2017 WL 2188526 (Patent Tr. & App. Bd.)
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FISHER & PAYKEL HEALTHCARE LIMITED1, Petitioner,
v.
RESMED LIMITED, Patent Owner.

Patent Trial and Appeal Board.
Case IPR2017–00340
Patent 8,950,404 B2
Entered: May 16, 2017

Attorneys and Law Firms

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

DECISION

Institution of *Inter Partes* Review

37 C.F.R. § 42.108

MAYBERRY, Administrative Patent Judge.

I. INTRODUCTION

***1** Petitioner, Fisher & Paykel Healthcare Ltd. ("Fisher"), filed a Petition (Paper 1, "Pet.") requesting *inter partes* review of claims 1–66 (the "Challenged Claims") of U.S. Patent No. 8,950,404 B2 (Ex. 1001, the "'404 patent"). Patent Owner, ResMed Ltd. ("ResMed"), filed a Preliminary Patent Owner Response to the Petition. Paper 6 ("Prelim. Resp."). We have jurisdiction under 35 U.S.C. § 314 and 37 C.F.R. § 42.4(a).

To institute an *inter partes* review, we must determine that the information presented in the Petition shows "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). For the reasons set forth below, upon considering the Petition and evidence, we conclude that the information presented in the Petition establishes a reasonable likelihood that Fisher will prevail with respect to at least 1 of the Challenged Claims, and we institute *inter partes* review on claims 1–8, 13–20, 22–36, 40–46, 48–55, and 59–65. We do not institute on claims 9–12, 21, 37–39, 47, 56–58, and 66.

Our factual findings and conclusions at this stage of the proceeding are based on the evidentiary record developed thus far. This decision to institute trial is not a final decision as to patentability of the claims for which *inter partes* review is instituted. Our final decision will be based on the full record developed during trial.

A. Related Matters

Fisher indicates that the '404 patent is involved in district court litigation in the Southern District of California, in a case styled *Fisher & Paykel Healthcare Ltd. v. ResMed Corp*., Case No. 3:16–cv–02068–DMS–WVG (S.D. Cal.). Pet. 6; *see also* Paper 4, 2 (identifying the litigation).

B. The '196 Patent

The '404 patent, titled "Headgear for Masks," issued February 10, 2015, with claims 1–66. Ex. 1001, (54), (45), 23:14–28:53. The '404 patent is generally directed "to headgear ... for use in holding a mask in position on a patient's face, the mask being used for treatment, e.g., of Sleep Disordered Breathing (SDB) with Continuous Positive Airway Pressure (CPAP) or Non–Invasive Positive Pressure Ventilation (NIPPV)." *Id.* at 1:16–21. Figures 1 and 6 of the '404 patent depict embodiments of the '404 patent's headgear and are reproduced below.

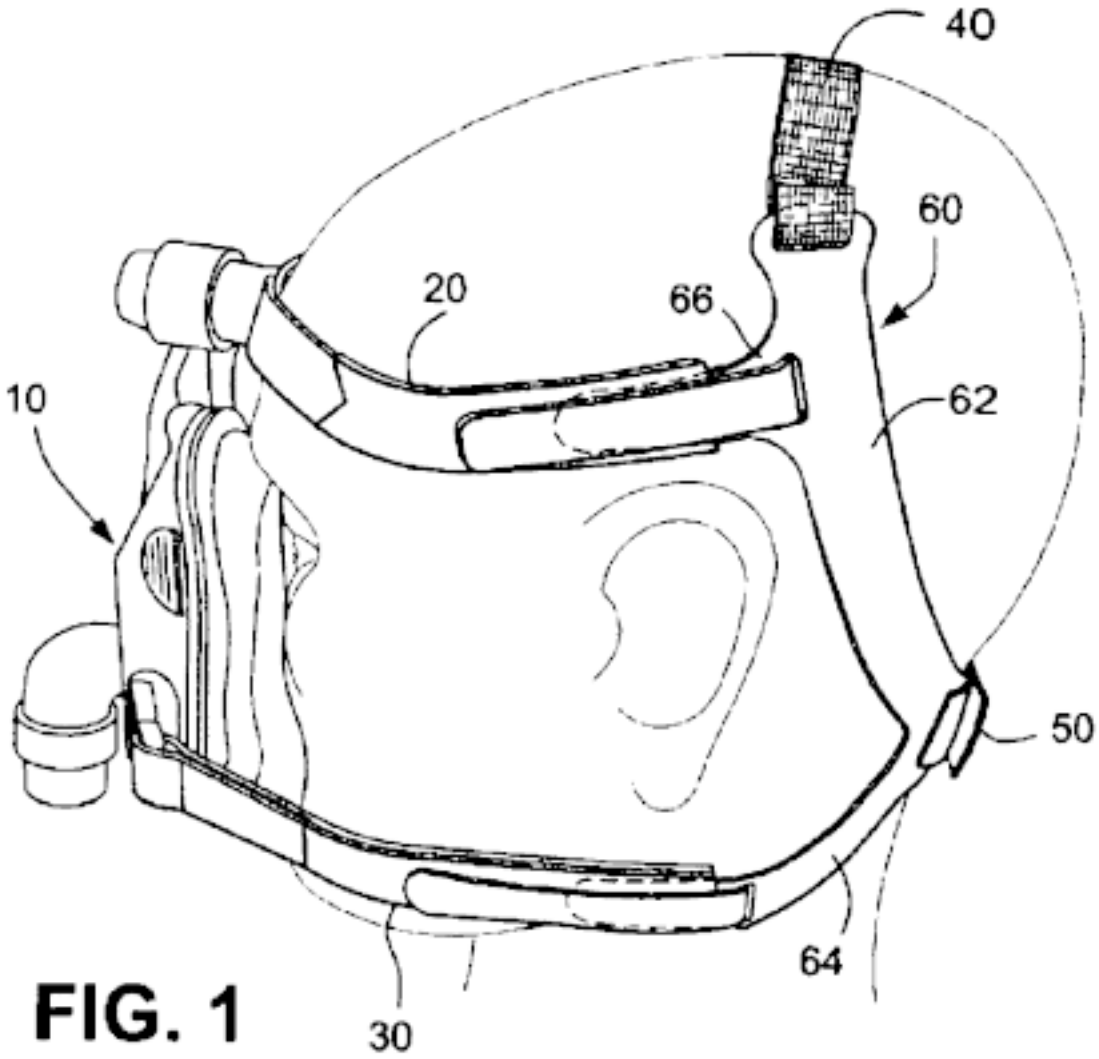


FIG. 1

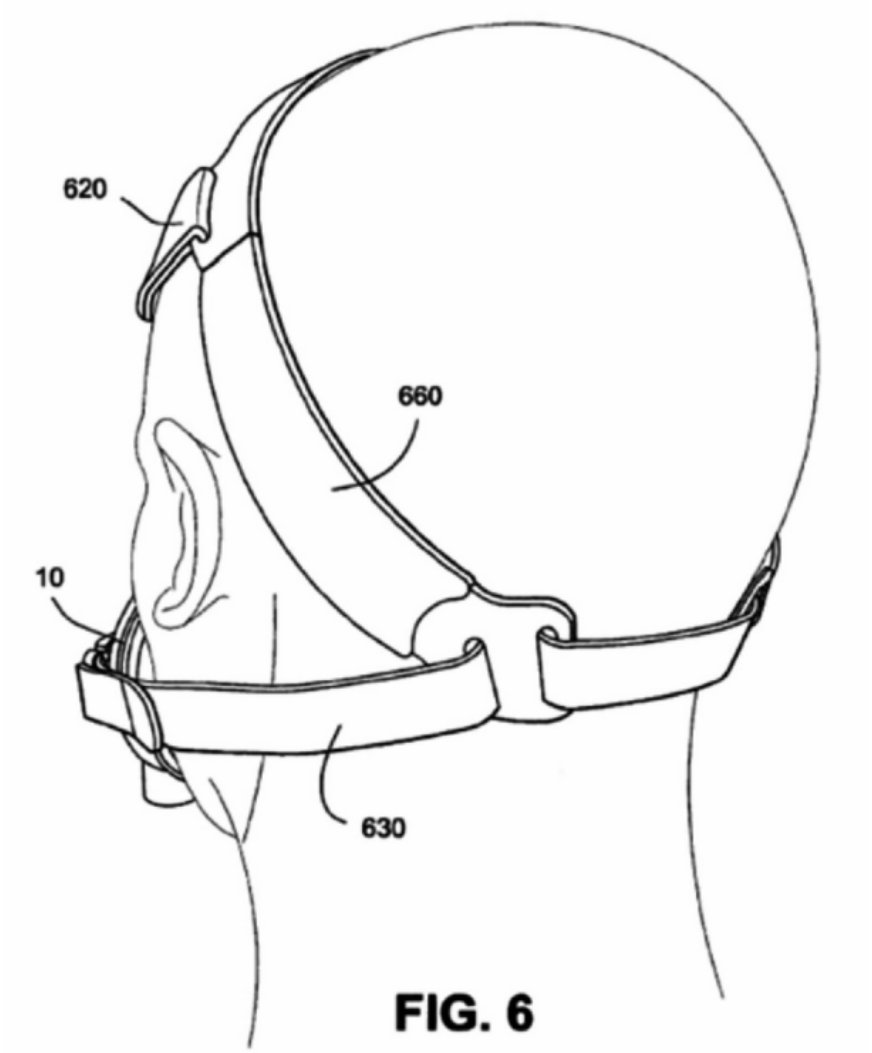


FIG. 6

Figure 1 depicts "a side view of headgear in position on a patient's head according to an embodiment of the" '404 patent and Figure 6 depicts "a rear perspective view of headgear in position on a patient's head according to another embodiment of the" '404 patent. Ex. 1001, 4:9–10, 4:26–28. In the embodiment of Figure 1, mask 10 is connected to upper side strap 20 and lower side strap 30. *Id.* at 8:9–12. Top strap 40 is configured to pass over the top of a wearer's head and attach to the top ends of two opposing rigidizers 60, with rear strap 50 interconnecting the lower ends of opposing rigidizers 60. *Id.* at 8:12–18. Rigidizers of the '404 patent are "constructed of a rigid or semi-rigid material that ... add[s] rigidity to the headgear .... [The rigidizers] ... resist or prevent stretching of the headgear in the lengthwise direction of the rigidizer [and] [t]he rigidizers may be substantially inextensible." *Id.* at 7:36–39.

***2** The headgear of the embodiment of Figure 6 includes upper side strap 620 and lower side strap 630 attached to mask 10. Ex. 1001, 10:5–9. Rigidizer 660 is substantially circular or oval in shape, with an arc removed at the lower portion of rigidizer 660 to allow the size of the shape to be adjusted. *Id.* at 10:1–4. In the embodiments of Figures 1 and 6, straps 20, 30, 620, and 630 include VELCRO® tabs "to engage the remainder of the strap to secure the strap in place and allow" mask 10 to be adjusted. *Id.* at 15:35–39.

Figures 14C and 14G are reproduced below:

FIG. 14C

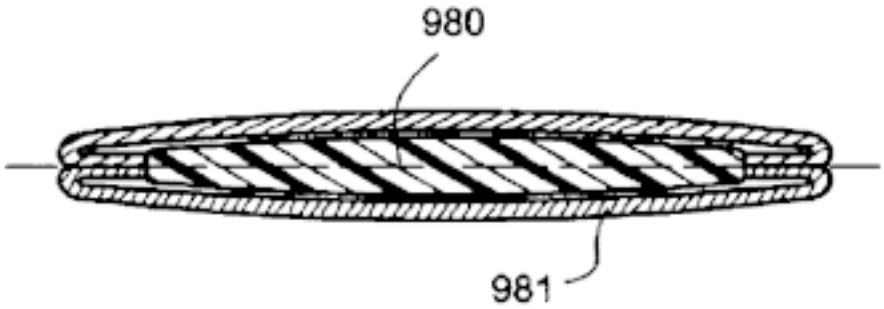
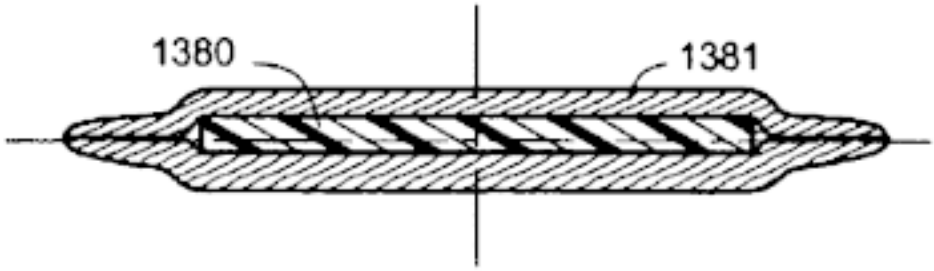


FIG. 14G



Figures 14C and 14G depict "cross-sectional views showing alternative rigidizer configurations." Ex. 1001, 16:58–59. In the embodiment depicted in Figure 14C, "the rigidizer may include a semi-rigid molded component 980 that is covered in fabric 981, e.g., two pieces of fabric joined by stitching." *Id.* at 17:21–23. The embodiment depicted in Figure 14G includes fabric layers 1381 around rigidizer 1380, with the fabric layers joined together at abutting ends, with the joint offset from the flat surface of the layers. *See id.*, Fig. 14G. "The fabric outer layers may be heat sealed together, stitched, ultrasonically cut, CNC knife cut, or otherwise joined." *Id.* at 17:44–46.

C. Challenged Claims

Claims 1, 29, and 48 of the '404 patent are independent. Claim 29 differs from claim 1 by requiring a rear portion that (1) circumscribes the rear of a wearer's head, (2) includes material that is relatively inextensible, and (3) is joined to upper and lower straps by stitched joins. Claim 48 is similar to claim 29. These claims are reproduced below:

> 1. 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, said plurality of straps comprising:
>
> 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; and
>
> a rear portion,
>
> 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 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.

Ex. 1001, 23:14–38.

29. 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, said plurality of straps comprising:

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;

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; and

***3** a rear strap portion having a rear loop configured and dimensioned to circumscribe the rear of the patient's head, the at least one upper strap and the at least one lower strap being attached to the rear strap portion via stitched joins, the rear strap portion comprising a material that is relatively inextensible compared to a relatively extensible material of the at least one upper strap,

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, 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.

Ex. 1001, 24:65–25:28.

48. 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, said plurality of straps comprising:

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;

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; and

a rear strap portion having a rear loop configured and dimensioned to circumscribe the rear of the patient's head, each said upper strap and each said lower strap being attached to the rear strap portion via stitched joins, 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,

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, 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.

Ex. 1001, 26:37–27:9.

D. The Prior Art

Fisher's asserted grounds of unpatentability for the Challenged Claims rely on the following references:

Amarasinghe	WO 2004/041341 A1	May 21, 2004	Ex. 1002
Ho	WO 2008/030831 A2	Mar. 13, 2008	Ex. 1003
Corrigall	US 3,424,633	Mar. 13, 2008	Ex. 1004

E. Asserted Grounds of Unpatentability

***4** Fisher asserts the following grounds of unpatentability for the Challenged Claims:

References	Basis[1]	Claims Challenged
Amarasinghe and Corrigall	35 U.S.C. § 103(a)	1, 5–9, 14, 16, 17, 19, 21, 27, and 28
Amarasinghe, Corrigall, and Ho	35 U.S.C. § 103(a)	2–4, 10–13, 15, 18, 20, 22–26, and 29–66

[Editor's Note: The preceding image contains the reference for footnote [1]].

II. ANALYSIS

A. Level of Ordinary Skill in the Art

Fisher asserts that the level of ordinary skill in the art to which the '404 patent pertains is "at least a bachelor's degree in mechanical engineering, biomedical engineering or other similar type of engineering degree combined with at least two years of experience in the field of masks, respiratory therapy, patient interfaces or relevant product design experience." Pet. 13–14 (citing Ex. 1013 (Decl. of Richard Lordo) ¶ 26). In its Preliminary Patent Owner Response, ResMed does not offer an alternative definition of the level of ordinary skill in the art to which the '404 patent pertains nor does it dispute Fisher's asserted definition.

Factual indicators of the level of ordinary skill in the art include "the various prior art approaches employed, the types of problems encountered in the art, the rapidity with which innovations are made, the sophistication of the technology involved, and the educational background of those actively working in the field." *Jacobson Bros., Inc. v. United States*, 512 F.2d 1065, 1071 (Ct. Cl. 1975); *see also Orthopedic Equip. Co., Inc. v. United States*, 702 F.2d 1005, 1011 (Fed. Cir. 1983) (quoting with approval *Jacobson Bros.*). We find, based on our review of the record before us, that Fisher's asserted level of ordinary skill in the art is reasonable and, for the purposes of this Decision only, we adopt Fisher's definition.

B. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *see also Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142–46 (2016) (concluding that 37 C.F.R. § 42.100(b) "represents a reasonable exercise of the rulemaking authority that Congress delegated to the Patent Office"). Under the broadest reasonable construction standard, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Also, we are careful not to read a particular embodiment appearing in the written description into the claim if the claim language is broader than the embodiment. *See In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993) ("[L]imitations are not to be read into the claims from the specification.").

Fisher contends that the terms of the Challenged Claims should be "given their 'broadest reasonable interpretation' in light of the [S]pecification of the '404 [p]atent" and does not offer any express constructions for any term in the Challenged Claims. *See* Pet. 10. In its Preliminary Patent Owner Response, ResMed proffers express constructions for three terms, which we address below.

1. "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"

***5** Claim 1 requires at least one of the plurality of straps to include a "joint configured to be positioned away from the patient's face when" the claimed headgear system is in use. Ex. 1001, 23:24–33. ResMed asserts that, when read in light of the Specification of the '404 patent, the "at least one strap" with the recited joint must be a strap that extends along the face of a patient when the headgear is in use. Prelim. Resp. 10. As ResMed explains, the purpose of this recitation is to prevent joints contacting a patient's face and leaving marks. *Id.* at 11 (citing Ex. 1001, 2:52–58).

We agree with ResMed that the at least one strap of claim 1 with a joint configured to be positioned away from the patient's face is limited to a strap that contacts, at least at some point, the patient's face. An alternative reading of this claim limitation, such that the strap may be exclusively positioned at the back of the head and away from the wearer's face, would render the claim language superfluous. *See Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006) (stating that "claims are interpreted with an eye toward giving effect to all terms in the claim," so that physical structures and characteristics specifically described in a claim are not rendered "merely superfluous").

This construction is consistent with the Specification. *See* Ex. 1001, 2:52–58, 16:58–18:3 (discussing alternative rigidizer configurations and stating that certain aspect of the configuration provide more comfort to the user's face). Our review of the Specification informs us that the exemplary rigidizers are shown as a component of the rear portions of the headgear —portions positioned away from the user's face. However, we do not read the Specification as limiting the rigidizer to the rear portion of the headgear and the repeated reference to comfort to a patient's face in the discussion of the alternative rigidizer configurations supports this construction.

Accordingly, we interpret, for this Decision only, the phrase "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" in claim 1 to be limited to an at least one strap that contacts, at some point, a patient's face when the headgear is in use.

2. "a substantially circular or oval shape"

Claims 10, 15, 37, 41, 56, and 60 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 "substantially circular or oval shape" limitation. *See, e.g.*, Ex. 1001, 23:63–67 (providing claim 10, which recites "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"). [2]

ResMed asserts that the "substantially circular or oval shape" limitation should be given its plain and ordinary meaning such that "the rear portion of the headgear forms a loop having an oval, i.e., ellipsoidal shape, or a substantially circular shape." Prelim. Resp. 11–12. ResMed explains that the "substantially" language allows the shape to vary somewhat from a precise oval or circular shape. *Id.* at 12. ResMed stresses that the terms "oval" and "circular" are well-understood geometric terms and differ from other geometric terms, such as triangles, trapezoids, and rectangles.

***6** For the purposes of this Decision, we agree with ResMed the "substantially circular or oval shape" limitation should be given its plain and ordinary meaning and we further agree with ResMed's articulation of that meaning.

3. "inextensible"

ResMed contends that "[t]he '404 patent provides a clear and unambiguous definition of [the claim term] 'inextensible,' " which appears in a number of claims, including independent claim 29. Prelim. Resp. 16. Specifically, ResMed contends that the '404 patent defines the term "inextensible" 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%, more preferably less than about 3%." *Id.* (citing Ex. 1001, 6:4–8) (emphasis omitted).

As explained in greater detail below, we agree with ResMed's contention that the Specification provides definitions of certain terms, but we disagree that the term "inextensible," alone, is clearly defined.

At the beginning of the "Detailed Description of Illustrated Embodiments," the '404 patent provides definitions for a number of terms. *See* Ex. 1001, 5:62–6:20. In one such definition, it states: "In this specification, a substantially 'inextensible' structure will be taken 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%, more preferably less than about 3%." *Id.* at 6:4–8. We find, based on our review of the entire Specification, including the claims, that the above definition is for the term "substantially inextensible," not "inextensible."

First, it is clear from the above-quoted language that the patentee is defining "substantially inextensible." The plain and ordinary meaning of the word "inextensible," is "not extensible, incapable of being stretched." *See, e.g.*, MERRIAM–WEBSTER ONLINE DICT., available at https://www.merriam-webster.com/dictionary/inextensible (last visited May 4, 2017). The definition included in the Specification provides a numerical standard for the word "substantially," which is a term of degree that is used in patent claim drafting to avoid a strict numerical boundary. *See, e.g.*, *Ecolab, Inc. v. Envirochem, Inc.*, 264 F.3d 1358, 1367 (Fed. Cir. 2001) ("We note that like the term 'about,' the term 'substantially' is a descriptive term commonly used in patent claims to 'avoid a strict numerical boundary to the specified parameter.' ") (quoting *Pall Corp. v. Micron Seps., Inc.*, 66 F.3d 1211, 1217 (Fed.Cir.1995)); *cf. Biosig Instruments, Inc. v. Nautilus, Inc.*, 783 F.3d 1374, 1378 (Fed. Cir.), *cert. denied*, 136 S. Ct. 569, 193 L.Ed. 2d 431 (2015) ("When a 'word of degree' is used, the court must determine whether the patent provides 'some standard for measuring that degree.' ") (internal citations omitted). The Specification clearly sets as a standard for what constitutes a material that is "substantially inextensible"—a material that will elongate less than about 5 percent when subject to the forces normally encountered in use of a respiratory mask. That is, the material is "substantially inextensible," rather than "inextensible," because it will elongate a small amount (less than 5 percent) under normal forces as opposed to not elongating at all, which is the understood meaning of "inextensible."

***7** Second, the claims themselves support a reading of the definition in the Specification to be for the term "substantially inextensible," rather than just "inextensible." For example, claim 10 recites "the first strap having at least a portion that is *substantially inextensible*." Ex. 1001, 23:66–67 (emphasis added). If the term defined in the Specification was simply "inextensible," then the Specification provides no standard to determine what would be "substantially inextensible"—that is, the Specification does not provide a standard to determine how far from the 5 percent elongation value could the strap stretch and still be "substantially inextensible." Further, claim 13 recites "wherein the rear portion comprises a *relatively inextensible* rear portion that is configured to be located at the upper half of the patient's head while in use." *Id.* at 24:9–12 (emphasis added). The adverb "relatively" means that the rear portion is inextensible as compared to another part of the headgear. Such a term of relative degree or extent does not lend itself to an exact standard of measure provided in the Specification.

We recognize that the Specification puts the term "inextensible" in quotations, not the term "substantially inextensible." Although this use of punctuation in the Specification lends support to a position that the provided definition is for the term "inextensible," the other evidence outweighs this point.

Accordingly, based on the foregoing, we construe the term "inextensible," when it appears unmodified in a claim,[3] in accordance with its plain and ordinary meaning—"not extensible, incapable of being stretched." Further, we construe the term "substantially inextensible" 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%." We construe the term "relatively inextensible" to encompass a structure that is less extensible relative to another structure.

C. Overview of the Asserted Prior Art

The Petition relies on three prior art references in its asserted grounds of unpatentability—Amarasinghe, Ho, and Corrigall. We briefly discuss relevant portions of these references, below.

1. Amarasinghe

Amarasinghe, titled "Headgear Assembly for a Respiratory Mask Assembly," published as an international application on May 21, 2004. Ex. 1002, (54), (43). Amarasinghe's "Applicant" is ResMed. *Id.* at (71). Amarasinghe is generally directed to "a headgear assembly for use in holding a respiratory mask assembly in position on a patient's face, the mask assembly being used for treatment, e.g., of Sleep Disordered Breathing (SDB) with Non-invasive Positive Pressure Ventilation (NPPV)." *Id.* at 1:7–10. Amarasinghe's Figures 1 and 2 are reproduced below:

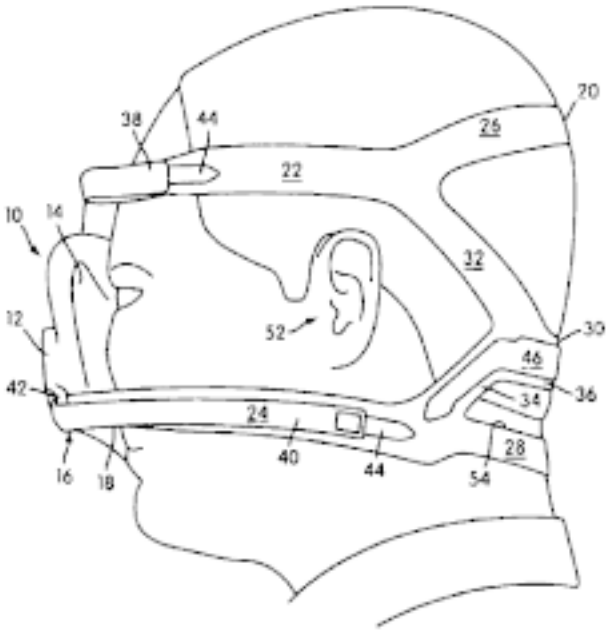


FIG. 1

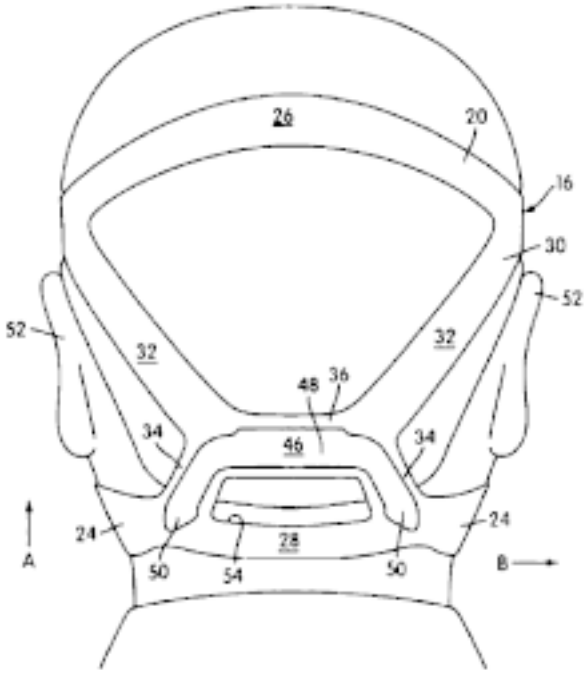


FIG. 2

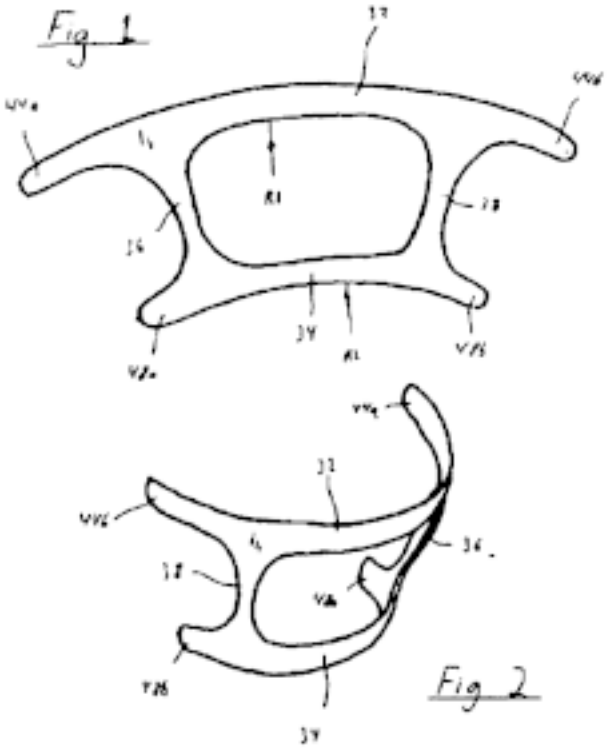
Figures 1 and 2 depict "a side view illustrating a mask assembly having a headgear assembly ... mounted on a patient's head" and "a rear view illustrating the headgear assembly of [Figure] 1," respectively. Ex. 1002, 3:23–26. Mask assembly 10 is removably attached to headgear assembly 16 at frame 12. Ex. 1002, 4:21–23. Headgear assembly 16 includes upper side strap 22, lower side strap 24, and rear portion 20, which interconnects with the upper and lower side straps. *Id.* at 5:3–6. Rear portion 20 includes upper strap 26, lower strap 28, and intermediate strap arrangement 30. *Id.* at 5:5–7. Intermediate strap arrangement 30 is formed by upper straps 32, lower straps 34, and cross-bar strap 36. *Id.* at 5:7–8. Curved upper strap 26 engages a posterior portion of the parietal bone of the patient's head and cross-bar strap 36 is structured to engage a lower portion of the occipital bone of the patient's head. *Id.* at 8:3–6.

Upper side straps 22 and lower side straps 24 connect to the upper and lower portion of frame 12, respectively. Ex. 1002, 5:15–16. End portions of the upper and lower side straps have a reduced width to wrap around clip structure 42 on frame 12. *Id.* at 5:17–19. Upper side straps 22 and lower side straps 24 may employ hook and loop material to secure the straps to themselves. *Id.* at 5:19–24.

***8** Headgear assembly 16's straps are made "from a soft, flexible composite material such as BREATHE–O–PRENE ™ ." [4] Ex. 1002, 6:3–4. Rear portion 20 includes stiffener 46, which "is constructed from a semi-rigid skin-compatible material such as thermoplastics, e.g., nylon or polyester or a thermoplastic elastomer, e.g. santoprene." *Id.* at 6:17–19. "[S]tiffener 46 is secured to [ ] straps 34, 36 by stitching around the periphery of [ ] stiffener 46." *Id.* at 6:23–24. Stiffener 46 adds rigidity to headgear assembly 16—it "reduces the flexibility of [ ] straps 34, 36 at the back of the patient's head along the direction of arrow A or in a reverse direction of arrow A, as shown in [Figure] 2." *Id.* at 7:3–8.

2. Ho

Ho, titled "Headgear Assembly," published as an international application on March 13, 2008. Ex. 1003, (54), (43). Ho is generally directed to "a headgear having curved beams that enable the headgear to assume a spherical configuration when donned by a user." *Id.* ¶ 2. Ho's Figures 1, 2, and 3 are reproduced below:



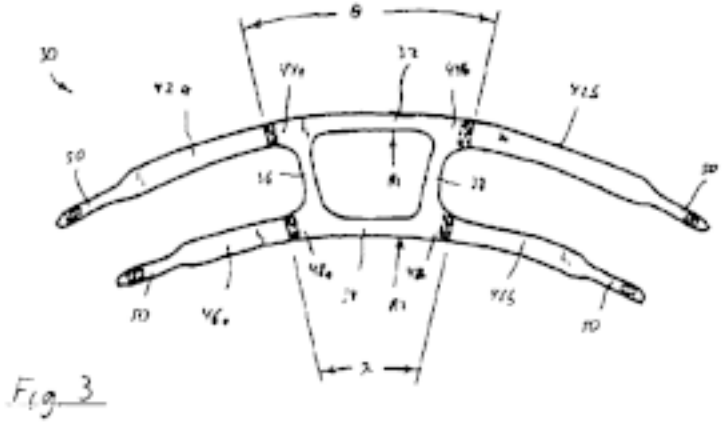


Figure 1 depicts "plan view of a portion of a first embodiment headgear assembly" of Ho. Ex. 1003 ¶ 11. Figures 2 and 3 depict "a perspective view of the headgear portion shown in [Figure] 1" and "a plan view a headgear assembly that includes the portion shown in [Figure] 1," respectively. *Id.* ¶ 12–13. Headgear assembly 30 includes a rear portion formed by first beam 32, second beam 34, first member 36, and second member 38. *Id.* ¶ 26, 29. "First beam 32 and second beam 34 are generally planer, i.e., are relative thin, and are flexible or semi rigid." *Id.* ¶ 27.

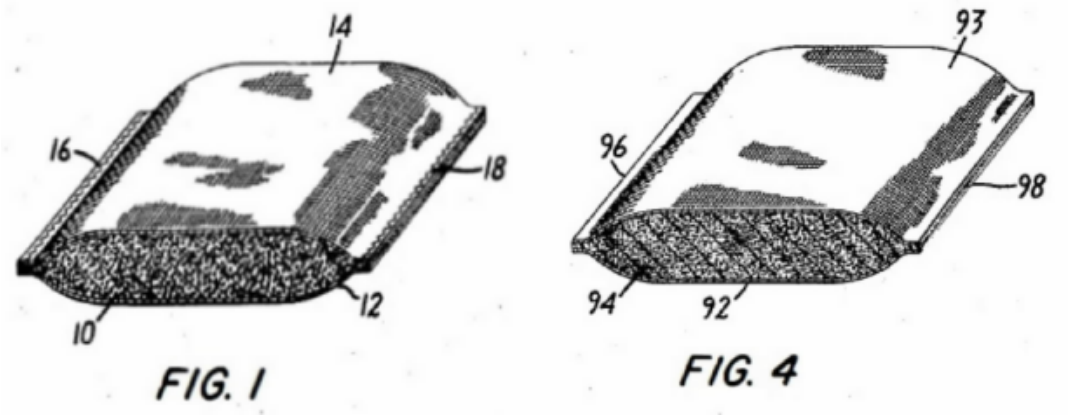
> [W]hen the headgear assembly is lying flat, such as on a flat surface, the first beam and the second beam also lie flat on that surface. First beam 32 is curved along its length such that it has a first radius of curvature R1 defined in the first plane. Second beam 34 is also curved with respect to its lengthwise axis such that it has a second radius of curvature R2 that is also defined in the first plane. The first radius of curvature R1 and the second radius of curvature R2 are in the same direction.

Id. "[W]hen headgear assembly 30 is worn by a user, first beam 32 and second beam 34 bend or wrap around the head/neck of the user" and "the structure defined by the first and second beams has a generally spherical shape." Ex. 1003 ¶ 32.

Coupling members 42a, 42b, 46, and 46b are made of fabric and are attached to the ends of the first and second beams by stitching, sewing, or sonic/heat welding. Ex. 1003 ¶ 34.

3. Corrigall

Corrigall, titled "Method of Making Strap Material," issued January 28, 1969. Ex. 1004. Corrigall is generally directed to "[a] method for making laminated fully air breathable foam-fabric articles." *Id.* at 1:15–17. Corrigall's strap construction results in a more comfortable garment. *Id.* at 2:16–19. Corrigall's Figures 1 and 4 are reproduced below:



Figures 1 and 4 depict segments of strap material from alternative embodiments. Ex. 1004, 2:70–3:6. In the embodiment of Figure 1, fabric strips 12, 14, and foam strip 10 form a laminate structure, with strips 12, 14 preferably adhered to foam strip 10. *Id.* at 3:50–54. Fabric strip 12 is an inner, body-contacting fabric chosen for its softness and fabric strip 14 is chosen for its durability. *Id.* at 3:44–49. Strips 12, 14 are made of an extensible fabric. *Id.* at 3:35–36.

"[F]oam and fabric strips of equal widths [are] adhered together to form a laminate, and the edges of the laminate then stitched together, the stitching serving ... to join the fabric strips [and] to compress the edge portions of the foam to form ... rounded edges." Ex. 1004, 4:3–8. In the embodiment of Figure 4, strips 92, 93 are mechanically adhered to foam layer 94. *Id.* at 6:2–6. Foam layer 94 is heat-formed to collapse the foam cells at the lateral edges 96, 98 of the laminate strip, such that the edges do not require stitching. *Id.* at 6:6–17.

D. Asserted Grounds of Unpatentability

***9** Fisher proposes two grounds of unpatentability for the Challenged Claims of the '404 patent: 1) claims 1, 5–9, 14, 16–17, 19, 21, 27, and 28 are unpatentable under 35 U.S.C. § 103(a) over Amarasinghe and Corrigall; and 2) claims 2–4, 10–13, 15, 18, 20, 22–26, 29–66 are unpatentable under 35 U.S.C. § 103(a) over Amarasinghe, Corrigall, and Ho.

> Section 103(a) [of 35 U.S.C.] forbids issuance of a patent when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."

KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 406 (2007).

The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) when available, secondary considerations, such as commercial success, long felt but unsolved needs, and failure of others. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). We address these underlying factual issues with respect to each asserted ground, below. [5]

1. Claims 1, 5–9, 14, 16–17, 19, 21, 27, and 28 over Amarasinghe and Corrigall

a. Independent Claim 1

(i) Fisher's assertions as to the subject matter of claim 1 and reasons to combine Amarasinghe and Corrigall

Claim 1 requires "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; and a rear portion." Ex. 1001, 23:19–23. Fisher contends that Amarasinghe discloses this subject matter. Pet. 17–18, 22–23. Specifically, Fisher contends that Amarasinghe's headgear system 16 includes (1) upper side strap 22, configured to extend above the patient's ears during use of the headgear system; (2) lower side strap 24, configured to extend below the patient's ears during use; and (3) rear portion 20. *Id.* ResMed does not dispute these contentions at this time. In support of its position, Fisher annotates Amarasinghe's, which we reproduce below.

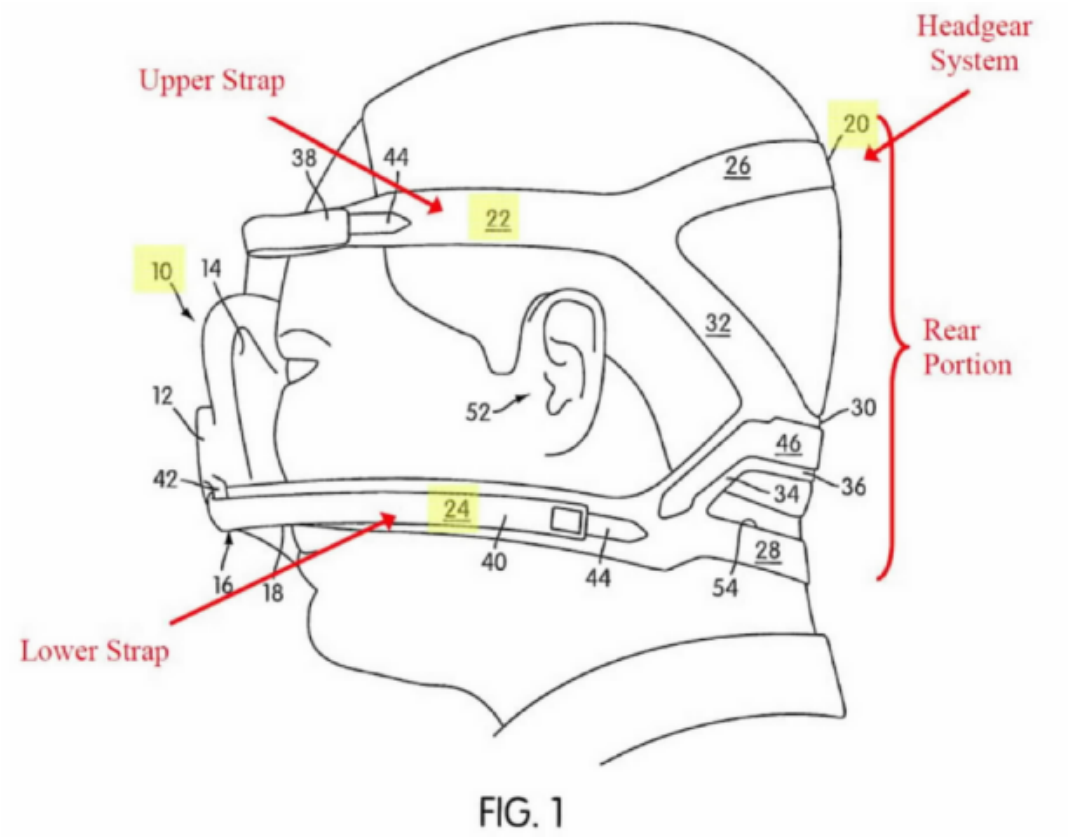


FIG. 1

Fisher's annotated Figure 1 from Amarasinghe indicates the upper strap, lower strap, and rear portion. *See* Pet. 19. ResMed does not dispute Fisher's contentions with respect to this subject matter at this time. We find, based on the current record, that Fisher has adequately demonstrated that Amarasinghe discloses the above-quoted subject matter.

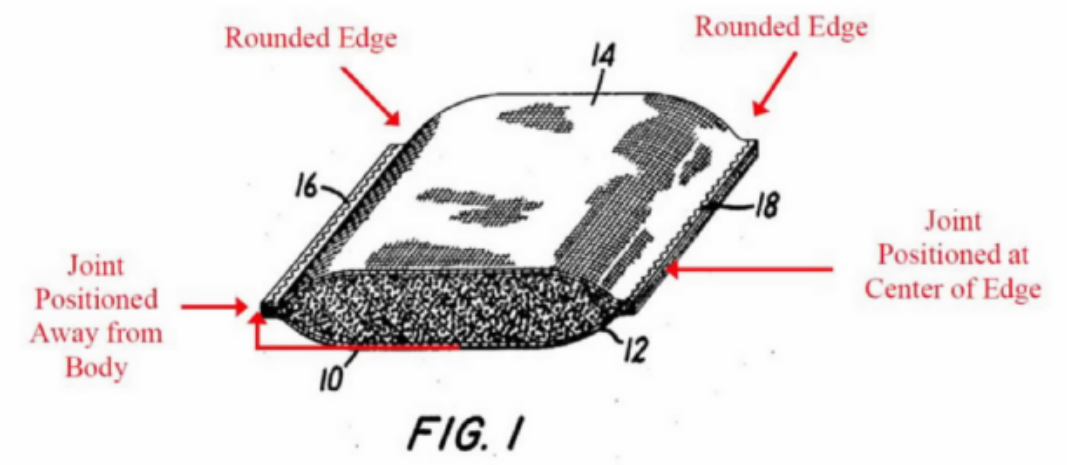
Claim 1 further recites:

> 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 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.

***10** Ex. 1001, 23:24–33. Fisher further contends that Amarasinghe discloses this subject matter. Fisher explains that Amarasinghe discloses that headgear 16's straps are made of BREATHE–O–PRENE. Pet. 18, 24–25. Fisher's expert, Mr. Richard Lordo, declares that BREATHE–O–PRENE is a stretchable fabric well known at the relevant time for the '404 patent. Ex. 1013 ¶ 44. Mr. Lordo explains that BREATHE–O–PRENE is a composite laminate of fabric and foam having three layers—two fabric layers with a foam layer in between. *Id.* Mr. Lordo also explains that the patient-contacting side of the laminate is made of polyester/nylon and the non-patient-contacting side is made of hook material. *Id.* Fisher further explains that Amarasinghe discloses that its straps include two layers, with the outside layer having loop material to facilitate attaching its strap ends with hook material to the outside layer of the straps. Pet. 25.

ResMed does not dispute Fisher's contentions with respect to this subject matter at this time. We find, based on the current record, that Fisher has adequately demonstrated that Amarasinghe discloses this strap construction subject matter.

Claim 1 further recites "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." Ex. 1001, 23:33–38. Fisher acknowledges that Amarasinghe fails to explicitly disclose this subject matter. Fisher contends that Corrigall discloses a strap material that includes a first rounded lateral edge when viewed in cross-section and a joint connecting two fabric layers that is positioned at approximately a center or middle of the first rounded lateral edge when viewed in cross-section. Pet. 20, 26. To support its position, Fisher annotates Corrigall's Figure 1, which we reproduce below.



Fisher's annotated version of Corrigall's Figure 1 identifies the straps rounded edges and joint. *See* Pet. 27. Fisher explains that Corrigall discloses that the joined edges of its strap are above the normal contour of the body, such that the joint is positioned away from the body. Pet. 27. Fisher further contends that Corrigall's embodiment depicted in Figure 4 also discloses the recites strap configuration subject matter. *Id.* at 28. ResMed does not dispute Fisher's contentions with respect to this subject matter at this time. We find, based on the current record, that Fisher has adequately demonstrated that Corrigall discloses this strap configuration subject matter.

(ii) Corrigall as analogous art

ResMed argues that Corrigall is not analogous art and, thus, does not qualify as prior art available for an obviousness combination. Prelim. Resp. 44–51. Whether a prior art reference is "analogous art" that is proper to consider in an obviousness analysis is a question of fact. *In re Bigio*, 381 F.3d 1320, 1324 (Fed. Cir. 2004).

> Two separate tests define the scope of analogous prior art: (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.

Id. at 1325. In order for a reference to be "**reasonably pertinent**" to the problem, it must "logically [ ] have commended itself to an inventor's attention in considering his problem." *In re Icon Health and Fitness, Inc.*, 496 F.3d 1374, 1379–80 (Fed. Cir. 2007); *see also KSR Int'l Co.*, 550 U.S. at 417 ("When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one."). The scope of analogous art is to be construed broadly. *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1238 (Fed. Cir. 2010).

***11** ResMed argues that the Petition fails to demonstrate that Corrigall is from the same field of endeavor as the '404 patent. Prelim. Resp. 44. Fisher contends that Corrigall is in the same field of endeavor, as both Corrigall and the'404 patent "both relate to providing comfortable, wearable, strap material." Pet. 20 (citing Ex. 1013 ¶ 64). ResMed responds that, as Fisher's expert declares, the relevant field of the '404 patent is "headgear systems for breathing apparatuses and interface masks." Prelim. Resp. 44–45 (quoting Ex. 1013 ¶ 25). ResMed contends that Corrigall is not directed to this field of endeavor. *Id.* at 45–46. We agree with ResMed. We find that the field of endeavor of the '404 patent is headgear for use in holding a mask in position on a patient's face while treating the patient for a breathing disorder. *See* Ex. 1001, 14–21. Corrigall's field of endeavor is strap material for wearing apparel. *See* Ex. 1004, 1:34–35.

As for the second prong, Fisher contends that Corrigall is **reasonably pertinent** to the particular problem with which the inventor is involved. Specifically, Fisher contends that Corrigall is pertinent to the problem of making comfortable straps. Pet. 29; *see also* Ex. 1013 ¶ 64 ("Corrigall method of making strap material is also pertinent to the same problems faced by Amarasinghe[ ] and the Applicant for the '404 [p]atent, including making straps that contact the skin of a user and are still comfortable even when worn for long periods of time"). Mr. Lordo explains that "both [Amarasinghe and Corrigall] teach forming straps using a multilayer combination, including the use of a multilayer fabric/foam/fabric laminate for wearable comfort straps to minimize patient discomfort and provide appropriate support." Ex. 1013 ¶ 65.

ResMed contends that the law governing analogous art requires the reference, in this case, Corrigall, to be **reasonably pertinent** to the *entire* problem faced by the inventors. Prelim. Resp. 47 (citing *Schott Gemtron Corp. v. SSW Holding Co.*, IPR No. 2014–00367 (PTAB May 26, 2015)). ResMed states that the '404 patent is directed to several problems, "including maintaining a 'mask seal' between a respiratory mask and the user's face for pressure therapy, particularly while a patient sleeps, as well as 'a continuous need in the art for headgear that is comfortable, fits a wide range of patients, is easily manufactured, and is inexpensive.' " *Id.* ResMed continues that another problem addressed by the '404 patent is the awkward and complicated use of certain prior art headgear. *Id.* ResMed argues that the '404 patent addresses each of these problems and Corrigall addresses none of these problems. *Id.* at 48. ResMed further argues that Corrigall's straps are not used on the face or head, are not used during sleep, and are not used to seal a respiratory mask to a face. *Id.* at 50–51.

ResMed further contends that any reliance on Corrigall to solve a problem addressed by the inventors is a product of hindsight. Prelim. Resp. 50. ResMed argues that:

> Petitioner has not presented any evidence that a person of ordinary skill in the art—faced with the problem of providing comfortable headgear that maintains an adequate mask seal—would have considered Corrigall pertinent, despite Corrigall's public availability for decades during which persons of ordinary skill in the art were grappling with these problems.

Id.

Based on the current record, we find ResMed's arguments unpersuasive. ResMed appears to argue that to satisfy the second prong of the analogous art test, the reference must address **each problem** addressed by the inventors—that is, the *entire problem* is the same as *each and* ***every problem***. *See* Prelim. Resp. 49 ("Petitioner fails to explain why one of

ordinary skill in the field of the '404 patent would have looked to Corrigall to address any of these problems, *let alone to provide a solution that would solve all of them*.") (emphasis added). We do not read the law to be that restrictive. We find that Corrigall is **reasonably pertinent** to *an* entire problem addressed by the '404 patent—strap comfort where the strap does not dig into the user's skin. *See* Ex. 1004, 2:3–41; Ex. 1001, 1:45–46, 16:58–17–15, 17:62–18:9. Our finding is also supported by Mr. Lordo, whose testimony on this issue we credit for the purposes of this Decision. *See* Ex. 1013 ¶ 65.

***12** Most of ResMed's arguments as to the second prong of the analogous art test includes an overarching theme—Corrigall's straps are not used for securing respiratory masks. We find this argument unpersuasive as it collapses the second prong of the test into the first prong.

ResMed relies on the Board's decision in *Schott Gemtron Corp.*, which follows the Federal Circuit's decision in *In re Klein*. *See Schott Gemtron Corp. v. SSW Holding Co.*, IPR No. 2014–00367, at *21–22 (PTAB May 26, 2015); *In re Klein*, 647 F.3d 1343 (Fed. Cir. 2011). In *Klein*, the Federal Circuit found the five references used in five separate obviousness rejections to not be analogous art. *See Klein*, 647 F.3d at 1348–52. *Klein* is distinguishable from the facts here. The invention at issue in *Klein* addressed a single problem—making a nectar feeder with a movable divider to prepare different ratios of sugar and water for different animals." *Id.* at 1348. One of the references at issue disclosed an apparatus with receptacles subdivided into compartments designed to receive statement cards. *Id.* at 1348–49. Another reference disclosed a tool tray with movable dividers to form compartments for small articles such as nuts and bolts. *Id.* at 1349. A third reference disclosed a drawer with dividers designed to form compartments of a desired size. *Id.* at 1349–50. The Federal Circuit found that these references were not directed to the entire problem addressed by the inventors, as they were directed to separating solid objects and were not adapted to receive liquid. *Id.* at 1350–51. The fourth reference was a blood plasma bottle with a divider that separated dried plasma and water, where the divider did not move. The fifth reference disclosed a container for mixing two fluids, where the container had two compartments, with one of the compartments having a valve that would open and close the partition between the compartments. The Federal Circuit found that these references were not directed to using a moveable divider to separate the compartments. *Id.* at 1351–52. In that way, none of the five references addressed the entire problem addressed by the inventor in *Klein*.

Here, we find, based on the current record, that Corrigall addresses a discrete problem addressed by the inventors of the '404 patent and included in the Challenged Claims—having a strap that is comfortable and whose edges do not mark the user's face. *See* Ex. 1004, 2:30–41; Ex. 1001, 1:43–3:64 (identifying discrete aspects of the invention, including "to provide headgear that comfortably fits a wide range of patients."); *see also* Prelim. Resp. 47–48 (acknowledging that the '404 patent addresses several different problems). Accordingly, we find that Corrigall logically would have commended itself to the attention of the inventors of the '404 patent when considering the problem of strap comfort.

As to ResMed's argument that any reliance on Corrigall to solve a problem addressed by the inventors of the '404 patent is a product of hindsight, we do not agree. Corrigall itself expressly discloses the comfort aspects of its straps. With respect to the passage of time argument, such an argument may represent an indicia of non-obviousness, but otherwise is not a factor in our analogous art analysis. [6] We address ResMed's other hindsight-based arguments, below.

(iii) Combining Amarasinghe and Corrigall

***13** Fisher contends that a person having ordinary skill in the art would have modified Amarasinghe with straps as disclosed in Corrigall. Pet. 29–31. Fisher reasons that an artisan of ordinary skill would have chosen Corrigall's strap configuration to make the strap edge more comfortable. *Id.* at 30. Mr. Lordo explains that one known problem of mask headgear was causing strap marks on a wearer's face. Ex. 1013 ¶ 66. Mr. Lordo further explains that one known solution was to employ change the edge profile of the straps or use softened, rounded straps. *Id.* (referencing Ex. 1020, 1021, and 1022).

ResMed argues that the combination of Amarasinghe and Corrigall is the product of improper hindsight. Prelim. Resp. 17. First, ResMed argues that Corrigall's straps are inconsistent with a stated objective of Amarasinghe—to form a headgear from a single, continuous piece of material. *Id.* (referencing Ex. 1002, 2:1–5). As ResMed argues, Amarasinghe states that it is desirable to cut the headgear from a flat piece of fabric or composite, for cost reasons. *Id.* ResMed argues that Corrigall is inconsistent with this objective, as its method for making straps would not result in a headgear made from a single piece of material. [7]

We are not persuaded, on the present record, by ResMed's argument. We find that the benefits disclosed in Corrigall —the comfort of its strap—outweigh additional manufacturing costs, if any. *See Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349 n.8 (Fed. Cir. 2000) ("The fact that the motivating benefit comes at the expense of another benefit, however, should not nullify its use as a basis to modify the disclosure of one reference with the teachings of another. Instead, the benefits, both lost and gained, should be weighed against one another.").

Further, we are not convinced, on the present record, that Corrigall's method could not have been adapted to produce a single sheet of composite from which a headgear could be cut or stamped, with the cut edges then closed using the same process as disclosed in Corrigall. That is, the width of strips 10, 12, and 14 could be increased to provide a sheet wide enough to form an entire headgear.

Second, ResMed argues that Corrigall's process could not be employed to form Amarasinghe's straps, as Corrigall's process forms narrow straps of the same width, and Amarasinghe's straps have varying width. Prelim. Resp. 21–24.

We are not persuaded by ResMed's argument, as it asserts that Corrigall's straps could not be bodily incorporated into Amarasinghe's headgear assembly 16.

> "The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference," *In re Keller*, 642 F.2d 413, 425 (CCPA 1981). *See also In re Mouttet*, 686 F.3d 1322, 1332 (Fed. Cir. 2012) (citing *In re Keller*, 642 F.2d at 425), but rather whether "a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention," *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007).

Allied Erecting & Dismantling Co. v. Genesis Attachments, LLC, 825 F.3d 1373, 1381 (Fed. Cir. 2016). We find, based on the current record, that an artisan of ordinary skill would have been motivated to combine the teachings of comfortable straps of Corrigall with Amarasinghe's headgear assembly. *See PAR Pharm., Inc. v. TWI Pharm., Inc.*, 773 F.3d 1186, 1196 (Fed. Cir. 2014) (quoting *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1289 (Fed. Cir. 2006)) (" 'The presence or absence of a motivation to combine references in an obviousness determination is a pure question of fact.' "). This finding is based, in part, on the express teachings in Corrigall of the comfort of its straps. *See* Ex. 1004, 2:3–41. We also credit, for this Decision only, Mr. Lordo's testimony on this issue. *See* Ex. 1013 ¶¶ 63–70.

(iv) Conclusion

***14** For the reasons discussed above, we determine, based on the current record, that Fisher has demonstrated a reasonable likelihood that it will prevail in its assertion that claim 1 is unpatentable under 35 U.S.C. § 103(a) over Amarasinghe and Corrigall.

b. Dependent Claims 9 and 14

Claim 9 depends from claim 1 and further recites "wherein said plurality of straps comprises an extensible portion and an inextensible portion." Ex. 1001, 23:60–62. Claim 14 depends from claim 1 and further recites "wherein the plurality of straps is relatively extensible and the rear portion is relatively inextensible." *Id.* at 24:13–15. Fisher contends that Amarasinghe discloses this subject matter. Pet. 38.

Fisher contends that Amarasinghe discloses that headgear assembly 16 includes straps made from a soft, flexible composite material, for example, BREATHE–O–PRENE, and that BREATHE–O–PRENE is known to be extensible. Pet. 38. Fisher further contends that Amarasinghe discloses that stiffeners 46 are added to the straps of rear portion 20 of headgear assembly 16, and these stiffeners make that part of rear portion 20 relatively inextensible. *Id.* at 39. The Petition quotes Amarasinghe: "stiffener 46 reduces the flexibility of the straps 34, 36 at the back of the patient's head along the direction of arrow A or in a reverse direction of arrow A, as shown in Fig. 2." *Id.* (quoting Ex. 1002, 7:6–8).

ResMed contends that Fisher fails to properly address any claim limitation including the term "inextensible," including claims 9 and 14. Prelim. Resp. 25–27. As we discussed above in our claim construction analysis, ResMed argues that the '404 patent provides a lexicographic definition of the term "inextensible." *Id.* at 25. ResMed's position is that Fisher did not apply this definition to claims reciting the term "inextensible" in its analysis against the prior art. As such, ResMed argues that we should deny institution of those claims. *Id.* at 26–27. [8]

As we discussed in our claim construction analysis, we find that the '404 patent provides a lexicographic definition for the term "*substantially inextensible*," not "*inextensible*." We did determine, however, that the plain and ordinary meaning of the term "inextensible" is "not extensible, incapable of being stretched" and the plain and ordinary meaning of the term "relatively inextensible" encompasses a structure that is less extensible relative to another structure.

Applying our constructions, we determine that Fisher has adequately demonstrated that Amarasinghe discloses that the plurality of straps is relatively extensible and the rear portion is relatively inextensible as required by claim 14. As Fisher asserts, Amarasinghe discloses that the straps are made of a material such as BREATHE–O–PRENE and the rear portion includes stiffeners, which make the straps less extensible. *See* Pet. 38–39; Ex. 1013 ¶¶ 90–95.

***15** We further determine, however, that Fisher has not adequately demonstrated that Amarasinghe discloses that the plurality of straps comprises an extensible portion *and an inextensible portion*, as required by claim 9. Amarasinghe discloses that "stiffener 46 *reduces* the flexibility of the straps 34, 36," not that it makes the strap inextensible, that is, incapable of being stretched. *See* Ex. 1002, 7:6–8 (emphasis added). Neither Fisher nor Mr. Lordo explains how Amarasinghe disclosing that stiffener 46 *reduces* flexibility would indicate to a person having ordinary skill in the art that the portion of the rear portion with stiffener 46 would be *incapable* of stretching. *See* Ex. 1013 ¶ 95 ("Amarasinghe[ ] discloses an extensible or stretchable portion and a rear portion that is relatively inextensible ....").

For the reasons discussed above, we determine, based on the current record, that Fisher has demonstrated a reasonable likelihood that it will prevail in its assertion that claim 14 is unpatentable under 35 U.S.C. § 103(a) over Amarasinghe and Corrigall, but not as to claim 9.

b. Dependent Claims 19 and 21

Claim 19 depends from claim 1 and further recites "wherein the first fabric layer and the second fabric layer are stitched in a region to stiffen the at least one strap of said plurality of straps." Ex. 1001, 24:32–34. Claim 21 depends from claim 1 and further recites "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." *Id.* at 24:39–41.

With respect to claim 19, Fisher contends that Amarasinghe discloses that "stiffener 46 is secured to the straps 34, 36 by stitching around the periphery of the stiffener 46." Pet. 41 (referencing Ex. 1002, 6:21–24). Fisher further contends that Corrigall discloses stitching the fabric layer 12 to fabric layer 14 along its edges. *Id.* at 41–42. Mr. Lordo declares that "[a] person of skill would have understood that the portions including the stitching would stiffen the strap." Ex. 1013 ¶ 100.

ResMed argues that, with respect to stitching stiffener 46 to straps 34, 36, this stitching is on the alleged rear portion, and claim 19 requires the stitching to be on the recited straps rather than the rear portion. Prelim. Resp. 34–36. We agree with ResMed that the Petition fails to demonstrate that Amarasinghe discloses the subject matter of claim 19.

With respect to Corrigall, ResMed argues that Corrigall's stitching forms a neat edge and that, even with the stitching, the Corrigall states that the strap should be extensible. Prelim. Resp. 36–37. ResMed continues that Corrigall does not teach or suggest that its stitching stiffens the strap.

We are persuaded, on the current record, that Corrigall discloses the recited subject matter of claim 19. The claim language requiring the stitching "to stiffen the at least one strap of said plurality of straps" is functional language. This functional language describes a characteristic of the claimed structure—that the presence of the stitching makes the straps stiffer. *Cf. K–2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1363 (Fed. Cir. 1999) ("[T]he functional language tells us something about the structural requirements of the attachment between the bootie and the base."). We credit Mr. Lordo's testimony that stitching would add stiffness to a strap. *See* Ex. 1013 ¶ 100. ResMed fails to point to any persuasive evidence to the contrary. ResMed's reliance on Corrigall's disclosure that the straps should be extensible is unavailing. ResMed fails to explain how a strap being stiffer with stitching than without equates to the strap being inextensible. That is, a strap that is less extensible is not the same as a strap that is inextensible.

With respect to claim 21, Fisher contends that Corrigall discloses, for the embodiment of Figure 1, that stitching compresses the edge portions of the foam to form rounded edges. Pet. 43. Fisher further contends that, with respect to Corrigall's embodiment of Figure 4, heat sealing the edges collapses the foam. *Id.* at 44. Mr. Lordo declares that "[a] person of skill would have understood that the portions including the compressed regions [of Corrigall's strap] stiffen the strap." Ex. 1013 ¶ 103.

***16** ResMed argues that the teachings in Corrigall relied on by Fisher are directed to compressing the foam, not the fabric layers. Prelim. Resp. 39–40. We agree. Claim 21 requires the fabric layers to be compressed, not an intervening layer.

For the reasons discussed above, we determine, based on the current record, that Fisher has demonstrated a reasonable likelihood that it will prevail in its assertion that claim 19 is unpatentable under 35 U.S.C. § 103(a) over Amarasinghe and Corrigall, but not as to claim 21.

b. Dependent Claims 5–8, 16, 17, 27, and 28

Dependent claims 5–8, 16, 17, 27, and 28 depend, directly or indirectly, from claim 1. We have reviewed Fisher's contentions as to how the combination of Amarasinghe and Corrigall disclose the subject matter of these claims and as to why a person having ordinary skill in the art would have modified Amarasinghe with Corrigall's teachings. *See* Pet. 31–41. We find that Fisher has made the requisite showing as to these claims. ResMed does not, at this time, dispute any of Fisher's contentions specifically addressing these claims.

We determine, based on the current record, that Fisher has demonstrated a reasonable likelihood that it will prevail in its assertion that claims 5–8, 16, 17, 27, and 28 are unpatentable under 35 U.S.C. § 103(a) over Amarasinghe and Corrigall.

2. Claims 2–4, 10–13, 15, 18, 20, 22–26, and 29–66 over Amarasinghe, Corrigall, and Ho

a. Independent Claims 29 and 48

(i) Subject matter of claims 29 and 49

Independent claim 29 recites "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." Ex. 1001, 25:3–6. Claim 29 further recites "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." *Id.* at 25:7–11. Similarly, independent claim 48 recites:

> 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.

Id. at 26:42–47. Claim 48 further recites:

> 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.

Id. at 25:48–54.

Fisher contends that Amarasinghe discloses this subject matter. In support of its contentions, Fisher annotates Amarasinghe's Figure 1, which we reproduce below.

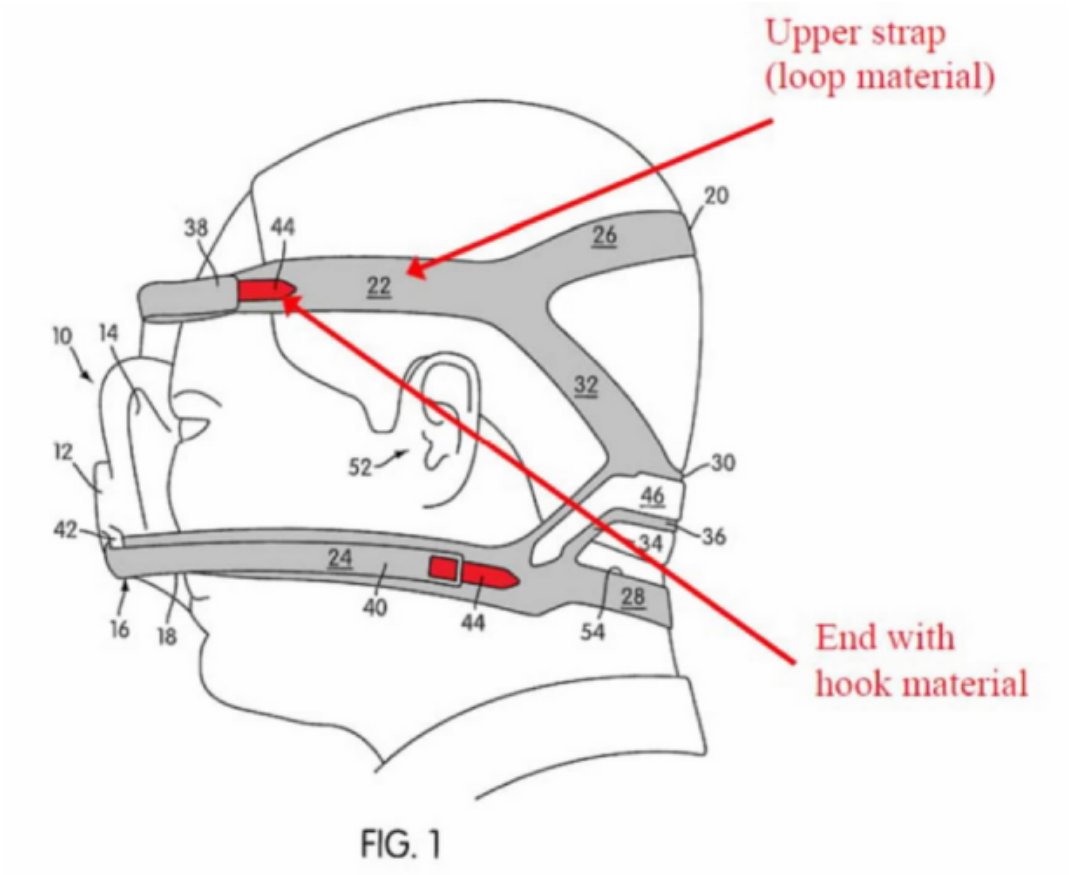


FIG. 1

The annotated Figure 1 illustrates straps 22, 24 having loop material, with ends 44 having hook material. Pet. 49. As to the requirement that the upper straps attach to slots in a forehead support, Fisher contends that Amarasinghe discloses that upper straps 22 may be connected to clips on a forehead support. *Id.* (citing Ex. 1002 at 5:25—6:2). Fisher further

contends that Amarasinghe does not expressly disclose a slot in a forehead support, but Ho discloses this subject matter. *Id.* Fisher also contends, with respect to the lower straps, that Amarasinghe discloses that lower straps 24 may engage frame 12 with locking clips. *Id.* at 51.

***17** ResMed does not dispute Fisher's contentions with respect to this subject matter at this time. We find, based on the current record, that Fisher has adequately demonstrated that Amarasinghe discloses the above-quoted subject matter.

Claims 29 and 48 further recite "a rear strap portion having a rear loop configured and dimensioned to circumscribe the rear of the patient's head." Ex. 1001, 25:12–14, 26:55–57. Fisher contends that both Amarasinghe and Ho disclose this subject matter. Pet. 52–53. ResMed does not dispute Fisher's contentions with respect to this subject matter at this time. We find, based on the current record, that Fisher has adequately demonstrated that Amarasinghe discloses the above-quoted subject matter.

Claim 29 further recites "the at least one upper strap and the at least one lower strap being attached to the rear strap portion via stitched joins" and claim 48 further recites "each said upper strap and each said lower strap being attached to the rear strap portion via stitched joins." Ex. 1001, 25:14–16, 26:57–58. Fisher concedes that Amarasinghe does not disclose this subject matter, but contends that Ho does. Pet. 54. ResMed does not dispute Fisher's contentions with respect to this subject matter at this time. We find, based on the current record, that Fisher has adequately demonstrated that Ho discloses the above-quoted subject matter.

Claim 29 further recites "the rear strap portion comprising a material that is relatively inextensible compared to a relatively extensible material of the at least one upper strap" and claim 48 recites "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." Ex. 1001, 25:16–18, 26:59–63.

ResMed contends that Fisher fails to properly address any claim limitation including the term "inextensible," including independent claim 29 and claims 30–47, which depend, directly or indirectly, from claim 29. Prelim. Resp. 25–27. ResMed argues that the '404 patent provides a lexicographic definition of the term "inextensible" and Fisher did not apply this definition to claims reciting the term "inextensible" in its analysis against the prior art for these claims. *Id.*

Claim 29 recites the term "relatively inextensible." As we discussed above in connection with our analysis of claims 9 and 14 with respect to Ground 1 and our claim construction analysis, the '404 patent provides a lexicographic definition for the term "*substantially inextensible*," not "*inextensible*." Further, we determine that the plain and ordinary meaning of the term "relatively inextensible" encompasses a structure that is less extensible relative to another structure. Fisher has adequately demonstrated, at this stage of the proceeding, that Amarasinghe discloses a rear strap portion comprising a material that is relatively inextensible compared to a relatively extensible material of the at least one upper strap as required by claim 29, as Amarasinghe discloses the addition of stiffener 46 to the rear portion of headgear assembly 16. *See* Pet. 56.

ResMed does not dispute Fisher's contentions as to the "extensibility" limitation of claim 48. We find, based on the current record, that Fisher has adequately demonstrated that Amarasinghe discloses the above-quoted subject matter of the extensibility limitation.

***18** Claim 29 further recites:

> 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, 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.

Ex. 1001, 25:19–28. Similarly, claim 48 recites:

> 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, 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.

Id. at 26:64–27:9. Fisher contends that Amarasinghe, as modified by the teachings of Corrigall, disclose the subject matter of these limitations. ResMed does not dispute Fisher's contentions with respect to this subject matter at this time. We find, based on the current record, that Fisher has adequately demonstrated that Amarasinghe discloses the above-quoted subject matter.

(ii) Reasons to combine Amarasinghe, Corrigall, and Ho

Fisher contends that a person having ordinary skill in the art would have had reason to combine the teachings of Amarasinghe, Corrigall, and Ho. Specifically, Fisher provides reasoning for adding Ho's slots for attaching straps, Ho's stitching, and Ho's rear portion circumscribing the rear of a user's head. *See* Pet. 60–61; *see also* Pet. 29–31 (providing reasons for combining Amarasinghe and Corrigall); Ex. 1013 ¶¶ 63–71, 135–141 (providing testimony supporting reasons to combine Amarasinghe, Corrigall, and Ho).

Except for arguments we addressed above, with respect to our analysis of claim 1 over Amarasinghe and Corrigall, ResMed does not provide any arguments addressing Fisher's reasons to combine Amarasinghe, Corrigall, and Ho. We find, based on the current record before us, that Fisher has provided adequate reasoning, with rational underpinnings, for combining the teachings of Amarasinghe, Corrigall, and Ho with respect to claims 29 and 48. *See KSR Int'l Co.*, 550 U.S. at 418 (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)) ("[O]bviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.").

(iii) Conclusion

For the reasons discussed above, we determine, based on the current record, that Fisher has demonstrated a reasonable likelihood that it will prevail in its assertion that claims 29 and 48 are unpatentable under 35 U.S.C. § 103(a) over Amarasinghe, Corrigall, and Ho.

b. Dependent Claims 10, 11, 12, 37–39, 47, 56–58, and 66

***19** Dependent claims 10, 11, 12, 37–39, 47, 56–58, and 66 each requires an element of the of the claimed headgear system to have at least a portion that is "substantially inextensible." *See, e.g.*, Ex. 1001, 23:63–67 ("10. The headgear system of claim 1, 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, the first strap having at least a portion that is substantially inextensible."). As we discussed above in our claim construction analysis, we found that the Specification of the '404 patent provides a lexicographic definition of the term "substantially inextensible," meaning "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%."

ResMed contends that Fisher fails to properly address any claim limitation including the term "inextensible," including claims 10, 11, 12, 37–39, 47, 56–58, and 66. Prelim. Resp. 25. With respect to these claims, which all recite the term "substantially inextensible," we agree.

Fisher contends that Amarasinghe discloses this subject matter, as it discloses adding stiffener 46 to the straps of headgear assembly 16's rear portion and that, based on Amarasinghe teachings, a person having ordinary skill in the art would have known that this approach could be applied to the upper straps. *See* Pet. 70–71. Fisher further contends that Ho discloses this subject matter, as Ho provides that its elements 70a, 70b, 64, 66, and 68 are "semi-rigid, non-stretchy." *Id.* at 72 (citing Ex. 1003 ¶ 37). However, neither Fisher nor Mr. Lordo adequately explain how the teachings of Amarasinghe or Ho disclose that any strap of their headgear is constructed such that, when subject to the forces normally encountered in use of a respiratory mask, the structure will have an elongation of less than about 5%. That is, Fisher fails to offer any persuasive evidence that the results of adding stiffener 46 to a strap of Amarasinghe's headgear assembly 16 or the semi-rigid, non-stretchy nature of Ho's elements 70a, 70b, 64, 66, and 68 results in a structure that satisfies the "substantially inextensible" claim limitation.

For the reasons discussed above, we determine, based on the current record, that Fisher has not demonstrated a reasonable likelihood that it will prevail in its assertion that claims 10, 11, 12, 37–39, 47, 56–58, and 66 are unpatentable under 35 U.S.C. § 103(a) over Amarasinghe, Corrigall, and Ho.

c. Dependent Claims 13, 40, and 59

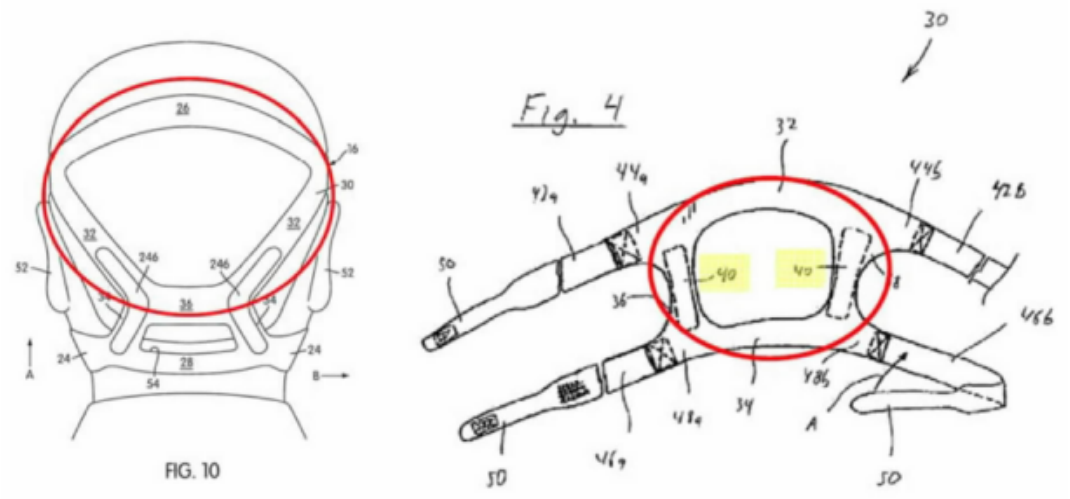
Claim 13 depends from claim 1 and further recites "wherein the rear portion comprises a relatively inextensible rear portion that is configured to be located at the upper half of the patient's head while in use." Ex. 1001, 24:9–12. Claims 40 and 59 depend from claims 29 and 48, respectively, and recite similar additional subject matter, including the "relatively inextensible" language. *See id.* at 25:62–65, 27:49–52. ResMed contends that Fisher fails to properly address any claim limitation including the term "inextensible," including claims 13, 40, and 59. Prelim. Resp. 25. As we discussed above in our claim construction analysis and our analysis of claim 14 over Amarasinghe and Corrigall, we do not agree with ResMed that the term "inextensible" alone or modified by the word "relatively" is defined in the Specification.

We find that Fisher has made the requisite showing as to claims 13, 40, and 59—that it would have been obvious to modify Amarasinghe's headgear assembly 16 to include a stiffener at strap 26 such that the rear portion of the headgear comprises a relatively inextensible rear portion that is configured to be located at the upper half of the patient's head while in use. *See* Pet. 70–72. ResMed does not, at this time, dispute any of Fisher's contentions specifically addressing these claims, other than with respect to the "relatively inextensible" language, addressed above.

***20** We determine, based on the current record, that Fisher has demonstrated a reasonable likelihood that it will prevail in its assertion that claims 13, 40, and 59 are unpatentable under 35 U.S.C. § 103(a) over Amarasinghe, Corrigall, and Ho.

d. Dependent Claims 15, 41, and 60

Claim 15 depends from claim 1 and recites "wherein the rear 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 and assume, in use, a substantially circular or oval shape." Ex. 1001, 24:17–21. Claims 41 and 60 depend from claims 29 and 48, respectively, and recite similar additional subject matter. *See id.* at 25:66–26:3, 27:53–28:3. Fisher contends that Amarasinghe, or alternatively, Ho, discloses this subject matter. Fisher illustrates its position by annotating Amarasinghe's Figure 10 and Ho's Figure 4, which we reproduce below.



Fisher's annotation of Amarasinghe's Figure 10 superimposes an oval over the rear portion of headgear assembly 16 and Fisher's annotation of Ho's Figure 4 superimposes an oval over the rear portion of headgear 30. *See* Pet. 76, 77.

ResMed contends that neither Amarasinghe nor Ho discloses a rear portion of a headgear assembly that 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 and assume, in use, a substantially circular or oval shape as required by claims 15, 41, and 60.[9] Specifically, ResMed argues that Amarasinghe discloses an H-shaped rear portion or, if considering only the upper portion of the rear portion, that this structure has sharp angles where the straps meet, forming a trapezoid. Prelim. Resp. 28–29. ResMed argues that these shapes are not substantially oval or circular. *Id.* at 30–31.

ResMed similarly argues that Ho fails to disclose the recited subject matter, as the loop formed in the rear portion of its headgear is substantially rectangular or trapezoidal in shape. Prelim. Resp. 31–32. ResMed emphasizes that the radii of curvature of the top and bottom segments forming Ho's loop curve in the same direction, in contrast to a circle or oval. *Id.* at 32.

We do not find ResMed's arguments persuasive. At this stage of the proceeding, Fisher's burden is to show a reasonable likelihood of prevailing with respect to at least 1 of the Challenged Claims. *See* 35 U.S.C. § 314(a). "The 'reasonable likelihood' standard is a somewhat flexible standard that allows the Board room to exercise judgment." *Office Patent Trial Practice Guide*, 77 Fed. Reg. 48,756, 48,765 (Aug. 14, 2012). We find that Fisher has made the requisite showing, at least with respect to Ho's disclosure.

Significantly, each of claims 15, 41, and 60 require the substantially oval or circular shape when the headgear is in use. We find, for the purposes of this Decision only, that Ho illustrates, in its Figure 2, a headgear with a rear portion 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 and assume, in use, a *substantially* oval shape as required in claim 15, 41, and 60. We base this finding, in part, on the curved nature of Ho's opening—that is, the rounded corners of Ho's loop opening creates a loop that is not only substantially rectangular, as ResMed acknowledges, but is substantially oval as well. Further, ResMed's arguments with respect to Ho are directed to Ho's headgear's configuration when not in use, but the claims at issue require the recited substantially oval or circular shape when the headgear is in use—depicted in Ho's Figure 2.

***21** We also find, based on the current record before us, that Fisher has provided adequate reasoning, with rational underpinnings, for combining the teachings of Amarasinghe, Corrigall, and Ho to arrive at the subject matter of claims 15, 41, and 60. *See* Pet. 82–83.

For the reasons above, we determine, based on the current record, that Fisher has demonstrated a reasonable likelihood that it will prevail in its assertion that claims 15, 41, and 60 are unpatentable under 35 U.S.C. § 103(a) over Amarasinghe, Corrigall, and Ho.

e. Dependent Claims 20 and 22

Claim 20 depends from claim 1 and further recites "wherein the first fabric layer and the second fabric layer are ultrasonically welded in a region to stiffen the at least one strap of said plurality of straps." Ex. 1001, 24:35–38. Claim 22 depends from claim 1 and further recites "wherein the first fabric layer and the second fabric layer are thickened or treated in a region to stiffen the at least one strap of said plurality of straps." *Id.* at 24:42–45.

With respect to claim 20, Fisher contends that "Ho discloses that the upper and lower straps can be 'sonic/heat welded' onto the rear portion [and] [a] person of [ordinary] skill would have understood that the sonic welding would stiffen the strap." Pet. 84 (referencing Ex. 1003 ¶ 34; Ex. 1013 ¶ 224).

ResMed contends that Ho discloses that ultrasonic welding is used to join two separate components of the headgear (a beam to a strap), not two layers of fabric forming a strap. Prelim. Resp. 37–38. ResMed further contends that Ho discloses nothing about ultrasonic welding stiffening the strap. *Id.* at 38.

On the current record at this stage of the proceeding, we find ResMed's argument unpersuasive. Fisher's position is that Ho discloses ultrasonic welding as a technique for joining two fabric components and that a person of ordinary skill in the art would understand that this technique would stiffen a strap if used to join the two fabric layers of the strap composite material. *See* Pet. 84 (relying, in part, on Mr. Lordo's testimony). We find that Fisher has made the requisite showing at this stage of the proceeding with respect to this subject matter.

With respect to claim 22, Fisher contends that Amarasinghe, or alternatively Ho, discloses the subject matter of this claim. Pet. 84–85. First, Fisher contends that Amarasinghe discloses adding stiffener 46 and that stiffener 46 may vary in thickness, such that the region with stiffener 46 is stiffer. *Id.* at 84. Second, Fisher contends that Ho discloses adding a stiffening agent to the straps. *Id.* at 85.

ResMed contends that claim 22 requires the fabric layers to be thickened and Amarasinghe's stiffener 46 is a separate component from the fabric layers of the strap. We agree with ResMed that the Petition fails to adequately explain how Amarasinghe discloses the subject matter of claim 22.

ResMed further contends that Ho fails to disclose adding its stiffening agent to both fabric layers—instead, Ho merely discloses adding a thickening agent to the straps. Prelim. Resp. 41. We do not find this argument persuasive. We find that Ho adequately discloses adding a stiffening agent to its straps, which would make the straps stiffer. The fact that Ho fails to disclose adding the agent to two fabric layers is inapposite. Fisher's obviousness position is based on modifying Amarasinghe's headgear assembly 16 with Corrigall's strap, which includes two fabric layers. Fisher then contends that a person having ordinary skill in the art would employ Ho's teaching of using a stiffening agent to these two layers. *See* Pet. 85; *see also* Ex. 1013 ¶ 226 ("[T]reating first and second fabric layers to stiffen the strap ... was common in prior art CPAP headgear.")

***22** For the reasons above, we determine, based on the current record, that Fisher has demonstrated a reasonable likelihood that it will prevail in its assertion that claims 20 and 22 are unpatentable under 35 U.S.C. § 103(a) over Amarasinghe, Corrigall, and Ho.

f. Dependent Claims 2–4, 18, 23–26, 30–36, 42–46, 49–55, and 61–65

Dependent claims 2–4, 18, 23–26, 30–36, 42–46, 49–55, and 61–65 depend, directly or indirectly, from independent claims 1, 29, or 48. We have reviewed Fisher's contentions as to how the combination of Amarasinghe, Corrigall, and Ho disclose the subject matter of these claims and as to why a person having ordinary skill in the art would have modified Amarasinghe with Corrigall's and Ho's teachings. *See* Pet. 62–88. We find that Fisher has made the requisite showing as to these claims. ResMed does not, at this time, dispute any of Fisher's contentions specifically addressing the subject matter recited in these claims.

We determine, based on the current record, that Fisher has demonstrated a reasonable likelihood that it will prevail in its assertion that claims 2–4, 18, 23–26, 30–36, 42–46, 49–55, and 61–65 are unpatentable under 35 U.S.C. § 103(a) over Amarasinghe, Corrigall, and Ho.

III. CONCLUSION

After considering the evidence and arguments presented in the Petition, including its supporting testimonial evidence, and the Preliminary Patent Owner Response, we determine that Fisher has demonstrated a reasonable likelihood of success in proving that claims 1–8, 13–20, 22–36, 40–46, 48–55, and 59–65 of the '404 patent are unpatentable. We determine, however, that that Fisher has not demonstrated a reasonable likelihood of success in proving that claims 9–12, 21, 37–39, 47, 56–58, and 66 of the '404 patent are unpatentable.

IV. ORDER

After due consideration of the record before us, it is:

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is instituted as to claims 1–8, 13–20, 22–36, 40–46, 48–55, and 59–65 of the '404 patent on the following grounds:

A. Claims 1, 5–8, 14, 16, 17, 19, 27, and 28 are unpatentable under 35 U.S.C. § 103(a) over Amarasinghe and Corrigall; and

B. Claims 2–4, 13, 15, 18, 20, 22–26, 29–36, 40–46, 48–55, and 59–65 are unpatentable under 35 U.S.C. § 103(a) over Amarasinghe, Corrigall, and Ho.

FURTHER ORDERED that no other ground of unpatentability other than those specified above is authorized for *inter partes* review; and

FURTHER ORDERED, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial. The trial will commence on the entry date of this Decision.

Footnotes

1 The Leahy–Smith America Invents Act ("AIA"), Pub. L. No. 112–29, 125 Stat. 284, 296–307 (2011), took effect on September 16, 2012. Because the application for the patent at issue in this proceeding has an effective filing date before that date, we refer to the pre–AIA versions of the statute.

2 Each of claims 10, 15, 37, 41, 56, and 60 use slightly different language with respect to this claim limitation. *See* Prelim. Resp. 12–13 (reproducing the "substantially circular or oval shape" limitation for each of these claims).

3 Claim 9 recites "[t]he headgear system of claim 1, wherein said plurality of straps comprises an extensible portion and an inextensible portion." Ex. 1001, 23:60–62.

4 Fisher indicates that BREATHE–O–PRENE is now a registered trademark. *See* Pet. 39.

5 We address the level of ordinary skill in the art in Section II.A., *supra*. The record does not include any evidence of secondary considerations.

6 We do not read the Preliminary Response as providing, at this point in the proceeding, any secondary indicia of non-obviousness, including the claims of the '404 patent solving a long-felt, yet unresolved need.

7 ResMed seems to suggest that the combination would render Amarasinghe inoperable for its intended purpose. *See* Prelim. Resp. 20. ResMed fails, however, to explain how the proposed modification would result in an inoperable headgear—that is, the intended purpose of Amarasinghe is a headgear for a mask system, not a headgear formed from a single sheet of material.

8 ResMed also asserts that we should deny institution because Fisher failed to comply with our rules requiring a Petition to identify how the claims should be construed. Prelim. Resp. 26. We determine that Fisher has adequately complied with our rules and do not deny institution of claims reciting "inextensible" based on Fisher's failure to provide an express construction of the term.

9 ResMed makes a similar contention with respect to claims 10, 37, and 56. As we have already determined that the Petition has not shown a reasonably likelihood that those claims are unpatentable, based on the "substantially inextensible" claim limitation of those claims, we need not analyze these claims here.

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