, is shown in more detail in another ResMed patent filing, *Ging*, for example Figure 6b of *Ging* . . . , with the mask frame referenced as 20.” *Id.* at 18–19. Figure 6b of *Ging* is reproduced below.

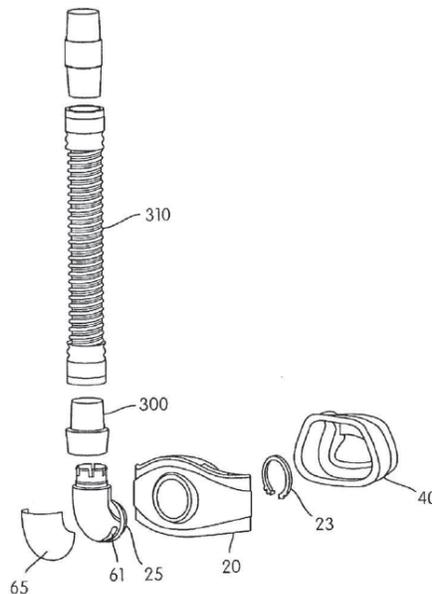


FIG. 6b

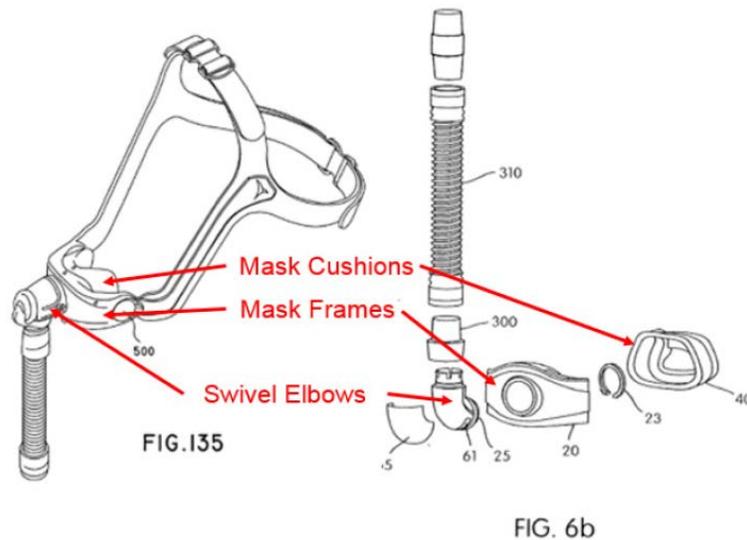
Ex. 1005, Fig. 6b. Figure 6b shows mask frame 20, elbow assembly 60 (not identified in the figure), and C-clip 23, which is used to attach elbow

assembly 60 to mask frame 20. *Id.* ¶ 113.

c. Analysis

(i) “a ring engaged with the mask body”

Petitioner argues that the mask frame in Gunaratnam’s Figure 135, which Petitioner asserts is identical to mask frame 20 in Ging’s Figure 6b, corresponds to the “ring” in claim 1. Pet. 18. Petitioner provides an annotated figure, reproduced below, identifying the mask frame in the asserted Gunaratnam/Ging combination:



Id. Petitioner argues that “[t]he Gunaratnam/Ging mask frame 20 meets the claimed ‘ring,’ despite not having a circular periphery.” *Id.* at 20 (citing Ex. 1008 ¶¶ 77–85). This argument is based on Petitioner’s proposed construction of “ring,” which we have rejected. *See supra* Section II.B.1.

Patent Owner argues that the mask frame in Gunaratnam and Ging is *not* a generally circular band of material and thus is not a “ring” under a proper claim construction. Prelim. Resp. 44–45. We agree with, and adopt, Patent Owner’s argument. As Patent Owner argues, the mask frame in the Gunaratnam/Ging combination is “oblong” or “horseshoe-shaped”—i.e., it

“includes upper and lower peripheral edges that form two surfaces that are generally parallel with each other across the length of the frame”—and thus is not a generally circular band of material as required under our claim interpretation of “ring.” *See id.; supra* Section II.B.1.

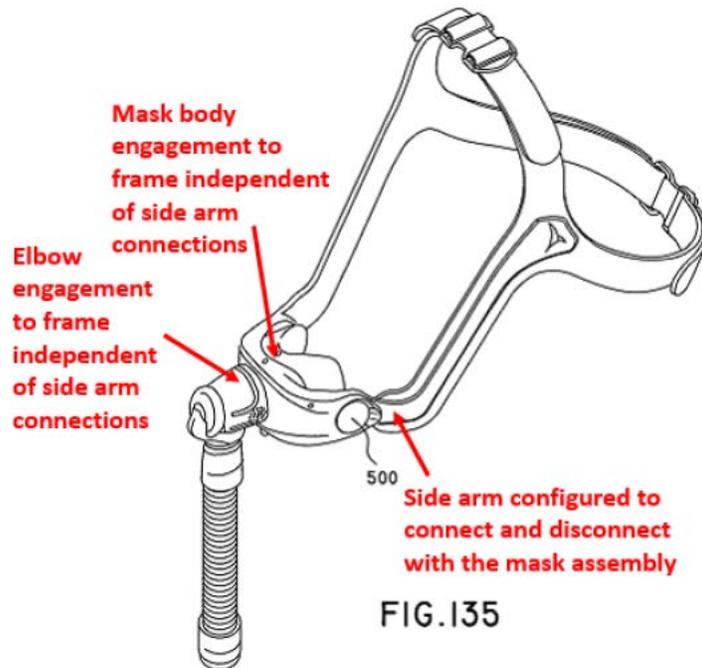
(ii) *“wherein the two side straps are configured to connect and disconnect with the mask assembly”*

Petitioner argues that the side straps in Gunaratnam’s Figure 135 are “configured to connect and disconnect with the mask assembly” as claim 1 requires “because the elbow is connected at the front center of the mask assembly, and the two side straps independently connect and disconnect at the sides.” Pet. 28 (citing Ex. 1008 ¶¶ 96–99). In support of Petitioner’s argument, Dr. Izuchukwu testifies that a skilled person would have understood that the side straps in Figure 135 could be connected to and disconnected from the mask assembly:

[A] person of ordinary skill in the art would have understood that the straps located on either side of the mask frame depicted in the patient interface in Figure 135 of Gunaratnam could be connected to and disconnected from the mask assembly (indirectly, via the yokes (side arms)) while the swivel elbow remains rotatably engaged with the ring and the ring remains engaged with the mask body. The details of how the side arms could be connected and disconnected from the frame are shown and described with respect to Figs. 108–114 in Gunaratnam, for example. Of course, Figure 135 is different from Figs. 108–114 in that the elbow is located in front of the frame, rather than inserted from the side, but the manner in which the yokes connect to the frame would be substantially the same.

Ex. 1008 ¶ 97.

Petitioner provides an annotated version of Figure 135, reproduced below, purporting to show side arms configured to connect and disconnect with the mask assembly:



Pet. 28. The figure above includes an annotation that states “[s]ide arm configured to connect and disconnect with the mask assembly.” *Id.* Petitioner explains that “[t]he side straps in Figure 135 do not connect directly to the mask assembly, but the claims do not require a direct connection.” *Id.*

Patent Owner disputes Petitioner’s argument that the side arms (side yokes) of Figure 135 are removable from the frame. Prelim. Resp. 58–59. Patent Owner asserts that instead, as shown in Figure 135, “the side yokes are formed as a single piece with the frame.” *Id.* at 58. Patent Owner also disputes Petitioner’s assertion that the side arms in Figure 135 attach to the frame in a manner similar to the side arms in Figures 108–113. *Id.* at 59. Patent Owner asserts that Figures 108–113 disclose a nozzle assembly

affixed to a “tubular shaped frame,” but the nozzle assembly in Figure 135 does not have a tubular shaped frame. *Id.* Patent Owner further argues that Petitioner “provide[s] no explanation why it would have been obvious to further alter Petitioners’ already modified Figure 135 to add a removable connection for the yokes.” *Id.*

We are *not* persuaded by Petitioner’s argument that the two side straps in Figure 135 independently connect and disconnect at the sides. *See* Pet. 28. Nor are we persuaded by Dr. Izuchukwu’s testimony that a skilled person would have understood that the side straps in Figure 135 *could be* disconnected indirectly from the mask assembly via the side arms or yokes. *See* Ex. 1008 ¶ 97.

Petitioner’s assertion “that the two side straps in Figure 135 independently connect and disconnect at the sides” is unsupported by any evidence in the record. As depicted in Figure 135, the side straps are attached to the inside of the side arms or yokes. Nothing in Figure 135 or elsewhere in Gunaratnam or in Ging teaches or suggests that the side straps can be disconnected from the side arms or yokes.

Further, we agree with Patent Owner that nothing in Gunaratnam, including Figures 108–113, teaches or suggests that the side arms or yokes in the Figure 135 embodiment can be disconnected from the mask assembly. *See* Prelim. Resp. 58–59. Rather, as Patent Owner argues, the side arms or yokes in Figure 135 are formed as a single piece with the frame. *Id.* at 58. Thus, we are not persuaded that the side straps in Figure 135 could be connected to and disconnected from the mask assembly via the side arms or yokes.

Finally, Petitioner and Dr. Izuchukwu have not explained why a skilled person would have modified the side arms or yokes in Figure 135 such that they “connect and disconnect with the mask assembly.” *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.”). Dr. Izuchukwu’s testimony that the side arms “*could be connected to and disconnected* from the mask assembly (indirectly, via the yokes (side arms))” is insufficient to show that a person of ordinary skill would have been motivated to do so. *See Ex. 1008 ¶ 97* (emphasis added); *see also InTouch Techs., Inc. v. VGO Comms., Inc.*, 751 F.3d 1327, 1352 (Fed. Cir. 2014) (determining that an expert witness had “succumbed to hindsight bias in her obviousness analysis” in testimony that “primarily consisted of conclusory references to her belief that one of ordinary skill in the art *could* combine [the] references, not that [the person skilled in the art] *would* have been motivated to do so.”).

Moreover, Dr. Izuchukwu’s further testimony that Figures 108–114 provide the details of how the side arms in Figure 135 could be configured to connect and disconnect from the frame is conclusory and unpersuasive. *See Ex. 1008 ¶ 97*. In particular, Dr. Izuchukwu fails to reconcile the differences between the embodiments depicted in the figures. As shown in Figure 108, one end of cushion assembly 604 is provided with plug 622 and the other end is provided with swivel elbow 612. *Ex. 1004 ¶ 377, Fig. 108*. Figure 109 shows that yokes 608 include yoke rings 610. *Id.* ¶ 379. As depicted in Figure 109, yoke rings 610 connect yokes 608 to the tubular shaped ends of cushion assembly 604. In the Figure 135 embodiment, however, the side arms are formed as a single piece with the mask frame, the

elbow connects in front of the mask frame, and the mask frame lacks a tubular shape that would accommodate attachment of the side arms in the manner depicted in Figures 108–114. *See* Prelim. Resp. 59. Accordingly, we are not persuaded that the yoke connections depicted in Figures 108–114 teach or suggest a manner of connecting and disconnecting the side arms in Figure 135.

Petitioner also argues that it would “have been an obvious modification for the *Gunaratnam* Figure 135 headgear assembly to have the *side straps* connect *directly* to the mask assembly, rather than connecting via *yokes* as in Figure 135.” Pet. 29 (citing Ex. 1008 ¶ 98). To support its argument, Petitioner cites the testimony of Dr. Izuchukwu. *Id.* In the opinion of Dr. Izuchukwu, “it would have been predictable, and indeed obvious to apply the strap connect[-]and[-]disconnect feature from Figures 107G–H⁶ of *Gunaratnam* into the Figure 135 embodiment (as modified by *Ging*).” Ex. 1008 ¶ 98. Dr. Izuchukwu asserts that the goal of more readily and easily connecting and disconnecting the mask assembly from the headgear assembly would have motivated the modification:

One of ordinary skill would have been motivated to apply the teachings from Figures 107G–H to allow patients to more readily connect and disconnect the mask assembly from the headgear assembly, thereby minimizing the effort required for a patient to don and remove the mask and headgear assemblies in use.

Id.

Dr. Izuchukwu’s testimony is conclusory, and does not explain sufficiently why or how a person of ordinary skill in the art would have chosen to incorporate the side strap connect-and-disconnect feature from

⁶ Figures 107G and 107H are reproduced above.

Figures 107G–H of Gunaratnam into the Figure 135 embodiment. As discussed above, the side straps in the Figure 135 embodiment are attached to the inside of the side arms or yokes, which each are formed as a single piece with the frame. Dr. Izuchukwu does not explain how the attachment of the side straps to the side arms or yokes in the Figure 135 embodiment would need to be changed in order to incorporate the side strap connect-and-disconnect feature from Figures 107G–H. In particular, Dr. Izuchukwu does not explain whether the side straps would need to be detached from the inside of the side arms or yokes and, if so, how the functionality of the side arms or yokes would be affected. Moreover, Dr. Izuchukwu fails to disclose any underlying facts or data on which he bases his opinion that the side strap connect-and-disconnect feature of Figures 107G–H would have allowed patients to connect and disconnect, more readily and easily, the mask assembly from the headgear assembly in the Figure 135 embodiment. Accordingly, we give little weight to Dr. Izuchukwu’s testimony. *See* 37 C.F.R. §42.65(a).

For these reasons, we are unpersuaded that a person of ordinary skill in the art would have incorporated the side strap connect-and-disconnect feature of Figures 107G–H into the Figure 135 embodiment.

(iii) Summary

For the reasons discussed above, we determine that Petitioner has not established a reasonable likelihood of prevailing on its challenge to independent claim 1 as obvious over Gunaratnam and Ging. As Petitioner’s arguments and evidence with respect to dependent claims 2–7, 17–19, 24, and 25 do not remedy the deficiencies with respect to independent claim 1,

we also determine that Petitioner has not established a reasonable likelihood of prevailing on its challenges to those dependent claims.

2. Asserted Obviousness over Gunaratnam, Ging, and McAuley

Petitioner contends that McAuley remedies any failure of the Gunaratnam/Ging combination to teach or suggest a “ring.” See Pet. 43. Petitioner provides an annotated version of McAuley’s Figure 9, reproduced below, depicting McAuley’s “nasal cannula”:

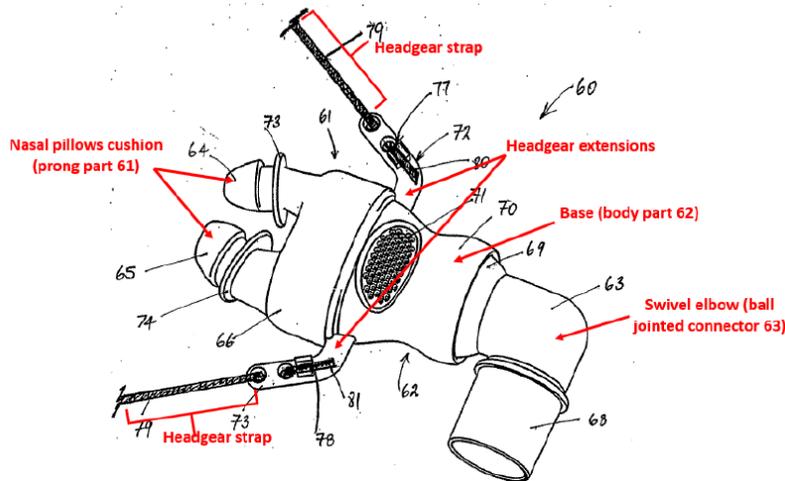


Figure 9

Id. at 41. As shown in annotated Figure 9 above, McAuley’s cannula includes body part 62, which Petitioner asserts is a “ring” as recited in claim 1. *Id.* at 42. The nasal cannula also includes “a flexible prong part 61 (i.e., a nasal pillows mask body) . . . and a ball jointed connector 63 (swivel elbow).” *Id.* at 41–42 (citing Ex. 1034, 6:11–7:26). Petitioner explains that McAuley’s “body part 62 has a generally-circular exterior and serves as a frame or base to which the swivel elbow 63 and the nasal pillows mask body 61 connect.” *Id.* at 42 (citing Ex. 1034, 7:5–10).

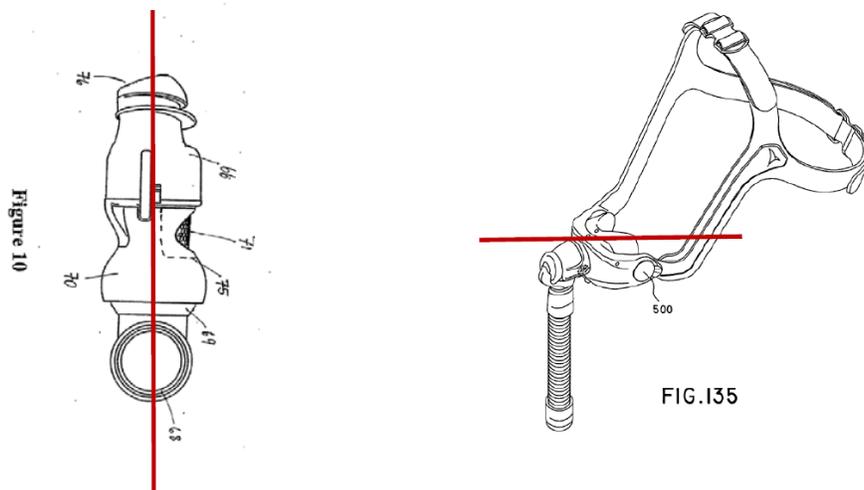
Petitioner argues that one of skill in the art would have been motivated to use McAuley's teachings to modify the Gunaratnam/Ging patient interface [i.e., to make the exterior of the frame generally circular], because, according to Petitioner, "doing so would reduce the weight of the mask on the patient's face, make the frame more compact (and therefore less obstructive to the patient's view), and reduce material costs in manufacturing the frame." *Id.* at 42–43 (citing Ex. 1008 ¶¶ 181–185). Petitioner relies on Dr. Izuchukwu's testimony to support its rationale for the combination:

With *McAuley's* teachings in mind, I believe that persons of ordinary skill in the art would have seen reason to have modified the combination of *Gunaratnam* and *Ging* (i.e., the Figure 135 embodiment from *Gunaratnum* modified to include nasal pillows and additional detail of certain features shown by *Ging*) to make the exterior of *Gunaratnam's* frame generally circular. I believe this, because skilled artisans would have understood that the circular configuration would have been smaller and therefore would have reduced the weight of the mask, which would have increased patient comfort when wearing the mask. Another reason that skilled artisans would have seen a reason to have designed the *Gunaratnam* frame to be circular was that the circular frame would have been more compact and therefore users would have had a view that was less obstructed by the patient interface. And even further, a modification to make *Gunaratnam's* frame circular would have required less material and therefore would have reduced the material costs in manufacturing. In a patient interface that has been modified to have a generally circular frame, I believe that *Gunaratnam's* headgear straps could connect to structures that project from the sides of the generally-circular frame, like *McAuley's* extension members 72 and 73, or could connect directly to attachment points on the surface of the rounded frame, without extensions 72 and 73. In some instances, connecting the headgear straps to extension members 72 or 73 would serve to

provide additional stability of the mask assembly on the patient's face due to the connection points being further outward from the center of the patient's face in use.

Ex. 1008 ¶ 184.

In opposition, Patent Owner argues that a skilled person would not have modified the Gunaratnam/Ging frame in view of McAuley to be “generally circular.” Prelim. Resp. 60–67. Patent Owner argues that “[m]odifying the oblong, horseshoe shaped frame of Gunaratnam Figure 135 to make it a ring would require substantial modifications to the frame” and “Petitioners provide almost no details as to how the mask frame of McAuley could be combined with a reasonable expectation of success with the frame shown in Gunaratnam Figure 135 (as already modified by Petitioners in view of Ging).” *Id.* at 60–61. Patent Owner additionally argues that the McAuley “ring” extends vertically from the nasal mask body and attaches to the nozzle assembly in a horizontal plane while the Gunaratnam/Ging frame extends horizontally from the nasal mask body and attaches to the nozzle assembly in a vertical plane. *Id.* at 62–63. Patent Owner provides an annotated figure, reproduced below, to demonstrate its argument:



Id. at 63. In the above figure, Patent Owner uses a vertical line through McAuley’s Figure 10 to show the vertical orientation of McAuley’s ring and a horizontal line through Gunaratnam’s Figure 135 to show the horizontal orientation of the Gunaratnam/Ging frame. Patent Owner further argues that “modifying the horseshoe-shaped frame to be generally circular would substantially change the connection of the horseshoe-shaped frame with the yokes” and that “[n]othing in McAuley discloses or suggests attaching a yoke with either of the extension members 72, 73 [*see* Patent Owner’s annotated version of McAuley’s Figure 9 reproduced above] or directly with the frame.” *Id.* at 65, 66.

Finally, Patent Owner argues that “Petitioners’ conclusory assertions are insufficient to demonstrate any reason why a POSITA would have replaced the frame of Gunaratnam Figure 135 with a ring.” *Id.* at 67. Patent Owner asserts that “Petitioners do not explain how or why a generally circular frame (about which Petitioners have provided virtually no detail) would be lighter, more compact, or . . . less expensive to manufacture than the frame shown in Gunaratnam Figure 135.” *Id.* Patent Owner further asserts that Dr. Izuchukwu similarly does not provide any reasoned explanation. *Id.* (citing Ex. 1008 ¶ 184).

We agree with Patent Owner that Petitioner’s asserted reasons for modifying the Gunaratnam/Ging patient interface in view of McAuley are conclusory and unpersuasive. Petitioner has not explained sufficiently why a person of ordinary skill in the art who wanted to modify the frame of Gunaratnam to make it lighter or more compact would have changed its exterior shape from oblong to generally circular. Petitioner does not assert that McAuley teaches using a generally circular frame for that purpose.

Rather, Petitioner relies on the testimony of Dr. Izuchukwu. As Dr. Izuchukwu recognizes, however, using a generally circular frame of smaller size than Gunaratnam's oblong frame would have required shortening or even eliminating Gunaratnam's side arms and extending Gunaratnam's side straps toward the frame. *See* Ex. 1008 ¶ 184. (As discussed above in Section II.C.1, the side arms in Figure 135 are formed as a single piece with the frame, and the side straps are attached beneath the side arms). The testimony of Dr. Izuchukwu that the side straps “*could* connect to structures that project from the sides of the generally-circular frame, like McAuley's extension members 72 and 73, or *could* connect directly to attachment points on the surface of the rounded frame, without extensions 72 and 73” (Ex. 1008 (emphasis added)), does not explain sufficiently why a person of ordinary skill in the art would have been motivated to shorten or eliminate the side arms, to lengthen the side straps, and to change the side strap attachments, as proposed. *See id.*; *see also InTouch Techs.*, 751 F.3d at 1352 (determining that conclusory assertions that a skilled person *could* have combined the teachings of the references was insufficient to show that the skilled person *would* have been motivated to do so).

Further, Petitioner does not contend that McAuley remedies the failure of the Gunaratnam/Ging combination to teach or suggest side straps that are configured “to connect *and disconnect* with the mask assembly” (emphasis added) as required by the challenged claims. *See supra* Section II.C.1. Indeed, Dr. Izuchukwu's testimony that Gunaratnam's headgear straps “could connect to structures that project from the sides of the generally-circular frame, like McAuley's extension members 72 and 73, or

could connect directly to attachment points on the surface of the rounded frame, without extensions 72 and 73” (Ex. 1008 ¶184), does not address the connect-and-disconnect feature. Accordingly, for the reasons discussed in connection with the combination of Gunaratnam and Ging above, we determine that the combination of Gunaratnam, Ging, and McAuley fails to teach or suggest that limitation.

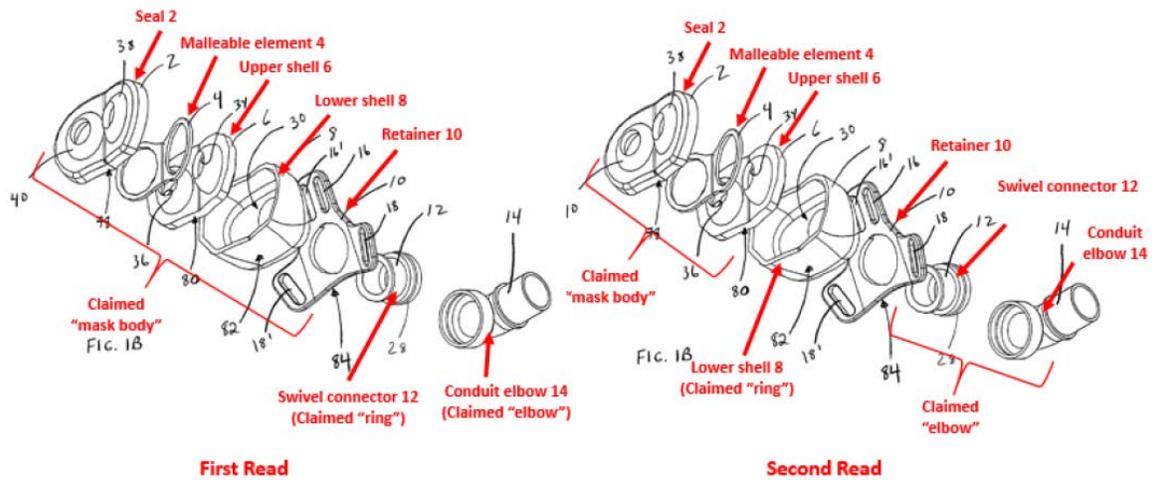
For the reasons discussed above, we determine that Petitioner has not established a reasonable likelihood of prevailing on its challenge to claims 1–7, 17–19, 24, and 25 as obvious over Gunaratnam, Ging, and McAuley.

3. Asserted Obviousness over Lovell and Gunaratnam

Petitioner argues that claims 1–7, 17–19, 24, and 25 would have been obvious over Lovell and Gunaratnam. Pet. 44–65.

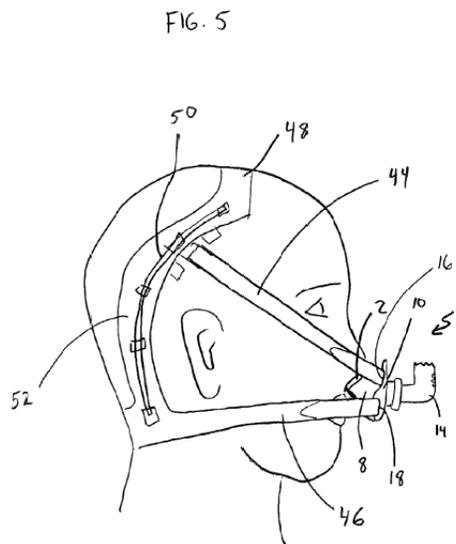
a. Overview of Lovell

Lovell discloses nasal mask 1 having upper shell 6, lower shell 8, malleable element 4, and swivel connector 12. Ex. 1012, 4:20–5:25. Petitioner contends that either swivel connector 12 or lower shell 8 is a “ring” as required by the claims. Petitioner provides two annotated versions of Lovell’s Figure 1B, reproduced below, to illustrate its alternative contentions. Pet. 47.



In the annotated figure on the left, swivel connector 12 is identified as the “ring”; and in the annotated figure on the right, lower shell 8 is identified as the “ring.”

Figure 5 of Lovell is reproduced below.



Ex. 1012, Fig. 5. Figure 5 shows a user donning nasal mask 1. *Id.* at 3:51, 6:18–19. Nasal mask 1 is maintained on the area around a user’s nares with headgear apparatus 48, which includes two upper retention straps 44 and two lower retention straps 46. *Id.* at 6:18–22, Fig. 5. The upper and lower

retention straps connect to retainer 10 at two upper and two lower connection points, e.g., upper connection point 16 and lower connection point 18 shown in Figure 5. *Id.* at 6:44–54, Fig. 5. “This four point restraining system allows for the nasal mask 1 to be securely positioned against the nares of a user.” *Id.* at 6:58–59.

b. Contentions of the Parties

Petitioner contends that one of skill in the art would have been motivated to apply the two-strap headgear design of Gunaratnam’s Figure 135 to Lovell’s four point restraining system in order to reduce the number of connections, thus resulting in a “less cumbersome” and “simpler” design. Pet. 53–54; *see also id.* at 44 (“It would have been obvious to have modified the *Lovell* patient interface to include the two-point connection *Gunaratnam* headgear assembly in place of the four-point connection headgear assembly shown in *Lovell*, to provide an alternative and simplified headgear configuration” (citing Ex. 1008 ¶¶ 44–48, 58–60, 186–208, 226–236)). Petitioner argues that “*Gunaratnam* teaches that rigid side arms (yokes) extending along the side straps provide any additional stability needed to compensate for the use of only two straps connected to the mask assembly, rather than four.” *Id.* at 54 (citing Ex. 1008 ¶ 376). Petitioner further argues that “the side arms could attach directly to a pair of connection points on *Lovell*’s retaining structure 10” or, “[a]lternatively, the two side straps could be directly and releasably connected to the retaining structure 10, while side arms run along the side straps for added stability.” *Id.* at 55 (citing Ex. 1008 ¶ 199).

Petitioner also argues that one of skill in the art would have disagreed with Patent Owner’s argument during prosecution that modifying Lovell’s

mask to connect to only two side straps would prevent the nasal mask from being positioned securely against the nares of a user. *Id.* at 53–54 (citing Ex. 1008 ¶¶ 36–38). Petitioner asserts that “*Gunaratnam* discloses numerous nasal pillows masks in which the mask assembly connects to only two side straps, while the mask is still capable of being securely positioned on the patient’s face.” *Id.* at 54 (citing Ex. 1004, Figs. 107G–H, 108, 135; Ex. 1035; Ex. 1036; Ex. 1008, ¶¶ 36–38, 198–199).

In opposition, Patent Owner argues, as it did during prosecution, that removing two of Lovell’s four side straps would change the basic principle of operation of Lovell’s four point restraining system for securely positioning the mask against the nares of a user. Prelim. Resp. 68–70; *see supra* Section I.E. Petitioner further argues that the headgear in Figure 135 is designed to maintain the nasal cushion against the outer periphery of the patient’s nose rather than seal against the patient’s nares. *Id.* at 71 (citing Ex. 1008 ¶ 124).

c. Analysis

Claim 1 recites, *inter alia*, that “the two side straps are configured to connect and disconnect with the mask assembly while the elbow remains rotatably engaged with the ring and the ring remains engaged with the mask body wherein the mask assembly is configured to connect to only the two side straps.” Thus, claim 1 and its dependent claims require two, *and only two*, side straps that are each configured to connect and disconnect with the mask assembly.

Petitioner has not persuaded us that the Lovell/*Gunaratnam* combination teaches or suggests this claim requirement. Petitioner concedes that Lovell discloses four side straps and thus does not meet this claim

requirement. To remedy that deficiency, Petitioner proposes to combine Lovell and the Gunaratnam Figure 135 embodiment. We already have determined above, however, in connection with Petitioner's first two grounds, that Gunaratnam's Figure 135 embodiment does not teach or suggest the connect-and-disconnect feature and thus also does not meet this claim requirement.

Further, we are not persuaded by Petitioner's alternative argument that "the two side straps [in Figure 135 of Gunaratnam] *could be* directly and releasably connected to [Lovell's] retaining structure 10, while side arms run along the side straps for added stability." *See* Pet. 55 (emphasis added). Petitioner has not advanced any reasoning with rational underpinning to explain *why* a skilled person would have modified the side arms and side straps in that fashion. *See Kahn*, 441 F.3d at 988 (requiring "some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness"). The cited testimony of Dr. Izuchukwu, moreover, provides no support for Petitioner's argument. First, the testimony does not address whether the side straps could be "releasably" connected as Petitioner argues. *See* Ex. 1008 ¶ 199 ("Alternatively, the two side straps could connect directly to the retaining structure 10, while side arms run along the side straps for added stability."). Second, Dr. Izuchukwu's testimony that "the two side straps "*could connect* directly to the retaining structure 10" (emphasis added) is not probative of whether a person of ordinary skill in the art would have been motivated to connect the parts in that fashion. *See* Ex. 1008 ¶ 199; *InTouch*, 751 F.3d at 1352 (giving no weight to conclusory expert testimony that a skilled person *could* have combined the teachings of the references).

For the reasons discussed above, we determine that Petitioner has not established a reasonable likelihood of prevailing on its challenge to claims 1–7, 17–19, 24, and 25 as obvious over Lovell and Gunaratnam.

III. CONCLUSION

For the reasons give, Petitioner has not shown a reasonable likelihood that it would prevail in establishing unpatentability of claims 1–7, 17–19, 24, and 25.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner’s Petition for an *inter partes* review of claims 1–7, 17–19, 24, and 25 of U.S. Patent No. 8,443,807 B2 is *denied*.

IPR2016-01726
Patent 8,443,807 B2

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