Filed: June 22, 2017

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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. IPR2017-01658
U.S. Patent No. 9,119,931

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,119,931

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EXHIBIT LIST

Exhibit No.	Description
1401	U.S. Patent No. 9,119,931
1402	Declaration of Jason Eaton, P.E.
1403	Curriculum Vitae of Jason Eaton, P.E.
1404	Complaint of ResMed Ltd, ResMed Inc., and ResMed Corp. Under Section 337 of the Tariff Act of 1930, as amended, Investigation No. 337-TA-1022
1405	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.)
1406	U.S. Provisional Application No. 61/064,406
1407	U.S. Provisional Application No. 61/071,893
1408	U.S. Provisional Application No. 61/136,617
1409	Excerpts from the File History of U.S. Patent No. 9,119,931
1410	PCT Publication No. WO 2007/048174 (Ng)
1411	U.S. Publication No. 2005/0011524 (Thomlinson)
1412	U.S. Publication No. 2007/0044804 (Matula-II)
1413	U.S. Patent No. 6,796,308 (Gunaratnam-I)
1414	U.S. Patent No. 6,412,488 (Barnett)
1415	PCT Publication No. WO 2007/045008 (Worboys)
1416	Affidavit of Christopher Butler, Ultra Mirage Brochure (Ultra Mirage), dated September 6, 2016

Exhibit No.	Description
1417	Affidavit of Christopher Butler, FlexiFit Instructions (FlexiFit), dated September 6, 2016
1418	Declaration of Fiona Cresswell
1419	U.S. Publication No. 2004/0182398 (Sprinkle)
1420	PCT Publication No. WO 2007/041751 (D'Souza)
1421	PCT Publication No. WO 2006/000046 (Hitchcock)
1422	U.S. Patent No. 5,662,101 (Ogden)
1423	PCT Publication No. WO 2007/147088 (Matula-I)
1424	U.S. Patent No. 7,827,990 (Melidis)
1425	PCT Publication No. WO 2005/123166 (Frater)
1426	U.S. Patent No. 6,631,718 (Lovell)
1427	U.S. Patent No. 6,851,425 (Jaffre)
1428	U.S. Publication No. 2004/0067333 (Amarasinghe)
1429	U.S. Publication No. 2004/0226566 (Gunaratnam-II)
1430	U.S. Publication No. 2006/0060200 (Ho)
1431	U.S. Publication No. 2005/0155604 (Ging)
1432	PCT Publication No. WO/2005/021075 (McAuley)
1433	U.S. Publication No. 2004/0118406 (Lithgow)
1434	U.S. Publication No. 2006/0042629 (Geist)
1435	U.S. Patent No. 5,921,239 (McCall)

Exhibit No.	Description
1436	U.S. Patent No. 6,435,181 (Jones, Jr.)
1437	U.S. Publication No. 2006/0201514 (Jones)
1438	PCT Publication No. WO 2004/041342 (Berthon-Jones)
1439	U.S. Publication No. 2006/0124131 (Chandran)
1440	PCT Publication No. WO 2006/074515 (Hitchcock-II)
1441	U.S. Patent No. 5,657,752 (Landis)
1442	PCT Publication No. WO2005051468 (Darkin)
1443	Malloy, Robert A., Plastic Part Design for Injection Molding: An Introduction, pp. 336–345 (Hanser Gardner Publications, Inc. 1994) (Malloy)
1444	U.S. Patent No. 6,581,594 (Drew)
1445	U.S. Patent No. 6,561,190 (Kwok)
1446	PCT Publication No. WO 00/50122 (Fecteau)
1447	Excerpt from Webster’s II New College Dictionary
1448	Excerpt from Oxford American College Dictionary

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 1, 4–8, 10–22, 25, 26, 28–32, 46, 51, 53–56, and 65 ("Challenged Claims") of U.S. Patent No. 9,119,931 ("'931 Patent") (Ex. 1401), which is purportedly owned by ResMed Limited ("Patent Owner" or "ResMed").

I. INTRODUCTION

Petitioner filed four previous petitions for *inter partes* review of the '931 Patent claims, including the Challenged Claims. *See* Ex. 1409 at 383–485. The Board instituted review of the claims that do not include the "protruding vent arrangement," but denied institution of the claims that include this limitation (the Challenged Claims). *Id*. As its basis for denying institution of the "protruding vent arrangement" claims, the Board adopted a construction of this limitation that was not proposed by either party. Specifically, the Board determined that the broadest reasonable interpretation of "a protruding vent arrangement" is "a discrete vent structure that extends above the surrounding surface of the frame and contains a plurality of vent holes." *Id.* at 391–393, 417–419. By adopting this claim construction, the Board then concluded that the prior art presented in the previous petitions did not disclose a "protruding vent arrangement."

Petitioner was surprised by the Board's construction of this limitation that draws a fine distinction between a protruding portion of the frame that includes

vent holes (as readily shown in the asserted prior art), and a "discrete" protruding vent structure. However, even under the Board's unexpectedly narrow construction of this limitation, the "protruding vent arrangement" claims would have been obvious to a person of skill in the art. Such discrete vent structures that extend above the surrounding surface of the frame were well-known and disclosed in numerous prior art CPAP references. *See infra* § VII(B)(3)(a)(vi). Had Petitioner been able to predict that the Board would have crafted and adopted this construction for the "protruding vent arrangement" limitation, which neither party had advanced, Petitioner would have included those other prior art references in its initial petitions.

As shown below, WO 2007/048174 (Ng) discloses the same general features as the ’931 Patent. Ex. 1402 ¶ 67.

’931 Patent

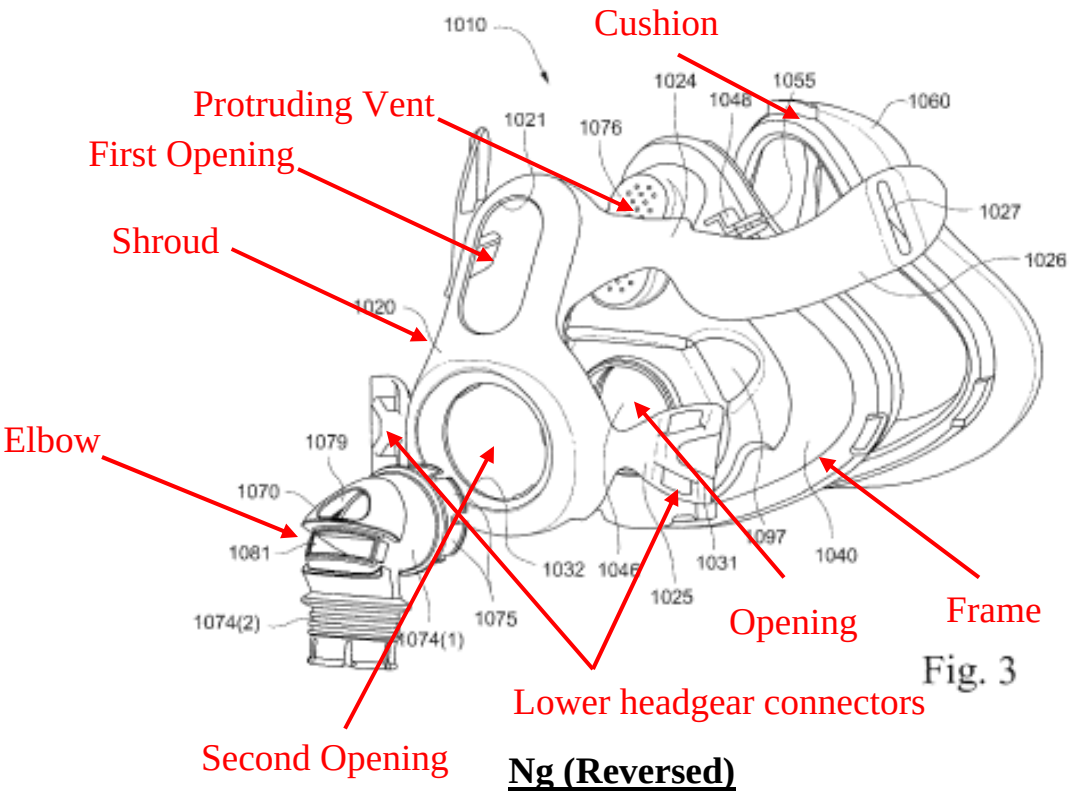


Fig. 3

Ng (Reversed)

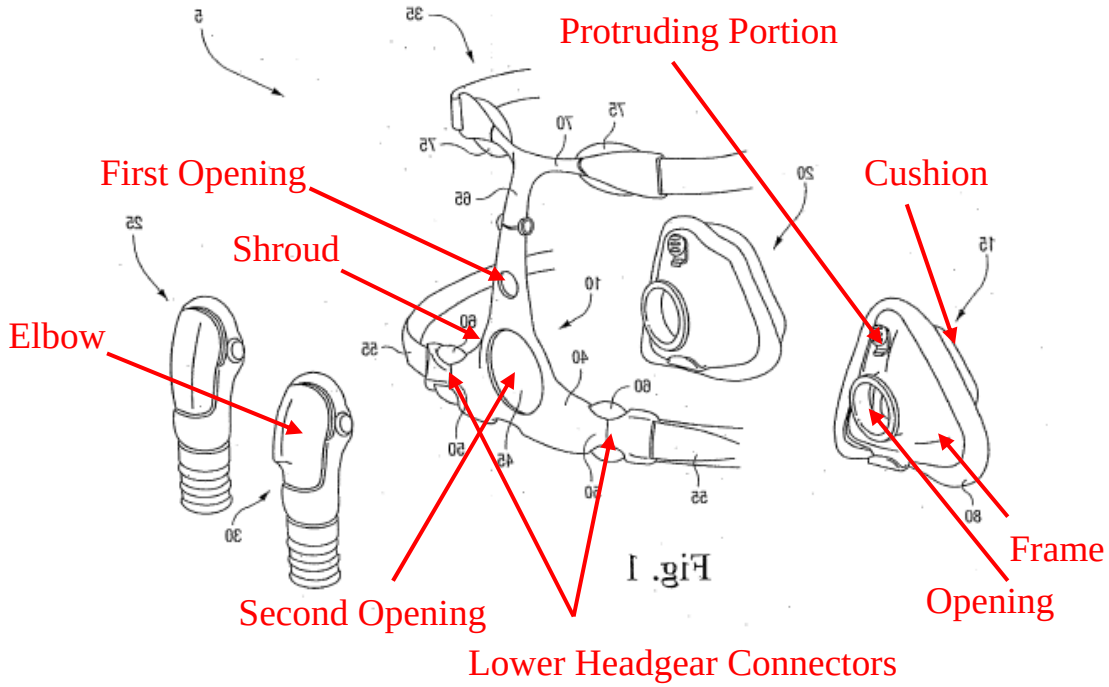


Fig. 1

Ng discloses a shroud opening that accommodates a protruding portion of the frame, but it does not disclose a protruding vent arrangement. However, protruding vent arrangements were well-known prior to the '931 Patent. *See infra* § VII(B)(3)(a)(vi). For example, as shown below, Thomlinson discloses a protruding vent arrangement 38 that is accommodated by the opening in the shroud 92.

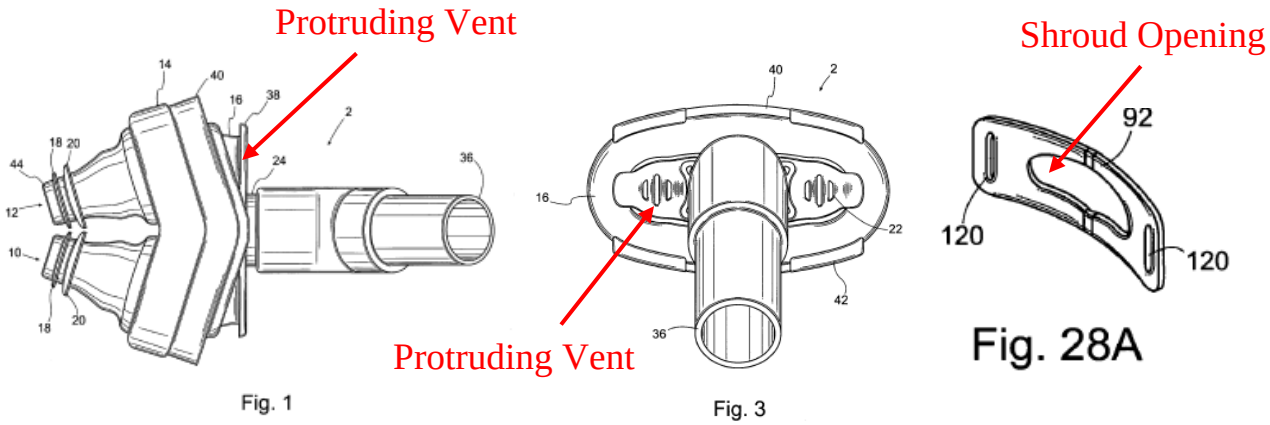


Fig. 1 Fig. 3 Fig. 28A

Thomlinson discloses other protruding vent arrangements with a plurality of holes, one of which is provided below. *See* Ex. 1411 at Fig. 8.

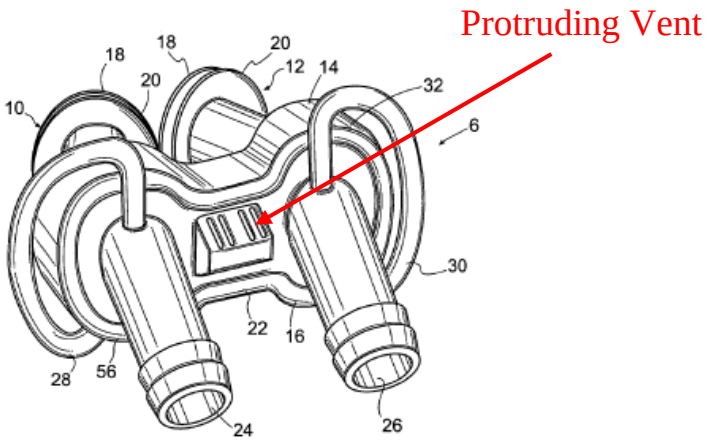


Fig. 8

As explained below, any additional differences between the Challenged Claims and the teachings of Ng were well-known and disclosed in other prior art CPAP masks, including ResMed's own publications. *See infra* §§ VII(B)–(M). A person of skill at the time of the purported invention would have been motivated to combine and had a reasonable expectation of success in combining the features of Ng with those of the other prior art CPAP masks.

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 and co-pending IPR petitions challenging the '931 Patent. This petition is based on different prior art and challenges only the "protruding vent arrangement" claims that were not instituted in the previous IPRs. Ex. 1409 at 383–485.

This petition relies on Ng and Thomlinson, while the concurrently filed petition relies on D'Souza (Ex. 1420) in view of Hitchcock (Ex. 1421). Because these two concurrently-filed petitions rely on different prior art and obviousness arguments, Petitioner respectfully requests that the Board institute both IPR proceedings. *See ABS Global Inc. v. XY, LLC*, IPR2014-01161, Paper No. 9 at 19 (PTAB Jan. 13, 2015).

The prior art and arguments in this petition are not the same or substantially the same as the previously-filed petitions. In view of the Board's seemingly

narrow construction of "protruding vent arrangement," which was not reasonably foreseeable, Petitioner provides different prior art and arguments showing that discrete vent structures were also well-known and a person of skill would have known and been motivated to include such a vent on the CPAP mask frame. For example, Ng and Thomlinson were not used in the previous petitions but are used in each ground of this Petition. Thus, the Board should decline to exercise its discretion under § 325(d). *See Valeo North America, Inc. v. Magna Electronics, Inc.*, IPR2014-01204, Paper No. 13 at 11–13 (PTAB Jan. 28, 2015) (finding that the art and arguments in the later petition are not the same or substantially the same where petitioner uses the same primary reference, but a different secondary reference); *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 challenging the same claims); *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); *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); *Arista Networks, Inc. v. Cisco Systems, Inc.*, IPR2016-00309, Paper No. 8 at 6–7 (PTAB Jun. 11, 2016) (declining to

exercise discretion where the obviousness grounds were presented in a previous petition but were found to be insufficiently articulated).

The Board should also decline to deny institution of this petition based on its broader discretion under 35 U.S.C. § 314(a). This statutory section provides general discretion to the Board to institute IPR petitions, but does not require or compel the Board to institute an IPR. 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;

(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 institution 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 petitioner provides adequate explanation for the time elapsed between the filings of multiple petitions directed to the same claims.

Medtronic Xomed, Inc. v. Neurovision Medical Products, Inc., IPR2016-01405, Paper No. 12 at 7 (PTAB Dec. 29, 2016). More recently, the Board broadly evaluated the last factor (7) as "whether the petitioner provides adequate explanation why we should permit another attack on the same claims of the same patent." *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 many of the claims of the '931 Patent that share nearly all of the same limitations with the Challenged Claims. In fact, the protruding vent arrangement is the only significant limitation addressed in this petition and not a part of the instituted reviews. 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, the parties are engaged in district court litigation, 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 factors (3) and (5), although Petitioner previously filed petitions challenging the same Challenged Claims, Patent Owner did not file any preliminary responses and did not propose any claim constructions. Therefore, Petitioner did not learn from any preliminary response and Patent Owner is not prejudiced by this petition challenging the claims in view of the Board's claim construction.

Regarding factors (4) and (6), Petitioner did not think the new prior art references (*e.g.*, Ng and Thomlinson) were necessary when it filed the earlier petitions, relying on a reasonable "ordinary meaning"-type claim construction. Upon receiving the Board's decisions with the unexpected construction of the "protruding vent arrangement," Petitioner gathered numerous references that specifically addressed this new construction. Since receiving the earlier decisions, 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 the petitioner's failure to show the prior art was unavailable is insufficient to exercise discretion under 35 U.S.C. § 314(a)).

Regarding factor (7), there is more than adequate explanation and justification for filing this petition to outweigh any factors in favor of the Board

exercising its discretion. For example, as described above the Board provided a construction of "protruding vent arrangement" in earlier decisions that was unexpected and not proposed by either party. Petitioner believes that its implied "ordinary meaning" construction of this limitation was reasonable, but now requests that the Board allow Petitioner to challenge the claims based on the Board's own construction that it crafted and adopted *sua sponte* in rendering its recent institution decisions. *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 petitions challenging the '931 Patent were 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 own recently adopted claim 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, Inc. v. Cresta Tech Corp.*, IPR2015-00615, Paper 9 at 25 (PTAB Aug. 14, 2015) (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))

Petitioner Fisher & Paykel Healthcare Limited is the real party-in-interest. Petitioner 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 were involved in proceedings with the United States International Trade Commission in which ResMed asserted that certain Fisher & Paykel products infringe one or more claims of the '931 Patent

(Investigation No. 337-TA-1022). Ex. 1404. However, ResMed withdrew its complaint and the investigation was terminated on May 17, 2017.

ResMed and Fisher & Paykel are currently involved in pending litigation in the Southern District of California involving the '931 Patent. *See Fisher & Paykel Healthcare Ltd. v. ResMed Corp*., Case No. 3:16-cv-02068-DMS-WVG (S.D. Cal.). ResMed asserted a claim for infringement of the '931 Patent in its counterclaims on September 7, 2016. Ex. 1405.

Fisher & Paykel has concurrently filed an additional petition for *inter partes* review of the '931 Patent that would affect, or be affected by, a decision in this proceeding. Petitioner also previously filed four petitions for *inter partes* review of the '931 Patent (2017-00061, 2017-00062, 2017-00064 and 2017-00065).

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

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

Lead Counsel	Back-up Counsel
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	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 address: BoxFPH529-5@knobbe.com.

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

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

Petitioner hereby certifies that the '931 Patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting *inter partes* review regarding the Challenged Claims on the grounds identified in this petition.

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

1. Prior Art

Petitioner respectfully requests institution of an *inter partes* review of the Challenged Claims of the '931 Patent, filed July 31, 2014, which is a continuation of U.S. Application No. 13/964,280, filed August 12, 2013, which is a continuation of U.S. Application No. 13/745,077, filed January 18, 2013, which is a continuation of U.S. Application No. 12/736,024, filed as PCT Application No. PCT/AU2009/000241 on February 27, 2009, which claims priority benefit of U.S. Provisional Application Nos. 61/064,406, 61/071,893, and 61/136,617 (collectively the "Provisional Applications"), filed March 4, 2008, May 23, 2008 and September 19, 2008, respectively. Ex. 1401 at 1–2. The earliest possible

priority date of the ’931 Patent is March 4, 2008, but this date does not apply to the Challenged Claims, as explained below.

The Challenged Claims of the ’931 Patent are obvious in view of the following prior art:

a. WO 2007/048174 (“Ng”) (Ex. 1410)

Ng was filed on October 24, 2006 and published in English on May 3, 2007. Ex. 1410 at 1. The earliest-filed provisional application from which the ’931 Patent claims priority benefit did not disclose a vent on the frame. Ex. 1406 ¶¶ 66–69; Ex. 1402 ¶ 31. And a protruding vent arrangement is not shown or described in any of the Provisional Applications. Ex. 1406; Ex. 1407; Ex. 1408; Ex. 1402 ¶ 31. Thus, the earliest possible priority date for the Challenged Claims is the filing date of the parent application, U.S. Application No. 12/736,024, on February 27, 2009. Because Ng published more than one year before February 27, 2009, Ng is prior art under at least 35 U.S.C. § 102(b) for the Challenged Claims.[1]

b. U.S. 2005/0011524 (“Thomlinson”) (Ex. 1411)

Thomlinson published on January 20, 2005. Ex. 1411 at 1. Because Thomlinson published more than one year before the earliest possible priority date, it is prior art under 35 U.S.C. § 102(b).

[1] Reference to 35 U.S.C. §§ 102 and 103 throughout this petition are to the pre-AIA versions, which are applicable to the ’931 Patent.

c. U.S. Publication No. 2007/0044804 ("Matula-II") (Ex. 1412)

Matula-II published on March 1, 2007. Ex. 1412 at 1. Because Matula-II published more than one year before the earliest possible priority date, it is prior art under 35 U.S.C. § 102(b).

d. U.S. Patent No. 6,796,308 ("Gunaratnam-I") (Ex. 1413)

Gunaratnam-I issued on September 28, 2004. Ex. 1413 at 1. Because Gunaratnam-I issued more than one year before the earliest possible priority date, it is prior art under 35 U.S.C. § 102(b).

e. U.S. 6,412,488 ("Barnett") (Ex. 1414)

Barnett issued on July 2, 2002. Ex. 1414 at 1. Because Barnett issued more than one year before the earliest possible priority date, it is prior art under 35 U.S.C. § 102(b).

f. WO 2007/045008 ("Worboys") (Ex. 1415)

Worboys was filed on January 12, 2006 and published on April 26, 2007. Ex. 1415 at 1. Because Worboys published more than one year before the earliest priority date of the Challenged Claims, it is prior art under at least 35 U.S.C. § 102(b).

g. Ultra Mirage Full Face Mask Brochure ("Ultra Mirage") (Ex. 1416 at 6–7)

Ultra Mirage was publicly available on ResMed's website at least by September 1, 2006 and various pages bear the copyright dates of 2004 and 2005. Ex. 1416 at 7. The Internet Archive Wayback Machine shows that the public had access to a ResMed webpage containing links to Ultra Mirage by at least September 1, 2006. Ex. 1416 at 8. The authenticity of Ultra Mirage is established by the accompanying affidavit of Christopher Butler, attaching Ultra Mirage and testifying as to how the Wayback Machine works and its reliability. Ex. 1416 at 1–2; *see also EMC Corp. v. Personalweb Techs., LLC*, IPR2013-00084, Paper No. 64 at 45 (PTAB May 15, 2014).

The prior art status of Ultra Mirage is further supported by the declaration of Jason Eaton, P.E., explaining that a person of skill in the art would have kept informed about CPAP products on the market and would have visited the websites of well-known companies providing CPAP products, such as ResMed. Ex. 1402 ¶¶ 192–196.

Because Ultra Mirage was available to the public more than one year before the earliest possible priority date, it is prior art under 35 U.S.C. § 102(b).

h. FlexiFit Series, HC 431 Full Face Mask, Instructions for Use ("FlexiFit") (Ex. 1417 at 9–10)

FlexiFit was publicly available by at least October 16, 2006. Ex. 1417 at 5, 8, 11. The authenticity of FlexiFit is established by the accompanying affidavit of Christopher Butler, attaching FlexiFit and testifying as to how the Wayback Machine works and its reliability. *Id.* at 1–2; *see EMC Corp.*, Paper No. 64 at 45. The Wayback Machine shows that the public had access to a Fisher & Paykel webpage containing links to FlexiFit by at least October 16, 2006. Ex. 1417 at 5, 8, 11.

The authenticity and public availability of FlexiFit is further supported by the declaration of Fiona Cresswell, a Fisher & Paykel employee, testifying to personal knowledge that the documents are authentic and were available. Ex. 1418 at 1–4; *see EMC Corp.*, Paper No. 64 at 45.

The prior art status of FlexiFit is further supported by the declaration of Jason Eaton, P.E., explaining that a person of skill in the art would have kept informed about CPAP products on the market and would have visited the websites of well-known companies providing CPAP products, such as Fisher & Paykel. Ex. 1402 ¶¶ 192–196.

Because FlexiFit was available to the public more than one year before the earliest possible priority date, FlexiFit is prior art under 35 U.S.C. § 102(b).

i. U.S. Publication No. 2004/0182398 ("Sprinkle") (Ex. 1419)

Sprinkle published on September 23, 2004. Ex. 1419 at 1. Because Sprinkle published more than one year before the earliest possible priority date, it is prior art under 35 U.S.C. § 102(b).

2. Grounds

Petitioner requests *inter partes* review of the Challenged Claims. Because ResMed claimed a laundry list of well-known features in its many lengthy patent claims, this petition necessarily includes several different prior art references that disclose those various common features. The grounds below are not overlapping in that each challenged claim is subject to only one ground of unpatentability.

Ground 1. Claims 1, 6, 11, 16, 31, and 32 would have been obvious over Ng in view of Thomlinson under 35 U.S.C. § 103.

Ground 2. Claims 4, 5, 10, and 26 would have been obvious over Ng in view of Thomlinson and Matula-II under 35 U.S.C. § 103.

Ground 3. Claims 7, 8, and 18 would have been obvious over Ng in view of Thomlinson and Gunaratnam-I under 35 U.S.C. § 103.

Ground 4. Claims 12 and 14 would have been obvious over Ng in view of Thomlinson and Barnett under 35 U.S.C. § 103.

Ground 5. Claims 13 and 15 would have been obvious over Ng in view of Thomlinson, Barnett, and Worboys under 35 U.S.C. § 103.

Ground 6. Claim 17 would have been obvious over Ng in view of Thomlinson and Ultra Mirage under 35 U.S.C. § 103.

Ground 7. Claims 19, 21, and 25 would have been obvious over Ng in view of Thomlinson and FlexiFit under 35 U.S.C. § 103.

Ground 8: Claim 20 would have been obvious over Ng in view of Thomlinson, FlexiFit, and Sprinkle under 35 U.S.C. § 103.

Ground 9. Claim 22 would have been obvious over Ng in view of Thomlinson, FlexiFit, and Matula-II under 35 U.S.C. § 103.

Ground 10. Claims 28–30 would have been obvious over Ng in view of Thomlinson, Matula-II, Gunaratnam-I, and Barnett under 35 U.S.C. § 103.

Ground 11. Claims 46, 51, and 53–56 would have been obvious over Ng in view of Thomlinson, Barnett, FlexiFit, Matula-II, Worboys, and Sprinkle under 35 U.S.C. § 103.

Ground 12. Claim 65 would have been obvious over Ng in view of Thomlinson, Barnett, and Matula-II under 35 U.S.C. § 103.

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 ’931 Patent such that the claims are given their broadest reasonable

interpretation in light of the specification of the '931 Patent.[2] 37 C.F.R. § 42.100(b); *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278–79 (Fed. Cir. 2015), *aff'd*, 136 S. Ct. 2131 (2016). All terms have their ordinary and customary meaning in light of the 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). In that light, Petitioner provides the following analyses for the construction of two limitations of the Challenged Claims.

1. "protruding vent arrangement"

Claims 1, 46, and 51 recite "the frame includes a protruding vent arrangement having a plurality of holes." Claim 65 recites, "the frame includes a protruding vent arrangement having a plurality of gas washout holes." In previous decisions, the Board determined that the broadest reasonable interpretation for this feature is "a discrete vent structure that extends above the surrounding surface of the frame and contains a plurality of vent holes." Ex. 1409 at 391–393, 417–419. Although neither party proposed this construction, the analysis provided in this petition adopts this construction from the Board.

[2] 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.

2. “accommodate”

Claims 1, 46, and 51 recite “the shroud module includes a first opening to accommodate said protruding vent arrangement.” Claim 65 recites “the shroud module includes an upper opening to accommodate said protruding vent arrangement.”

The plain and ordinary meaning of the term “accommodate” in this context is to provide enough space for something. Ex. 1402 ¶¶ 38–41.

The claims themselves do not provide any further description or explanation of accommodation made by the opening. The ’931 Patent refers briefly to this feature and states “[t]he top end includes an opening or vent receiving hole 1021 to accommodate the vent arrangement 1076 that protrudes from the frame 1040, and the bottom end includes an opening or elbow hole 1032 to accommodate the elbow 1070 and elbow opening into the frame 1040 (e.g., shroud provides no contact with elbow when assembled).” Ex. 1401 at col. 7:21–27. This description refers to Figure 3 (next page) and suggests that the accommodating openings do not have to contact the vent arrangement and elbow when assembled, and that the openings are not constrained by the shape or size of the elbow and vent arrangement. Ex. 1402 ¶ 40.

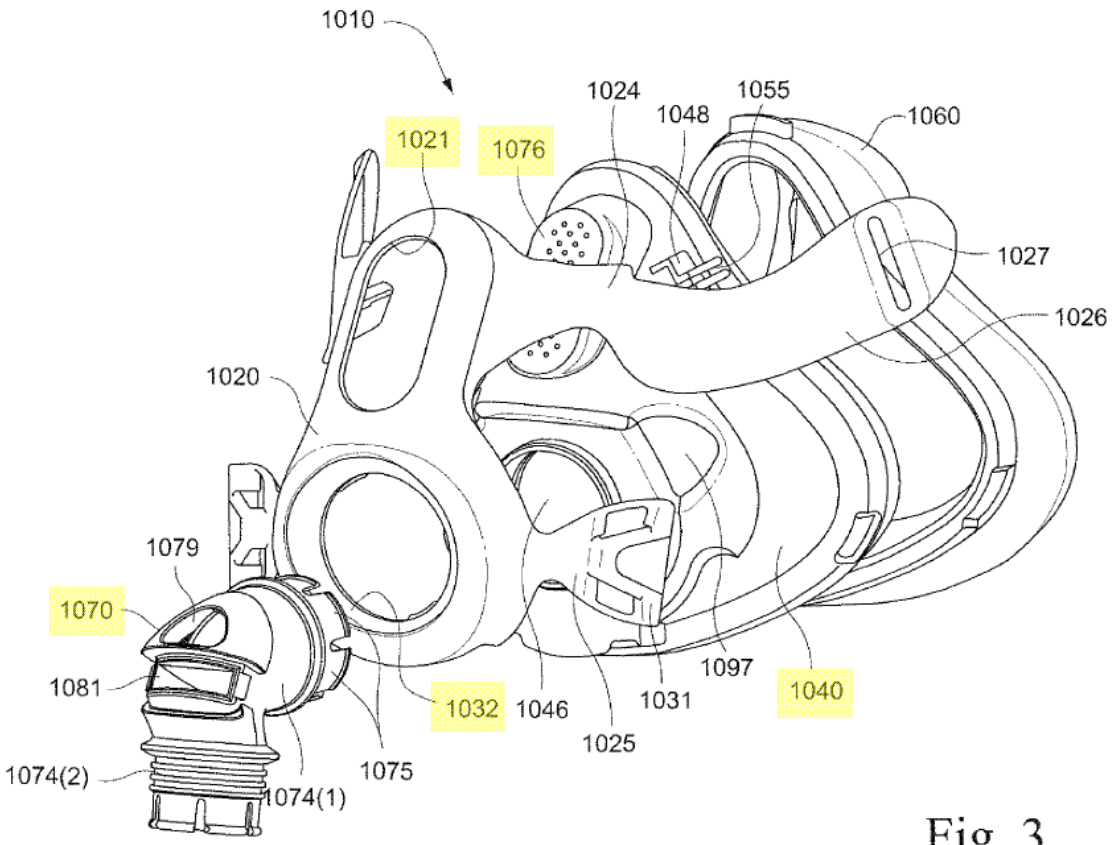


Fig. 3

This claim construction is fully supported by the ordinary understanding of the term "accommodate" in dictionary definitions, which indicate that an opening "accommodates" when there is "enough space for" or "allow[s] for" another object. Ex. 1447 at 7. Other dictionaries provide similar definitions, such as provide "sufficient space for." Ex. 1448 at 7.

V. THE ’931 PATENT

A. Example Embodiments

The ’931 Patent discloses a CPAP mask system 1010 having a frame 1040 that supports a cushion 1060 and attaches to a shroud 1020, as illustrated below. Ex. 1401 at col. 6:51–54. The shroud 1020 includes an opening 1021 that receives the protruding vent 1076. *Id*. at col. 7:9–23.

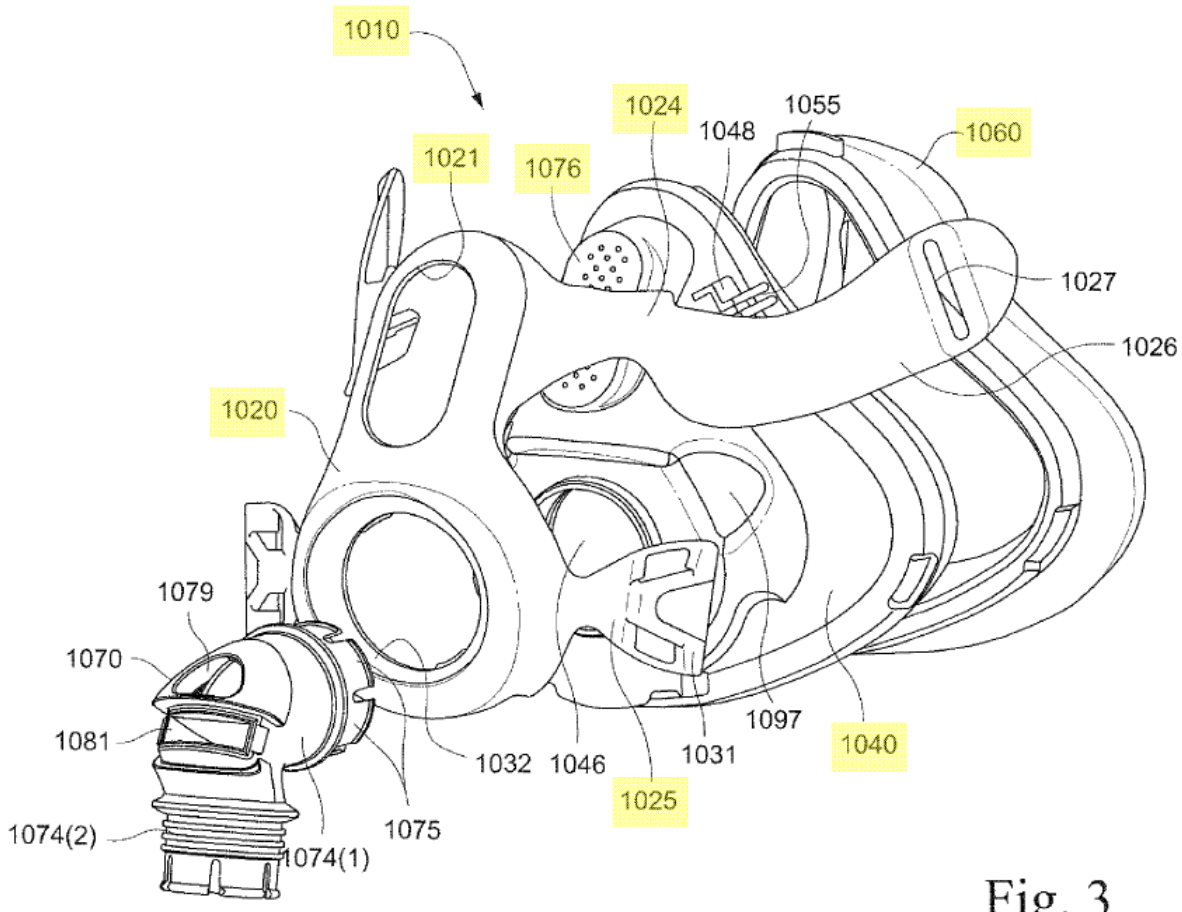


Fig. 3

Upper and lower headgear connectors 1024, 1025 extend from each side of the shroud. *Id*. at col. 7:28–30. Each lower headgear connector 1025 includes a clip receptacle 1031. *Id*. at col. 8:29–32.

As shown below, headgear 1090 includes upper and lower straps 1092, 1094. Upper straps 1092 split into top straps 1096 that pass over the patient's head. *Id*. at col. 10:52–59.

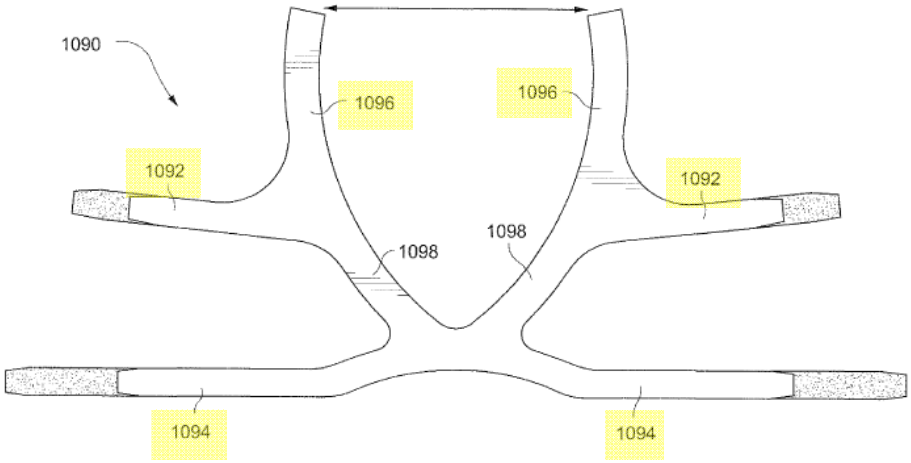


Fig. 9

Frame 1140 is connected to shroud 1120 by snap fingers 1145(1) that engage collar 1149, as shown below. *Id.* at col. 18:48–67.

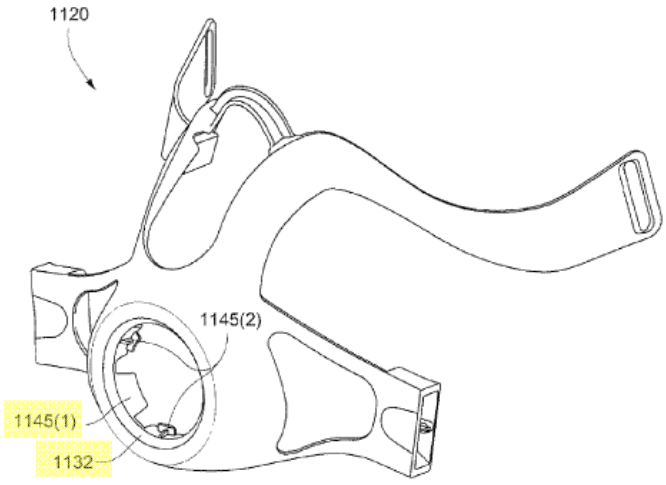


Fig. 14

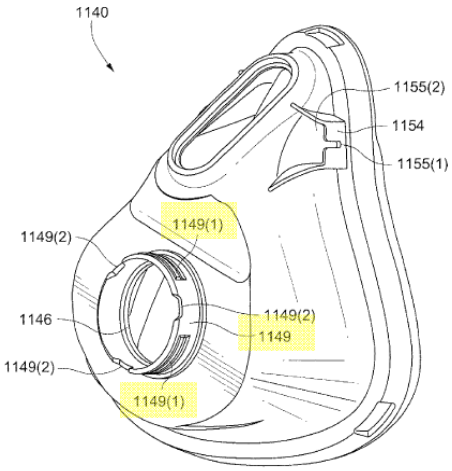


Fig. 11

B. Summary of the Prosecution History of the ’931 Patent

The ’931 Patent was originally filed as U.S. Application No. 14/447,673 on July 31, 2014.

On December 8, 2014, the Examiner rejected all pending claims based on U.S. Publication No. 2006/0272646 (“Ho”) in view of other prior art. Ex. 1409 at 166–171. In response, Applicant amended Claim 1 to include the “non-rotatably coupleable” limitation and added Claims 22–33. *Id*. at 237–243. Claim 29 included, *inter alia*, “a protruding vent arrangement.” *Id*. at 241.

On February 3, 2015, the Examiner rejected almost all the pending claims based on U.S. Publication No. 2006/0042629 (“Geist”) in view of other prior art. *Id*. at 258–272. The Examiner also indicated that Claims 29 and 33 would be allowable if rewritten in independent form. *Id*. at 272. In response, Applicant amended Claim 1 to include the features of Claim 29. *Id.* at 324. Applicant also added new Claims 34–83. *Id*. at 331–341. The Examiner issued a notice of allowability on July 15, 2015. *Id*. at 354–361.

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 ’931 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. 1402 ¶ 26.

VII. THE CHALLENGED CLAIMS OF THE '931 PATENT ARE UNPATENTABLE

This petition explains why the Challenged Claims are unpatentable and is supported by the declaration of Jason Eaton, P.E. Ex. 1402. As explained in his declaration, Mr. Eaton has extensive industry experience in CPAP mask systems and design. *Id*. ¶¶ 2–8.

A. Legal Standard

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." 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: Claims 1, 6, 11, 16, 31, and 32 would have been obvious over Ng in view of Thomlinson

1. Overview of Ng (Ex. 1410)

Ng was submitted, but not cited, during the prosecution of the '931 Patent. Ex. 1401 at 9.

As shown below, Ng discloses a CPAP mask system 5 with a common frame 10 that selectively couples to an elbow component 25, 30 and to one of the different cushion components 15, 20. Ex. 1410 ¶ 31.

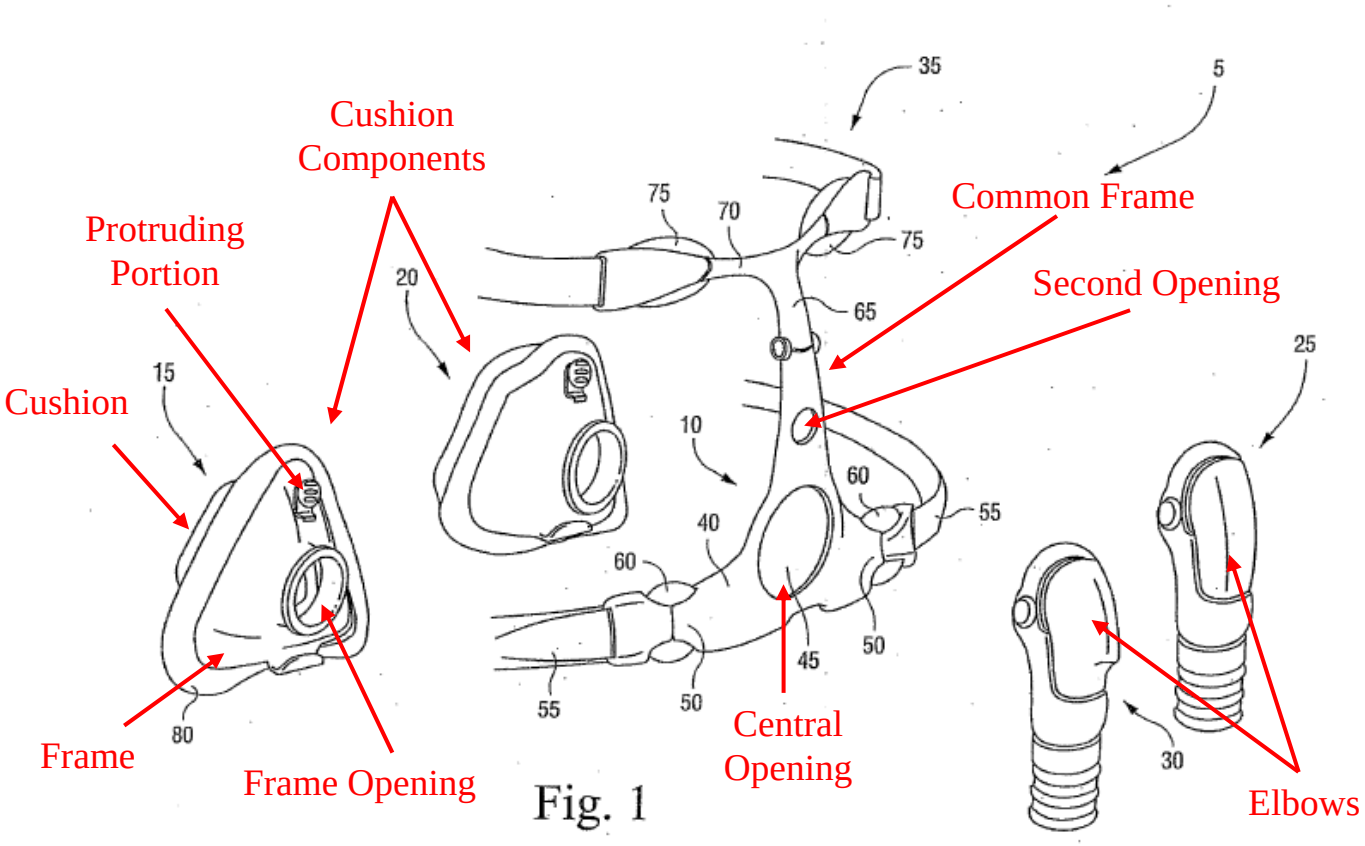


Fig. 1

The common frame 10 has a central opening 45 and a second opening to receive a protruding portion of the cushion component 15, 20. *Id.* ¶ 30, Fig. 1.

2. Overview of Thomlinson (Ex. 1411)

Thomlinson was not submitted or considered during the prosecution of the ’931 Patent. Ex. 1401 at 1–12.

Thomlinson describes patient interfaces for users with sleep apnea. Ex. 1411 ¶ 188. As shown below in Figure 1, nasal interface body 2 includes one or more locking tabs 38 that releasably engage strap attachment plate 92, separately shown below in Figure 28A. *Id.* ¶ 203.

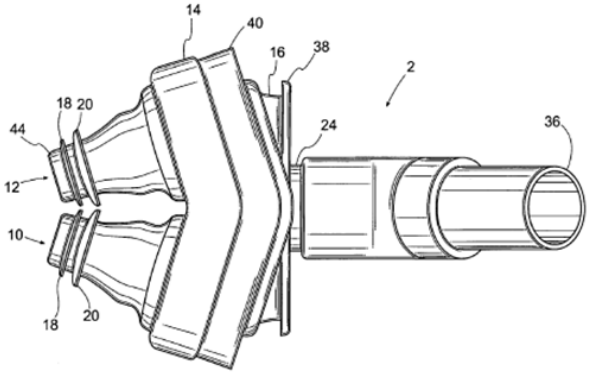


Fig. 1

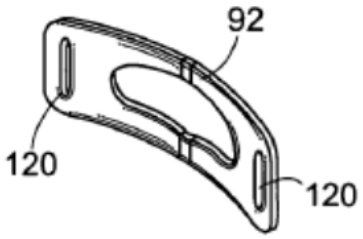


Fig. 28A

Figure 3 below illustrates another view of the nasal interface body 2, which shows one or more protruding exhalation ports 22 with integral locking tabs 38. *See id.* ¶ 204; Ex. 1402 ¶ 63.

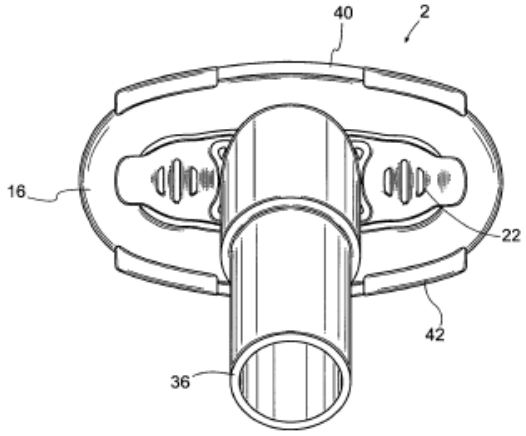


Fig. 3

Alternatively, Figure 8 shows a protruding exhalation port 22 positioned between two inlets 24, 26. *See* Ex. 1411 ¶ 209; Ex. 1402 ¶ 64.

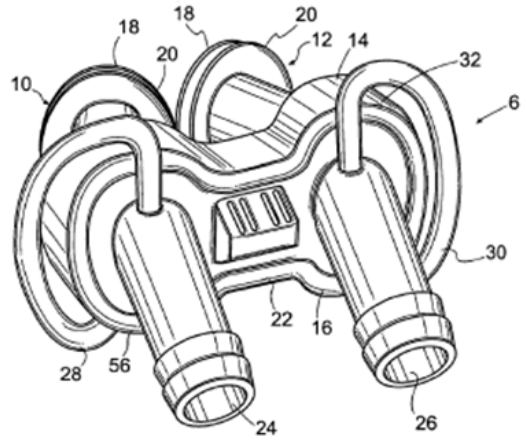


Fig. 8

3. Limitations of Claims 1, 6, 11, 16, 31, and 32

As shown in the annotated drawing below, Ng discloses nearly all of the features of Claim 1. Ex. 1402 ¶¶ 65–67.

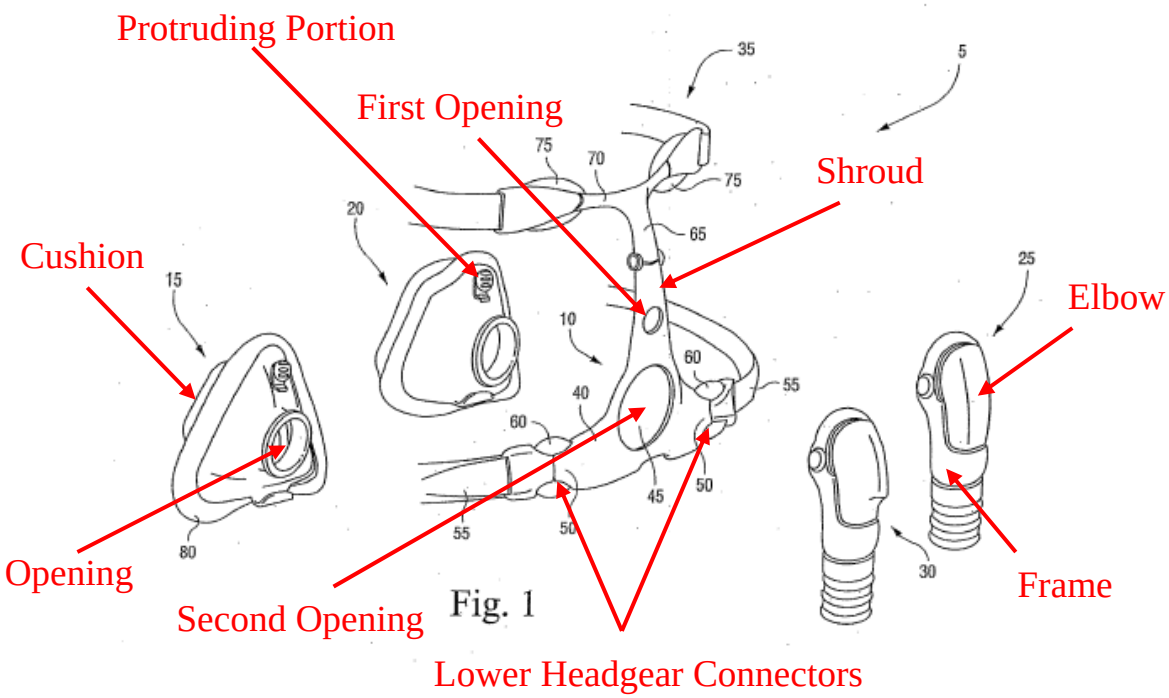


Fig. 1

Any potential differences between Claims 1, 6, 11, 16, 31, and 32 and Ng were minor, well-known at the time of the invention, and taught by Thomlinson. *See infra* §§ VII(B)(3)(a)–(f).

Because Ng and Thomlinson both describe CPAP patient interfaces, the features of Thomlinson would have been readily compatible with and easily incorporated into the Ng mask with a reasonable expectation of success. Ex. 1402 ¶ 69. Although the Thomlinson interfaces are designed for patients who prefer direct airflow to the nares, many of the features are common with and interchangeable among all patient interfaces, for example the elbow connection,

exhaust vents, tubing, etc. Ex. 1402 ¶ 69. Combining these familiar CPAP 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. Claim 1

Independent Claim 1 includes:

i. Abstract: "A mask system, comprising:"

As shown below, Ng discloses a CPAP mask system 5. Ex. 1410 ¶ 29.

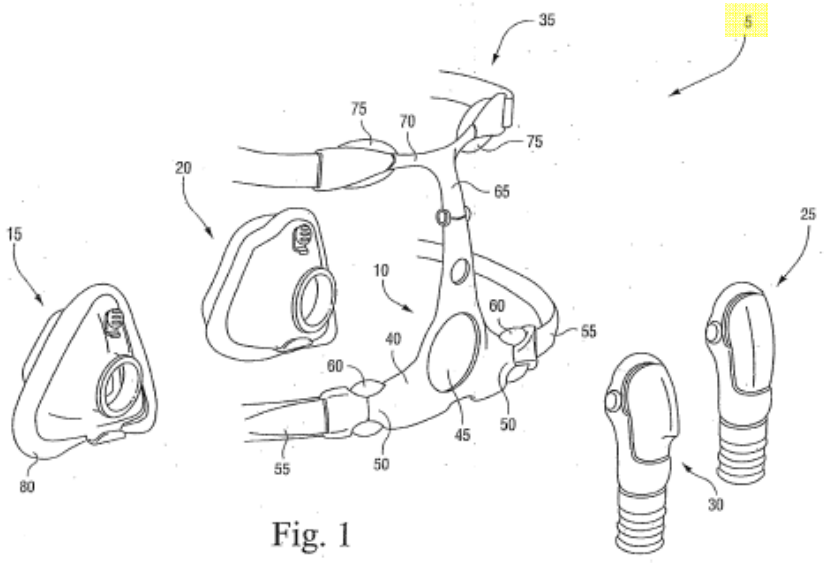


Fig. 1

ii. "(i) a shroud module; wherein the shroud module includes headgear connectors adapted to removably attach to respective headgear straps of headgear; and"

As shown below, Ng discloses lower headgear connectors connected to headgear straps 55 using press-fit connectors 60. Ex. 1410 ¶ 30.

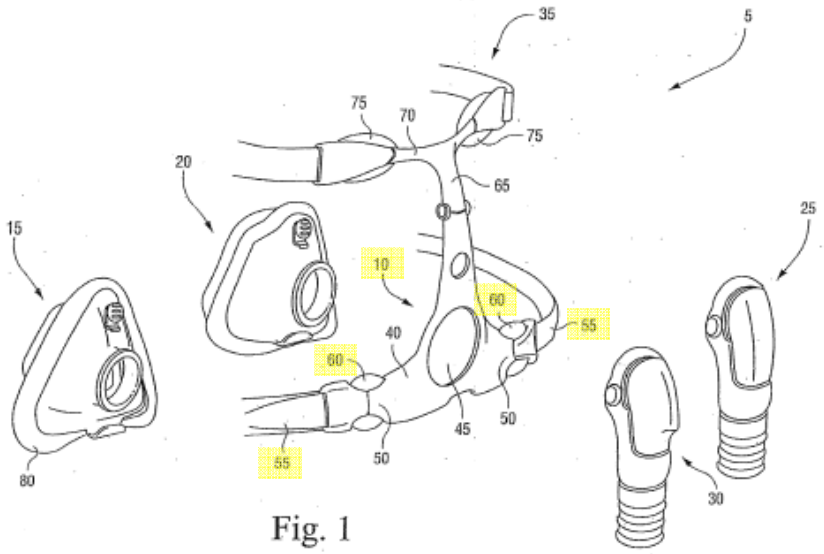


Fig. 1

To the extent Ng provides insufficient teachings for the removability of the headgear straps, this feature was common in the prior art. Ex. 1402 ¶¶ 72–74. For example, Thomlinson discloses a strap system that "can be fastened/unfastened using alternative methods to Velcro, such as snaps, buckles, buttons and ties." Ex. 1411 ¶ 312.

A person of skill in the art at the time of the invention would have been motivated to provide such headgear connectors to enable quick and easy mask

fitting, separation for cleaning, and convenient removal in an emergency. Ex. 1402 ¶ 75. Further, a person of skill would have recognized that removable headgear allows the mask to be removed without resetting the headgear. *Id.*

iii. "(ii) a cushion module, comprising: a rigid or semi-rigid frame defining a breathing chamber; and a cushion to form a seal with the patient's face in a nasal bridge region, a cheek region and a lower lip/chin region of the patient's face,"

As shown below and explained in the next section, Ng discloses a cushion module 15, 20 including a rigid frame defining a breathing chamber and a soft cushion that forms a seal with the patient's face. Ex. 1410 ¶¶ 3, 31; *see infra* § VII(B)(3)(a)(iv).

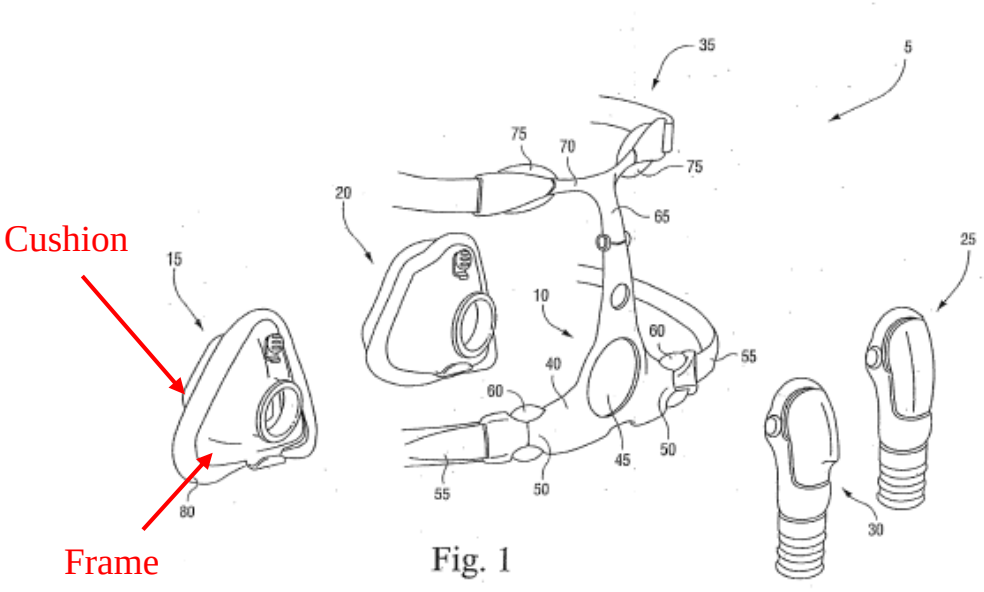


Fig. 1

Although Figure 1 illustrates a nasal mask, Ng recognizes that the cushion module 15, 20 could be full-face to seal with a nasal bridge region, a cheek region and a lower lip/chin region of the patient's face. *See* Ex. 1410 at Abstract.

iv. "wherein the cushion is constructed of a first, relatively soft, elastomeric material and the frame is constructed of a second material that is more rigid than the cushion,"

Ng discloses that mask assemblies "typically included a soft-face contacting portion, such as a cushion, and a rigid shell or frame." Ex. 1410 ¶ 3.

A person of skill would have recognized that the Ng cushion module 15, 20 includes a frame constructed of a material that is more rigid than the cushion material. Ex. 1402 ¶¶ 78–80. Ng discloses that cushion module 15 may be as described in U.S. Application No. 10/655,622, published as U.S. Publication No. 2004/0118406 (Lithgow). Ex. 1410 ¶¶ 31, 60. Lithgow discloses a silicone cushion and a frame having a "stiffer grade material." Ex. 1433 ¶ 139. Because Lithgow is incorporated by reference, this disclosure should be considered as if it were explicitly contained in Ng.

Prior art masks commonly included elastomeric cushions to form a comfortable seal. Ex. 1402 ¶ 77. Further, a person of skill would have been

motivated to provide a rigid frame to support the soft cushion and to facilitate engagement with the shroud. *See* Ex. 1433 ¶ 139; Ex. 1402 ¶ 80.

v. "wherein the shroud module and the cushion module are configured to be removably and non-rotatably coupleable to one another; and"

Ng discloses a shroud module 10 configured to removably couple to an interchangeable cushion module 15, 20. *See* Ex. 1410 ¶ 31; Ex. 1402 ¶ 57.

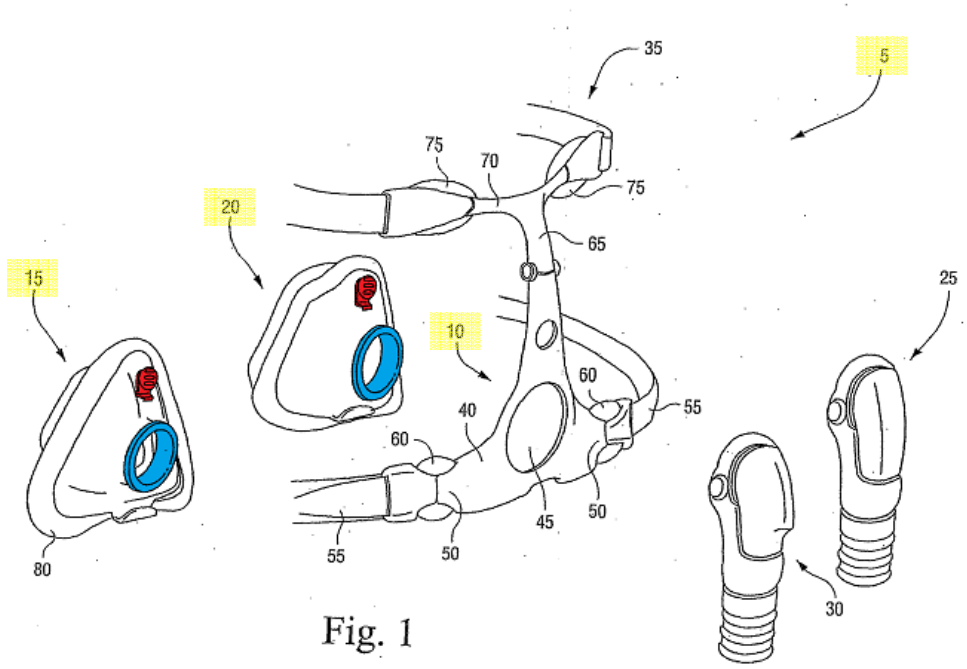


Fig. 1

A person of skill would have understood that the shroud module 10 and the cushion module 15, 20 are non-rotatably coupleable because the components attach at multiple points (the frame opening and the protruding portion (shaded above)). Ex. 1402 ¶ 66.

vi. "wherein the frame includes a protruding vent arrangement having a plurality of holes, wherein the shroud module includes a first opening to accommodate said protruding vent arrangement, and"

The protruding portion of Ng is a discrete structure that extends above the surrounding surface of the frame. Ex. 1402 ¶ 86. The protruding portion is not a vent with holes, but discrete protruding vent structures were commonly used in the prior art. *Id.* ¶¶ 86–97.

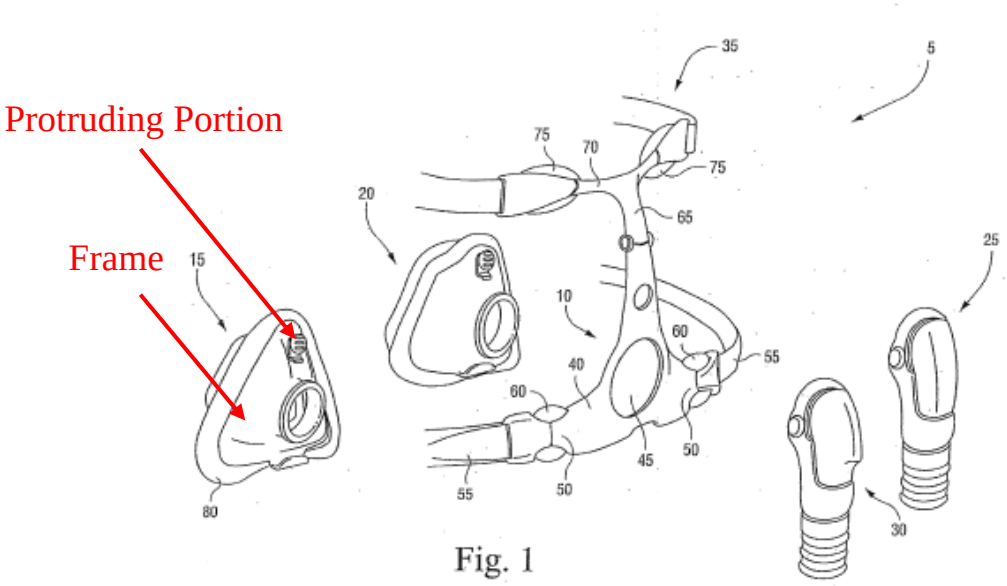
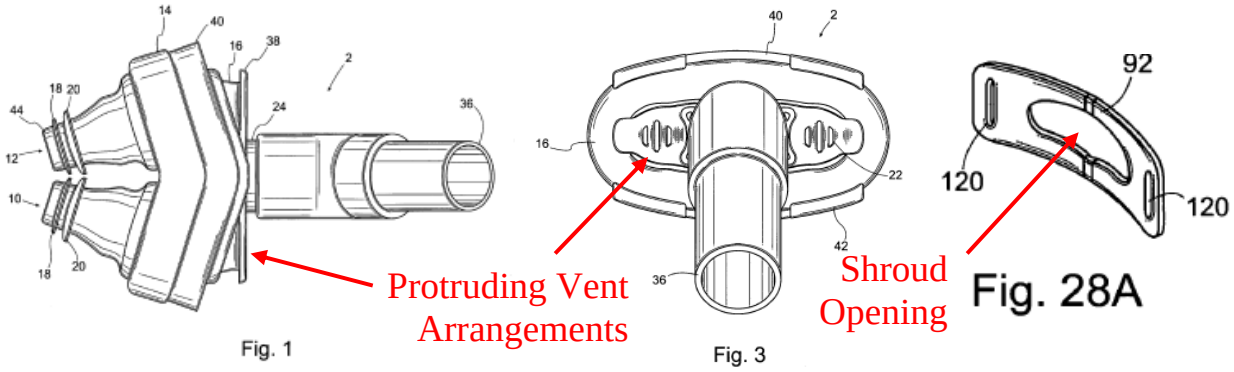


Fig. 1

For example, Thomlinson discloses a frame 16 having two protruding vent arrangements, each of which has a plurality of vent holes 22 and functions as a clip. Ex. 1411 ¶ 203. The Thomlinson shroud 92 includes an opening that accommodates these protruding vent arrangements. Ex. 1402 ¶ 86.



Prior to the '931 Patent, vents in the nasal bridge region of the frame were well-known, especially on full-face masks. Ex. 1402 ¶ 85. Although Ng discloses a vent on the elbow (Ex. 1410 ¶ 32), other Ng embodiments include a vent on the cushion module. *Id.* ¶ 43. A person of skill at the time of the purported invention would have been motivated to provide a protruding vent arrangement, like that disclosed by Thomlinson, in place of the protruding clip in the nasal bridge region of the Ng mask. Ex. 1402 ¶ 87. A person of skill would have recognized that this positioning of the vent would minimize noise output and promote greater air movement within the dead space from the inlet to the vent and minimize re-breathing of exhaled air. *Id.* ¶ 85. Further, a person of skill would have recognized that using the protruding vent arrangement of Thomlinson would

preserve the clip functionality of Ng while also providing an exhaust vent. *Id.* ¶ 88.

As explained above, "a first opening to accommodate said protruding vent arrangement" includes an opening having enough space for the protruding vent arrangement. *See supra* § IV(C)(2). Because the protruding portion in Ng is a clip structure, the first opening must provide enough space for the clip to serve its intended purpose. Ex. 1402 ¶ 84. As modified, the first opening would accommodate the protruding vent arrangement so that the arrangement extends through the opening to secure the cushion module 15, 20 and the shroud module 10. *Id.* ¶ 87.

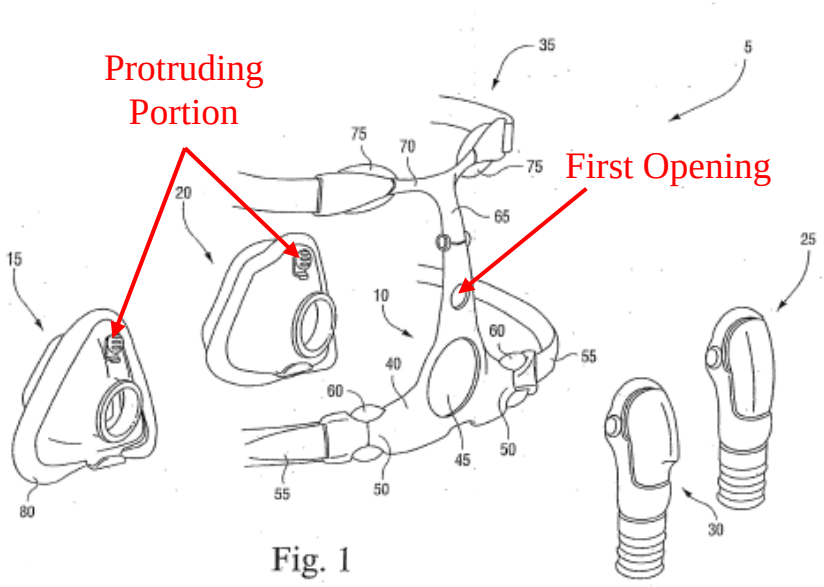


Fig. 1

Alternatively, if a person of skill did not want to integrate the clipping function with the protruding vent arrangement, Thomlinson also discloses a discrete protruding vent arrangement (shaded below) with a plurality of holes and

without any clipping function. *See* Ex. 1411 ¶ 209; Ex. 1402 ¶ 89. A person of skill would have been motivated to position this protruding vent above the frame opening of the Ng cushion module 15, 20 and in the nasal bridge region. Ex. 1402 ¶ 89.

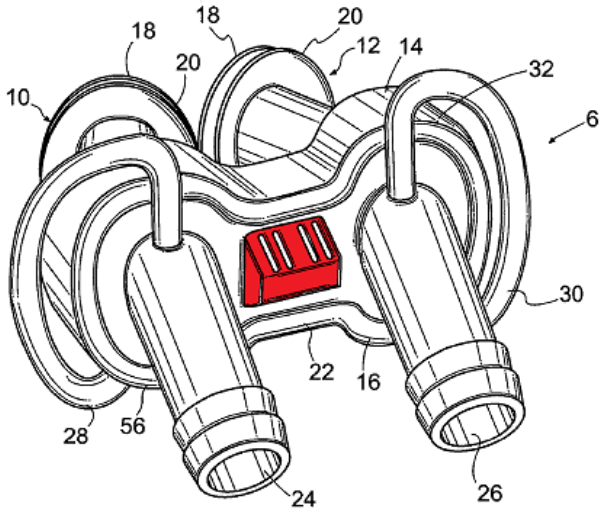


Fig. 8

In this alternative configuration, a person of skill would have provided an additional opening on the Ng shroud to accommodate the protruding vent arrangement in the nasal bridge region. Ex. 1402 ¶ 90. Otherwise, the shroud would block the vent and cause excessive noise as a result of interference with the vented air. *Id.*

As described above, it was well-known to place the vent in the nasal bridge region to minimize blockage, minimize noise output, prevent draft, and clear CO_2 more efficiently. *Id.* ¶ 85. Further, a person of skill would have been motivated to

provide either of the above-described protruding vent arrangements to enable design options that would minimize interference between the vented air and the surrounding structure. *Id.* ¶ 94. As demonstrated in the prior art, it was also common to include a protruding vent arrangement that also serves as an engagement feature for the shroud module. *Id.* ¶ 95.

Protruding vent arrangements were commonly made from a separate part, which provides an interchangeable arrangement and makes manufacturing easier. *Id.* ¶¶ 96–97.

vii. "further wherein the shroud module includes a second opening positioned to align with a frame opening of the frame leading to the breathing chamber."

As shown below, Ng discloses a second shroud opening 45 that aligns with a frame opening leading to the breathing chamber. Ex. 1410 ¶ 30.

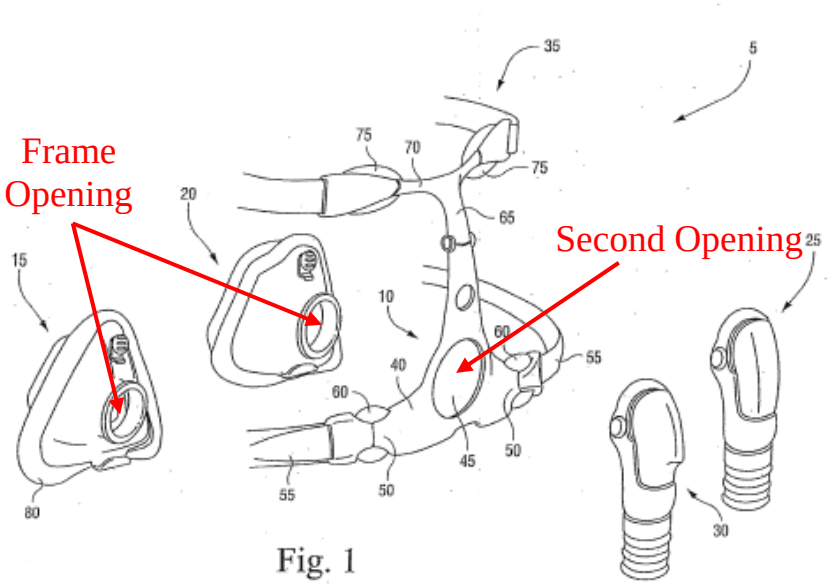


Fig. 1

b. Claim 6

Claim 6 depends from Claim 1 and includes:

"wherein the shroud module includes upper and lower headgear connectors on each side of the shroud module."

As shown below, Ng discloses upper and lower headgear connectors on each side of the shroud module 10. Ex. 1410 ¶ 30.

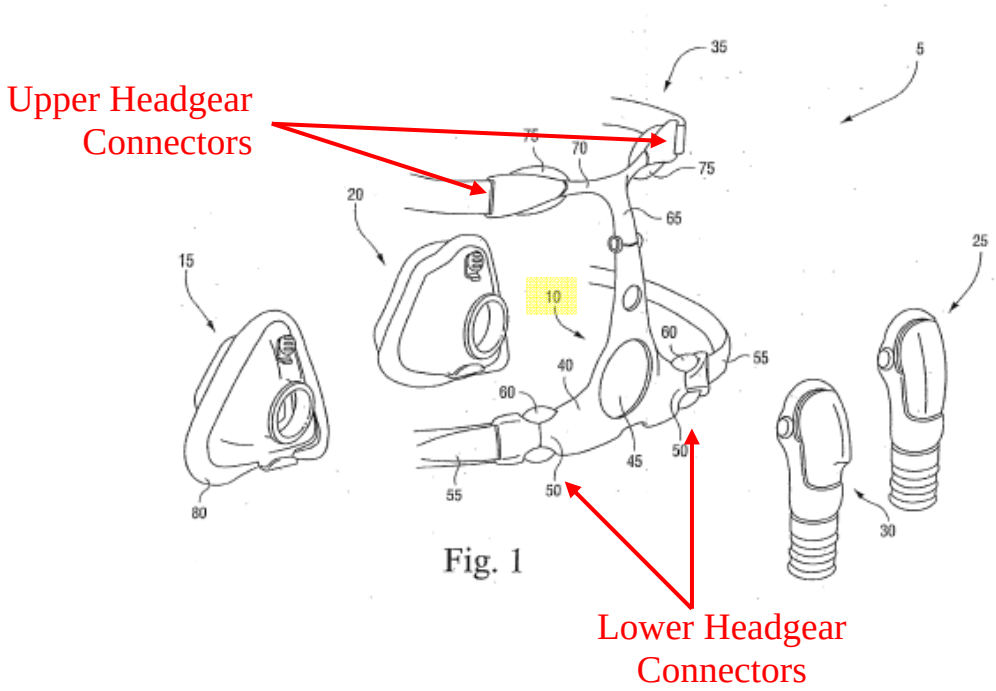


Fig. 1

c. Claim 11

Claim 11 depends from Claim 1 and includes:

"further comprising an elbow module adapted to be connected to an air delivery tube that delivers breathable gas to the patient."

As shown below, Ng discloses an elbow module 25, 30 and an air delivery tube. Ex. 1410 ¶¶ 3, 29.

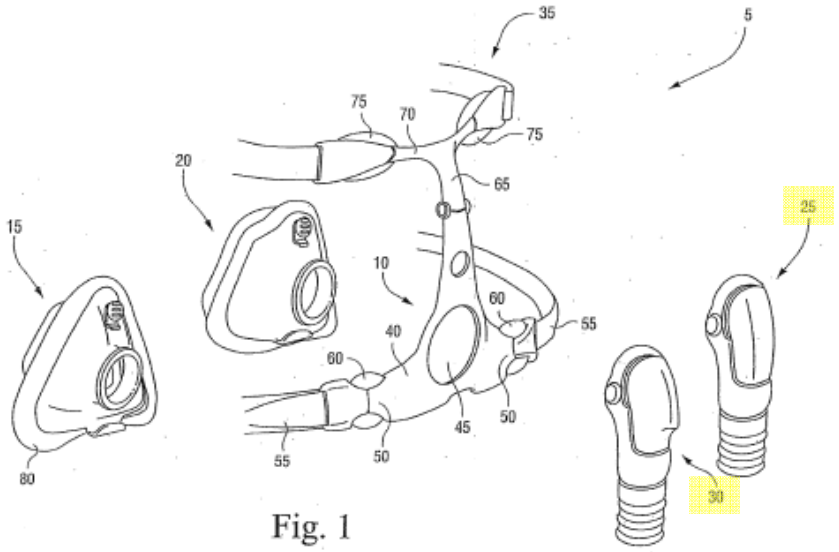


Fig. 1

It was common knowledge to connect the flow generator to an elbow module using an air delivery tube, as shown below in Figure 29 of Thomlinson. *See* Ex. 1411 ¶ 316; Ex. 1402 ¶¶ 99–100. A person of skill would have recognized that tubing was necessary to provide positive pressure flow from the flow generator to the mask assembly. Ex. 1402 ¶ 100.

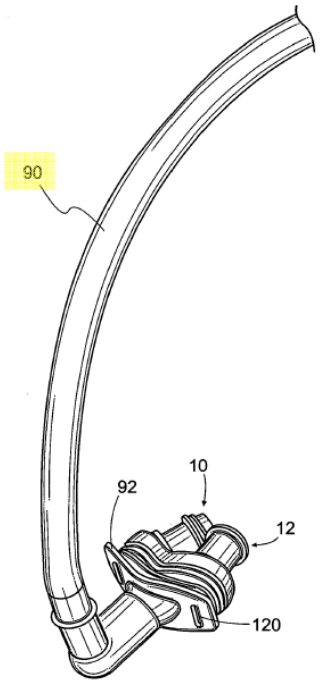


Fig. 29

d. Claim 16

Claim 16 depends from Claim 1 and includes:

"wherein the cushion module includes at least first and second cushion modules adapted to be provided to the shroud module, said at least first and second cushion modules being different from one another in at least one aspect."

As shown below, Ng discloses first and second cushion modules 15, 20 adapted to be provided to the shroud module 10. Ex. 1410 ¶ 31. Cushion modules 15, 20 "differ in at least one respect." *Id.*

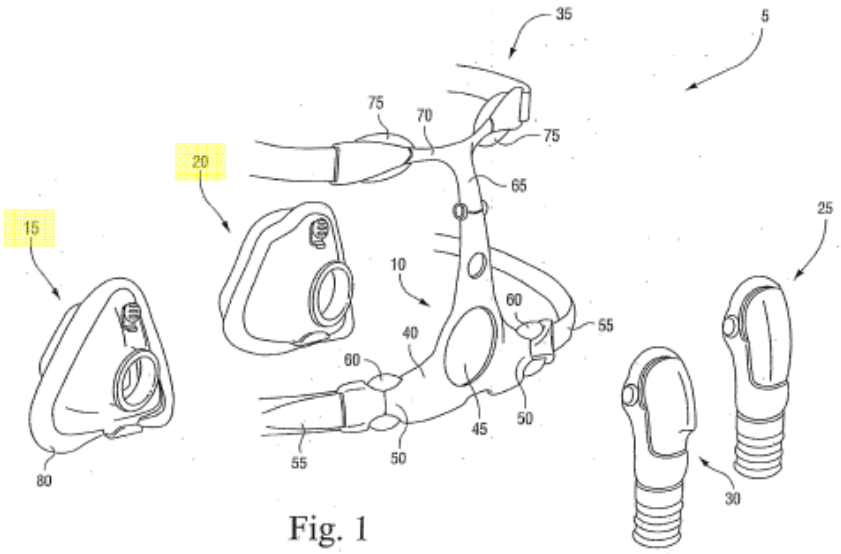


Fig. 1

e. Claim 31

Claim 31 depends from Claim 1 and includes:

"wherein the frame is rigid."

As explained above, Ng discloses a rigid frame. *See supra* §§ VII(B)(3)(a)(iii)–(iv).

f. Claim 32

Claim 32 recites a system for treating a patient with sleep disordered breathing including:

"the mask system of claim 1"

As explained above, the combination of Ng and Thomlinson teaches the mask system of claim 1. *See supra* § VII(B)(3)(a).

"a flow generator to generate a supply of air at positive pressure to be delivered to the mask system; and an air delivery tube configured to deliver the supply of air from the flow generator to the mask system."

Ng discloses a flow generator that supplies air at positive pressure. Ex. 1410 ¶ 3. As explained above, it was common knowledge to connect the flow generator to the mask system using an air delivery tube. *See supra* § VII(B)(3)(c).

C. Ground 2: Claims 4, 5, 10, and 26 would have been obvious over Ng in view of Thomlinson and Matula-II

1. Overview of Matula-II (Ex. 1412)

Matula-II was submitted, but not cited, during the prosecution of the '931 Patent. Ex. 1401 at 7.

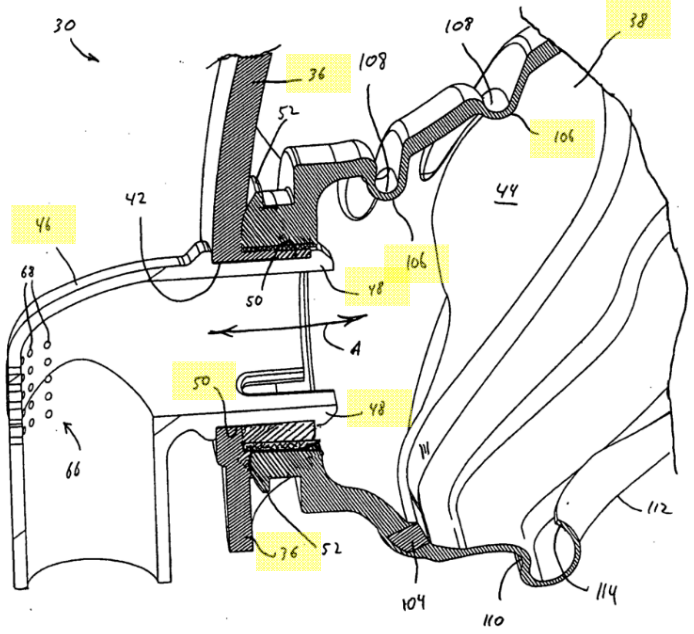


Fig. 4

As shown above, coupling member 46 includes a pair of prongs 48 that create a channel 50 to receive the wall of the faceplate 36 and the end of the seal member 38. Ex. 1412 ¶¶ 52–53. The seal member 38 has folds 106 provided at an upper portion of the seal member "so that the seal member has the desired degree of flexibility." *Id.* ¶ 66.

2. Limitations of Claims 4, 5, 10, and 26

A person of skill in the art at the time of the purported invention would have been motivated to combine the teachings of Ng, Thomlinson, and Matula-II for at least the reasons provided above. *See supra* § VII(B)(3). Because Matula-II discloses CPAP a patient interface with similar structural features, its features would have been readily compatible with and easily incorporated into the Ng mask with a reasonable expectation of success. Ex. 1402 ¶ 103. Combining these familiar CPAP mask features according to known methods would have done no more than yield predictable results. *See id.* ¶¶ 103–135; *see also KSR*, 550 U.S. at 416.

a. Claim 4

Claim 4 depends from Claim 1 and includes:

"wherein a nasal bridge portion of the cushion includes one or more folds to provide in use a higher level of adaptability or flexibility to the nasal bridge region of the cushion module relative to another region of the cushion module; and further wherein each of said one or more folds comprises adjacent first side walls interconnected by a second side wall."

As shown below, Ng discloses a gusset 80 on cushion module 15. Ex. 1410 ¶ 31. Ng does not expressly disclose a higher level of adaptability or flexibility in the nasal bridge region, but these fold configurations were well-known prior to the '931 Patent. Ex. 1402 ¶¶ 105–111.

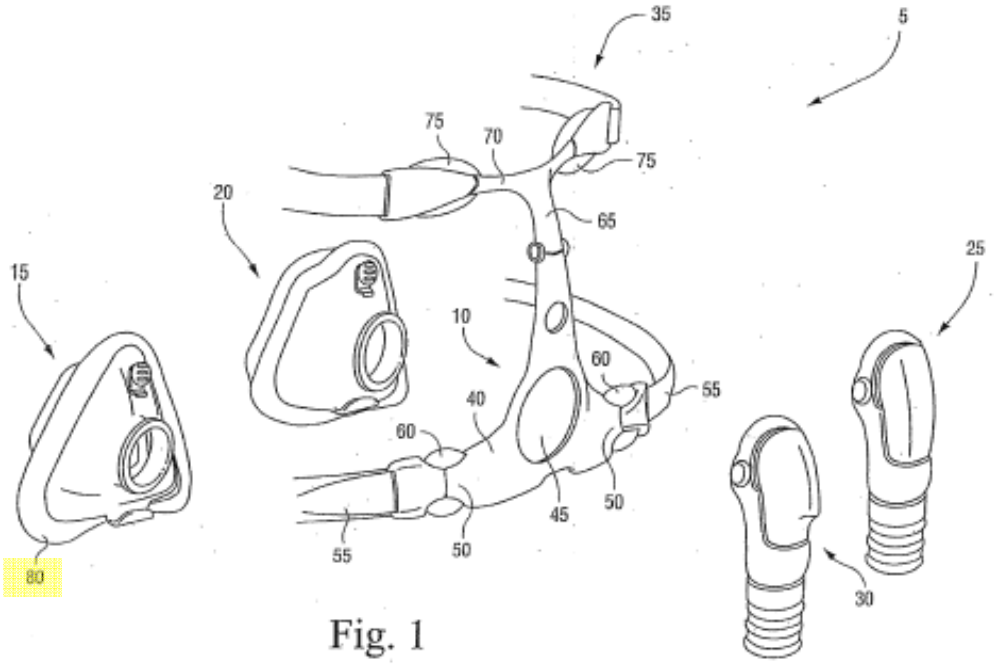
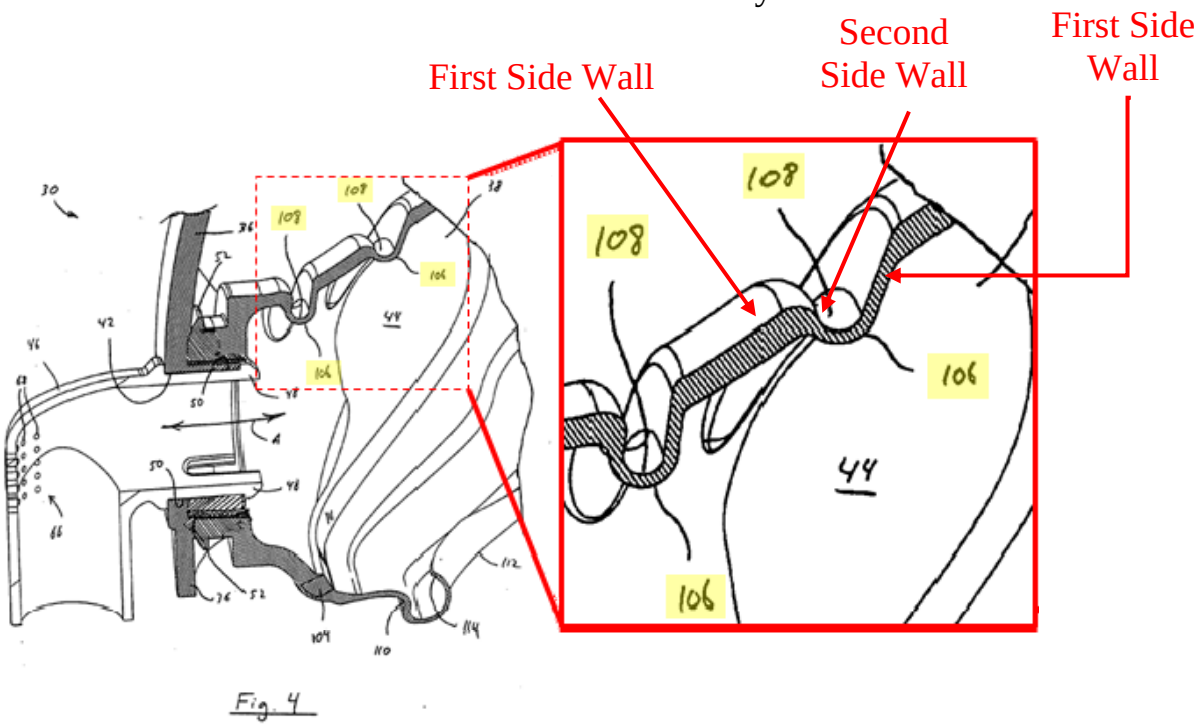


Fig. 1

For example, Matula-II discloses folds 106 in the nasal bridge region of the cushion 38 to provide "the desired degree of flexibility." Ex. 1412 ¶ 66. As shown below, the fold 106 has first side walls interconnected by a second side wall. *Id.* ¶ 90.



The Matula-II fold configuration is similar to the fold disclosed in the '931 Patent, which has adjacent first side walls 52(1) interconnected by a second side wall 52(2), as shown below. Ex. 1401 at col. 14:40–42; Ex. 1402 ¶ 107.

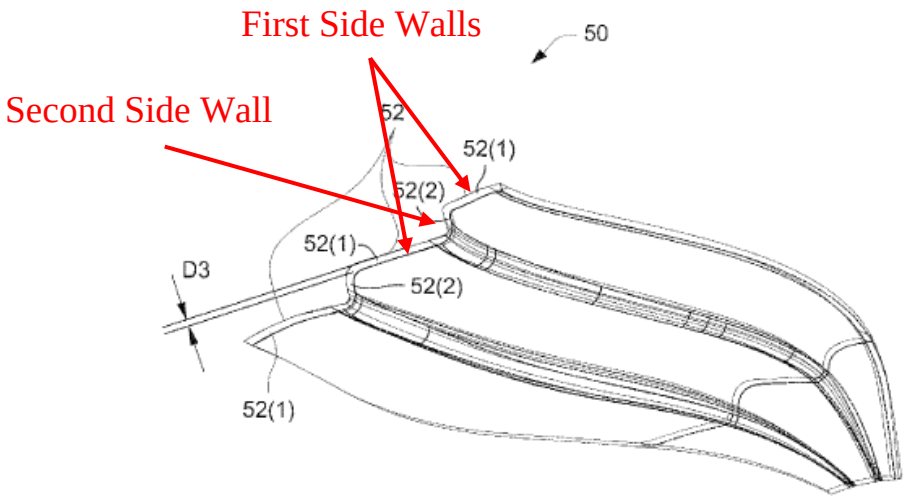


Fig. 32-3

A person of skill in the art would have been motivated to incorporate the Matula-II fold so there would be a higher level of flexibility in the nasal bridge region of the cushion module. *See* Ex. 1412 ¶ 66; Ex. 1402 ¶¶ 110–111. A person of skill would have recognized that this modification would increase patient comfort and improve sealing force. *See* Ex. 1412 ¶ 3; Ex. 1402 ¶¶ 110–111. By providing a higher degree of flexibility in the delicate nasal bridge region, less force is transmitted to the nasal bridge region, while more force is transmitted to other areas (*e.g.*, cheeks) that are better suited to support higher pressures. Ex. 1402 ¶¶ 110–111.

b. Claim 5

Claim 5 depends from Claim 1 and includes:

"wherein the frame includes a collar surrounding said frame opening, and"

As shown below, Ng discloses a collar surrounding the frame opening. *See* Ex. 1410 at Fig. 1.

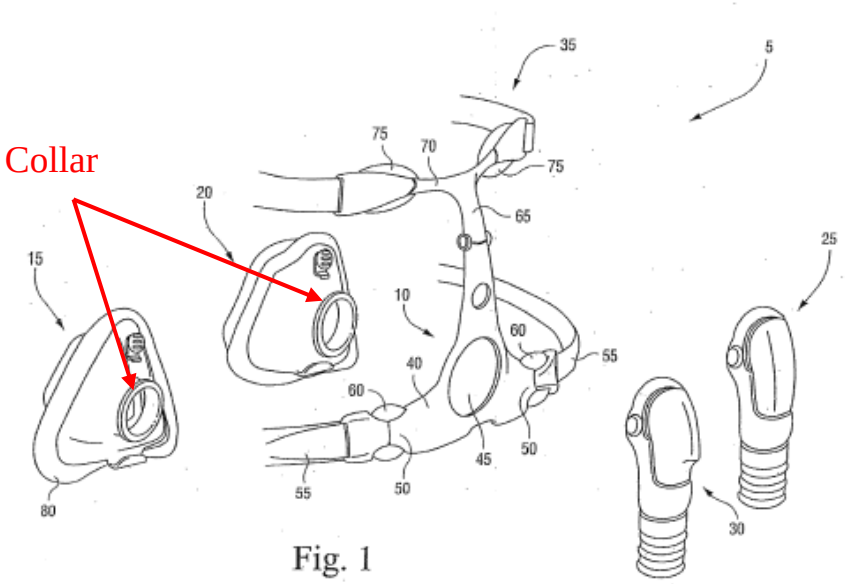


Fig. 1

Matula-II also discloses a collar 52 surrounding the frame opening to facilitate a stable mechanical coupling with the shroud 36, as shown below. Ex. 1412 ¶ 53.

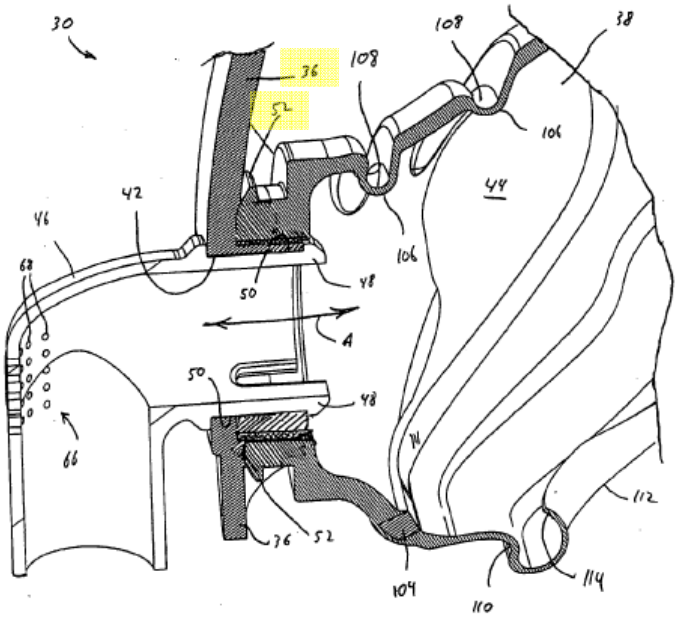


FIG. 4

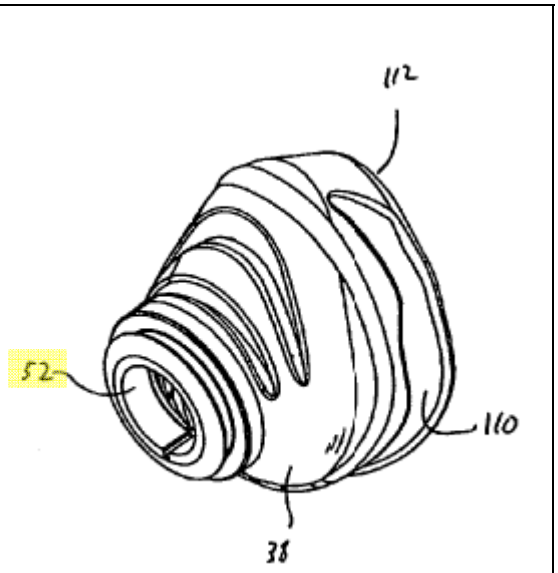


FIG. 5 (PARTIAL)

"wherein the shroud includes a retaining portion with a plurality snap fingers structured to engage the collar with a snap-fit."

Ng does not expressly disclose a plurality of snap fingers, but snap fingers were well-known and commonly used in the prior art. Ex. 1402 ¶¶ 116–125. For example, as shown on the next page, Matula-II discloses snap fingers 48 structured to mechanically couple the collar 52 to the shroud 36. Ex. 1412 ¶ 53. Because the Matula-II shroud 36 is semi-rigid, the snap fingers 48 deflect radially inward and

elastically recover to mechanically couple the collar 52 to the shroud 36 with a snap-fit. *Id.*; Ex. 1402 ¶ 116.

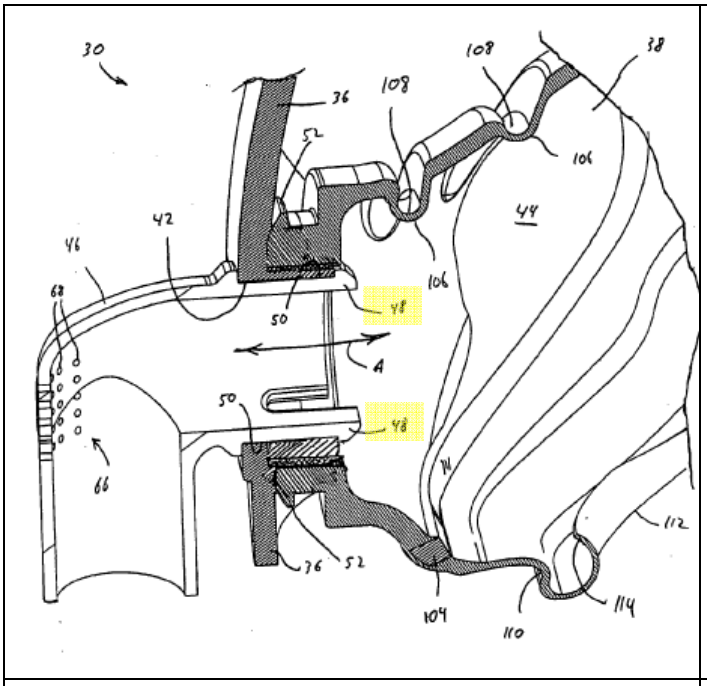


FIG. 4

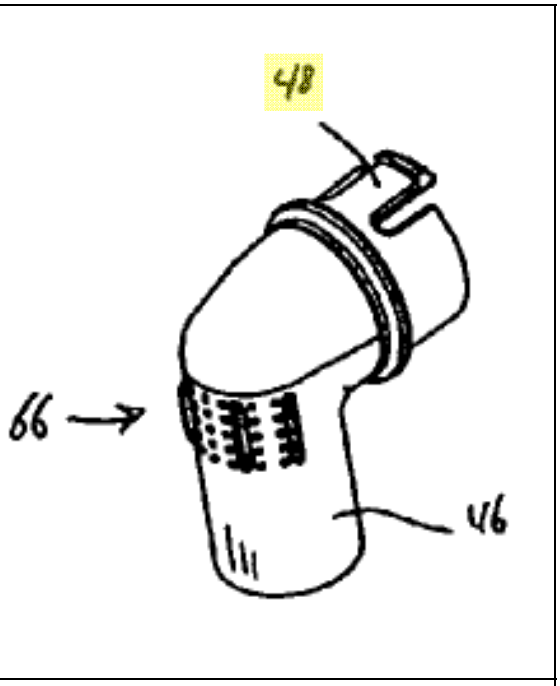


FIG. 5 (PARTIAL)

A person of skill in the art would have been motivated to modify Ng to include a plurality of snap fingers, as taught by Matula-II, that extend rearward from the second shroud opening. Ex. 1402 ¶ 117. As modified, the snap fingers would extend rearward into the frame opening to engage an underside of the Ng collar with a snap-fit, as taught by Matula-II. *See* Ex. 1412 ¶ 53; Ex. 1402 ¶ 117. Alternatively, the snap fingers would extend rearward and engage the outer periphery of the collar. Ex. 1402 ¶ 117.

Although the Matula-II snap fingers are on the elbow, it was common knowledge to incorporate snap fingers into the shroud to achieve the same purpose

of providing a secure connection between the shroud and the cushion module. *Id.* ¶ 118. A person of skill would have recognized that modifying Ng to include snap fingers would make it easier to join the shroud and the cushion module and allow for repeated interlocking without destroying the parts. *Id.* ¶¶ 122–125.

c. Claim 10

Claim 10 depends from Claim 1 and includes:

"wherein the shroud module includes an annular or part annular cushion retaining portion structured to retain the cushion module."

As shown below, Ng discloses a shroud module 10, including an annular opening 45, that retains the cushion module 15, 20. Ex. 1410 ¶¶ 29–31.

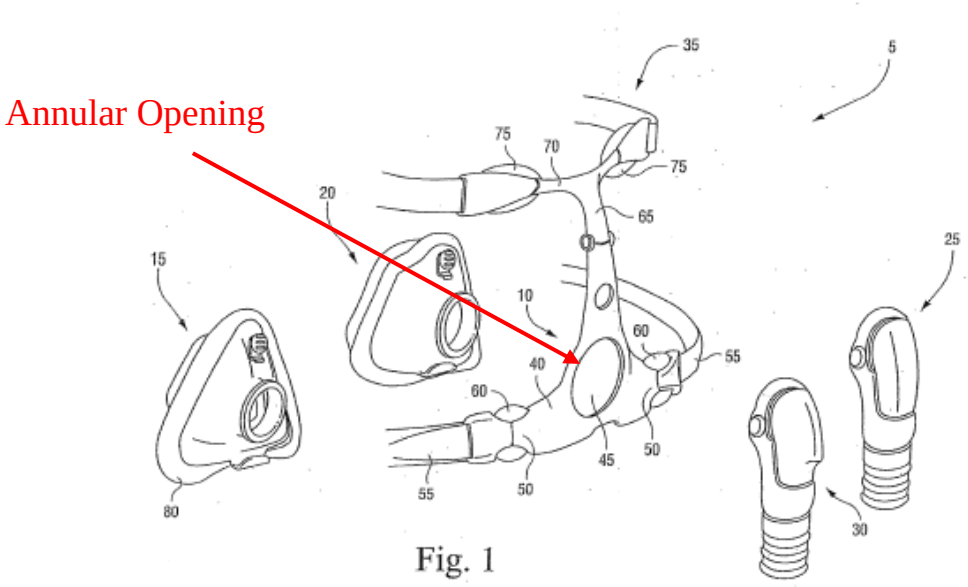


Fig. 1

As explained above, a person of skill would have been motivated to modify Ng to include a plurality of snap fingers extending rearward from the second opening 45 (*see supra* § VII(C)(2)(b)), which would provide an annular or part

annular cushion retaining portion structured to retain the cushion module. Ex. 1402 ¶ 128.

d. Claim 26

Claim 26 depends from Claim 1 and includes:

"wherein the second opening of the shroud module and the frame opening of the frame are aligned along a common longitudinal axis, and"

As shown below, the second shroud opening 45 and the frame opening are aligned along a common longitudinal axis when the Ng mask is assembled.

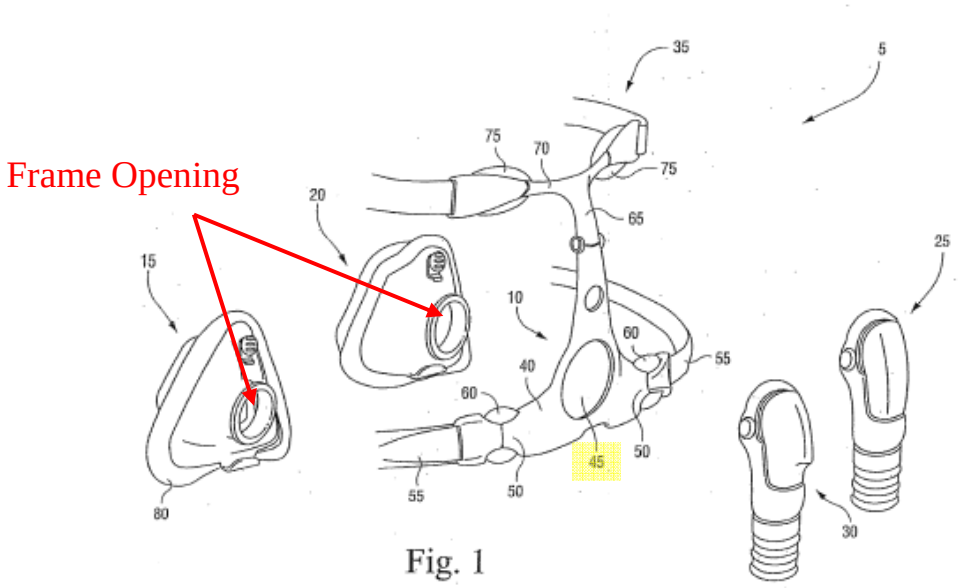


Fig. 1

"wherein the mask system further comprises a snap-fit arrangement to removably snap-fit attach the shroud module and the cushion module to one another by moving the shroud module and the cushion module towards one another along the longitudinal axis."

As explained above, the shroud module and the cushion module are removably attached. *See supra* § VII(B)(3)(a)(v). A person of skill would have recognized that the shroud module in Ng engages the cushion module with a snap-fit. Ex. 1402 ¶ 131.

Snap-fit arrangements between cushion modules and shroud modules were well-known prior to the '931 Patent. *Id.* ¶¶ 132–135. As explained above, a person of skill would have been motivated to modify the shroud module to include a plurality of snap fingers. *See supra* § VII(C)(2)(b). Ng, as modified with snap fingers, provides a snap-fit arrangement in which the snap fingers elastically deform to removably couple the cushion module to the shroud module by moving the components towards one another along the longitudinal axis. Ex. 1402 ¶¶ 133–135. A person of skill also would have recognized that snap-fit arrangements ensure secure attachments, but are reversible for removal or replacement of parts. *Id.* ¶ 135.

D. Ground 3: Claims 7, 8, and 18 would have been obvious over Ng in view of Thomlinson and Gunaratnam-I

1. Overview of Gunaratnam-I (Ex. 1413)

Gunaratnam-I was submitted, but not cited, during the prosecution of the ’931 Patent. Ex. 1401 at 5.

Gunaratnam-I describes masks for treating sleep-disordered breathing. Ex. 1413 at col. 1:21–25. The figures below illustrate frame 160/162 with various headgear strap connection points. *Id.* at col. 4:32–34.

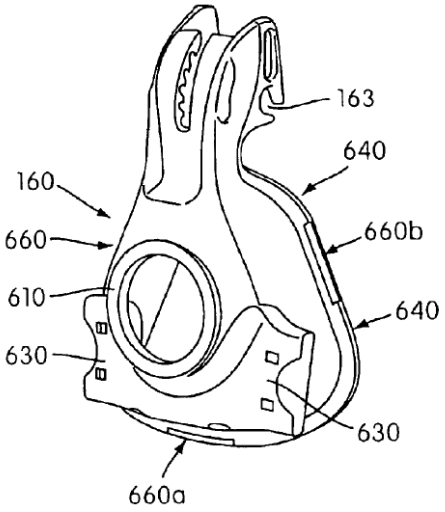


FIG. 5a

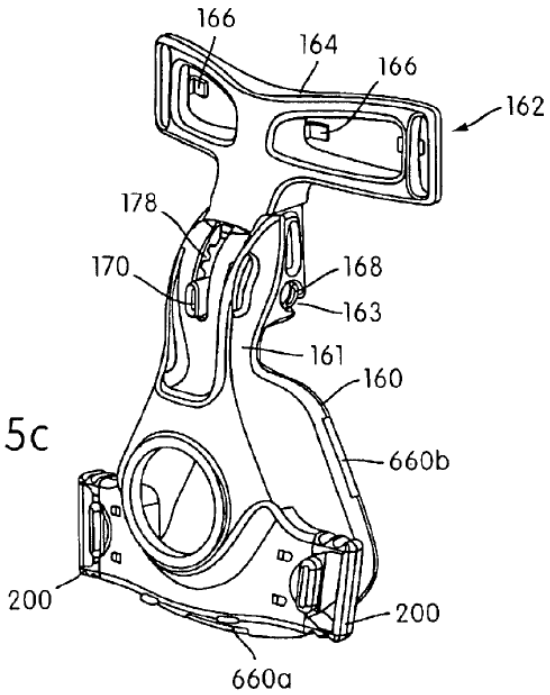


FIG. 5c

2. Limitations of Claims 7, 8, and 18

Because Gunaratnam-I discloses CPAP patient interfaces with structurally similar features, its features would have been readily compatible with and easily

incorporated into the Ng mask with a reasonable expectation of success. Ex. 1402 ¶ 138. Combining these familiar features would have done no more than yield predictable results. *See id.* ¶¶ 138–158; *see also KSR*, 550 U.S. at 416.

a. Claim 7

Claim 7 depends from Claim 6 and includes:

"wherein each upper headgear connector includes a slot adapted to receive a respective headgear strap in use."

Ng discloses upper headgear connectors at each end of bridge 70, and a person of skill would have understood that the headgear connectors include slots that receive the headgear straps. *See* Ex. 1410 at Fig. 1; Ex. 1402 ¶ 140. Such slots were common in the prior art and Thomlinson discloses similar headgear connector slots 120. Ex. 1411 ¶ 306; Ex. 1402 ¶¶ 140–143.

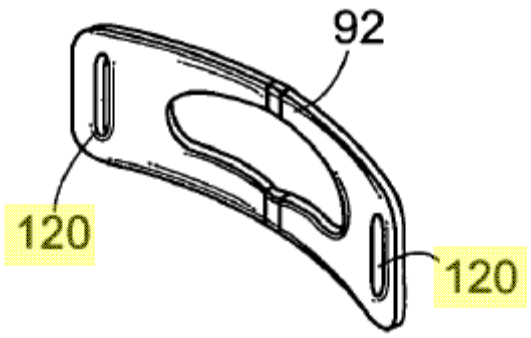


Fig. 28A

As shown below, Gunaratnam-I also included slots. Ex. 1402 ¶ 141.

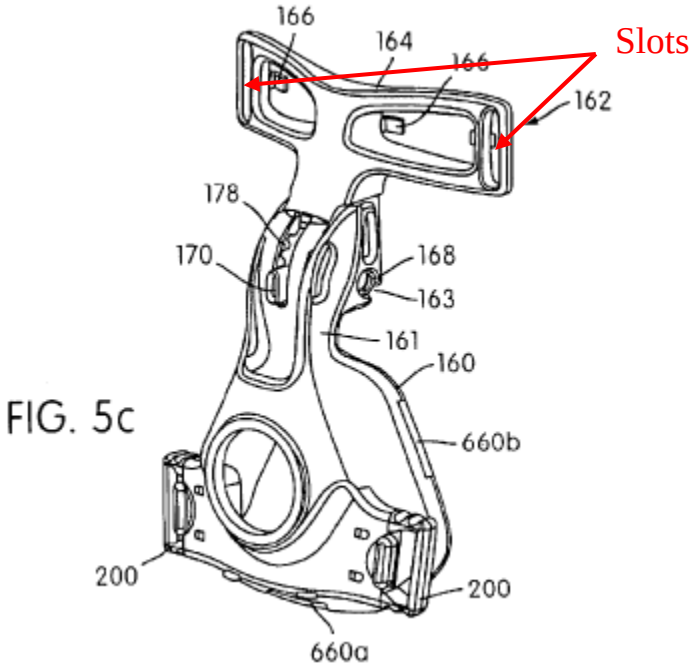


FIG. 5c

Since upper headgear straps undergo minimal tension when putting on the headgear, a person of skill would have known to provide upper headgear slots to simplify design, simplify manufacturing, and reduce parts. Ex. 1402 ¶¶ 141–143.

b. Claim 8

Claim 8 depends from Claim 7 and includes:

"wherein each lower headgear connector is adapted to be removably interlocked with a headgear clip associated with a respective headgear strap."

As shown below, Ng discloses lower headgear connectors that interlock with press-fit clips or connectors 60 associated with the straps. Ex. 1410 ¶ 30.

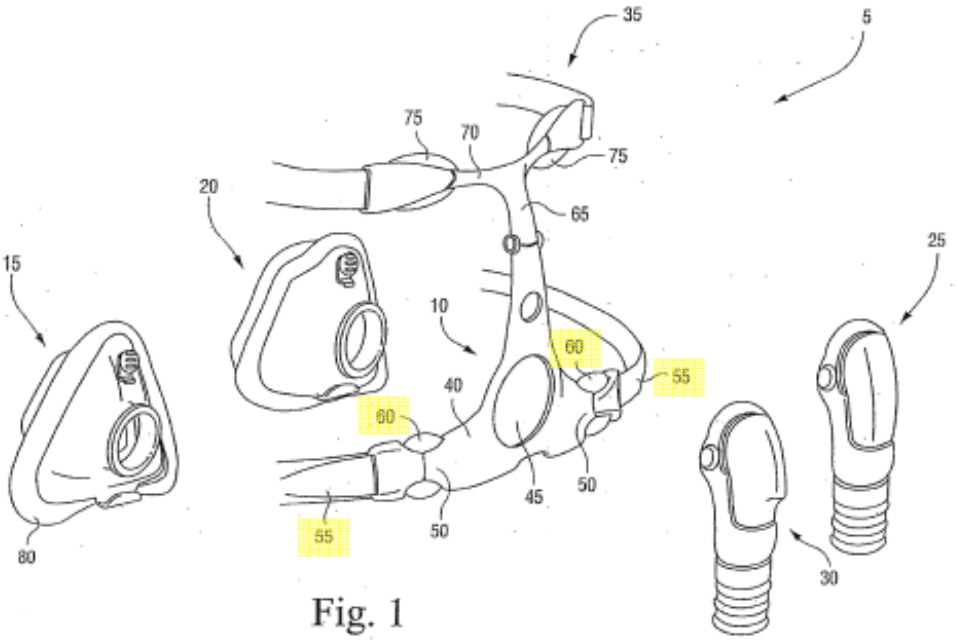


Fig. 1

To the extent Ng somehow provides insufficient teachings for lower headgear clips, such clips were common in the prior art and one of a finite number of predictable options for attaching headgear. Ex. 1402 ¶¶ 146–152; *see also KSR*, 550 U.S. at 420. For example, as shown below, Gunaratnam-I discloses lower

headgear connectors 630 that removably interlock with clips 200. Ex. 1413 at col. 4:31–33.

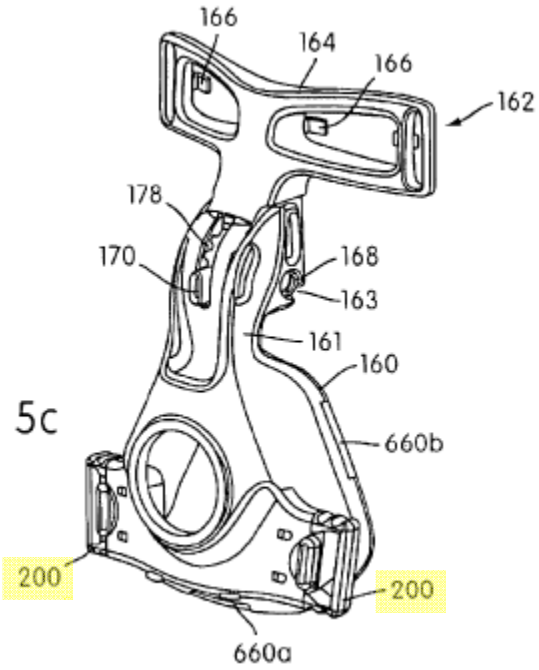


FIG. 5c

A person of skill would have been motivated to provide lower headgear clips and upper headgear slots, as taught by Gunaratnam-I. Ex. 1402 ¶¶ 147–152. Unlike the upper straps, the lower headgear straps undergo significant tension when the headgear is pulled over a user's head, making it difficult to position the lower headgear straps. *Id.* ¶ 151. A person of skill would have been motivated to provide lower headgear clips, so the user would not have to force the lower headgear straps over his/her head. *Id.*

c. Claim 18

Claim 18 depends from Claim 1 and includes:

"wherein the shroud module and the frame comprise polycarbonate and the cushion comprises silicone."

As explained above, Ng discloses a rigid frame and a soft cushion. *See supra* §§ VII(B)(3)(a)(iii)–(iv). Ng discloses a polycarbonate frame in a different embodiment (Ex. 1410 ¶ 66), but Ng does not specify a polycarbonate shroud module or a silicone cushion.

Polycarbonate and silicone were commonly used in the prior art. Ex. 1402 ¶¶ 154–158. For example, Gunaratnam-I discloses a silicone cushion and polycarbonate frame components. Ex. 1413 at cols. 1:34–39, 5:33–34.

A person of skill would have selected polycarbonate and silicone as suitable for the intended purpose of the rigid frame/shroud and soft cushion, respectively. Ex. 1402 ¶¶ 157–158; s*ee also* M.P.E.P. 2144.07 ("Art Recognized Suitability for an Intended Purpose."). A person of skill would have recognized that silicone cushions were typical and desirable because they provide a compliant and comfortable seal. *See* Ex. 1413 at col. 1:36–39; Ex. 1402 ¶ 157. Further, it was well-known to construct the shroud module and the frame from polycarbonate to provide strength, rigidity, and toughness to support the headgear. Ex. 1402 ¶ 158. Additionally, polycarbonate CPAP components can be cleaned, disinfected, and/or sterilized by most commonly used methods. *Id.*

E. Ground 4: Claims 12 and 14 would have been obvious over Ng in view of Thomlinson and Barnett

1. Overview of Barnett (Ex. 1414)

Barnett was submitted, but not cited, during the prosecution of the '931 Patent. Ex. 1401 at 5.

As shown below, Barnett discloses a nasal CPAP mask assembly 30 including a collar 34 connected to a seal member 32. Ex. 1414 at cols. 1:7–32, 3:48–52. An elbow 36 is rotatably mounted to the collar 34 and freely rotates 360°. *Id*. at col. 3:52–56.

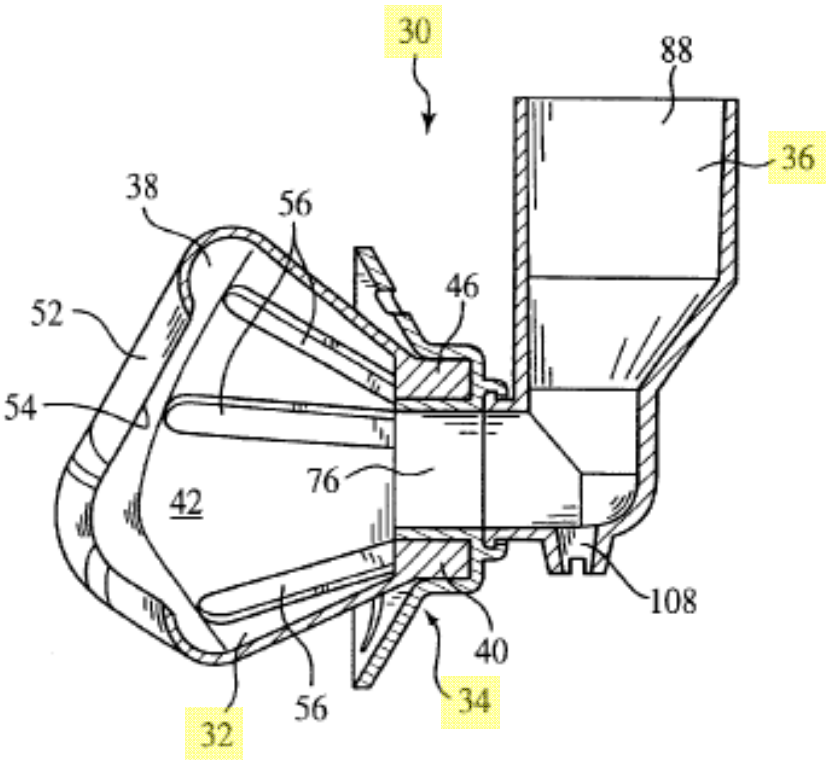


FIG. 1A

2. Limitations of Claims 12 and 14

A person of skill in the art at the time of the purported invention would have been motivated to combine the teachings of Ng, Thomlinson, and Barnett for at least the reasons provided above. *See supra* §VII(B)(3). Because Barnett discloses a CPAP patient interface with structurally similar features, its features would have been readily compatible with and easily incorporated into the Ng mask with a reasonable expectation of success. Ex. 1402 ¶ 162. Combining these familiar elements according to known methods would have done no more than yield predictable results. *See id.* ¶¶ 162–177; *see also KSR*, 550 U.S. at 416.

a. Claim 12

Claim 12 depends from Claim 11 and includes:

"wherein the elbow module is provided to the shroud module."

The '931 Patent discloses a shroud module 1020 that accommodates the elbow 1070, but provides no contact with elbow when assembled. Ex. 1401 at col. 7:21–27.

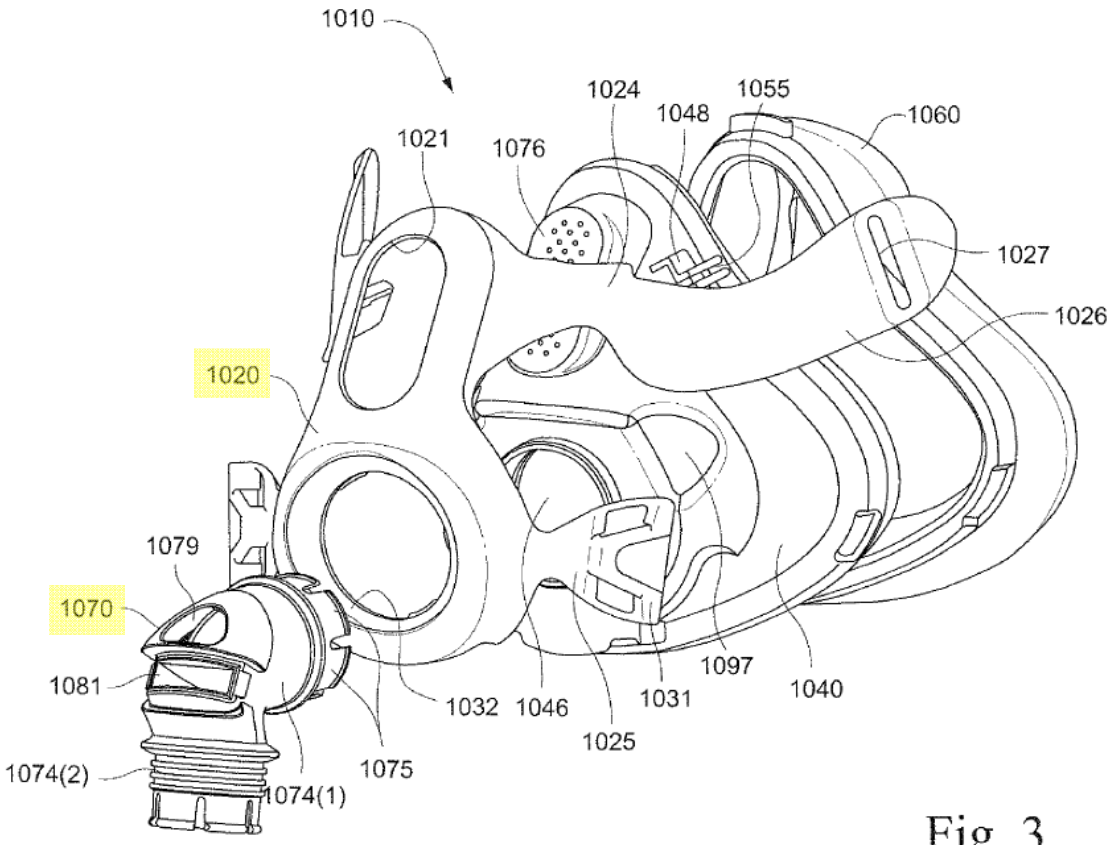


Fig. 3

Ng discloses a shroud module 10 that couples to the cushion component 15, 20 and the elbow component 25, 30. Ex. 1410 ¶ 31. However, Ng does not explain exactly how these parts are coupled.

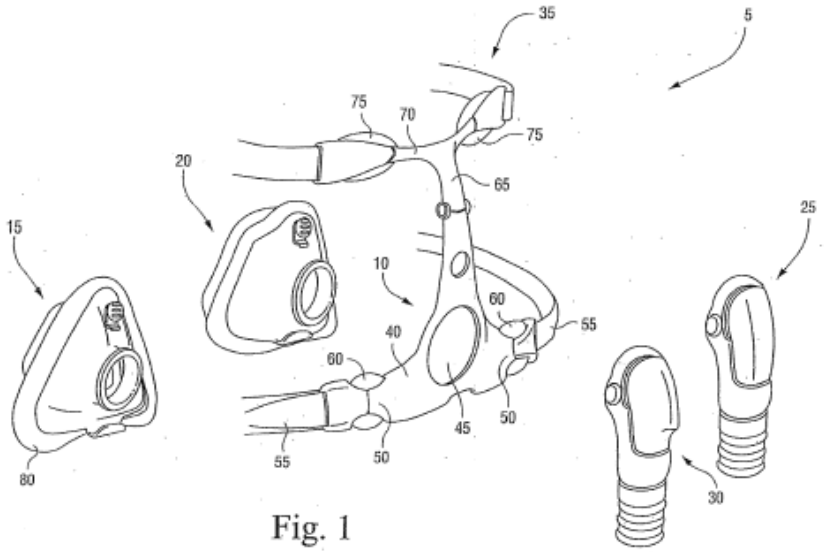


Fig. 1

To the extent the term "provided to" is interpreted narrowly to require a direct connection, such connections were well-known. Ex. 1402 ¶¶ 165–171.

For example, as shown below, Barnett discloses an elbow module 36 that is directly mounted to the shroud 34. Ex. 1414 at col. 3:52–57.

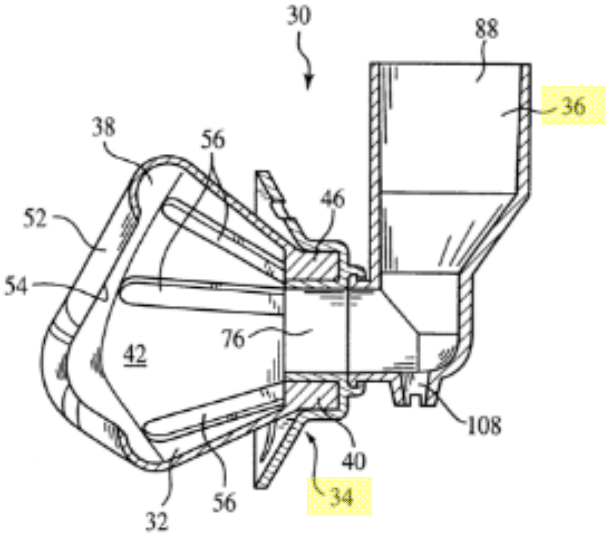


FIG. 1A

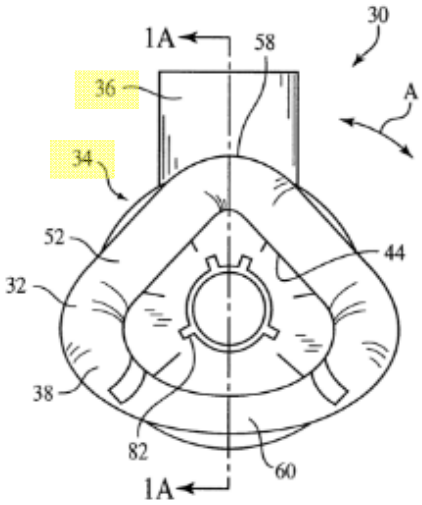


FIG. 1B

A person of skill at the time of the purported invention would have been motivated to modify Ng to directly attach the elbow to the shroud module, *e.g.*, by including a flange connection on a front side of the shroud module, as taught by Barnett. *See* Ex. 1414 at col. 9:13–30; Ex. 1402 ¶¶ 165–171. A person of skill would have recognized that this direct connection would make it easier to detach the elbow without affecting the engagement of mask components and would provide more design flexibility. Ex. 1402 ¶¶ 170–171.

b. Claim 14

Claim 14 depends from Claim 11 and includes:

"wherein the elbow module and the shroud module are directly connected with a mechanical interlock while allowing 360 degree rotation of the elbow module."

For at least the reasons provided above, a person of skill would have been motivated to directly and mechanically interlock the elbow module 36 and the shroud module 34. *See supra* § VII(E)(2)(a). Further, it was well-known to provide a rotatable engagement between the elbow module and the shroud module. Ex. 1402 ¶¶ 174–177. For example, as shown below, the Barnett elbow module 36 is mechanically interlocked with the shroud module 34 and allows 360° rotation in direction A. Ex. 1414 at col. 3:52–57.

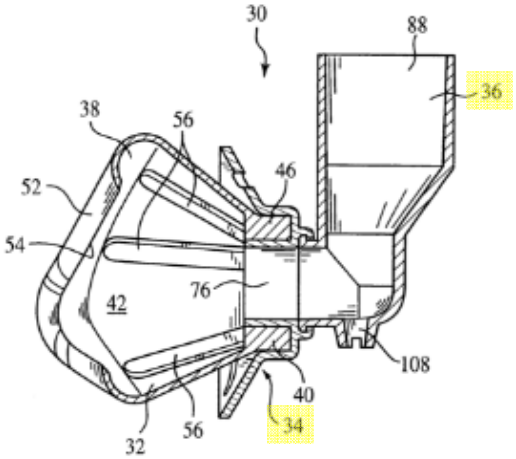


FIG. 1A

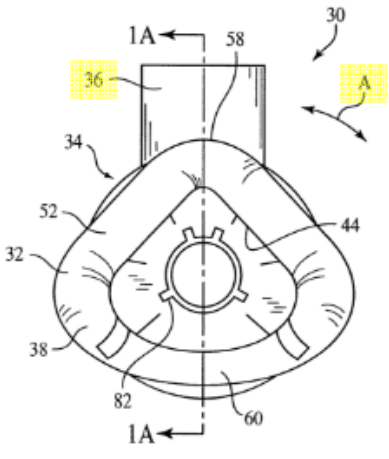


FIG. 1B

A person of skill at the time of the invention would have been motivated to make the elbow rotatable over a 360° range, as taught by Barnett, to provide

control over the tubing and to provide the most convenient, comfortable, and low force mask connection. Ex. 1402 ¶¶ 176–177.

F. Ground 5: Claims 13 and 15 would have been obvious over Ng in view of Thomlinson, Barnett, and Worboys

1. Overview of Worboys (Ex. 1415)

Worboys is a ResMed application and was not submitted or cited during the prosecution of the '931 Patent. *See* Ex. 1401 at 1–9.

Worboys discloses a respiratory mask elbow assembly 5 connected to an air delivery tube with a swivel joint. Ex. 1415 ¶¶ 104–105. The Worboys elbow 10 has an anti-asphyxia valve (AAV) assembly 15 with a flap portion 45. *Id.* ¶ 106.

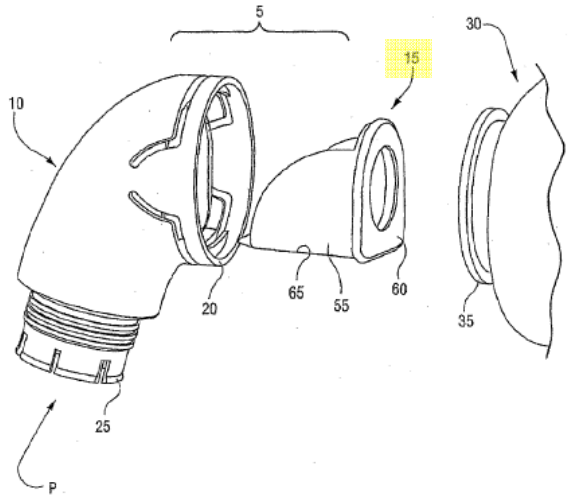


Fig. 1

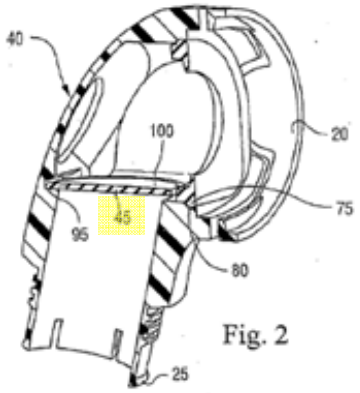


Fig. 2

2. Limitations of Claims 13 and 15

Because Worboys discloses a structurally similar CPAP patient interface, its features would have been readily compatible with and easily incorporated into the

Ng mask with a reasonable expectation of success. Ex. 1402 ¶¶ 179–180. Combining these familiar elements according to known methods would have done no more than yield predictable results. *See id.* ¶¶ 179–188; *see also KSR*, 550 U.S. at 416.

a. Claim 13

Claim 13 depends from Claim 11 and includes:

"wherein the elbow module comprises polycarbonate."

Ng discloses an elbow, but does not specify that it is polycarbonate. However, polycarbonate elbows were common, as taught by Worboys. *See* Ex. 1415 ¶ 105; Ex. 1402 ¶ 182.

It was well-known at the time of the invention to construct polycarbonate elbows to provide strength, rigidity, and toughness to support the air delivery tubing. Ex. 1402 ¶ 183. Additionally, polycarbonate elbows can be cleaned, disinfected, and/or sterilized by most commonly used methods. *Id.*

b. Claim 15

Claim 15 depends from Claim 11 and includes

"wherein the elbow module includes an anti-asphyxia valve and wherein the anti-asphyxia valve includes a flap portion adapted to selectively close a port provided in the elbow module."

Ng discloses an elbow, but does not expressly disclose an AAV. However, AAVs in CPAP elbows were common in the prior art. Ex. 1402 ¶¶ 185–188. As shown below, Worboys discloses an elbow 10 with an AAV 15 having a flap portion 45 that selectively closes port 40. Ex. 1415 ¶ 106.

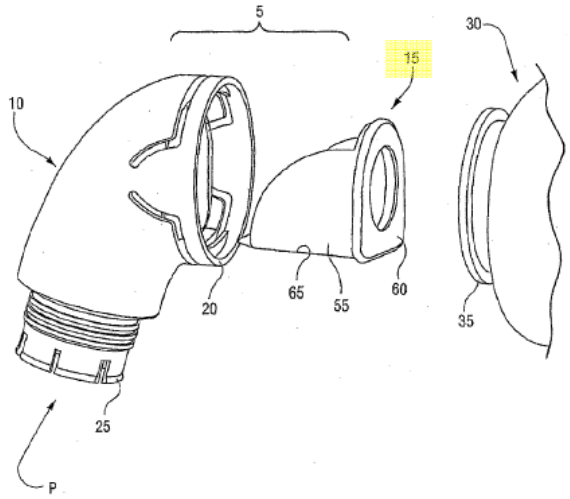


Fig. 1

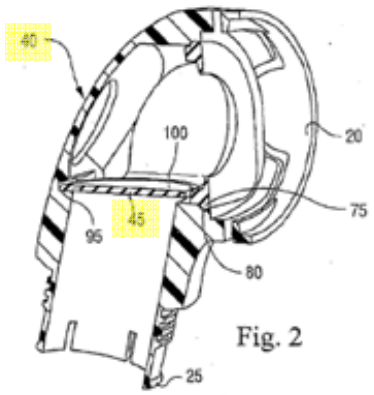


Fig. 2

A person of skill would have known to include the Worboys AAV in the Ng elbow to provide breathable fresh air when the flow generator does not provide flow. *See* Ex. 1415 ¶ 4; Ex. 1402 ¶ 187. Further, a person of skill would have

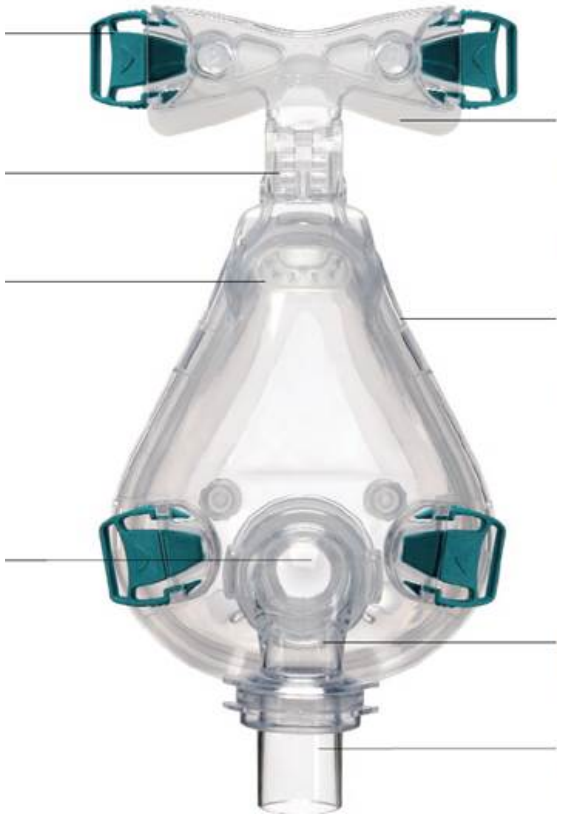
understood that an AVV with a flap is advantageous because the flap easily moves by airflow and pressure. Ex. 1402 ¶ 188.

G. Ground 6: Claims 17 would have been obvious over Ng in view of Thomlinson and Ultra Mirage

1. Overview of Ultra Mirage (Ex. 1416)

Ultra Mirage was not submitted or cited during the prosecution of the '931 Patent. Ex. 1401 at 1–12.

Ultra Mirage is a brochure for a ResMed full face CPAP mask. Ex. 1416 at 6. The components card discloses product sizes for small, medium, and large masks. *Id.* at 7.



2. Limitation of Claim 17

Claim 17 depends from Claim 1 and includes:

"a small cushion module, a medium cushion module and a large cushion module, wherein each of said small cushion module, said medium cushion module and said large cushion module is removably coupleable to the same shroud module."

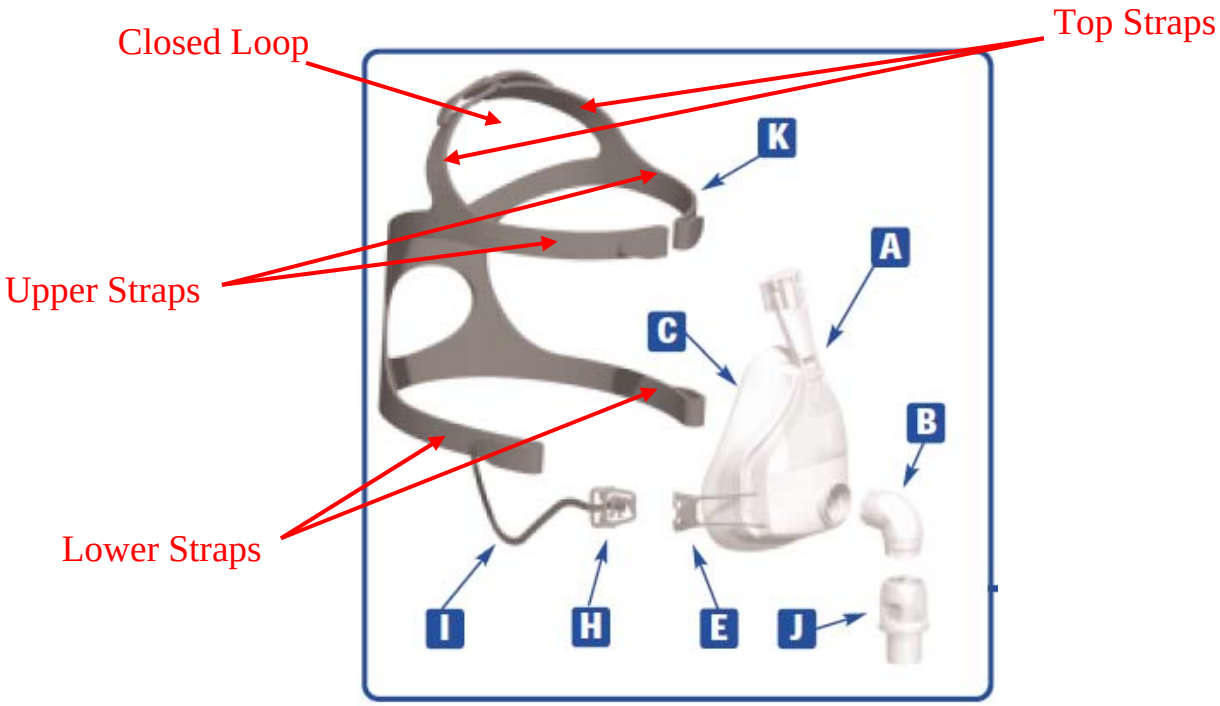
As explained above, Ng discloses different cushion modules 15, 20 that are removably coupled to the same shroud module. *See supra* §§ [Claims 1 and 16]. Ng does not expressly disclose small, medium, and large cushion modules, but a person of skill in the art would have known to provide different-sized cushion modules. Ex. 1402 ¶¶ 199–203. For example, Ultra Mirage specifically discloses product sizes for small, medium, and large masks. Ex. 1416 at 7.

A person of skill in the art would have been motivated to provide different-sized, interchangeable cushions modules (*e.g.*, small, medium, and large) for different-sized patient populations. Ex. 1402 ¶¶ 199–203. Further, a person of skill would have designed these cushion modules to fit a common shroud module to reduce the number of required components. *Id.* ¶¶ 202–203. Combining these familiar elements according to known methods would do no more than yield predictable results. *See id.* ¶¶ 197–203; *see also KSR*, 550 U.S. at 416.

H. Ground 7: Claims 19, 21, and 25 would have been obvious over Ng in view of Thomlinson and FlexiFit

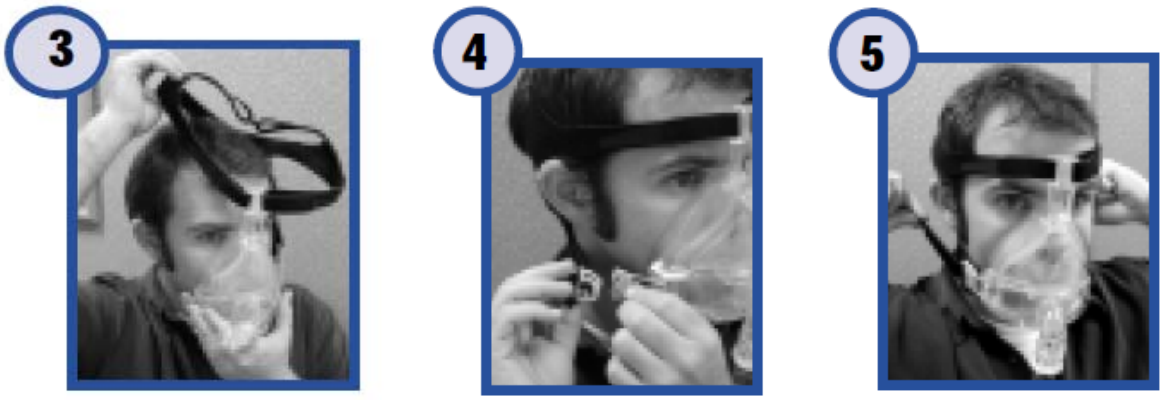
1. Overview of FlexiFit (Ex. 1417)

FlexiFit was not submitted or considered during the prosecution of the '931 Patent. Ex. 1401 at 1–12.



As shown above, FlexiFit shows headgear (K) with upper and lower straps removably coupleable to mask base (A). Ex. 1417 at 10 ("FITTING YOUR MASK"). The upper straps split to form a pair of top straps and rear straps that form a closed loop. *Id.*

The upper, lower, and top straps can be re-adjusted to prevent leaks. *Id.* at 10 ("FITTING YOUR MASK").



2. Limitations of Claims 19, 21, and 25

A person of skill in the art at the time of the purported invention would have been motivated to combine the teachings of Ng, Thomlinson, and FlexiFit for at least the reasons provided above. *See supra* § VII(B)(3). Because FlexiFit discloses headgear with upper and lower straps, the FlexiFit headgear would have been readily compatible with, and easily incorporated, into the Ng mask assembly with a reasonable expectation of success. Ex. 1402 ¶ 207. Combining these familiar elements according to known methods would have done no more than yield predictable results. *See id.* ¶¶ 207–230; *see also KSR*, 550 U.S. at 416.

a. Claim 19

Claim 19 depends from Claim 1 and includes:

"the headgear includes a pair of upper straps and a pair of lower straps, with the upper straps being removably attached to respective ones of the headgear connectors and the lower straps being connected to respective ones of the headgear connectors,"

As shown below, the Ng headgear includes pairs of upper and lower headgear straps coupled to the shroud module 10. Ex. 1410 ¶ 30.

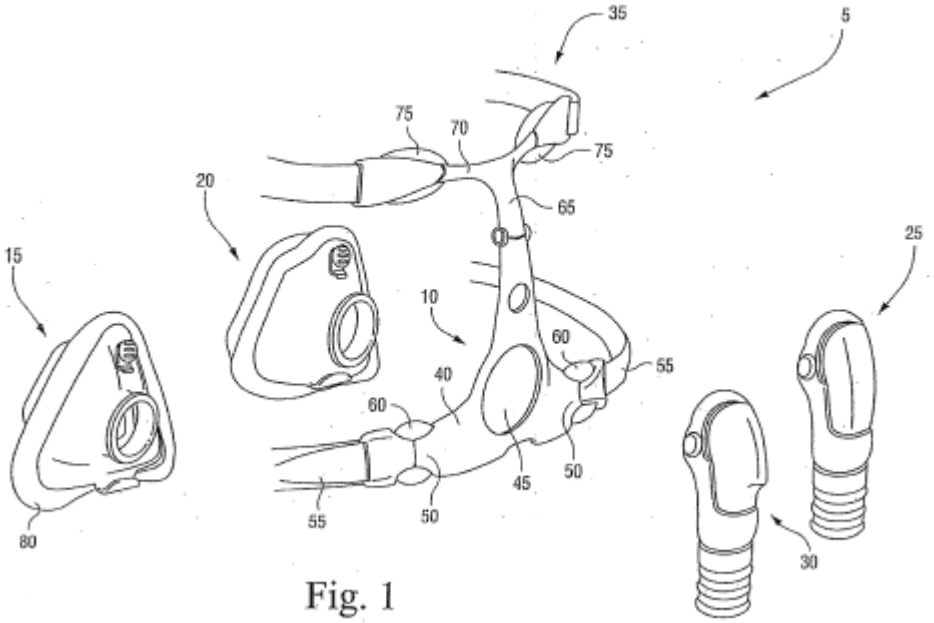
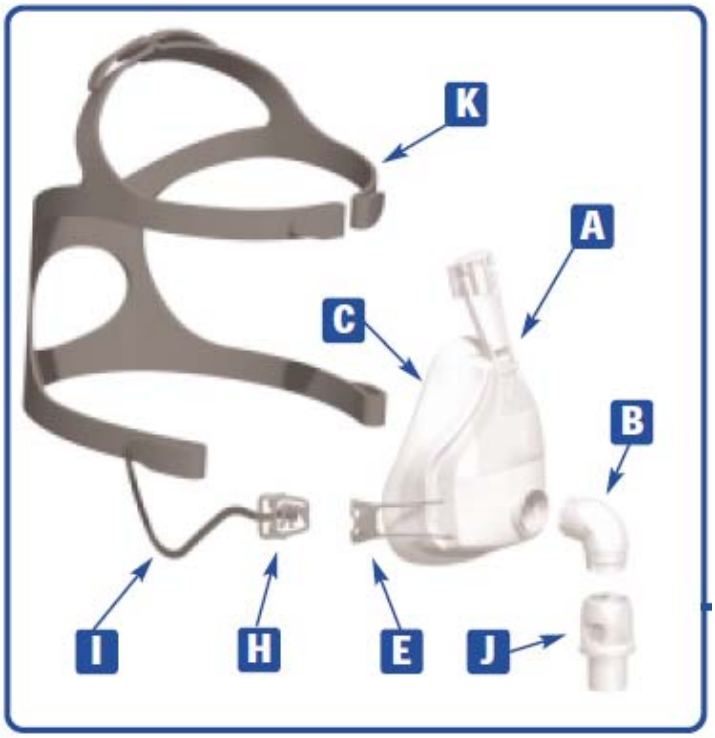


Fig. 1

To the extent Ng somehow provides insufficient teachings for this feature, removably attachable headgear straps were well-known and taught by Thomlinson, as explained above. *See supra* § VII(B)(3)(a)(ii). It was common for upper and

lower straps to be removably attached to respective headgear connectors, as shown below in FlexiFit. Ex. 1417 at 10.



"a free end of each of the upper straps and the lower straps includes a hook tab structured to engage a remainder of the respective upper strap and respective lower strap to secure the upper and lower straps in place in a length adjustable manner,"

Ng discloses that each headgear strap includes hook and loop fastening elements. Ex. 1410 ¶ 67. Positioning the hook tabs at the free ends of the straps was typical in the prior art (*see e.g.*, Ex. 1417 at 10) and would have been a matter of simple design preference to facilitate headgear adjustment. Ex. 1402 ¶¶ 212–215.

"the upper straps split to form a pair of top straps and a pair of rear straps, the top straps being connected together by a buckle and configured to pass over the top of the patient's head in use, the rear straps being adapted to pass behind the patient's head in use,"

Figure 1 of Ng does not show upper straps that split to form pairs of top and rear straps. However, other embodiments of Ng, including Figure 16 below, include straps splitting to form pairs of top and rear straps. The top straps are connected together by a buckle that passes over the top of the patient's head and the rear straps pass behind the patient's head.

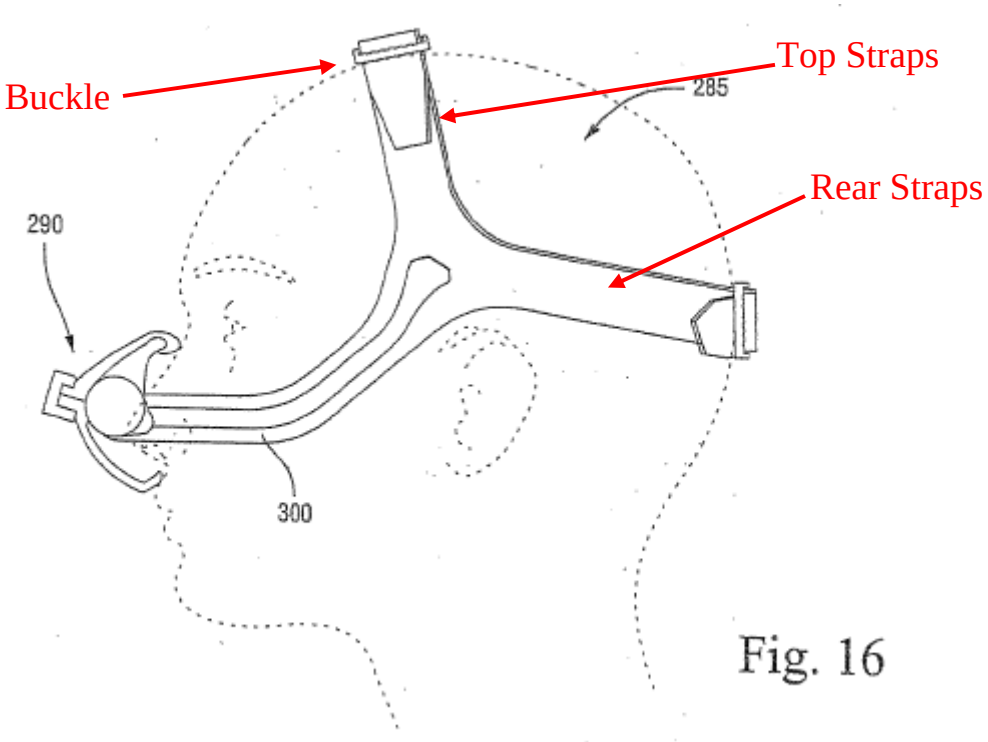
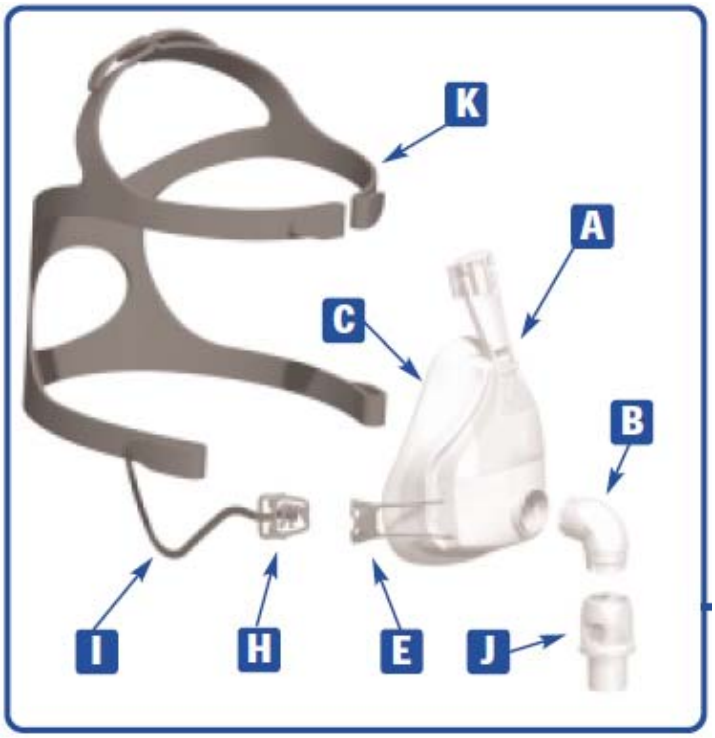


Fig. 16

As shown below, it was common for CPAP headgear to include upper straps that split into top and rear straps, as taught by FlexiFit. Ex. 1417 at 10.



A person of skill in the art would have been motivated to include upper straps that split into top and rear straps to better support and secure the upper portion of the mask. Ex. 1402 ¶¶ 217–219. Further, a person of skill would have known to join the top straps using a buckle to facilitate adjustments for a better fit and to maintain the straps in a desired position. *Id.* ¶¶ 221–223.

"and a free end of each of the top straps has a hook tab threaded through the buckle to engage a remainder of the respective top strap to secure the top straps in place relative to the buckle in a length adjustable manner."

As explained earlier in this section, it was common practice to provide a hook tab on a free end of each strap. A person of skill also would have provided a hook tab on the free end of each top strap. Ex. 1402 ¶ 225.

b. Claim 21

Claim 21 depends from Claim 19 and includes:

"wherein the rear straps and the top straps form a closed loop to encircle a rear portion of the patient's head when in use."

As explained above, a person of skill would have been motivated to include upper straps that split to form pairs of top and rear straps. *See supra* § VII(H)(2)(a). It was common in CPAP headgear to provide rear and top straps that form a closed loop encircling a rear portion of the patient's head, as shown below in Figure 16 of Ng. Ex. 1402 ¶¶ 227–230.

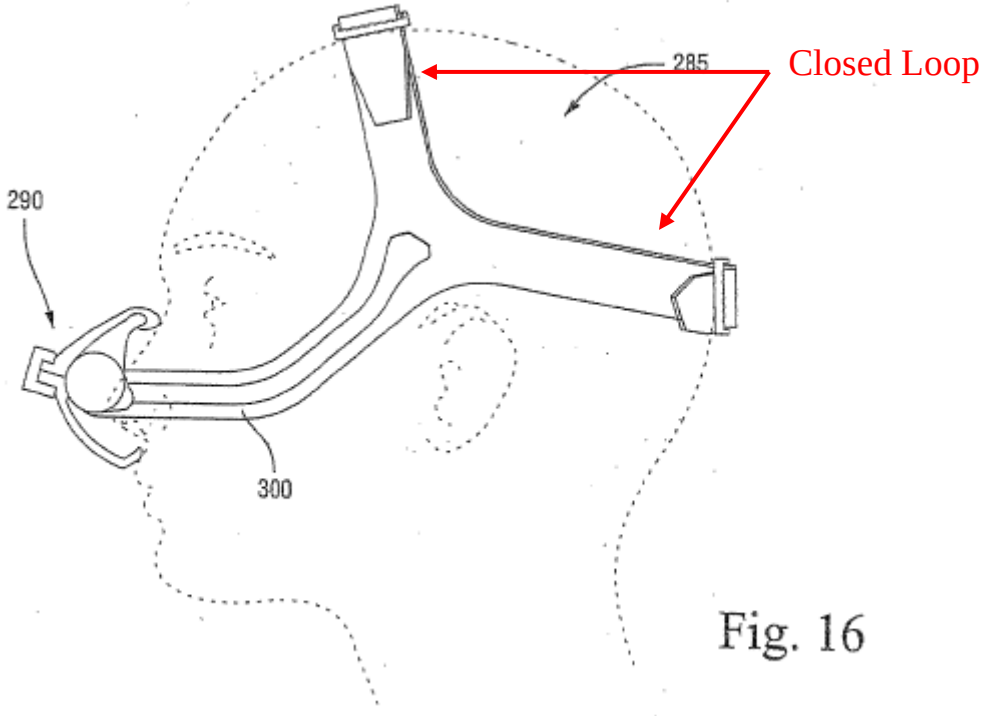
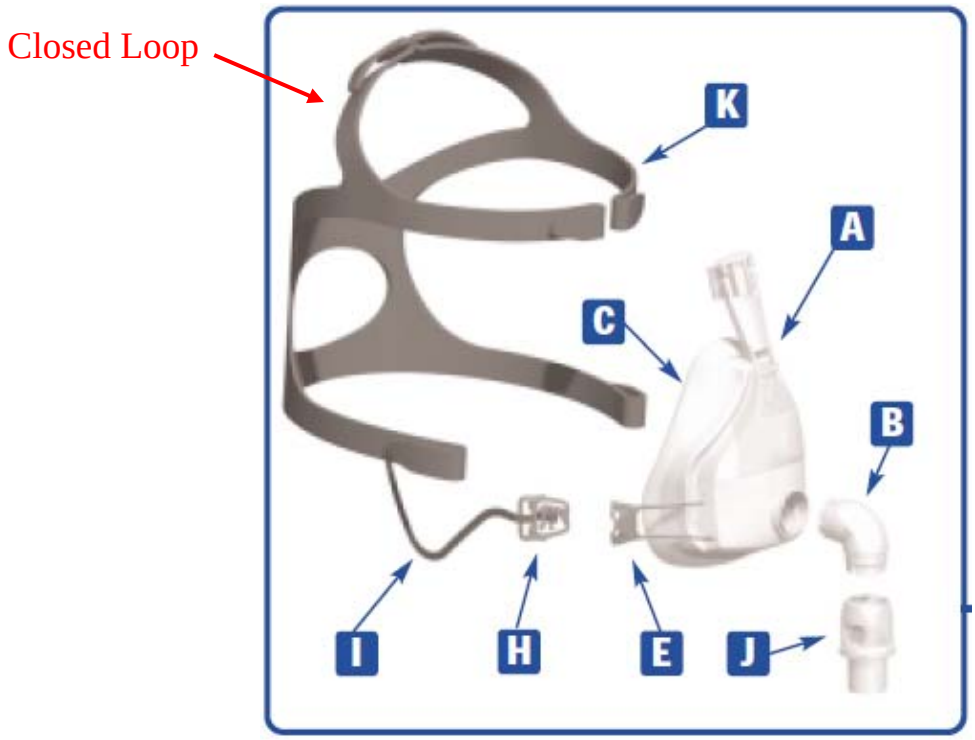


Fig. 16

As shown below, FlexiFit also discloses a rear closed loop. Ex. 1417 at 10.



A person of skill at the time of the invention would have been motivated to provide the rear loop configuration, as taught by Ng and FlexiFit, to stabilize the upper and lower straps, while minimizing the total amount of material required for the headgear. Ex. 1402 ¶ 230.

c. Claim 25

Claim 25 depends from Claim 19 and recites:

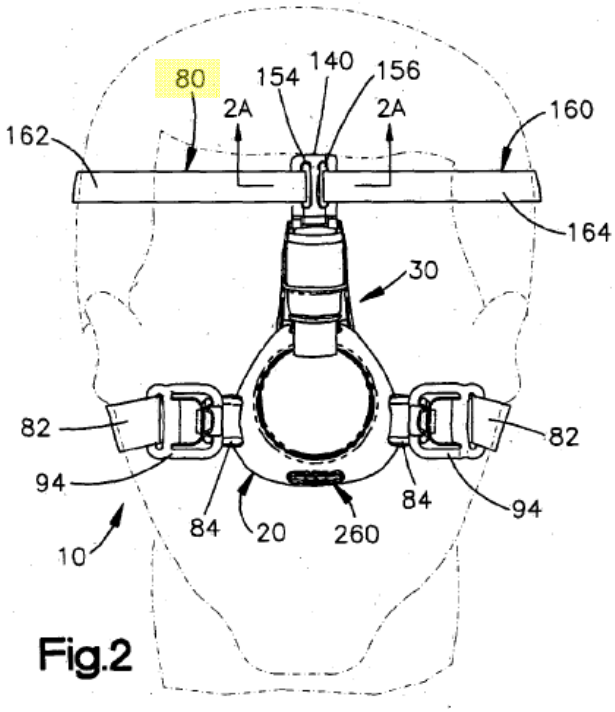
"wherein the frame is rigid."

As explained above, Ng discloses a rigid frame. *See supra* §§ VII(B)(3)(a)(iii)–(iv).

I. Ground 8: Claim 20 would have been obvious over Ng in view of Thomlinson, FlexiFit, and Sprinkle

1. Overview of Sprinkle (Ex. 1419)

Sprinkle was submitted, but not cited, during the prosecution of the '931 Patent. Ex. 1401 at 6.



As shown above, Sprinkle discloses a CPAP mask 10 with headgear straps 162, 164 that provide substantial cushion between the the user's forehead and the upper headgear connectors. Ex. 1419 ¶¶ 72, 74.

2. Limitations of Claim 20

Claim 20 depends from Claim 19 and includes:

"wherein the upper straps provide padding to the respective headgear connectors of the shroud module on the patient's face in use."

Ng does not specify that its straps provide padding, but such straps were common in prior art CPAP masks. Ex. 1402 ¶¶ 234–235. For example, Sprinkle specifically discloses upper headgear straps that provide padding. Ex. 1419 ¶ 74.

A person of skill would have known to provide padding to the upper straps to provide cushioning between the user's face and the mask assembly. *See* Ex. 1419 ¶ 74; Ex. 1402 ¶ 235. Combining these familiar elements according to known methods would have done no more than yield predictable results. *See* Ex. 1402 ¶¶ 232–235; *KSR*, 550 U.S. at 416.

J. Ground 9: Claim 22 would have been obvious over Ng in view of Thomlinson, FlexiFit, and Matula-II

1. Limitations of Claim 22

A person of skill in the art at the time of the purported invention would have been motivated to combine the teachings of Ng, Thomlinson, FlexiFit, and Matula-II for at least the reasons provided above. *See supra* §§ VII(B)(3), VII(C)(2), VII(H)(2). Additionally, combining these familiar elements according to known

methods would have done no more than yield predictable results. *See KSR*, 550 U.S. at 416.

a. Claim 22

Claim 22 depends from Claim 19 and includes:

"wherein the frame includes a frame opening leading to the breathing chamber, and wherein the front opening of the shroud module and the frame opening of the frame are aligned along a common longitudinal axis, and wherein the shroud module and the cushion module are removably snap-fit attached to one another by moving the shroud module and the cushion module towards one another along the longitudinal axis."

As explained above, Ng, as modified by Matula-II, teaches this arrangement. *See supra* § VII(C)(2)(d).

K. Ground 10: Claims 28–30 would have been obvious over Ng in view of Thomlinson, Matula-II, Gunaratnam-I, and Barnett

1. Limitations of Claims 28–30

A person of skill in the art at the time of the purported invention would have been motivated to combine the teachings of Ng, Thomlinson, Matula-II, Gunaratnam-I, and Barnett for at least the reasons provided above. *See supra* §§ VII(B)(3), VII(C)(2), VII(D)(2), VII(E)(2). Combining these familiar elements

according to known methods would have done no more than yield predictable results. *See KSR*, 550 U.S. at 416.

a. Claim 28

Claim 28 depends from Claim 1 and includes:

"the frame includes a collar surrounding said frame opening, and wherein the shroud includes a retaining portion with at least one snap finger structured to engage the collar with a snap-fit,"

As explained above, the combination of Ng and Matula-II teaches this arrangement. *See supra* § VII(C)(2)(b).

"the shroud module includes upper and lower headgear connectors on each side of the shroud module,"

As shown below, Ng discloses upper and lower headgear connectors on each side of the shroud module 10. Ex. 1410 ¶ 30.

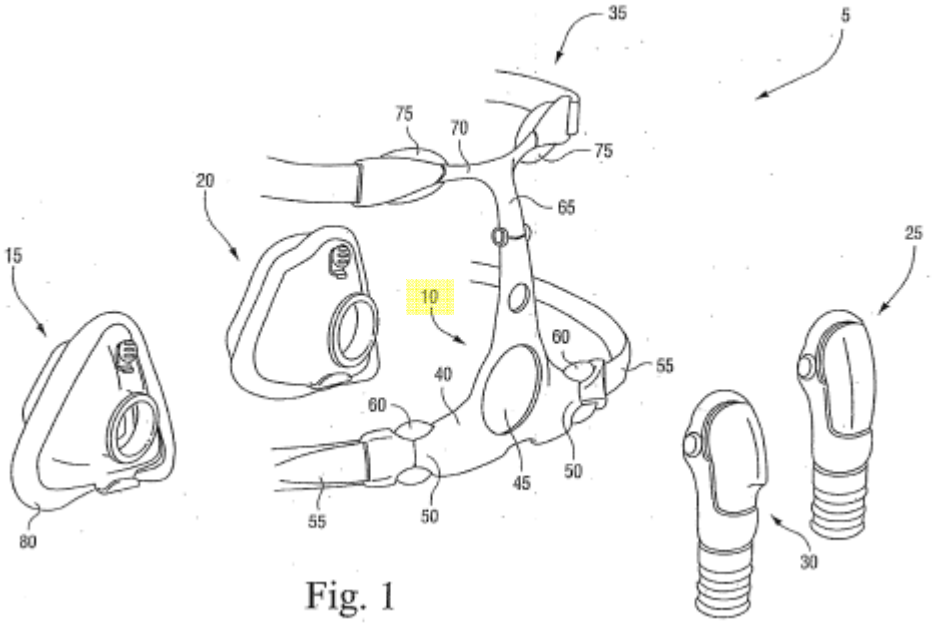


Fig. 1

"each upper headgear connector includes a slot adapted to receive a respective headgear strap in use,"

As explained above, the combination of Ng, Thomlinson, and Gunaratnam-I teaches this feature. *See supra* § VII(D)(2)(a).

"each lower headgear connector is adapted to be removably interlocked with a headgear clip associated with a respective headgear strap,"

As explained above, Ng discloses press-fit connectors, and Gunaratnam-I discloses lower headgear clips. *See supra* § VII(D)(2)(b).

"the mask assembly further comprises an elbow module adapted to be connected to an air delivery tube that delivers breathable gas to the patient, and"

As explained above, Ng discloses an elbow module and it was common knowledge to connect an air delivery tube. *See supra* § VII(B)(3)(c).

"the elbow module is rotatably attached to the shroud module while allowing 360 degree rotation of the elbow module."

As explained above, the combination of Ng and Barnett teaches an elbow module rotatably attached to the shroud module. *See supra* § VII(E)(2)(b).

b. Claim 29

Claim 29 depends from Claim 28 and includes:

"wherein each of the shroud module and the frame comprises polycarbonate, and the cushion comprises silicone."

As explained above, the combination of Ng and Gunaratnam-I teaches a polycarbonate shroud module, a polycarbonate frame, and a silicone cushion. *See supra* § VII(D)(2)(c).

c. Claim 30

Claim 30 depends from Claim 28 and includes:

"wherein the frame is rigid."

As explained above, Ng discloses a rigid frame. *See supra* §§ VII(B)(3)(a)(iii)–(iv).

L. Ground 11: Claims 46, 51, and 53–56 would have been obvious over Ng in view of Thomlinson, Barnett, FlexiFit, Matula-II, Worboys, and Sprinkle

1. Limitations of Claims 46, 51, and 53–56

A person of skill in the art at the time of the purported invention would have been motivated to combine the teachings of Ng, Thomlinson, Barnett, FlexiFit, Matula-II, Worboys, and Sprinkle for at least the reasons provided above. *See supra* §§ VII(B)(3), VII(C)(2), VII(E)(2), VII(F)(2), VII(H)(2), VII(I)(2). Although Claim 43 is not challenged herein, Claim 43 is discussed below because Claim 46 depends from Claim 43.

a. Claim 43

Independent Claim 43 includes:

i. "A mask system for delivery of a supply of air at positive pressure to a patient's airway, the mask system comprising:"

Ng discloses a mask system for treating sleep-disordered breathing. Ex. 1410 ¶ 29.

ii. "a cushion module comprising a frame defining a breathing chamber configured to receive the positive pressure air, and a cushion to form a seal with the patient's face in a nasal bridge region, a cheek region and a lower lip/chin region of the patient's face,"

As discussed above, Ng discloses a cushion modules with a frame and a full-face cushion. *See supra* § (V)(B)(3)(a)(iii).

iii. "wherein the cushion is constructed of a first, relatively soft, elastomeric material and the frame is constructed of a second material that is more rigid than the cushion"

As discussed above, Ng discloses a soft cushion and a rigid frame. *See supra* §§ VII(B)(3)(a)(iii)–(iv).

iv. "the frame including a washout vent"

As discussed above, Ng and Thomlinson both disclose a frame including a washout vent. *See supra* § VII(B)(3)(a)(vi).

v. "the frame including an opening"

As shown below, Ng discloses a frame opening. *See* Ex. 1410 at Fig. 1.

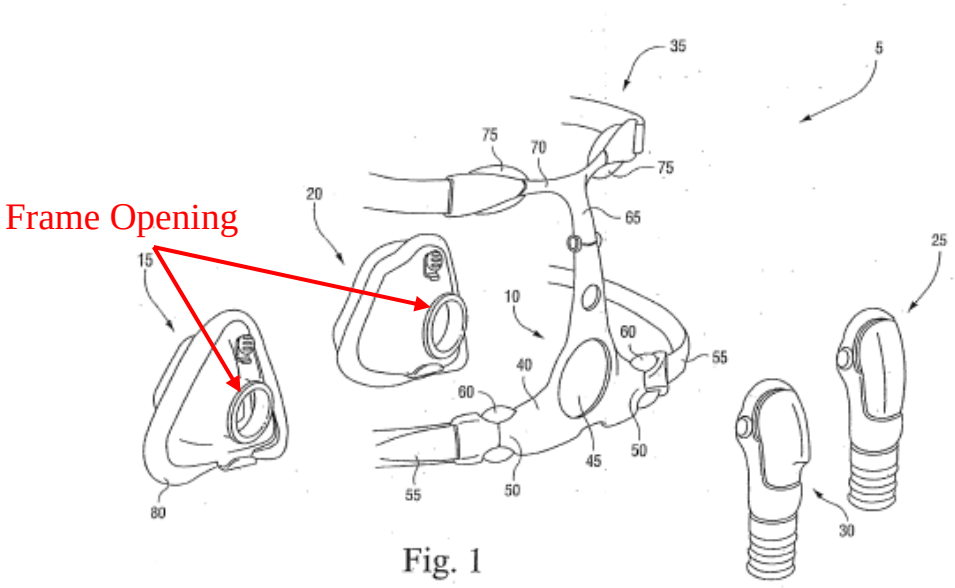


Fig. 1

vi. "headgear to maintain the mask system in a desired position on the patient's face, the headgear comprising a pair of upper headgear straps each configured to extend above a respective one of the patient's ears in use and a pair of lower headgear straps each configured to extend below a respective one of the patient's ears in use"

As shown below, Ng discloses pairs of upper and lower headgear straps 55. Ex. 1410 ¶ 30.

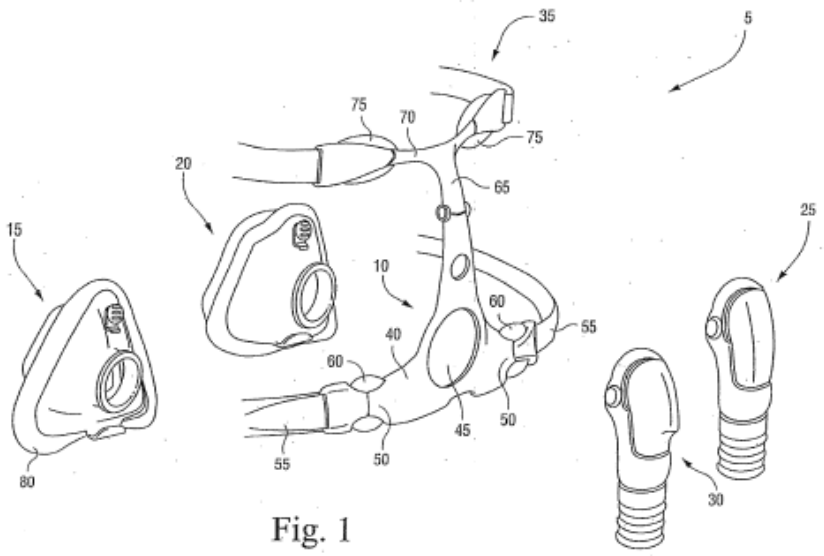


Fig. 1

vii. "wherein a free end of each of the upper headgear straps and the lower headgear straps includes a hook tab structured to engage a remainder of the respective upper headgear strap and respective lower headgear strap to secure the upper and lower straps in place in a length adjustable manner"

As discussed above, Ng and FlexiFit both teach this feature. *See supra* § VII(H)(2)(a).

viii. "wherein the headgear includes a pair of top straps and a pair of rear straps, each said top strap being configured to extend from generally above a respective ear of the patient such that the top straps cross over the top of the patient's head in use, the rear straps being adapted to pass behind the patient's head in use, and"

As discussed above, Ng and FlexiFit both teach pairs of top and rear straps. *See supra* § VII(H)(2)(a).

ix. "wherein the rear straps and the top straps together at least partly form a closed loop to encircle a rear portion of the patient's head when in use"

As discussed above, Ng and FlexiFit both teach a rear closed loop. *See supra* § VII(H)(2)(b).

x. "a shroud module including headgear connectors adapted to removably attach to the headgear"

As discussed above, Ng and Thomlinson both disclose a shroud module with headgear connectors. *See supra* § VII(B)(3)(a)(ii).

xi. "wherein the headgear connectors include two upper connectors associated with the upper headgear straps"

As discussed above, Ng and FlexiFit both disclose two upper headgear connectors. *See supra* § VII(H)(2)(a).

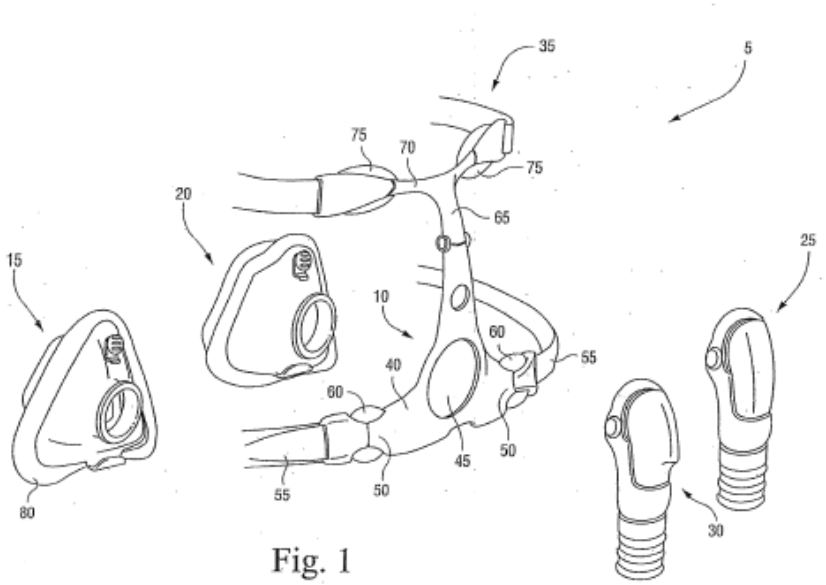


Fig. 1

xii. "the shroud module having an opening of circular shape, and two lower connectors associated with the lower headgear straps"

As shown below, Ng discloses a circular shroud opening 45 and two lower headgear connectors associated with headgear straps 55. Ex. 1410 ¶ 30.

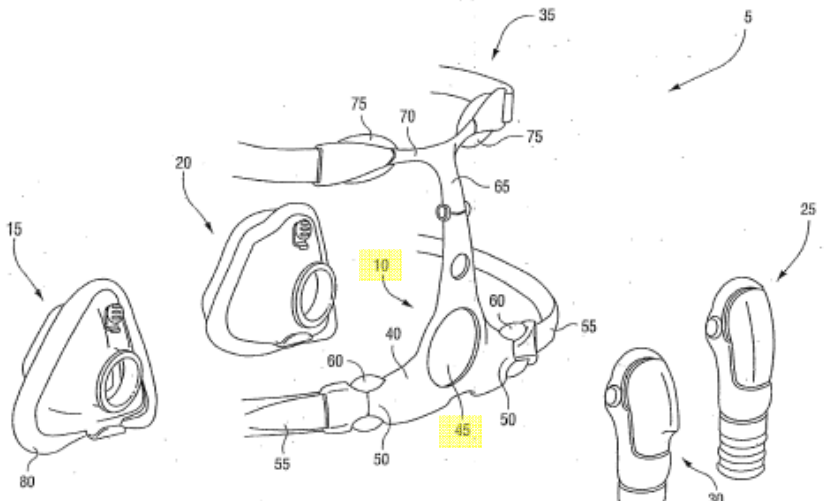
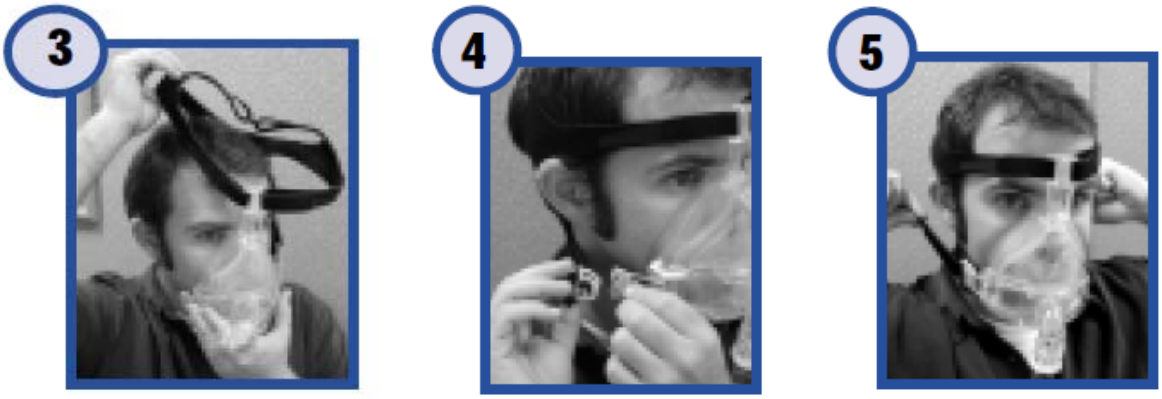


Fig. 1

xiii. "each said upper headgear connector including a slot or receiving hole adapted to receive one of the upper headgear straps"

As explained above, the combination of Ng and Thomlinson teaches upper headgear connector slots. *See supra* § VII(D)(2)(a). As shown below, FlexiFit also discloses upper headgear slots. Ex. 1417 at 10 ("ASSEMBLING YOUR MASK").



xiv. "wherein the shroud module and the frame of the cushion module are configured to be removably snap-fit attached to one another in a non-rotatable manner by pushing the shroud module towards the frame along a longitudinal axis of both the opening of the frame and the opening of the shroud"

As explained above, Ng discloses the shroud module and the frame are attached in a non-rotatable manner. *See supra* § VII(B)(3)(a)(v). Further, as explained above, the combination of Ng and Matula-II teaches this snap-fit arrangement. *See supra* § VII(C)(2)(d).

xv. "and an elbow rotatably attached to and carried by the shroud module or the frame of the cushion module, the elbow being configured to deliver the positive pressure air to the breathing chamber"

As explained above, the combination of Ng and Barnett teaches an elbow rotatably attached to and carried by the shroud module. *See supra* § (VII)(E)(2).

xvi. "the elbow including a swivel adapted to connect to an air delivery tube"

Ng does not expressly disclose a swivel, but swivels were well-known prior to the '931 Patent. Ex. 1402 ¶¶ 250–254. For example, Worboys discloses that the

elbow "typically will be provided with a swivel joint which in turn is connected to an air delivery tube." Ex. 1415 ¶ 105.

A person of skill would have been motivated to provide the swivel to facilitate easy adjustment and disconnection of the air delivery tube. Ex. 1402 ¶ 254. Combining these features would have been a mere combination of familiar elements according to known methods that does no more than yield predictable results. *KSR*, 550 U.S. at 416.

xvii. "the elbow including an anti-asphyxia valve (AAV) and a port that is selectively closed by a flap portion of the AAV."

As explained above, the combination of Ng and Worboys teaches an elbow with an AAV having a flap portion. *See supra* § VII(F)(2)(b).

b. Claim 46

Claim 46 depends from Claim 43 and includes:

"wherein: the elbow is rotatably attached the shroud module,"

As explained above, the combination of Ng and Barnett teaches an elbow that is rotatably attached to the shroud module. *See supra* § (VII)(E)(2).

“the upper headgear straps provide padding to the respective headgear connectors of the shroud on the patient's face in use,”

As explained above, the combination of Ng and Sprinkle teaches padded upper straps. *See supra* § VII(I)(2).

“the frame includes a protruding vent arrangement having a plurality of holes, wherein the shroud module includes a first opening to accommodate said protruding vent arrangement,”

As explained above, the combination of Ng and Thomlinson teaches the protruding vent arrangement. *See supra* § VII(B)(3)(a)(vi).

"further wherein the shroud module includes a second opening to accommodate the elbow,"

As explained above, a person of skill would have modified the Ng shroud module to directly couple with the elbow module. *See supra* § VII(E)(2)(a). As modified, the second opening in the shroud module would accommodate the elbow. Ex. 1402 ¶ 247.

"the frame includes an opening and the frame further includes a collar surrounding said opening, and wherein the shroud module includes a retaining portion with one or more rearward extending snap fingers structured to engage the collar with a snap-fit, and"

As explained above, the combination of Ng and Matula-II teaches this arrangement. *See supra* § VII(C)(2)(b).

"the top straps are connected together with a buckle allowing independent adjustment of each of the top straps."

As explained above, Ng teaches top straps connected together with a buckle. *See supra* § VII(H)(2)(a).

c. Claim 51

Claim 51 consists of a subset of the claim limitations recited in Claims 43 and 46. *See supra* §§ VII(L)(1)(a)–(b).

d. Claim 53

Claim 53 depends from Claim 51 and includes:

"wherein the second shroud opening and the frame opening are aligned along a common longitudinal axis, and wherein the shroud and the frame are removably snap-fit attached to one another by moving the shroud and the frame towards one another along the longitudinal axis."

As explained above, the combination of Ng and Matula-II teaches this snap-fit arrangement. *See supra* § VII(C)(2)(d).

e. Claim 54

Claim 54 depends from Claim 51 and includes:

"wherein the frame is semi-rigid or rigid."

As explained above, Ng discloses a rigid frame. *See supra* §§ VII(B)(3)(a)(iii)–(iv).

f. Claim 55

Claim 55 depends from Claim 54 and includes:

"wherein the frame is rigid."

As explained above, Ng discloses a rigid frame. *See supra* §§ VII(B)(3)(a)(iii)–(iv).

g. Claim 56

Claim 56 recites a system for treating a patient with sleep disordered breathing including:

"**the mask system of claim 51;"**

As explained above, the combination of Ng, Thomlinson, FlexiFit, Matula-II, Worboys, and Sprinkle teaches the mask system of claim 51. *See supra* § VII(L)(1)(c).

"and a flow generator to generate a supply of air at positive pressure to be delivered to the mask system, wherein the air delivery tube is configured to deliver the supply of air from the flow generator to the mask system."

As explained above, Ng discloses a flow generator, and it was common knowledge to use an air delivery tube to deliver air from the flow generator. *See supra* §§ VII(B)(3)(c), VII(B)(3)(f).

M. Ground 12: Claim 65 would have been obvious over Ng in view of Thomlinson, Barnett, and Matula-II

1. Limitations of Claim 65

A person of skill in the art at the time of the purported invention would have been motivated to combine the teachings of Ng, Thomlinson, Barnett, and Matula-II for at least the reasons provided above. *See supra* §§ VII(B)(3), VII(C)(2),

VII(E)(2). Although Claim 57 is not being challenged in this Petition, Claim 57 is discussed below because Claim 65 depends from Claim 57.

a. Claim 57

Independent Claim 57 includes:

i. "A mask system for treating a patient with sleep disordered breathing with a supply of air at positive pressure, comprising:"

Ng discloses a mask system for treating sleep-disordered breathing. Ex. 1410 ¶ 29.

ii. "headgear including headgear straps"

As shown below, Ng discloses headgear straps 55. Ex. 1410 ¶ 30.

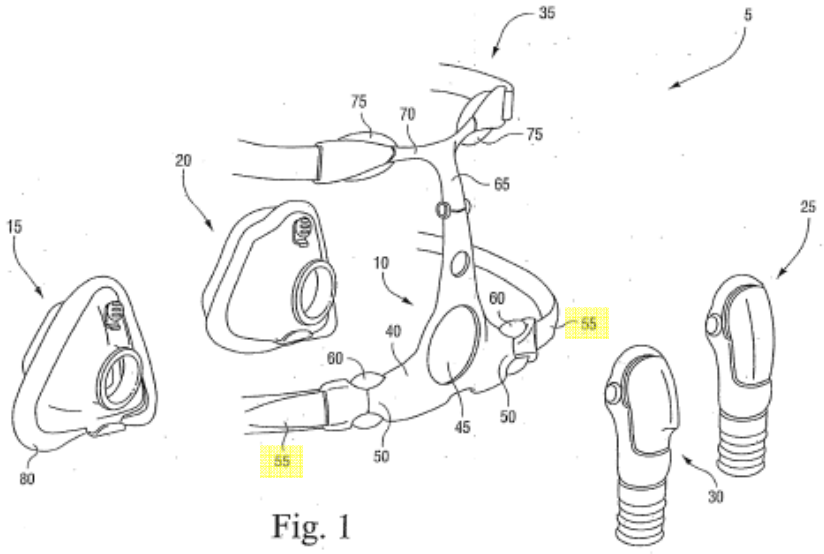


Fig. 1

iii. "a shroud module having a pair of upper headgear connectors and a pair of lower headgear connectors adapted to removably attach to the respective headgear straps of the headgear"

As explained above, the combination of Ng and Thomlinson teaches the claimed headgear connectors. *See supra* § VII(B)(3)(a)(ii).

iv. "the shroud module having a front opening"

As shown below, Ng discloses a front shroud opening 45. Ex. 1410 ¶ 30.

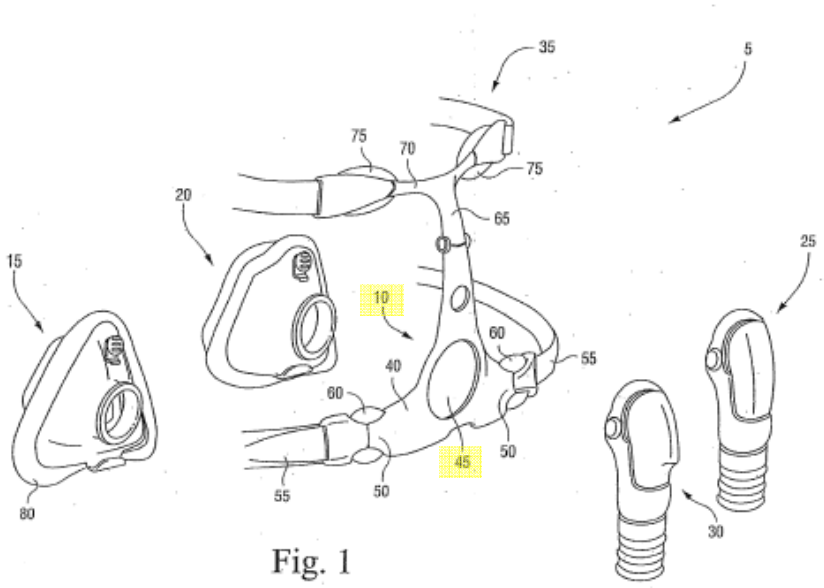


Fig. 1

v. "a rotatable elbow directly attached to the shroud; and"

As explained above, the combination of Ng and Barnett teaches this feature. *See supra* § (E)(2).

vi. "a cushion module, the cushion module comprising a frame defining a breathing chamber, the frame having a frame opening leading to the breathing chamber; and a cushion to form a seal with the patient's face,"

As explained above, Ng discloses a cushion module 15, 20 having a frame and a full-face cushion. *See supra* § (V)(B)(3)(a)(iii).

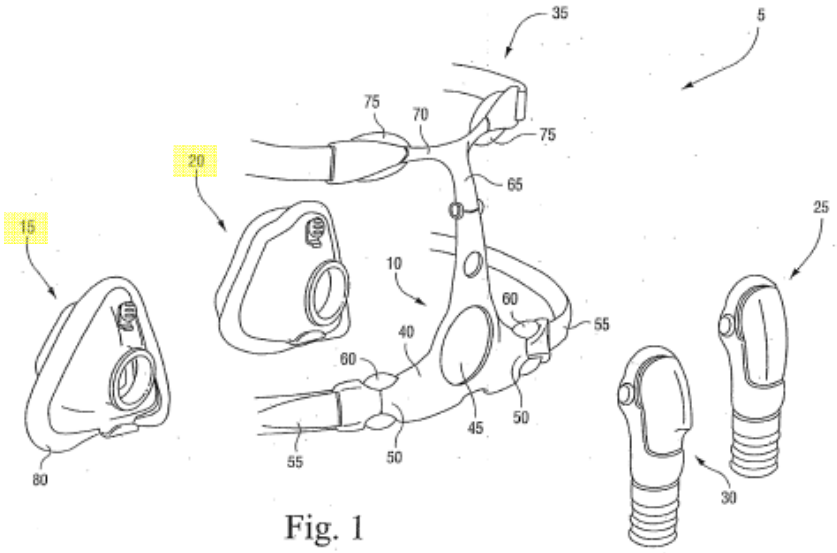


Fig. 1

vii. "wherein the cushion comprises a first, relatively soft, elastomeric material and the frame comprises a second material that is more rigid than the cushion"

As explained above, Ng discloses a soft cushion and a rigid frame. *See supra* §§ VII(B)(3)(a)(iii)–(iv).

viii. "wherein: the front opening of the shroud module and the frame opening of the frame are aligned along a common longitudinal axis, and wherein the shroud module and the cushion module are structured and arranged to be removably snap-fit attached to one another by moving the shroud module and the cushion module towards one another along the longitudinal axis, and the shroud module includes a retaining portion positioned rearwardly of the front opening, towards the frame, and structured to snap fit with the cushion module."

As explained above, the combination of Ng and Matula-II teaches this snap-fit arrangement. *See supra* §§ VII(C)(2)(b), VII(C)(2)(d).

b. Claim 65

Claim 65 depends from Claim 57 and includes:

"wherein the frame includes a protruding vent arrangement having a plurality of gas washout holes, wherein the shroud module includes an upper opening to accommodate said protruding vent arrangement."

As explained above, the combination of Ng and Thomlinson teaches the protruding vent arrangement. *See supra* § (VII)(B)(3)(a)(vi).

N. Secondary Considerations, Even if Considered, Fail to Overcome the Prima Facie Evidence of Obviousness

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). Further, a showing of secondary considerations requires a nexus between the evidence of the secondary consideration and a novel feature of the claims of the ’931 Patent. *See, e.g.*, *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010).

Patent Owner has not presented any evidence of secondary considerations in any of the instituted reviews of the ’931 Patent. Further, Petitioner does not believe that any potential evidence of 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, Petitioner will address those allegations in due course.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: June 22, 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 13,883 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,

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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 9,119,931** and **Fisher & Paykel Healthcare Exhibits 1401-1448** are being served on June 22, 2017, via FedEx Priority Overnight service on counsel of record for U.S. Patent 9,119,931 patent owner **RESMED LIMITED** at the address below:

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