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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FISHER & PAYKEL HEALTHCARE LIMITED,
Petitioner

v.

RESMED LIMITED,
Patent Owner

Case No. IPR2017-01905
U.S. Patent No. 8,950,404

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT 8,950,404

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OTHER AUTHORITIES

EXHIBIT LIST

Exhibit No.	Description
1101	U.S. Patent No. 8,950,404 (Formica)
1102	PCT Publication No. WO 2004/041341 (Amarasinghe-I)
1103	PCT Publication No. WO 2008/030831 (Ho)
1104	U.S. Patent No. 3,424,633 (Corrigall)
1105	PCT Publication No. WO 02/47749 (Amarasinghe-II)
1106	PCT Publication No. WO 2010/066004 of PCT Application No. PCT/AU2009/001605
1107	AU Application No. 2008906390
1108	AU Application No. 2009900327
1109	AU Application No. 2009902731
1110	AU Application No. 2009904236
1111	U.S. Provisional Application No. 60/842,741 (Ho)
1112	U.S. Publication 2011/0072553 of U.S. Application No. 11/849,675
1113	Declaration of Richard Lordo
1114	*Curriculum Vitae* of Richard Lordo
1115	Excerpts from the File History of U.S. Patent No. 8,950,404 – U.S. Application No. 12/998,420
1116	Answer of ResMed Corp. to Complaint for Patent Infringement and Counterclaims, *Fisher &Paykel Healthcare Ltd. v. ResMed Corp.*, Case No. 3:16-cv-02068-DMS-WVG (S.D. Cal.)

Exhibit No.	Description
1117	U.S. Publication No. 2004/0025882 (Madaus)
1118	U.S. Patent No. 6,119,694 (Correa)
1119	PCT Publication No. WO 2009/059353 (Doherty)
1120	U.S. Publication No. 2009/0044808 (Guney)
1121	PCT Publication No. WO 2009/026627 (Henry)
1122	PCT Publication No. WO 2009/052560 (Rummery)
1123	PCT Publication No. WO 2006/130903 (Lubke)
1124	U.S. Patent No. 7,210,481 (Lovell)
1125	PCT Publication No. WO 2007/006089 (Carroll)
1126	U.S. Publication No. 2006/0118117 (Berthon-Jones)
1127	PCT Publication No. WO 2008/068966 (Omura)
1128	Certified Translation of PCT Publication No. WO 2008/068966 (Omura)
1129	U.S. Patent No. 2,126,755 (Dreyfus)
1130	Decision on Institution of Inter Partes Review Pending Case IPR2017-00340, Paper No. 8, May 16, 2017

Pursuant to 35 U.S.C. §§ 311–319 and 37 C.F.R. § 42.100 *et seq.*, Petitioner Fisher & Paykel Healthcare Limited ("Petitioner" or "Fisher & Paykel") requests *inter partes* review of Claims 9–12, 21, 37–39, 47, 56–58, and 66 ("Challenged Claims") of U.S. Patent No. 8,950,404 ("'404 Patent") (Ex. 1101), which is purportedly owned by ResMed Limited ("Patent Owner" or "ResMed"). Petitioner authorizes the Patent and Trademark Office to charge any required fees to Deposit Account No. 11-1410, including the fee as set forth in 37 C.F.R. § 42.15(a) and any excess claim fees.

I. INTRODUCTION

Petitioner filed a previous petition for *inter partes* review of the '404 Patent claims, including the Challenged Claims. *See* Ex. 1130 at 2. The Board instituted review of over 50 challenged claims, but denied institution of the few claims that included features with an "inextensible" portion, a portion that is "substantially inextensible," or a portion with fabric layers "compressed in a region" to stiffen a strap. *Id.* As its basis for denying institution of the "inextensible" claims, the Board adopted a construction of this limitation that was not proposed by either party. The Board also construed the "substantially inextensible" and "compressed in a region" limitations. Under its claim constructions, the Board concluded that the prior art as presented in the previous petition did not disclose these strap limitations.

Petitioner had no opportunity to address the Board's constructions, as those claims were not instituted. This petition addresses those new constructions and explains that, even under the Board's construction, the few remaining Challenged Claims would have also been obvious to a person of skill in the art and multiple prior art references each disclose the identified features.

With the previous petition being instituted on almost all claims, including all independent claims, it is in the interest of judicial economy for the Board to institute review of the few remaining Challenged Claims. These claims were not instituted in the prior petition because of the Board's unexpected claim constructions, not because they disclosed inventive features. None of the claim features currently at issue were central to the allowance of the patent during prosecution.

II. THE BOARD SHOULD DECLINE TO EXERCISE ITS DISCRETION UNDER 35 U.S.C. §§ 314(a) AND 325(d)

This petition is not redundant under 35 U.S.C. § 325(d) with Petitioner's previous IPR petition challenging the '404 Patent because the prior art combinations and arguments are not the same or substantially the same. In view of the Board's construction, Petitioner provides different prior art combinations and arguments showing that the construed "inextensible," "substantially inextensible," and "compress to stiffen" features were also well-known and a person of skill

would have been motivated to include them in CPAP headgear straps. For example, the previous petition did not include the Carroll, Berthon-Jones, Omura, or Dreyfus references, at least one of which is used in each of the grounds of this petition. Thus, the Board should decline to exercise its discretion under § 325(d). *See Facebook, Inc. v. TLI Communications, LLC,* IPR2015-00778, Paper No. 17 at 26–27 (PTAB Aug. 28, 2015) (instituting review even though there is some overlap with the arguments and prior art of a previous petition); *Silicon Labs, Inc. v. Cresta Tech Corp.*, IPR2015-00615, Paper 9 at 24-25 (PTAB Aug. 14, 2015) (instituting review where the later challenges rely on different reasoning, despite some commonality); *Valeo North America, Inc. v. Magna Electronics, Inc.*, IPR2014-01204, Paper No. 13 at 11–13 (PTAB Jan. 28, 2015) (instituting later petition where petitioner uses the same primary reference, but a different secondary reference); *Wavemarket Inc. v. Locationet Systems Ltd.*, IPR2014-00920, Paper No. 11 at 9–10 (PTAB Dec. 16, 2014) (instituting a later petition based on the same primary reference because it contained new prior art and arguments).

The Board should also decline to deny institution of this petition based on its broader discretion under 35 U.S.C. § 314(a). In deciding whether to exercise discretion under § 314(a), the Board has considered the following factors:

(1) the resources of the Board;

(2) the requirement to issue a final determination not later than 1 year after the date on which the Director notices institution of review;

(3) whether the same petitioner already previously filed a petition directed to the same claims of the same patent;

(4) whether at the time of filing of the first petition the petitioner knew of the prior art asserted in the second petition or should have known about it;

(5) whether at the time of filing of the second petition the petitioner already received patent owner's preliminary response to the first petition or received the Board's decision;

(6) the length of time that elapsed between the time petitioner learned of the prior art asserted in the second petition and filing of the second petition; and

(7) whether the petitioner provides adequate explanation why we should permit another attack on the same claims of the same patent.

Medtronic Xomed, Inc. v. Neurovision Medical Products, Inc., IPR2016-01405, Paper No. 12 at 7 (PTAB Dec. 29, 2016); *Xactware Solutions, Inc. v. Eagle View Tech., Inc.*, IPR2017-00034, Paper No. 9 at 7–8 (PTAB Apr. 13, 2017).

Regarding factors (1) and (2), the PTAB has already instituted review of the vast majority of the claims of the '404 Patent that share nearly all of the same

limitations with the Challenged Claims. In fact, other than Claim 9 ("inextensible") and Claim 21 ("compress to stiffen"), all of the 11 remaining Challenged Claims have only one limitation ("substantially inextensible") that is addressed in this petition and not a part of the previously instituted claims pending review. Any additional burden on the Board caused by institution of these similar claims would be minimal and would not significantly affect the Board's ability to render a final decision. *See Polygroup Ltd v. Willis Electric Co., Ltd.*, IPR2016-00801, Paper No. 8 at 15–16 (PTAB Oct. 17, 2016) (instituting review on grounds similar to a previous petition where the Board is already committed to reviewing similar issues with little additional burden, and it would be inefficient for the Board and the district court to have to decide the same issues with respect to the same patent).

Regarding factor (3) and (5), Petitioner had anticipated a broadest reasonable construction and ordinary meaning of all of the "inextensible" features, while the Patent Owner argued for a narrow construction. Instead, the Board distinguished between "inextensible" unmodified, "substantially inextensible," and "relatively inextensible." Neither party had proposed or anticipated these three constructions related to "inextensible" features. Accordingly, seeing Patent Owner's preliminary response gave no advantage to Petitioner. Therefore, Patent Owner is not prejudiced by this petition challenging the remaining claims in view of the Board's

newly introduced claim constructions.

Regarding factors (4) and (6), Petitioner did not think the new prior art (*e.g.*, Carroll, Berthon-Jones, Omura) was necessary when it filed the earlier petition. Upon receiving the Board's decision with the constructions of "inextensible" and "substantially inextensible," Petitioner gathered numerous references that specifically addressed these new constructions. Since receiving the earlier decision, Petitioner has been diligent in preparing and filing this petition with the new prior art. Moreover, whether the new prior art was available at the time of the first petition is insufficient to justify the Board exercising its discretion. *Facebook*, Paper No. 17 at 26–27 (concluding that petitioner's failure to show the prior art was unavailable is insufficient to exercise discretion under § 314(a)).

Regarding factor (7), there is more than adequate explanation and justification for this petition to outweigh any factors in favor of the Board exercising its discretion. For example, as described above, the Board previously denied institution of these Challenged Claims based on its own new construction of the limitations specific to those dependent claims. Petitioner believes that its implied "ordinary meaning" construction of those limitations was reasonable, but now requests that the Board allow Petitioner to challenge the claims based on the Board's construction. *See Medtronic Xomed, Inc. v. Neurovision Medical Products, Inc.*, IPR2016-01405, Paper No. 12 at 8–9 (PTAB Dec. 29, 2016)

(declining to exercise discretion under 35 U.S.C. §§ 314(a) and 325(d) where the prior petition relied on an improper definition of a claim term and the later petition relied on the correct construction). While the Board is not constrained by the parties' proposed constructions and is free to adopt its own construction, the Board must also give the parties an opportunity to respond. *See SAS Institute, Inc. v. ComplementSoft, LLC,* 825 F.3d 1341, 1351 (Fed. Cir. 2016).

Moreover, this petition is easily distinguished from the typical follow-on petitions that are denied by the Board for using the preliminary response and institution decision as a road map. In those situations, the original petition is typically deficient (*e.g.*, fails to address a claim limitation, fails to authenticate prior art, etc.). In contrast, here, Petitioner's prior petition challenging the '404 Patent was not deficient, but instead relied on a claim construction that the Board later determined to be incorrect. Thus, Petitioner is not attempting to take multiple bites at the apple and is instead making a first attempt at challenging the claims in view of the Board's construction. Congress provided a one-year window for petitioners to request institution of *inter partes* review, and the Board should not use its discretion to shorten that window simply because Petitioner has already filed a petition on the same claims earlier in that window. *Silicon Labs*, Paper 9 at 25 (concluding that it is not a "prudent exercise of discretion granted by § 325(d)

to truncate the ability of a petitioner to make full use of the one-year window Congress expressly provided").

III. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(a)(1)

A. Real Party-In-Interest (37 C.F.R. § 42.8(b)(1))

Fisher & Paykel Healthcare Limited is the real party-in-interest. Petitioner Fisher & Paykel provides patients with a broad range of innovative products and systems for use in the treatment of obstructive sleep apnea (OSA) and sells its products in over 120 countries.

B. Related Matters Under 37 C.F.R. § 42.8(b)(2)

ResMed and Fisher & Paykel currently are involved in pending litigation in the Southern District of California involving the '404 Patent. *See Fisher & Paykel Healthcare Ltd. v. ResMed Corp*., Case No. 3:16-cv-02068-DMS-WVG (S.D. Cal.). Ex. 1116. ResMed asserted a claim for infringement of the '404 Patent in its counterclaims on September 7, 2016. *Id*.

Petitioner also previously filed a petition for *inter partes* review of the '404 Patent (2017-00340).

C. Lead and Back-up Counsel Under 37 C.F.R. § 42.8(b)(3)

Petitioner provides the following designation of counsel, all of whom are included in Customer No. 20,995 identified in Fisher & Paykel's Power of Attorney.

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Brenton R. Babcock (Reg. No. 39,592) 2brb@knobbe.com Postal and Hand-Delivery Address: Knobbe, Martens, Olson & Bear, LLP 2040 Main St., 14th Floor Irvine, CA 92614 Telephone: (949) 760-0404 Facsimile: (949) 760-9502	Curtis R. Huffmire (Reg. No. 48,877) 2crh@knobbe.com Benjamin J. Everton (Reg. No. 60,659) 2bje@knobbe.com Postal and Hand-Delivery Address: Knobbe, Martens, Olson & Bear, LLP 2040 Main St., 14th Floor Irvine, CA 92614 Telephone: (949) 760-0404 Facsimile: (949) 760-9502

D. Service Information Under 37 C.F.R. § 42.8(b)(4)

Service information for lead and back-up counsel is provided in the designation of lead and back-up counsel above. Petitioner also consents to service by email at the following email address: BoxFPH537-2@knobbe.com.

IV. REQUIREMENTS UNDER 37 C.F.R. § 42.104

A. Grounds for Standing (37 C.F.R. § 42.104(A))

Petitioner hereby certifies that the ’404 Patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting *inter partes* review challenging the patent claims on the grounds identified herein.

B. Statement of Relief Requested Under 37 C.F.R. §§ 42.104(B)(1)–(2)

1. Prior Art

Petitioner respectfully requests *inter partes* review of the Challenged Claims of the ’404 Patent, filed December 10, 2009 as PCT/AU2009/001605, later published as WO 2010/066004 (Ex. 1106). The ’404 Patent lists foreign priority applications (Exs. 1107–1110); however, priority under 35 U.S.C. § 102(b) is limited to the filing date of the earliest U.S. application on December 10, 2009. *See* M.P.E.P § 2133.

The Challenged Claims would have been obvious in view of the following prior art:

Reference	Relevant Date	Basis[1]
WO 2004/041341 ("Amarasinghe-I") (Ex. 1102)	Published May 21, 2004	§ 102(b)
WO 2008/030831 ("Ho") (Ex. 1103)	Published March 13, 2008	§ 102(b)
U.S. 3,424,633 ("Corrigall") (Ex. 1104)	Issued January 28, 1969	§ 102(b)
WO 2007/006089 ("Carroll") (Ex. 1125)	Published January 18, 2007	§ 102(b)
U.S. Pub. No. 2006/0118117 ("Berthon-Jones") (Ex. 1126)	Published June 8, 2006	§ 102(b)
WO 2008/068966 ("Omura") (Ex. 1127)[2]	Published June 12, 2008 in Japanese	§ 102(b)
U.S. 2,126,755 ("Dreyfus") (Ex. 1129)	Issued August 16, 1938	§ 102(b)

[1] Reference to 35 U.S.C. §§ 102 and 103 throughout this Petition are to the pre-AIA versions of these statures, which are applicable to the '404 Patent.

[2] An English translation of Omura, including an affidavit attesting to the accuracy of the translation, is submitted as Ex. 1128.

2. Grounds

Ground	References	Challenged Claims	Basis
1	Amarasinghe-I, Corrigall, and Carroll	9	§ 103(a)
2	Amarasinghe-I, Corrigall, and Berthon-Jones	9	§ 103(a)
3	Amarasinghe-I, Corrigall, Ho, and Carroll	10–12, 37–39, 47, 56–58, and 66	§ 103(a)
4	Amarasinghe-I, Corrigall, Ho, and Berthon-Jones	10–12, 37–39, 47, 56–58, and 66	§ 103(a)
5	Amarasinghe-I, Corrigall, Ho, and Omura	10–12, 37–39, 47, 56–58, and 66	§ 103(a)
6	Amarasinghe-I, Corrigall, and Dreyfus	21	§ 103(a)

C. Claim Construction (37 C.F.R. § 42.104(B)(3))

Solely for the purpose of this review, Petitioner construes the Challenged Claims of the '404 Patent, and related independent claims, such that the claims are given their broadest reasonable interpretation in light of the specification of the '404 Patent, except as otherwise noted below.[3] *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278–79 (Fed. Cir. 2015), *aff'd*, 136 S. Ct. 2131 (2016); 37 C.F.R. § 42.100(b). All terms have their ordinary and customary meaning in light of the

[3] Petitioner's position regarding the scope of the claims should not be taken as an assertion regarding the appropriate claim scope in other adjudicative forums where a different standard of claim construction may apply.

specification, as commonly understood by those of ordinary skill in the art at the time of the invention. *In re Translogic Tech.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

The analyses provided herein adopt the construction of five limitations related to the Challenged Claims as previously addressed by the Board.

1. "At Least One Strap"

Previously instituted Claim 1 recites "at least one strap of said plurality of straps is constructed from a laminate having at least a first fabric layer and a second fabric layer . . . wherein said first fabric layer and said second fabric layer are joined at a joint configured to be positioned away from the patient's face when in use." The Board interpreted this phrase as limited to "an at least one strap that contacts, at some point, a patient's face when the headgear is in use." Ex. 1130 at 12.

2. "Substantially Circular or Oval Shape"

Claims 10, 37, and 56 each requires the rear portion of the headgear to engage the back of a wearer's head in a substantially circular or oval shape. The Board determined that the "substantially circular or oval shape" limitation should be given its plain and ordinary meaning. The Board suggested that it agreed with an articulation of that meaning that may include "the rear portion of the headgear

forms a loop having an oval, i.e., ellipsoidal shape, or substantially circular shape," and that also may include "a substantially oval shape." *Id.* at 13, 48–49.

3. "Inextensible"

Claim 9 recites "inextensible" unmodified in the claim. The Board construed this term as "not extensible, incapable of being stretched." *Id.* at 16.

4. "Substantially Inextensible"

Claims 10–12, 37–39, 47, 56–58, and 66 recite the term "substantially inextensible." The Board construed that term to mean "a structure that when subject to the forces normally encountered in use of a respiratory mask, will have an elongation of less than about 5%." *Id.*

5. "Relatively Inextensible"

Claim 47 recites the term "relatively inextensible." The Board construed that term to encompass "a structure that is less extensible relative to another structure." *Id.*

V. THE '404 PATENT

A. Example Embodiments

The '404 Patent describes headgear for CPAP masks, which includes "a relatively inextensible rear portion and a plurality of relatively extensible straps." Ex. 1101 at col. 2:12–16. The upper and lower side straps "may be constructed from a composite material such as Breath-O-Prene™ [*sic* – Breathe-O-Prene®]."

Id. at col. 8:55–57. The rear portion can include a patient contacting material (*e.g.*, Breathe-O-Prene®) wrapped or slid over a rigidizer. *Id.* at col. 16:44–53. "'Rigidizer' means and includes any reinforcing element that increases the rigidity of an [*sic*] another item and may include an object that increases rigidity in one or more axes." *Id.* at col. 5:67—6:3.

Many of these features are identified in annotated Figure 37 of the '404 Patent below. Ex. 1113 ¶ 26. Other embodiments are also shown below to illustrate different limitations because no single embodiment supports all of the claim limitations at issue. *Id.*

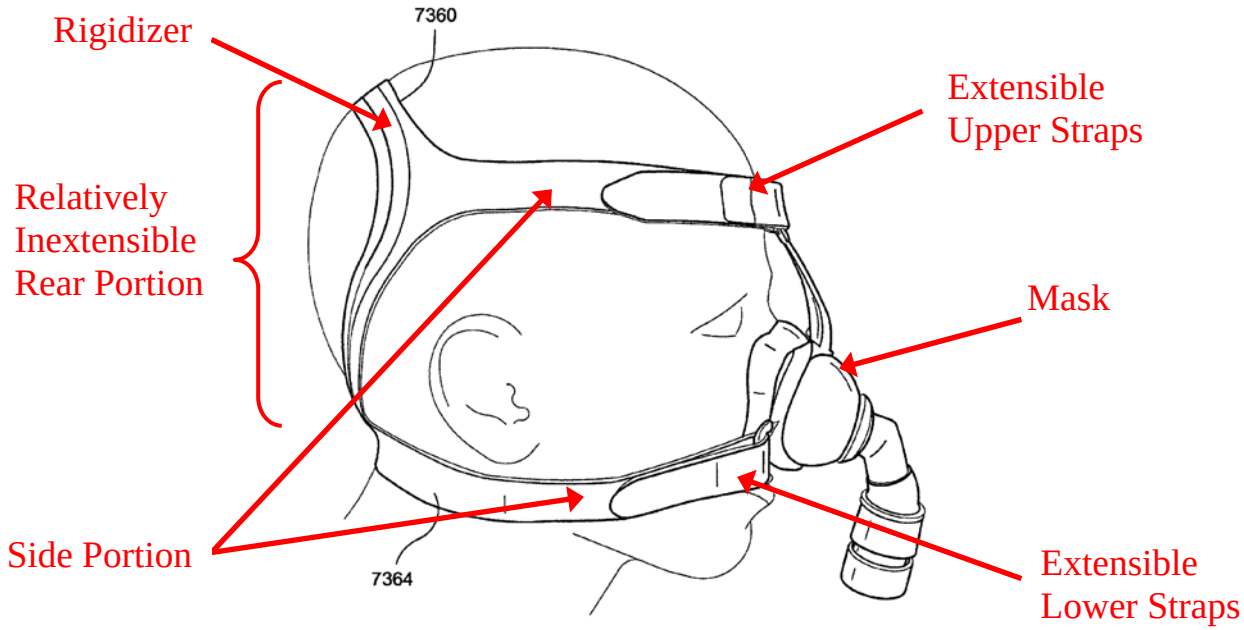


FIG. 37

As shown in Figure 21 below, the upper and lower straps can be attached to the rear portion at a "join" (4035). *See* Ex. 1101 at col. 12:48–58.

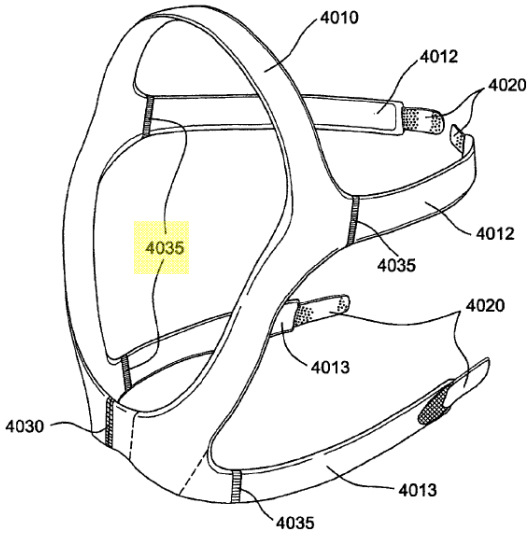
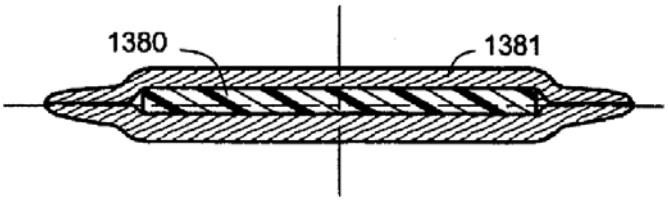


FIG. 21

The '404 Patent describes several configurations for the edges of the straps. For example, Figure 14G shows a rigidizer 1380 surrounded by a fabric outer layer 1381 that forms a joint at the edge of the strap. *Id.* at col. 17:40–52.

FIG. 14G



B. Summary of the Prosecution History of the ’404 Patent

The ’404 Patent was originally filed as U.S. Application No. 12/998,420 (“’420 Application”) on April 19, 2011. Ex. 1115 at 1–321. The Office Action dated August 29, 2014 rejected the claims under 35 U.S.C. §§ 112, 102, and 103. *Id.* at 548–563. The Office Action relied primarily upon U.S. Publication No. 2004/0025882 to Madaus (Ex. 1117). *Id.* at 553–561. After an Examiner Interview, ResMed narrowed the claim to add the limitation “and wherein the joint is positioned at approximately a center or middle of the first rounded lateral edge when viewed in cross section,” to what would later issue as Claim 1. *Id.* at 584. New claims were also added, but that limitation was not included in the new independent claims despite the Examiner’s interview summary specifically recommending that ResMed “clearly state that the first and second layers form a joint at the center of the lateral edge.” *Id.* at 615. A Notice of Allowance was mailed December 22, 2014. *Id.* at 634–642.

VI. LEVEL OF ORDINARY SKILL IN THE ART

A person having ordinary skill in the field at the time of the purported invention of the ’404 Patent would have at least a bachelor’s degree in mechanical engineering, biomedical engineering or other similar type of engineering degree, combined with at least two years of experience in the field of masks, respiratory therapy, patient interfaces or relevant product design experience. Ex. 1113 ¶ 25.

VII. CLAIMS 9-12, 21, 37-39, 47, 56-58, AND 66 OF THE '404 PATENT ARE UNPATENTABLE

A. Legal Standard for Obviousness

A claim is obvious "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." 35 U.S.C. § 103. The obviousness analysis includes an assessment of the *Graham* factors: (1) the scope and content of the prior art; (2) any differences between the claims and the prior art; (3) the level of ordinary skill in the art; and (4) any objective indicia of nonobviousness. *KSR Int'l v. Teleflex Inc.*, 550 U.S. 398, 406 (2007).

B. Ground 1: Claim 9 would have been obvious over Amarasinghe-I in view of Corrigall and Carroll

1. Overview of Amarasinghe-I (Ex. 1102)

Amarasinghe-I, owned by ResMed, was submitted, but not applied, during prosecution of the '404 Patent. Ex. 1101 at 2.

Amarasinghe-I discloses a headgear assembly 16 that includes a rear portion 20, upper side straps 22, and lower side straps 24, as shown in Figure 1 below. *Id.* at 5:3–5.

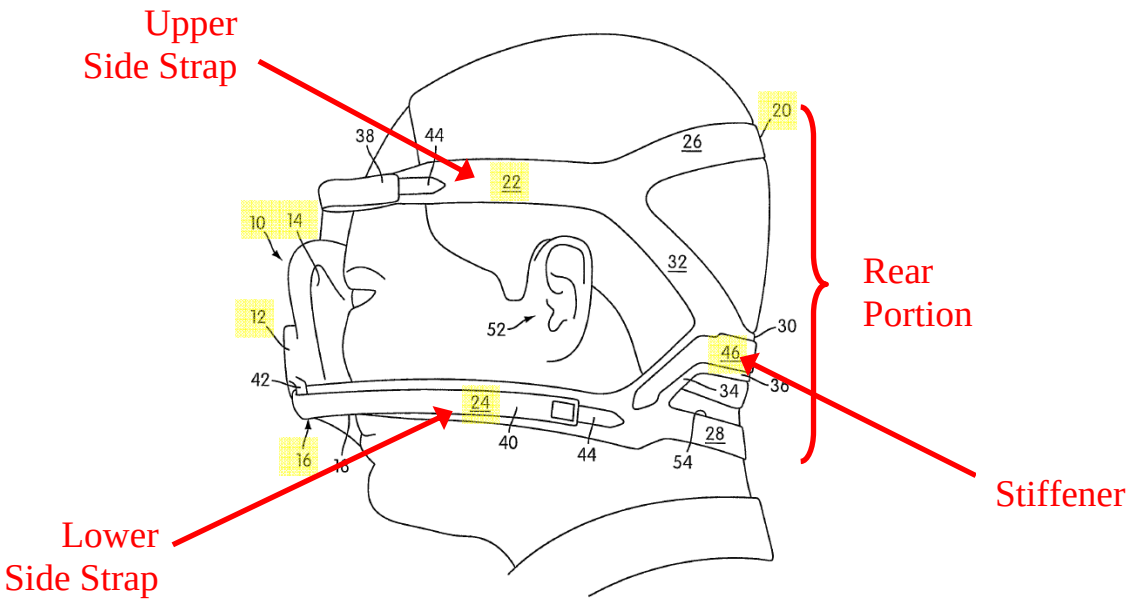


FIG. 1

Amarasinghe-I also discloses that "[t]he straps of the headgear assembly 16 are constructed from a soft, flexible composite material such as Breathe-O-Prene™ [*sic* – Breathe-O-Prene®]." *Id.* at 6:3–4. As shown above, the headgear assembly 16 can also include stiffeners 46 to reduce the flexibility of the straps 34,

36. *Id.* at 7:6–8. The stiffener 46 is constructed from a semi-rigid skin-compatible material such as thermoplastics. *Id.* at 6:17–19.

2. Overview of Corrigall (Ex. 1104)

Corrigall was not of record during prosecution of the ’404 Patent. Ex. 1101 at 2.

Corrigall relates to “novel and improved extensible strap material for use as straps in support garments.” Ex. 1104 at col. 1:34–40.

Referring to Figure 1 below, Corrigall discloses that “[o]n the surfaces of the foam strip 10 are strips 12 and 14 of extensible fabric.” Ex. 1104 at col. 3:35–36. The foam and fabric strips are adhered together to form a laminate. *Id.* at col. 4:3–5. The edges of the laminate are then stitched together to join the fabric strips and to “compress the edge portions of the foam to form tapered or smoothly rounded edges.” *Id.* at col. 4:5–8.

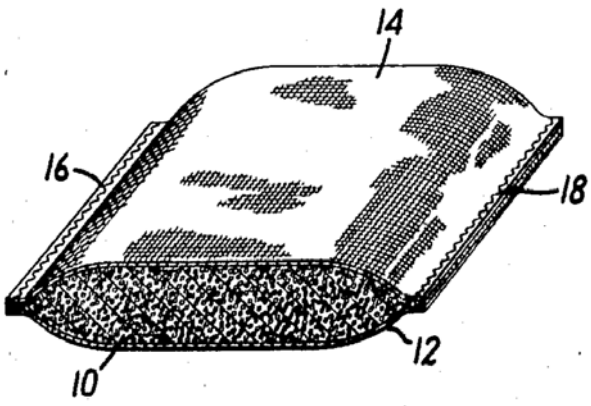


FIG. 1

As shown in Figure 4 below, Corrigall also discloses the use of heat-forming to join the outer webs 92, 93. *Id.* at col. 6:1–10. Such heat-formed edges "are also less rough or harsh and therefore more comfortable to wear." *Id.* at col. 2:60–65.

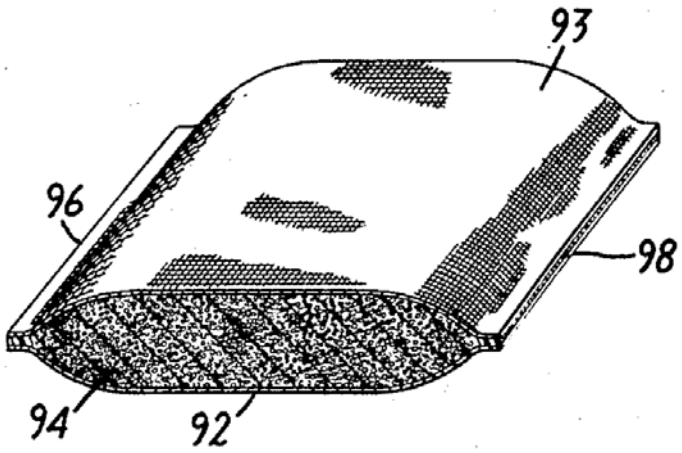


FIG. 4

Corrigall is analogous art to the claimed masks of the '404 Patent. The Federal Circuit has outlined the considerations for determining analogous art as "(1) whether the art is from the same field of endeavor, regardless of the problem addressed, and (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved." *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1237 (Fed. Cir. 2010).

The Corrigall method of making strap material is pertinent to one of the same problems faced by the Applicant for the '404 Patent, namely making comfortable straps. Ex. 1101 at col 1:25–39; Ex. 1113 ¶ 60.

Prior art mask headgear systems were known to have the problem of causing strap markings on the patient. Ex. 1113 ¶¶ 75–77. One of skill in the art would have been motivated to resolve this known problem by considering known solutions for strap design, such as those taught by Corrigall. *Id.* ¶ 77. Investigating solutions in the undergarment industry would have been a likely source for resolving wearability and comfort issues given that undergarments are worn for similar or longer duration as CPAP masks and continued comfort would be a prime concern for the wearer in both instances. *Id.* ¶ 78.

Thus, Corrigall meets at least the second test for analogousness and is proper prior art for obviousness, as previously determined by the Board. *See* Ex. 1130 at 26–30.

3. Overview of Carroll (Ex. 1125)

Carroll, owned by ResMed, was not of record during prosecution of the '404 Patent. Ex. 1101 at 2.

Carroll discloses that in known embodiments, headgear "had a non-extensible strap sewn into the headgear to eliminate elasticity and mask bounce." Ex. 1125 ¶ 81.

Carroll also discloses that "the elasticity of the headgear material of headgear 210, 310, 410 may be selected such that it provides between about 4 mm and about 14 mm of displacement for forces up to about 0.02 kN." *Id.* ¶ 82. As explained below, compared with lengths of between about 195 mm and 570 mm, an elongation of about 4 mm is between about 0.7 and 2% elongation. Ex. 1113 ¶ 64; *see infra* § VII.D.4.

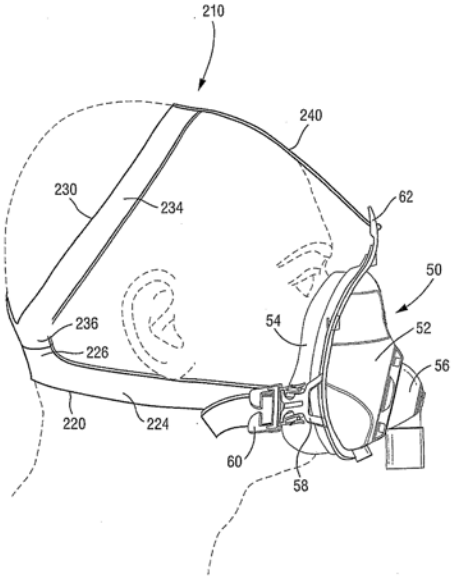


FIG. 12

4. Limitations of Claims 1 and 9

Although Claim 1 is not challenged herein, Claim 1 is discussed below because Claim 9 depends from Claim 1.

For convenience, many of these features in Claim 1 are identified below in the annotated version of Figure 1 of Amarasinghe-I and are described in detail below. *See infra* § VII.B.4.a.; Ex. 1113 ¶ 45.

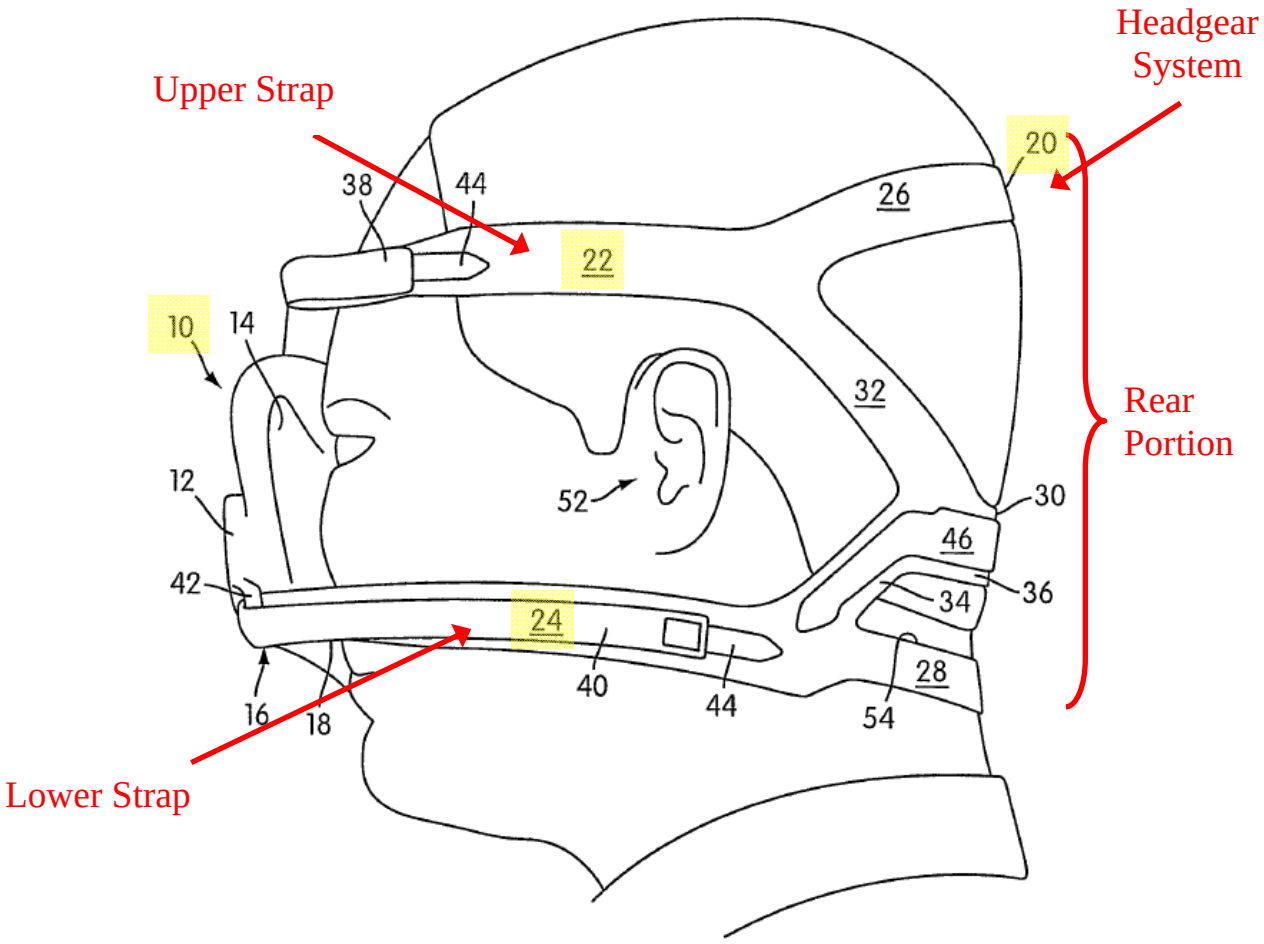


FIG. 1

As outlined below, any differences between Amarasinghe and Claims 1 and 9 were minor, well-known at the time of the invention, and taught by Corrigall or Carroll, and a person of skill would have been motivated to combine the teachings of Amarasinghe-I, Corrigall, and Carroll to arrive at the features of Claims 1 and 9. *See infra* §§ VII.B.4.a.–b.

Because Amarasinghe-I, Corrigall, and Carroll all seek to provide comfortable and supportive straps, the features taught in Corrigall and Carroll would have been readily compatible with and easily incorporated into the headgear of Amarasinghe-I. Ex. 1113 ¶ 69. Combining these familiar CPAP mask features according to known methods would have done no more than yield predictable results. *See id.*; *see also KSR*, 550 U.S. at 416.

a. Independent Claim 1

i. "A headgear system for holding a respiratory mask in a position on a face of a patient to enhance a mask seal with the patient's face, the headgear system including a plurality of straps providing a four-point arrangement for attachment with the respiratory mask"

As shown in Figure 1, Amarasinghe-I discloses a headgear assembly 16 including a rear portion 20, an upper strap 22, and a lower strap 24. Ex. 1102 at

5:3–5. Each strap 22, 24 connects to the frame 12 to form a four-point arrangement. *See id.* at 5:15–16.

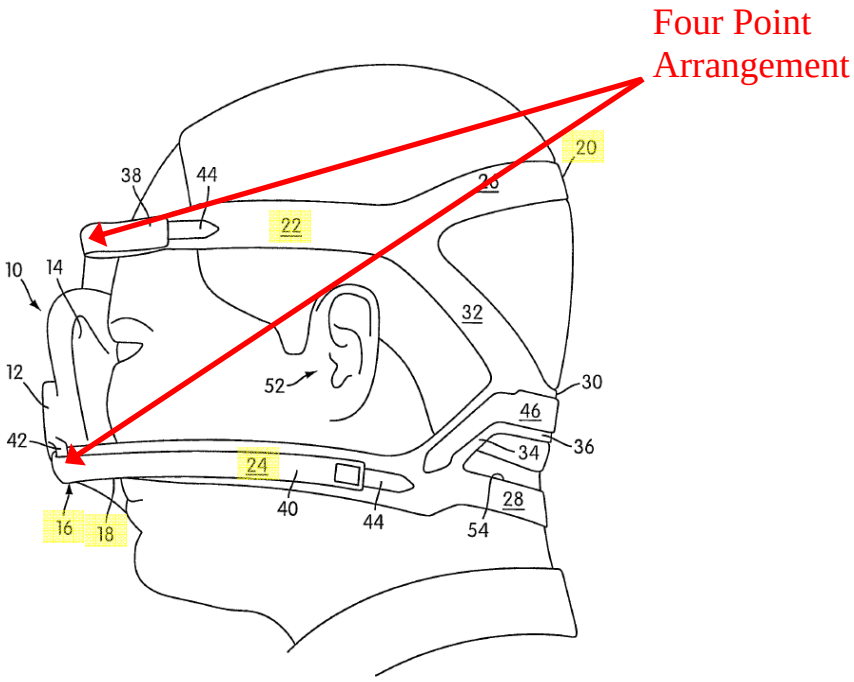


FIG. 1

ii. "at least one upper strap configured to extend above the patient's ears in use; at least one lower strap configured to extend below the patient's ears in use"

Amarasinghe-I discloses the upper side strap 22 above the patient's ears 52, and the lower side strap 24 below the patient's ear 52, as shown in Figure 1. Ex. 1102 at 7:16–18.

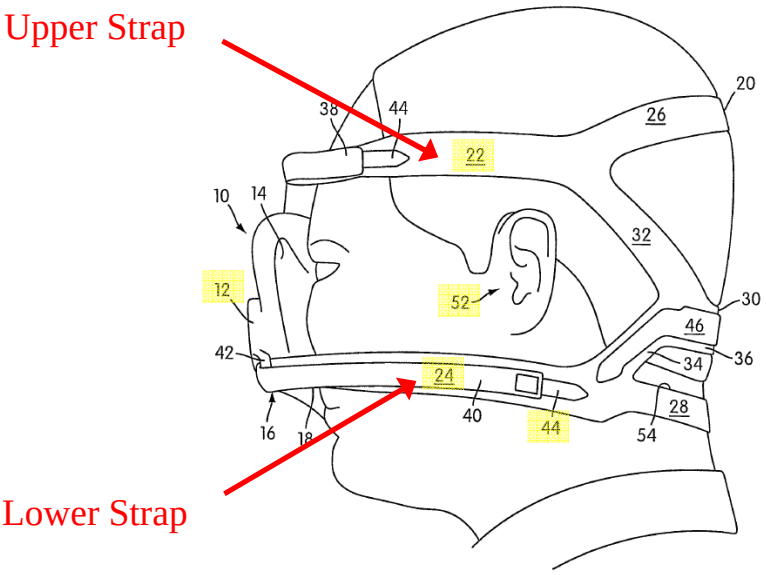


FIG. 1

iii. "and a rear portion"

Amarasinghe-I discloses a rear portion 20, as shown in Figures 1 and 4. Ex. 1102 at 5:5–7.

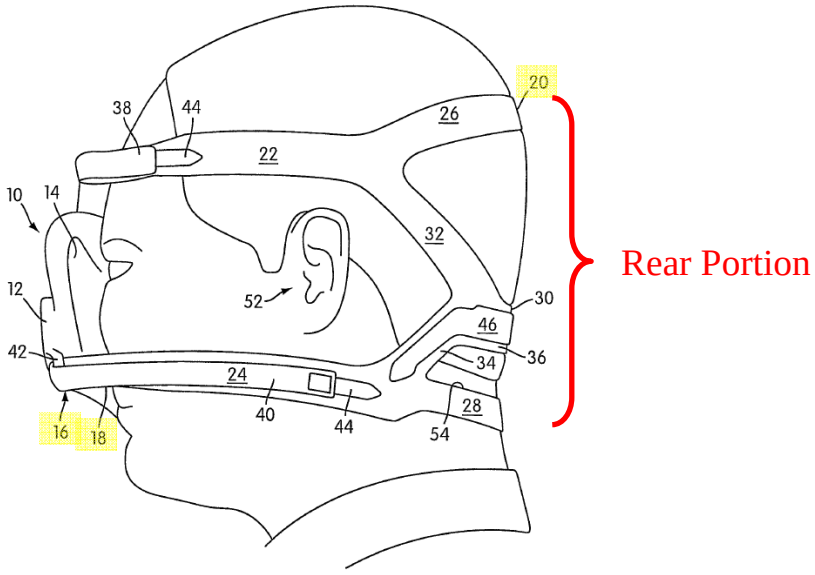


FIG. 1

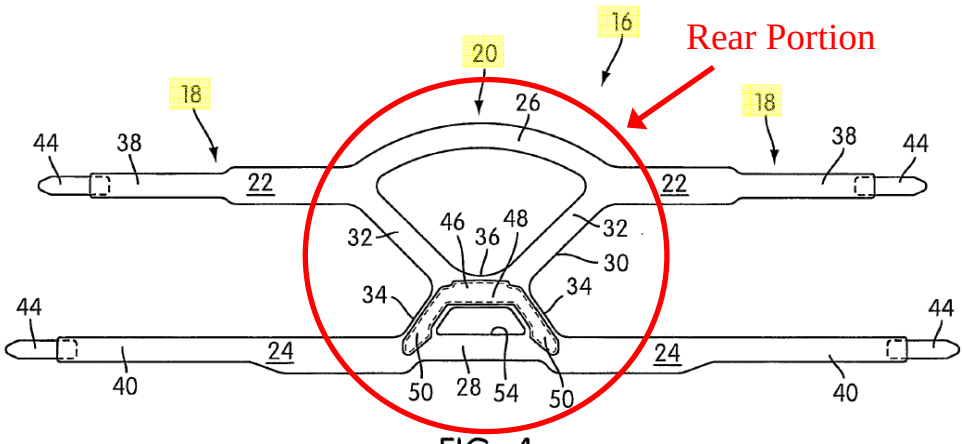


FIG. 4

iv. "wherein at least one strap of said plurality of straps is constructed from a laminate having at least a first fabric layer and a second fabric layer, said first fabric layer being constructed and arranged to be located on a patient-contacting side in use, and said second fabric layer being constructed and arranged to be located on a non patient-contacting side in use"

Amarasinghe-I also discloses that "[t]he straps of the headgear assembly 16 are constructed from a soft, flexible composite material such as Breathe-O-Prene™ [*sic* – Breathe-O-Prene®]." Ex. 1102 at 6:3–4.

ResMed's PCT Publication No. WO/02/47749 (Amarasinghe-II), published June 20, 2002, explains the known construction of Breathe-O-Prene®. Ex. 1105 at 7:1–6. Amarasinghe-II discloses:

> The first layer, which in use is positioned against the head of the patient, is constructed from polyester/nylon fabric. The second, middle layer is constructed from an [*sic*] hypoallergenic breathable polyurethane foam. The third layer is constructed from loop material. A suitable material for constructing the composite is BREATH-A-PRENE® [*sic* – Breathe-O-Prene®].

Id. Thus, Breathe-O-Prene® includes first and second fabric layers, as recited in Claim 1. Ex. 1113 ¶ 49.

Additionally, Amarasinghe-I discloses: "As shown in Fig. 7, the straps include two layers of material A, B with one of the layers A having a loop material to facilitate the connection with the strip of hook material 44 provided on the free ends the upper and lower straps 22, 24." Ex. 1102 at 6:4–8.

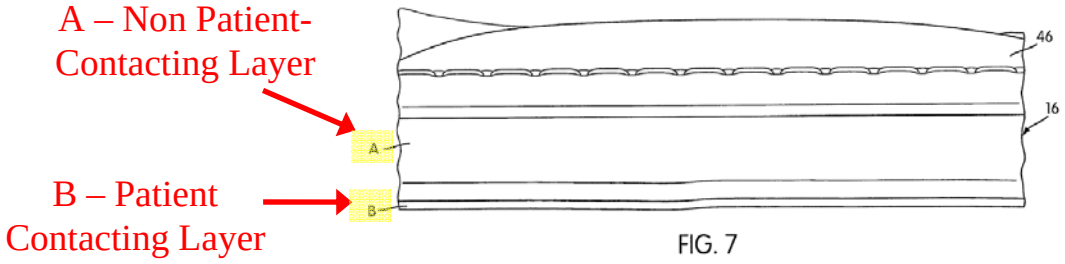
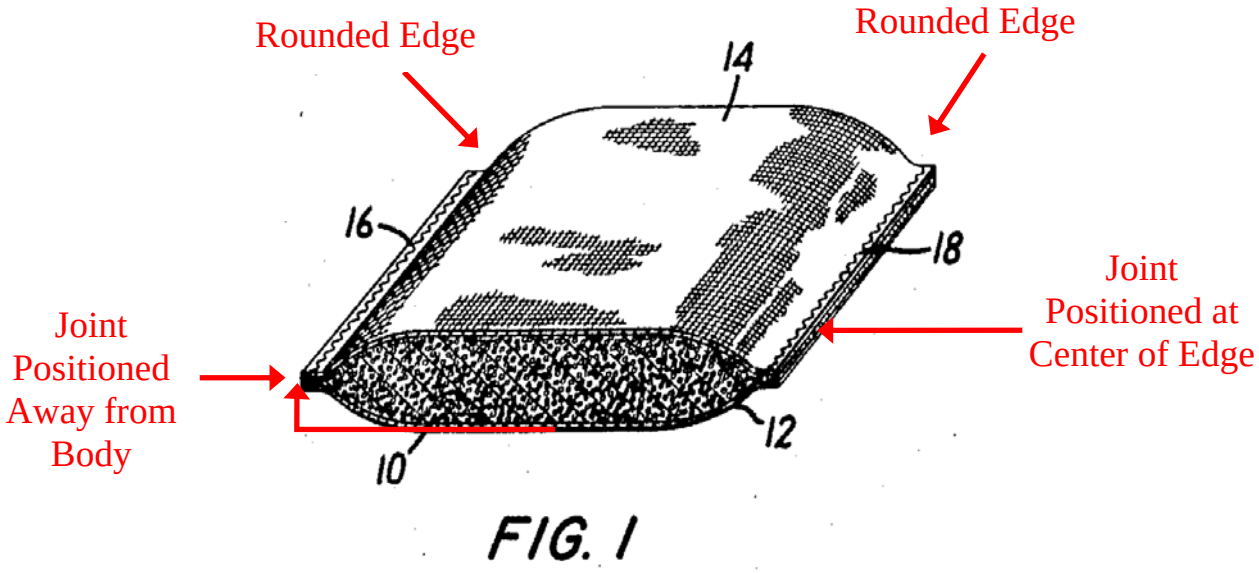


FIG. 7

v. "and further wherein said first fabric layer and said second fabric layer are joined at a joint configured to be positioned away from the patient's face when in use and wherein said at least one strap of said plurality of straps has a first rounded lateral edge when viewed in cross-section, and wherein the joint is positioned at approximately a center or middle of the first rounded lateral edge when viewed in cross section."

Amarasinghe-I does not expressly disclose these features, but such rounded edge features were common in skin contacting straps and would have been well-known to a person of skill in the art. Ex. 1113 ¶¶ 70, 74–76. For example,

Figure 1 of Corrigall shows a cross-section of a strap including first and second fabric layers 12, 14 on the surfaces of the foam layer 10. Ex. 1104 at col. 3:35–36. Additional features of the rounded edge are identified in annotated Figure 1 below. Ex. 1113 ¶ 71.



Foam and fabric layers are adhered together to form a laminate. Ex. 1104 at col. 4:3–5. The edges of the laminate are stitched together "to ***join the fabric strips***" and "to compress the edge portions of the foam to form tapered or smoothly ***rounded edges***." *Id.* at col. 4:3–8 (emphasis added). As shown in Figure 1 above, the stitched joints 16, 18 are positioned at the center or middle of the rounded lateral edges on each side of the strap. *See id.* at col. 4:3–8; Ex. 1113 ¶ 72. The edges of the strap material can be above the normal body contour when the center portion of the body contacting strap is pressing into the body. *See* Ex. 1104 at col. 2:33–39.

As shown below in Figure 4, Corrigall illustrates another strap including fabric layers 92, 93 adhered to a foam layer 94. Ex. 1104 at col. 6:1–17. The edges 96, 98 of the fabric layers 92, 93 are joined together by heat-forming. *Id.* at col. 6:1–10. The cell structure of the heat-formed edges 96, 98 "has not been fully destroyed but has been compressed to a gradually lesser degree until the full thickness of the original sheet material remains," resulting in a rounded lateral edge configuration and joints positioned at approximately a center or middle of the rounded lateral edge. *See id.* at col. 6:1–17; Ex. 1113 ¶ 73.

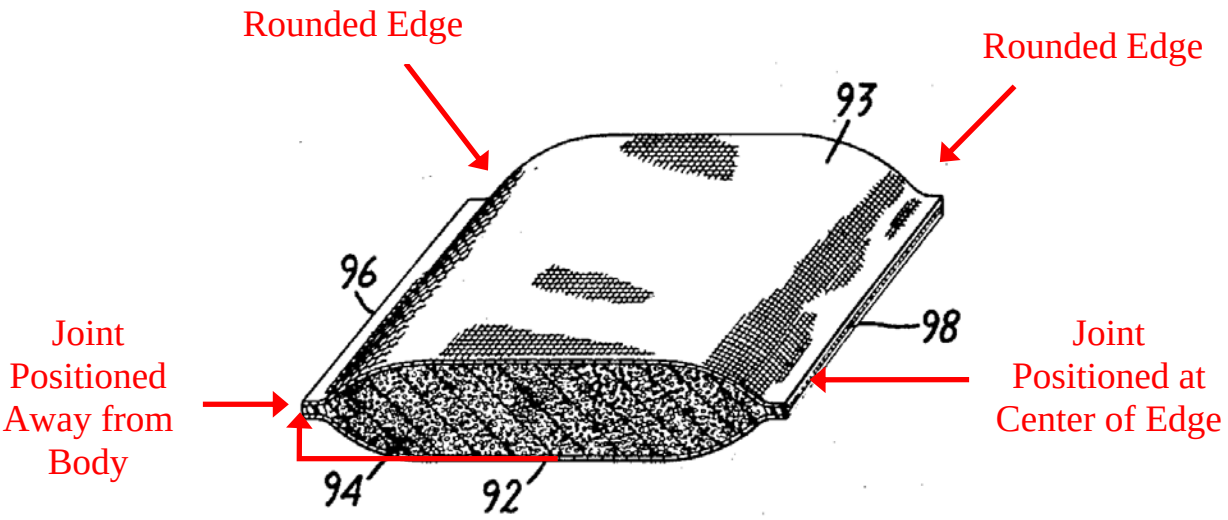


FIG. 4

A person of skill would have been motivated to modify the Amarasinghe-I to include features of the Corrigall straps based on the desire to improve patient comfort and operability of the headgear system of Amarasinghe-I by using the

comfortable rounded edge strap configurations of Corrigall with "no digging in of the edges of the strap material." *See* Ex. 1104 at col. 2:39–41; Ex. 1113 ¶¶ 77–81. Further, the edges of Corrigall were known to be "less rough or harsh and therefore more comfortable to wear." *See* Ex. 1104 at col. 2:57–65. One of skill in the art would have understood that patient comfort is a key factor to a patient achieving compliance with respect to CPAP treatment. Ex. 1113 ¶ 81. Accordingly, improving comfort and eliminating unsightly marks on a patient's face from use of the mask and headgear is a key focus of a mask designer. *Id.*

Choosing the strap configuration of Corrigall was just one of a limited number of known options for configuring a strap edge to make it more comfortable. *Id.* ¶ 80; *see also KSR,* 550 U.S. at 421.

b. Dependent Claim 9

Claim 9 depends from Claim 1 and includes "wherein said plurality of straps comprises an ***extensible portion and an inextensible portion***." From Claim 1, said "plurality of straps" refers generally to any of the headgear straps.

Amarasinghe-I discloses that "[t]he straps of the headgear assembly 16 are constructed from a soft, flexible composite material such as Breathe-O-Prene™ [*sic* – Breathe-O-Prene®]," which is known to be extensible. *See* Ex. 1102 at 6:3–4; Ex. 1113 ¶ 84.

As shown below, Amarasinghe-I further discloses the use of stiffeners (shaded blue) to add rigidity in at least sections of the rear portion of the headgear assembly, thus making the rear portion as a whole relatively inextensible. *See* Ex. 1102 at 6:9–10, 7:21–22, 9:6–12; Ex. 1113 ¶ 86.

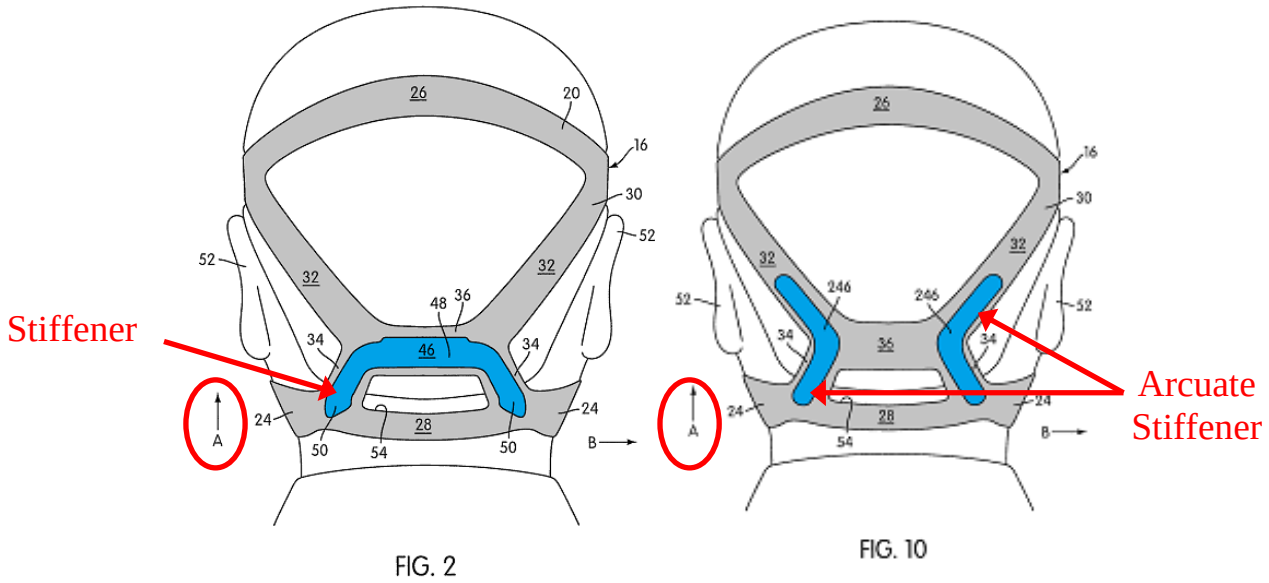


FIG. 2 FIG. 10

One of skill in the art would have recognized that where portions of the rear straps are directly attached to the semi-rigid stiffener of Amarasinghe-I by stitching, those rear strap portions are inextensible. *See* Ex. 1102 at 6:21–27; Ex. 1113 ¶ 87. The rear strap portions attached to the stiffeners are incapable of being stretched under forces typically encountered in use due to the rigidity of the stiffener. *Id.*

However, to the extent Patent Owner alleges that Amarasinghe-I does not expressly disclose that the plurality of straps include a portion that is incapable of being stretched, such "inextensible" portions were well-known in prior art CPAP

mask systems. Ex. 1113 ¶¶ 88–91. For example, Carroll discloses headgear that "had a ***non-extensible strap*** sewn into the headgear to eliminate elasticity and mask bounce." Ex. 1125 ¶ 81 (emphasis added). A person of ordinary skill in the art would understand that "non-extensible" as used by Carroll means not extensible or incapable of being stretched. Ex. 1113 ¶ 62.

A person of skill would have been motivated to combine the non-extensible headgear strap of Carroll with the headgear of Amarasinghe-I to securely support and position the headgear at the rear of the user's head. *Id.* ¶ 92. A person of skill would have understood that the non-extensible strap of the Carroll headgear was compatible and/or interchangeable with the relatively inextensible straps of Amarasinghe-I as one option from a finite number of solutions for providing a reliable fit on the user's head and maintaining a seal between the mask and the user's face. *Id.*; *see also KSR*, 550 U.S. at 421. One of skill would have understood that sewing Carroll's non-extensible straps in the rear headgear portions of Amarasinghe-I would have been one predictable solution to provide a more uniform and secure anchor point for the headgear by further limiting elasticity in the rear portion. *Id.*

A person of skill would have known that the inextensible portion would reliably and repeatedly position the headgear in a known location, for example by anchoring the headgear around a bony structure of the user's head. *Id.* ¶ 93. A

person of skill would have also known that extensible strap portions would accommodate user movement to maintain a seal between the mask and the user's face. *Id.* A person of skill seeking to achieve both of these objectives would have known to include both extensible and inextensible strap portions. *Id.*

C. Ground 2: Claim 9 would have been obvious over Amarasinghe-I in view of Corrigall and Berthon-Jones

1. Overview of Berthon-Jones (Ex. 1126)

Berthon-Jones, owned by ResMed, was submitted during prosecution of the '404 Patent, but was not applied by the Examiner. Ex. 1101 at 2.

Berthon-Jones discloses that mask and headgear assembly 410 "comprises a mask assembly 412, headgear 414, and an inflatable bladder which takes the form of an occipital pneumatic pillow 416 coupled to the headgear 414 to adjust the fit of the headgear 414." Ex. 1126 ¶ 131.

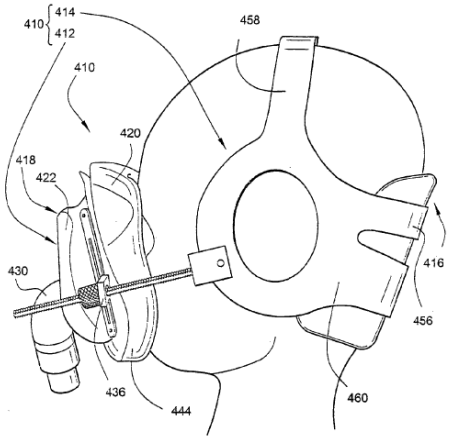


Fig. 16

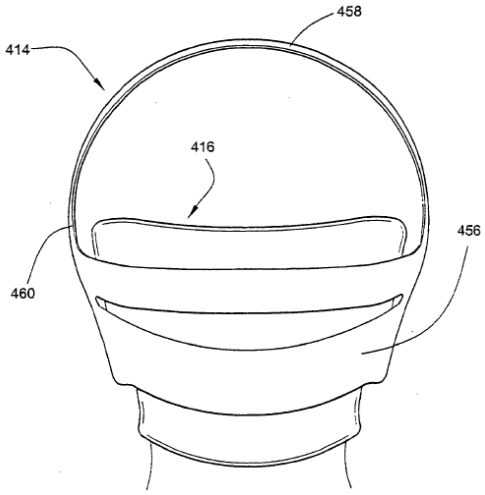


Fig. 18

Berthon-Jones further discloses that an apparatus for holding a mask sealingly against a patient's face may include "a second set of inextensible straps, again passing from the back of the head forwards to the mask." *Id.* ¶ 160.

Additionally, Berthon-Jones discloses that a "mask system may include headgear having straps that are substantially inextensible." *Id.* at Abstract. For example, in one embodiment Berthon-Jones discloses that the straps "would not generally extend more than 1-2 mm when subject to 2 KgF tension." *Id.* ¶ 144. Berthon-Jones discloses that the straps would be at least about 15 cm from side to side (150 mm). *Id.* ¶ 167. As explained below, the substantially inextensible straps of Berthon-Jones have a percent elongation of about 0.6% to about 1.3% under typical forces encountered in use. Ex. 1113 ¶ 97; *see infra* § VII.E.

2. Limitations of Claims 1 and 9

Because Berthon-Jones teaches headgear straps for CPAP masks, the features of Berthon-Jones would have been readily compatible with and easily incorporated into the headgear of Amarasinghe-I. Ex. 1113 ¶ 98.

Combining these familiar CPAP mask features according to known methods would have done no more than yield predictable results. *See id.*; *see also KSR*, 550 U.S. at 416.

a. Independent Claim 1

The combination of Amarasinghe-I and Corrigall teaches the headgear system of Claim 1, as discussed above. *See supra* § VII.B.4.a.

b. Dependent Claim 9

Claim 9 depends from Claim 1 and includes "wherein said plurality of straps comprises an ***extensible portion and an inextensible portion***."

As discussed above, Amarasinghe-I discloses an extensible portion and a relatively inextensible rear portion that includes inextensible portions where the rear straps are directly attached to the semi-rigid stiffener. *See supra* § VII.B.4.b.

However, to the extent that Patent Owner alleges that Amarasinghe-I does not expressly disclose that the plurality of straps include a portion that is incapable of being stretched, such "inextensible" portions were well-known in prior art CPAP mask systems. Ex. 1113 ¶ 101. For example, Berthon-Jones discloses that "[a]n apparatus for holding a mask sealingly against a patient's face may include a ***first set of extensible straps***, passing from the back of the head forwards to the mask," and "a ***second set of inextensible straps***, again passing from the back of the head forwards to the mask, and lying over the first set." Ex. 1126 ¶ 160 (emphasis added).

A person of skill would have been motivated to combine the inextensible headgear strap of Berthon-Jones with the headgear of Amarasinghe-I to securely support and position the headgear at the rear of the user's head. Ex. 1113 ¶ 102. A person of skill would have understood that the inextensible straps of the Berthon-Jones headgear were compatible and/or interchangeable with the relatively

inextensible straps of Amarasinghe-I as one option from a finite number of solutions for providing a reliable fit on the user's head and maintaining a seal between the mask and the user's face. *Id.*; *see also KSR*, 550 U.S. at 421. One of skill would have understood that sewing Berthon Jones's inextensible straps in the rear headgear portions of Amarasinghe-I would have been one predictable solution to provide a more uniform and secure anchor point for the headgear by further limiting elasticity in the rear portion. *Id.*

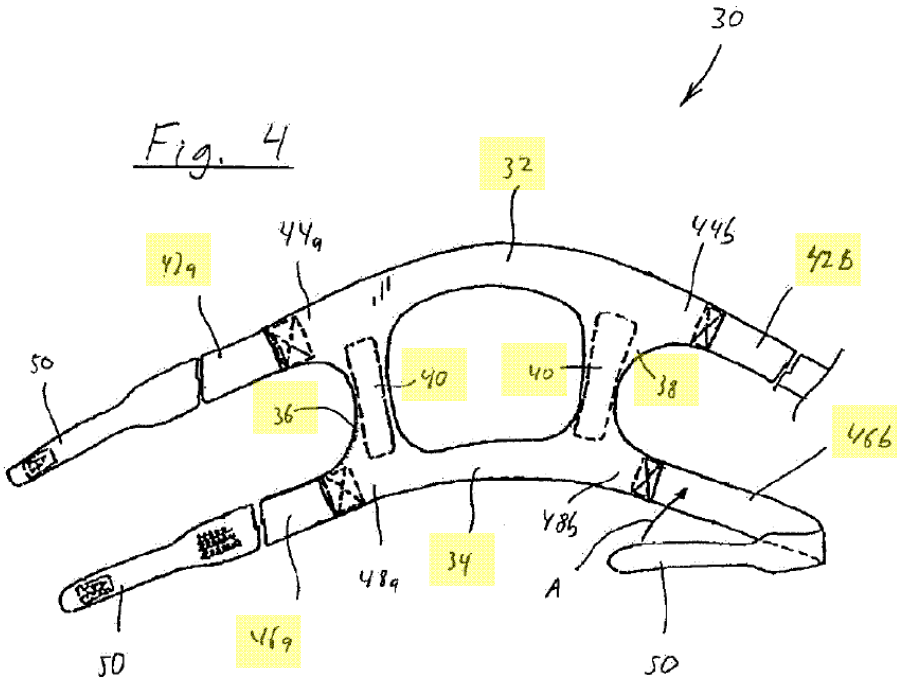
A person of skill would have also known to include both extensible and inextensible strap portions for at least the reasons provided above for Carroll. *See supra* § VII.B.4.b.

D. Ground 3: Claims 10–12, 37–39, 47, 56–58, and 66 would have been obvious over Amarasinghe-I in view of Ho, Corrigall, and Carroll

1. Overview of Ho (Ex. 1103)

Ho was submitted, but not applied, during prosecution of the '404 Patent. Ex. 1101 at 2.

Ho discloses headgear to maintain the mask seal against a patient's face without discomfort. Ex. 1103 ¶ 4.



As shown in Figure 4 above, he straps (coupling members 42a, 42b, 46a, 46b) are attached to the ends of the rear portion (first and second beams 32, 34), for example, by stitching, sewing, or sonic/heat welding. *Id.* Ho further discloses that the rear portion of the headgear is semi-rigid. *Id.* ¶ 29.

2. Limitations of Claims 10–12, 37–39, 47, 56–58, and 66

A person of skill in the art at the time of the purported invention would have been motivated to combine the teachings of Amarasinghe-I, Corrigall, and Carroll, for at least the reasons provided above. *See supra* § VII.B.4. Because Ho teaches headgear for holding a CPAP mask in position, the features taught in Ho would have been readily compatible with and easily incorporated into the headgear of Amarasinghe-I as described below. Ex. 1113 ¶ 111.

3. Independent Claims 29 and 48

Although Claims 29 and 48 are not being challenged in this petition, Claims 29 and 48 are discussed below because Claims 37–39, 47, 56–59, and 66 depend from Claim 29 or 48.

a. Headgear System

Independent Claims 29 and 48 include the same preamble as Claim 1. Accordingly, Amarasinghe-I discloses these features, as discussed above. *See supra* § VII.B.4.a.i.

b. Upper Strap

Claim 29 includes "***at least one upper strap*** configured to extend above the patient's ear in use, ***the at least one upper strap including loop material and an end with hook material***, for adjustable attachment to ***a slot of a forehead support***." Claim 48 includes "***a pair of upper straps*** each configured to extend above the

patient's ear in use, ***each said upper strap including an outwardly facing loop material layer and an end with hook material*** to adjustably engage the outwardly facing loop material layer, for length-adjustable attachment to ***a slot of a forehead support***."

Amarasinghe-I discloses, "The upper and lower straps 22, 24 are constructed of a loop material that engages the strip of hook material 44 when the upper and lower straps 22, 24 are connected to the frame 12." Ex. 1102 at 5:19–24.

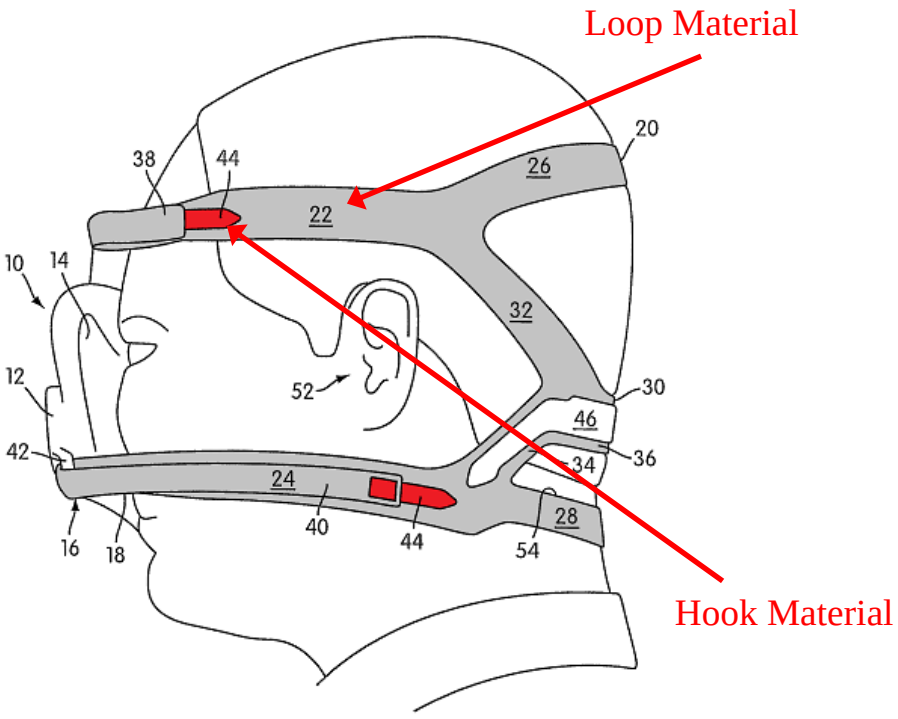


FIG. 1

Amarasinghe-I discloses that the upper straps 22 may be removably connected to clip structures provided on a forehead support. *Id.* at 5:25—6:2.

Although a person of skill would have understood that the clip structures include slots, Amarasinghe-I does not expressly disclose a slot of a forehead support. Ex. 1113 ¶ 117. However, headgear connector slots were well known in CPAP prior art. *Id.* For example, Ho discloses "threading a free end 50 of the coupling member through a slot or orifice provide[d] in the patient interface." Ex. 1103 ¶ 36.

A person of skill would have understood that headgear clips and slots were interchangeable options from a finite number of solutions for connecting headgear straps to a mask. Ex. 1113 ¶ 118; *see also KSR,* 550 U.S. at 421.

c. Lower Strap

Claim 29 includes "***at least one lower strap*** configured to extend below the patient's ear in use, ***the at least one lower strap including loop material and an end with hook material*** for adjustable attachment to ***a headgear clip*** that connects with a lower part of the mask." Claim 48 includes "***a pair of lower straps*** each configured to extend below the patient's ear in use, ***each said lower strap including an outwardly facing loop material layer and an end with hook material*** to adjustably engage the outwardly facing loop material layer, for length-adjustable attachment to ***a headgear clip*** that connects with a lower part of the mask."

Amarasinghe-I discloses, "The upper and lower straps 22, 24 are constructed of a loop material that engages the strip of hook material 44 when the upper and lower straps 22, 24 are connected to the frame 12." Ex. 1102 at 5:19–24.

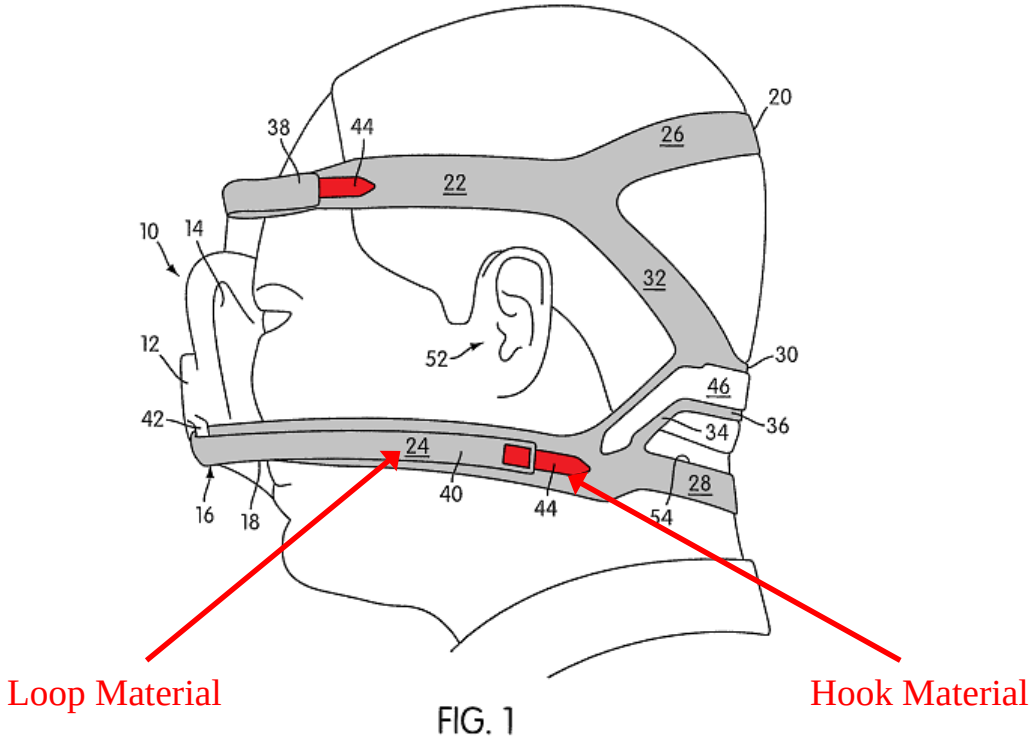


FIG. 1

Amarasinghe-I also discloses that "the upper and lower straps 22, 24 may include locking clips attached thereto that are adapted to interlockingly engage with the frame 12." Ex. 1102 at 5:25–27.

d. Rear Loop

Claims 29 and 48 require "a rear strap portion having ***a rear loop configured and dimensioned to circumscribe the rear of the patient's head***."

A loop can have a variety of shapes that will circumscribe the rear of the head, including those taught by Amarasinghe-I and shown in at least Figure 2 below. Ex. 1102 at Fig. 2; Ex. 1113 ¶ 120.

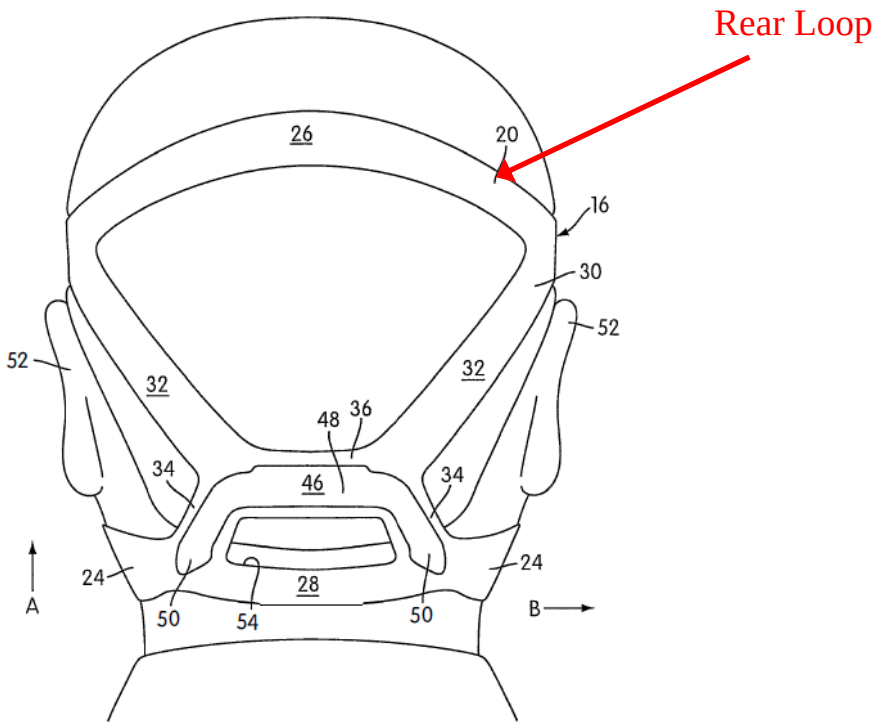
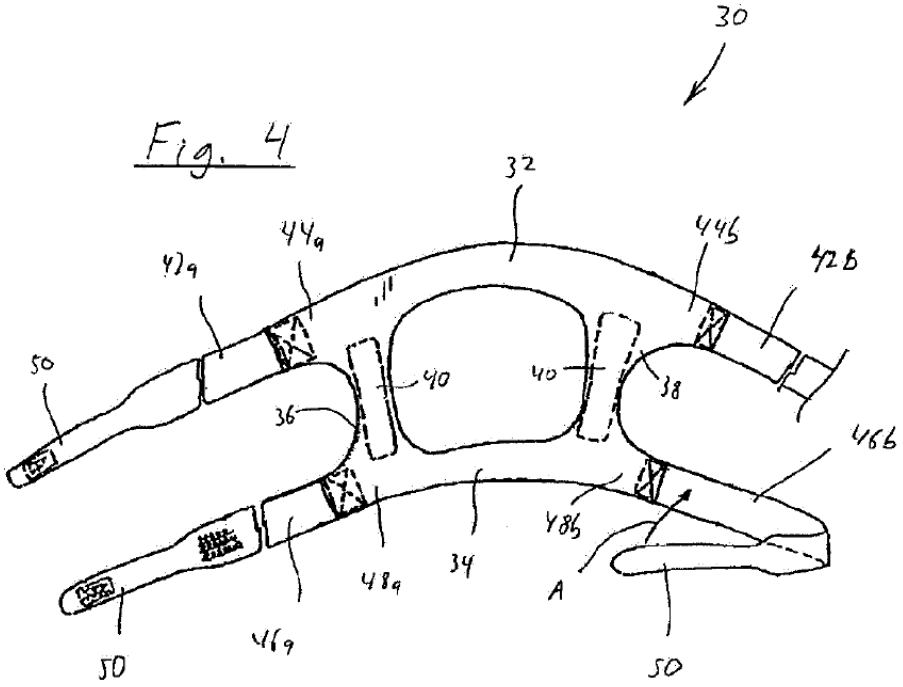


FIG. 2

Figure 4 of Ho also shows a generally circular or oval-shaped rear loop that circumscribes the rear of the patient's head. Ex. 1113 ¶ 121.

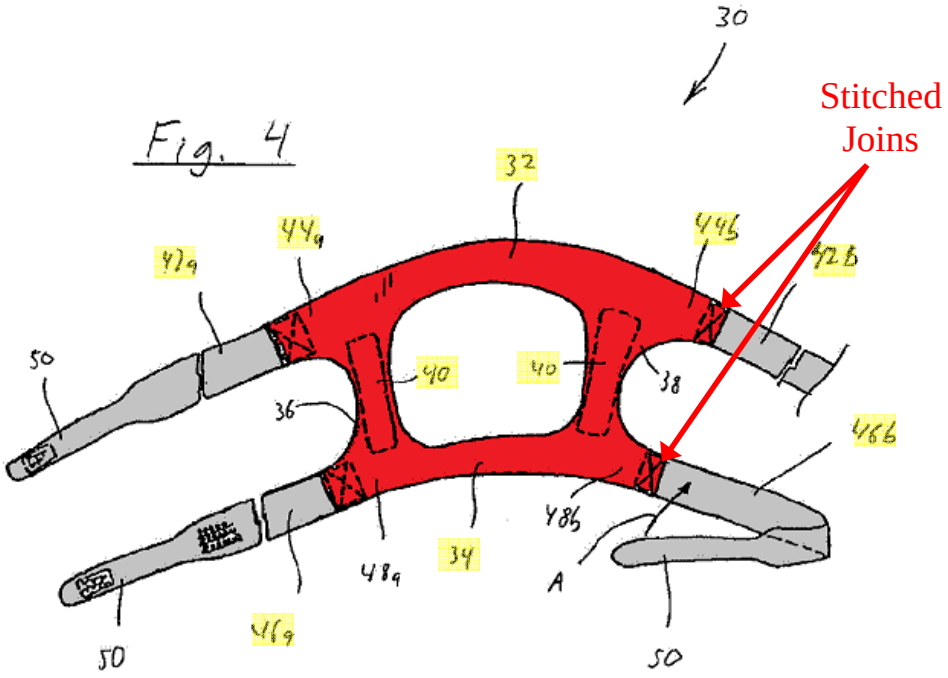


A person of skill would have recognized that providing a generally circular or oval-shaped rear loop would have been a matter of design choice. *Id.* ¶ 123. Further, a person of skill would have recognized that a rear loop configuration would have been desirable to create a stable means of securement that comfortably fits a wide range of patient populations. *See* Ex. 1103 ¶ 32; Ex. 1113 ¶ 123.

e. Stitched Joins

Claim 29 includes "the at least one upper strap and the at least one lower strap being attached to the rear strap portion ***via stitched joins***." Claim 48 includes "each said upper strap and each said lower strap being attached to the rear strap portion ***via stitched joins***."

Amarasinghe-I does not expressly disclose this feature, but such a feature was well known in CPAP prior art. Ex. 1113 ¶¶ 124–125. For example, as shown at least in Figure 4 below, Ho discloses that upper and lower straps 42a, 42b, 46a, and 46b "can be ***stitched***, sewn, or sonic/heat welded" onto the rear portion 32, 34. Ex. 1103 ¶ 34 (emphasis added).



A person of skill also would have known that attaching straps to a rear portion using stitched joins was an alternative to forming unitary straps and stitching was one of a few common methods for attaching straps. Ex. 1113 ¶ 126; *see also KSR*, 550 U.S. at 421. Indeed, Ho provides examples of both unitary headgear configurations (*see, e.g.*, Ex. 1103 at Figs. 1–2) and stitched configurations (*see, e.g.*, *id.* at Figs. 3–4). A person of skill would have been motivated to select the stitching method to provide increased support in the stitched join region, reduce waste, and allow for variations in extensibility and stiffness between the side and rear portions. *See* Ex. 1104 at col. 1:46–50; Ex. 1113 ¶ 126.

f. Relatively Inextensible

Claim 29 includes "***the rear strap portion comprising a material that is relatively inextensible*** compared to ***a relatively extensible material of the at least one upper strap***." Claim 48 includes "***the rear strap portion comprising a first material with a first extensibility*** and ***each said upper or lower strap comprising a second material with a second extensibility*** that is different than the first extensibility of the first material."

As explained above, Amarasinghe-I discloses a rear portion that includes stiffeners 46 that provide relative inextensibility or different extensibility than the upper and lower straps 22, 24. *See supra* § VII.B.4.b.

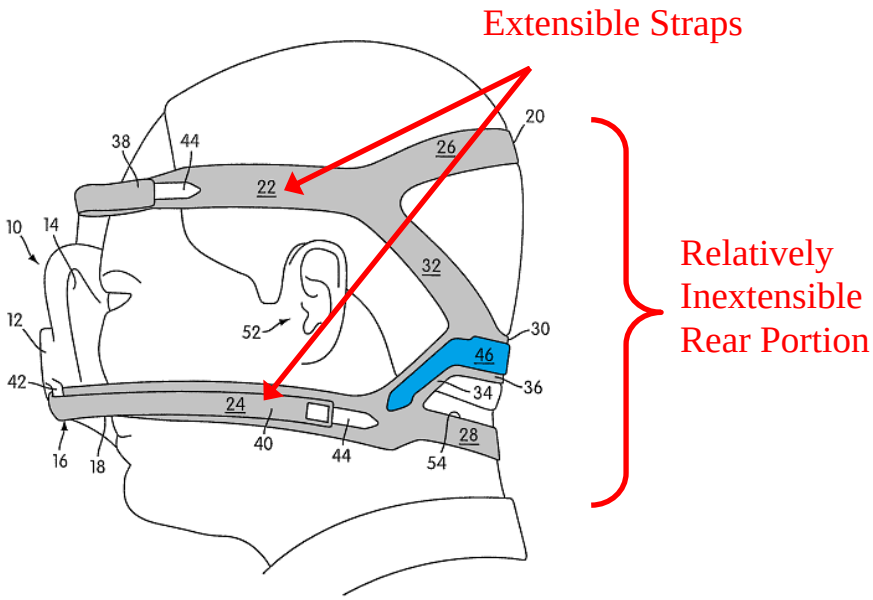


FIG. 1

g. Layers

Claim 29 includes "wherein at least one strap of said plurality of straps is constructed from ***a laminate having at least a first layer and a second layer***, said first layer being constructed and arranged to be located on a patient-contacting side in use, and said second layer being constructed and arranged to be located on a non patient-contacting side in use." Claim 48 includes "wherein each of said upper strap and each said lower strap is constructed from at least ***a patient-contacting fabric material layer and a respective said outwardly facing loop material layer***, each said patient-contacting fabric material layer being constructed and arranged to engage the patient's face while in use."

Amarasinghe-I discloses laminate straps having the claimed first fabric layer and second, outwardly-facing loop material layer. *See supra* § VII.B.4.a.iv. These features are identified in annotated Figure 7 of Amarasinghe-I below. Ex. 1113 ¶ 50.

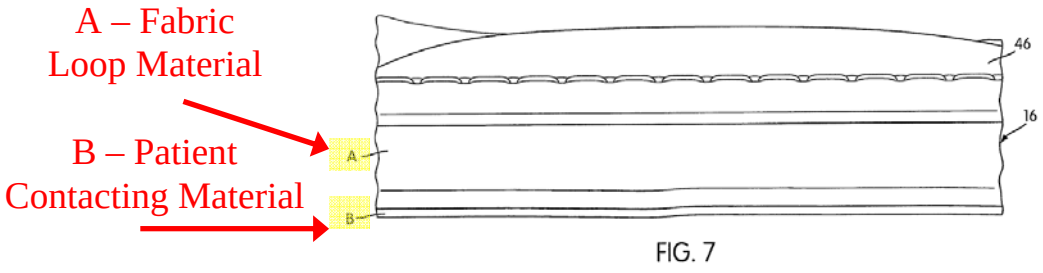


FIG. 7

Although Figure 7 shows a stiffener 46 adjacent the fabric loop material, the stiffener 46 only extends across part of the headgear. Ex. 1102 at Fig. 1. Thus, in

other regions (*e.g.*, grey regions), the loop material would be the exterior layer. Ex. 1113 ¶ 50.

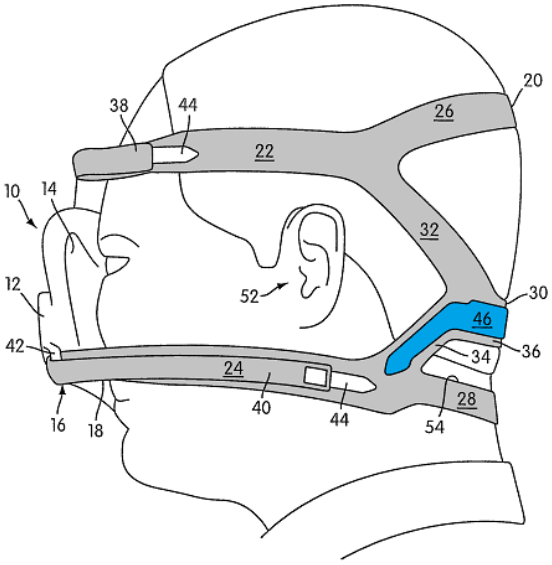


FIG. 1

h. Rounded Edge Configurations

Claim 29 includes "and further wherein each of said first layer and said second layer forms a part of ***at least one rounded lateral edge*** of the at least one strap when viewed in cross-section." Claim 48 includes "and further wherein mutual edges of the patient-contacting fabric material layer and said outwardly facing loop material layer form ***a joint*** positioned, as seen in cross-section, at a lateral edge of each said upper strap and each said lower strap, ***each said joint being spaced away from the patient's face*** in use while the patient-contacting fabric material layer contacts the patient's face in use."

Amarasinghe-I does not expressly disclose these features, but Corrigall does as discussed above. *See supra* § VII.B.4.a.v. Features of the rounded edge are identified in annotated Figure 1 of Corrigall below. Ex. 1113 ¶ 130.

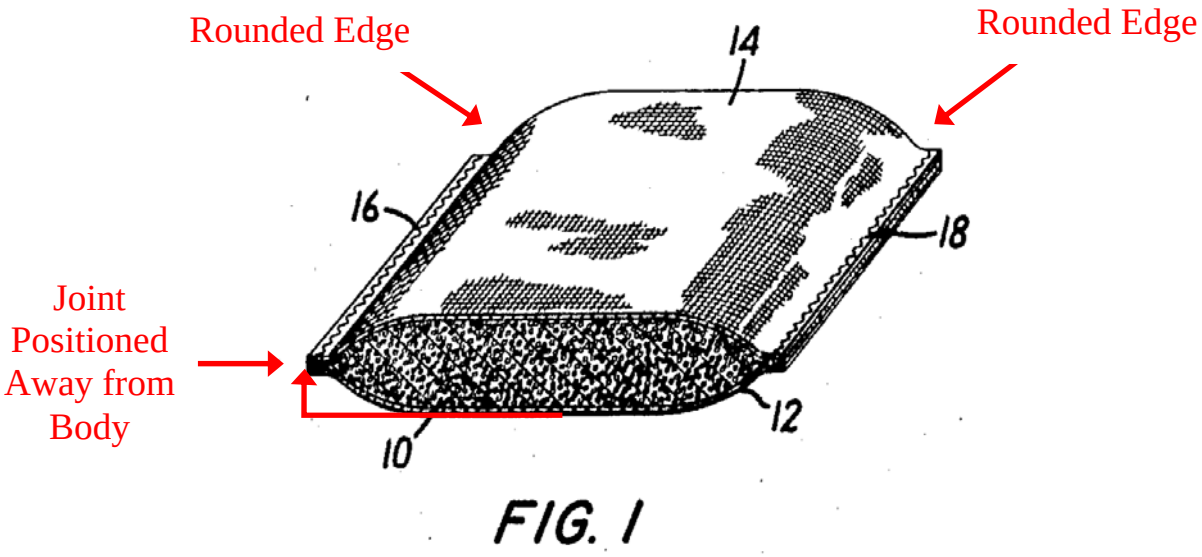


FIG. 1

4. Dependent Claims 10, 37, and 56

Dependent Claims 10, 37, and 56 depend from Independent Claims 1, 29, and 48, respectively.

a. Substantially Circular or Oval Shape

Claim 10 includes "wherein the rear portion comprises a first strap being configured to engage a back of a patient's head in a ***substantially circular or oval shape***." Claims 37 and 56 include "wherein the rear loop comprises a first strap being configured to engage a back of a patient's head in a ***substantially circular or oval shape***."

As construed, the term "substantially circular or oval shape" is given its plain and ordinary meaning consistent with the specification. Ex. 1130 at 13, 48–49.

To the extent Amarasinghe-I somehow provides insufficient teachings for these features, such features were common in CPAP prior art. Ex. 1113 ¶¶ 134–139. For example, Ho shows a rear portion configured to engage a back of a patient's head in a substantially circular or oval shape. *See* Ex. 1103 at Figs. 2, 4; Ex. 1113 ¶ 134.

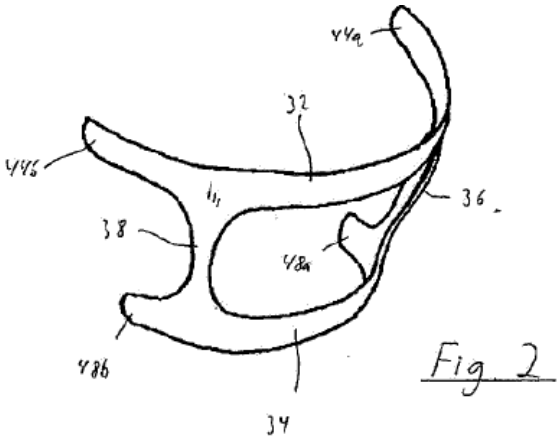


Fig. 2

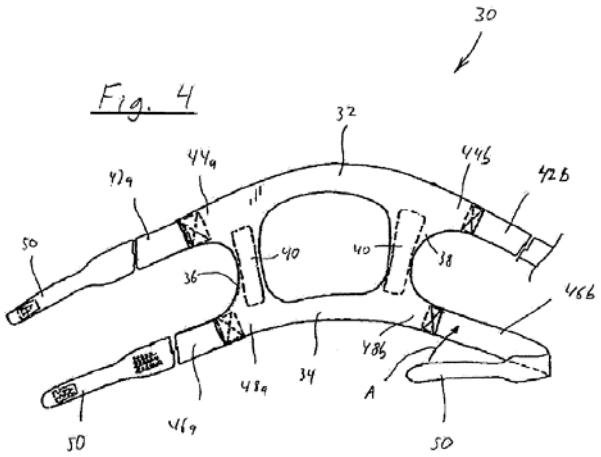


Fig. 4

Additionally, as shown below, Carroll shows rear loop portions configured to engage a back of a patient's head in a substantially circular or oval shape. Ex. 1125 at Figs. 13, 25; Ex. 1113 ¶¶ 135–136.

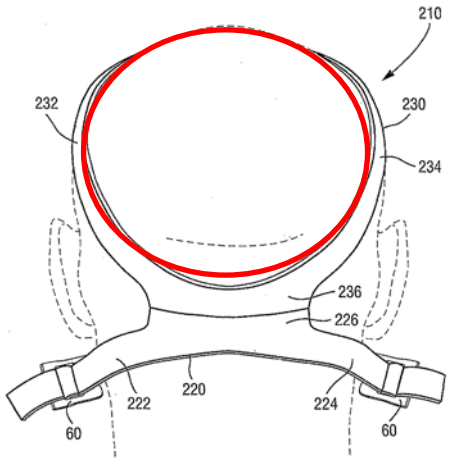


FIG. 13

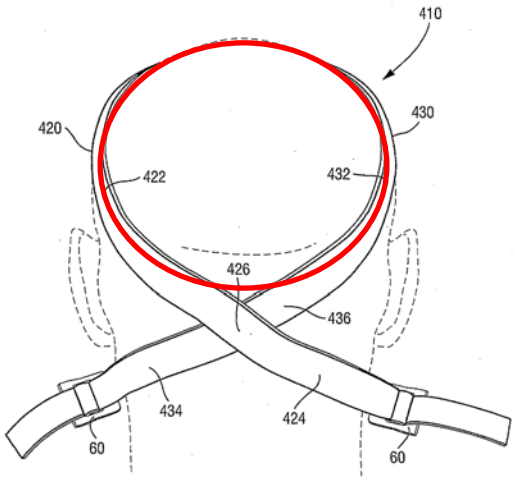


FIG. 25

A person of skill would have been motivated to include a substantially circular or oval shape at the rear portion of the headgear to better accommodate the crown of the patient's head. *See* Ex. 1125 ¶ 61; Ex. 1113 ¶ 140. This arrangement

makes the headgear intuitive to fit onto the patient and minimizes the time required to fit the mask to the patient. *See* Ex. 1125 ¶¶ 77, 83; Ex. 1113 ¶ 140.

b. Substantially Inextensible

Claim 10 includes "the first strap [of the rear portion] having at least a portion that is ***substantially inextensible***." Claim 37 includes "the at least one strap [of the rear loop] having at least a portion that is substantially inextensible." Claim 56 includes "the first strap [of the rear loop] having at least a portion that is ***substantially inextensible***."

Under the Board's construction, "substantially inextensible" means "a structure that when subject to the forces normally encountered in use of a respiratory mask, will have an elongation of less than about 5%." Ex. 1130 at 16. A headgear strap, or strap portion, would normally encounter up to 20 N of force in use of a respiratory mask. Ex. 1113 ¶¶ 143–145. Additionally, forces greater than 20 N would not typically be encountered by a headgear strap, or strap portion, in normal use. *Id*. ¶¶ 144–145.

As described above, Amarasinghe-I discloses the rear loop having a strap portion that is at least relatively inextensible, including portions of the rear straps that are inextensible at least where they are directly attached to the semi-rigid stiffener. *See supra* §§ VII.B.4.b., VII.D.3.d., VII.D.3.f. Ho also discloses "a rigid or semi-rigid support or batten can be provided in the fabric or material forming

the portion of the headgear." Ex. 1103 ¶ 31. The rear strap portions attached to the support or batten are not extensible and are incapable of being stretched under forces typically encountered in use of the headgear straps due to the rigidity of the support or batten. Ex. 1113 ¶ 146. Because Amarasinghe-I and Ho each disclose "inextensible" rear portions, those rear portions are also "substantially inextensible" because the inextensible portions of Amarasinghe-I and Ho include structures that when subject to the forces normally encountered in use of a respiratory mask, will have an elongation of less than about 5%. *Id.*

To the extent Amarasinghe-I and Ho somehow provide insufficient teachings for the "substantially inextensible" features, such headgear straps with an elongation of less than about 5% were well-known in prior art CPAP mask systems. *Id*. ¶¶ 147–164.

For example, as shown below in Figures 12 and 13, Carroll discloses that the headgear 210 includes crown strap section 230. Ex. 1125 ¶ 59.

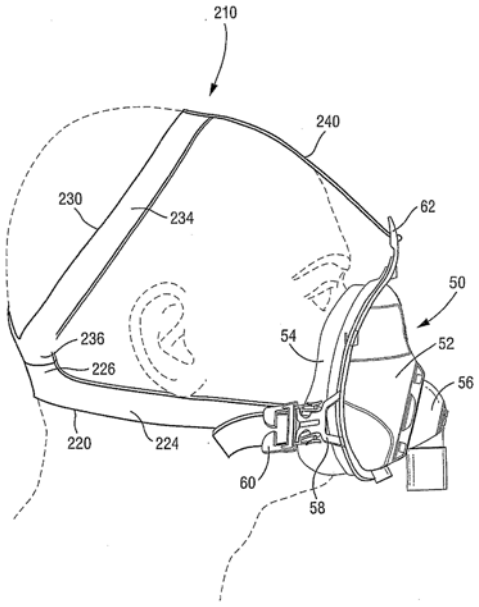


FIG. 12

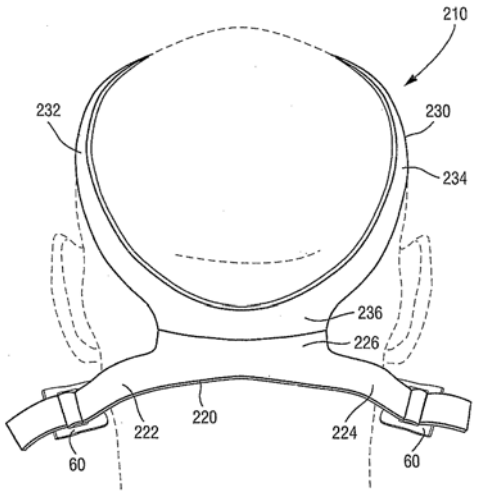


FIG. 13

For the crown strap section 230 (as shown in Figure 15), "CD_2 is 195.13 mm, CD_3 is 208.13 mm." *Id.* ¶ 64.

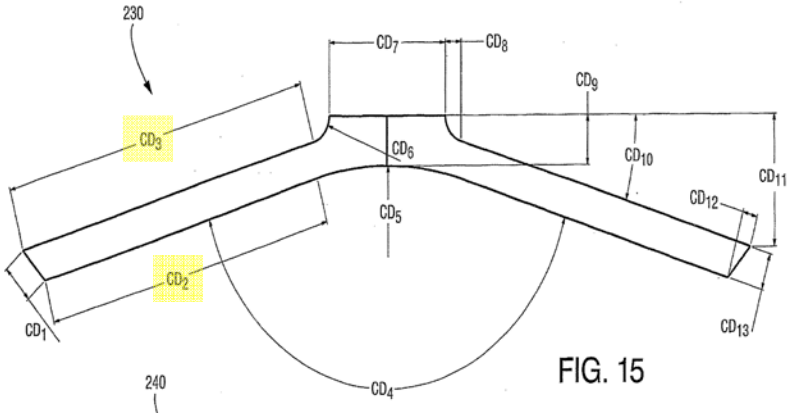


FIG. 15

Carroll discloses that the "headgear material according to embodiments of headgear 210, 310, 410 may have minimal elasticity." *Id.* ¶ 81. For example, "the

elasticity of the headgear material of headgear 210, 310, 410 may be selected such that it provides between about 4 mm and about 14 mm of displacement for forces up to about 0.02 kN." *Id.* ¶ 82.

Accordingly, for headgear 210, when subject to the forces up to about 0.02 kN (about 20 N), which may be normally encountered in use of a respiratory mask, a 4mm displacement/elongation relative to CD_2 (at 195.13 mm) or CD_3 (at 208.13 mm) is a percent elongation of about 2.0% or 1.9%, respectively. Ex. 1113 ¶ 151.

In another embodiment, as shown below in Figures 24 and 25, Carroll discloses that the headgear 410 includes crown straps 420, 430. Ex. 1125 ¶ 70.

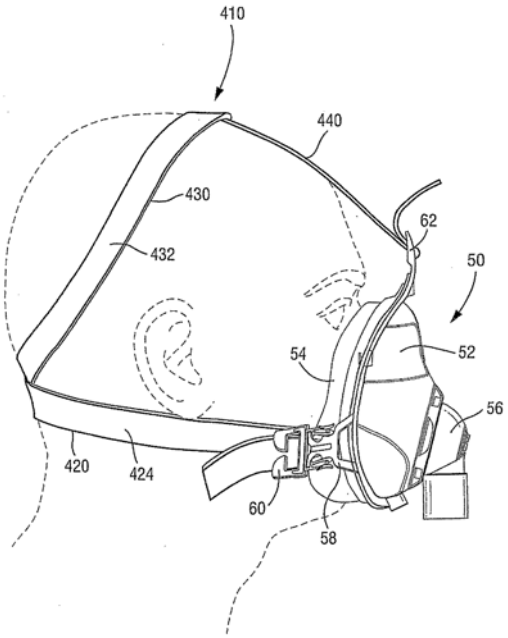


FIG. 24

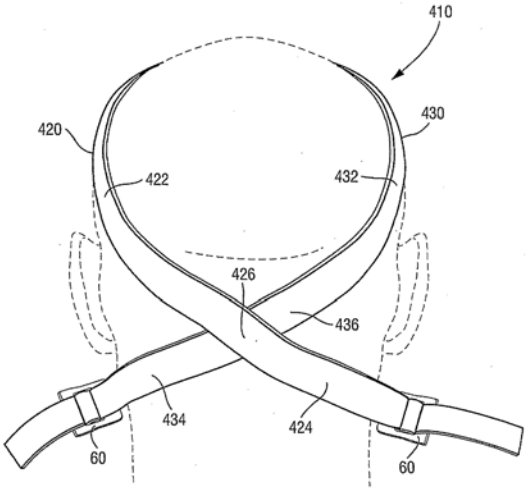


FIG. 25

For the crown straps 420, 430 (as shown in Figure 21), "CS_1 is 256 mm, CS_2 is 570 mm, CS_3 is 252 mm, CS_4 is 293.6 mm, CS_5 is 297.6 mm" Ex. 1125 ¶ 75.

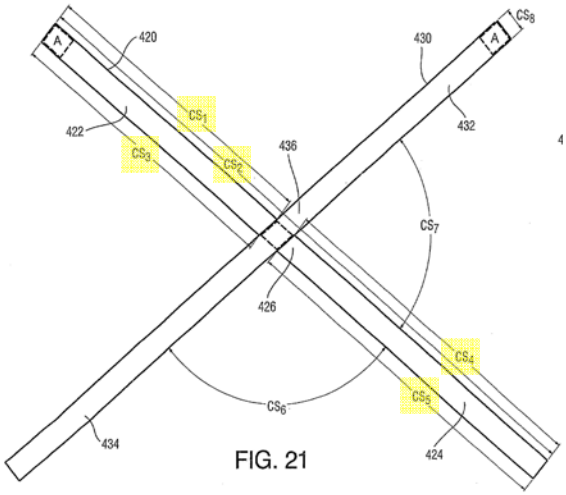


FIG. 21

As discussed above, Carroll discloses that the headgear material of 410 may have minimal elasticity and may be selected such that it provides between about 4 mm and about 14 mm of displacement for forces up to about 0.02 kN. Ex. 1125 ¶¶ 81–82.

Accordingly, for headgear 410, when subject to the forces up to about 0.02 kN (about 20 N), which may be normally encountered in use of a respiratory mask, a 4 mm displacement/elongation relative to CS_1 (at 256 mm), CS_2 (at 570 mm), CS_3 (at 252 mm), CS_4 (at 293.6 mm), or CS_5 (at 297.6 mm) is a percent elongation of about 1.6%, 0.7%, 1.6%, 1.4%, or 1.3%, respectively. Ex. 1113 ¶ 155.

Because the range of substantial inextensibility, as construed, overlaps with the ranges disclosed in Carroll, a *prima facie* case of obviousness exists. *See*

M.P.E.P. 2144.05(I). The ’404 Patent does not describe its range of elongation as critical to achieve any particular purpose. Ex. 1113 ¶ 147.

A person of skill would have recognized that an extensible strap portion that stretches too much causes leakages between the mask and the user’s face, but would have recognized that at least some elasticity is desirable so the headgear comfortably adapts to the user’s head and allows for user movement without dislodging the mask. *See* Ex. 1128 at 8; Ex. 1113 ¶ 166. A person of skill would have been motivated to combine the substantially inextensible headgear straps of Carroll with the headgear of Amarasinghe-I to securely support and position the headgear at the rear of the user’s head. Ex. 1113 ¶¶ 165–166. A person of skill would have understood that substantially inextensible straps, like that of the Carroll headgear, were one option from a finite number of solutions to maintain and secure a comfortable fit on the patient’s head. *Id.* ¶ 166; *see also* KSR, 550 U.S. at 421. One of skill in the art would have understood that sewing Carroll’s substantially inextensible straps into the rear headgear portions of Amarasinghe-I would have been one predictable solution to provide a more uniform and secure anchor point for the headgear by further limiting elasticity in the rear portion. Ex. 1113 ¶ 165.

5. Dependent Claims 11, 38, and 57

Dependent Claims 11, 38, and 57 depend from Independent Claims 1, 29, and 48, respectively.

a. Rear Loop

Claim 11 includes "wherein the rear portion comprises ***a rear loop of straps*** that circumscribes the rear of the head." Claim 38 includes "wherein the rear loop comprises ***a rear loop of straps*** configured to circumscribe the rear of the patient's head." Claim 57 includes "wherein the rear loop comprises ***a rear loop of straps*** configured to circumscribe the rear of the patient's head."

As described above, Amarasinghe-I, Ho, and Carroll all teach this feature. *See supra* §§ VII.D.3.d., VII.D.4.a; Ex. 1113 ¶¶ 170–172.

b. Substantially Inextensible

Claims 11, 38, and 57 each include "the rear loop being ***substantially inextensible*** along its length."

As discussed above, Amarasinghe-I, Ho, and Carroll disclose a rear loop having at least a portion that is substantially inextensible. *See supra* § VII.D.4.

To the extent these claims are narrowly construed to require that the rear loop be substantially inextensible along its entire circumferential length, a person of skill in the art would have considered such an arrangement to provide more control at the upper portion for mask stability. Ex. 1113 ¶¶ 174–177. For

example, Amarasinghe-I also discloses that "the straps of the headgear assembly 16 and the stiffener 46, 246 may be formed of a single material." Ex. 1102 at 9:13–15.

c. Substantially Extensible Upper Straps

Claim 38 includes "the at least one ***upper strap being substantially extensible*** along its length." Claim 57 includes "each said ***upper strap being substantially extensible*** along its length."

Amarasinghe-I discloses upper straps 22 constructed from Breathe-O-Prene®, which was well-known to be an extensible fabric. Ex. 1102 at 6:3–10; *see* Ex. 1113 ¶¶ 45–49, 84.

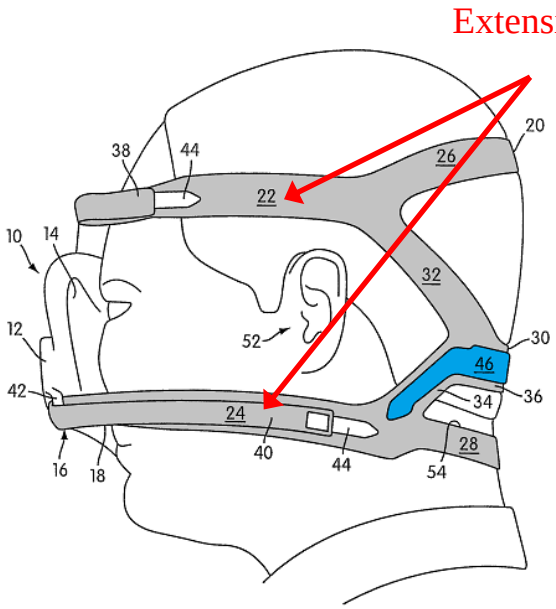


FIG. 1

6. Dependent Claims 12, 39, and 58

Dependent Claims 12, 39, and 58 depend from Independent Claims 1, 29, and 48, respectively.

Claims 12, 39, and 58 include the rear portion (or the rear strap portion) "comprises a ***substantially inextensible*** arcuate region constructed to resiliently return to a ***predetermined shape*** when not in use."

As discussed above, Amarasinghe-I, Ho, and Carroll disclose a substantially inextensible region in the rear portion. *See supra* § VII.D.4.b.

Amarasinghe-I discloses that in use, "the headgear assembly should conform to a complex three-dimensional shape." Ex. 1102 at 2:1–3. Amarasinghe-I further discloses the use of "arcuate-shaped stiffeners" and that "[d]ue to the added rigidity provided by the stiffener 46, all the straps of the headgear assembly 16 are better able to maintain a predetermined shape." *See, e.g., id.* at 7:21–22, 9:6–12.

Ho also discloses that "the headgear assembly assumes a generally spherical shape, at least in the portion that extends over the back of the user's head/neck." Ex. 1103 ¶ 9. Ho further states that the rear portion is "formed so that the overall structure is rigid or semi-rigid," and explains that "'semi-rigid' means that these structures retain their shape when no load is applied on them, but flex to some degree to allow them to conform to the patient to reduce pressure points when a load is applied." *Id.* ¶ 29. Thus, Ho discloses headgear constructed to resiliently

return to a predetermined shape or maintain a three-dimensional shape when not in use. Ex. 1113 ¶ 182.

Additionally, Carroll discloses that "the headgear 210 achieves a three-dimensional form from two-dimensional cut-out geometries," and that the "two-dimensional first cross strap 420, second cross strap 430, and top strap 440 are attached to one another, *e.g.*, stitched, welded, glued or otherwise formed, to form a three-dimensional headgear 410." Ex. 1125 ¶¶ 61, 72.

A person of skill would have been motivated to provide a rear portion configured to resiliently return to a predetermined three-dimensional shape to provide a better fit and ease of use. *See* Ex. 1125 ¶¶ 61, 83; Ex. 1113 ¶¶ 184–186.

7. Dependent Claims 47 and 66

Dependent Claims 47 and 66 depend from Independent Claims 29 and 48, respectively.

a. Dependent Claim 47

i. "the first and second layers have mutual abutting edges that define a joint positioned at approximately a center or middle of the at least one rounded lateral edge when viewed in cross section"

As discussed above with respsect to Claim 1, Corrigall teaches the at least one rounded lateral edge. *See supra* § VII.B.4.a.v.

Corrigall further discloses that the edges of the strap are heated to form "a closed, mechanically-bonded edge or border of the article." Ex. 1104 at col. 1:24–29. A person of skill would have recognized that the closed, mechanically-bonded edge or border forms mutual abutting edges that define a joint. Ex. 1113 ¶ 190.

A person of skill in the art would have recognized that a joint having an exposed foam layer could be abrasive against the user's skin and would have been motivated to extend the fabric layers to form mutual abutting edges at the joint to cover the edge of the foam layer and prevent contact between the foam layer and the patient. *Id.* ¶ 191. A person of skill would have recognized that the covered foam layer would make the strap more comfortable. *Id.*

ii. "wherein the laminate further comprises a foam layer"

As discussed above, Breathe-O-Prene® was a well-known headgear strap material including a composite laminate of fabric and foam layers. Ex. 1113 ¶¶ 193–194; *see supra* § VII.B.4.a.iv.

iii. "wherein said foam layer is substantively encapsulated between said first layer and said second layer"

As explained above, a person of skill would have recognized that Corrigall teaches mutual abutting edges that define a joint and would have known to include

this feature in the Amarasinghe-I headgear. *See supra* §§ VII.B.4.a.v, VII.D.7.a.i. A person of skill would have recognized that the mutual abutting edges encapsulate the foam layer between the first fabric layer and the second fabric layer. Ex. 1113 ¶¶ 197–198.

iv. "wherein the rear strap portion comprises a rear loop of straps dimensioned to circumscribe the rear of the head, the rear loop being substantially inextensible along its length"

As discussed above, the combination of Amarasinghe-I, Ho, and Carroll teach these features. *See supra* §§ VII.D.4–5.b.

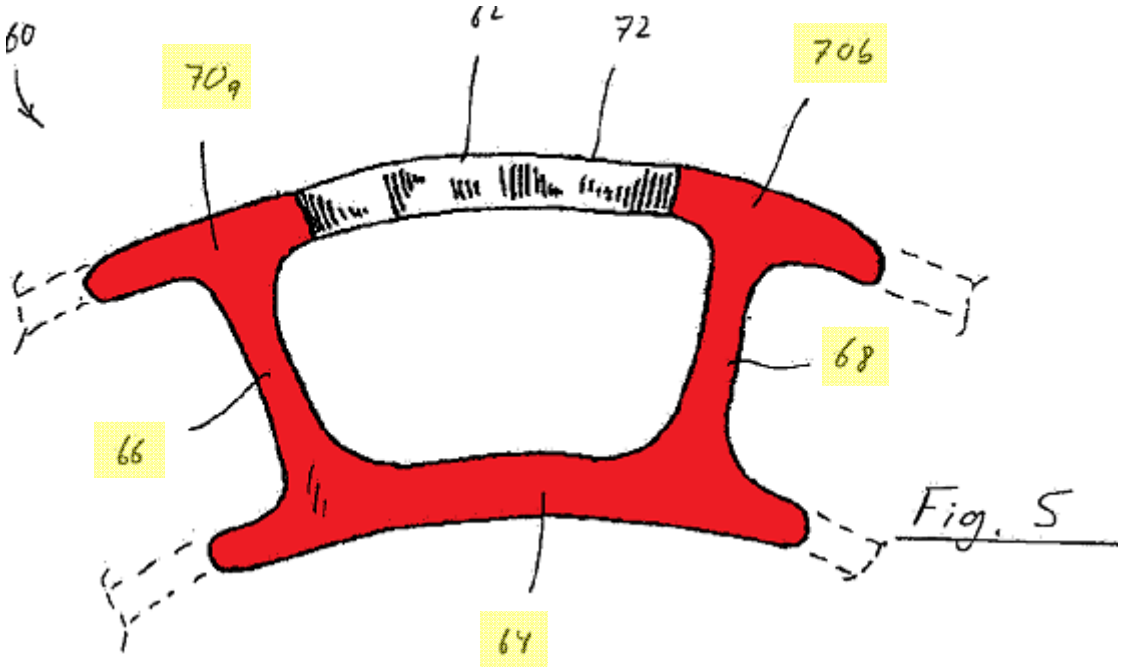
v. "wherein the rear strap portion comprises an arcuate region constructed to resiliently return to a predetermined 3D shape when not in use"

As explained above, the combination of Amarasinghe-I, Ho, and Carroll teach this feature. *See supra* § VII.D.6.

vi. "wherein the relatively inextensible material of the rear strap portions is configured to be located at an upper half of the patient's head while in use."

As described above, Amarasinghe-I teaches a relatively inextensible rear portion. *See supra* § VII.D.3.f. A person of skill would have recognized that the

Amarasinghe-I stiffener could be located on the upper strap 26 such that it would be a relatively inextensible rear portion located at the upper half of the patient's head. Ex. 1113 ¶ 201. This feature was common in the prior art. *Id.* ¶¶ 202–207. Figure 5 of Ho (below) shows a "semi-rigid, non-stretchy" rear portion (shaded red). Ex. 1103 ¶ 37. The upper half of the semi-rigid, non-stretchy portion (shaded red) is located at the upper half of the patient's head while in use. *Id.*; Ex. 1113 ¶¶ 202–204.



A person of skill would have been motivated to modify the headgear of Amarasinghe-I with a relatively inextensible rear portion that is configured to be located at the upper half of the patient's head to provide better support and maintain the position of the upper straps. *Id.* ¶¶ 204–205.

b. Dependent Claim 66

i. "wherein each said lateral edge includes a rounded or tapered portion including a part of the patient-contacting fabric material layer and a part of the outwardly facing loop material layer; wherein each said joint is positioned at approximately a center or middle of said rounded or tapered portion when viewed in cross section"

As discussed above, Corrigall discloses this feature. *See supra* § VII.B.4.a.v.

ii. "wherein a foam material layer is between said patient-contacting fabric material layer and said outwardly facing loop material layer"

As discussed above, Amarasinghe-I discloses this feature. *See supra* § VII.D.7.a.iii.

iii. "wherein the plurality of straps further comprises a stretch portion and a portion configured not to stretch"

As discussed above, Amarasinghe-I, Carroll, and Berthon-Jones disclose these features. *See supra* §§ VII.B.4.b., VII.C.2.b.

iv. "wherein the rear loop comprises a rear loop of straps configured to circumscribe the rear of the patient's head, the rear loop being substantially inextensible along its length"

As discussed above, the Amarasinghe-I, Ho, and Carroll teach this feature. *See supra* §§ VII.D.4.–5.b.

v. "each said upper strap being substantially extensible along its length"

As discussed above, Amarasinghe-I discloses this feature. *See supra* § VII.D.5.c.

vi. "wherein the rear strap portion comprises a substantially inextensible arcuate region constructed to resiliently return to a predetermined shape when not in use"

As discussed above, Amarasinghe-I, Ho, and Carroll teach this feature. *See supra* § VII.D.6.

vii. "wherein the rear strap portion is configured to be located at the upper half of the patient's head while in use."

As discussed above, Amarasinghe-I and Ho teach this feature. *See supra* § VII.D.7.a.vi. Further, a person of skill would have recognized that the substantially inextensible straps, as taught by Carroll and as described above, are compatible and/or interchangeable with the relatively inextensible straps of Amarasinghe-I. *See supra* §§ VII.D.4.–6.

viii. "wherein the rear strap portion is configured to engage a back of a patient's head and extend on either side of the patient's parietal bone behind the patient's ears, in use"

Amarasinghe-I discloses a curved upper strap 26 extending across a rear upper portion of the patient's head and "structured to engage a posterior portion of the parietal bone of the patient's head." Ex. 1102 at 7:30—8:6.

As shown in Figures 1 and 2 below, and with reference to an example diagram of a skull showing the parietal bone, the rear portion 20 of Amarasinghe-I engages the back of the patient's head and extends on either side of the patient's parietal bone behind the patient's ears. Ex. 1113 ¶ 223.

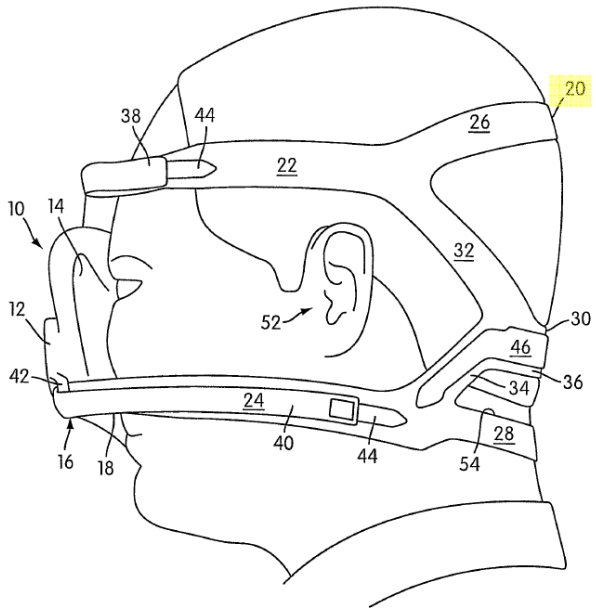


FIG. 1

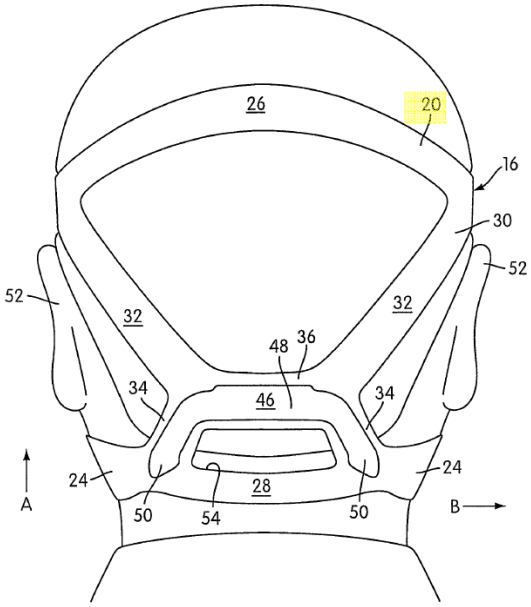
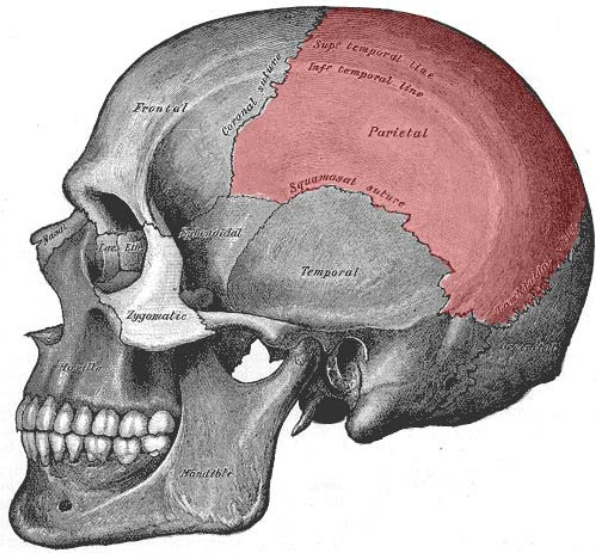


FIG. 2



Parietal Bone Diagram

These features were common in CPAP prior art. Ex. 1113 ¶¶ 224–225. For example, Ho also discloses that, when donned by the user, the headgear assembly assumes a generally spherical shape that will "bend or wrap around the head/neck

of the user." Ex. 1103 at Abstract, ¶ 32. Thus, the rear portion engages the back of the patient's head and extends on either side of the patient's parietal bone behind the patient's ears. Ex. 1113 ¶ 225.

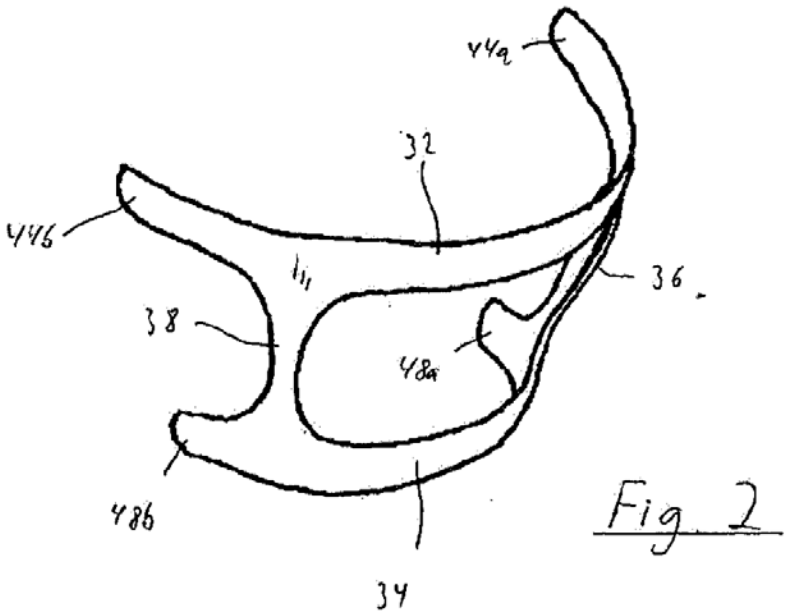


Fig. 2

A person of skill would have been motivated to include a rear strap portion that extends on either side of the patient's parietal bone to provide better comfort and support. Ex. 1113 ¶ 226. Because the parietal bone region has a relatively small amount of soft tissue, a person of skill would have recognized that headgear anchored at the parietal bone region would be more stable and not easily dislodged during sleep. *Id.*

ix. "wherein the plurality of straps comprises a portion that is configured to be relatively self-supporting such

that the headgear system maintains a three dimensional shape when not in use"

Amarasinghe-I discloses that in use, "the headgear assembly should conform to a complex three-dimensional shape." Ex. 1102 at 2:1–3. Amarasinghe-I further discloses the use of "arcuate-shaped stiffeners" and that "[d]ue to the added rigidity provided by the stiffener 46, all the straps of the headgear assembly 16 are better able to maintain a predetermined shape." *See, e.g.*, *id.* at 7:21–22, 9:6–12.

Relatively self-supporting portions were common in prior art CPAP headgear. Ex. 1113 ¶¶ 229–230. For example, Ho discloses that "the headgear assembly assumes a generally spherical shape, at least in the portion that extends over the back of the user's head/neck." Ex. 1103 ¶ 9. Ho further states that the rear portion is "formed so that the overall structure is rigid or semi-rigid," and explains that "'semi-rigid' means that these structures retain their shape when no load is applied on them, but flex to some degree to allow them to conform to the patient to reduce pressure points when a load is applied." *Id.* ¶ 29. Thus, the rear portion of the headgear of Ho forms a portion that is relatively self-supporting such that the headgear assembly maintains a three dimensional shape when not in use. Ex. 1113 ¶ 229.

A person of skill also would have been motivated to include a rear portion configured to resiliently return to a predetermined three-dimensional shape for a better fit and ease of use. *Id.* ¶¶ 180–186, 230.

x. "wherein said plurality of straps comprises a crown strap; wherein the crown strap is configured to lie flat on the crown of a patient's head in use; and wherein the rear strap portion is configured to lie flat on the rear of a patient's head in use."

Amarasinghe-I discloses that "as shown in Fig. 1, the curved upper strap 26 extends across a rear upper portion of the patient's head." Ex. 1102 at 7:30—8:6. A person of skill would have recognized that the curved upper strap 26 is a crown strap that lies flat. Ex. 1113 ¶ 232. Additionally, as shown in Figure 1 below, the rear portions are also configured to lie flat. *Id.*

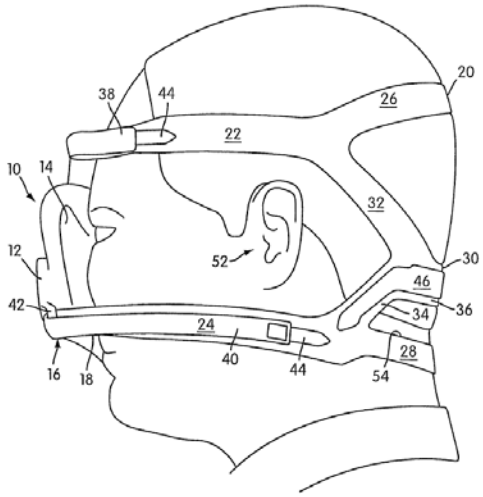


FIG. 1

Such features were common in CPAP prior art. Ex. 1113 ¶ 233–237. For example, Ho discloses a crown strap 186 that is "a flexible or semi-rigid member that is capable of flexing or molding to the shape of the top of the user's head." Ex. 1103 ¶ 47. As shown below, the crown strap 186 and the rear portion of Ho are configured to lie flat in use. Ex. 1113 ¶¶ 233–234.

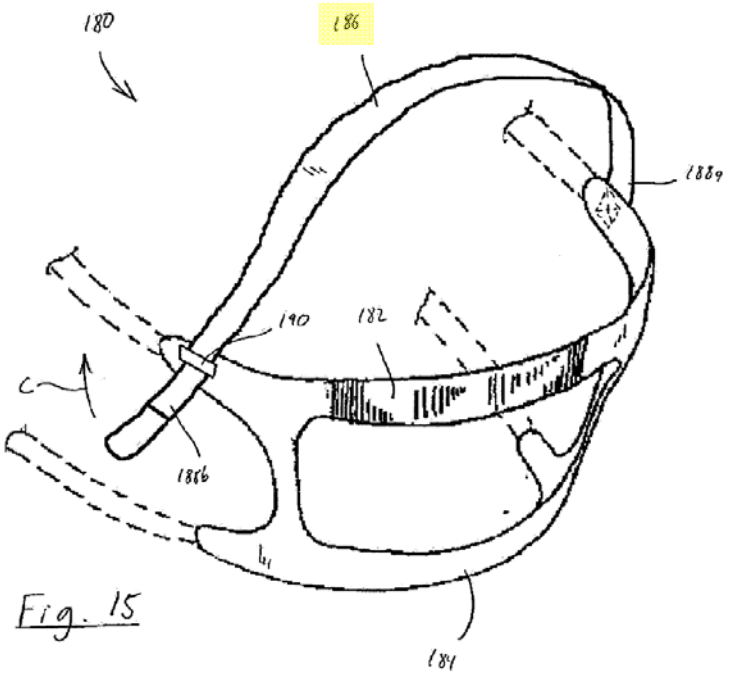


Fig. 15

A person of skill would have been motivated to include a crown strap portion and a rear strap portion that lie flat on the patient's head to provide additional support and structure for better fit and ease of use for the user. *Id.* ¶¶ 235–237.

E. Ground 4: Claims 10–12, 37–39, 47, 56–58, and 66 would have been obvious over Amarasinghe-I in view Corrigall, Ho, and Berthon-Jones

As discussed above, the combination of Amarasinghe-I, Corrigall, and Ho disclose nearly all of the features of dependent Claims 10–12, 37–39, 47, 56–58, and 66. *See supra* §§ VII.D.4.–7.

Each of these claims includes a rear portion or rear loop that has a ***substantially inextensible*** portion. *See supra* §§ VII.D.4.–6., VII.D.7.a.iv., VII.D.7.b.iv. As discussed above, a headgear strap, or strap portion, would normally encounter up to 20 N of force in use of a respiratory mask. *See supra* § VII.D.4.b.

As discussed above, Amarasinghe-I and Ho disclose a rear loop having at least a portion that is substantially inextensible. *See supra* § VII.D.4. Additionally, such headgear straps with a "substantially inextensible" portion were well-known in prior art CPAP mask systems. Ex. 1113 ¶¶ 241–259.

For example, Berthon-Jones discloses that it is desirable to provide "headgear including straps that are substantially inextensible," which may assist with improving patient compliance and/or treatment. Ex. 1126 ¶ 11. Berthon-Jones discloses that "[t]o maintain a secure and comfortable fit of the mask assembly 15, the straps of the headgear assembly 20 are preferably formed to be

substantially inextensible. Stated differently, the straps may be somewhat flexible, however, the straps are preferably not capable of significant elongation." *Id.* ¶ 66.

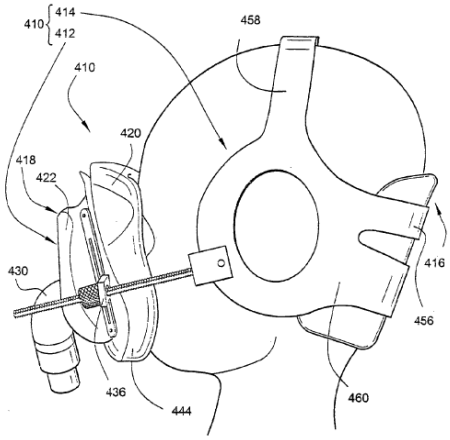


Fig. 16

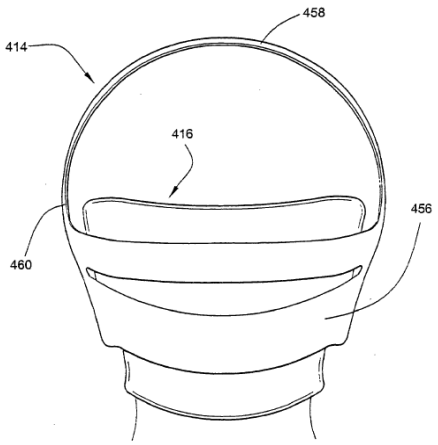


Fig. 18

Berthon-Jones discloses straps constructed from a "flexible but generally inextensible plastic material" that "can conform to the shape of a patient's head, but ***they would not generally extend more than 1-2 mm when subject to 2 KgF tension***." Ex. 1126 ¶ 144 (emphasis added). Berthon-Jones also discloses that "[t]he projected area of contact with ***the straps will be about 15 cm side to side*** by 10 cm top to bottom." Ex. 1126 ¶ 167 (emphasis added).

Accordingly, for headgear 410, when subject to the forces up to about 2 kgF tension (about 20 N), which may be normally encountered in use of a respiratory mask, a 1-2 mm displacement/elongation relative to a strap length of at least about 15 cm side to side (150 mm) is a percent elongation of about 0.6% to about 1.3%. Ex. 1113 ¶ 246.

A person of skill would have recognized that an extensible strap portion that stretches too much causes leakage between the mask and the user's face, but would have recognized that at least some elasticity is desirable so the headgear comfortably adapts to the user's head and allows for user movement without dislodging the mask. *See* Ex. 1128 at 8; Ex. 1113 ¶ 262. Thus, a person of skill would have understood that substantially inextensible straps, like that of the Berthon-Jones headgear, were one option from a finite number of solutions to maintain and secure a comfortable fit on the patient's head. *See* Ex. 1126 ¶ 66; Ex. 1113 ¶ 262; *see also* KSR, 550 U.S. at 421. One of skill in the art would have understood that sewing Berthon-Jones's substantially inextensible strap into the rear portions of Amarasinghe-I would have been an obvious modification to provide a more uniform and secure anchor point for the headgear by further limiting elasticity in the rear portion. Ex. 1113 ¶ 260.

In an alternative configuration, one of skill would have optimized the stiffener(s) of Amarasinghe-I to make the rear portion substantially inextensible through routine experimentation. *Id.* ¶ 261; *see also* M.P.E.P. § 2144.05(II)(A). A person of skill would have known that elongation of less than about 5% was workable based on the teachings of Berthon-Jones. Ex. 1113 ¶ 261; *see also* M.P.E.P. § 2144.05(II)(A). A person of skill would have recognized that the level of extensibility was a result-effective variable because strap extensibility was one

of a finite number of options for maintaining and securing a comfortable fit on the patient's head, as explained in the previous paragraph. Ex. 1113 ¶ 261; *see also* M.P.E.P. § 2144.05(II)(B).

Additionally, one of skill would have recognized that a substantially inextensible strap portion made of 1 mm polypropylene sheet, as taught by Berthon Jones, would have a semi-rigid configuration. Ex. 1126 ¶ 144; Ex. 1113 ¶ 261. Accordingly, in some alternative configurations, one of skill would have been motivated to combine the substantially inextensible semi-rigid strap portion of Berthon-Jones in the rear portion of Amarasinghe-I for an additional advantage of eliminating the need for using the Amarasinghe-I stiffeners. Ex. 1113 ¶ 261.

A person of skill in the art at the time of the purported invention would have been motivated to combine the teachings of Amarasinghe-I, Corrigall, Ho, and Berthon-Jones, for at least the reasons provided above. *See supra* §§ VII.B.4., VII.C.2., VII.D. Combining these features of Amarasinghe-I, Corrigall, Ho, and Berthon-Jones would have been a mere combination of familiar elements according to known methods that does no more than yield predictable results. Ex. 1113 ¶ 262; *see also KSR*, 550 U.S. at 416.

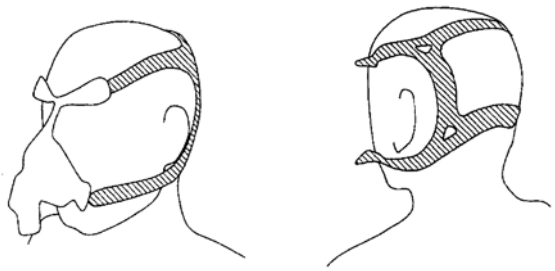
F. Ground 5: Claims 10-12, 37-39, 47, 56-58, and 66 would have been obvious over Amarasinghe-I in view Corrigall, Ho, and Omura

1. Overview of Omura (Ex. 1128)

Omura was submitted during prosecution of the '404 Patent, in Japanese, but was not applied by the Examiner. Ex. 1101 at 2.

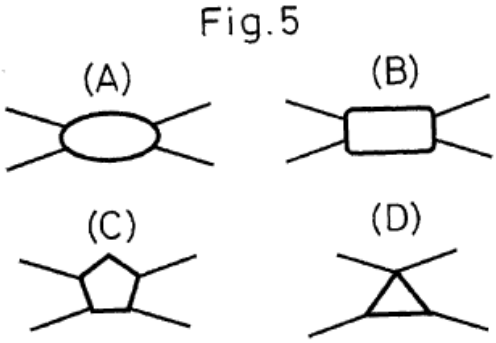
Omura relates to a "headgear that is suitable for fitting a respiratory mask system to the head of the user." Ex. 1128 at Abstract.

Fig.4



Omura discloses that "it is desirable to form at least the strap part of a material wherein the stretching when pulled at 1.96 N is 0.05% to 20%, and is preferably 1% to 10%." Ex. 1128 at 8.

Omura also discloses that "it is preferable that the shape of the closed curved belt be substantially circular, elliptical, or regular polygonal, because these have good shape balance and facilitate adjustment of the center of the closed curved belt to the occipital point of the head of a user." Ex. 1128 at 9.



2. Dependent Claims 10–12, 37–39, 47, 56–58, and 66

As discussed above, the combination of Amarasinghe-I, Corrigall, and Ho teaches nearly all of the features of dependent Claims 10–12, 37–39, 47, 56–58, and 66. Ex. 1113 ¶ 267; *see supra* §§ VII.D.4.–7. To the extent these references provide insufficient teachings for the claimed "***substantially inextensible***" features or the "***substantially circular or oval***" features, Omura discloses at least these features. Ex. 1113 ¶ 267.

Because Omura seeks to provide secure and comfortable headgear, the features taught in Omura would have been readily compatible with and easily incorporated into the headgear of Amarasinghe-I. *See* Ex. 1128 at 6; Ex. 1113 ¶ 268. Combining these features of Amarasinghe-I, Corrigall, Ho, and Omura would

have been a mere combination of familiar elements according to known methods that does no more than yield predictable results. Ex. 1113 ¶ 268; *see also KSR*, 550 U.S. at 416.

a. Substantially Inextensible

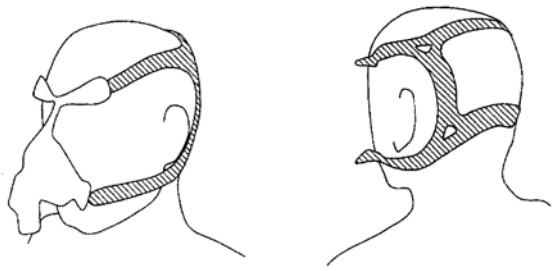
Each of Claims 10–12, 37–39, 47, 56–58, and 66 includes a rear portion or rear loop that has a ***substantially inextensible*** portion. *See supra* §§ VII.D.4.–6., VII.D.7.a.iv., VII.D.7.b.iv. As discussed above, a headgear strap, or strap portion, would normally encounter up to 20 N of force in use of a respiratory mask. *See supra* § VII.D.4.b.

As discussed above, Amarasinghe-I and Ho, disclose a rear loop having at least a portion that is substantially inextensible. *See supra* § VII.D.4. Additionally, headgear straps with a "substantially inextensible" portion were common knowledge to one skilled in the art to make the head mounted part of the headgear difficult to stretch. *See* Ex. 1128 at 8; Ex. 1113 ¶¶ 272–290.

For example, Omura discloses that "it is desirable to form at least the strap part of a material wherein ***the stretching when pulled at 1.96 N is 0.05% to 20%, and is preferably 1% to 10%***." Ex. 1128 at 8 (emphasis added). Because the range of substantial inextensibility, as construed, overlaps with the range disclosed in Omura, a *prima facie* case of obviousness exists. *See* M.P.E.P. 2144.05(I). The

'404 Patent does not describe its range of elongation as critical to achieve any particular purpose. Ex. 1113 ¶ 276.

Fig.4



To the extent that the Omura headgear may be subject to greater forces, such as, for example, up to approximately 20 N, the percent displacement/elongation relative to the lower range disclosed by Omura would still be less than about 5% in use. *Id.* One of skill in the art would understand that, based on the disclosed materials and displacement ranges, a ten-fold increase in force in use would produce a substantially proportional increase in displacement/elongation. *Id.* At the low range disclosed, a ten-fold increase over 0.05% elongation results in an elongation of about 0.5%, well under 5%. *Id.*

A person of skill would have recognized that an extensible strap portion that stretches too much causes leakage between the mask and the user's face, but would have recognized that at least some elasticity is desirable so the headgear comfortably adapts to the user's head and allows for user movement without dislodging the mask. *See* Ex. 1128 at 8; Ex. 1113 ¶ 292. One of skill in the art

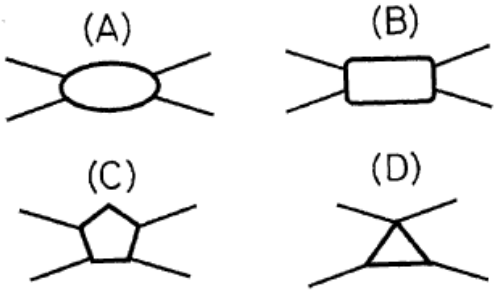
would have understood that sewing Omura's substantially inextensible strap into the rear portions of Amarasinghe-I would have been one predictable solution to provide a more uniform and secure anchor point for the headgear by further limiting elasticity in the rear portion. Ex. 1113 ¶ 291. Further, a person of skill would have understood that substantially inextensible straps, like that of the Omura headgear, was one option from a finite number of solutions for preventing leaks and providing a comfortable fit on the patient's head. *Id.* ¶ 292; *see also* KSR, 550 U.S. at 421.

b. Substantially Circular or Oval

Claim 10 includes "wherein the rear portion comprises a first strap being configured to engage a back of a patient's head in a ***substantially circular or oval shape***." Claims 37 and 56 include "wherein the rear loop comprises a first strap being configured to engage a back of a patient's head in a ***substantially circular or oval shape***."

To the extent Amarasinghe-I and Ho somehow provide insufficient teachings for the substantially circular or oval shape, Omura discloses that "it is preferable that the shape of the closed curved belt be substantially circular, elliptical, or regular polygonal." Ex. 1128 at 9.

Fig.5



A person of skill would have been motivated to modify Amarasinghe-I to include a rear strap portion configured to engage a back of a patient's head in a substantially circular or oval shape to better fit the head of the user. A rear portion having a substantially circular or oval shape has improved balance, is easier to quickly locate in the proper position, and simpler to adjust the center of the closed curved belt to the occipital point of the head of a user compared with the rear portion of Amarasinghe-I. *See id.* at 9; Ex. 1113 ¶ 296.

G. Ground 6: Claim 21 would have been obvious over Amarasinghe-I in view Corrigall, and Dreyfus

1. Overview of Dreyfus (Ex. 1129)

Dreyfus was not of record during the prosecution of the ’404 Patent. Ex. 1101 at 2.

Dreyfus relates to “the preparation of stiffened fabrics.” Ex. 1129 at col. 1:1–4. For example, Dreyfus discloses that an assembly of fabric layers is subjected to pressure to impart “desired stiffness.” *Id.* at col. 2:34–44.

Dreyfus meets the test for analogousness at least under the second prong and is proper prior art for obviousness. *See Wyers*, 616 F.3d at 1237.

The Dreyfus method of stiffening fabric layers to produce a stiffer material is pertinent to an entire problem faced by the Applicant for the ’404 Patent, namely providing strap comfort, while maintaining a relatively fixed position in use. Ex. 1101 1:51–53, Ex. 1113 ¶ 297. A person of skill would have recognized that making selectively stiffer straps in a rear portion of the headgear would provide a more comfortable fit. Ex. 1113 ¶ 297.

The problem of creating a combination of appropriately flexible and stiffened straps was appreciated by those of skill in the art at the time of the purported invention. Ex. 1102 at 7:3-28, Ex. 1113 ¶ 298. One of skill in the art would have been motivated to resolve this known problem by considering known

solutions for stiffening fabric layers, such as those taught by Dreyfus. Ex. 1113 ¶ 298. Investigating solutions in the fabric stiffening industry would have been a likely source for resolving flexibility and stiffness issues. *Id.*

2. Dependent Claim 21

Claim 21 includes "wherein the first fabric layer and the second fabric layer are ***compressed*** in a region to stiffen the at least one strap of said plurality of straps."

As discussed above, Amarasinghe-I discloses that localized stiffening is known and desirable for headgear straps to improve support and positioning. *See supra* § VII.B.4.b. Dreyfus discloses an alternative manner to achieve localized stiffening. Ex. 1113 ¶¶ 300–301. For example, Dreyfus discloses that an assembly of fabric layers is subjected to pressure to impart "desired stiffness." Ex. 1129 at col. 2:34–44. In particular, Dreyfus discloses that multiple "fabrics may be treated with water, and in the presence of a plasticizer, heat and pressure applied to the whole surface to form a composite fabric that is united throughout, or only in local areas by application of heat and pressure only at the desired local areas." *Id.* at col. 3:43–49.

A person of skill would have understood that the materials and methods disclosed by Dreyfus are applicable to the wearable straps of Amarasinghe-I and would have had a reasonable expectation of success of applying this technique to

the wearable straps of Amarasinghe-I. *See* Ex. 1129 at col. 2:1–5; Ex. 1113 ¶ 302–303.

A person of skill would have been motivated to stiffen straps based on the desire to retain the shape of certain regions of the strap and withstand repeated washing. *See* Ex. 1129 at cols. 1:50—2:1, 2:45–49; Ex. 1113 ¶ 303. A person of skill seeking to stiffen the straps would have known that compressing fabric layers was one of a finite number of known solutions for providing the desired stiffness and would have selected this method to be able to control the degree of stiffness, as taught by Dreyfus. *See* Ex. 1129 at col. 1:1–7, 5:49–57; Ex. 1113 ¶ 303; *see also KSR*, 550 U.S. at 421.

Such a modification would have involved no more than a combination of familiar elements according to known methods that does no more than yield predictable results. Ex. 1113 ¶ 303; *see also KSR*, 550 U.S. at 416.

VIII. SECONDARY CONSIDERATIONS

Secondary considerations should be taken into account, but they do not control the obviousness conclusion. *Newell Cos., Inc. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988). Where a strong *prima facie* obviousness showing exists, as here, the Federal Circuit has repeatedly held that even relevant secondary considerations supported by substantial evidence may not dislodge the primary conclusion of obviousness. *See, e.g., Leapfrog Enters. Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007). Also, there would be no nexus between the commercial sales and the claims of the '404 Patent. *See, e.g., Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010).

Petitioner is not aware of any secondary considerations that would be relevant to the obviousness inquiries presented here. Further, Petitioner does not believe that any potential secondary considerations could outweigh the strong *prima facie* case of obviousness. In the event that the Patent Owner puts forth any allegations regarding secondary considerations of non-obviousness, Petitioner will address those allegations in due course.

Respectfully submitted,

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Dated: August 2, 2017

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CERTIFICATE OF TYPE-VOLUME LIMITATIONS UNDER 37 C.F.R. § 42.24

Pursuant to 37 C.F.R. § 42.24(d), Counsel for Petitioner Fisher & Paykel Healthcare Limited hereby certifies that this document complies with the type-volume limitation of 37 C.F.R. § 42.24(a)(1)(i). According to Microsoft Office Word 2010's word count, this document contains approximately 13,880 words, including any statement of material facts to be admitted or denied in support, and excluding the table of contents, table of authorities, mandatory notices under § 42.8, exhibit list, certificate of service or word count, or appendix of exhibits or claim listing.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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CERTIFICATE OF SERVICE

I hereby certify that true and correct copies of the foregoing **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT 8,950,404** and **Fisher & Paykel Healthcare Exhibits 1101–1130** are being served on August 2, 2017, via FedEx Priority Overnight service on counsel of record for U.S. Patent 8,950,404 patent owner **RESMED LIMITED** at the address below:

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