

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Atty. Dkt.: PTB-4398-1485
Date: July 31, 2014

Attached for filing is the **UTILITY** patent application of:

Inventor: D'SOUZA et al.

Entitled: MASK SYSTEM

including the attachments as noted below:

Application and Signed Documents

41 pages of Specification, Claims and Abstract (including 21 numbered claims)

81 sheets of Drawing(s) (Figures 1 - 45)

- ☒ Declaration ☐ Combined Declaration and Assignment (submitted via EPAS) ☐ Verified Translation of Declaration
☐ Newly executed; ☒ A copy from a prior application (37 CFR 1.63(d))
☐ Assignment and Recordation Form Cover Sheet (paper filing) ☐ Assignment (submitted via EPAS)
☒ Power of Attorney ☐ 37 CFR 3.73(b) or 37 CFR 3.73(c) Statement ☒ General Power of Attorney Transmittal Letter
☒ Application Data Sheet
☐ English Translation

Priority Claim (Domestic and/or Foreign) (must be included in Application Data Sheet)

- ☒ Provisional/Nonprovisional Application(s) are identified in attached Application Data Sheet
☒ Continuation/Division/Continuation-In-Part parent application(s) are identified in attached Application Data Sheet
☒ PCT/foreign application(s) is/are identified in attached Application Data Sheet
☒ Incorporation by Reference statement is in the specification or Preliminary Amendment
☒ Copy the incorporation by reference from the specification or Preliminary Amendment and insert text here:

This application 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, now U.S. Patent 8,528,561, filed on January 18, 2013, which is a continuation of U.S. Application No. 12/736,024, now U.S. Patent 8,550,084, filed on September 2, 2010, which is the U.S. National Stage of PCT/AU2009/00241, filed February 27, 2009, which claims benefit to U.S. Provisional Application Nos. 61/064,406, filed March 4, 2008, 61/071,893, filed May 23, 2008, and 61/136,617, filed September 19, 2008, each of which is incorporated herein by reference in its entirety.

Certified Copy/Copies

- ☐ Certified copy(ies) of foreign application(s) attached
☐ Certified copy(ies) filed on _____ in prior Application No. _____ filed _____
☐ Interim copy(ies) of priority document(s) (effective March 16, 2013)
☐ Request to Retrieve Electronic Priority Application(s) (for a non-EPO priority doc that is of record in an EPO application or a non-JPO priority document that is of record in a JPO application)

Prior U.S. Application(s)

- ☐ Request under 37 CFR 1.48(a) to delete inventor(s) named in prior application
☐ Petition filed in prior application to extend its life to ensure co-pendency of parent application

Preliminary Amendment

- ☐ Preliminary Amendment (Please enter the attached Preliminary Amendment prior to calculation of claims fees.)

Information Disclosure Statement

- ☒ Information Disclosure Statement (IDS) and Form(s) PTO/SB/08
☐ Copies of newly cited publications, other than U.S. patents and U.S. patent application publications, are attached
☐ English language and/or "concise explanation" is/was provided for each foreign language document
☒ Form(s) PTO/SB/08 listing the references cited in the parent application(s) (for continuing cases)

Other Documents

- ☐ Non-Publication Request
☐ Nucleotide and/or Amino Acid Sequence Submission ☐ Computer Readable Form (CRF) ☐ Specification Sequence Listing on ☐ CD-ROM or CD-R (2 copies) or ☐ Paper ☐ Statements verifying identity of above copies
☐ Authorization to Permit Access to Search Results by the European Patent Office (EPO) (Form PTO/SB/69)

☒ Other (itemize each attachment): Certification and Request for Prioritized Examination Under 37 CFR 1.102(e)

Small Entity

☐ Applicant claims "small entity" status. ☐ "Small entity" statement(s) attached

Micro Entity

☐ Applicant claims "micro entity" status. ☐ Micro entity certification statement filed herewith.

Fee Calculation

FILING FEE IS BASED ON CLAIMS AS FILED LESS ANY HEREWITH CANCELED

Utility Basic Filing Fee		\$280.00 (1011)	\$	280.00
		\$140.00 (2011)/\$70.00 (4011)/\$70.00 (3011)		
Utility Search Fee		\$600.00 (1111)/\$300.00 (2111)/\$ 150.00 (3111)	\$	600.00
Utility Examination Fee		\$720.00 (1311)/\$360.00 (2311)/\$ 180.00 (3311)	\$	720.00
Utility Application Size Fee (\$400.00) for each <u>additional</u> 50 pages that exceeds 100 pages):				
Paper filing: Total pages: 0-100 = 0		\$0.00 (1081)/	\$0.00 (2081) /\$0.00 (3081)	\$
Surcharge for Paper Filing		\$400.00 (1090)/\$200.00 (2090)/\$200.00 (3090)		
E-filing:				
Total pages: 122 *.75 = 92-100 = 0/50	=	0	\$0.00(1081)/	\$0.00 (2081)/\$ 0.00 (3081)
Total effective claims	21 - 20 (at least 20) =	1	x \$ 80.00 = \$80.00 (1202)/\$40.00 (2202)/\$ 20.00 (3202)	\$ 80.00
Independent claims	1 - 3 (at least 3) =	0	x \$ 420.00 = \$0.00 (1201)/\$0.00 (2201)/\$ 0.00 (3201)	\$
If any proper multiple dependent claims now added for first time, add \$780.00 (1203)/\$390.00 (2203)/\$ 195.00 (3203)				\$
(ignore improper)				
Request for Prioritized Examination		\$4000.00 (1817)	\$	4000.00
Processing Fee for Prioritized Examination		\$140.00	\$	140.00
		TOTAL FEE	\$	5,820.00

☒ CREDIT CARD OR DEPOSIT ACCOUNT PAYMENT (CREDIT CARD FORM ATTACHED IF PAPER FILING).

Extension of Time

Any future submission requiring an extension of time is hereby stated to include a petition for such time extension.

Deposit Account Authorization

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to Deposit Account No. 14-1140. However, **authorization is NOT given hereby to charge any extra claims fees or multiple dependent claims fees.**

Correspondence Address:

Customer Number:

23117

Telephone: (703) 816-4000

Facsimile: (703) 816-4100

PTB:tlm

NIXON & VANDERHYTE P.C.

By Attorney: Paul T. Bowen, Reg. No. 38,009

Signature: /Paul T. Bowen/

Electronic Patent Application Fee Transmittal				
Application Number:				
Filing Date:				
Title of Invention:		MASK SYSTEM		
First Named Inventor/Applicant Name:		Errol Savio Alex D'SOUZA		
Filer:		Paul Thomas Bowen/Tanja Majca		
Attorney Docket Number:		PTB-4398-1485		
Filed as Large Entity				
Track I Prioritized Examination - Nonprovisional Application under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Utility application filing	1011	1	280	280
Utility Search Fee	1111	1	600	600
Utility Examination Fee	1311	1	720	720
Request for Prioritized Examination	1817	1	4000	4000
Pages:				
Claims:				
Claims in Excess of 20	1202	1	80	80
Miscellaneous-Filing:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Publ. Fee- Early, Voluntary, or Normal	1504	1	0	0
PROCESSING FEE, EXCEPT PROV. APPLS.	1830	1	140	140
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				5820

Electronic Acknowledgement Receipt	
EFS ID:	19735465
Application Number:	14447673
International Application Number:	
Confirmation Number:	3036
Title of Invention:	MASK SYSTEM
First Named Inventor/Applicant Name:	Errol Savio Alex D'SOUZA
Customer Number:	23117
Filer:	Paul Thomas Bowen/Tanja Majca
Filer Authorized By:	Paul Thomas Bowen
Attorney Docket Number:	PTB-4398-1485
Receipt Date:	31-JUL-2014
Filing Date:	
Time Stamp:	09:09:16
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$5820
RAM confirmation Number	8238
Deposit Account	141140
Authorized User	BOWEN, PAUL T.
<p>The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:</p> <p>Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)</p> <p>Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)</p>	

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)					
Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)					
Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)					
File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	TrackOne Request	4398-1485_Track_1_Transmittal.PDF	118572	no	2
			b45b0f040a88e0d5001bc03cb4b895386570acdf		
Warnings:					
Information:					
2	Power of Attorney	4398-1485_PowerOfAttorney.pdf	212137	no	2
			32bde7ada5ef7f82f38fd249f1a0aca59d42a374		
Warnings:					
Information:					
3	Oath or Declaration filed	4398-1485_Declaration.pdf	1507751	no	5
			74b3bede8bcbcd87c89cd5b9bc773a528e6a8be988		
Warnings:					
Information:					
4	Application Data Sheet	4398-1485_Application_Data_Sheet.PDF	1561914	no	9
			c4eec69260e0c306a793a3c1a0fc612878535be1		
Warnings:					
Information:					
5		4398-1485_Specification_for_continuation.pdf	216979	yes	41
			6ab728cd09c671382999ab2a189cac0df1d94665		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Specification		1	37	
	Claims		38	40	
	Abstract		41	41	
Warnings:					
Information:					
6	Drawings-only black and white line drawings	4398-1485_Drawings.pdf	1200169	no	81
			e512775d1312bdce7294b238a82d8db1443c7e50		
Warnings:					

Information:					
7		4398-1485_Information_Disclosure_Statement.pdf	480322 23fd3559c85cd3d2571cf2cc83551530ee16ad8b	yes	41
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Transmittal Letter		1	6	
	Information Disclosure Statement (IDS) Form (SB08)		7	41	
Warnings:					
Information:					
8	Transmittal of New Application	4398-1485_Application_Transmittal.pdf	58669 031d2223b9fed32b0e59db5d5c275363026369c8	no	2
Warnings:					
Information:					
9	Fee Worksheet (SB06)	fee-info.pdf	42180 619aed4075fc9920efe2c298aee8635d8a5fd72e	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			5398693		
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					

TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS			
NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5. If the Power of Attorney by Applicant form is not accompanied by this transmittal form or an equivalent, the Power of Attorney will not be recognized in the application.			
Application Number	Continuation of 13/964,280		
Filing Date	Herewith		
First Named Inventor	Errol Savio Alex D'Souza		
Title	MASK SYSTEM		
Art Unit	Unassigned		
Examiner Name	Unassigned		
Attorney Docket Number	PTB-4398-1485		
SIGNATURE of Applicant or Patent Practitioner			
Signature	/Paul T. Bowen/	Date	July 31, 2014
Name	Paul T. Bowen	Telephone	703-816-4019
Registration Number	38,009		
NOTE This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications.			
<input checked="" type="checkbox"/> *Total of <u>1</u> forms are submitted.			

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

- ☒ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above: 23117
- OR
- ☐ I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

- ☒ The address associated with the above-mentioned Customer Number
- OR
- ☐ The address associated with Customer Number:
- OR

Firm or Individual Name				
Address				
City	State	Zip		
Country				
Telephone	Email			

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

Resmed Limited

- ☐ Inventor or Joint Inventor (title not required below)
- ☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)
- ☒ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)
- ☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature	<u>[Signature]</u>	Date (Optional)	<u>12 MARCH 2014</u>
Name	<u>MAAK ABOURIZK</u>		
Title	<u>VICE PRESIDENT INTELLECTUAL PROPERTY & LEGAL COUNSEL</u>		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

☒ Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Doc code: Oath
Document Description: Oath or declaration filed

Attorney Docket Number	PTB-4398-1303
First Named Inventor	Eva NG

**INVENTOR'S DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)
USING AN APPLICATION DATA SHEET (37 CFR 1.76)**

☒ Declaration Submitted With Initial Filing

OR

☐ Declaration Submitted After Initial Filing (surcharge (37 C.F.R. § 1.16(f)) required)

MASK SYSTEM

(Title of the Invention)

As a below named inventor, I hereby declare that:

This declaration is directed to:

☒ The attached application.

OR

☐ United States Application Number or PCT International application number _____
filed on _____

The above-identified application was made or authorized to be made by me.

I believe I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in document filed in a parent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available. Petitioner/applicant is advised that documents which form the record of a patent application (such as the PTO/SB/01) are placed into the Privacy Act system of records DEPARTMENT OF COMMERCE, COMMERCE-PAT-7, System name: Patent Application Files. Documents not retained in an application file (such as the PTO-2038) are placed into the Privacy Act system of COMMERCE/PAT-TM-10, System name: Deposit Accounts and Electronic Funds Transfer Profiles.

Legal Name of Additional Joint Inventor, if any:

(E.g., Given Name (first and middle (if any)) and Family Name or Surname)

Errol

Savio Alex

D'SOUZA

Inventor's Signature:

Eva NG

Date:

20TH DECEMBER 2012

"Note: PTO Rules state "A person may not execute an oath or declaration for an application unless that person has reviewed and understands the contents of the application, including the claims, and is aware of the duty to disclose to the Office all information known to the person to be material to patentability as defined in [37 CFR] § 1.56."

Doc code: Oath
Document Description: Oath or declaration filed

Attorney Docket Number	PTB-4398-1303
First Named Inventor	Eva NG

**INVENTOR'S DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)
USING AN APPLICATION DATA SHEET (37 CFR 1.76)**

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MASK SYSTEM

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OR

☐ United States Application Number or PCT International application number _____
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Legal Name of Additional Joint Inventor, if any:

(E.g., Given Name (first and middle (if any)) and Family Name or Surname)

Matthew

EVES

Inventor's Signature:



Date:

14 DEC 2012

"Note: PTO Rules state "A person may not execute an oath or declaration for an application unless that person has reviewed and understands the contents of the application, including the claims, and is aware of the duty to disclose to the Office all information known to the person to be material to patentability as defined in [37 CFR] § 1.56."

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Legal Name of Additional Joint Inventor, if any:

(E.g., Given Name (first and middle (if any)) and Family Name or Surname)

David

James

LOCKWOOD

Inventor's Signature:

David Lockwood

Date:

15 JAN 2013

"Note: PTO Rules state "A person may not execute an oath or declaration for an application unless that person has reviewed and understands the contents of the application, including the claims, and is aware of the duty to disclose to the Office all information known to the person to be material to patentability as defined in [37 CFR] § 1.56."

2079114

Doc code: Oath
Document Description: Oath or declaration filed

Attorney Docket Number	PTB-4398-1303
First Named Inventor	Eva NG

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I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in document filed in a parent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available. Petitioner/applicant is advised that documents which form the record of a patent application (such as the PTO/SB/01) are placed into the Privacy Act system of records DEPARTMENT OF COMMERCE, COMMERCE-PAT-7, System name: Patent Application Files. Documents not retained in an application file (such as the PTO-2038) are placed into the Privacy Act system of COMMERCE/PAT-TM-10, System name: Deposit Accounts and Electronic Funds Transfer Profiles.

Legal Name of Additional Joint Inventor, if any:

(E.g., Given Name (first and middle (if any)) and Family Name or Surname)

Zoran

VALCIC

Inventor's Signature:

Eva NG

Date:

5 Dec 2012

"Note: PTO Rules state "A person may not execute an oath or declaration for an application unless that person has reviewed and understands the contents of the application, including the claims, and is aware of the duty to disclose to the Office all information known to the person to be material to patentability as defined in [37 CFR] § 1.56."

Doc code: Oath
Document Description: Oath or declaration filed

Attorney Docket Number	PTB-4398-1303
First Named Inventor	Eva NG

**INVENTOR'S DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)
USING AN APPLICATION DATA SHEET (37 CFR 1.76)**

☒ Declaration Submitted With Initial Filing

OR

☐ Declaration Submitted After Initial Filing (surcharge (37 C.F.R. § 1.16(f)) required)

MASK SYSTEM

(Title of the Invention)

As a below named inventor, I hereby declare that:

This declaration is directed to:

☒ The attached application,

OR

☐ United States Application Number or PCT International application number _____
filed on _____

The above-identified application was made or authorized to be made by me

I believe I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in document filed in a parent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available. Petitioner/applicant is advised that documents which form the record of a patent application (such as the PTO/SB/01) are placed into the Privacy Act system of records DEPARTMENT OF COMMERCE, COMMERCE-PAT-7, System name: Patent Application Files. Documents not retained in an application file (such as the PTO-2038) are placed into the Privacy Act system of COMMERCE/PAT-TM-10, System name: Deposit Accounts and Electronic Funds Transfer Profiles.

Legal Name of Additional Joint Inventor, if any:

(E.g., Given Name (first and middle (if any)) and Family Name or Surname)

Jaime Jane

Graeme

WEHBEH

Inventor's Signature:

[Signature]

Date:

14 Dec 12

"Note: PTO Rules state "A person may not execute an oath or declaration for an application unless that person has reviewed and understands the contents of the application, including the claims, and is aware of the duty to disclose to the Office all information known to the person to be material to patentability as defined in [37 CFR] § 1.56."

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	PTB-4398-1485
		Application Number	
Title of Invention	MASK SYSTEM		
<p>The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.</p> <p>This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.</p>			

Secrecy Order 37 CFR 5.2

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1					Remove
Legal Name					
Prefix	Given Name	Middle Name	Family Name	Suffix	
	Errol	Savio Alex	D'SOUZA		
Residence Information (Select One) <input type="radio"/> US Residency <input checked="" type="radio"/> Non US Residency <input type="radio"/> Active US Military Service					
City	Sydney	Country of Residence i	AU		
Mailing Address of Inventor:					
Address 1		c/o ResMed Limited			
Address 2		1 Elizabeth Macarthur Drive			
City	Bella Vista, New South Wales		State/Province		
Postal Code		2153	Country i	AU	
Inventor 2					Remove
Legal Name					
Prefix	Given Name	Middle Name	Family Name	Suffix	
	Matthew		EVES		
Residence Information (Select One) <input type="radio"/> US Residency <input checked="" type="radio"/> Non US Residency <input type="radio"/> Active US Military Service					
City	Sydney	Country of Residence i	AU		
Mailing Address of Inventor:					
Address 1		c/o ResMed Limited			
Address 2		1 Elizabeth Macarthur Drive			
City	Bella Vista, New South Wales		State/Province		
Postal Code		2153	Country i	AU	
Inventor 3					Remove
Legal Name					

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	PTB-4398-1485
		Application Number	
Title of Invention	MASK SYSTEM		

Prefix	Given Name	Middle Name	Family Name	Suffix
	David	James	LOCKWOOD	
Residence Information (Select One) <input type="radio"/> US Residency <input checked="" type="radio"/> Non US Residency <input type="radio"/> Active US Military Service				
City	Gosford	Country of Residence i	AU	

Mailing Address of Inventor:

Address 1	Unit 2, 14 Pacific St,			
Address 2	Wamberal, New South Wales			
City	Gosford	State/Province		
Postal Code	2260	Country i	AU	

Inventor 4	Remove			
Legal Name				
Prefix	Given Name	Middle Name	Family Name	Suffix
	Zoran		VALCIC	
Residence Information (Select One) <input type="radio"/> US Residency <input checked="" type="radio"/> Non US Residency <input type="radio"/> Active US Military Service				
City	Sydney	Country of Residence i	AU	

Mailing Address of Inventor:

Address 1	c/o ResMed Limited			
Address 2	1 Elizabeth Macarthur Drive			
City	Bella Vista, New South Wales	State/Province		
Postal Code	2153	Country i	AU	

Inventor 5	Remove			
Legal Name				
Prefix	Given Name	Middle Name	Family Name	Suffix
	Jamie	Graeme	WEHBEH	
Residence Information (Select One) <input type="radio"/> US Residency <input checked="" type="radio"/> Non US Residency <input type="radio"/> Active US Military Service				
City	Sydney	Country of Residence i	AU	

Mailing Address of Inventor:

Address 1	c/o ResMed Limited			
Address 2	1 Elizabeth Macarthur Drive			
City	Bella Vista, New South Wales	State/Province		
Postal Code	2153	Country i	AU	

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	PTB-4398-1485
		Application Number	
Title of Invention	MASK SYSTEM		

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button.

Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).

☐ An Address is being provided for the correspondence information of this application.

Customer Number 23117

Email Address

Add Email

Remove Email

Application Information:

Title of the Invention	MASK SYSTEM		
Attorney Docket Number	PTB-4398-1485	Small Entity Status Claimed	<input type="checkbox"/>
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	81	Suggested Figure for Publication (if any)	

Filing By Reference :

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32). Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	PTB-4398-1485
		Application Number	
Title of Invention	MASK SYSTEM		
Please Select One:	<input checked="" type="radio"/> Customer Number	<input type="radio"/> US Patent Practitioner	<input type="radio"/> Limited Recognition (37 CFR 11.9)
Customer Number	23117		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.

When referring to the current application, please leave the application number blank.

Prior Application Status			Remove		
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)		
	Continuation of	13964280	2013-08-12		
Prior Application Status	Patented	Remove			
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13964280	Continuation of	13745077	2013-01-18	8528561	2013-09-10
Prior Application Status	Patented	Remove			
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13745077	Continuation of	12736024	2010-09-02	8550084	2013-10-08
Prior Application Status	Expired	Remove			
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)		
12736024	a 371 of international	PCT/AU2009/000241	2009-02-27		
Prior Application Status	Expired	Remove			
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)		
PCT/AU2009/000241	Claims benefit of provisional	61064406	2008-03-04		
Prior Application Status	Expired	Remove			
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)		
PCT/AU2009/000241	Claims benefit of provisional	61071893	2008-05-23		
Prior Application Status	Expired	Remove			
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)		
PCT/AU2009/000241	Claims benefit of provisional	61136617	2008-09-19		
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the Add button.					Add

Foreign Priority Information:

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	PTB-4398-1485
		Application Number	
Title of Invention	MASK SYSTEM		

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(d). When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX) the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(h)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Remove			
Application Number	Country ⁱ	Filing Date (YYYY-MM-DD)	Access Code ⁱ (if applicable)
Additional Foreign Priority Data may be generated within this form by selecting the Add button.			Add

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

<p>This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.</p> <p><input type="checkbox"/> NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.</p>
--

Authorization to Permit Access:

<input type="checkbox"/> Authorization to Permit Access to the Instant Application by the Participating Offices

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	PTB-4398-1485
		Application Number	
Title of Invention	MASK SYSTEM		

If checked, the undersigned hereby grants the USPTO authority to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the World Intellectual Property Office (WIPO), and any other intellectual property offices in which a foreign application claiming priority to the instant patent application is filed access to the instant patent application. See 37 CFR 1.14(c) and (h). This box should not be checked if the applicant does not wish the EPO, JPO, KIPO, WIPO, or other intellectual property office in which a foreign application claiming priority to the instant patent application is filed to have access to the instant patent application.

In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the instant patent application with respect to: 1) the instant patent application-as-filed; 2) any foreign application to which the instant patent application claims priority under 35 U.S.C. 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the instant patent application; and 3) any U.S. application-as-filed from which benefit is sought in the instant patent application.

In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date of filing this Authorization.

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.			
Applicant 1			Remove
If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.			
Clear			
<input checked="" type="radio"/> Assignee	<input type="radio"/> Legal Representative under 35 U.S.C. 117	<input type="radio"/> Joint Inventor	
<input type="radio"/> Person to whom the inventor is obligated to assign.		<input type="radio"/> Person who shows sufficient proprietary interest	
If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:			
Name of the Deceased or Legally Incapacitated Inventor : <input type="text"/>			
If the Applicant is an Organization check here. <input checked="" type="checkbox"/>			
Organization Name	ResMed Limited		
Mailing Address Information:			
Address 1	1 Elizabeth Macarthur Drive		
Address 2			
City	Bella Vista, New South Wales	State/Province	
Country ⁱ	AU	Postal Code	2153
Phone Number		Fax Number	

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	PTB-4398-1485
		Application Number	
Title of Invention	MASK SYSTEM		
Email Address			
Additional Applicant Data may be generated within this form by selecting the Add button.			<input type="button" value="Add"/>

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Assignee 1				
Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.				
				<input type="button" value="Remove"/>
If the Assignee or Non-Applicant Assignee is an Organization check here.				<input type="checkbox"/>
Prefix	Given Name	Middle Name	Family Name	Suffix
Mailing Address Information For Assignee including Non-Applicant Assignee:				
Address 1				
Address 2				
City		State/Province		
Country i		Postal Code		
Phone Number		Fax Number		
Email Address				
Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.				<input type="button" value="Add"/>

Signature:

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications				
Signature	/Paul T. Bowen/		Date (YYYY-MM-DD)	2014-07-31
First Name	Paul	Last Name	Bowen	Registration Number
				38009
Additional Signature may be generated within this form by selecting the Add button.				<input type="button" value="Add"/>

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	PTB-4398-1485
		Application Number	
Title of Invention	MASK SYSTEM		

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

MASK SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application 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, now U.S. Patent 8,528,561, filed on January 18, 2013, which is a continuation of U.S. Application No. 12/736,024, now U.S. Patent 8,550,084, filed on September 2, 2010, which is the U.S. National Stage of PCT/AU2009/000241, filed February 27, 2009, which claims benefit to U.S. Provisional Application Nos. 61/064,406, filed March 4, 2008, 61/071,893, filed May 23, 2008, and 61/136,617, filed September 19, 2008, each of which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0002] The present invention relates to a mask system used for treatment, e.g., of Sleep Disordered Breathing (SDB) with Continuous Positive Airway Pressure (CPAP) or Non-Invasive Positive Pressure Ventilation (NIPPV).

BACKGROUND OF THE INVENTION

[0003] Patient interfaces, such as a full-face or nasal mask systems, for use with blowers and flow generators in the treatment of sleep disordered breathing (SDB), typically include a soft face-contacting portion, such as a cushion, and a rigid or semi-rigid shell or frame. In use, the interface is held in a sealing position by headgear so as to enable a supply of air at positive pressure (e.g., 2-30 cm H₂O) to be delivered to the patient's airways.

[0004] One factor in the efficacy of therapy and compliance of patients with therapy is the comfort and fit of the patient interface.

[0005] The present invention provides alternative arrangements of mask systems to enhance the efficacy of therapy and compliance of patients with therapy.

SUMMARY OF THE INVENTION

[0006] One aspect of the invention relates to a mask system provided without a forehead support adapted to engage the patient's forehead.

[0007] Another aspect of the invention relates to a mask system including a frame and a shroud removably connected to the frame and adapted to attach headgear.

[0008] Another aspect of the invention relates to a mask system including a frame defining a breathing chamber, a cushion provided to the frame and adapted to form a seal with the patient's face, and a shroud provided to the frame. The shroud and the frame are co-molded with one another. The frame is constructed of a first, relatively soft, elastomeric material and the shroud is constructed of a second material that is more rigid than the frame. At least a portion of the frame includes a concertina section having a plurality of folds. Each of the folds has a side wall with the side walls of the folds becoming progressively longer away from the patient's face.

[0009] Another aspect of the invention relates to a cushion module including a frame defining a breathing chamber and a cushion adapted to form a seal with the patient's face. The frame and the cushion are co-molded with one another. 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. At least a portion of the frame includes a concertina section.

[0010] Another aspect of the invention relates to a method for constructing a cushion module. The method includes molding a first part of the cushion module with a first, relatively soft, elastomeric material, co-molding a second part of the cushion module to the first part with a second material that is more rigid than the first material, and molding at least a portion of the second part to include a concertina section.

[0011] Another aspect of the invention relates to a shroud for a mask system including a retaining portion structured to retain a frame, a pair of upper headgear connectors each including an elongated arm and a slot at the free end of the arm adapted to receive a headgear strap, and a pair of lower headgear connectors each adapted to attach to a headgear strap, wherein the retaining portion, the upper headgear connectors, and the lower headgear connectors are integrally formed as a one piece structure.

[0012] Another aspect of the invention relates to a mask system including a frame defining a breathing chamber, a cushion provided to the frame and adapted to form a seal with the patient's face, a shroud provided to the frame and adapted to attach headgear, and an elbow provided to the frame and adapted to be connected to an air delivery tube that delivers breathable gas to the patient. The shroud includes a retaining mechanism structured to establish a positive connection between the shroud and the frame.

[0013] Another aspect of the invention relates to a mask system including a frame defining a breathing chamber and a cushion provided to the frame. The cushion is adapted to engage at least a portion of the patient's face. The cushion includes a base wall connected to an undercushion layer and a membrane, wherein the membrane extends around the perimeter of the cushion and contacts the patient's face. The undercushion layer is positioned underneath the membrane and supports the membrane. The under cushion layer provides differential support to the membrane at predetermined regions of the face.

[0014] Another aspect of the invention relates to a mask assembly for use in medical applications having a top and bottom ends defined by its position relative to a patient's face, wherein the mask assembly is connected to a plurality of flexible straps, which are adapted to engage the patient's head. The flexible straps engage at least two elongated rigid arms integrally molded to a portion of the mask assembly, and wherein the elongated arms are molded to the mask assembly proximal to the top end of the mask assembly.

[0015] Another aspect of the invention relates to a mask assembly for use in medical applications including a main body connected to a cushion adapted to cover nose and/or mouth and wherein the mask assembly is attached by a force substantially perpendicular towards the face and wherein the force is approximately constant along the length of the mask and is balanced by a portion of the cushion engaging the patient's cheeks.

[0016] Another aspect of the invention relates to a cushion for use with a medical mask including an outer membrane layer adapted to sealably engage a face and an undercushion layer adapted to support the membrane layer. The membrane or undercushion layer includes a surface positioned between the two layers adapted to allow the layers to slide against the respective surface.

[0017] Another aspect of the invention relates to a mask system including a frame defining a breathing chamber, a cushion provided to the frame and adapted to form a seal

with the patient's face, and a releasable shroud adapted to engage a portion of the outer surface of the frame, wherein the shroud is connected to straps to position the mask system.

[0018] Another aspect of the invention relates to a mask assembly for use in medical applications including an upper end and a lower end wherein the upper end is adapted to cover the nose and the lower end is adapted to cover the mouth of a patient. The mask assembly includes no forehead support and includes two stiffened members attached to the upper end on opposed sides of the mask assembly, and wherein the stiffened members include a general curved shape and adapted to avoid covering the patient's field of vision.

[0019] Another aspect of the invention relates to a cushion for attaching to a medical mask, wherein the cushion is flexible and includes a membrane attached to the circumference of the cushion adapted to seal against the face of a patient, and at least one undercushion adapted to support the membrane and positioned underneath the membrane to prevent collapse of the membrane, in use. The membrane is softer than the undercushion. The undercushion in the regions of nasal bridge or chin is between 0mm and 30mm in height as measured between the base and the tip of the undercushion.

[0020] Another aspect of the invention relates to a mask assembly for use in medical applications including an upper end and a lower end wherein the upper end is adapted to cover the nose and the lower end is adapted to cover the mouth of a patient. The mask assembly includes no forehead support and includes two stiffened members attached to the upper end on opposed sides of the mask assembly, and wherein the stiffened members include a general curved shape and adapted to avoid covering the patient's field of vision.

[0021] In an alternative embodiment, the mask system may include a headgear connector or rigidizer structured to attach to the frame with a snap-fit, mechanical interlock, friction fit, and/or grommet arrangement (e.g., constructed of rubber).

[0022] In an alternative embodiment, the mask system may include headgear having an arrangement of straps constructed of silicone and/or Breath-O-Prene™ material.

[0023] Other aspects, features, and advantages of this invention will become apparent from the following detailed description when taken in conjunction with the accompanying drawings, which are a part of this disclosure and which illustrate, by way of example, principles of this invention.

BRIEF DESCRIPTION OF THE DRAWINGS

- [0024] The accompanying drawings facilitate an understanding of the various embodiments of this invention. In such drawings:
- [0025] Fig. 1 is a front perspective view of a mask system according to an embodiment of the present invention;
- [0026] Fig. 1B is a perspective view showing the mask system of Fig. 1 with headgear positioned on a patient's head;
- [0027] Fig. 1C is a cross-sectional view through the mask system of Fig. 1;
- [0028] Fig. 1D is another cross-sectional view through the mask system of Fig. 1;
- [0029] Fig. 1E is a side view of the mask system of Fig. 1;
- [0030] Fig. 2 is a front perspective view showing the frame and cushion of the mask system of Fig. 1;
- [0031] Fig. 3 is an exploded perspective view of the mask system of Fig. 1 showing the frame, cushion, shroud, and elbow;
- [0032] Fig. 4 is another exploded perspective view of the mask system of Fig. 1 showing the frame, cushion, and shroud;
- [0033] Fig. 5 is an exploded perspective view of the mask system of Fig. 1 showing the shroud and assembled frame/cushion;
- [0034] Fig. 6 is a front perspective view showing the shroud of the mask system of Fig. 1;
- [0035] Fig. 7 is a front perspective view showing the cushion of the mask system of Fig. 1;
- [0036] Fig. 8 is a cross-sectional view showing a portion of the cushion of Fig. 7;
- [0037] Fig. 8B is a cross-sectional view through nasal bridge and chin regions of the cushion of Fig. 7;
- [0038] Fig. 9 is a plan view of headgear laid out flat according to an embodiment of the present invention;
- [0039] Fig. 10 is a front perspective view of a mask system according to another embodiment of the present invention;
- [0040] Fig. 11 is a front perspective view showing the frame of the mask system of Fig. 10;

- [0041] Fig. 12 is a front view showing the frame of the mask system of Fig. 10;
- [0042] Fig. 13 is a side view showing the frame of the mask system of Fig. 10;
- [0043] Fig. 14 is a front perspective view showing the shroud of the mask system of Fig. 10;
- [0044] Fig. 15 is a front view showing the shroud of the mask system of Fig. 10;
- [0045] Fig. 16 is a side view showing the shroud of the mask system of Fig. 10;
- [0046] Fig. 17 is a rear perspective view showing the shroud of the mask system of Fig. 10;
- [0047] Figs. 18-1 to 18-2 are cross-sectional views showing in sequential relation attachment of the shroud to the frame of the mask system of Fig. 10;
- [0048] Figs. 19-1 to 19-4 are cross-sectional views showing in sequential relation attachment of the shroud to the frame of the mask system of Fig. 10;
- [0049] Fig. 20 is a perspective view showing an alternative arrangement for attaching the shroud to the frame;
- [0050] Fig. 21 is a rear perspective view showing the shroud of the mask system of Fig. 10;
- [0051] Fig. 22 is a cross-sectional view showing attachment of the shroud to the frame of the mask system of Fig. 10;
- [0052] Fig. 23 is a cross-sectional view showing attachment of the shroud, frame, and elbow of the mask system of Fig. 10;
- [0053] Fig. 24 is a cross-sectional view showing an alternative arrangement for attaching the shroud to the frame;
- [0054] Fig. 25 is a front perspective view of a mask system according to another embodiment of the present invention;
- [0055] Fig. 26 is a rear perspective view of the mask system of Fig. 25;
- [0056] Fig. 27 is a front perspective view of a mask system according to another embodiment of the present invention;
- [0057] Fig. 28 is an exploded view of the mask system shown in Fig. 27;
- [0058] Fig. 29 is an enlarged front perspective view of the mask system shown in Fig. 17;
- [0059] Fig. 30 is a side view of the mask system shown in Fig. 27;

[0060] Figs. 31-1 is a rear view of a cushion according to an embodiment of the present invention;

[0061] Fig. 31-2 is a front view of the cushion shown in Fig. 31-1 with a partial cut-away;

[0062] Fig. 31-3 is a cross-section view through line 31-3-31-3 in Fig. 31-1;

[0063] Fig. 31-4 is a cross-section view through line 31-4-31-4 in Fig. 31-1;

[0064] Fig. 31-5 is a cross-section view through line 31-5-31-5 in Fig. 31-1;

[0065] Figs. 32-1 to 32-3 illustrate top, front, and side views respectively of a concertina section according to an embodiment of the present invention;

[0066] Fig. 33 is a side view of a mask system according to a variation of the present invention;

[0067] Fig. 34 illustrates a cushion including a concertina section according to an embodiment of the present invention;

[0068] Figs. 35-1 to 35-3 are front, side, and rear views of a mask system according to another embodiment of the present invention;

[0069] Fig. 36 is a perspective view of a shroud for a mask system according to an embodiment of the present invention;

[0070] Figs. 37-1 to 37-3 are perspective, front, and side views of a mask system according to another embodiment of the present invention;

[0071] Figs. 38-1 to 38-5 are perspective, front, top, side, and bottom views of a shroud of the mask system shown in Figs. 37-1 to 37-3;

[0072] Figs. 39-1 to 39-6 are perspective, front, side, bottom, and top views of a mask system according to another embodiment of the present invention;

[0073] Figs. 40-1 and 40-2 are perspective and side views of a mask system according to another embodiment of the present invention;

[0074] Fig. 40-3 is a perspective view of the frame of the mask system shown in Figs. 40-1 and 40-2;

[0075] Figs. 40-4 and 40-5 illustrate a retaining member of the frame shown in Fig. 40-3;

[0076] Figs. 40-6 and 40-7 illustrate a clip-on upper headgear connector of the mask system shown in Figs. 40-1 and 40-2;

- [0077] Figs. 41-1 and 41-2 are rear and front perspective views of a mask system according to another embodiment of the present invention;
- [0078] Figs. 41-3 and 41-4 are exploded views of the mask system shown in Figs. 41-1 and 41-2;
- [0079] Figs. 41-5 to 41-12 are various views of a clip-on upper headgear connector of the mask system shown in Figs. 41-1 and 41-2;
- [0080] Fig. 42-1 is a rear perspective view of a mask system according to another embodiment of the present invention;
- [0081] Fig. 42-2 is an exploded view of the mask system shown in Fig. 42-1;
- [0082] Figs. 42-3 to 42-7 are various views of a clip-on upper headgear connector of the mask system shown in Fig. 42-1;
- [0083] Figs. 43-1 to 43-4 are perspective, side, front, and rear views of a mask system according to another embodiment of the present invention;
- [0084] Fig. 44 illustrates a mask system according to another embodiment of the present invention; and
- [0085] Fig. 45 illustrates a mask system according to another embodiment of the present invention.

DETAILED DESCRIPTION OF ILLUSTRATED EMBODIMENTS

- [0086] The following description is provided in relation to several embodiments or examples which may share common characteristics and features. It is to be understood that one or more features of any one embodiment or example may be combinable with one or more features of the other embodiments or examples. In addition, any single feature or combination of features in any of the embodiments or examples may constitute additional embodiments or examples.
- [0087] In this specification, the word “comprising” is to be understood in its “open” sense, that is, in the sense of “including”, and thus not limited to its “closed” sense, that is the sense of “consisting only of”. A corresponding meaning is to be attributed to the corresponding words “comprise”, “comprised” and “comprises” where they appear.
- [0088] The term “air” will be taken to include breathable gases, for example air with supplemental oxygen.

[0089] The term “shroud” will be taken to include components that partially or fully cover a second component within the illustrated embodiments. In an embodiment, the shroud may include the component that partially covers or is mounted on the frame components of the illustrated embodiments.

[0090] The term “positive connection” will be taken to include connections between components of the illustrated embodiments wherein connectors mounted on respective components are adapted to engage each other respectively.

1. Mask System

[0091] Embodiments of the invention are directed towards a mask system provided without a forehead support adapted to engage the patient's forehead. Such arrangement provides the mask system with a less obtrusive arrangement which does not significantly affect the patient's field of view. Although the system is designed such that a forehead support is not required, such a forehead support can be added if desired.

[0092] As described in greater detail below, the mask system includes a frame, a cushion provided to the frame and adapted to form a seal with the patient's face, a shroud provided to the frame and adapted to attach headgear, and an elbow provided to the frame and adapted to be connected to an air delivery tube that delivers breathable gas to the patient. Headgear may be removably attached to the shroud to maintain the mask system in a desired adjusted position on the patient's face. The mask system is intended for use in positive pressure therapy for users with Obstructive Sleep Apnea (OSA) or another respiratory disorder.

[0093] While each embodiment below is described as including a full-face or oro-nasal interface type, each embodiment may be adapted for use with other suitable interface types. That is, the interface type is merely exemplary, and each embodiment may be adapted to include other interface types, e.g., nasal interface, nasal mask, nasal prongs, etc.

2. Stabilizing Mechanisms

[0094] The stabilizing mechanisms (e.g., frame, shroud, headgear with associated headgear vectors) of a mask system according to embodiments of the invention are structured to accommodate the elimination of a forehead support from a full-face type interface. For

example, a forehead support typically eliminates rotation of the mask system in the sagittal and coronal planes, so the mask system and headgear according to embodiments of the invention are structured to take on these functions since there is no forehead support.

[0095] The headgear is connected to the top and bottom of the frame either directly or via the shroud, which shroud provides headgear connection points for headgear positioned and arranged to stably maintain the mask system in position on the patient's face.

2.1 Frame

[0096] As shown in Figs. 1, 1B-1E, and 2-5, the frame 1040 of the mask system 1010 is structured to maintain the cushion 1060, shroud 1020, and elbow 1070 in an operative position with respect to the patient's face. The frame 1040 is constructed (e.g., injection molded) from a more rigid material (e.g., polyurethane) than the cushion 1060 (made of, e.g., silicone), however other materials may function likely as well (e.g., polycarbonate). In an embodiment, the frame has a general wall thickness of about 1-2 mm, e.g., 1.5 mm.

[0097] The frame 1040 defines a breathing chamber or cavity adapted to receive the patient's nose and mouth and provide air communication to the patient. One or the lower portion of the frame 1040 includes an opening 1046 adapted to receive or otherwise communicate with the elbow 1070 (e.g., swivel elbow) and another or upper portion of the frame 1040 includes a vent arrangement 1076 for gas washout. In addition, the upper portion of the frame 1040 includes an interfacing structure 1048 adapted to interface or otherwise removably connect to the shroud 1020.

[0098] Figs. 27-30 shows a mask system 10 including a frame 40 with a cushion 44 that provides a sealing portion or sealing ring adapted to form a seal with the patient's nose and/or mouth. Also, the frame 40 includes an opening 46 that is adapted to communicate with the elbow 70.

2.2 Shroud

[0099] As shown in Figs. 1 and 3-6, the shroud 1020 is connected to the frame 1040 and is structured to attach headgear to the mask system. In an embodiment, the shroud 1020 is constructed (e.g., injection molded) of a resilient material including but not limited to plastic or nylon (e.g., Nylon 12). However, the shroud may be constructed of other suitable materials, e.g., polycarbonate, polypropylene, thermoplastic elastomer (TPE), Pocan®, etc. In an embodiment, the shroud has a general wall thickness of about 1-2 mm, e.g., 1.3 mm.

[00100] The top end of the shroud 1020 is adapted to be positioned proximal to the nasal bridge region or nose of the patient and the bottom end is adapted to be positioned proximal to the mouth or chin of the patient. The 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).

[00101] Upper headgear connectors 1024 extend from each side of the top end, and lower headgear connectors 1025 extend from each side of the lower end. The headgear connectors 1024, 1025 may be integrally molded or otherwise attached to the shroud.

2.2.1 Upper Headgear Connectors

[00102] Each upper headgear connector 1024 includes an elongated arm 1026 and a slot or receiving hole 1027 at the free end of the arm 1026 adapted to receive a respective headgear strap. In use, the arms 1026 extend around the face of the patient in a generally concave angle below the eyes of the patient so as to avoid the patient's field of view, i.e., direct headgear away from the patient's eyes. For example, as shown in Fig. 1E, each arm 1026 may extend at an angle α between about 10-25° (e.g., 17°) with respect to horizontal. That is, each arm 1026 is suitably formed, shaped, or contoured to follow the contours of the patient's face and avoid line of sight in use. In an embodiment, the shape of the arms may be generally arcuate and adapted to extend in a direction across the cheek of the patient, while avoiding the eyes or limiting the field of vision. In an embodiment, the arms may be integrally molded to the shroud of the mask system. One possible advantage of molding the arms onto the shroud is that it greatly increases manufacturability and also the shroud may be

easily replaced in the case of accidental breakage of the arms rather than replacing the complete mask system. Additionally, molding of the arms onto the shroud may greatly increase the strength of the connection and reduce or limit the actual likelihood of breakage of the arms.

[00103] In an embodiment, the arms 1026 are at least semi-rigid (e.g., relatively rigid) so as to prevent up and down movement or bending of the arms relative to the face of the patient. Thus, the arms 1026 may act as rigidizers to effectively act as a level arrangement and generate a mechanical advantage wherein the pressure or force applied to top end of the mask system is readjusted to a fulcrum point being about the center of balance between the top and bottom ends of the mask system. In an embodiment, the arms are attached to the highest possible point relative to the mask system to additionally stabilize the configuration. In an embodiment, the fulcrum point or moment of pivoting is positioned between the upper and lower connection points of the straps, and wherein the design, angle, length and/or configuration of the arms 1026 may effectively adjust the fulcrum point. In the illustrated embodiment, the fulcrum point is shown to be between the vent arrangement and elbow of the mask system. Additionally, when positioned on the face, the mask system may have a fulcrum point around or about the region between the bottom of the patient's nose and lip area. This feature effectively stabilizes the mask system on the patient's face without the traditional need for a forehead support.

[00104] The net result of the arms 1026 mounted in a position extending from the top end of the mask system around the face of the patient is that the mask system is more stable and reduces the net torsional forces experienced about the x- axis 1001 (see Fig. 1) for the mask system in use. Please note that the arms 1026 may be rigidly connected to the mask system in other suitable positions to generate a similar result.

[00105] In an embodiment, the arms 1026 may be used to stabilize the mask system by contacting the patient's face at the cheeks. A cheek pad may be provided to the inner surface of the arm to support the arm on the patient's cheek in use. Also, the arms 1026 may be enveloped in a soft fabric sleeve to act as additional padding against the cheeks of the patient. The soft fabric sleeve may be in the configuration of an elastic tube covering a portion of the arms 1026.

2.2.2 Lower Headgear Connectors

[00106] Each lower headgear connector 1025 includes an abbreviated arm and a clip receptacle 1031 at the free end of the arm adapted to be removably interlocked with a headgear clip associated with a respective headgear strap. The clips allow for easier positioning or donning/removal of the mask system. In an embodiment, the abbreviated arms and clips are also relatively rigid so as to prevent lateral movement of the arms along the y-axis 1002, relative to the mask system in use.

[00107] Figs. 27-30 illustrate an exemplary headgear clip 33 adapted to be removably interlocked with a clip receptacle 31. As best shown in Fig. 28, each clip 33 includes two spring arms 35 adapted to interlock with the respective clip receptacle 31 with a snap-fit and a slot 37 adapted to receive a respective headgear strap in use.

2.2.3 Alternative Headgear Connectors

[00108] As shown in Figs. 27-30, the arm 26 may be removably coupled to the shroud, e.g., arm 26 includes clip structure adapted to removably interlock with a clip receptacle provided to the shroud. This arrangement allows different styles of upper and lower headgear connectors to be used with the shroud, e.g., arms for both upper and lower headgear connectors, clips for both upper and lower headgear connectors, different length arms for upper and lower headgear connectors, etc.

[00109] However, the shroud may provide other suitable arrangements for attaching headgear straps of headgear. Also, the shroud may include one or more additional components, e.g., forehead support.

2.2.4 Headgear Connector Positioning

[00110] In the embodiment of Figs. 1-6, the upper and lower headgear connectors 1024, 1025 provide headgear connection points that are as far from each other as possible (i.e., top and bottom of frame) to allow for greater adjustability (e.g., allows adjustment at the top and bottom of the mask system) and stability (e.g., anchor points spread out around the mask system so more secure on the patient's face). Also, the upper headgear connectors are positioned as close to the top of the mask system as possible without obstructing the patient's eyes in use.

2.2.5 Separate Shroud

[00111] In the embodiment of Figs. 1-6, the shroud 1020 is formed separately (e.g., molded) and attached to the frame 1040. Such arrangement facilitates molding of the shroud, allows different materials to be used for the frame and shroud (e.g., frame can be semi-rigid or rigid for stability and shroud with headgear rigidizers can be flexible for adjustment, allows the shroud to hide elbow retention features around elbow/frame opening for retaining elbow to frame (e.g., provides visual shroud for aesthetics), allows frame to be free of lower clip receptacles, allows shroud to be used with different size frames, and allows the shroud to be designed or stylized to minimize obtrusiveness of the mask system. The separate shroud may also allow the headgear, frame, cushion, and/or elbow to be replaced or washed independently.

2.2.6 Sleeves

[00112] In an embodiment, soft fabric sleeves may be mounted on the upper and/or lower headgear connectors. For example, the sleeves may be elastic and adapted to slide over the arms of the headgear connectors to form a tight fit. In an embodiment, the sleeves form elastic tubes. The sleeves may be padded to increase the comfort of the mask system in use. The sleeves may be particularly useful where the arms of the headgear connectors contact the patient's skin, e.g., to protect the patient's skin from irritation.

2.2.7 Arm Extends Over the Patient's Ear

[00113] Figs. 35-1 to 35-3 and 36 illustrate a shroud 220 for mask system 210 according to another embodiment of the present invention. The shroud 220 includes an annular retaining portion 222 structured to retain the frame 240 and upper and lower headgear connectors 224, 225 on each side of the retaining portion 222. In the illustrated embodiment, the shroud 220 is integrally formed in one piece (e.g., see Fig. 36).

[00114] In the illustrated embodiment, each upper headgear connector 224 includes an elongated arm 226 and a slot 227 at the free end of the arm 226 adapted to receive a respective rear strap 298 in use. As illustrated, the arm 226 is suitably contoured to extend along the cheeks and over the patient's ear just anterior of the patient's temple and retain the

respective rear strap 298 in spaced relation over the patient's ear, e.g., to avoid the strap rubbing or irritating the patient's ear in use.

[00115] Also, each arm 226 is structured to extend along and engage an upper strap 292 of the headgear in use. As illustrated, each arm 226 is secured to the upper strap 292 to add rigidity to the strap and stabilize the mask system on the patient's face in use. In addition, the strap 292 provides padding to the arm 226 on the patient's face in use. In an embodiment, the upper strap 292 may be fixed to the arm 226 by gluing or stitching for example. Alternatively, the arms 226 may be encapsulated by or inserted into respective straps 292 so that the arms 226 are substantially not visible.

[00116] Each lower headgear connector 225 includes an abbreviated arm 228 with a slot 229 at the free end of the arm 229 adapted to receive a respective lower strap 294 in use. As illustrated, the arm 228 is suitably oriented to retain the respective lower strap 294 in spaced relation under the patient's ear, e.g., to avoid the strap rubbing or irritating the patient's ear in use.

[00117] In an embodiment, each arm may be attached to the upper end of the mask system and curves below the patient's field of vision or eyes and curves upwards at an angle between about 10 to 20 degrees away from the horizontal axis.

[00118] In an alternative embodiment, as shown in Fig. 36, each lower headgear connector 225 may include a clip receptacle 231 adapted to be removably interlocked with a headgear clip (not shown) associated with a respective lower strap 294. In an embodiment, the headgear clip receptacle and clip may be similar to that on ResMed's Mirage Liberty™ mask. Exemplary clip arrangements are disclosed in U.S. Patent Publication Nos. 2007/0144525 and 2006/0283461, each of which is incorporated herein by reference in its entirety.

2.2.8 Shroud Without Upper Headgear Connector

[00119] Figs. 37-1 to 37-3 illustrate a mask system 310 according to another embodiment of the present invention. As illustrated, the mask system 310 includes a shroud 320, a frame 340, a cushion 344, and an elbow 370.

[00120] As best shown in Figs. 38-1 to 38-5, the shroud 320 includes an opening 322 structured to receive the elbow 370 and a headgear connector 325 on each side thereof. In the

illustrated embodiment, each headgear connector 325 includes a clip receptacle 331 adapted to be removably interlocked with a headgear clip (not shown) associated with a respective lower headgear strap.

[00121] The frame 340 is removably attached to the shroud 320, e.g., fingers and tabs 345 extending from opening 322 adapted to engage collar of frame 340.

[00122] The frame 340 includes an upper headgear connector 324 on each upper side thereof. Each headgear connector 324 includes a clip retainer 333 adapted to be removably interlocked with a headgear clip (not shown) associated with a respective upper headgear strap.

[00123] Figs. 39-1 to 39-6 illustrate an alternative version of the mask system 310, which is indicated with similar reference numerals. As illustrated, the frame 340 is provided without upper headgear connectors, and the each clip receptacle 331 includes an alternative configuration (e.g., holes for snap-fit tabs on the clip). Also, the shroud 320 in Figs. 39-1 to 39-6 includes support bars 329 structured to wrap around respective auxiliary ports 343, while the shroud 320 in Figs. 37-1 to 38-5 includes support bars 329 that extend in front of respective auxiliary ports 343.

2.3 Headgear

[00124] Headgear may be removably attached to the headgear connectors 1024, 1025 of the shroud 1020 to maintain the mask system 1010 in a desired position on the patient's face, e.g., see Fig. 1B.

[00125] As shown in Fig. 9, the headgear 1090 includes a pair of upper and lower straps 1092, 1094 with the upper straps 1092 removably attached to respective upper headgear connectors 1024 and the lower straps 1094 removably attached to respective lower headgear connectors 1025. The free end of each strap may include a Velcro® tab structured to engage the remainder of the strap to secure the strap in place. Such Velcro® attachment also allows adjustment of the length of the straps. However, the upper and lower headgear straps may be secured to the shroud in any other suitable manners, e.g., adjustable ladder-lock arrangement, etc.

[00126] The upper straps 1092 split at the crown of the patient's head to top straps 1096 (e.g., connected to one another by a buckle) adapted to pass over the top of the patient's

head in use and rear straps 1098 adapted to pass behind the patient's head in use. In an embodiment, the headgear 1090 is structured to be self-supporting.

[00127] In Fig. 9, the top straps 1096 are adapted to be connected to one another by a buckle. In an alternative embodiment, as shown in Fig. 27-30, headgear 90 may include upper and lower straps 92, 94, top strap 96, and rear strap 98, with the top straps 96 integral with one another.

[00128] The upper straps 1092 are designed to adjust the position of the mask in a similar way that an adjustable forehead support would alter the position of the mask system, i.e., move the top of the mask system closer or further away from the patient's nasal bridge.

[00129] Without the forehead support, the headgear is connected at the top and bottom of the mask frame 1040 via the shroud 1020, and in order to avoid the eyes and ears, the arm 1026 of the upper headgear connector extends at an angle. In doing so, the headgear vectors V1 and V2 (see Figs. 1 and 1B) are aligned such that the mask system may have a tendency to ride up the patient's face (i.e., upper headgear connectors position upper headgear vectors upwardly from horizontal and lower headgear connectors position lower headgear vectors generally horizontal). By splitting the upper headgear strap 1092 at the crown of the patient's head (i.e., top and rear straps 1096, 1098), the upper headgear vectors are realigned to prevent the mask system from sliding up the patient's face.

2.3.1 Headgear Adjustment

[00130] Figs. 35-1 to 35-3 illustrate headgear 290 attached to the headgear connectors 224, 225 of the shroud 220 to maintain the mask system in a desired position on the patient's face.

[00131] In the illustrated embodiment, the headgear 290 includes a pair of upper or top straps 292, a pair of lower or bottom straps 294, and a pair of rear straps 298. In use, the upper straps 292 are secured to respective upper connectors or arms 226, the lower straps 294 are removably attached to respective lower connectors via slots 229/clip arrangement 231, and the rear straps 298 are removably attached to respective upper connectors via slots 227. The upper straps 292 may include upper strap portions adapted to pass over the top of the patient's head and couple to one another, e.g., via a headgear buckle or adjustable ladder-lock

arrangement 299. In the illustrated embodiment, the lower straps 294 and rear straps 298 are formed in one piece.

[00132] This headgear arrangement allows adjustment to occur at three positions, i.e., upper straps 292 at the headgear buckle 299, lower straps 294 at the slot 229/clip 231 connection, and rear straps 298 at the slot 227 connection.

[00133] As illustrated, the free end of each strap may include a hook and loop tab 295 (e.g., Velcro®) structured to engage the remainder of the strap to removably secure the strap in place. Such hook and loop attachment also facilitates adjustment of the length of the straps.

[00134] In the illustrated embodiment, the lower straps 294 and rear straps 298 are adapted to join and pass behind the patient's head in use (e.g., see Fig. 35-3). As illustrated, the lower straps 294 join at an angle α (e.g., similar to the bottom strap in ResMed's Mirage Liberty mask) to prevent the strap from irritating the patient's neck and/or prevent movement of the strap due to movement of the patient's neck in use.

[00135] In an embodiment, the headgear may be similar to that for ResMed's Mirage Liberty mask, however the top straps have been modified and there is an added rigidizer system. The top straps may be similar to ResMed's Swift style headgear, with the rigidizers extending along the sides.

2.3.2 Alternative Headgear Material

[00136] Figs. 43-1 to 43-4 illustrate a mask system 610 including a mask 615 and headgear 690 according to another embodiment of the present invention. In the illustrated embodiment, the headgear 690 includes an arrangement of straps wherein some of the straps are constructed of silicone and some of the straps are constructed of Breath-O-Prene™ material. However, the headgear may be constructed such that the straps are completely constructed of silicone or completely constructed of Breath-O-Prene™.

[00137] As illustrated, the lower strap portion 692 of the headgear is constructed of Breath-O-Prene™ and extends along the cheeks and around the back of the patient's head. The upper strap portion 694 of the headgear is constructed of silicone and includes side straps 694(1) that extend along the upper cheek and over the patient's ear, a top strap 694(2) that extends over the top of the patient's head, rear straps 694(3) that extend behind the patient's

head and connects to the lower strap portion 692 (see Fig. 43-4), and connecting portions 694(4) that extend from respective side straps 694(1) in front of the patient's ear and connect to the lower strap portion 692.

[00138] The headgear straps may be connected to the mask in any suitable manner. For example, in the illustrated embodiment, the lower strap portion 692 is connected to the mask by a headgear clip arrangement and the upper strap portion 694 is connected to the mask using an elongated buckle 695 with buckle portions on each end thereof.

[00139] In an embodiment, the headgear straps are arranged such that the force vectors applied by the headgear to the mask are substantially perpendicular to the mask and substantially parallel to one another (e.g., as shown by the arrows in Fig. 43-2). This arrangement enhances the mask seal as the headgear forces the mask directly into the patient's face.

3. Seal

[00140] The seal (i.e., cushion) of the mask system is structured to accommodate the elimination of a forehead support from a full-face type interface.

3.1 Cushion

[00141] As shown in Figs. 1-5 and 7-8, the cushion 1060 is structured to interface with the frame 1040 and form a seal with the patient's nose and mouth in use. In the illustrated embodiment, the cushion is a full-face cushion adapted to engage the patient's face generally along nasal bridge, cheek, and lower lip/chin regions of the patient's face. However, other cushion interfaces are possible, e.g., nasal.

[00142] The cushion 1060 is structured be more compliant or flexible (e.g., particularly in the nasal bridge region) to accommodate more movement due to loss of some stability without a forehead support.

[00143] The cushion 1060 is constructed of a soft and flexible biocompatible material, e.g., such as silicone. In the illustrated embodiment, the cushion 1060 includes a dual wall configuration wherein the cushion comprises an undercushion or support wall 1062 underneath a membrane 1064 as shown in Fig. 8.

[00144] The membrane 1064 is generally softer and less stiff than the undercushion 1062 and provides a seal against the patient's face in use. The membrane may be relatively thin to allow for wider fit range and better conformance to the patient's face in view of less mask stability with a forehead support. The undercushion is structured to generally support the membrane and prevents collapse of the membrane when the mask system is attached and tightened using the headgear.

[00145] The membrane 1064 is generally concave and curves inwards towards the breathing chamber. The undercushion 1062 may also curve inwardly but is generally shorter, thicker, and more rigid than the membrane.

[00146] In an embodiment, the undercushion 1062 at the regions of the nasal bridge and/or chin of the patient is shorter in height or completely absent and the height from the tip to base of the undercushion 1062 may be between about 0 mm and 30 mm. The membrane is generally longer than the undercushion 1062 at any given cross-section and may be between about 1 mm and 40 mm. For example, Fig. 8B illustrates a cross-section through nasal bridge and chin regions of the cushion to illustrate the membrane 1064 without an undercushion in these regions.

[00147] In an embodiment, the undercushion 1062 may only be provided in selected regions of the mask system, e.g., where the mask system is to be pushed away from the patient's face. Certain pre-determined regions of the patient's face may be preferably avoided for applying pressure by the tightening of the headgear. In the illustrated embodiment, the nasal bridge and chin regions of the patient do not include an undercushion 1062. In these regions, the undercushion is only provided along lateral sides of the cushion (e.g., see Fig. 7) which press against the cheeks of a patient so as to more evenly distribute the force vectors applied by the mask system in use. In an embodiment, the undercushion may be relatively stiff along the cheek regions because these points of contact are acting as anchor points, i.e., holds mask system in position to provide effective seal.

[00148] This configuration of avoiding the nasal bridge and chin of the patient may increase the comfort of the mask system for patients by reducing the pressure or force applied to sensitive areas or to protruding regions of the patient's face that experience relatively higher contact pressures. Additionally, this arrangement avoids the cushion pinching the nasal bridge of the patient when the mask system is adjusted. Additionally, the cushion of

this embodiment may be noticeably softer in the regions of the nasal bridge and chin because of the absence of the undercushion.

[00149] In an embodiment, the undercushion may include a variable height, stiffness, and/or thickness to generate a variable softness in the aforementioned predetermined regions of the face that require lighter support.

[00150] In the illustrated embodiment, the cushion may be structured to seal lower down on the patient's nasal bridge and the eye sockets so that the cushion is less obtrusive.

[00151] In an embodiment, the cushion may be generally frosted except at patient contacting surfaces where it is polished. In an embodiment, the frosting of the cushion may reduce restriction between the face and membrane and/or the membrane and undercushion. The frosting allows the surface of the membrane and undercushion to slide against each other's respective surface without the same restriction of unfrosted silicone. This feature may also prevent or limit sticking of the membrane to the undercushion components and also may generally improve the overall comfort and sealing properties of the cushion. Additionally, the frosting of the cushion may be easier to manufacture and may lead to a reduction of costs of manufacturing. The cushion may be constructed of frosted silicone or other suitable materials.

3.2 Cushion Lower On Nasal Bridge

[00152] Figs. 31-1 to 31-5 illustrate various views of a cushion 44 (e.g., constructed of silicone) according to an embodiment of the present invention. As illustrated, the cushion 44 includes a base wall 44(1) provided to the frame, an undercushion layer (UCL) 44(2) extending away from the base wall 44(1), and a membrane 44(3) provided to substantially cover the UCL 44(2) and provide a sealing structure. In the illustrated embodiment, the cushion 44 is structured to sit lower on the nasal bridge to reduce mask obtrusiveness and improve "line of sight" in use.

[00153] Also, as best shown in Figs. 31-3 and 31-5, the UCL 44(2) design in the nasal bridge region is structured to provide improved stability across the nasal bridge in use. As shown in Fig. 31-1 and 31-3, the UCL is not provided in the lower lip/chin region. However, other arrangements of the UCL are possible, e.g., UCL around entire perimeter.

[00154] In an embodiment of the cushion shown in Figs. 31-1 to 31-5, D1 may be about 15-20 mm, e.g., 18.2 mm, D2 may be about 53-59 mm, e.g., 55.8 mm, D3 may be about 88-93 mm, e.g., 90 mm, D4 may be about 78-83 mm, e.g., 81.1, D5 may be about 58-63 mm, e.g., 60 mm, D6 may be about 95-100 mm, e.g., 98.1 mm, D7 may be about 57-62 mm, e.g., 59.7 mm, D8 may be about 77-82 mm, e.g., 79 mm, D9 may be about 88-93 mm, e.g., 90.7 mm, D10 may be about 30-35 mm, e.g., 33.1 mm, D11 may be about 14-19 mm, e.g., 16.4 mm, D12 may be about 8-13 mm, e.g., 9.6 mm, D13 may be about 0.3-0.5 mm, e.g., 0.35 mm, D14 may be about 0.4-0.6 mm, e.g., 0.5 mm, and D15 may be about 0.3-0.5 mm, e.g., 0.4 mm. Although specific dimensions and ranges are indicated, it is to be understood that these dimensions and ranges are merely exemplary and other dimensions and ranges are possible depending on application. For example, the exemplary dimensions may vary by 10-20% or more or less depending on application.

3.3 Cushion Higher On Nasal Bridge

[00155] Figs. 35-1 and 35-2 illustrate a full-face cushion 244 adapted to engage the patient's face generally along nasal bridge, cheek, and lower lip/chin regions of the patient's face. In this embodiment, the cushion 244 is structured such that it is positioned higher on the bridge of the nose for sealing and comfort (e.g., with respect to the cushion 44 described above). The cushion 244 may also be better for anthropometrics, i.e., the cushion will fit more people.

[00156] In an embodiment, the cushion 244 may include a concertina section as described below (e.g., in the nasal bridge region) to enhance the flexibility of the cushion in use.

3.4 Concertina Section

[00157] As best shown in Figs. 30 and 33, a concertina section 50 may be provided in a nasal bridge region of the cushion and/or frame. As illustrated, the concertina section 50 includes a bellows structure with one or more folds 52 that provide a higher degree of flexibility or increased movement. That is, the concertina section 50 provides a higher level of adaptability or flexibility to the nasal bridge region of the cushion/frame which is a more

sensitive region of the patient's face in use. Moreover, the concertina section 50 provides increased movement without compromising seal.

[00158] Figs. 32-1 to 32-3 illustrate various views of a concertina section 50 (isolated from the remainder of the cushion/frame) with one or more folds 52 according to an embodiment of the present invention. As best shown in Fig. 32-3, the folds may have different lengths, depths, and/or contours with respect to one another to optimize the concertina effect, e.g., provide sufficient degree of movement without compromising seal. For example, as shown in Fig. 32-3, each fold 52 includes a first side wall 52(1) and a second side wall 52(2) that interconnects adjacent side walls 52(1).

[00159] In the illustrated embodiment, the first side walls 52(1) and/or the second side walls 52(2) may become progressively longer away from the patient's face. For example, the first side wall 52(1) and/or the second side wall 52(2) adjacent patient's face, or the combination of side walls 52(1) and 52(2), may have a length that is longer than and in some cases significantly longer than the adjacent side wall 52(1) and/or 52(2) (e.g., one side wall at least 25% greater than and up to 5x as long as the other side wall, e.g., 1x, 2x, 3x, or 4x).

[00160] The folds may be constructed and arranged to provide a predetermined order of movement or folding, e.g., folds structured to fold in a sequential or progressive manner wherein one fold collapses before an adjacent fold collapses. For example, upon application of force, the folds closest to the patient's face may fold or collapse before the folds furthest from the patient's face. Also, the folds may be constructed and arranged to provide various degrees of fold or collapse, e.g., folds may fold or collapse more than others.

[00161] In an embodiment of the concertina section shown in Figs. 32-1 to 32-3, D1 may be about 50-60 mm, e.g., 55.7 mm, D2 may be about 5-15 mm, e.g., 9.7 mm, and D3 may be about 0.3-0.5 mm, e.g., 0.4 mm. Although specific dimensions and ranges are indicated, it is to be understood that these dimensions and ranges are merely exemplary and other dimensions and ranges are possible depending on application. For example, the exemplary dimensions may vary by 10-20% or more or less depending on application.

[00162] It should be appreciated that a concertina section 50 may be provided in other regions of the cushion and/or frame, e.g., depending on patient comfort. For example, the concertina section 50 may be provided around the entire perimeter of the cushion and/or frame or may be provided in selected regions of the cushion and/or frame.

[00163] Also, the flexibility of the concertina section 50 may be varied and may be varied in different regions of the cushion and/or frame, e.g., depending on patient comfort. For example, the cushion and/or frame may include a concertina section in the nasal bridge region with a relatively high degree of flexibility and a concertina section in the lower lip/chin region with a relatively low degree of flexibility. The flexibility of the concertina section 50 may be varied by varying the number of folds 52 (e.g., 1-5 folds), the wall lengths, the wall thickness of the folds 52, the depth of the folds 52, etc.

[00164] As noted above, the cushion and frame may be co-molded of two parts with different materials/rigidities or may be integrally formed of the same material. In both embodiments, the concertina section may be provided in the frame and/or the cushion.

[00165] In Figs. 27-30, the cushion 44 and frame 40 are co-molded of two parts with the concertina section 50 provided in the frame 40. The frame 40 and cushion 44 include different rigidities in order to optimize the function of each part. For example, one part (i.e., cushion 44) may be constructed of a relatively soft, supple material to optimize the sealing effect and the other part (i.e., frame 40) may be constructed of a more rigid material to provide adequate support for the cushion while at the same time allowing a sufficient degree of movement to optimize the concertina effect. While the frame is more rigid than the cushion, the frame may be constructed of a flexible material to allow the concertina effect.

[00166] In Fig. 33, the frame 40 and cushion 44 are integrally formed in one piece with the concertina section 50 provided in the frame 40. The material properties and/or dimensions may be selectively modified to optimize sealing and concertina effects.

[00167] For both embodiments of Figs. 27-30 and 33, it should be appreciated that the concertina section may be alternatively provided in the cushion 44 or in both the frame 40 and cushion 44. For example, Fig. 34 illustrates a concertina section 50 integrally formed with the cushion 44 in the nasal bridge region.

4. Elbow

[00168] As shown in Fig. 3, the elbow 1070 (e.g., constructed of a relatively hard material such as polycarbonate or polypropylene) includes a first end portion 1074(1) and a second end portion 1074(2). The first end portion 1074(1) provides an interfacing structure

structured to interface or otherwise attach to the frame 1040. The second end portion 1074(2) is adapted to be connected to an air delivery tube.

4.1 Elbow Connection to Frame

[00169] The frame 1040 is structured to maintain the elbow 1070 in an operative position with respect to the patient's face. That is, the frame acts as a carrier and bearing surface for the elbow. The frame and elbow may connect with a friction fit, snap-fit, mechanical interlock, or other suitable attachment mechanism. However, other suitable arrangements for attaching the elbow to the frame are possible.

[00170] In the illustrated embodiment, the elbow 1070 includes a series of tangs 1075 adapted to releasably engage within the opening 1046 of the frame 1040, e.g., with a snap-fit. The tangs 1075 hold the elbow in place (e.g., preferably a relatively airtight connection) and permit rotation or swiveling of the elbow with respect to the frame.

[00171] That is, the elbow is rotatably attached to the frame so that the elbow may be rotated relative to the frame in use, e.g., 360° rotation. This arrangement allows the elbow to assume different orientations in use, e.g., depending on patient preference. For example, the elbow may assume a first orientation so that the elbow extends generally downwardly from the mask to direct the air delivery tube under the patient's head in use. Alternatively, the elbow may be rotated and assume a second orientation so that the elbow extends upwardly from the mask to direct the air delivery tube over the patient's head in use. In an embodiment, the frame and elbow may be constructed of dissimilar materials to prevent or at least reduce squeak between the components in use.

[00172] The second end portion of the elbow may be provided to a swivel joint adapted to be connected to the air delivery tube. For example, Figs. 27-30 illustrate a swivel joint 80 provided to the second end portion 74(2) of elbow 70. In the illustrated embodiment, the swivel joint 80 is provided to a short tube 82 (e.g., extendable and retractable tube) that interconnects the elbow with the air delivery tube. In an embodiment, the swivel joint 80 may be integrally formed in one piece with the short tube 82.

4.2 AAV

[00173] The elbow 1070 includes a slot 1081 to receive an anti-asphyxia valve (AAV), a port 1079 that is selectively closed by a flap portion of the AAV (depending on the presence of pressurized gas), and structure for attaching the AAV, e.g., with a snap-fit.

[00174] Figs. 27-30 illustrate an exemplary AAV 85 including a flap portion 86 to selectively close port 79 in elbow 70. In this embodiment, a clip portion 88 is provided to the flap portion 86 for attaching the AAV 85 to the elbow 70. In the illustrated embodiment, the flap portion 86 and the clip portion 88 are co-molded with one another to form a one-piece, integrated component. However, the flap portion 86 and clip portion 88 may be secured to one another in other suitable manners, e.g., mechanical interlock.

[00175] In an embodiment, the flap portion 86 may be constructed of a relatively soft elastomeric material (e.g., silicone) and the clip portion 88 may be constructed of a more rigid material (e.g., rigid plastic) for interfacing with the elbow 70.

[00176] The clip portion 88 of the AAV 85 includes structure for removably interlocking with the elbow 70, e.g., with a snap-fit. For example, the clip portion 88 may include tabs structured to interlock with respective recesses/protrusions provided to the elbow.

[00177] Figs. 35-1 and 35-2 illustrate an elbow 270 including a port 279 that is selectively closed by a flap portion 286 of the AAV 285 (depending on the presence of pressurized gas). Also, Figs. 37-1 to 37-3 illustrate elbow 370 including a port 379 and a slot 381 to retain the AAV.

[00178] Alternative embodiments of the AAV are disclosed in PCT Application No. PCT/AU2006/000031, which is incorporated herein by reference in its entirety.

4.3 Large Diameter End Portion

[00179] As shown in Figs. 27-30, the first end portion 74(1) of the elbow 70 may provide a relatively large diameter which allows the potential for cleaner/smoothier lines thereby contributing to the overall mask aesthetic and reduced obtrusiveness. In addition, the relatively large diameter elbow offers the potential for the patient's nose to protrude into the elbow cavity thereby permitting the mask to be brought closer to the patient's face (i.e.,

reduced obtrusiveness), less moment since center of gravity of mask is closer to the patient's face, and/or improved line of sight.

5. Modular Design

[00180] The mask system provides a modular design that allows different styles and/or sizes of the frame (also referred to as a frame module), shroud (also referred to as a shroud module), cushion (also referred to as a cushion module), and/or elbow (also referred to as an elbow module) to be interchanged or mixed and matched with one another to provide a more customized mask system for the patient. In addition, such design allows selected modules to be easily replaced, e.g., treatment requirements change, worn out or damaged, etc.

[00181] In an embodiment, the mask system may be provided with a number of different cushions, e.g., each having cushions of different styles and/or sizes (e.g., depending on patient preference and/or fit). For example, the non-face contacting side of each cushion may include a common or universal configuration for interfacing with the frame, and the face-contacting side of the cushion may include different styles and/or sizes. This provides a modular arrangement that allows the frame to be selectively (e.g., and removably) coupled to one of multiple cushion. For example, the different cushions may include different size cushions (e.g., small, medium, and large) and may include a different cushion structures.

[00182] In an embodiment, the mask system may be provided with different shrouds, e.g., each shroud having a different style and/or size (e.g., shroud with different arrangement/style of headgear connectors, shroud with forehead support, different headgear vectors, etc).

[00183] In an embodiment, the mask system may be provided with different frames, e.g., each frame having a different style and/or size (e.g., frame with different vent arrangement, small, medium, and large size frame, etc).

[00184] In an embodiment, the mask system may be provided with a number of different elbows, e.g., each having a vent arrangement, AAV (in the case of an oro-nasal mask), and/or elbow of different styles and/or sizes. In the illustrated embodiment of Figs. 27-30, the vent arrangement 76 and AAV 85 are structured to be removably attachable to the elbow 70. This provides a modular arrangement that allows the elbow to be selectively and

removably coupled to one of multiple vent arrangements and/or AAVs. This also allows the vent arrangement and AAV to be easily replaced, e.g., if damaged.

5.1 Shroud to Frame Connection

[00185] The shroud is mounted on the outer surface of the frame, e.g., preferably with a tight, conforming fit on the frame.

5.1.1 Upper Retaining Mechanism

[00186] In the illustrated embodiment of Figs. 1-5, the shroud 1020 is connected to the frame 1040 by an upper retaining mechanism or interfacing structure 1048 located on the top end of the frame and shroud.

[00187] As shown in Figs. 2 to 5, the upper retaining mechanism 1048 is in the form of two taper locks structured to secure the shroud 1020 on the frame 1040 and prevent unintentional disassembly particularly due to headgear forces. In this embodiment, opposing sides of the frame include a female slot 1055 adapted to receive a respective tang protrusion (which tapers along its length) on the underside of the shroud 1020. The tapered protrusion engages within a respective female slot, e.g., with a friction fit.

[00188] Figs. 10 to 19-4 show another embodiment of a mask system 1110 which more clearly illustrates an embodiment of the taper lock. Figs. 10 to 17 show various views of the frame 1140, shroud 1120, and elbow 1170 of the mask system 1110.

[00189] As best shown in Figs. 11 to 13, opposing sides of the top end of the frame 1140 include a platform 1154 which provides a first female slot 1155(1). In addition, the space between the platform 1154 and the outer surface of the frame 1140 defines a second female slot 1155(2). As best shown in Fig. 17, opposing sides of the top end of the shroud 1120 include a tang protrusion 1156 on the underside of the shroud 1120. The tang protrusion 1156 includes a first tang 1156(1) and a second tang 1156(2) that extends generally transverse to the first tang 1156(1). As shown in Figs. 18-1 and 18-2, each tang may taper along its length, i.e., thinner towards its free end.

[00190] Figs. 18-1 and 18-2 and 19-1 to 19-4 sequentially illustrate attachment of the shroud 1120 to the frame 1140. As illustrated, the tangs 1156(1), 1156(2) of each tang protrusion 1156 are structured to engage with respective slots 1155(1), 1155(2), e.g., with a

friction fit. As best shown in Figs. 19-1 to 19-4, each slot 1155(2) includes lead-ins or guides 1157 that curve along their length (i.e., extend in vertical and horizontal direction) so as to guide the tang 1156(2) into the slot 1155(2) and aid assembly. Figs. 18-2 and 19-4 show the tangs 1156(1), 1156(2) when fully inserted with respective slots 1155(1), 1155(2).

[00191] In an alternative embodiment, as shown in Fig. 20, the upper retaining mechanism may include a clip-type arrangement. As illustrated, opposing sides of the top end of the frame 1240 provide a shoulder 1255(1) and a tapered protrusion 1255(2). Opposing sides of the top end of the shroud 1220 include a first tang 1256(1) and a second tang 1256(2) on the underside of the shroud 1220. In use, each first tang 1256(1) is engaged with the respective shoulder 1255(1) and the second tang 1256(2) is engaged or clipped onto the tapered protrusion 1255(2), e.g., with a snap-fit.

5.1.2 Lower Retaining Mechanism

[00192] In an embodiment, the shroud may also be connected to the frame by a lower retaining mechanism located on the bottom end of the frame and shroud. For example, a retaining mechanism may be provided to the opening of the shroud which is structured to interlock or otherwise engage with the opening of the frame.

[00193] For example, as shown in Figs. 14, 15, 17, and 21, the opening 1132 of the shroud 1120 may include structure adapted to engage the collar 1149 surrounding the frame opening 1146 with a snap-fit. As illustrated, the shroud 1120 includes snap fingers 1145(1) (e.g., three snap fingers) and sandwich tabs 1145(2) (e.g., three sandwich tabs) that extend from the opening 1132. The snap fingers and sandwich tabs are alternatively spaced about the opening.

[00194] In use, the snap fingers 1145(1) resiliently deflect (e.g., 0.5 mm deflection) and engage respective part-annular protrusions 1149(1) provided to the collar 1149 (e.g., see Figs. 22 and 23) to provide an initial retention of the shroud 1120 to the frame 1140 (e.g., with allowable stresses), e.g., to facilitate assembly and disassembly. In addition, as the snap fingers 1145(1) engage respective protrusions 1149(1), the sandwich tabs 1145(2) are received in respective recesses 1149(2) provided to the end of the collar 1149 (e.g., see Figs. 22 and 23). When the elbow 1170 is engaged with the frame 1140 (e.g., see Fig. 23), an annular protrusion 1171 on the elbow 1170 is positioned on an opposing side of the sandwich

tabs 1145(2) so that the sandwich tabs 1145(2) are sandwiched between the collar 1149 and the elbow 1170. Thus, the sandwich tabs utilize elbow retention forces to retain the shroud on the frame during use. The elbow 1170 has a distal shoulder 1173 adapted to extend under the edge of the frame 1140 to retain the elbow to the frame. The snap fingers 1145(1) allow the shroud to connect to the frame independent of the elbow.

[00195] In an alternative embodiment, as shown in Fig. 24, the shroud's lower section may be structured to clip to a single point below the collar. As illustrated, the lower end of the shroud 1320 includes a snap finger 1345 that is engaged or clipped onto a protrusion 1349(1) spaced below the collar 1349 of the frame 1340, e.g., with a snap-fit. In this embodiment, the protrusion 1349 extends from the cover enclosing auxiliary ports. This arrangement may facilitate molding of the collar on the frame, e.g., uniform thickness of the collar prevents molding distortions. In addition, removal of the protrusions 1149(1)/recesses 1449(2) from the collar may reduce the risk of leak.

5.1.3 Finger Grip

[00196] In an embodiment, the outer surface of the frame 1040 may include finger grips or recessed portions 1097, which are positioned to be exposed under the shroud 1020. The finger grips are adapted to allow the patient an improved ability to grip the frame and/or shroud which is particularly useful when disengaging the shroud from the frame.

5.1.4 Alternative Interfacing Structure

[00197] In an alternative embodiment, as shown in Fig. 27-30, the shroud 20 includes an open construction that provides an annular or part annular retaining portion 22 structured to retain the frame 40 and the elbow 70. As illustrated, the annular retaining portion 22 includes an interfacing structure 23 along an inner edge that is adapted to interface with or otherwise removably connect to an interfacing structure 48 along the outer perimeter of the frame 40 (e.g., see Fig. 28). In the illustrated embodiment, the interfacing structure 23 is in the form of opposed flanges 23(1) that are adapted to interlock with respective locking structures 48(1) provided on opposing sides of the frame 40. However, other suitable arrangements for attaching the frame 40 to the shroud 20 are possible, e.g., friction fit, snap-fit, mechanical interlock, or other suitable attachment mechanism.

[00198] For example, the frame 40 may be coupled to the shroud 20 in a manner that allows the frame 40 to be locked in different angular positions with respect to the shroud 20, e.g., pivotally mounted.

5.1.5 Alternative Upper Headgear Connector

[00199] Figs. 40-1 to 40-7 illustrate a frame and a clip-on upper headgear connector or rigidizer according to another embodiment of the present invention.

[00200] The frame 442 includes an opening 449 adapted to engage a frame shroud and/or elbow. Around and under the opening 449 is the u-shaped slot 402 for gas washout and auxiliary ports 443 on each side thereof.

[00201] In this embodiment, each upper side of the frame 442 includes a retaining member 433 and an upper intermediate portion of the frame 442 includes retaining grooves 435, which are structured and arranged to retain an upper headgear connector or rigidizer 424.

[00202] As best shown in Figs. 40-6 and 40-7, the upper headgear connector 424 includes a pair of elongated arms or rigidizers 426 coupled by a pair of wire members 428. Each rigidizer 426 includes a slot 427 at its free end adapted to receive a respective headgear strap in use.

[00203] In use, the upper headgear connector 424 is adapted to clip onto the frame 442 (e.g., see Figs. 40-1 and 40-2). Specifically, intermediate portions of the wire members 428 are received in respective grooves 435 of the frame 442, and end portions of the wire members 428 extend through respective retaining members 433 with the rigidizers 426 providing a shoulder to interlock with respective retaining members 433. Figs. 40-4 and 40-5 show an upper portion of a retaining member 433 to illustrate the groove 433(1) adapted to receive a respective wire. As illustrated, the end of the groove 433(1) includes tapered side walls 433(2) and drops off towards a rear side 433(3) to position the rigidizers 426 into interlocking engagement with the retaining member 433.

[00204] Figs. 41-1 to 41-12 illustrate an upper portion of a frame and a clip-on upper headgear connector or rigidizer according to another embodiment of the present invention.

[00205] As illustrated, the upper portion of the frame 542 includes a retaining member 533 on each side thereof and a retaining groove 535 along an intermediate portion thereof, which are structured and arranged to retain an upper headgear connector or rigidizer 524.

[00206] As best shown in Figs. 41-5 and 41-12, the upper headgear connector 524 includes a pair of elongated arms or rigidizers 526 coupled by a connecting portion 528. Each rigidizer 526 includes a slot 527 at its free end adapted to receive a respective headgear strap in use. In addition, the upper headgear connector 524 includes a clip structure 525 on each side of the connecting portion 528.

[00207] In use, the upper headgear connector 524 is adapted to clip onto the frame 542 (e.g., see Figs. 41-1 and 41-2). Specifically, the connecting portion 528 is received in the groove 535 of the frame 542, and the clip structures 525 releasably interlock with respective retaining members 533. As best shown in Figs. 41-3 and 41-4, each retaining member 533 provides a cross-bar, and each clip structure 525 provides a v-shaped configuration that is adapted to resiliently deflect through the cross-bar and provide a shoulder to releasably interlock with the cross-bar.

[00208] Figs. 42-1 to 42-7 illustrate an alternative embodiment for engaging the upper headgear connector with the frame. As illustrated, each retaining member 533 provides an open-ended cross-bar, and each clip structure 525 provides an elongated arm. In this embodiment, the cross-bar is structured to resiliently deflect to allow the clip structure 525 to extend through the cross-bar and releasably engage the cross-bar, e.g., with a friction fit. In addition, the upper headgear connector 524 of Figs. 42-1 to 42-7 includes a c-shaped clip structure 529 adapted to interlock with a tab 549 provided to the frame 542 (see Figs. 42-1 and 42-2).

5.1.6 Grommet Attachment

[00209] Figs. 44 and 45 illustrate an alternative mask arrangement in which the shroud is attached to the frame via a grommet.

[00210] For example, as shown in Fig. 44, the frame 740 includes a grommet 745 (e.g., constructed of a rubber) and the shroud 720 includes an opening 725 adapted to receive the grommet 745 to secure the shroud 720 to the frame 740. As illustrated, the shroud 720 includes elongated upper and lower arms 724, 726 each with a slot 727 at its free end adapted to receive a respective headgear strap in use.

[00211] Fig. 45 illustrates an alternative shroud 820 which includes a single arm with a slot 827 at each end adapted to receive a respective headgear strap in use. In addition, the

shroud 820 provides an elongated inner slot 825 adapted to receive the grommet 745 of the frame 740. The elongated slot 825 allows the grommet 745 to be fixed in one of multiple positions along the length of the slot 825, in contrast to the shroud 720 which provides a single fixed position. In an embodiment, the shroud 820 may be slidable with respect to the grommet 745 to allow an infinite number of positions with respect to the frame 740.

[00212] In each embodiment, the grommet 745 (e.g., constructed of a rubber) fixes the shroud in position but the inherent flexibility of the grommet provides a flexible connection to decouple the shroud from the frame and allow a range of movement between the two components, e.g., like a ball joint or gimbal. Such arrangement helps with fitting and sealing of the mask to the patient's face. That is, the flexible connection allows the mask to selectively adjust and/or self-fit with the patient's face.

5.2 Cushion to Frame Connection

[00213] In Figs. 1-8, the non-face contacting side of the cushion 1060 is connected to frame 1040 in a tongue and groove relationship. The tongue 1066 (see Figs. 1C, 1D, and 8) of the cushion 1060 is inserted within a groove 1041 (see Figs. 1C and 1D) provided along the perimeter of the frame 1040. The tongue and groove relationship may also include a locking lip or sealing lip 1068 (see Figs. 1C, 1D, and 8) on the cushion that is adapted to interlock with an undercut bead 1042 (see Figs. 1C and 1D) within the frame groove to fixably retain the cushion to the frame.

[00214] In the illustrated embodiment, the cushion 1060 also includes one or more positioning features located around its circumference to assist with proper alignment of the cushion with the frame 1040. As shown in Fig. 7, the cushion 1060 includes notches and/or protrusions (e.g., two notches 1067 and one protrusion 1069) adapted to engage with complementary features in the frame, e.g., interlocking relationship.

5.2.1 Co-Molding Frame and Cushion

[00215] In an embodiment, as shown in Figs. 27-30, the frame 40 and cushion 44 may be co-molded with one another to form a one-piece, integrated component. For example, the frame 40 may be molded of a first material adapted to interface with the shroud 20 and the

cushion 44 may be co-molded onto the frame 40 of a second material adapted to interface with patient's face.

[00216] In such embodiment, the cushion 44 may be constructed of a relatively soft elastomeric material (e.g., silicone) for sealing and the frame 40 may be constructed of a more rigid material than the cushion 44 (e.g., polycarbonate, polypropylene) for interfacing with the frame.

[00217] Co-molding the frame 40 to the cushion 44 provides a chemical bond without necessarily forming a mechanical interlock. As a result, the connection includes no cracks, a gas tight seal, and clean interface. Moreover, such co-molded connection relaxes tolerances as the mold materials are sufficiently flexible to fill in any gaps at the interface between the frame 40 and the cushion 44. Also, the co-molded frame/cushion provides a reduced part count (reduced cost) and facilitates assembly/disassembly to the shroud 20.

[00218] In an alternative embodiment, as shown in Fig. 33, the frame 40 and cushion 44 may be integrally formed in one piece, e.g., of a silicone material. That is, the frame 40 may have the same shape and structure as described above, but be integrally molded of the same material, e.g., silicone.

[00219] In an embodiment, the integrally formed frame 40/cushion 44 may be co-molded to the shroud 20, e.g., constructed of polycarbonate or polypropylene. For example, the shroud 20 may be constructed of a relatively rigid material (e.g., polycarbonate or polypropylene) and the frame 40/cushion 44 may be co-molded onto the shroud 20 of a relatively soft elastomeric material (e.g., silicone).

5.3 Vent Arrangement

[00220] In Figs. 1, 1B, 1C, 1D, and 2-5, the vent arrangement 1076 is provided to the frame and includes a plurality of holes 1077 (e.g., 5-100 holes, e.g., 20-50 holes, or about 35 holes) oriented at an angle (e.g., 45°) on the outer surface of the frame so as ensure the exhausted air is directed away from the patient and preferably their bed partner when the patient is sleeping. As shown in Figs. 1C and 1D, each hole 1077 may include a contour or taper along its length. However, it should be appreciated that the vent arrangement may include other suitable arrangements, e.g., different number of holes, hole arrangement, positioning on frame, vent provides part pf interlocking structure with shroud, etc.

[00221] Fig. 35-1 illustrates a vent arrangement 276 provided to the frame 240 for gas washout. In the illustrated embodiment, the vent arrangement 276 is in the form of a vent insert (e.g., elastomeric vent insert) that is adapted to be removably supported within an outlet opening in the frame 240. The vent insert may be similar those described in U.S. Patent Nos. 6,561,190, 6,561,191, and 7,207,335, each of which is incorporated herein by reference in its entirety. However, it should be appreciated that the vent arrangement may have other suitable forms (e.g., vent holes in frame 40 (Fig. 28), etc.).

[00222] Figs. 37-3, 39-2, and 39-4 illustrate a frame 340 that includes a u-shaped slot 302 that receives a u-shaped plug-type vent 305 for gas washout. As illustrated, the plug-type vent 305 wraps around and under the opening in the frame 340 for the elbow 370. The plug-type vent 305 includes a plurality of tracks or grooves 307 on each side thereof. In use, the grooved plug-type vent 305 forms a seal with the slot 302 so that exhausted air can exit between the slot walls and the grooves 307 on the plug-type vent 305. In an embodiment, the port caps 347 may be integrated or incorporated into the plug-type vent 305 (e.g., integrally formed in one piece). Further details of such a plug-type vent arrangement are provided in U.S. Patent Application No. 12/230,120, filed August 22, 2008, which is incorporated herein by reference in its entirety. Figs. 39-2 to 39-6 show the frame 340 with the grooved plug-type vent 305 removed so as to more clearly illustrate the u-shaped slot 302 and auxiliary ports 343 on each side thereof.

[00223] Also, it should be appreciated that the vent arrangement may be provided to the elbow. For example, as shown in Figs. 27-30, the vent arrangement 76 is in the form of a vent insert that is adapted to be removably supported within an outlet opening in the elbow 70. In an embodiment, the vent arrangement 76 includes a base adapted to be supported within the outlet opening, one or more grill components or media (e.g., filter, membrane, or other porous material) provided to the base and structured to diffuse vent flow, and a cover to maintain the grill components/media within the base. Only the cover 77 of the vent arrangement 76 is visible in Figs. 27-30.

[00224] Exemplary embodiments of such a vent arrangement are disclosed in U.S. Patent Application No. 12/230,120, filed August 22, 2008, which is incorporated herein by reference in its entirety.

[00225] However, it should be appreciated that the vent arrangement may include other suitable arrangements, e.g., vent insert with one or more vent holes.

[00226] Also, the elbow may provide an alternative venting arrangement to the vent insert. For example, as indicated in dashed lines in Fig. 30, the first end portion 74(1) of the elbow 70 (e.g., along the interfacing structure 75) may include one or more vent holes 276 for gas washout. The one or more holes 276 may be provided to a soft part (e.g., silicone seal as described below) and/or a hard part (e.g., polycarbonate, polypropylene) of the elbow. The holes 276 may extend around the entire perimeter of the first end portion 74(1) or may extend along one or more portions of the first end portion 74(1). It is noted that providing vent holes along the entire perimeter of the elbow may help to disperse the vent flow in use. However, other suitable hole arrangements, hole numbers, and/or hole shapes along the first end portion 74(1) and/or other portions of the elbow are possible.

5.4 Ports

[00227] In Figs. 1-5, the base of the frame 1040 includes two ports 1043 positioned so that in use, oxygen or other breathable gas can be delivered close to the patient's nares or pressure monitoring equipment can be attached. The ports 1043 may also be used to attach additional medical equipment such as pressure or flow sensors. The ports may be selectively closable or sealable by a ports cap.

[00228] In an alternative embodiment, as shown in Figs. 25 and 26, the frame 1040 may include a side port 1043.1, e.g., in addition to or as an alternative to the ports 1043.

[00229] Figs. 35-1 and 35-2 show a frame 240 that includes an auxiliary port or spigot 243 on an upper portion of the frame, e.g., for supplemental oxygen, measurement device, etc.

[00230] In Figs. 37-1 to 37-3 and 39-1 to 39-6, the frame 340 includes an auxiliary port or spigot 343 on each side thereof, e.g., for supplemental oxygen, measurement device, etc. Port caps 347 are provided to seal respective ports 343.

6. Interface Seal

[00231] In an embodiment, a seal may be provided at the interface between the elbow and the shroud, at the interface between the frame and the shroud, and/or at the interface

between the elbow and the frame. For example, a seal (e.g., elastomeric, ring-shaped seal) may be formed separately from the modules and attached at the interface (e.g., sandwiched between modules, adhesive, etc.). Alternatively, a seal may be co-molded with one or more of the modules. In an embodiment, a silicone lip seal may be provided to the frame to seal against the elbow, thereby reducing leak.

[00232] In another embodiment, as shown in Fig. 27-30, the interfacing structure 75 of the elbow 70 may be constructed of a relatively soft, sealing material (e.g., silicone, which may be co-molded to the harder material of the elbow) that is structured to provide a seal at the interface between the elbow 70 and the shroud 20. Also, the relatively soft interfacing structure 75 (e.g., silicone) provides a "soft" attachment to the relatively hard shroud 20 (e.g., polycarbonate, polypropylene) which may allow an interference type fit. As noted above, one or more vent holes may be provided to the softer interfacing structure and/or the harder elbow.

[00233] While the invention has been described in connection with what are presently considered to be the most practical and preferred embodiments, it is to be understood that the invention is not to be limited to the disclosed embodiments, but on the contrary, is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the invention. Also, the various embodiments described above may be implemented in conjunction with other embodiments, e.g., aspects of one embodiment may be combined with aspects of another embodiment to realize yet other embodiments. Further, each independent feature or component of any given assembly may constitute an additional embodiment. Furthermore, each individual component of any given assembly, one or more portions of an individual component of any given assembly, and various combinations of components from one or more embodiments may include one or more ornamental design features. In addition, while the invention has particular application to patients who suffer from OSA, it is to be appreciated that patients who suffer from other illnesses (e.g., congestive heart failure, diabetes, morbid obesity, stroke, bariatric surgery, etc.) can derive benefit from the above teachings. Moreover, the above teachings have applicability with patients and non-patients alike in non-medical applications.

WHAT IS CLAIMED IS:

1. A mask system, comprising:
 - (i) a shroud module; wherein the shroud module includes headgear connectors adapted to removably attach to respective headgear straps of headgear; and
 - (ii) a cushion module, comprising:
 - a 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,
 - 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, and 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 the shroud module and the cushion module are configured to be removably coupleable to one another.
2. The mask system of claim 1 wherein the cushion comprises one or more folds in a lower lip/chin region of the cushion.
3. The mask system of claim 2, wherein the one or more folds in the nasal bridge region has a relatively high degree of flexibility and the one or more folds in the lower lip/chin region have a relatively low degree of flexibility.
4. The mask system of claim 1, wherein each of said one or more folds comprises adjacent first side walls interconnected by a second side wall.
5. The mask system of claim 1, wherein the cushion is a full-face cushion.
6. The mask system of claim 1, wherein the shroud module includes upper and lower headgear connectors on each side of the shroud module.

7. The mask system of claim 6, wherein each upper headgear connector includes a slot adapted to receive a respective headgear strap in use.
8. The mask system of claim 6, wherein each lower headgear connector is adapted to be removably interlocked with a headgear clip associated with a respective headgear strap.
9. The mask system of claim 8, further comprising headgear including respective headgear clips, wherein each said headgear clip is adapted to snap-fit with the respective lower headgear connector.
10. The mask system of claim 1, wherein the shroud module includes an open construction that provides an annular or part annular cushion retaining portion structured to retain the cushion module.
11. The mask system of claim 1, further comprising an elbow module adapted to be connected to an air delivery tube that delivers breathable gas to the patient.
12. The mask system according to claim 11, wherein the elbow module is provided to the shroud module.
13. The mask system of claim 11, wherein the elbow module comprises polycarbonate.
14. The mask system of claim 11, wherein the elbow module and the shroud module are connected with a mechanical interlock while allowing 360 degree rotation of the elbow module.
15. The mask system of claim 11, wherein the elbow module includes an anti-asphyxia valve.
16. A mask system of claim 15, wherein the anti-asphyxia valve includes a flap portion adapted to selectively close a port provided in the elbow module.

17. The mask system of claim 1, 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.

18. The mask system of claim 1 comprising 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.

19. The mask system of claim 1, wherein the shroud module comprises polycarbonate.

20. The mask system of claim 1, wherein the cushion comprises silicone.

21. The mask system of claim 1, wherein the frame and the cushion are co-molded.

ABSTRACT

A mask system has a shroud module with headgear connectors adapted to removably attach to respective headgear straps of headgear; and a cushion module, including a 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. 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, and 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. The shroud module and the cushion module are configured to be removably coupleable to one another.

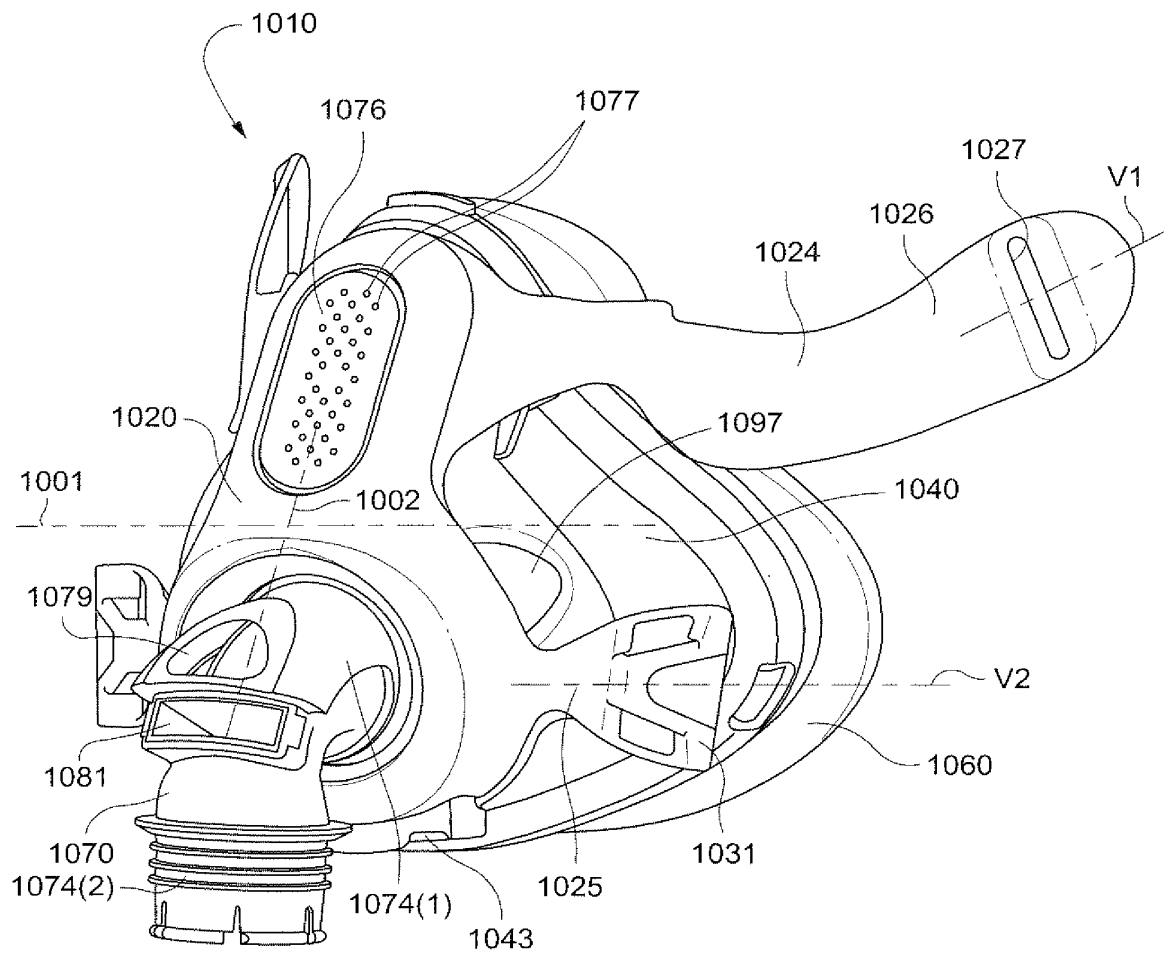


Fig. 1

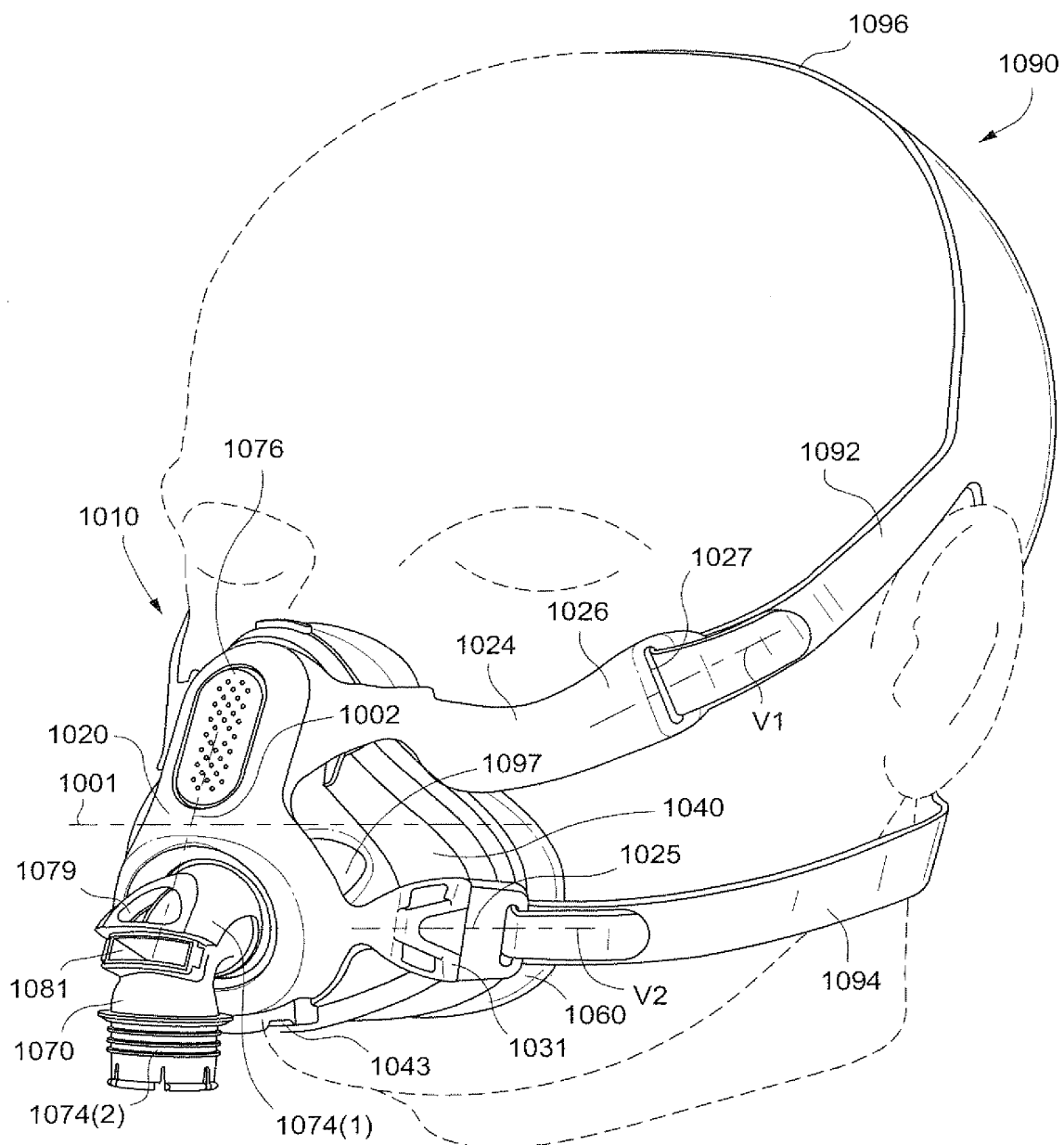
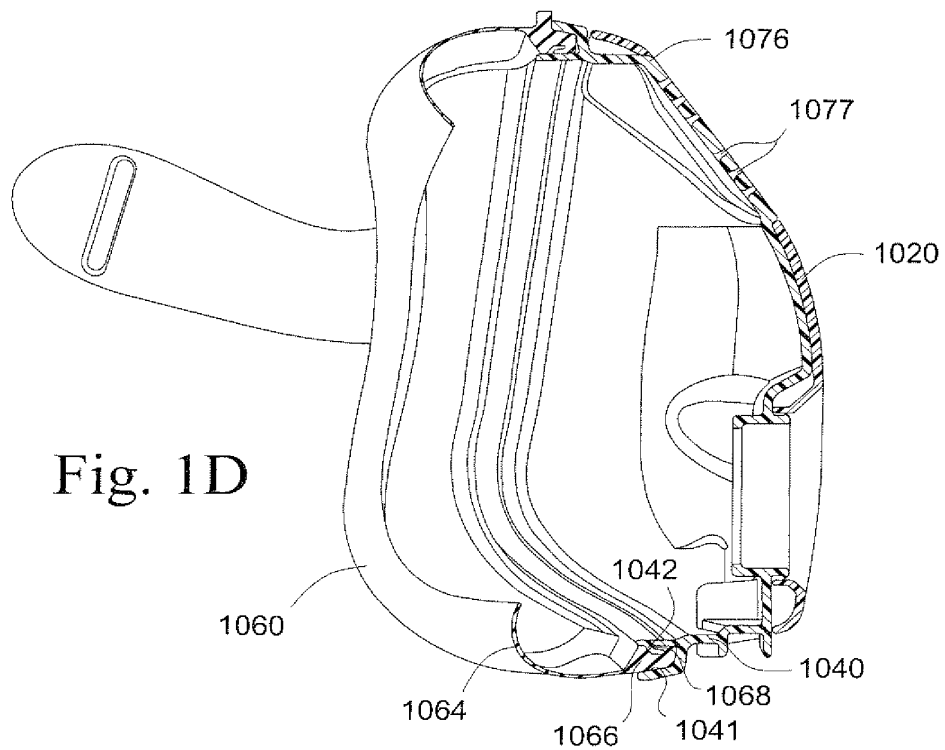
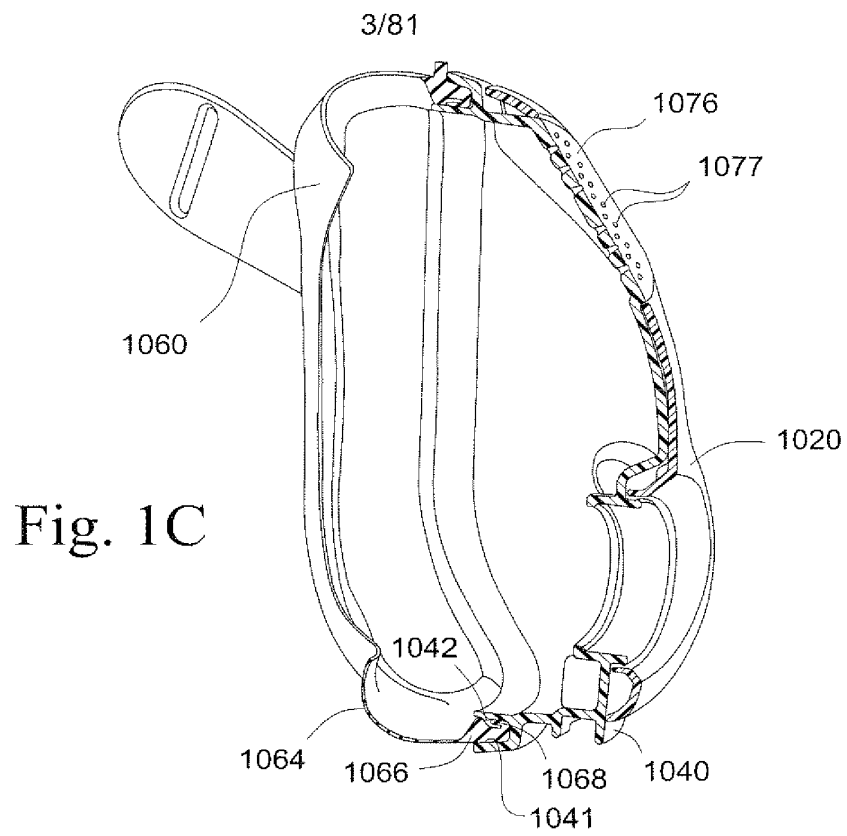
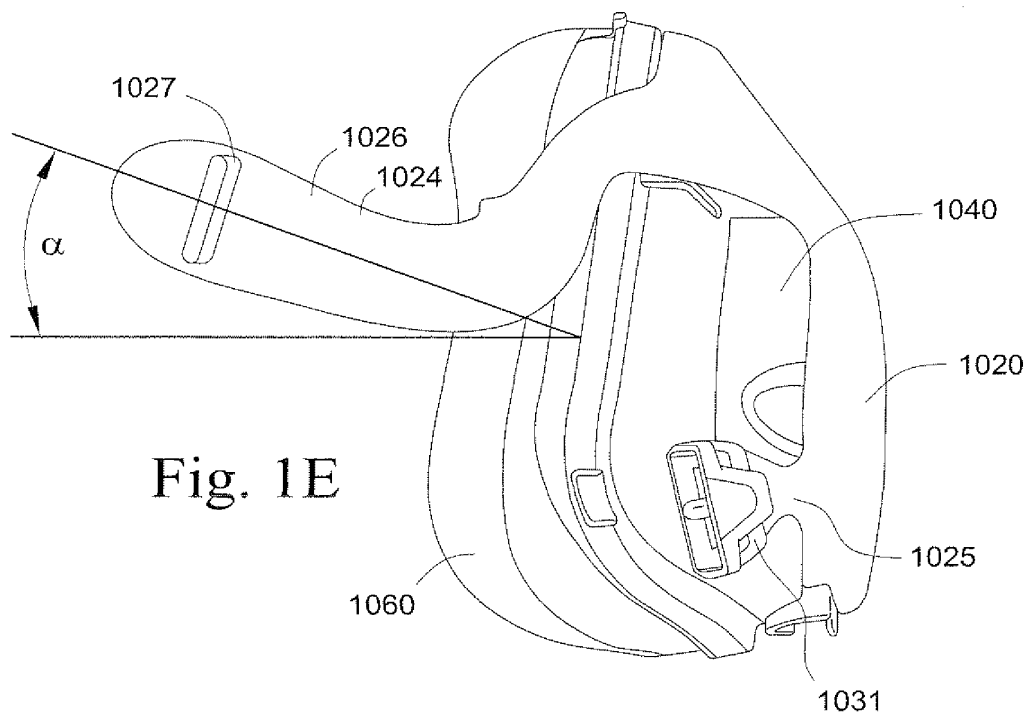


Fig. 1B





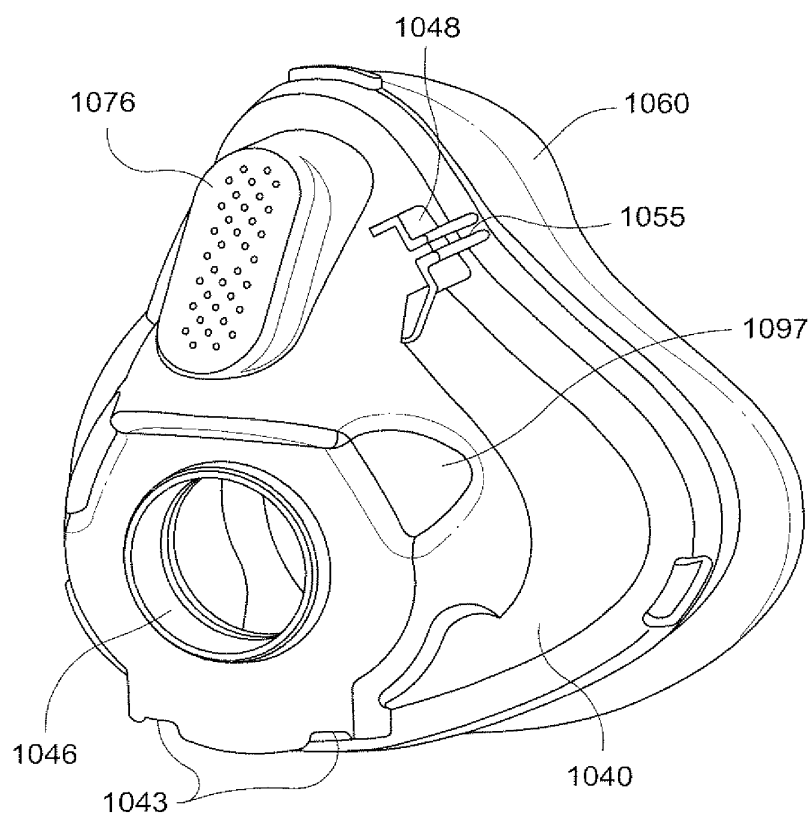


Fig. 2

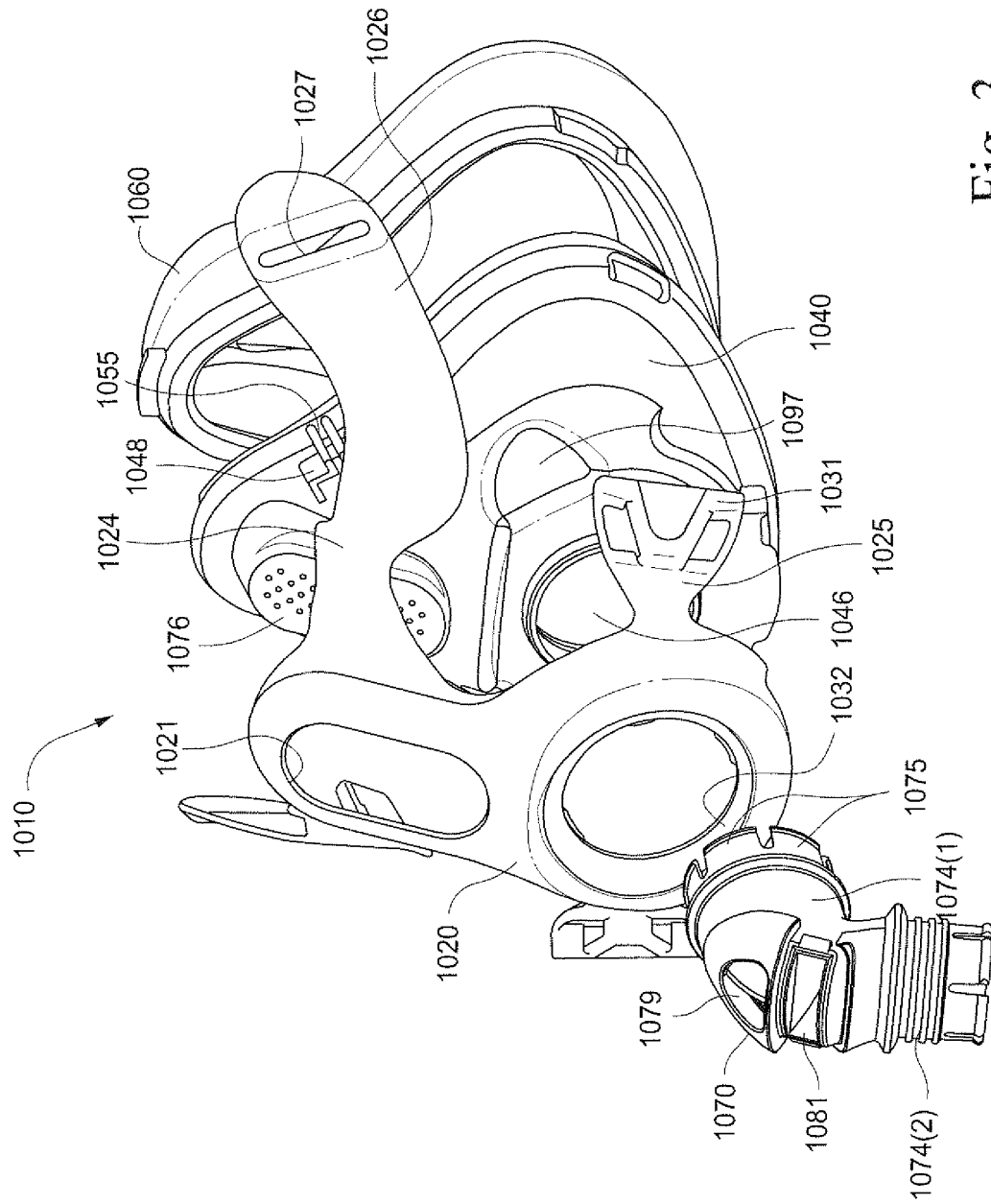


Fig. 3

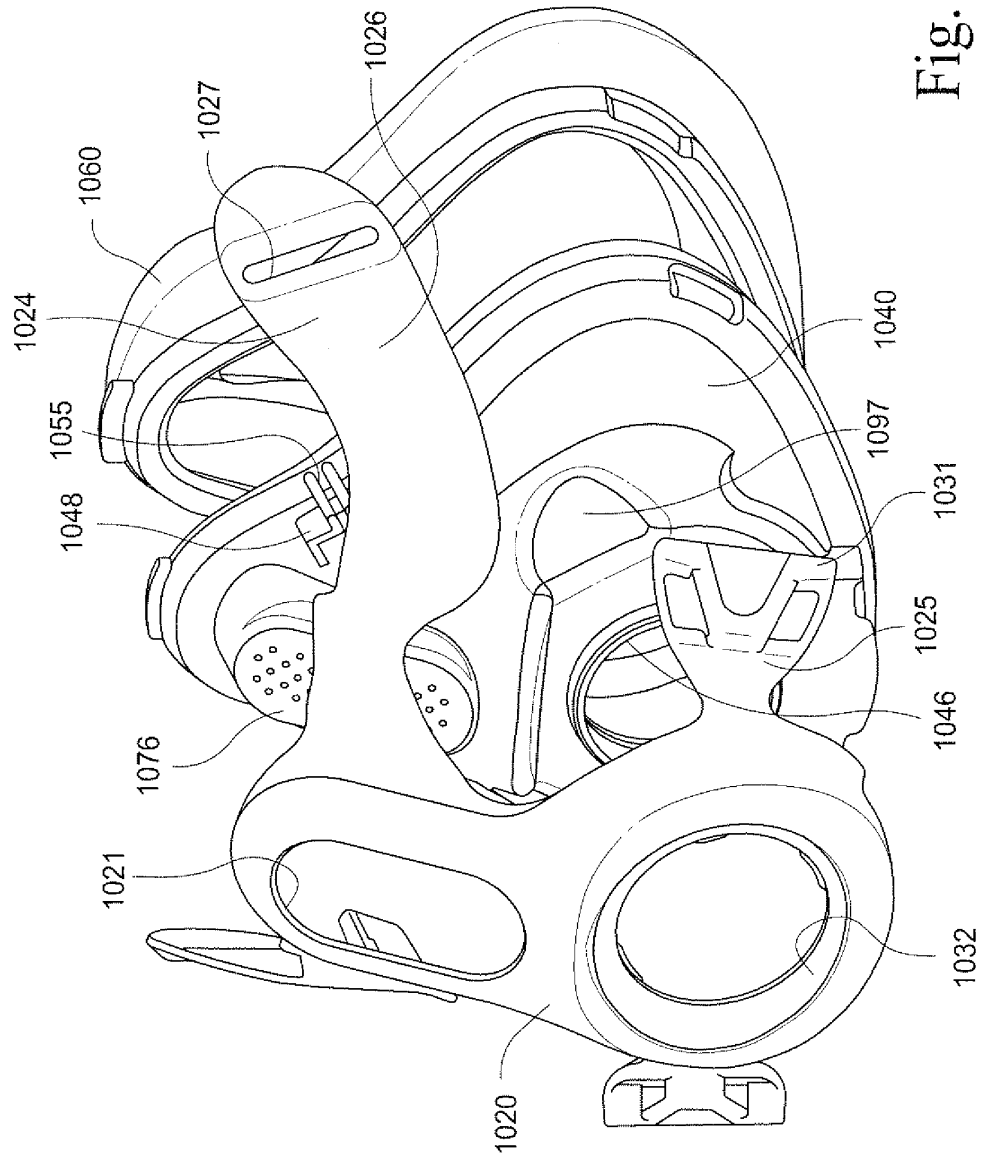


Fig. 4

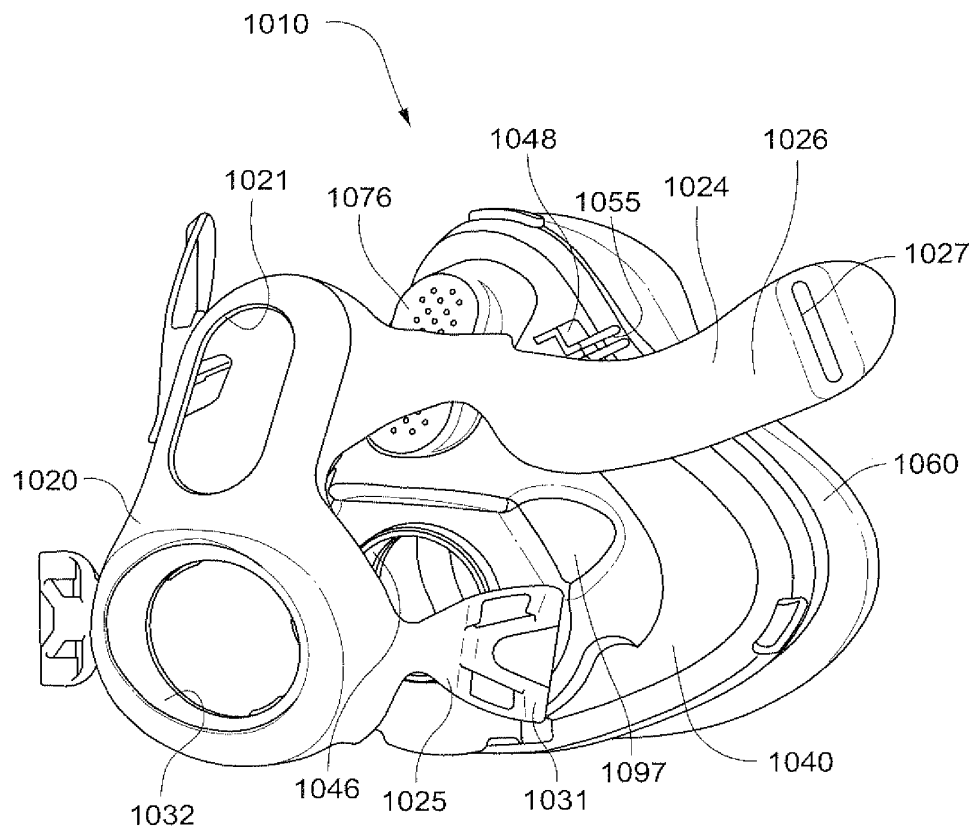


Fig. 5

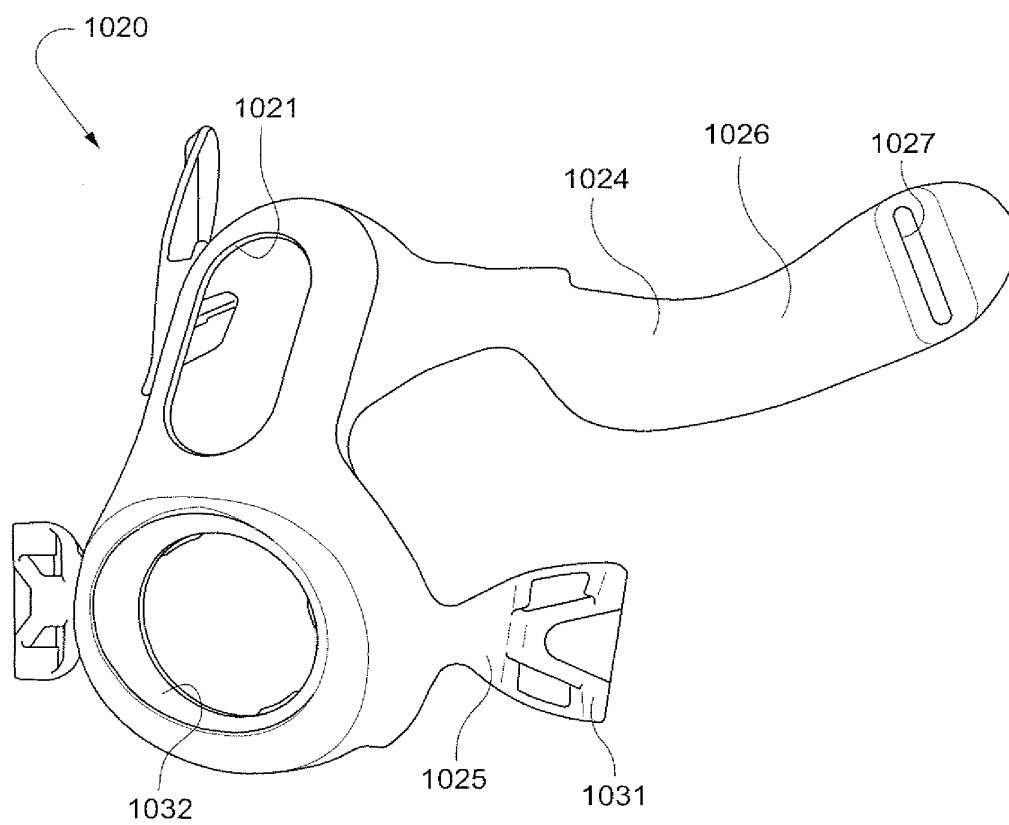


Fig. 6

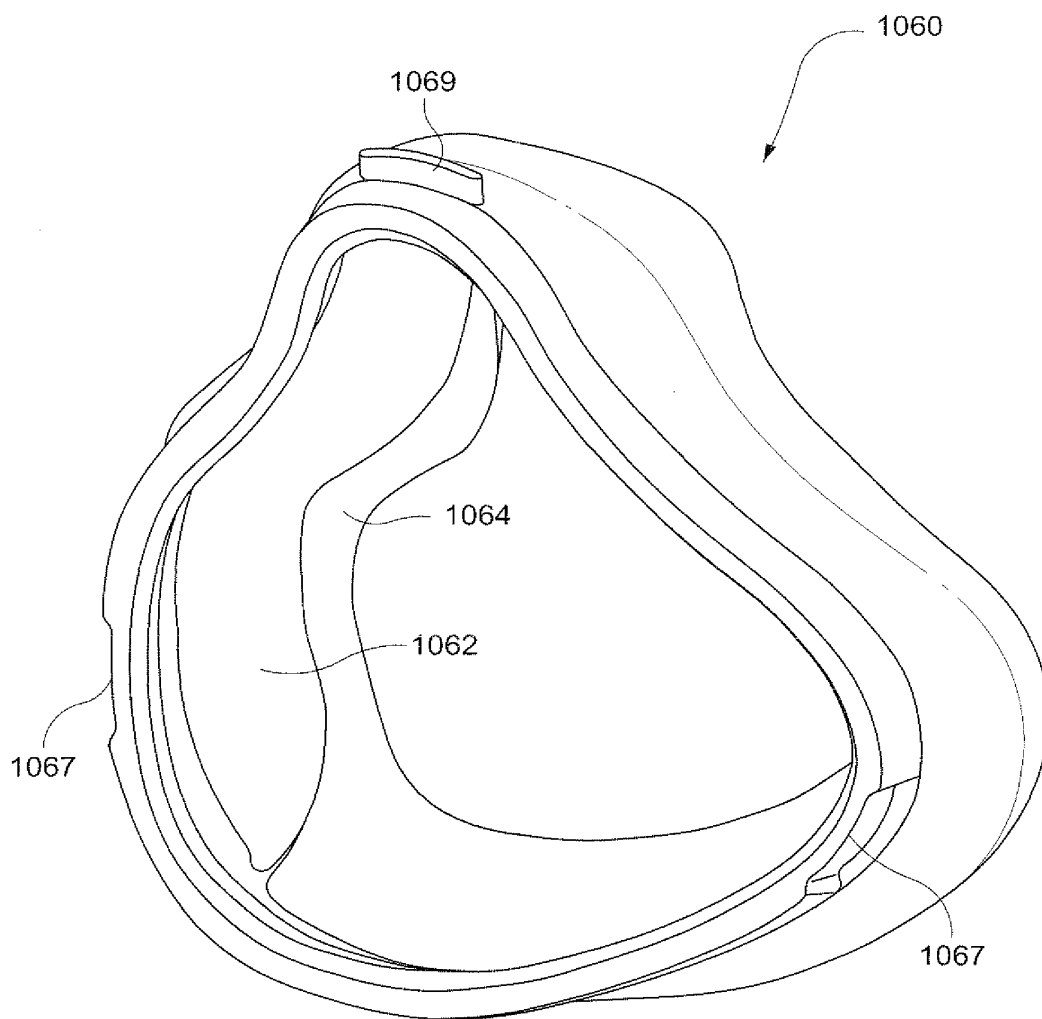


Fig. 7

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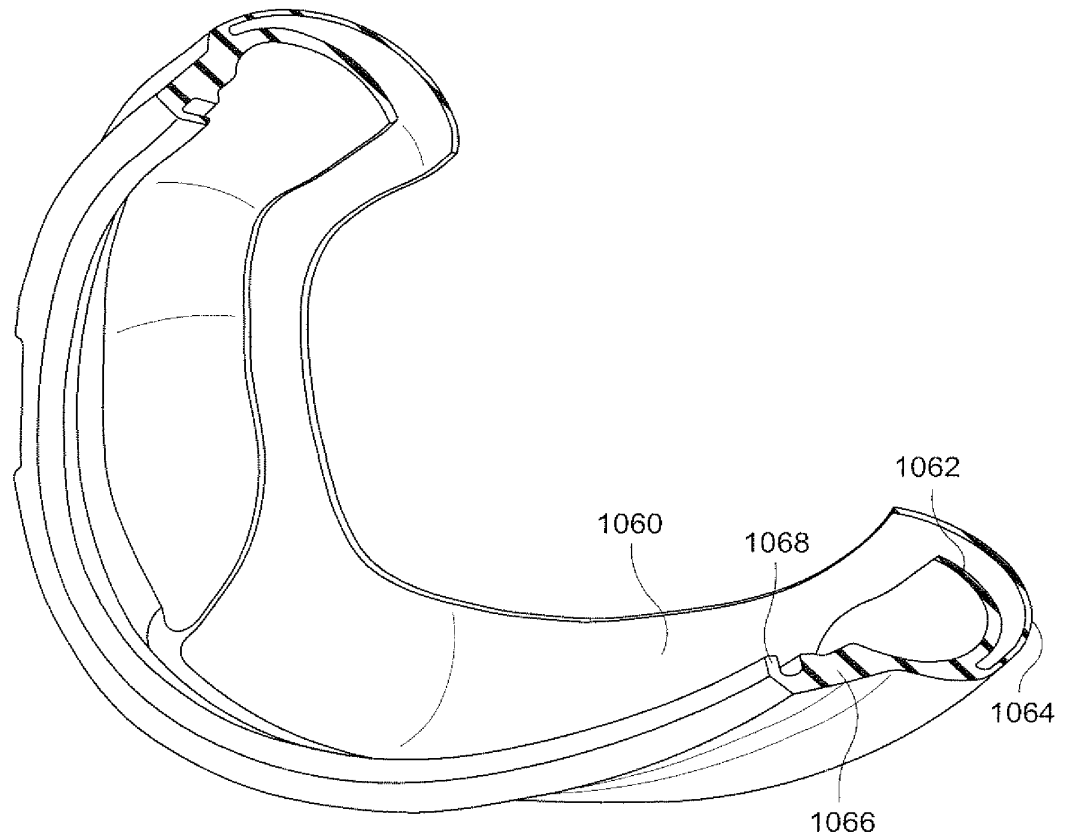


Fig. 8

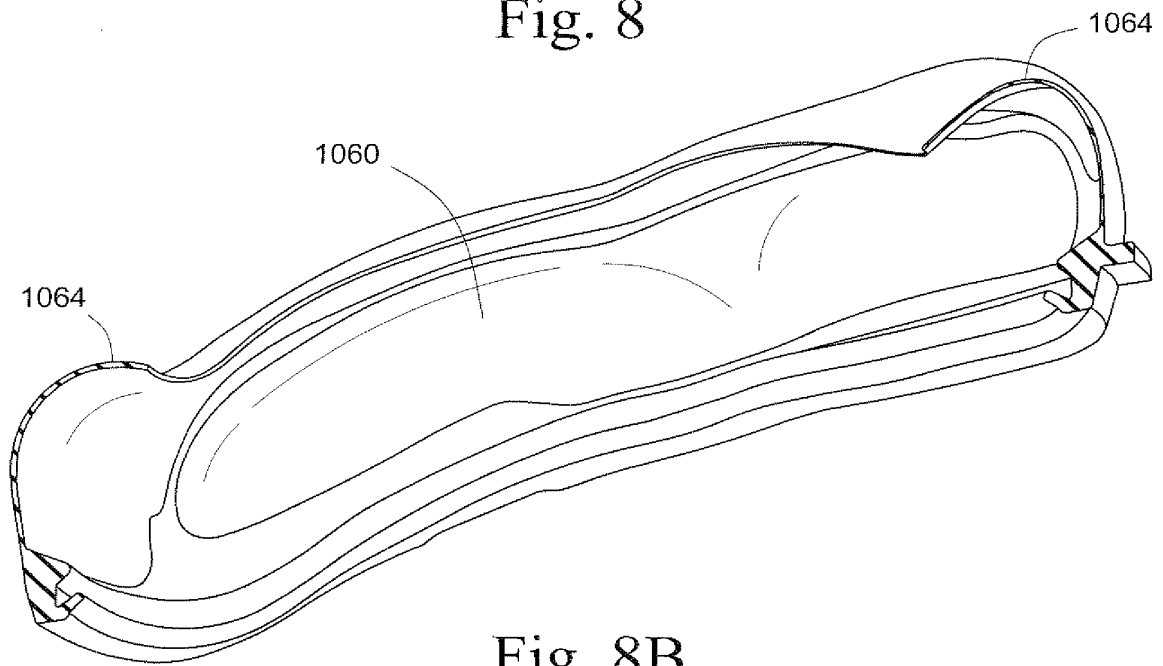


Fig. 8B

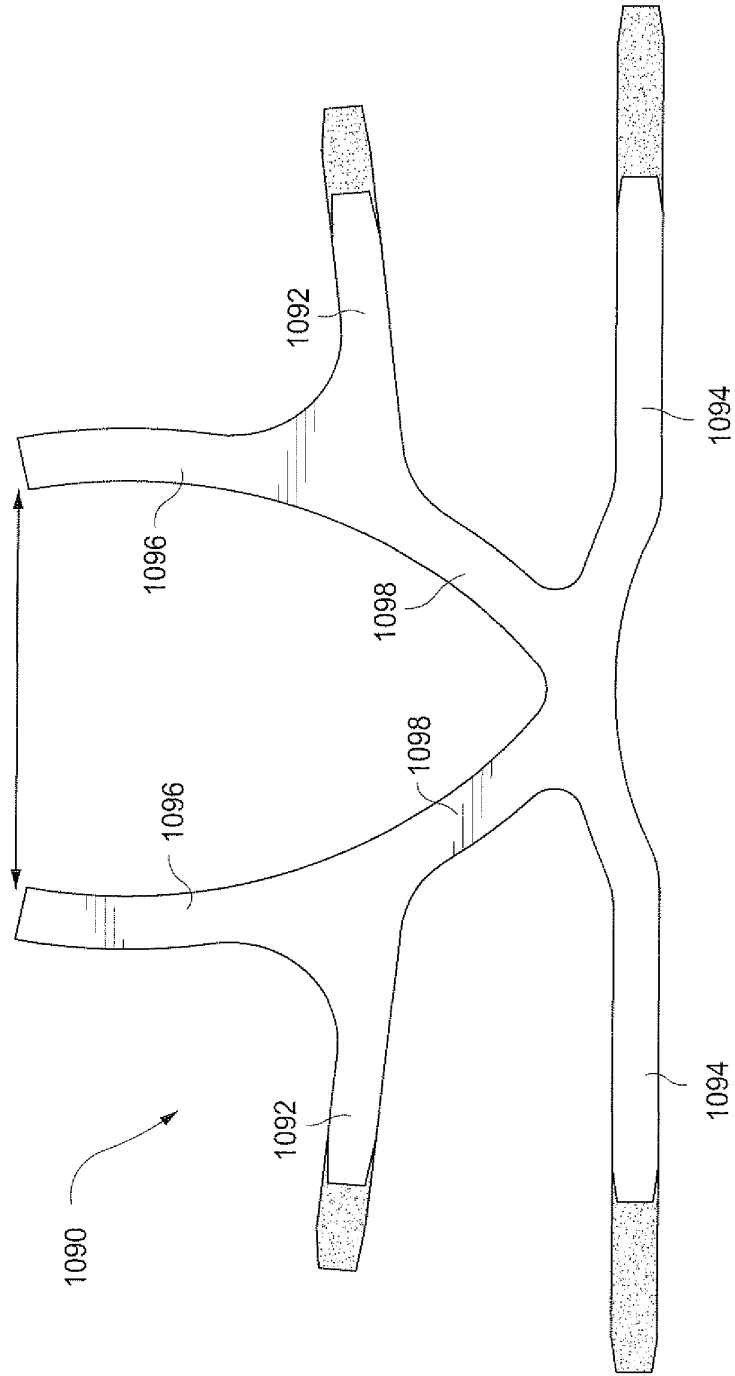


Fig. 9

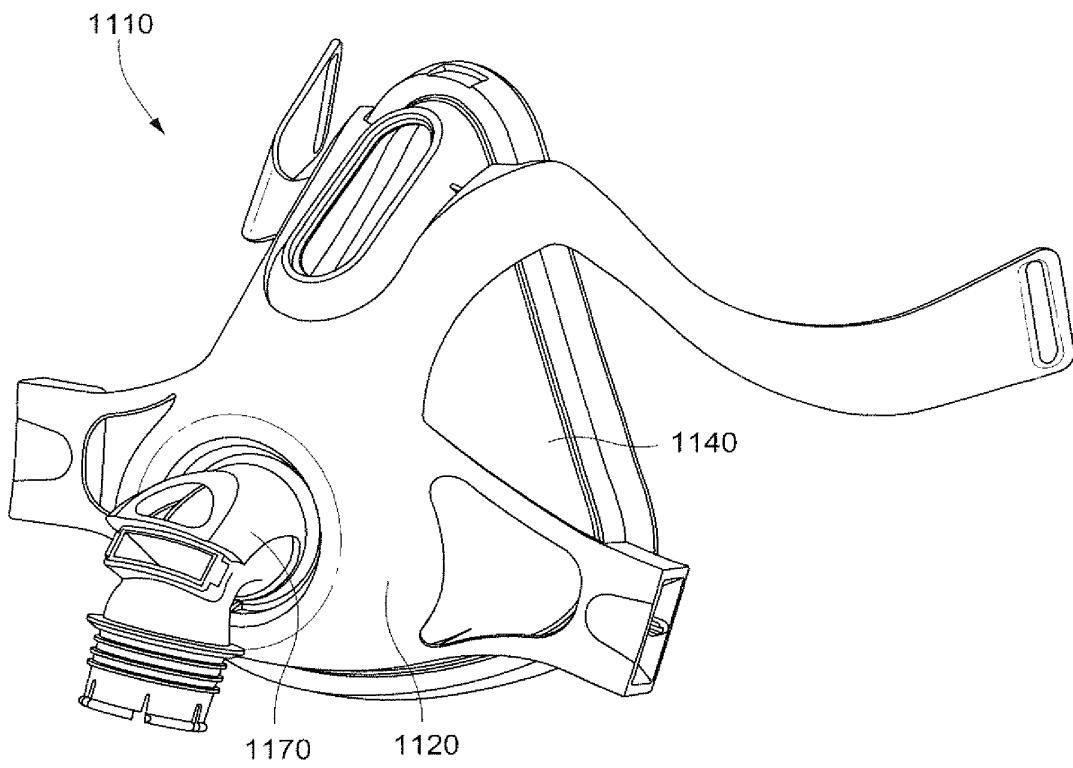


Fig. 10

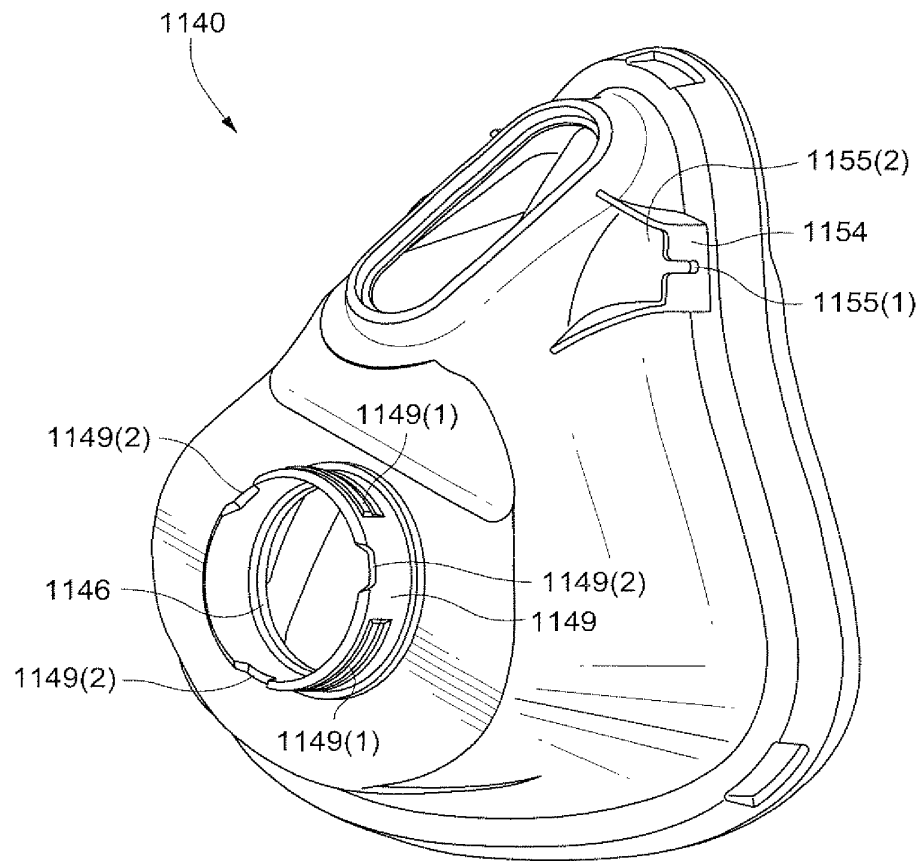


Fig. 11

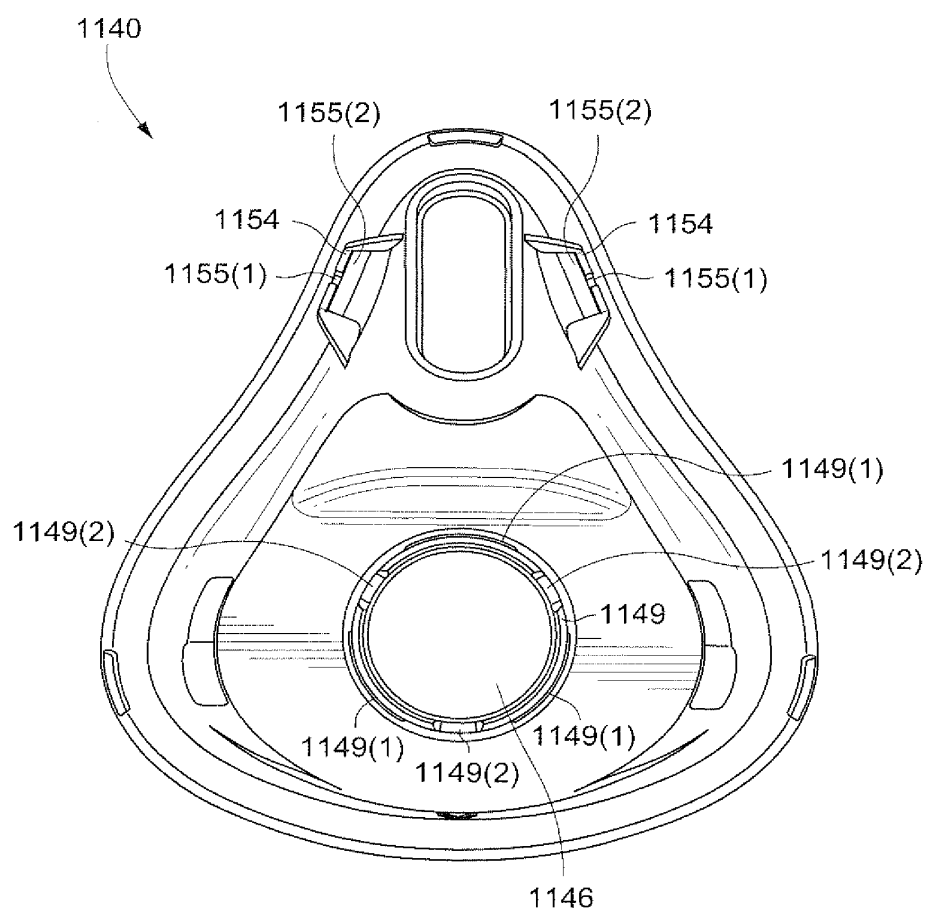


Fig. 12

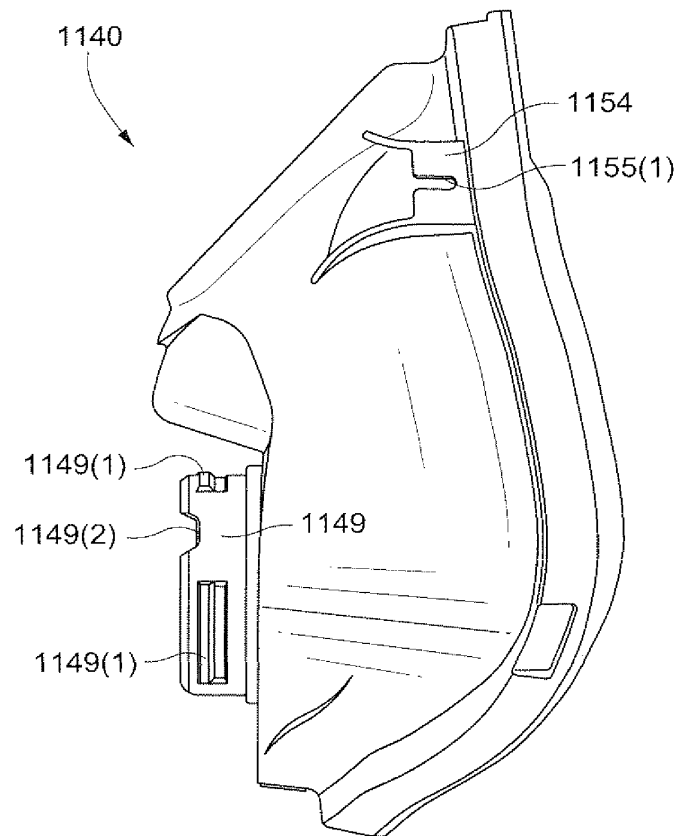


Fig. 13

17/81

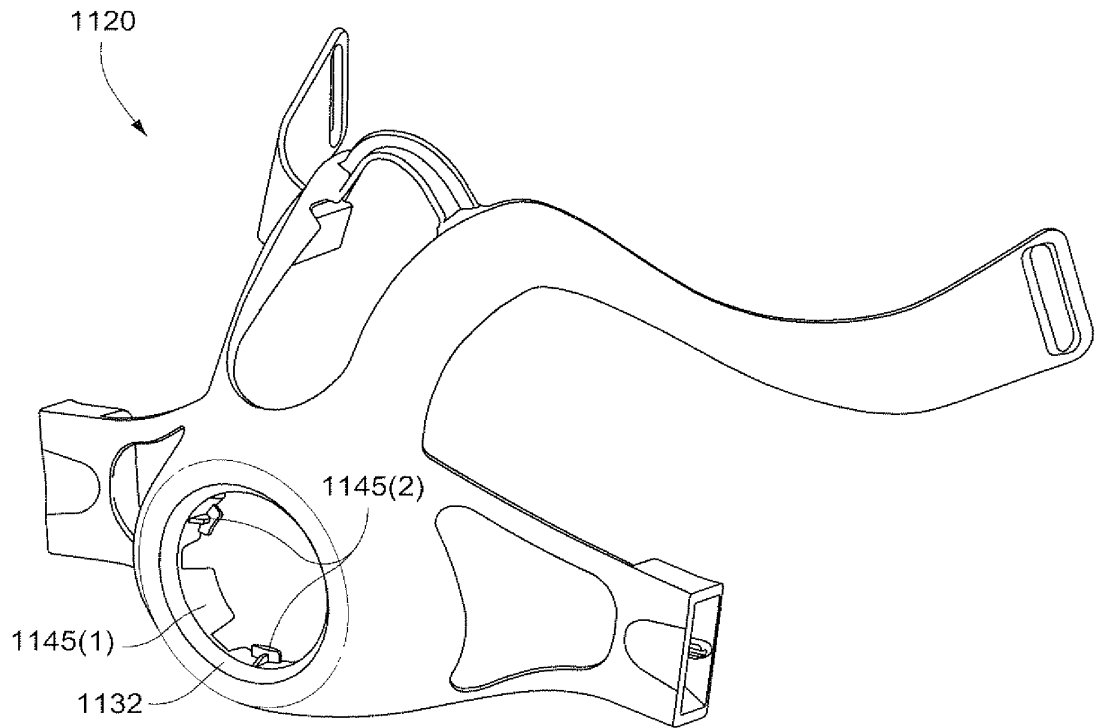


Fig. 14

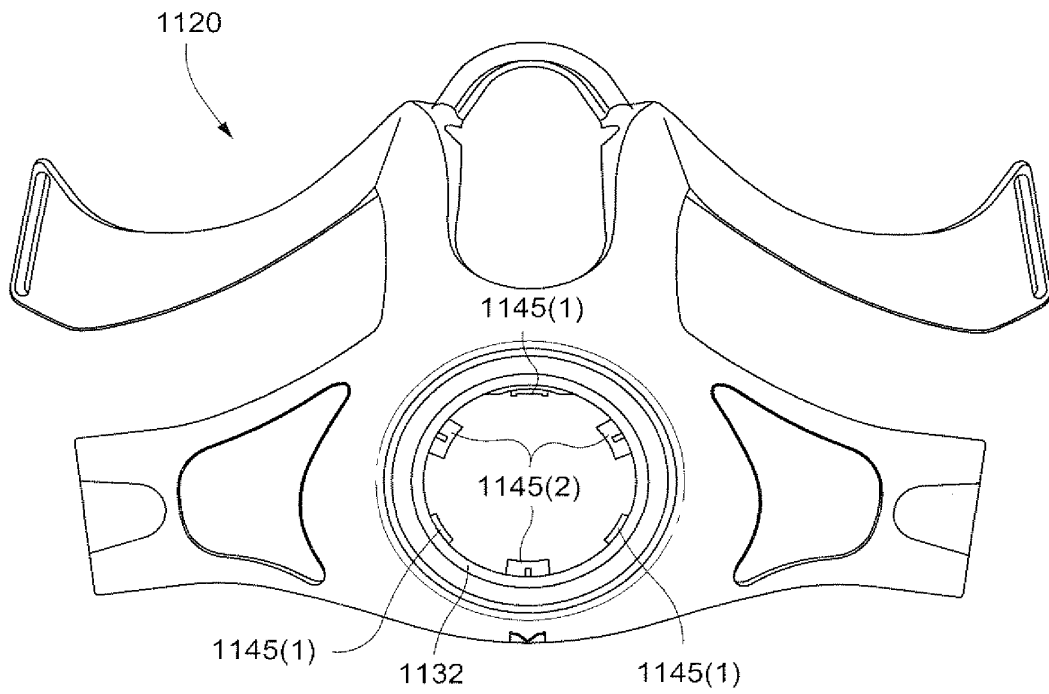


Fig. 15

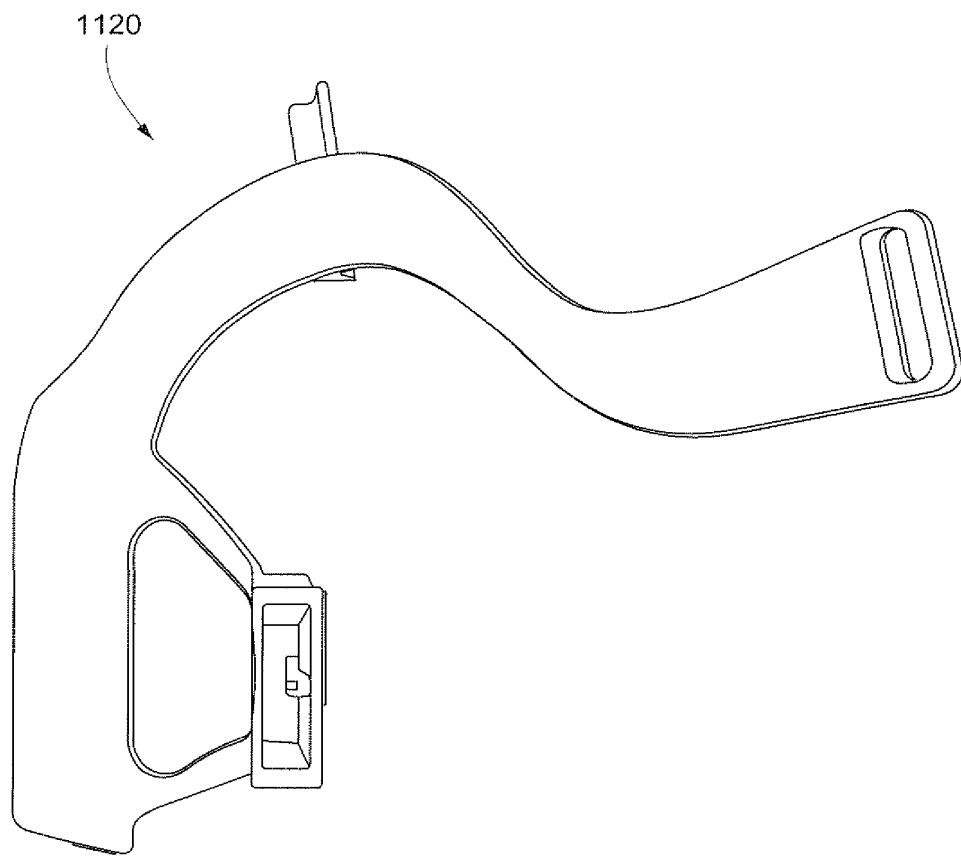


Fig. 16

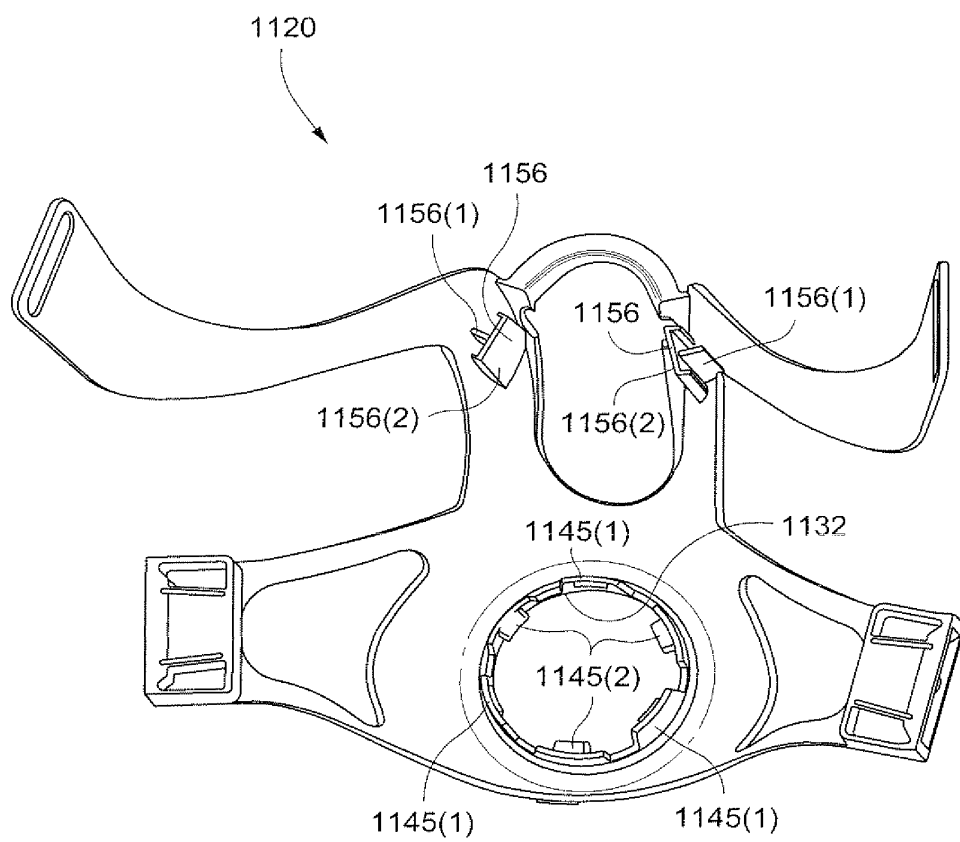


Fig. 17

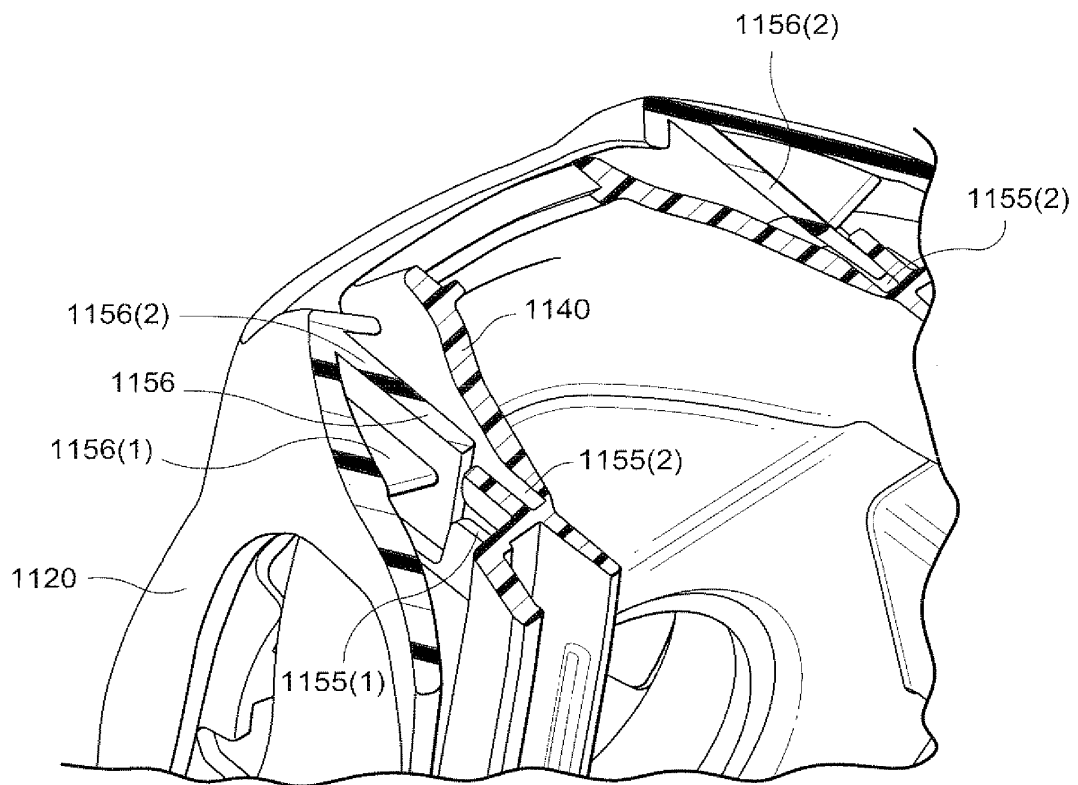


Fig. 18-1

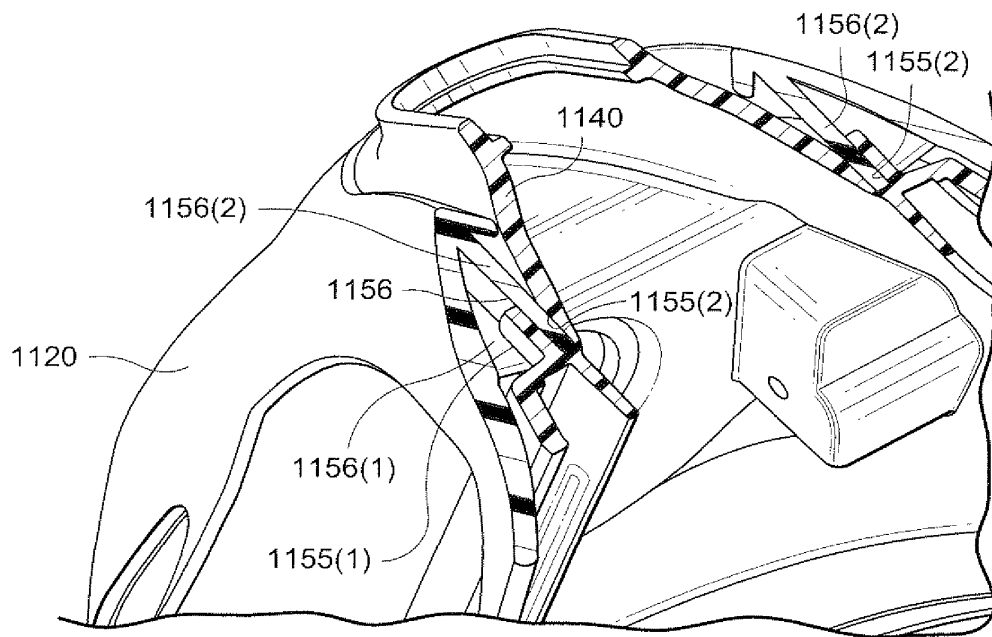


Fig. 18-2

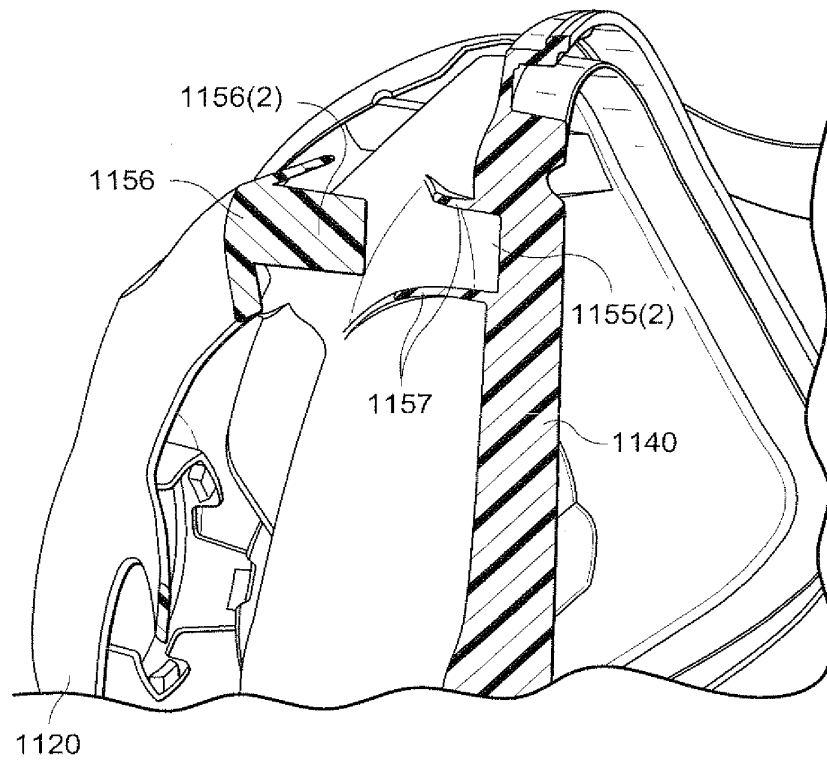


Fig. 19-1

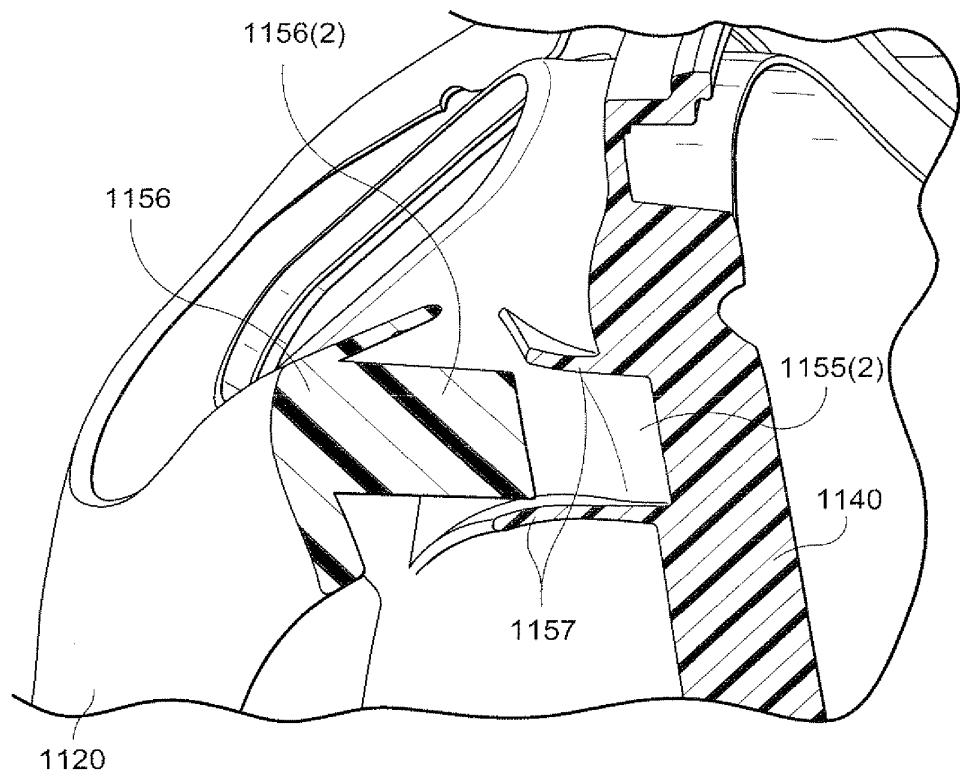


Fig. 19-2

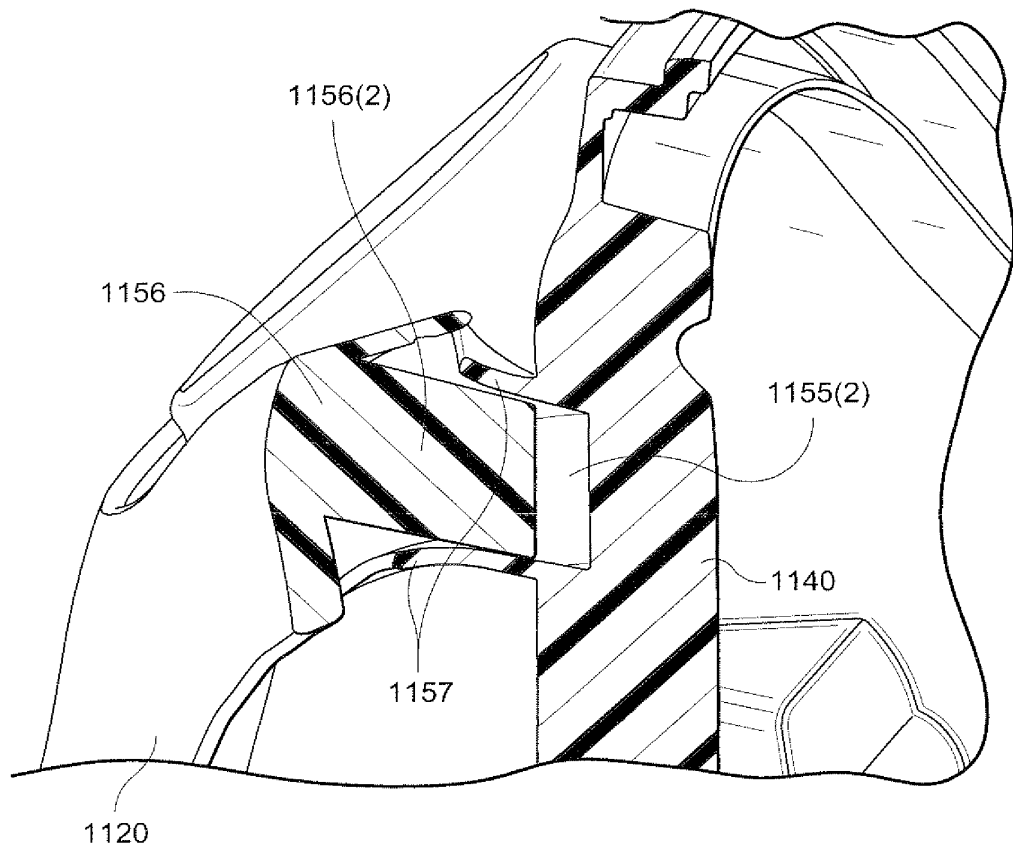


Fig. 19-3

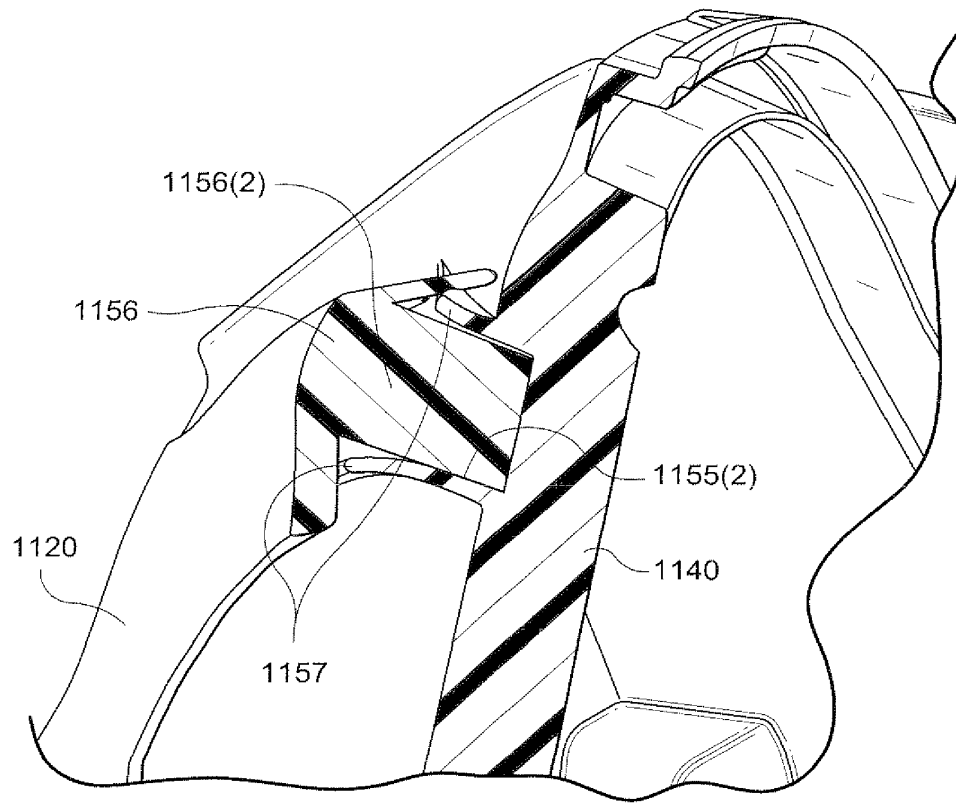


Fig. 19-4

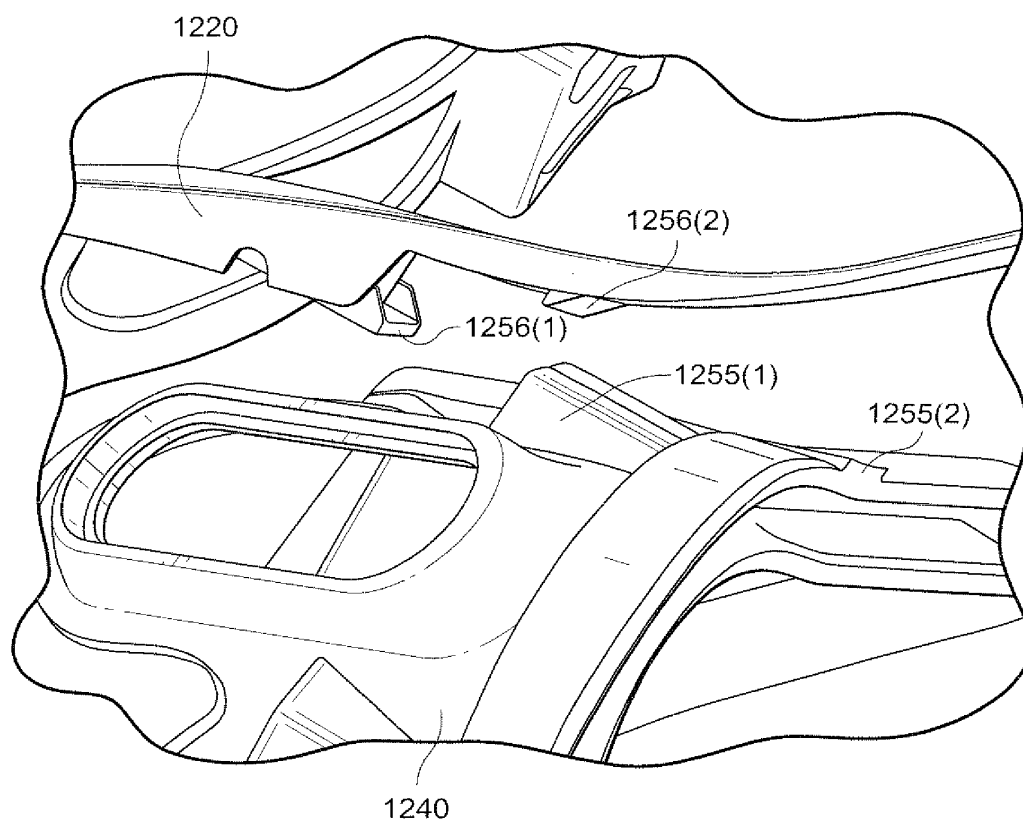


Fig. 20

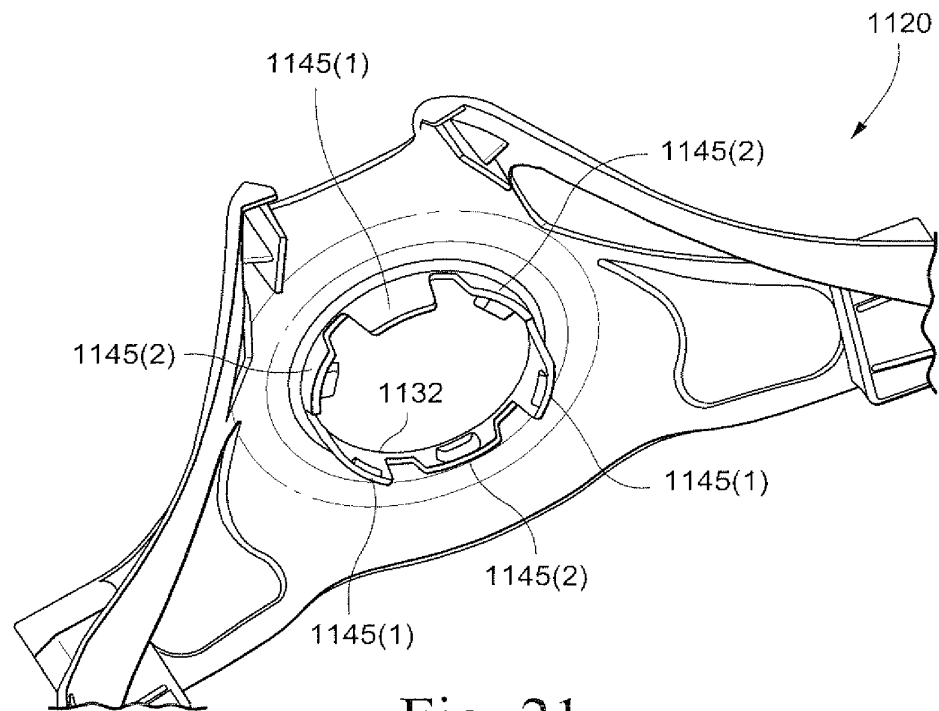


Fig. 21

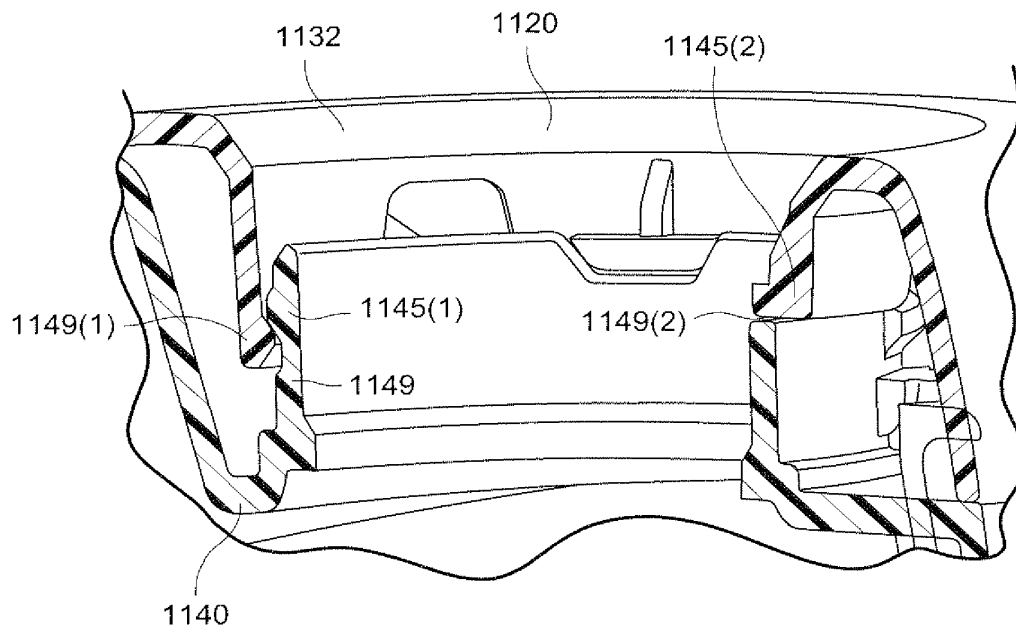


Fig. 22

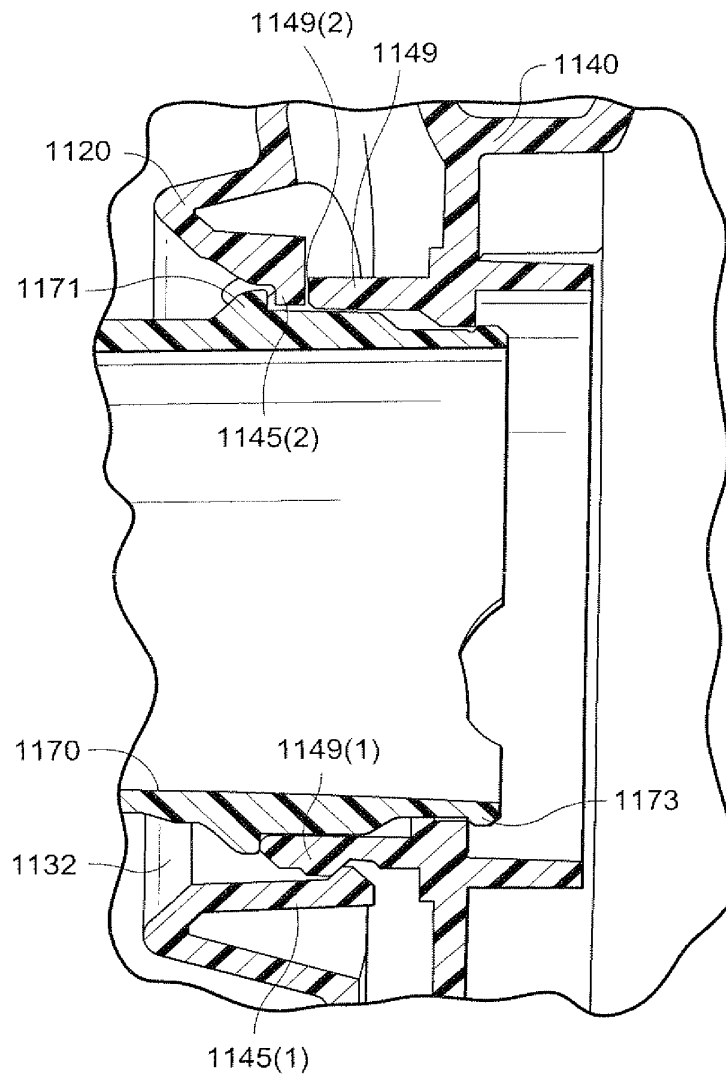


Fig. 23

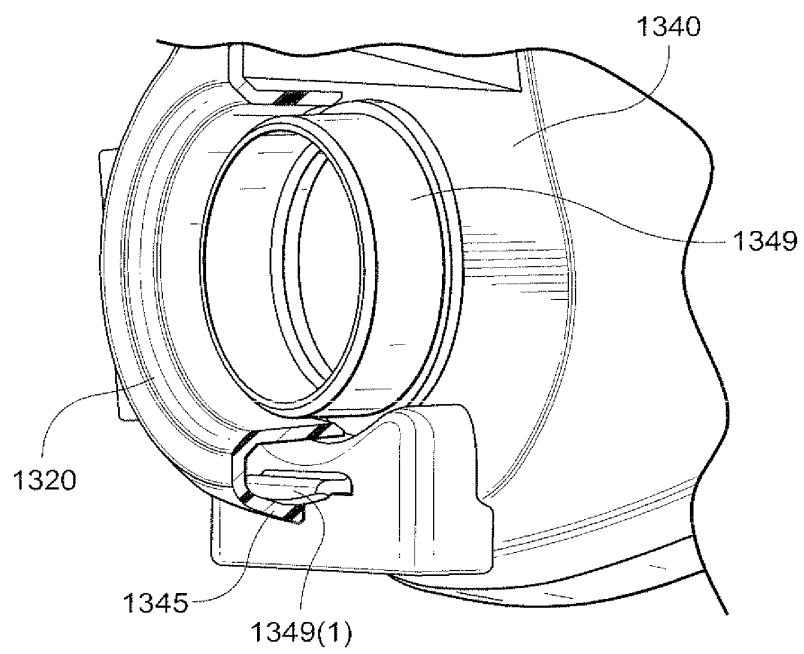


Fig. 24

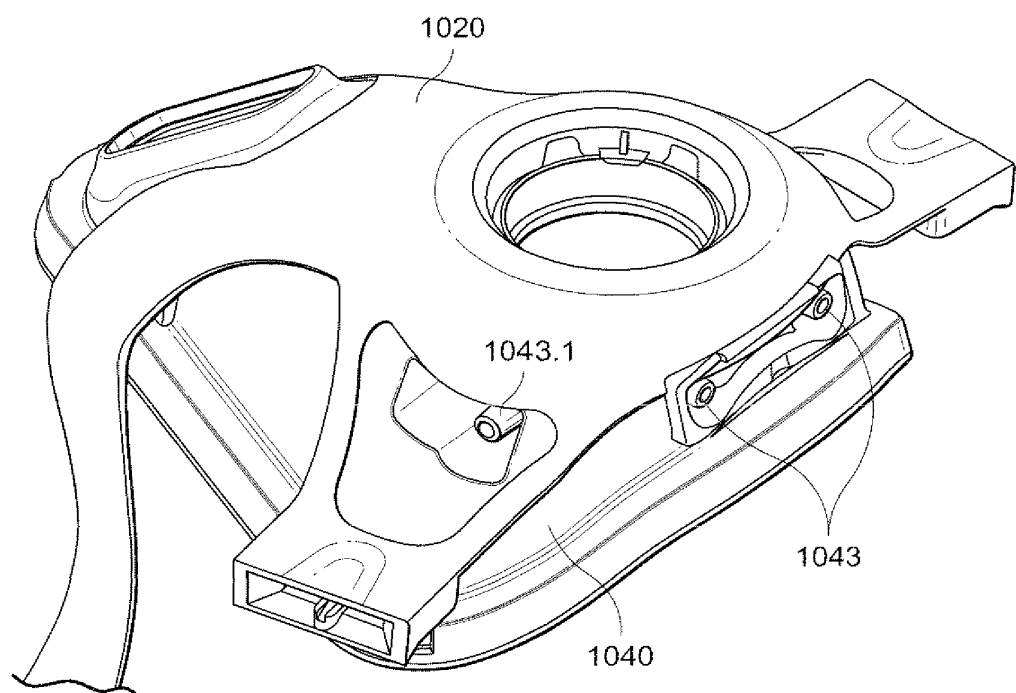


Fig. 25

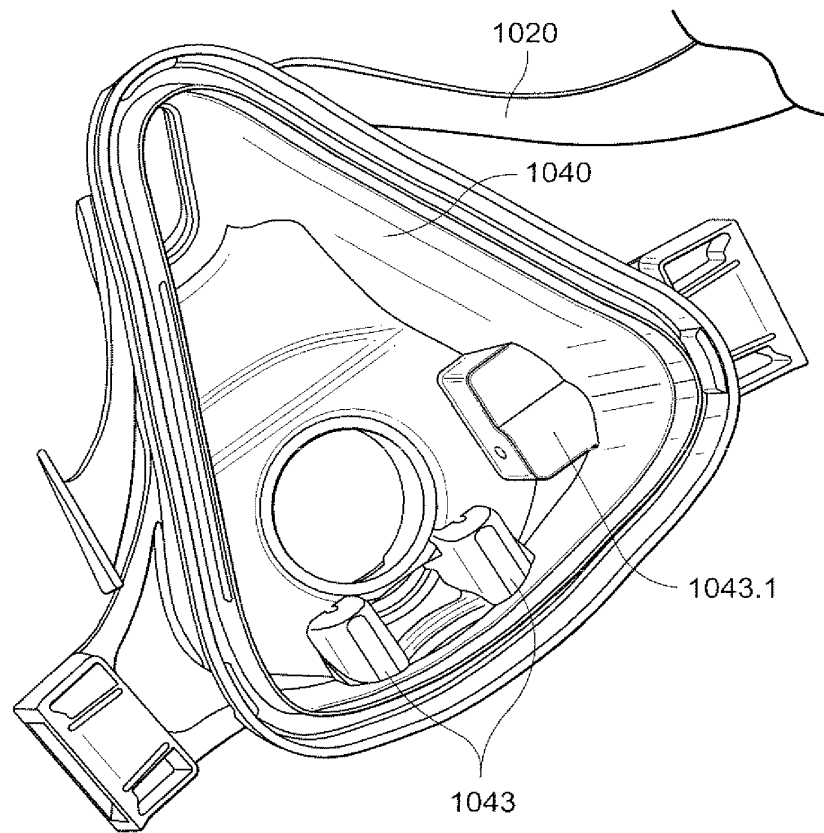


Fig. 26

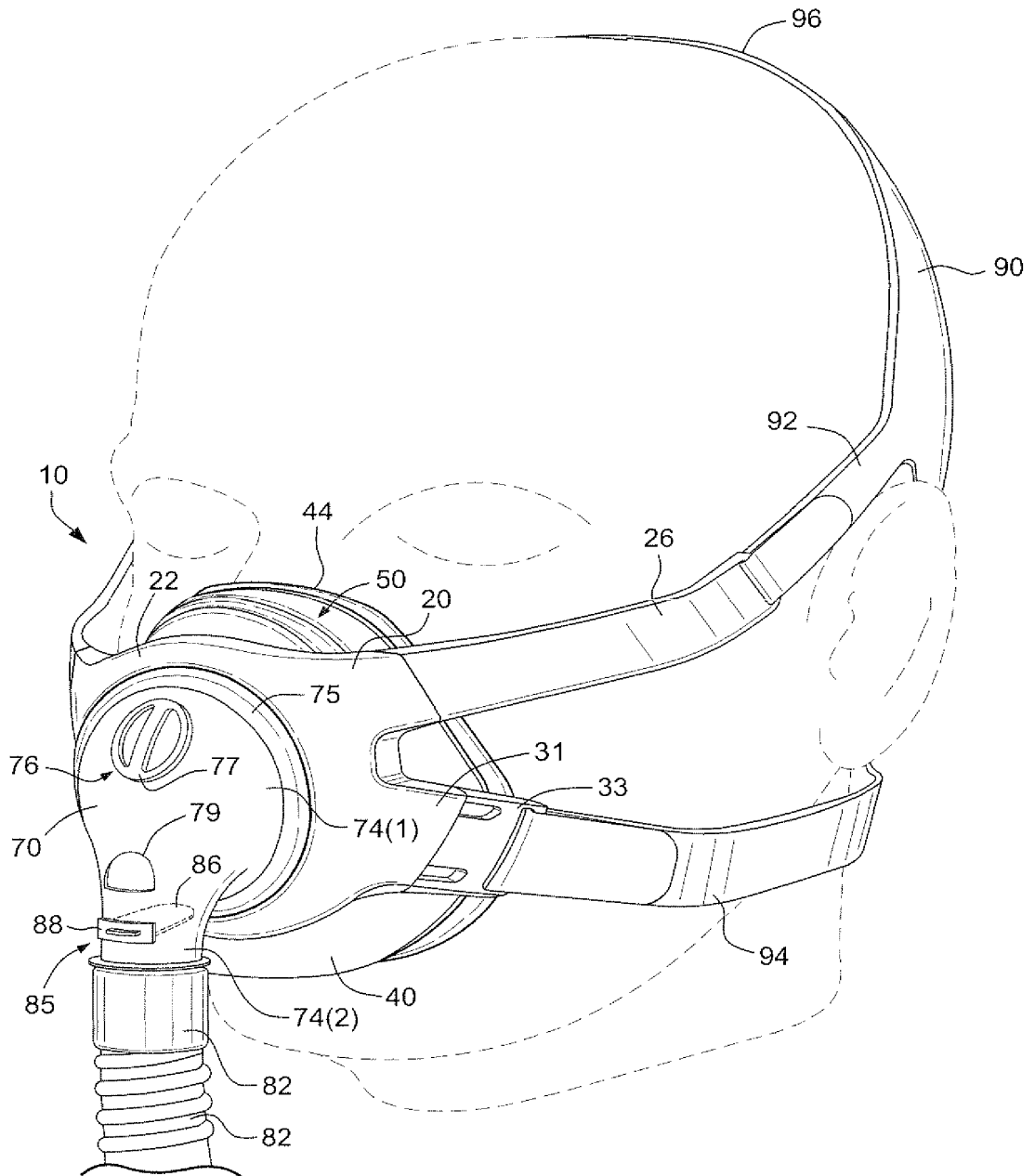


Fig. 27

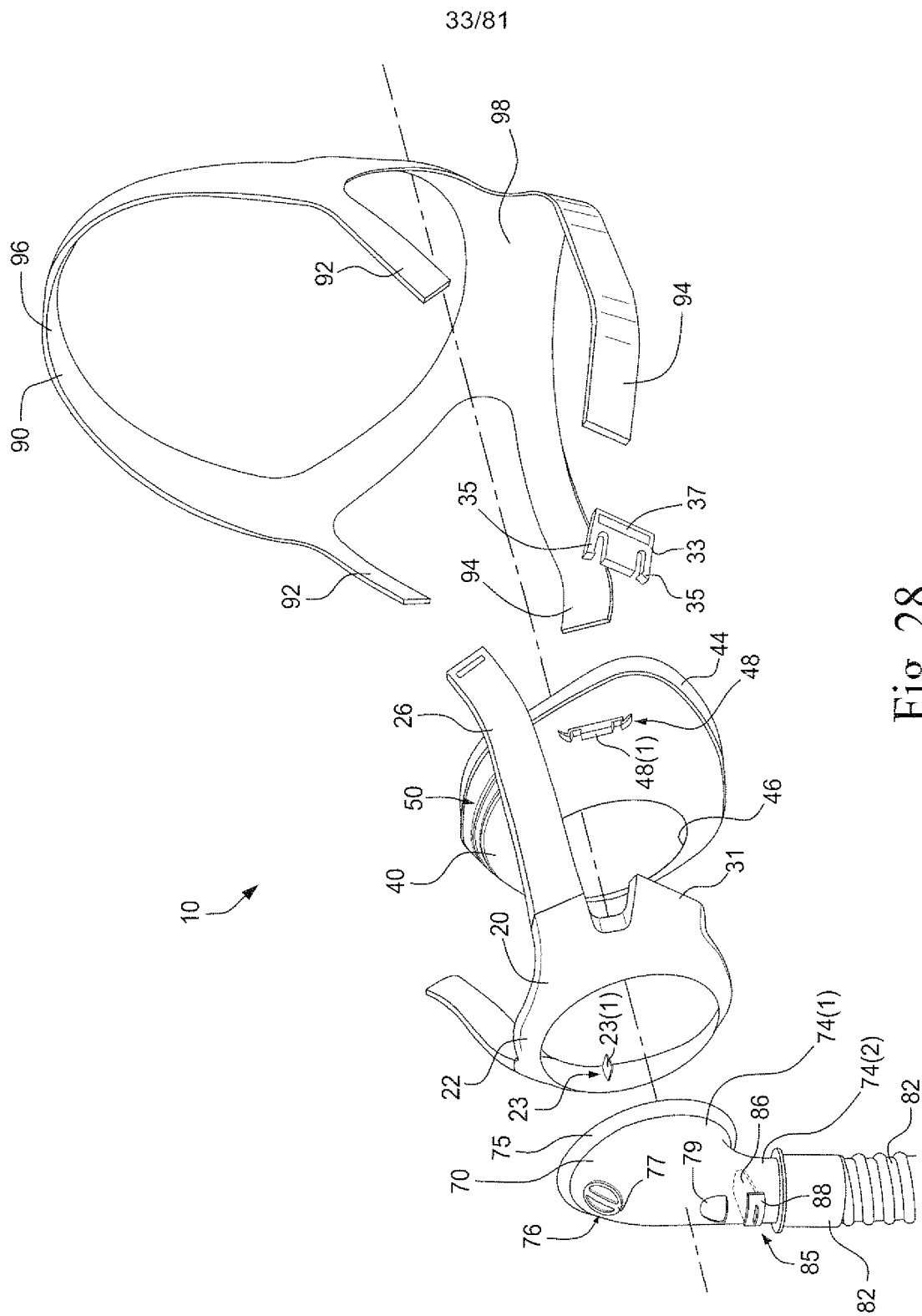


Fig. 28

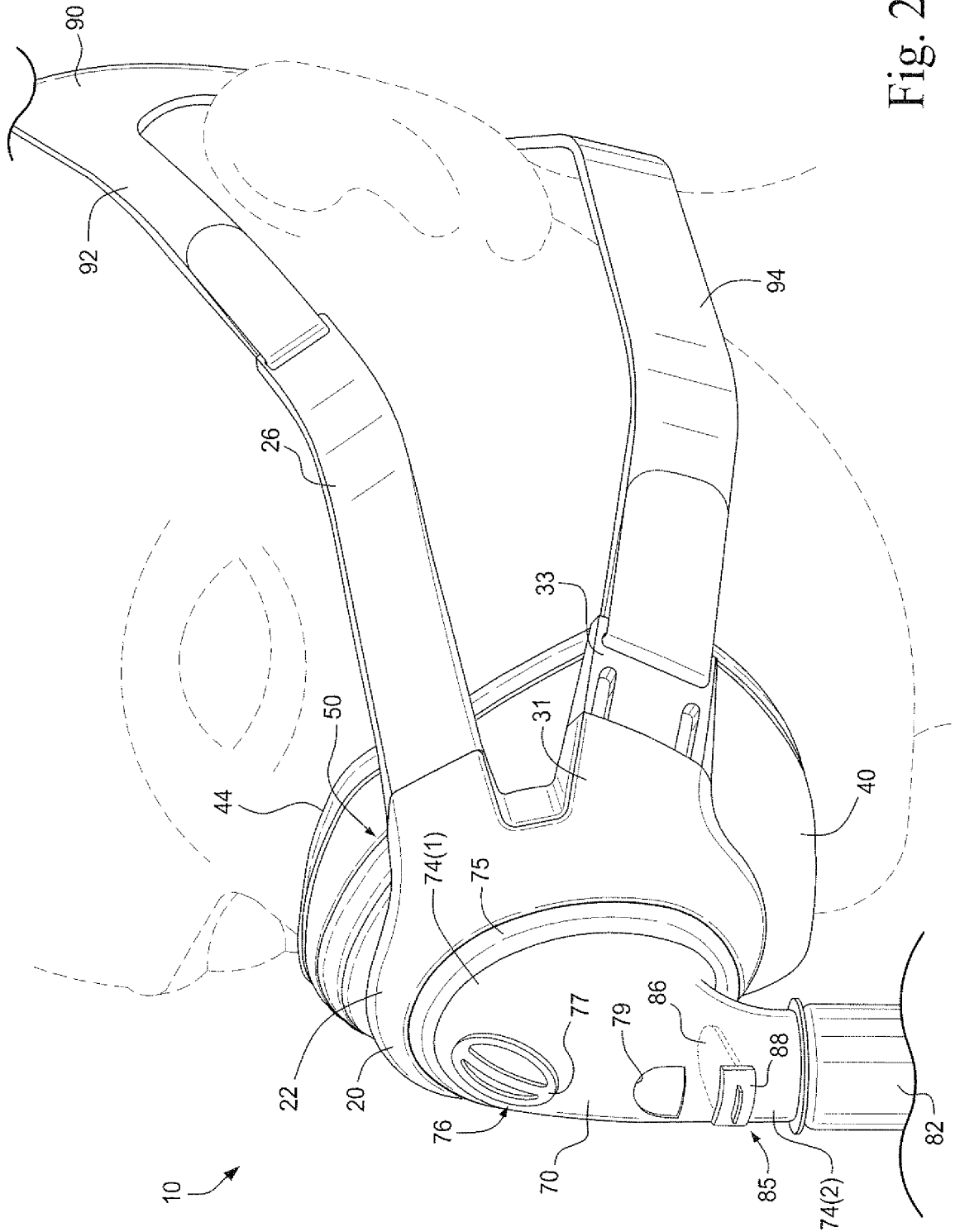


Fig. 29

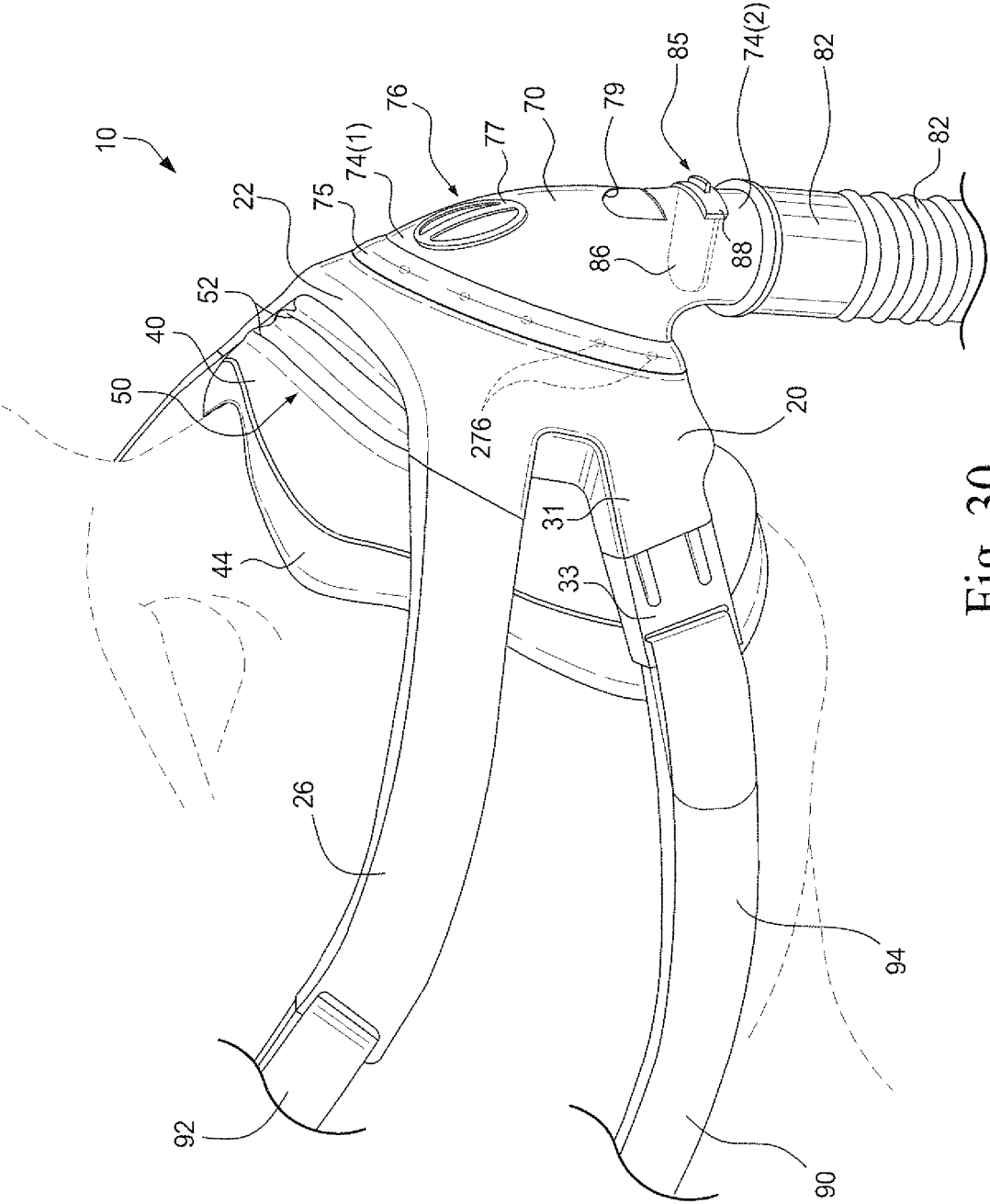


Fig. 30

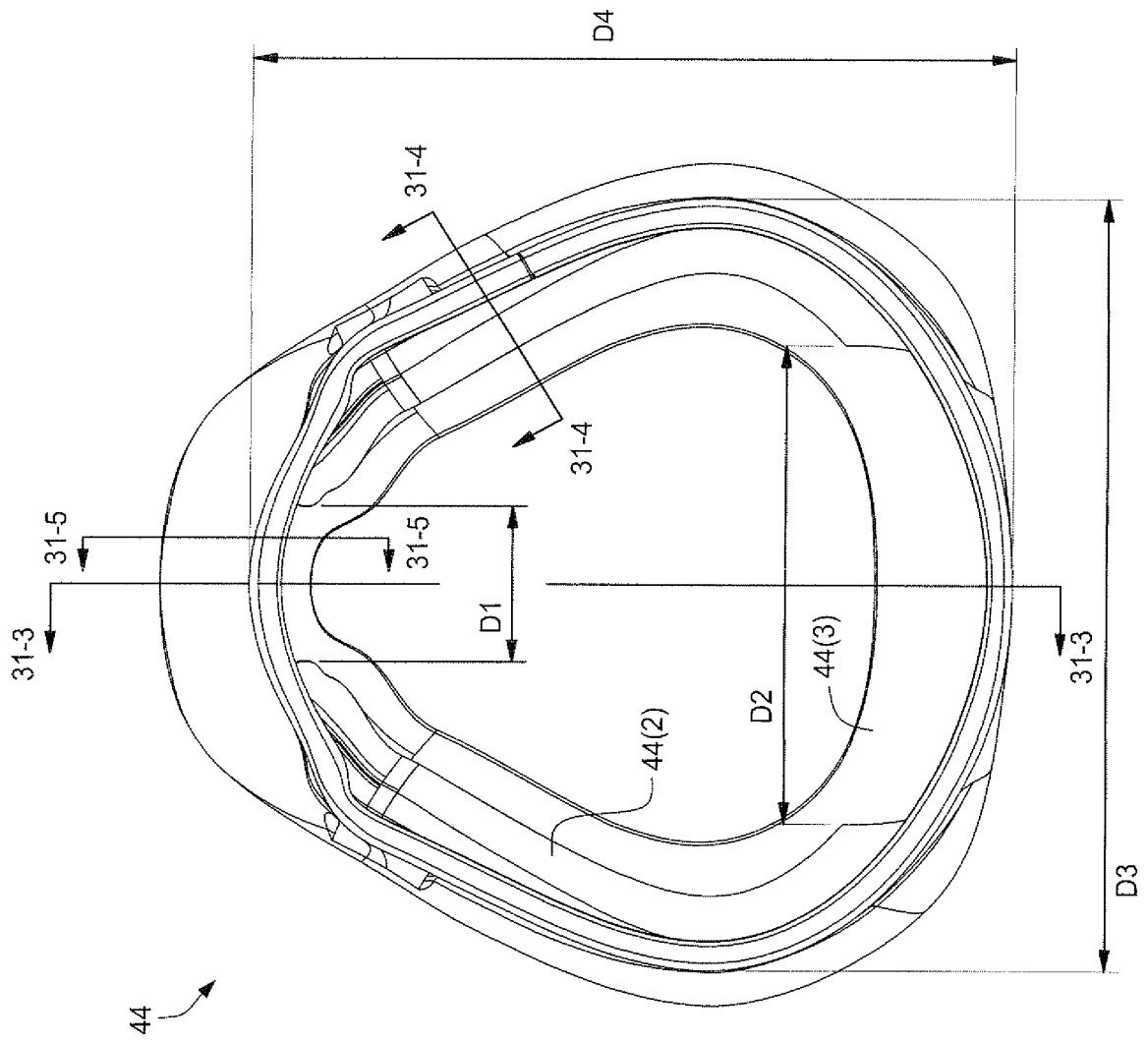


Fig. 31-1

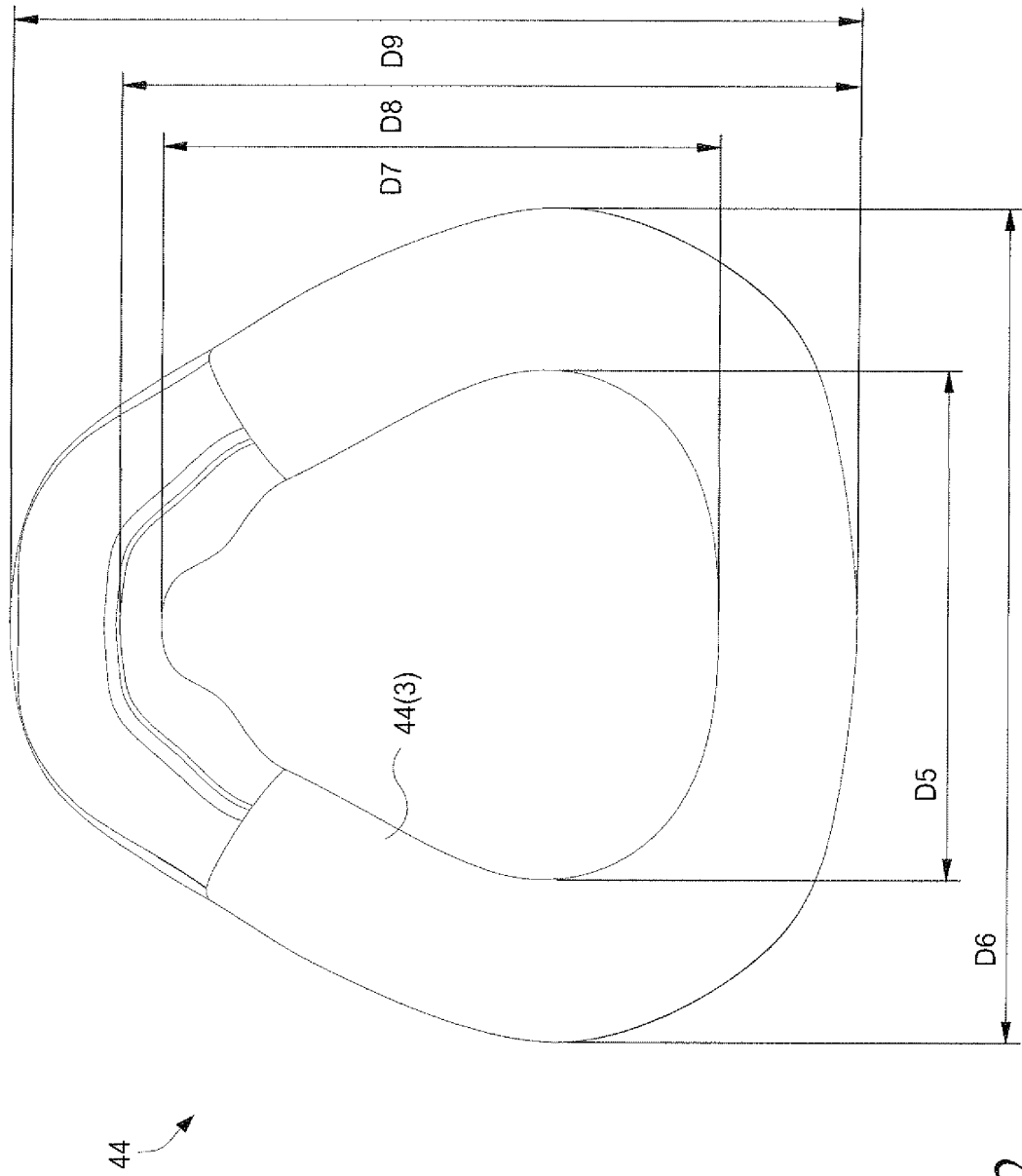


Fig. 31-2

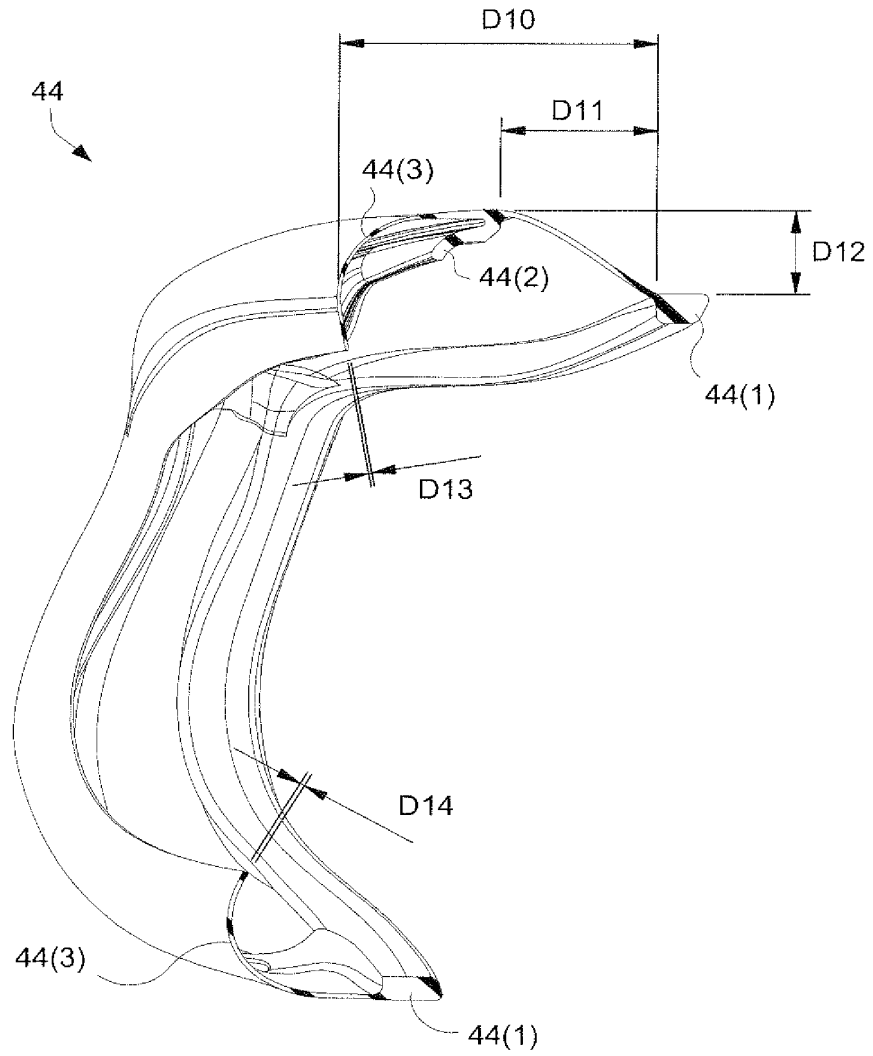


Fig. 31-3

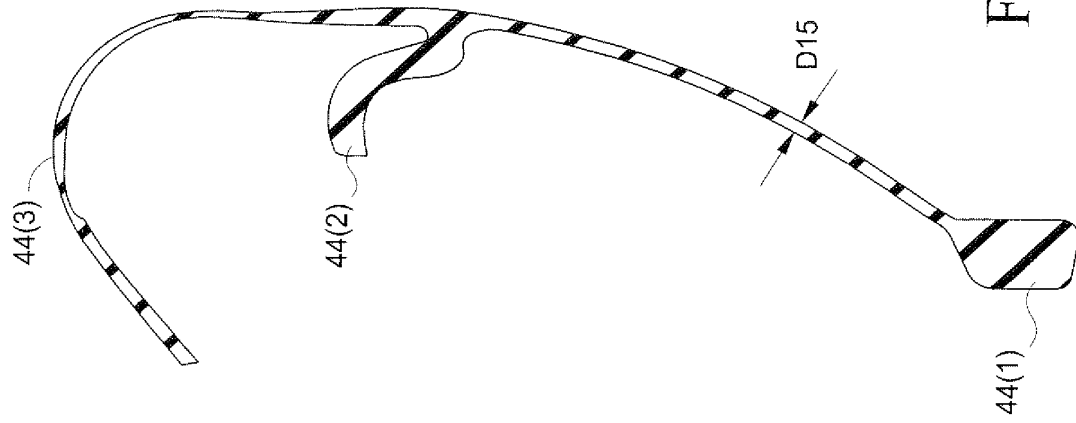


Fig. 31-5

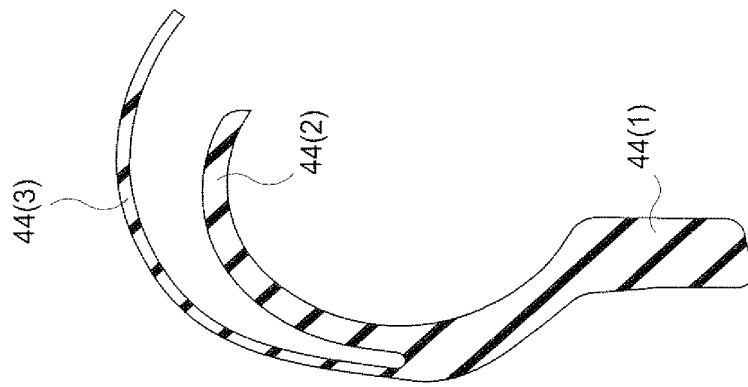


Fig. 31-4

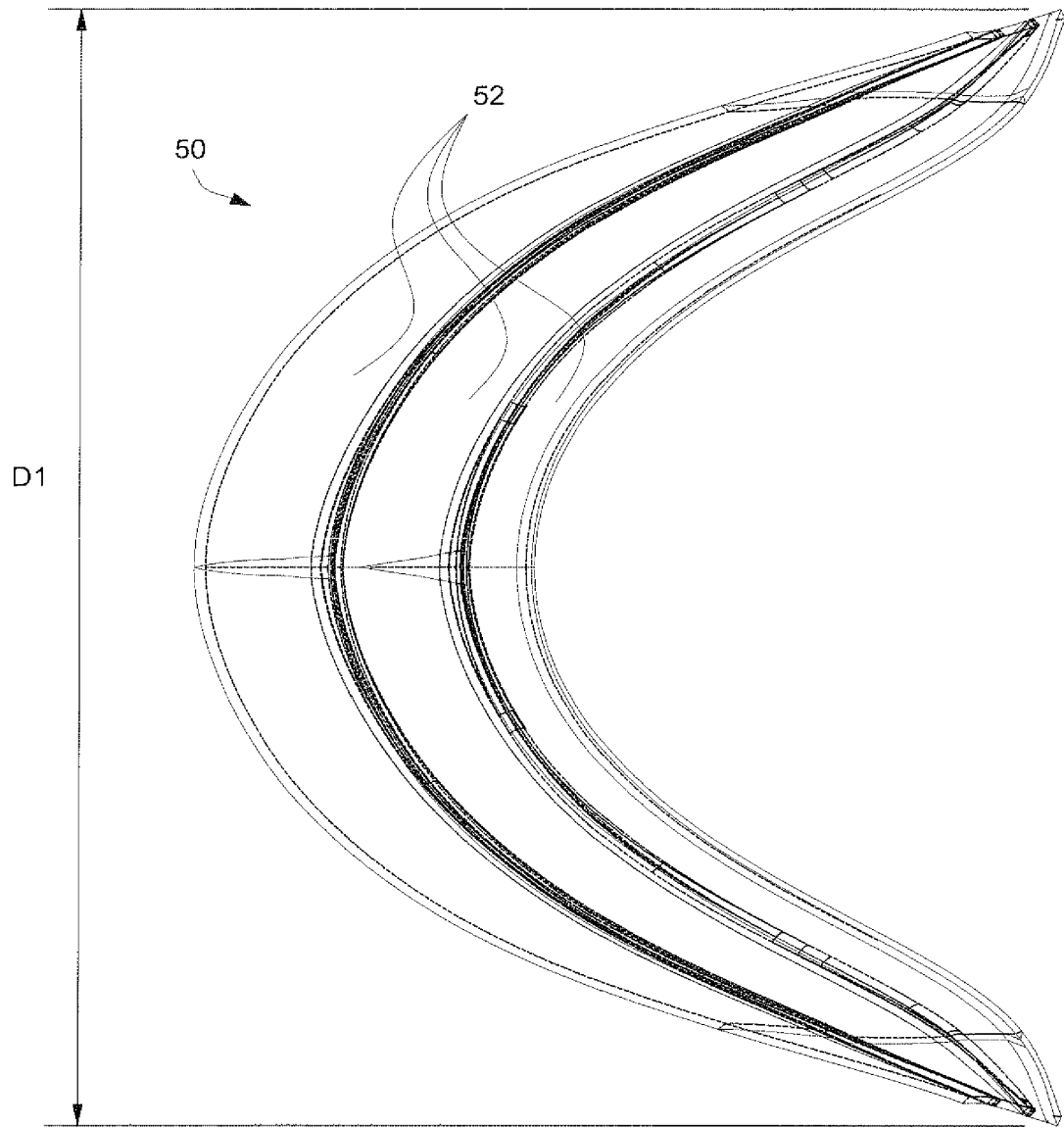


Fig. 32-1

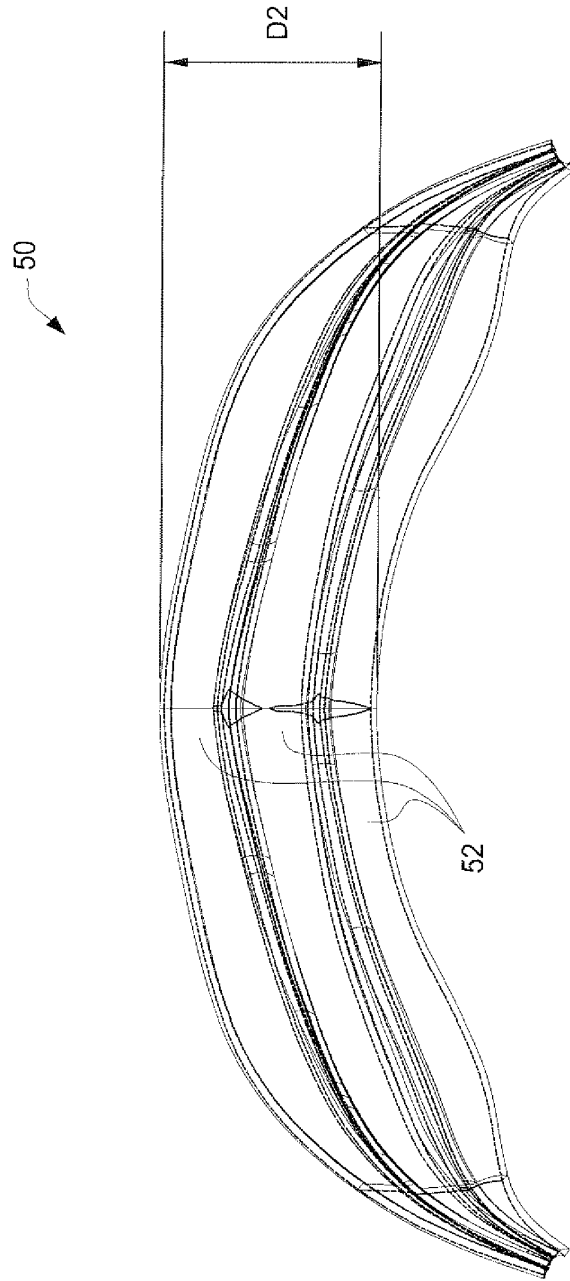


Fig. 32-2

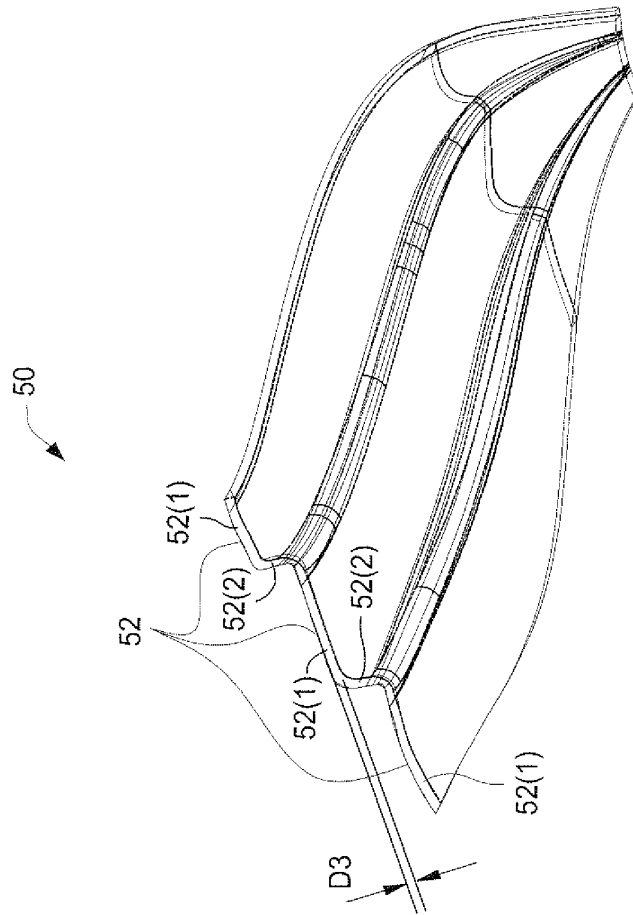


Fig. 32-3

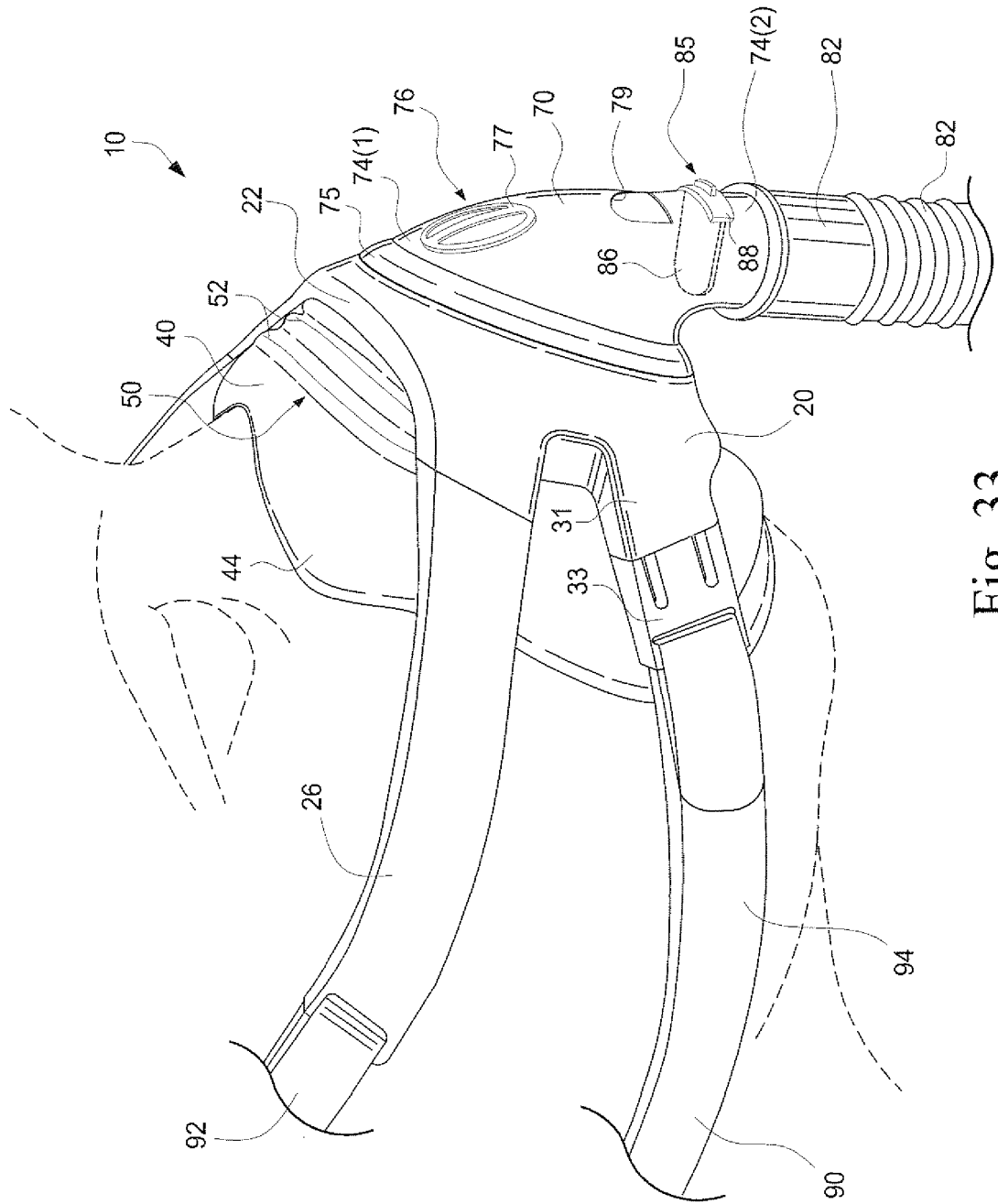


Fig. 33

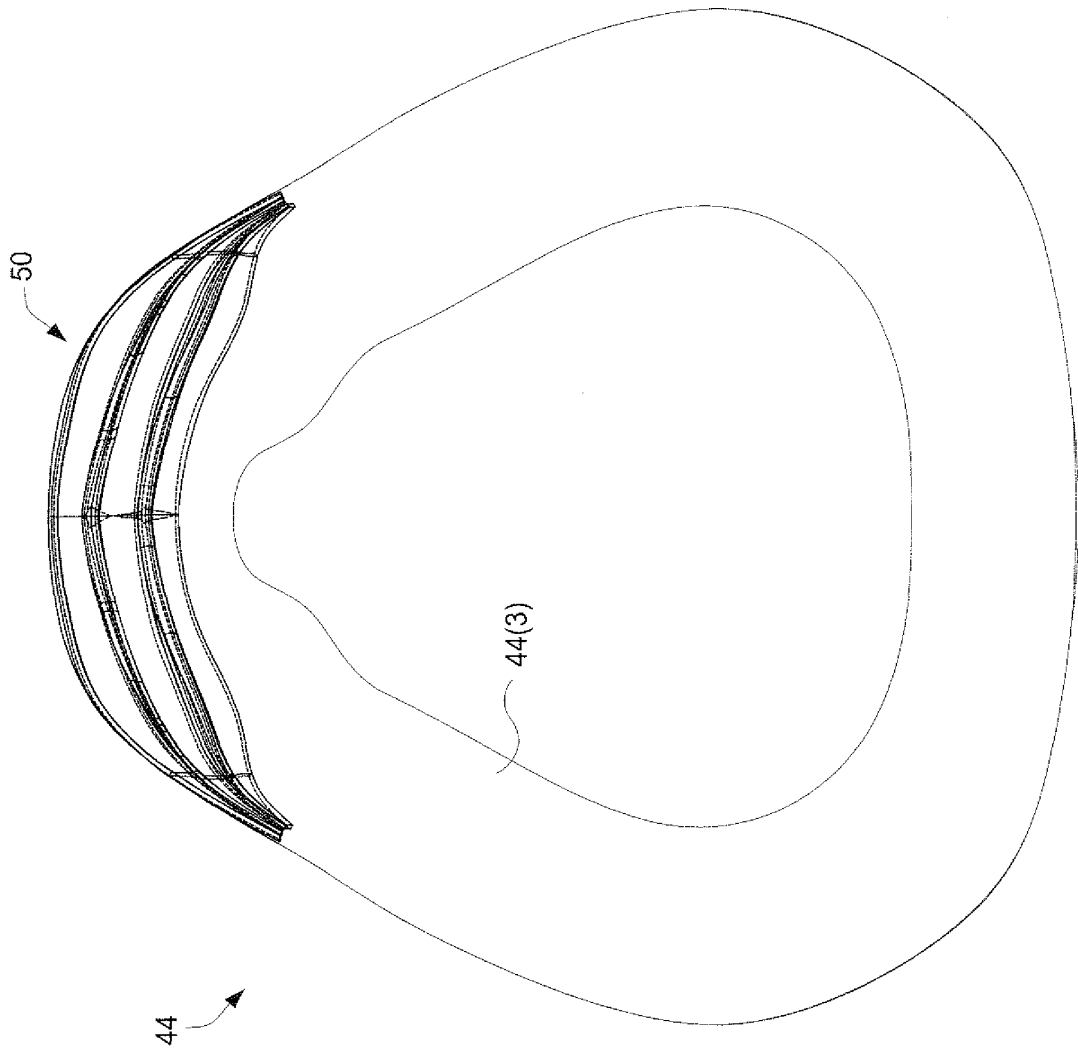


Fig. 34

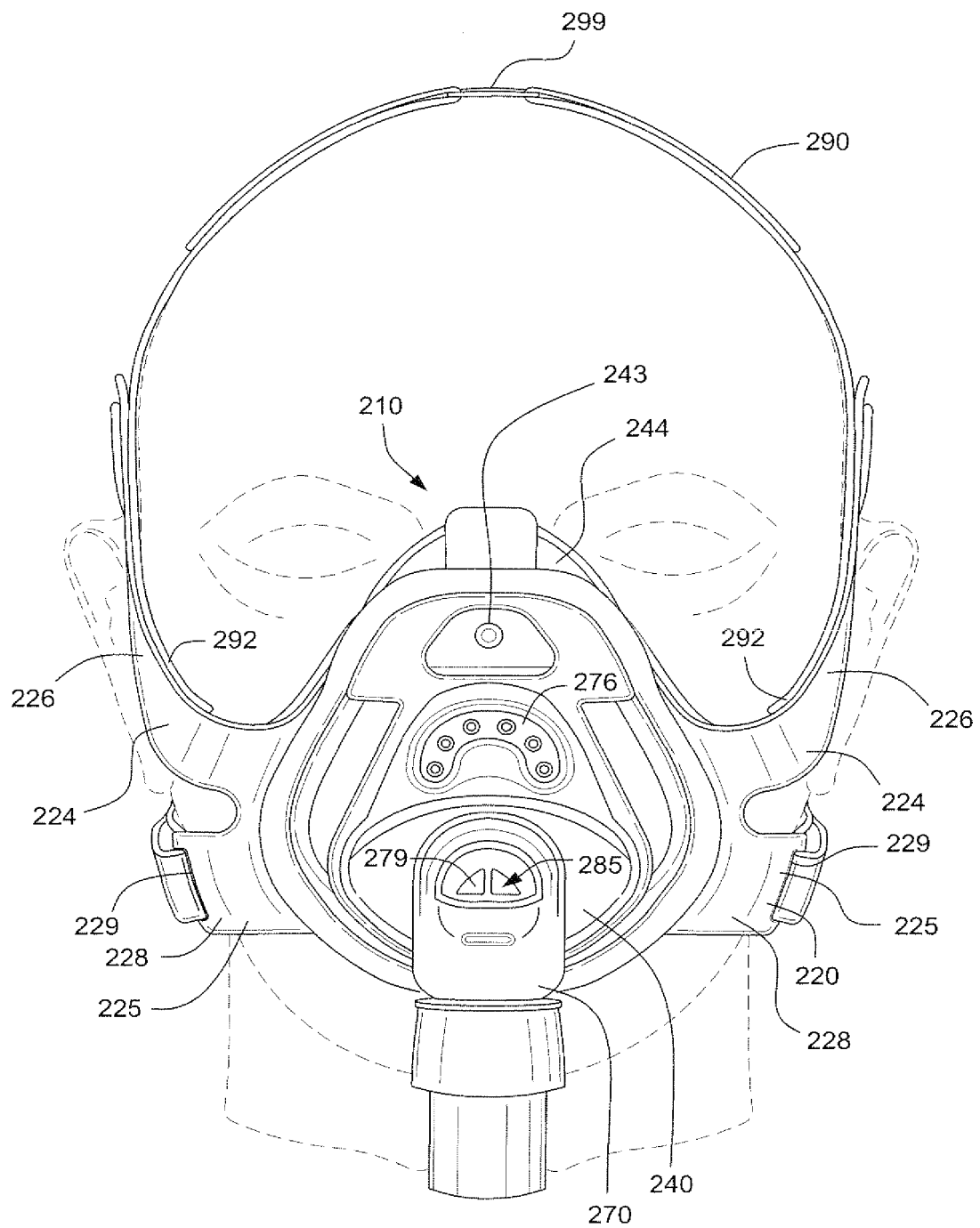


Fig. 35-1

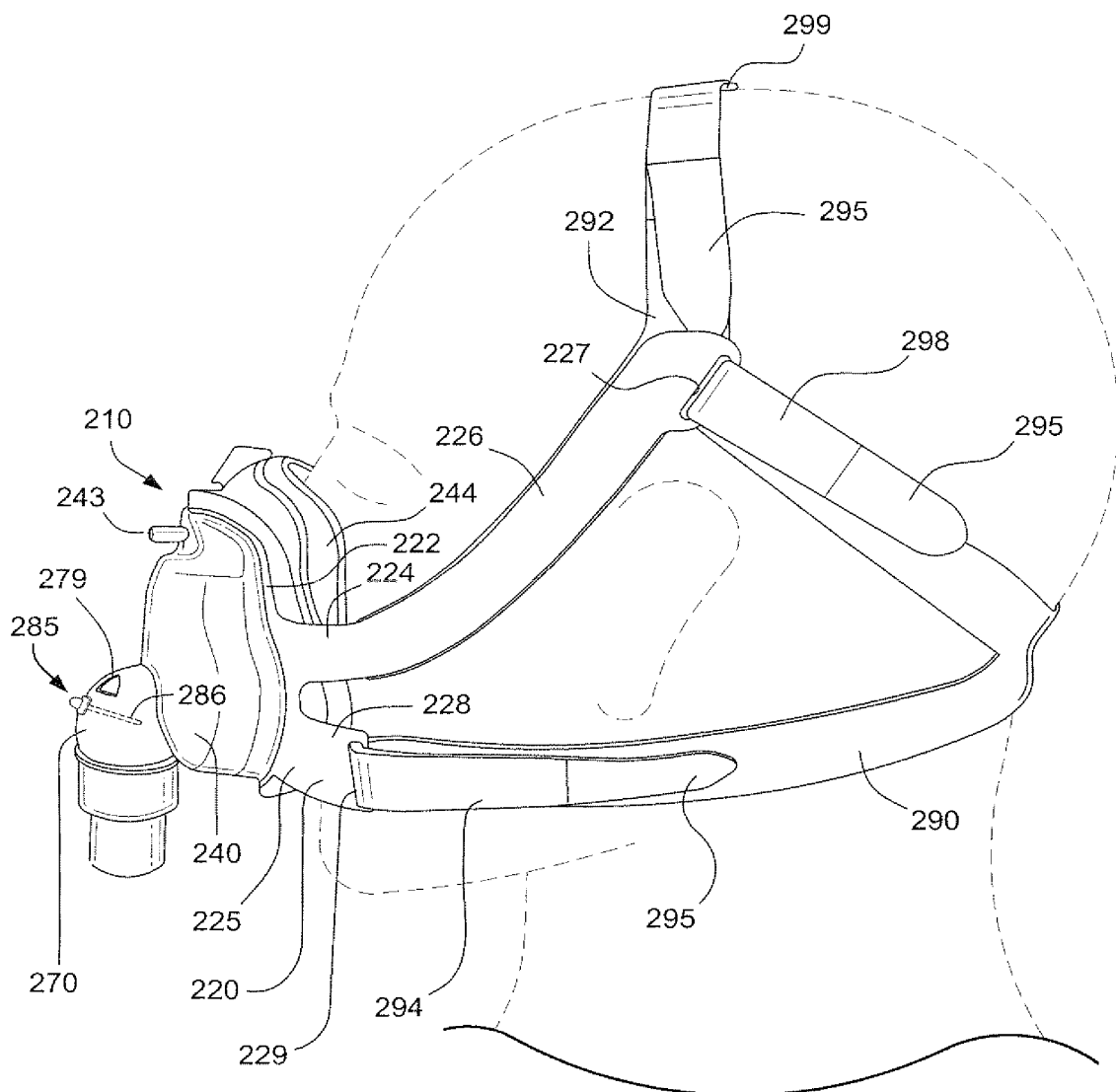


Fig. 35-2

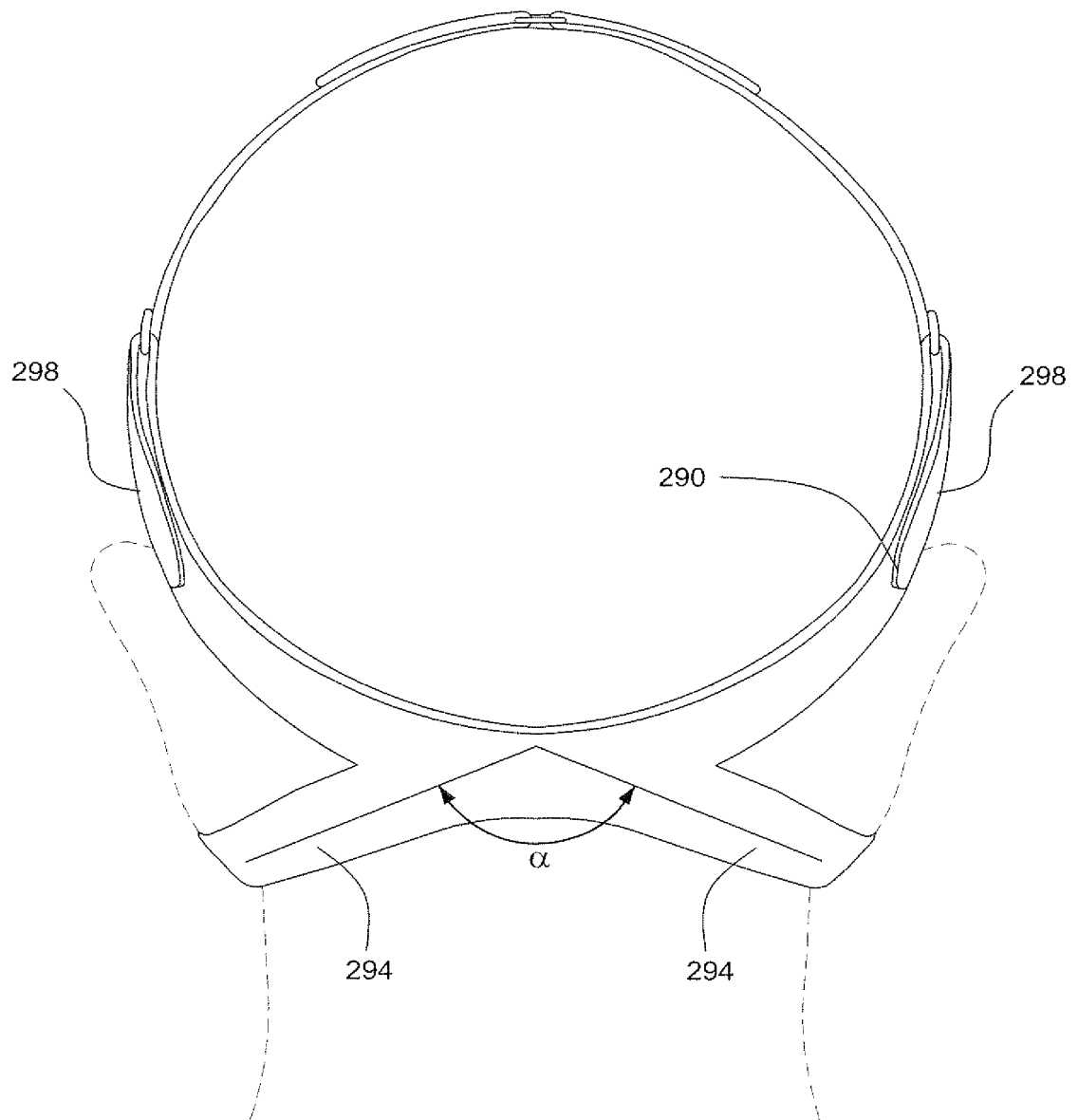


Fig. 35-3

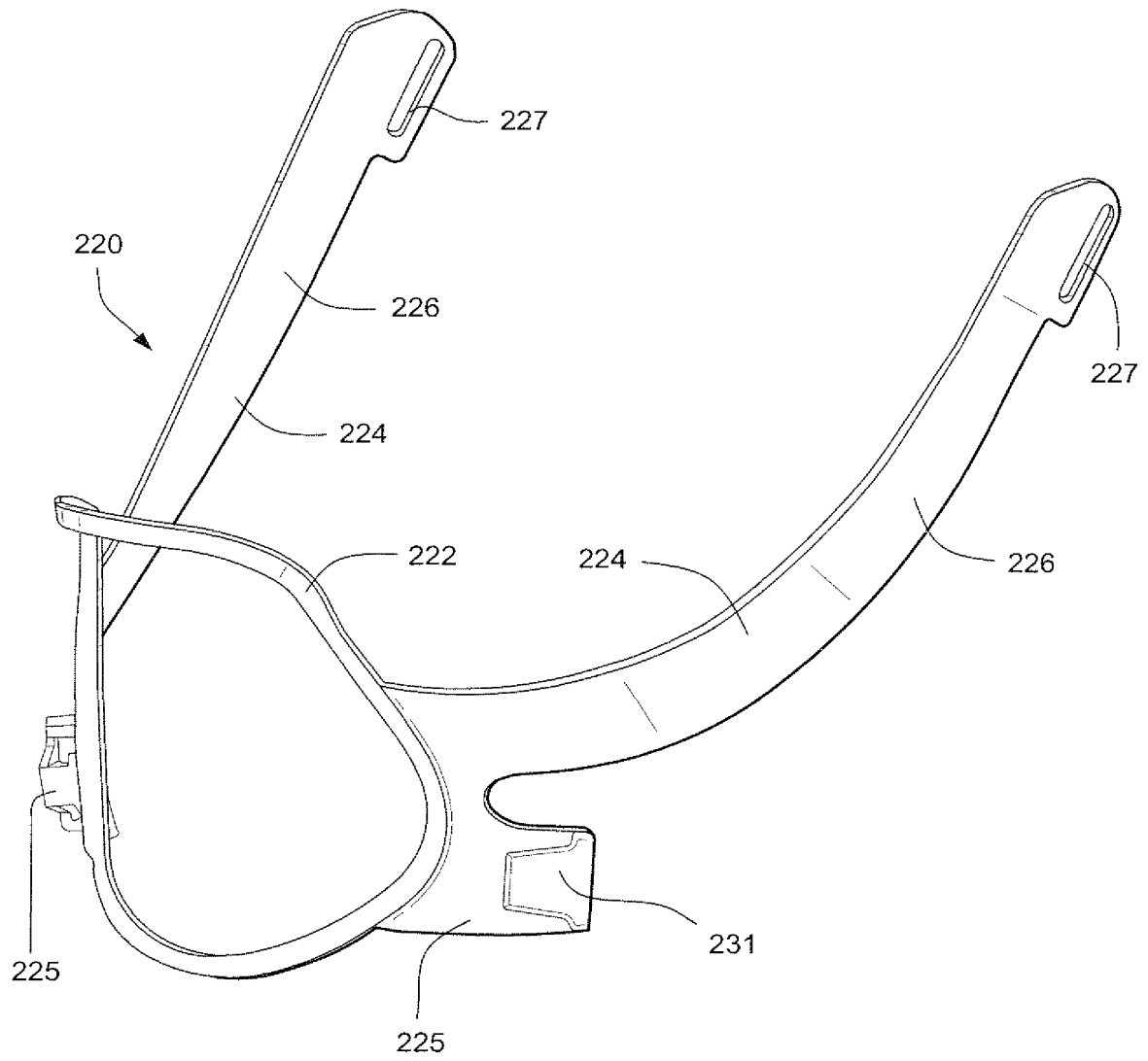


Fig. 36

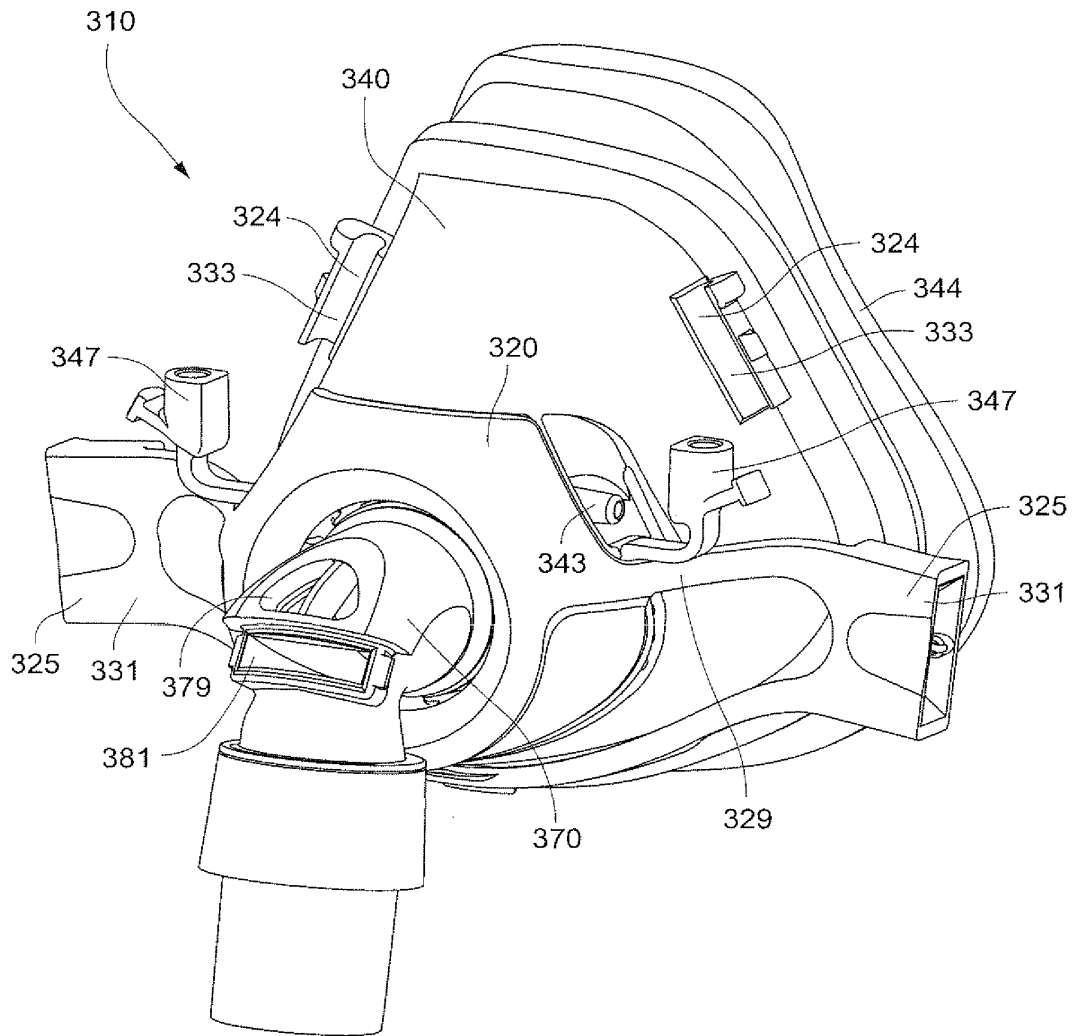


Fig. 37-1

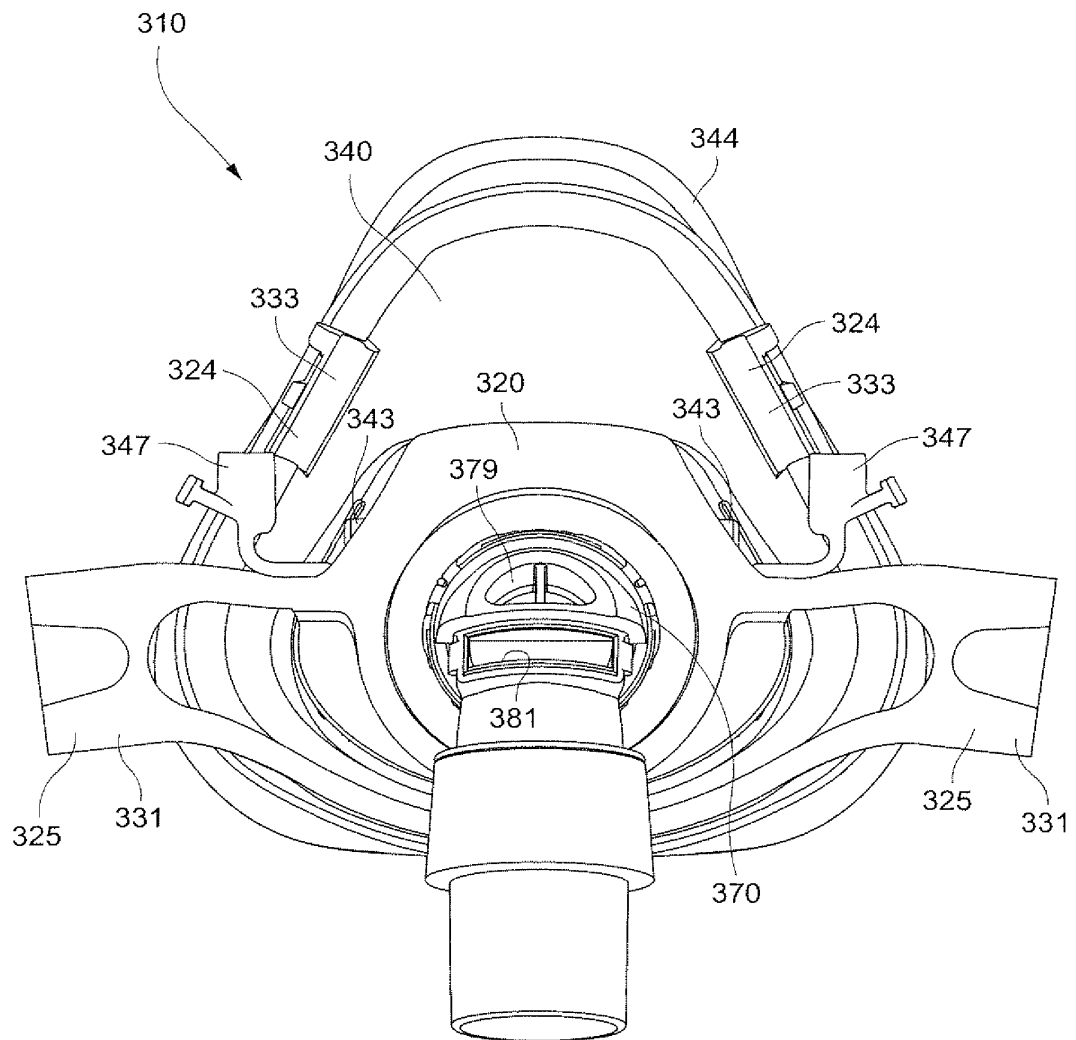


Fig. 37-2

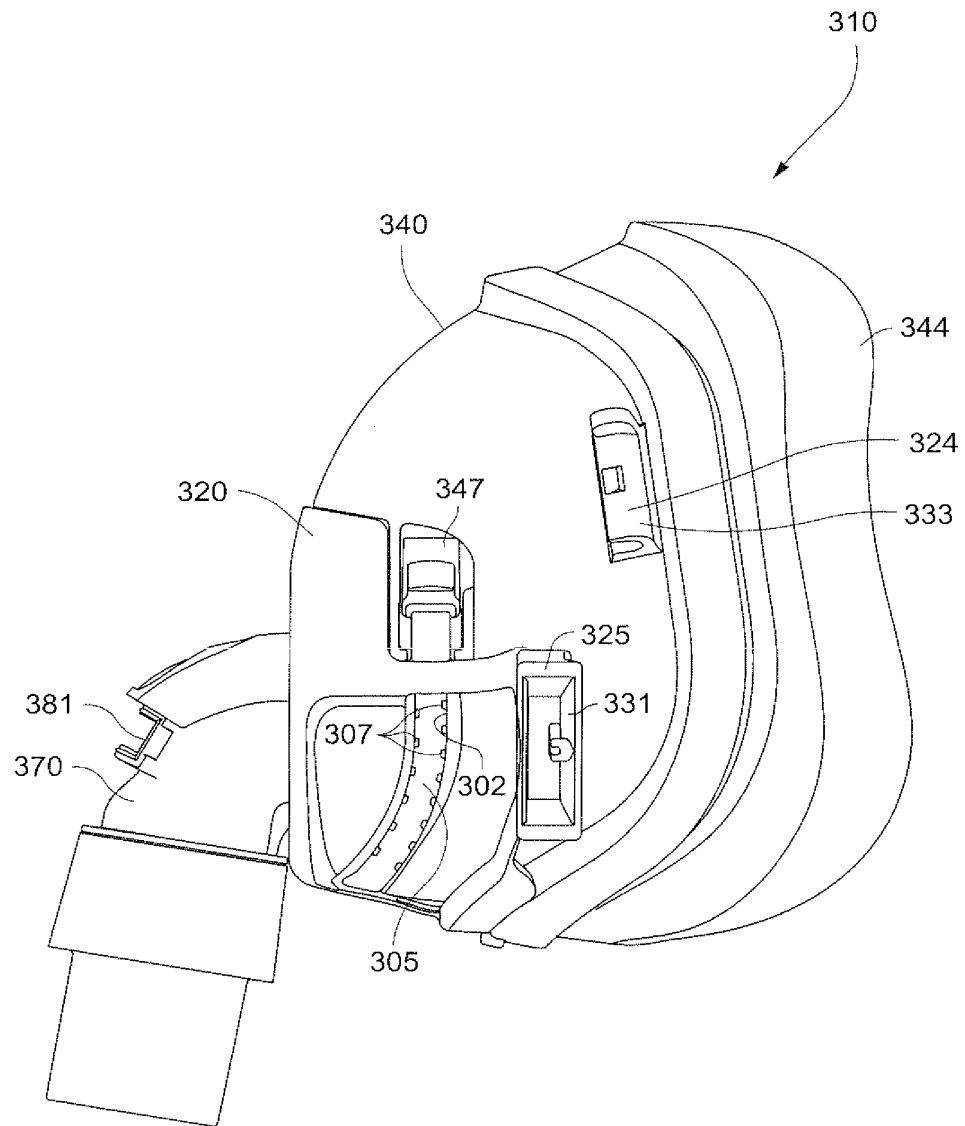


Fig. 37-3

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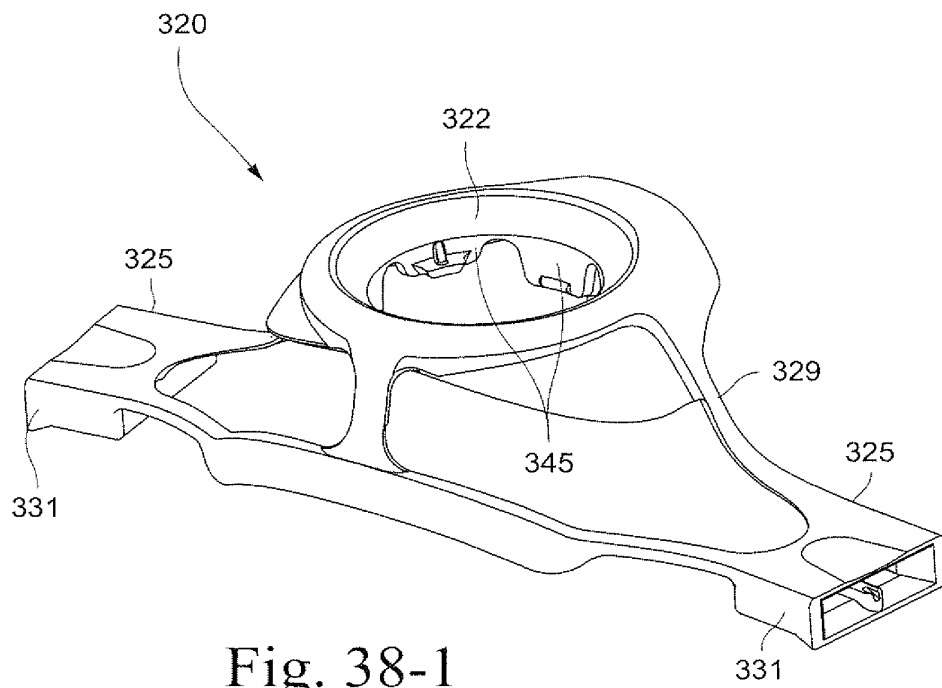


Fig. 38-1

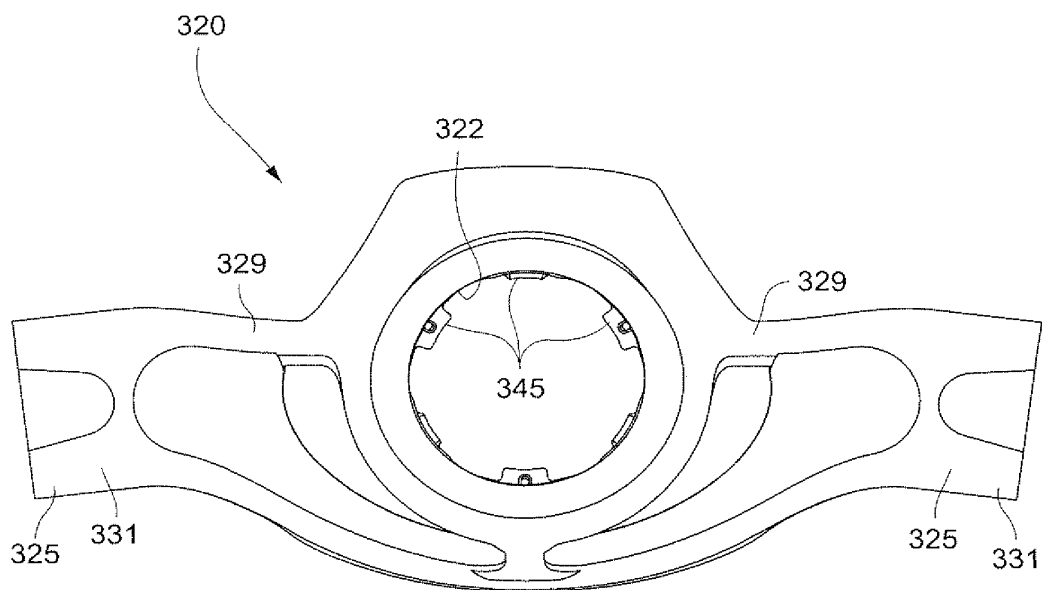


Fig. 38-2

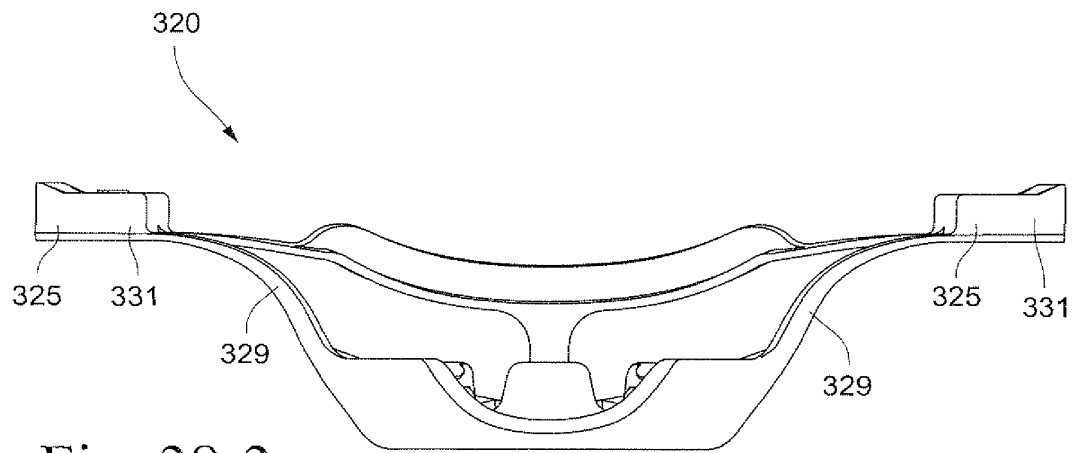


Fig. 38-3

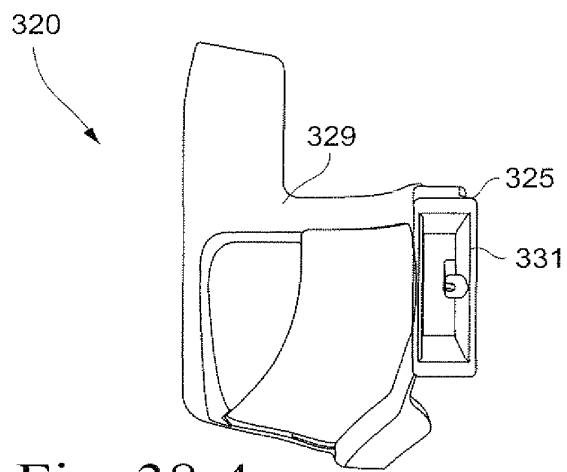


Fig. 38-4

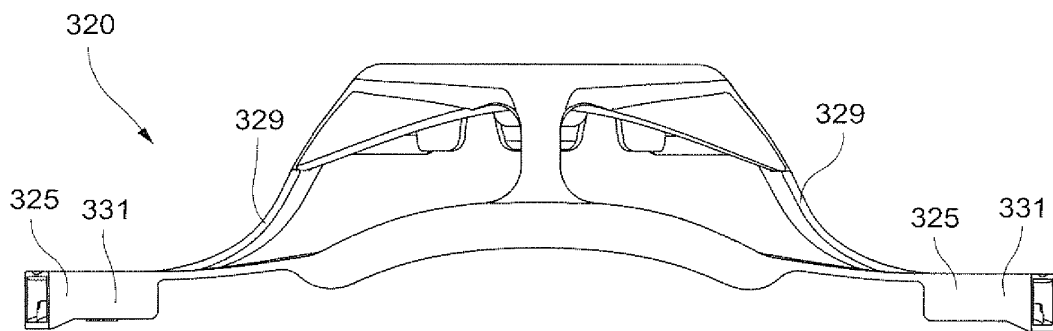


Fig. 38-5

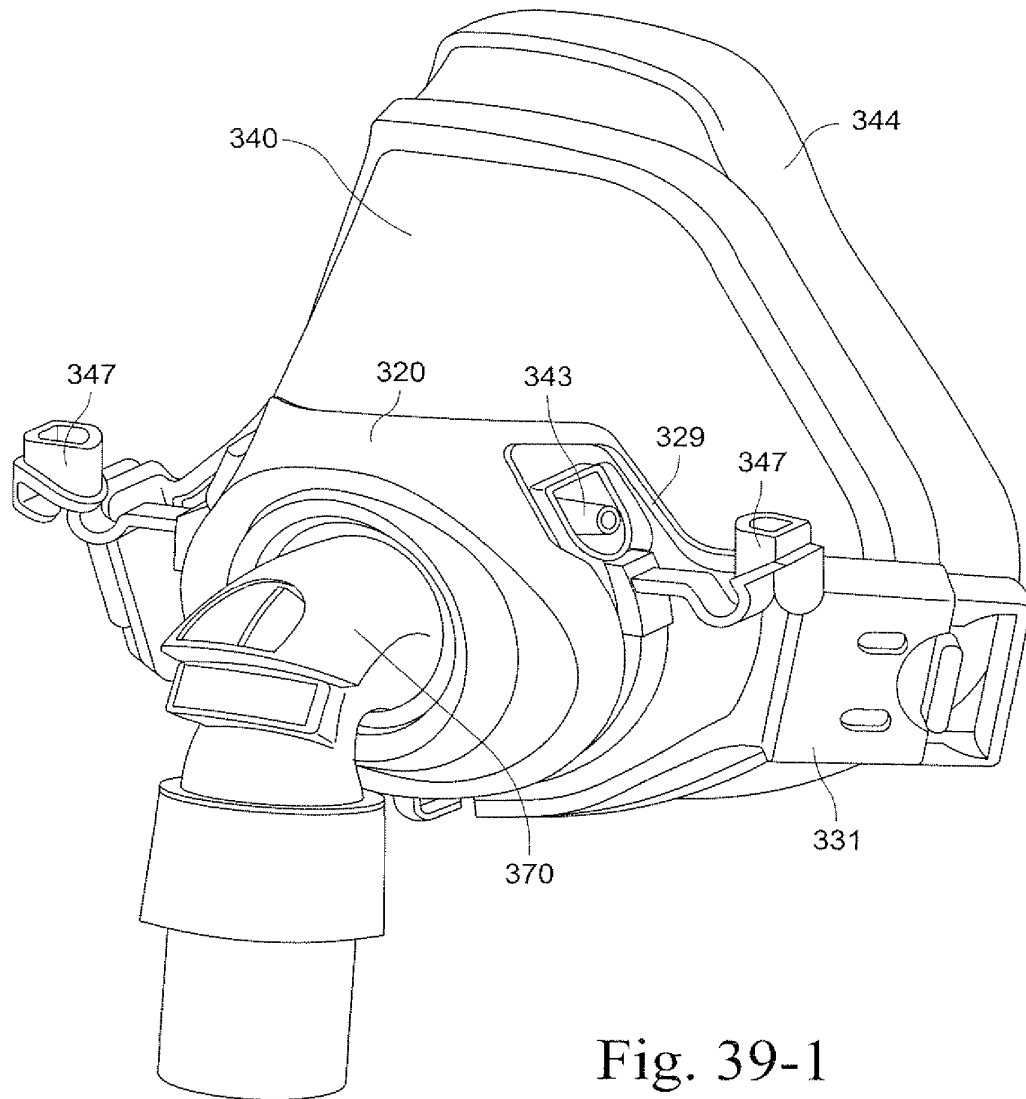


Fig. 39-1

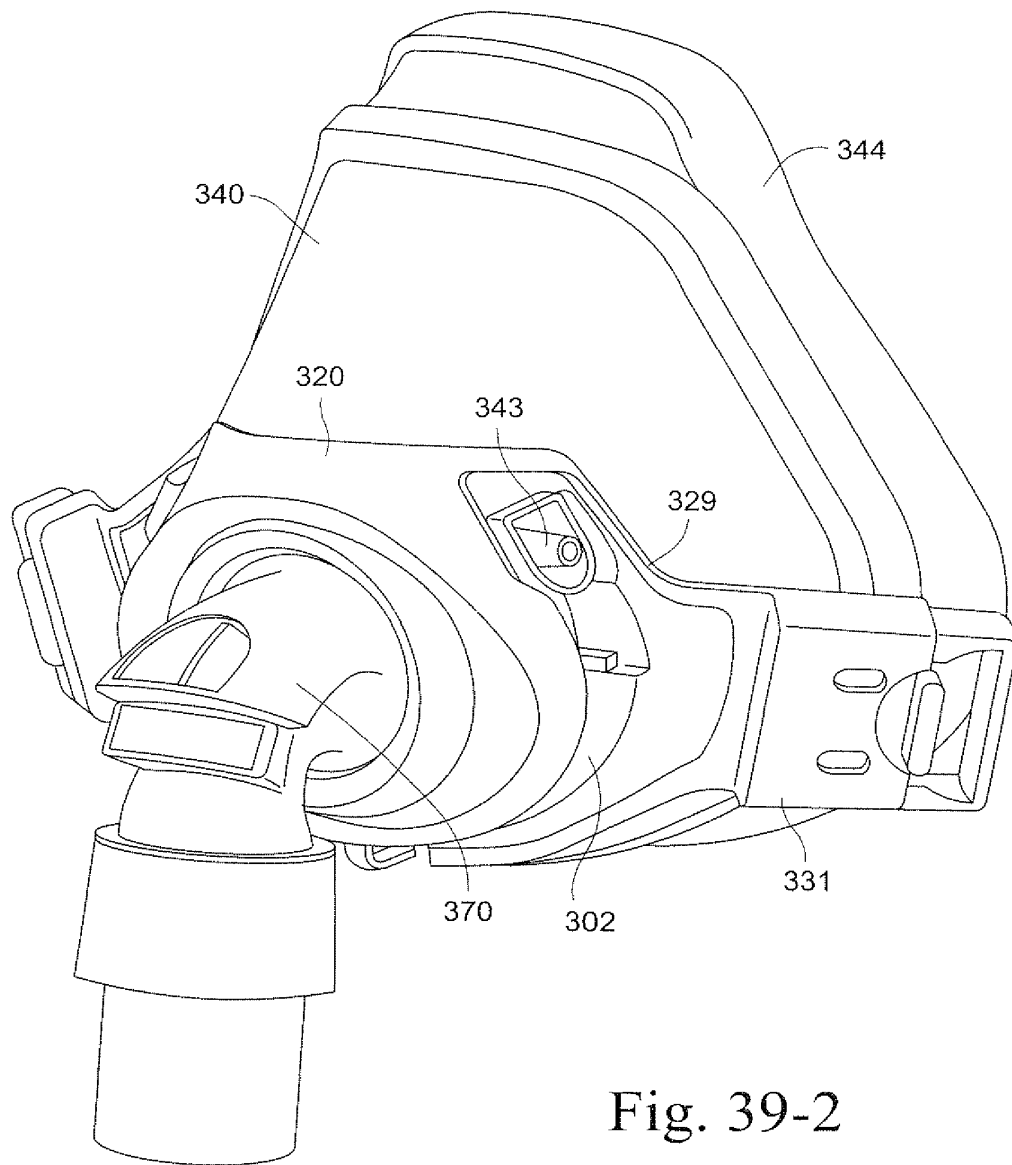


Fig. 39-2

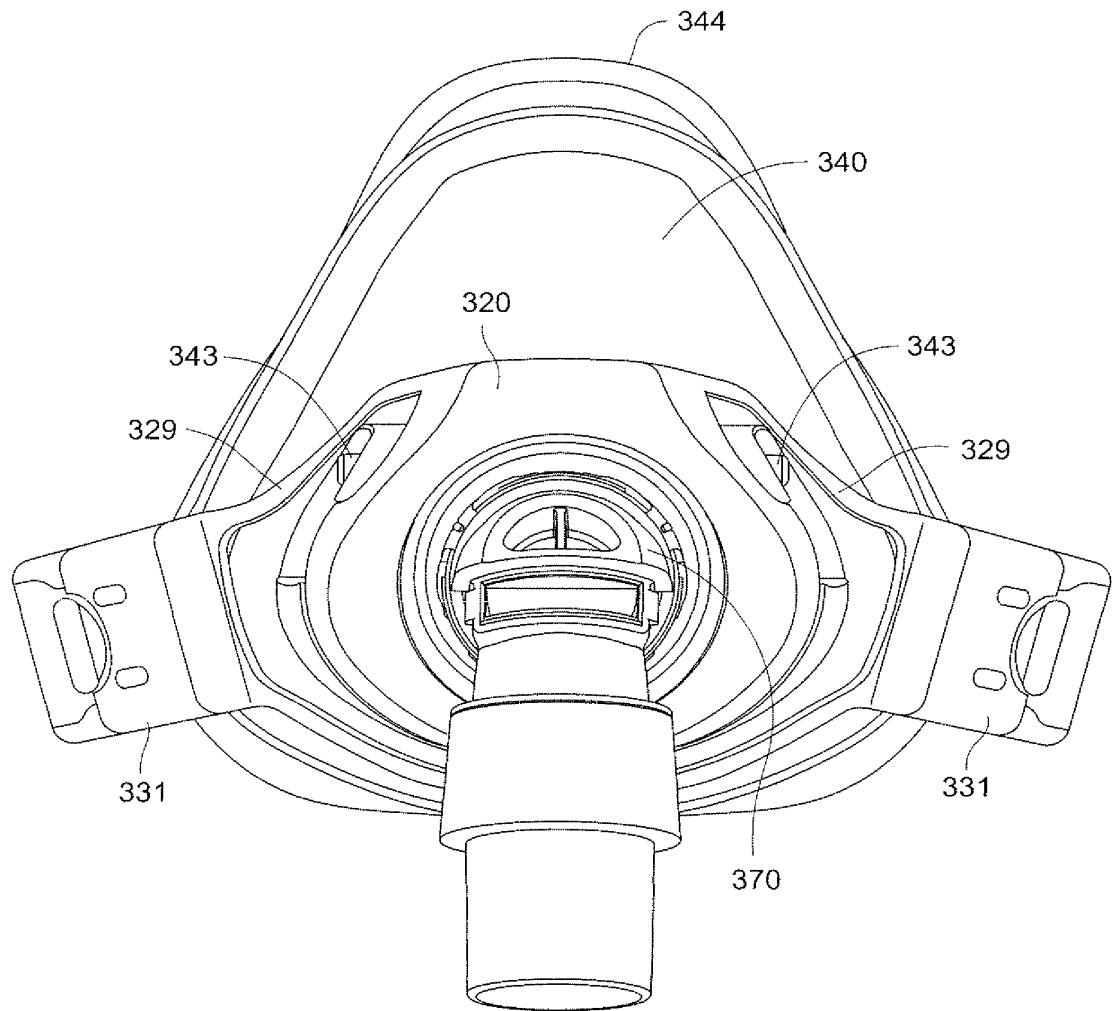


Fig. 39-3

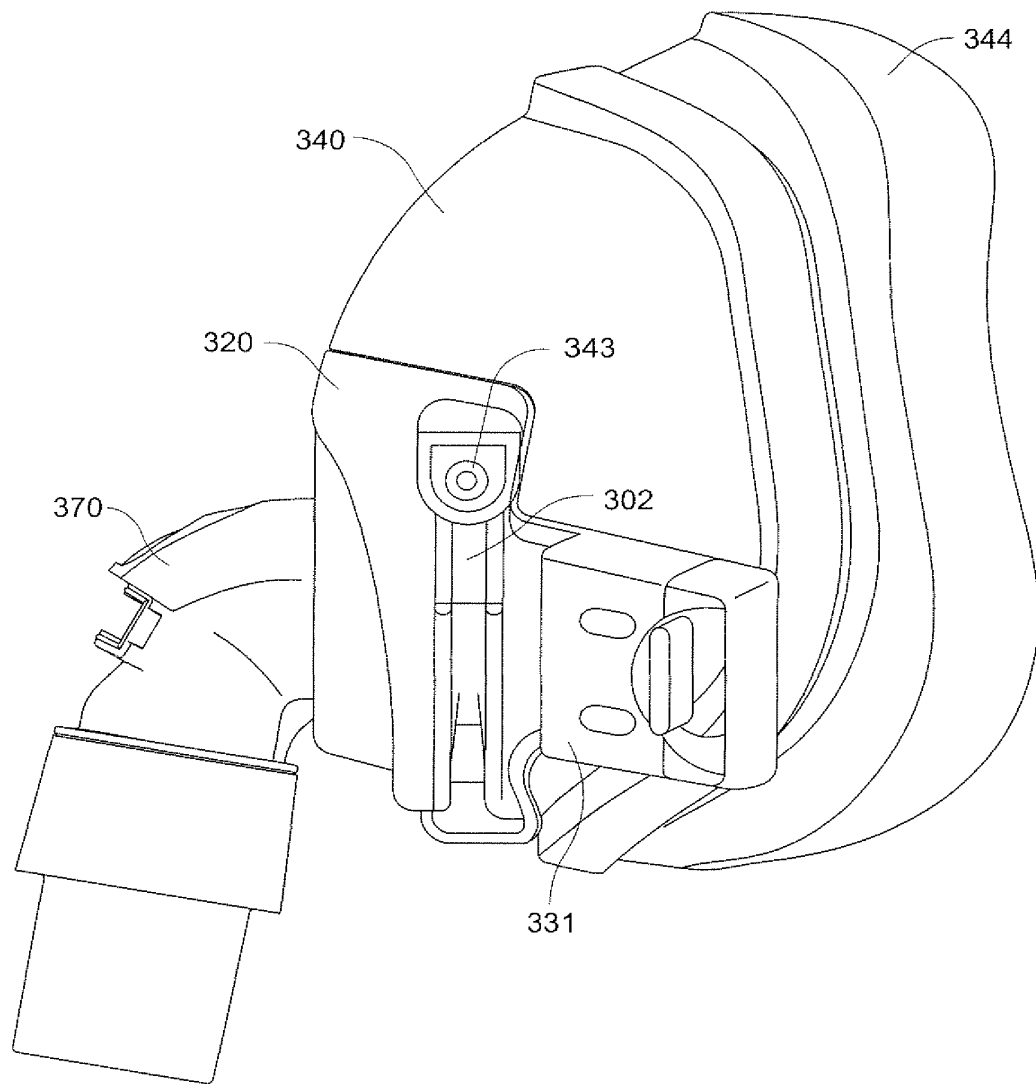


Fig. 39-4

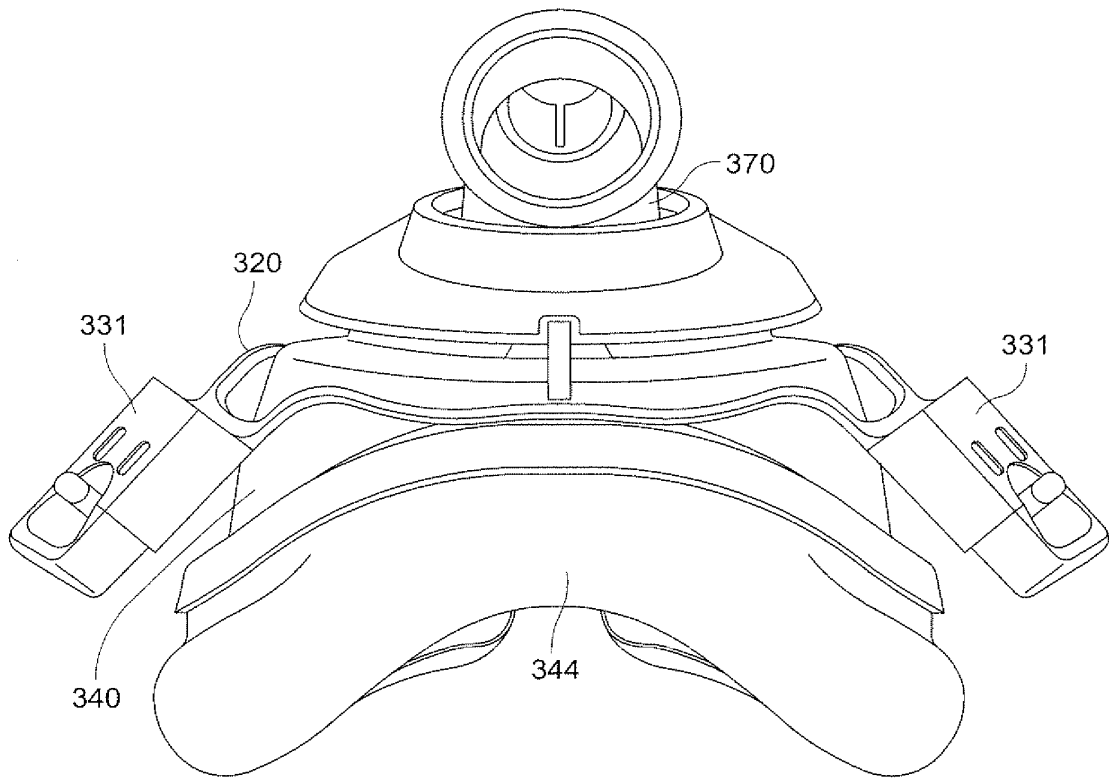


Fig. 39-5

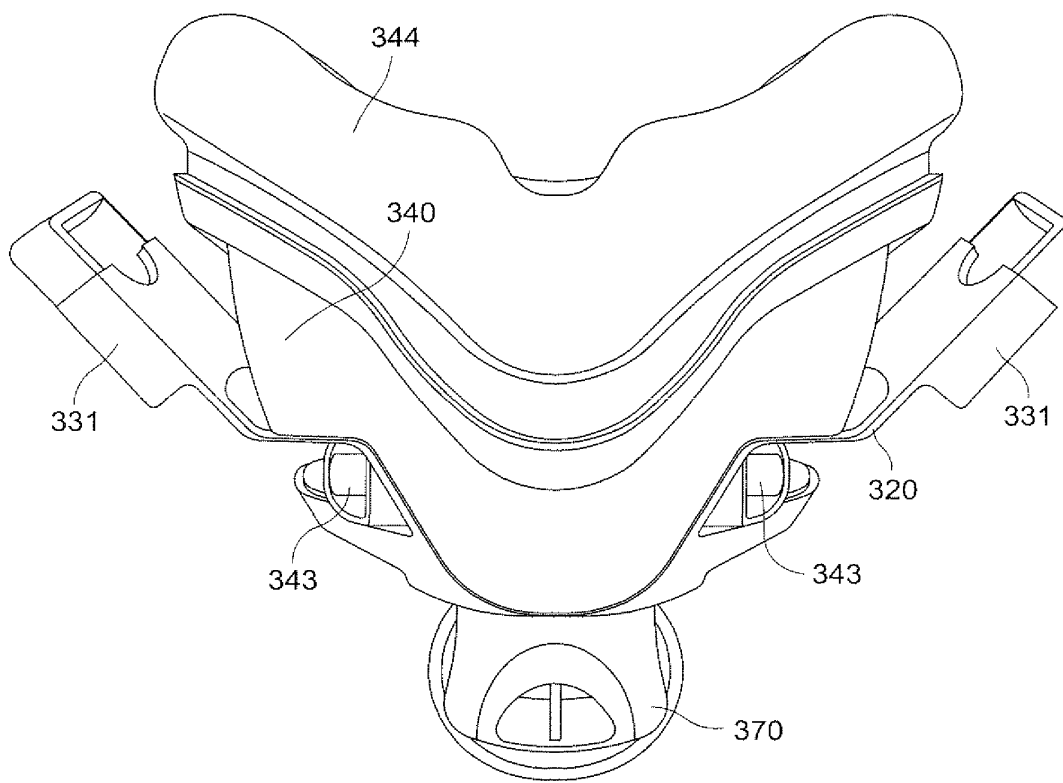


Fig. 39-6

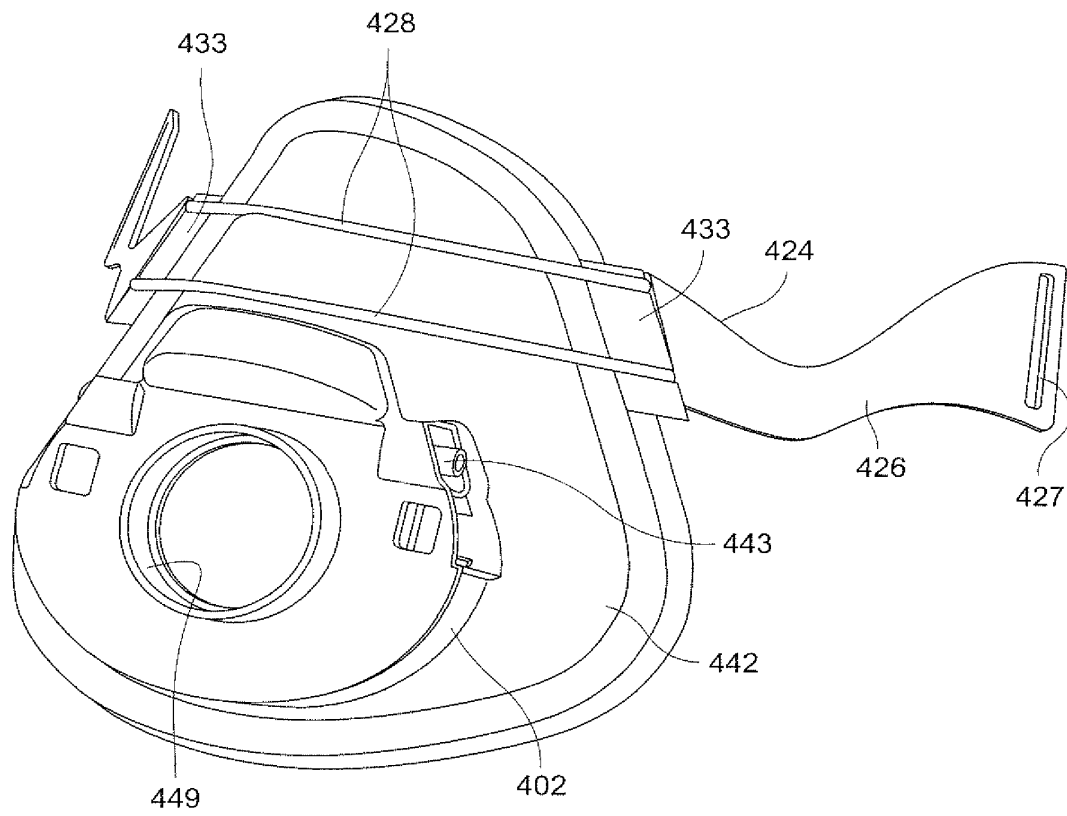


Fig. 40-1

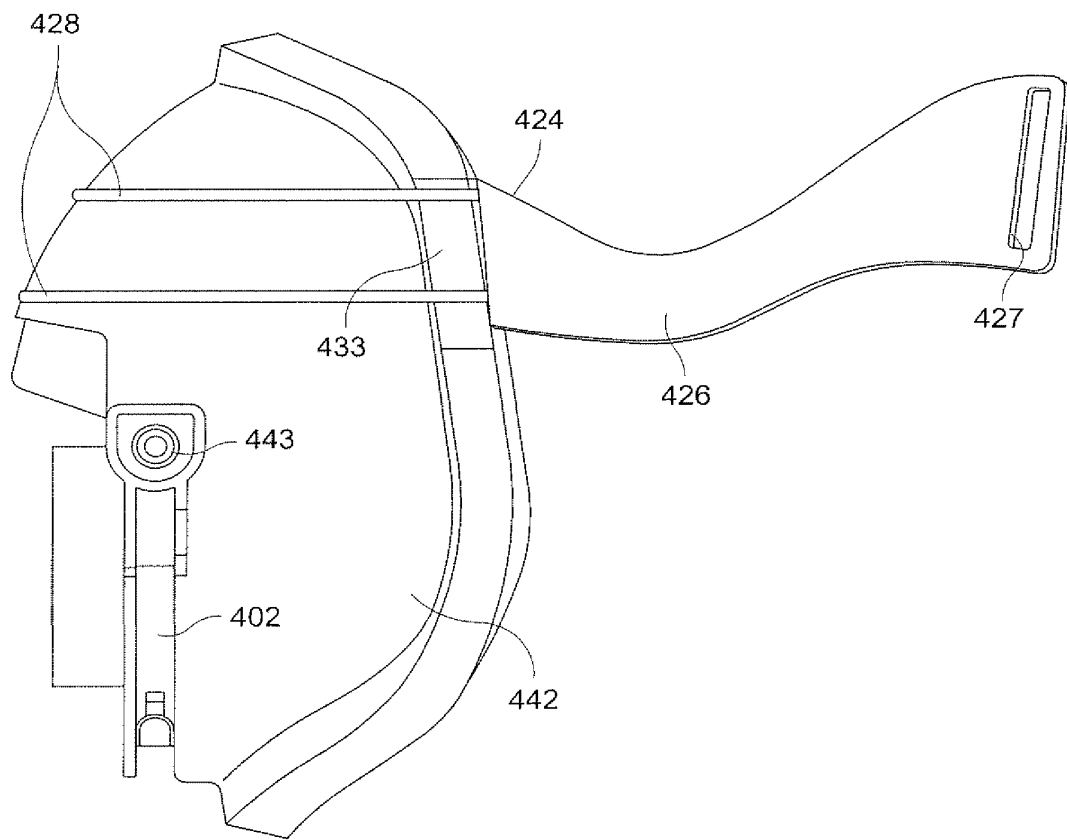


Fig. 40-2

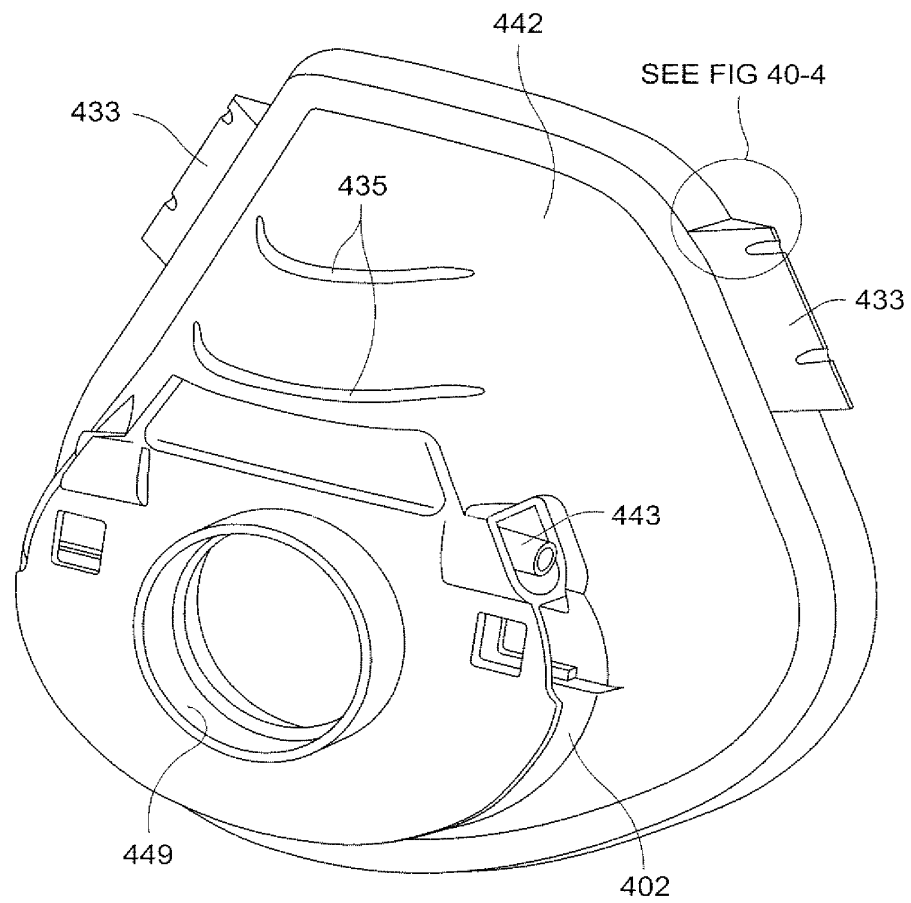


Fig. 40-3

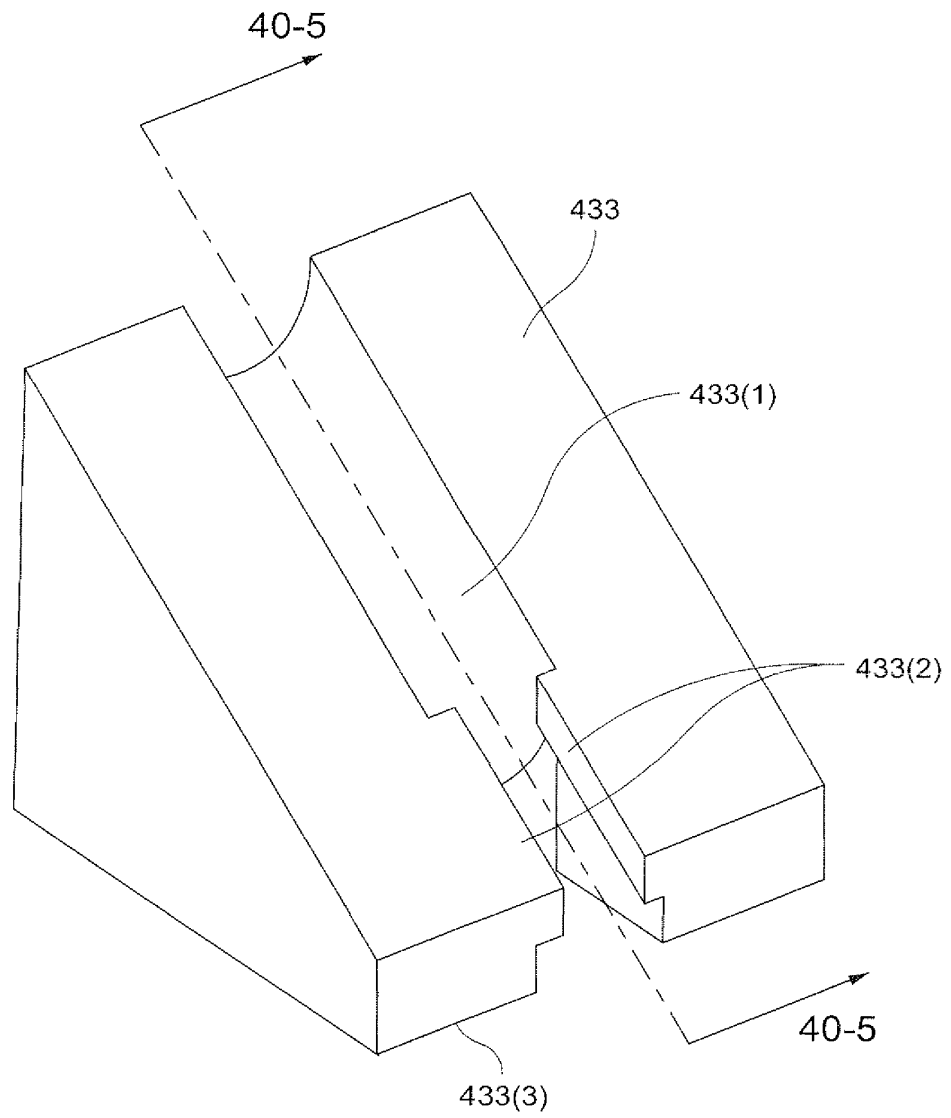


Fig. 40-4

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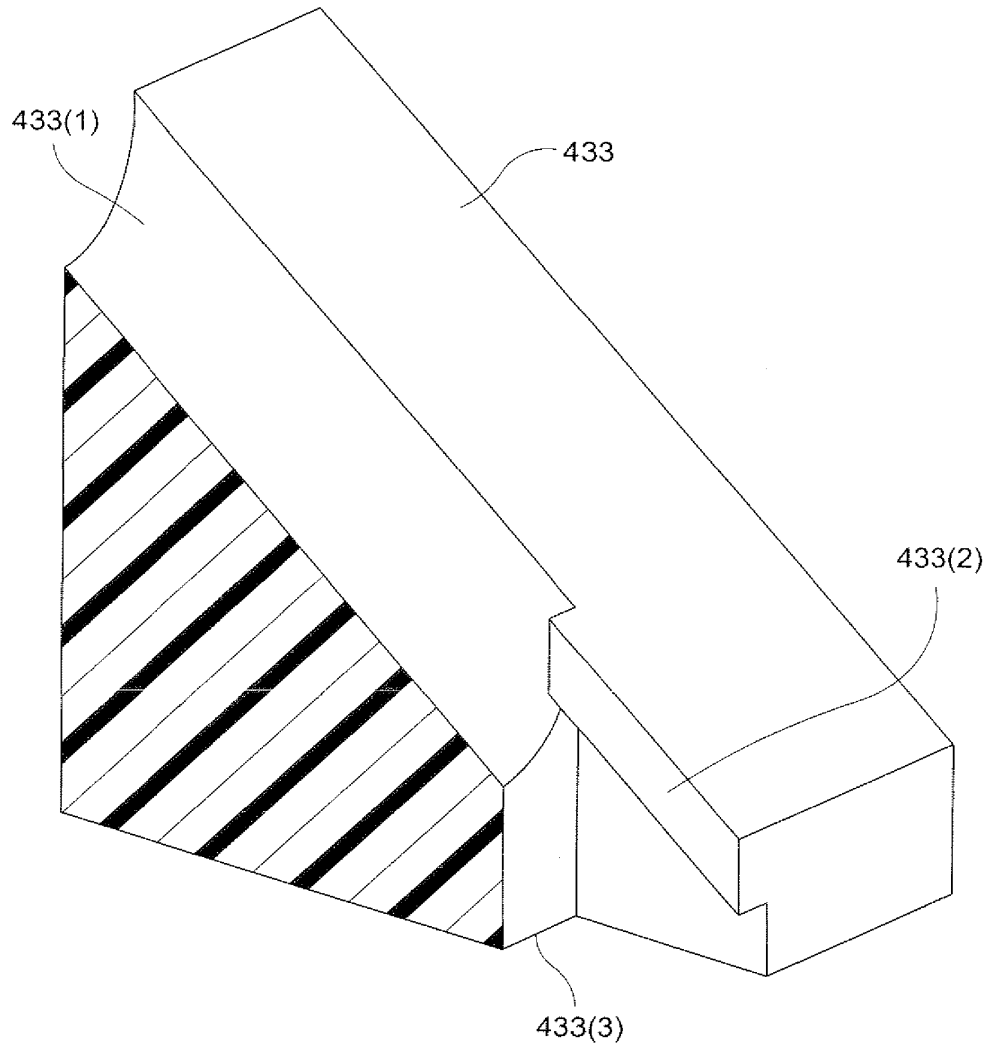


Fig. 40-5

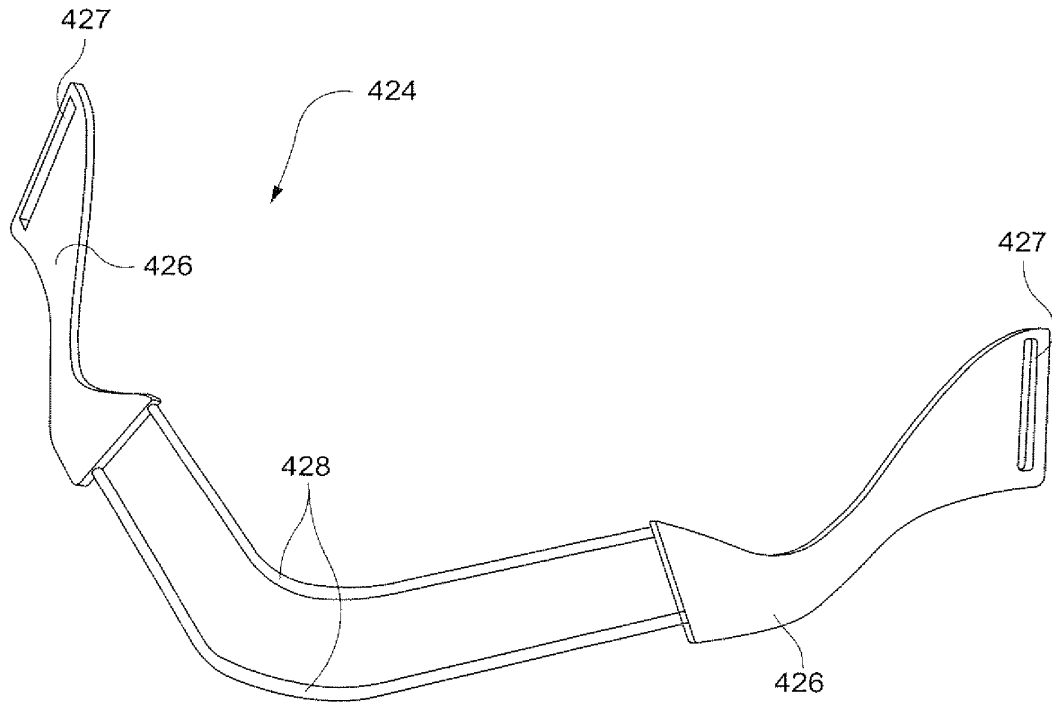


Fig. 40-6

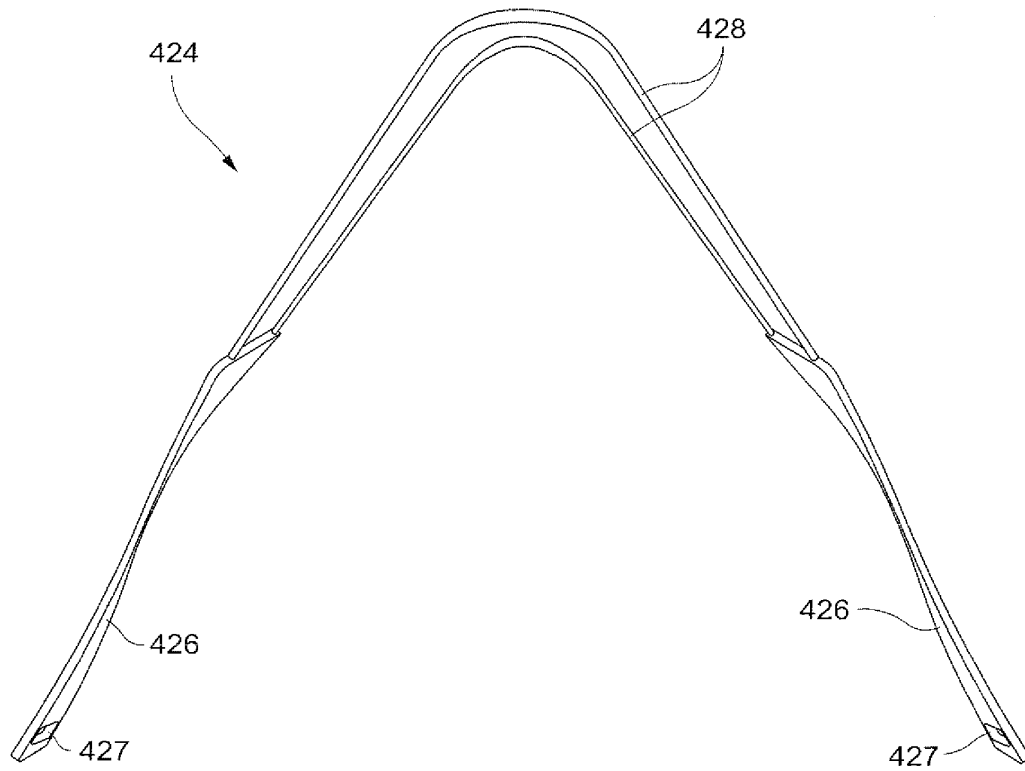


Fig. 40-7

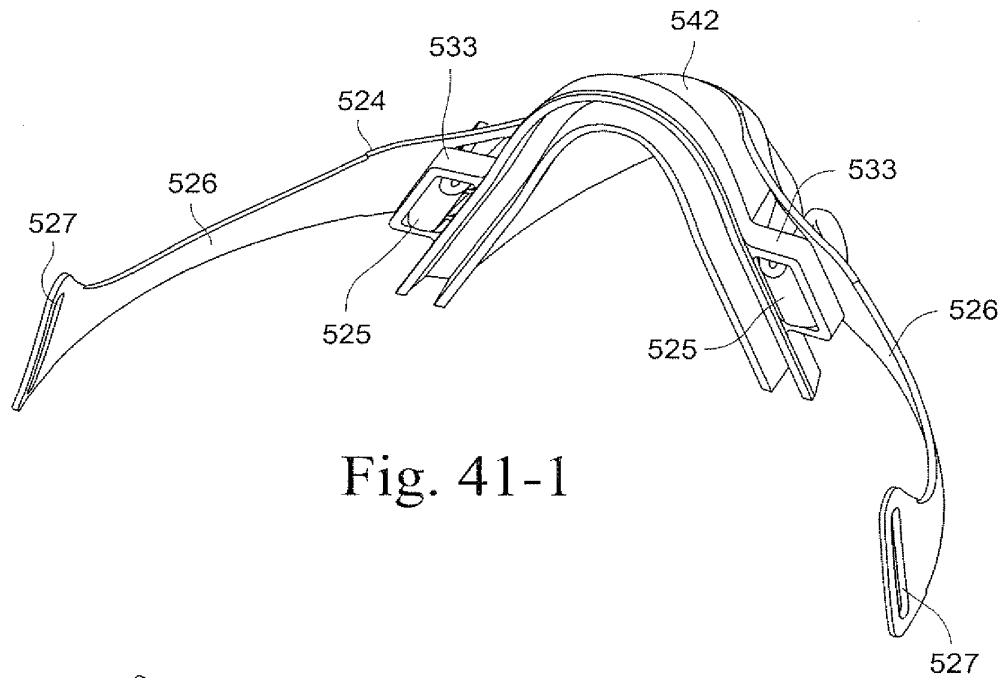


Fig. 41-1

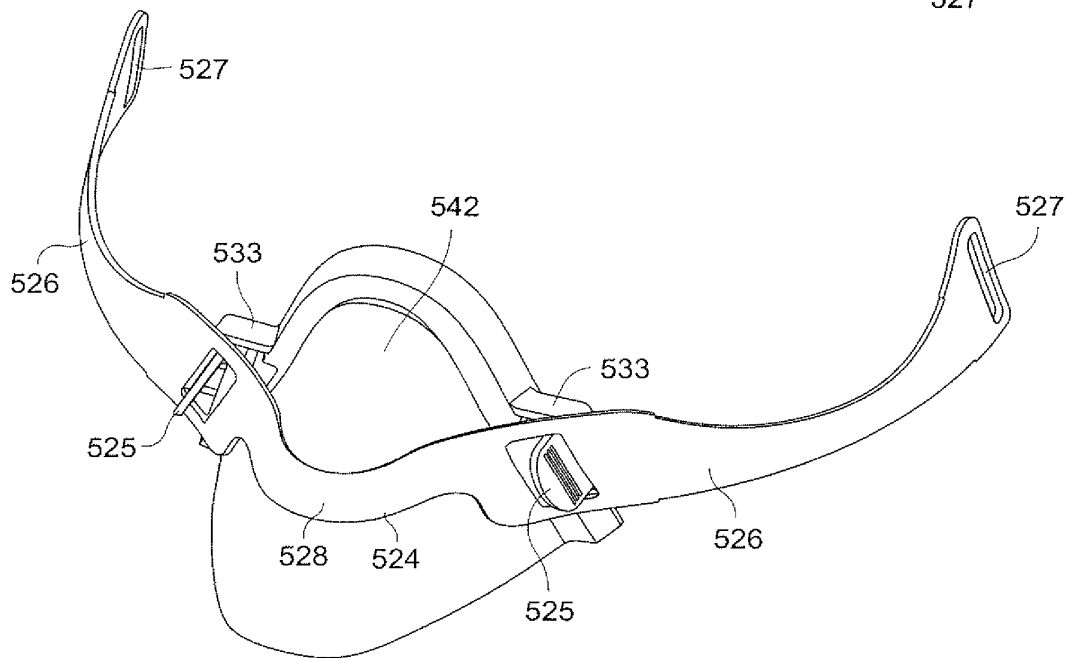


Fig. 41-2

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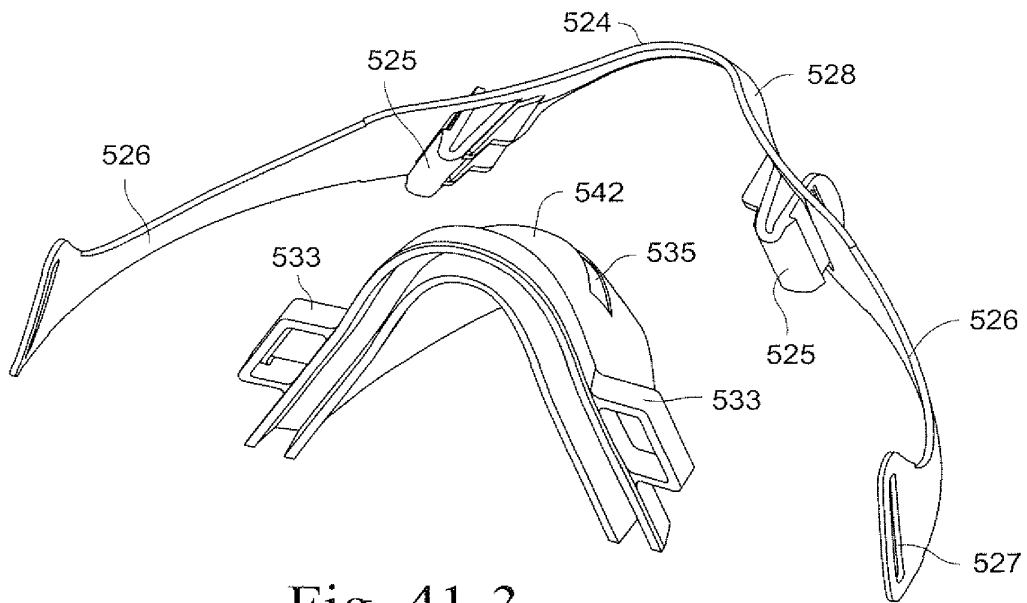


Fig. 41-3

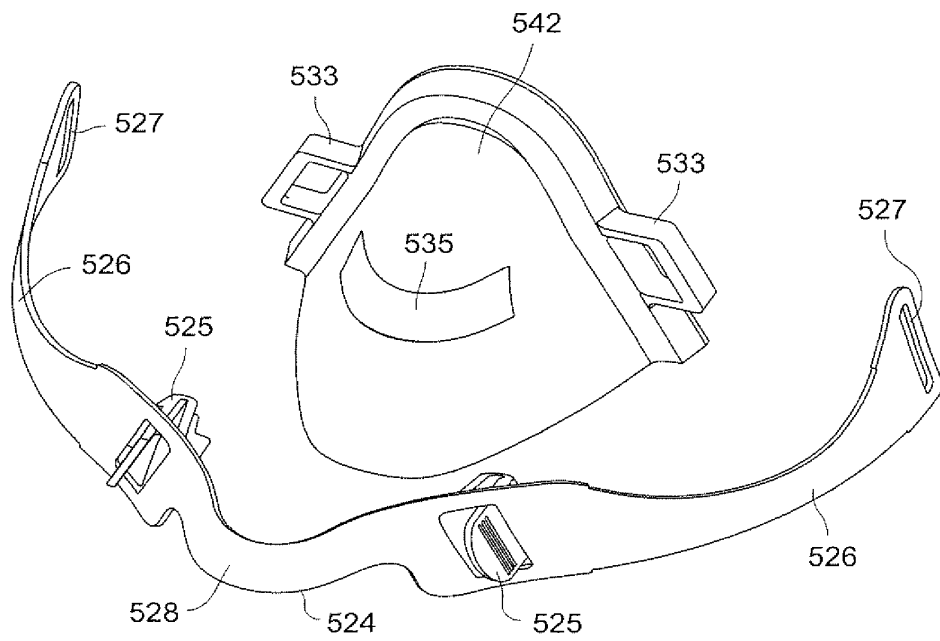


Fig. 41-4

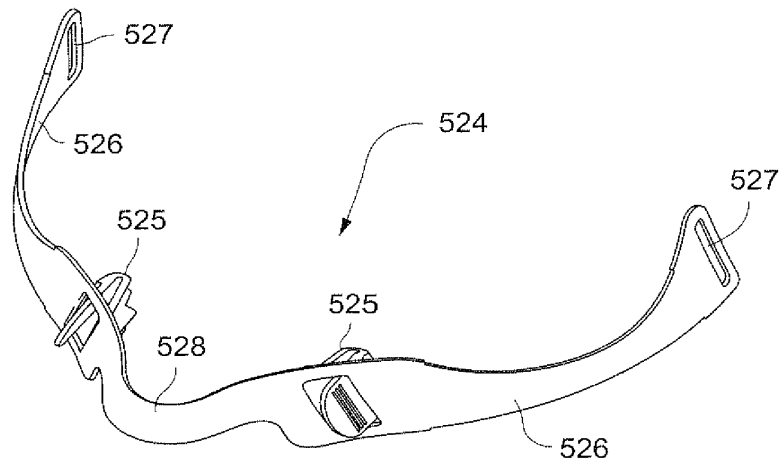


Fig. 41-5

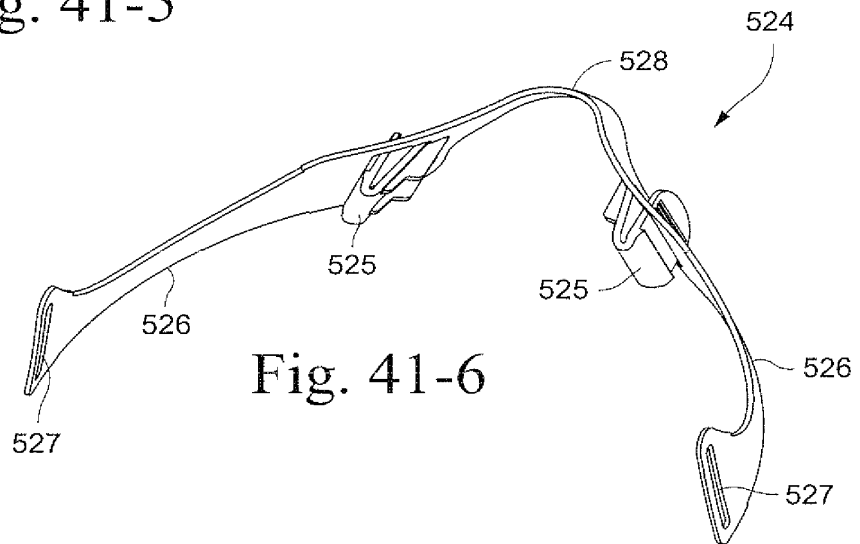


Fig. 41-6

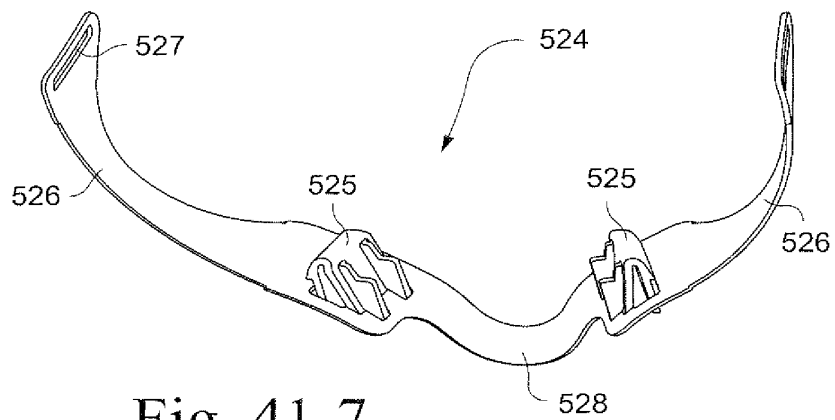


Fig. 41-7

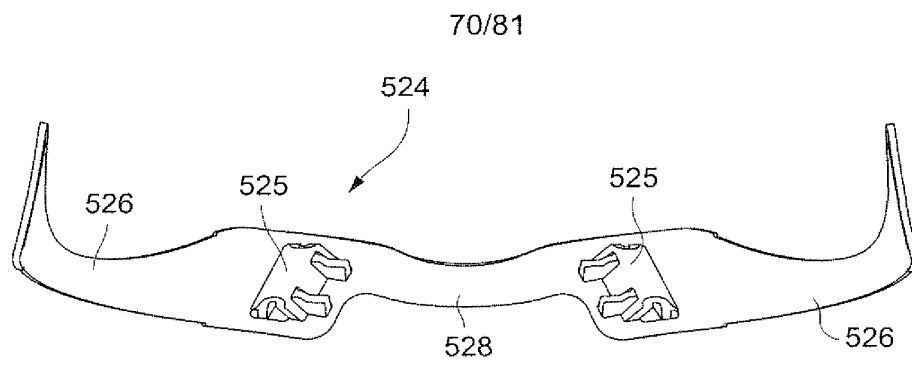


Fig. 41-8

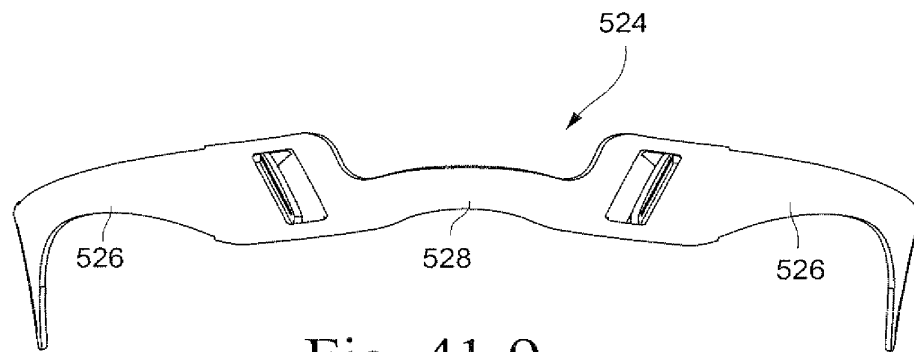


Fig. 41-9

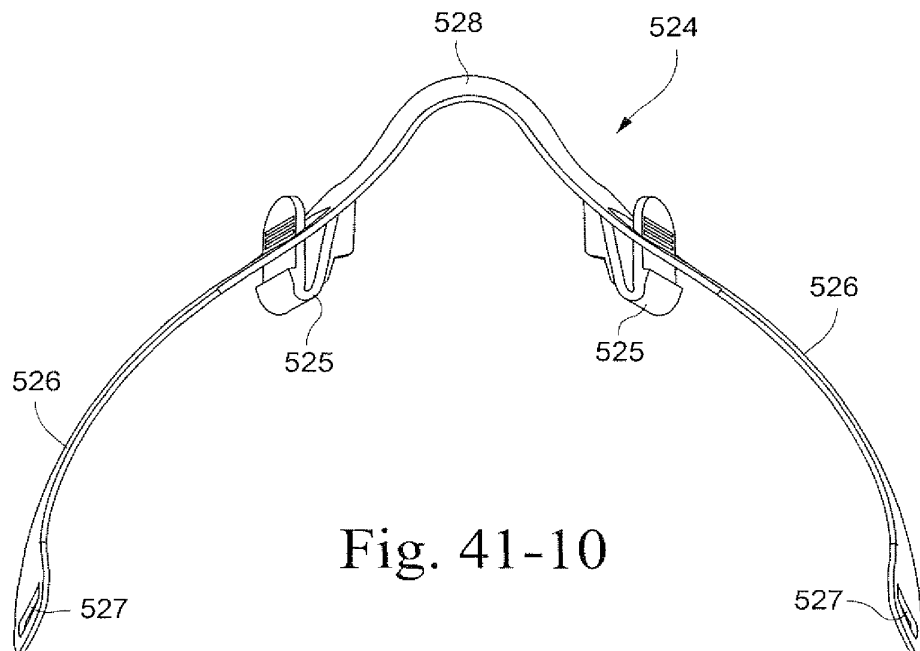


Fig. 41-10

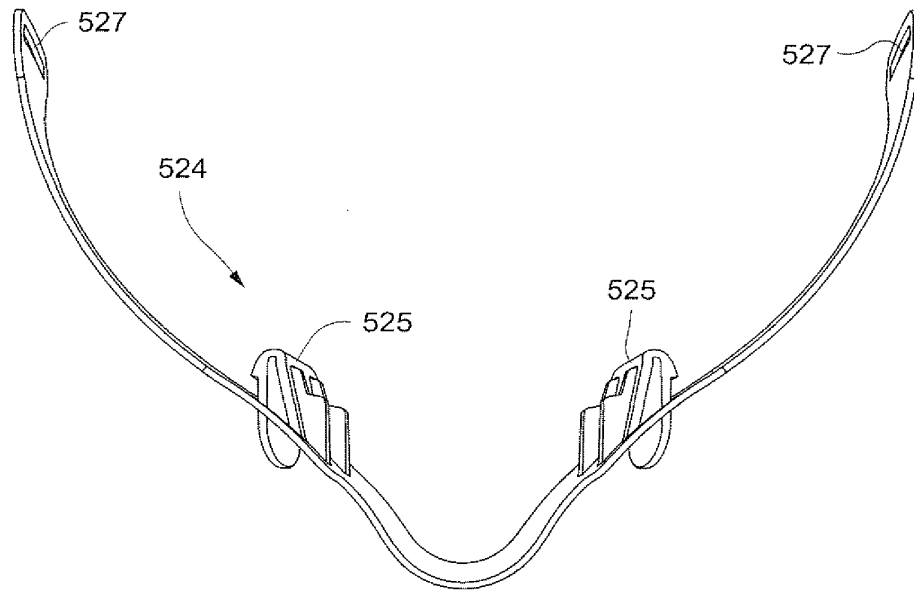


Fig. 41-11

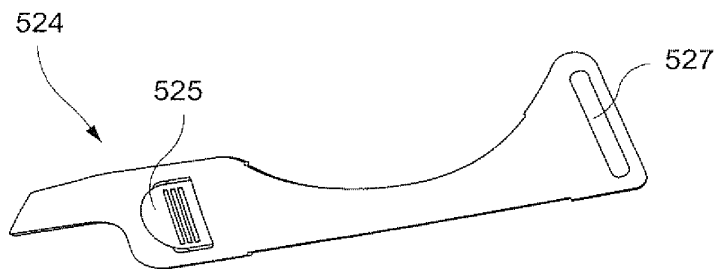


Fig. 41-12

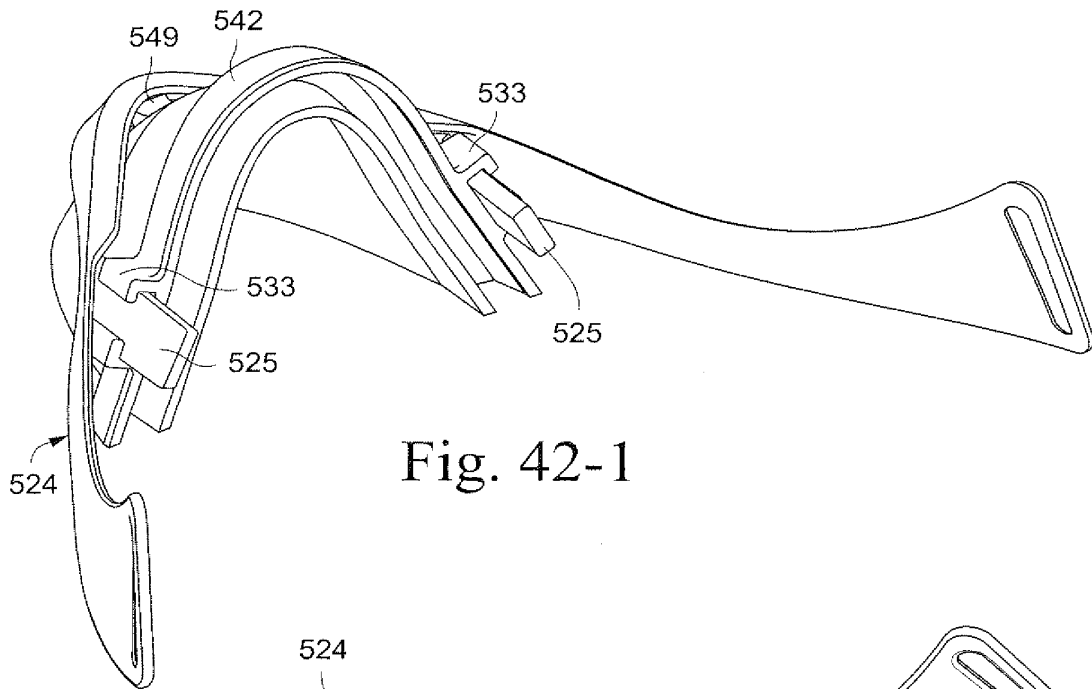


Fig. 42-1

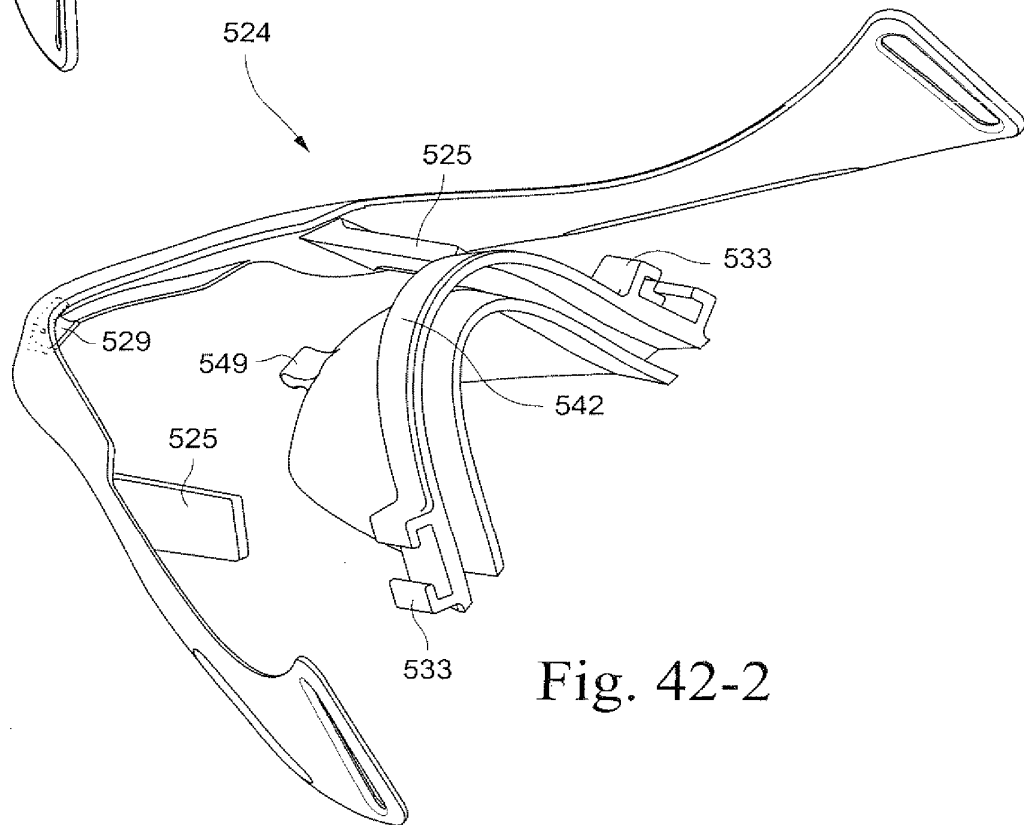


Fig. 42-2

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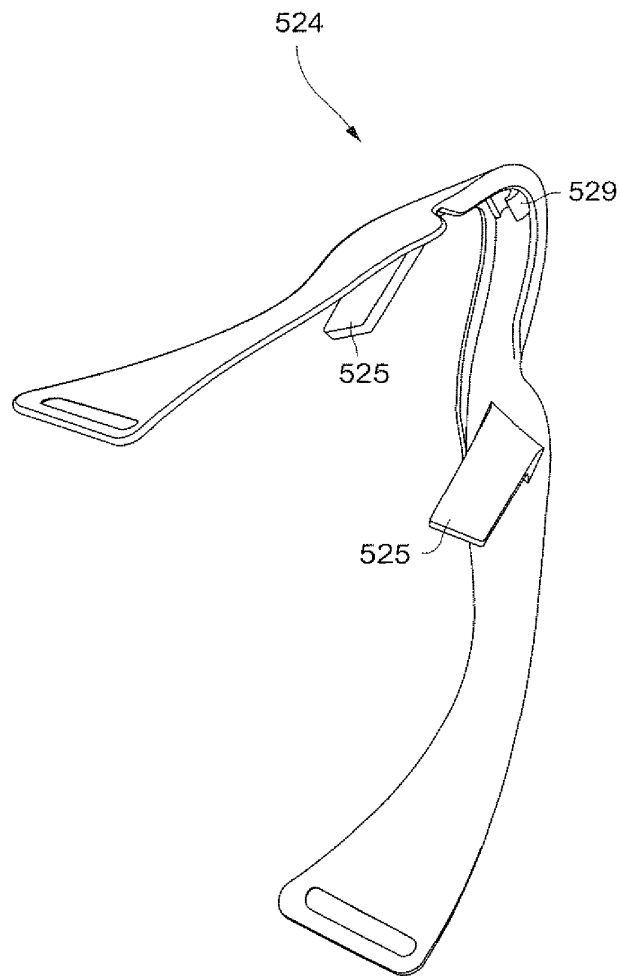


Fig. 42-3

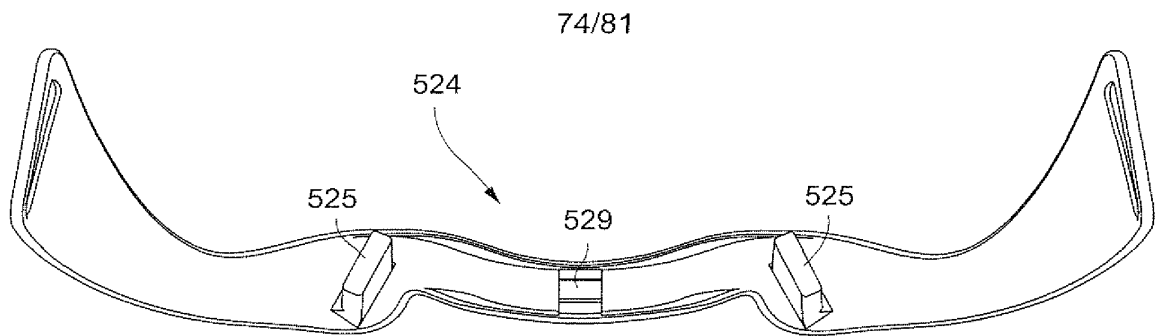


Fig. 42-4

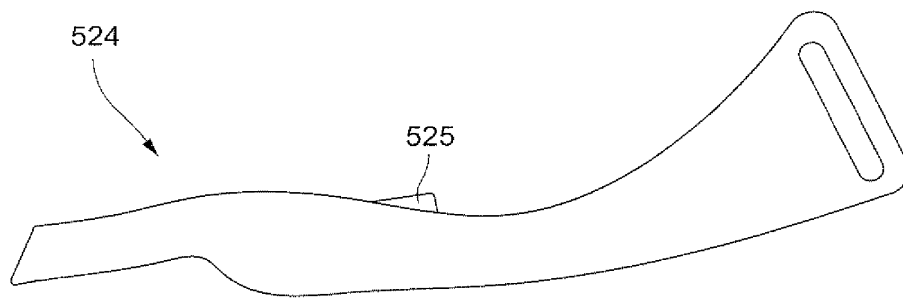


Fig. 42-5

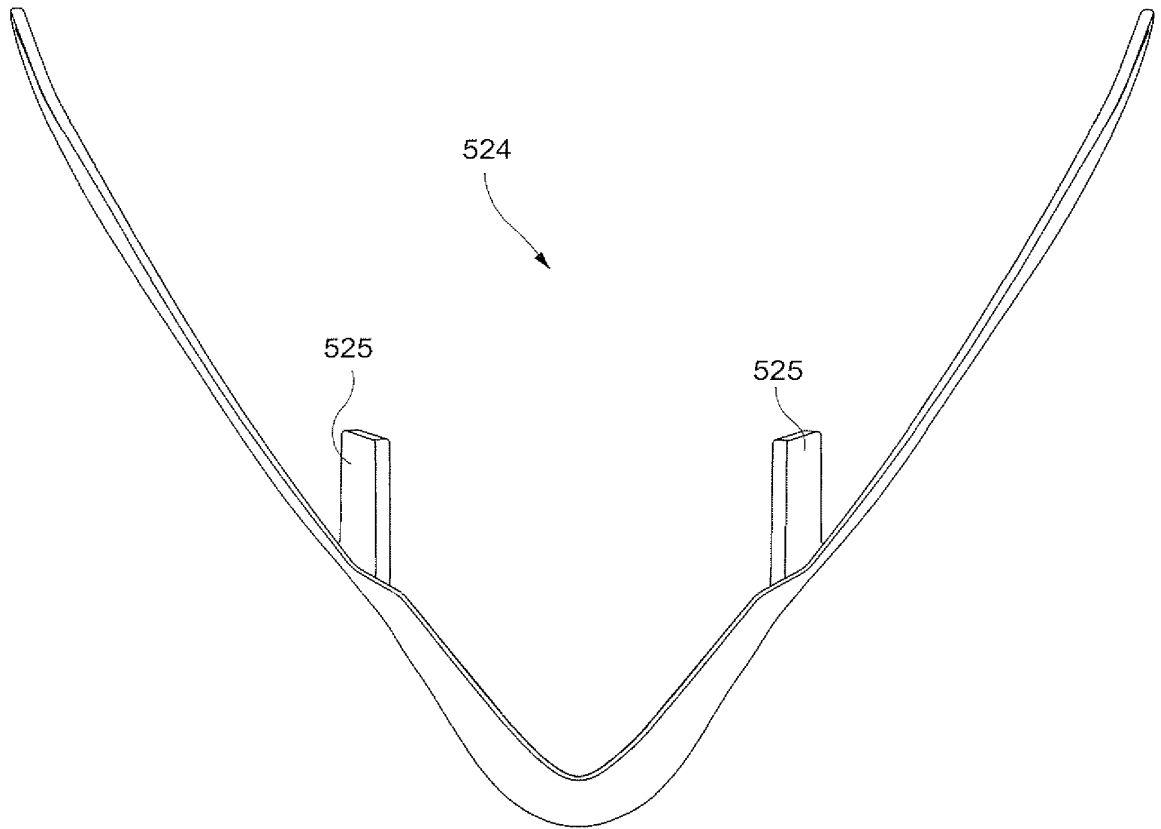


Fig. 42-6

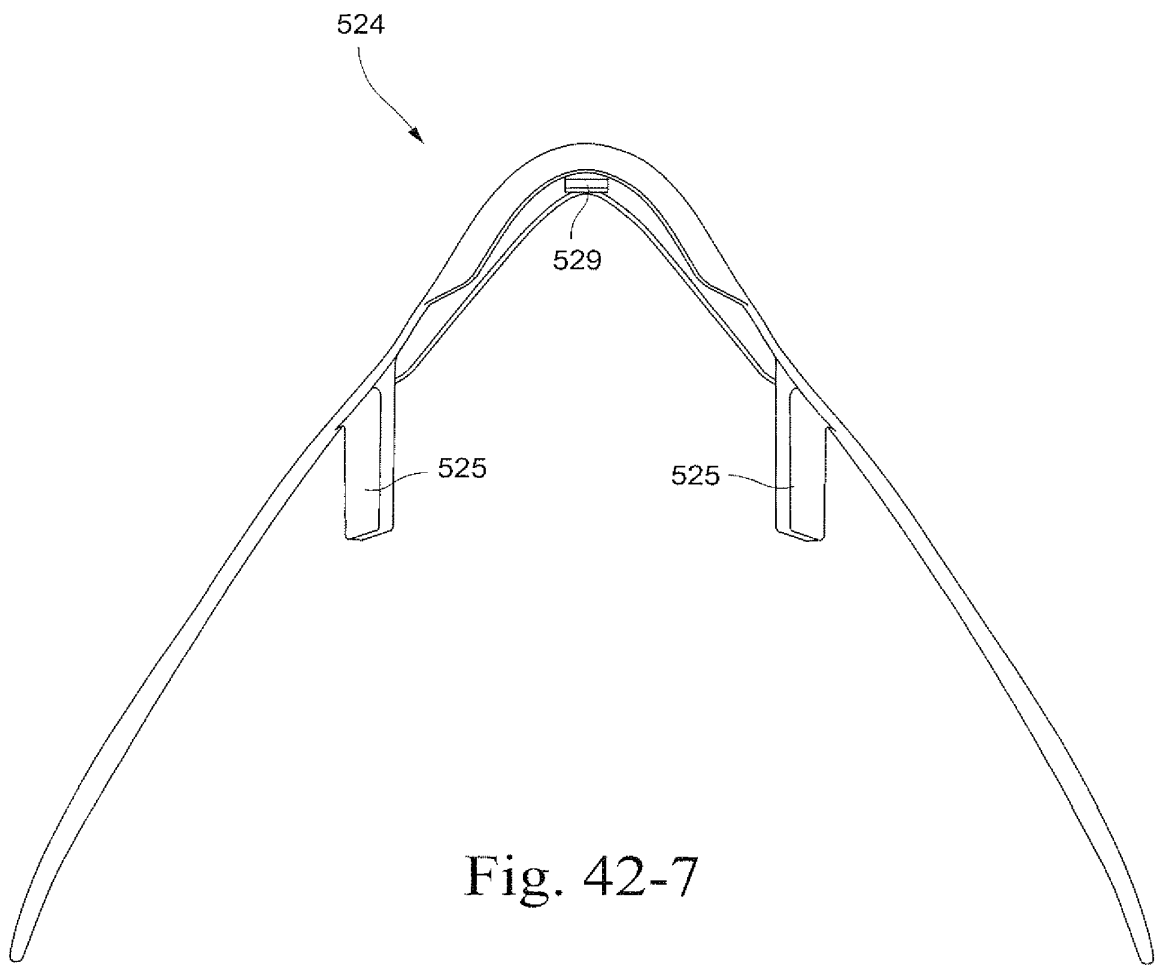


Fig. 42-7

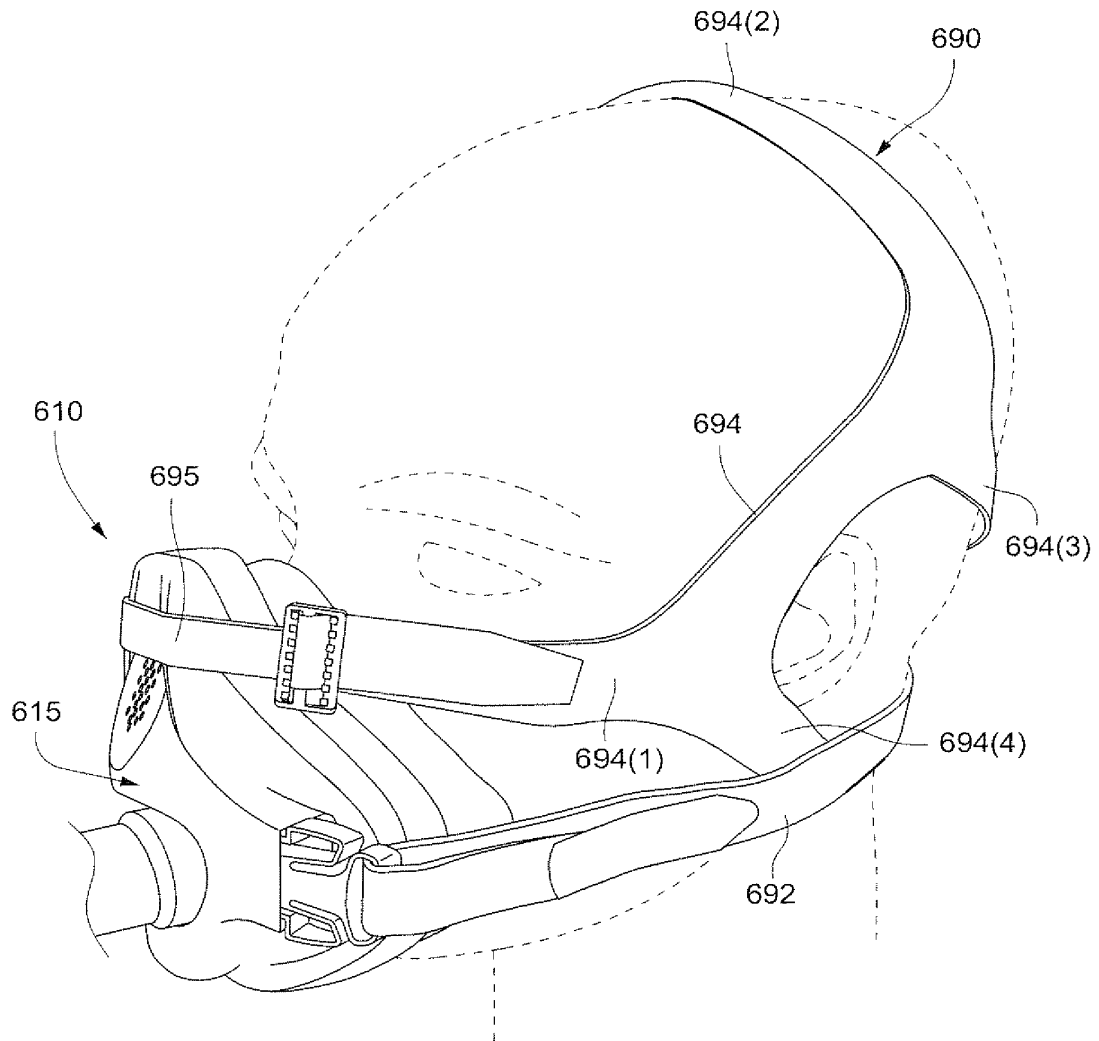


Fig. 43-1

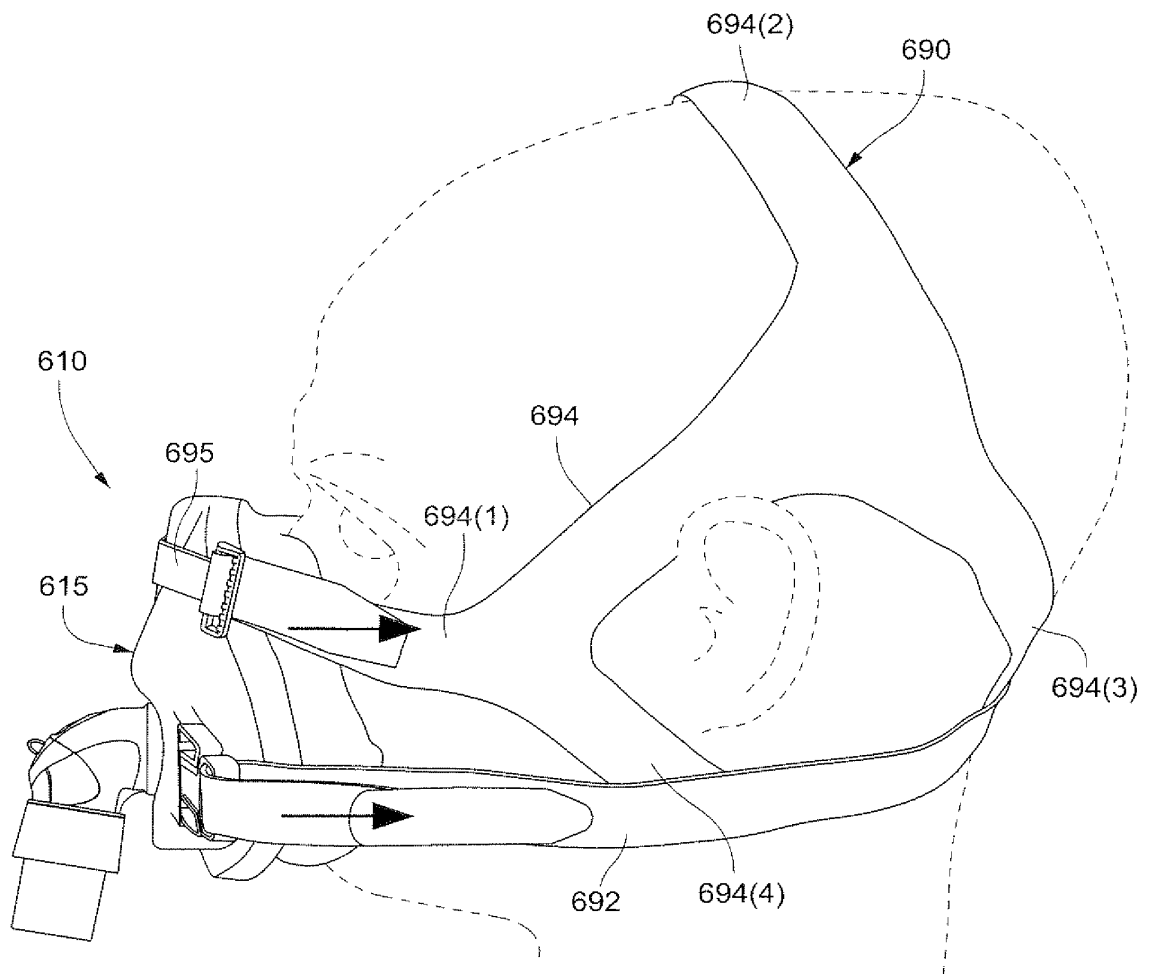


Fig. 43-2

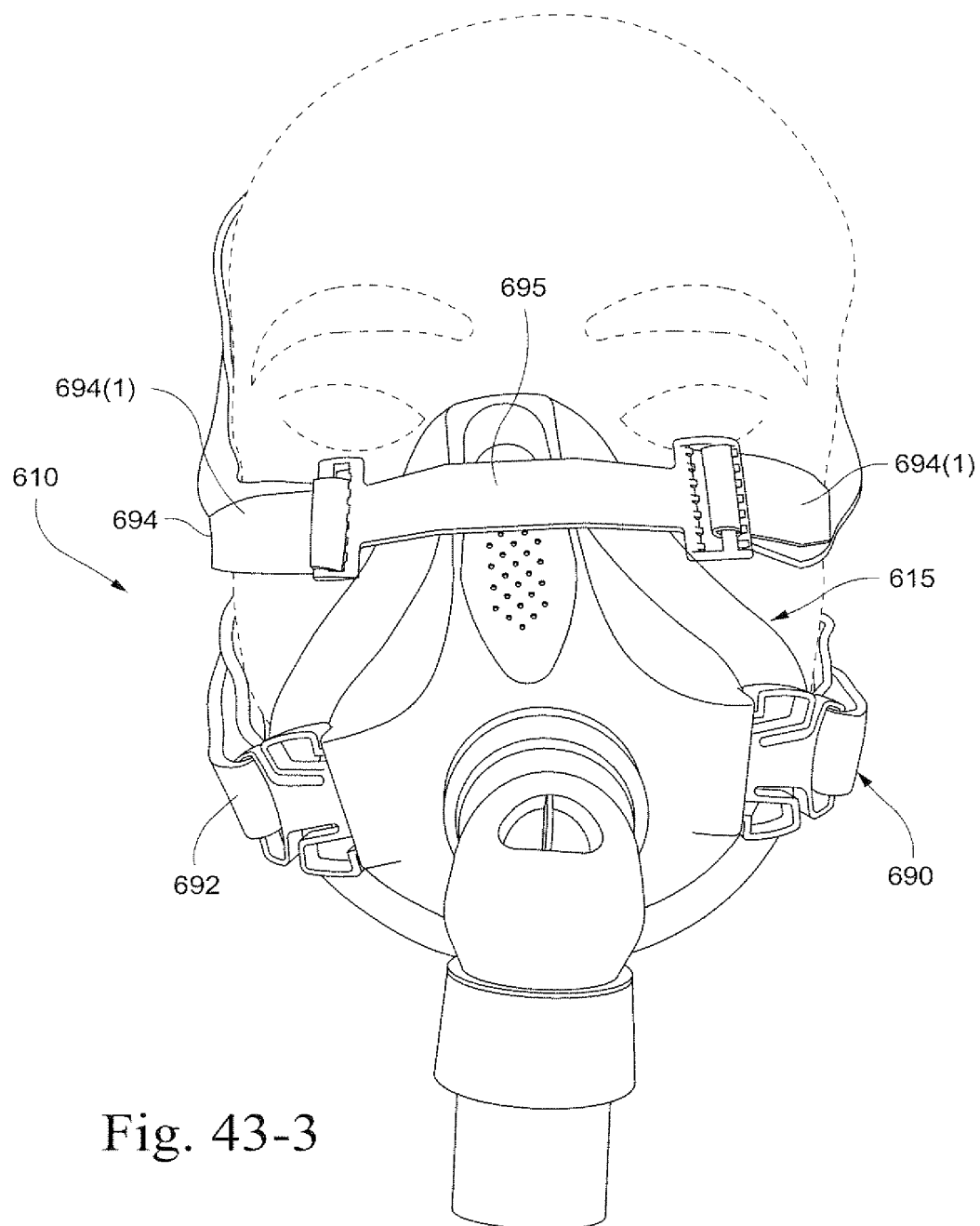


Fig. 43-3

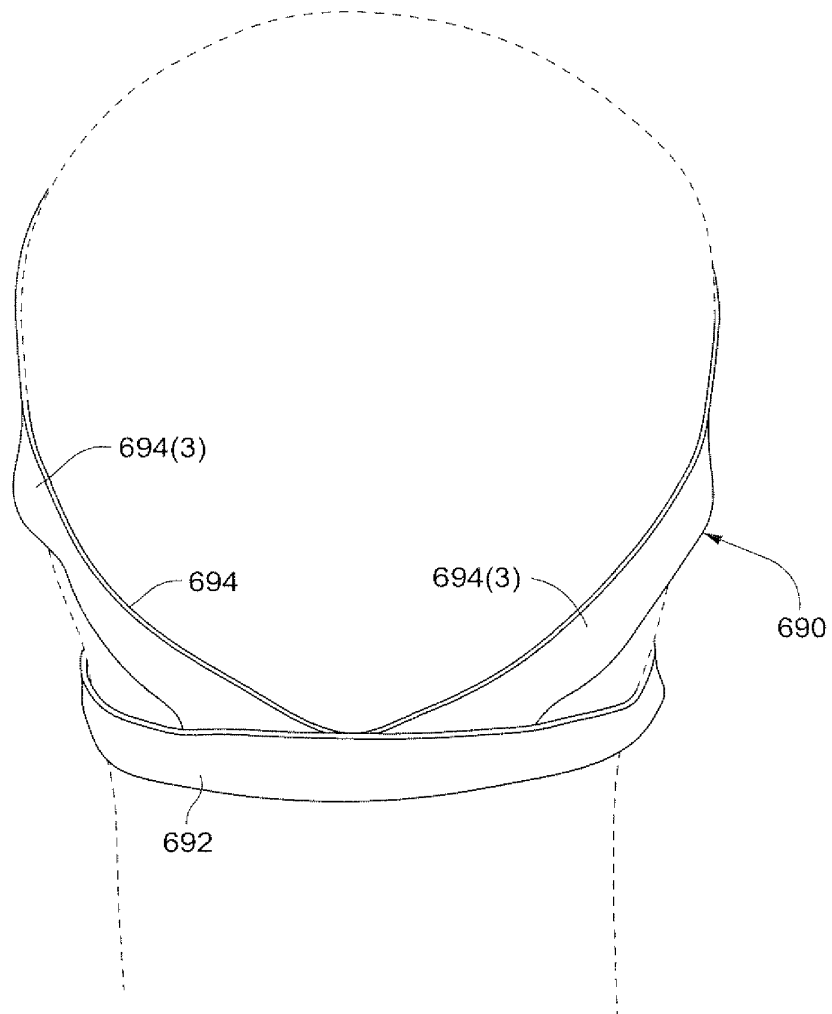


Fig. 43-4

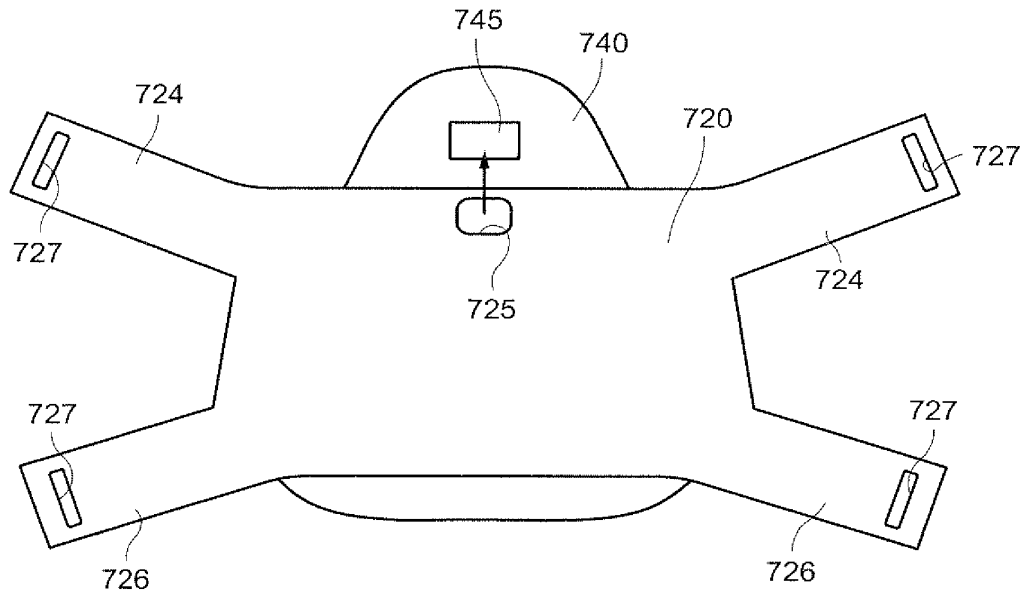


Fig. 44

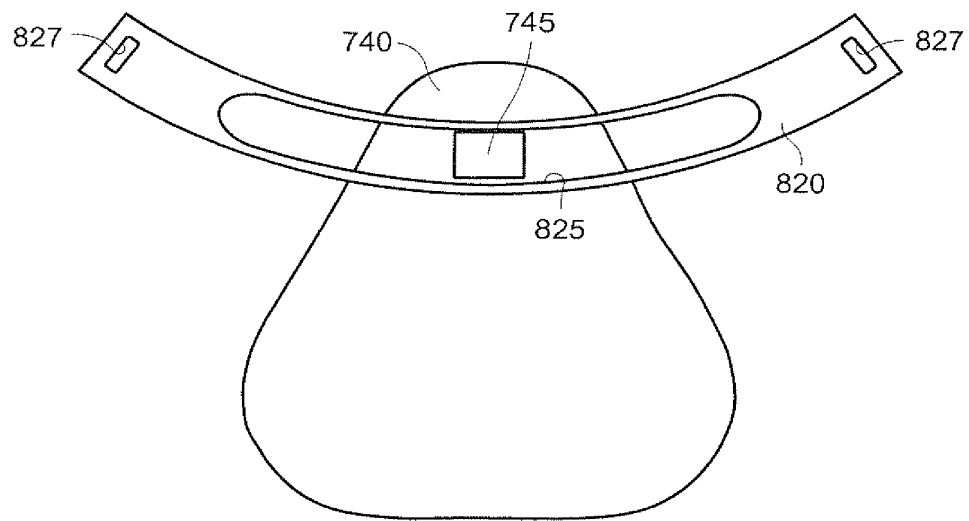


Fig. 45

**CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION
UNDER 37 CFR 1.102(e) (Page 1 of 1)**

First Named Inventor:	Errol Savio Alex D'SOUZA	Nonprovisional Application Number (if known):	
Title of Invention:	MASK SYSTEM		

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently \$0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.
2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed.
3. The applicable box is checked below:

I. ☒ Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)

- i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.
---OR---
(b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.
- ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, or the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.

II. ☐ Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)

- i. A request for continued examination has been filed with, or prior to, this form.
- ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
- iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
- iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
- v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature <u>/Paul T. Bowen/</u>	Date <u>July 31, 2014</u>
Name (Print/Typed) <u>Paul T. Bowen</u>	Practitioner Registration Number <u>38,009</u>
Note: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.*	
<input checked="" type="checkbox"/> *Total of <u>1</u> forms are submitted.	

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875						Application or Docket Number 14/447,673				
APPLICATION AS FILED - PART I										
(Column 1)		(Column 2)		SMALL ENTITY		OR OTHER THAN SMALL ENTITY				
FOR	NUMBER FILED	NUMBER EXTRA	RATE(\$)	FEE(\$)		RATE(\$)	FEE(\$)			
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	280			
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A			N/A	600			
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	720			
TOTAL CLAIMS (37 CFR 1.16(j))	21	minus 20 = *	1			x 80 =	80			
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1	minus 3 = *				x 420 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL		TOTAL	1680			
APPLICATION AS AMENDED - PART II										
(Column 1)		(Column 2)		(Column 3)		SMALL ENTITY		OR OTHER THAN SMALL ENTITY		
AMENDMENT A		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)
	Total (37 CFR 1.16(i))	*	Minus	**	=	x	=		x	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x	=		x	=
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
						TOTAL ADD'L FEE			TOTAL ADD'L FEE	
AMENDMENT B		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)
	Total (37 CFR 1.16(i))	*	Minus	**	=	x	=		x	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x	=		x	=
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
						TOTAL ADD'L FEE			TOTAL ADD'L FEE	
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3. ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20". *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3". The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.										



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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	TOT CLAIMS	IND CLAIMS
14/447,673	07/31/2014	3771	1680	PTB-4398-1485	21	1

CONFIRMATION NO. 3036

23117
NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

FILING RECEIPT



Date Mailed: 08/11/2014

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

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Zoran VALCIC, Sydney, AUSTRALIA;
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Applicant(s)

ResMed Limited, Bella Vista, AUSTRALIA

Power of Attorney: The patent practitioners associated with Customer Number 23117

Domestic Priority data as claimed by applicant

This application is a CON of 13/964,280 08/12/2013
which is a CON of 13/745,077 01/18/2013 PAT 8528561
which is a CON of 12/736,024 09/02/2010 PAT 8550084
which is a 371 of PCT/AU2009/000241 02/27/2009
which claims benefit of 61/064,406 03/04/2008
and claims benefit of 61/071,893 05/23/2008
and claims benefit of 61/136,117 08/13/2008 *

(*)Data provided by applicant is not consistent with PTO records.

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see <http://www.uspto.gov> for more information.) - None.

Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

If Required, Foreign Filing License Granted: 08/08/2014

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 14/447,673**

Projected Publication Date: 11/20/2014

Non-Publication Request: No

Early Publication Request: No
Title

MASK SYSTEM

Preliminary Class

128

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER
Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15

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The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

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The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

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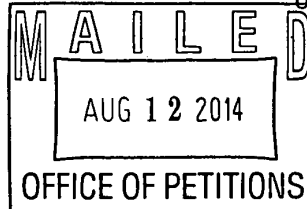
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ARLINGTON VA 22203



Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Doc Code: TRACK1.GRANT

Decision Granting Request for Prioritized Examination (Track I or After RCE)	Application No.: 14/447,673
<p>1. THE REQUEST FILED <u>July 31, 2014</u> IS GRANTED.</p> <p>The above-identified application has met the requirements for prioritized examination</p> <p>A. <input checked="" type="checkbox"/> for an original nonprovisional application (Track I).</p> <p>B. <input type="checkbox"/> for an application undergoing continued examination (RCE).</p> <p>2. The above-identified application will undergo prioritized examination. The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:</p> <p>A. filing a <u>petition for extension of time</u> to extend the time period for filing a reply;</p> <p>B. filing an <u>amendment to amend the application to contain more than four independent claims, more than thirty total claims,</u> or a multiple dependent claim;</p> <p>C. filing a <u>request for continued examination</u>;</p> <p>D. filing a notice of appeal;</p> <p>E. filing a request for suspension of action;</p> <p>F. mailing of a notice of allowance;</p> <p>G. mailing of a final Office action;</p> <p>H. completion of examination as defined in 37 CFR 41.102; or</p> <p>I. abandonment of the application.</p> <p>Telephone inquiries with regard to this decision should be directed to Brian W. Brown at 571-272-5338.</p> <p>/Brian W. Brown/ [Signature]</p> <p>Petitions Examiner, Office of Petitions (Title)</p>	



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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/447,673	07/31/2014	Errol Savio Alex D'SOUZA	PTB-4398-1485

CONFIRMATION NO. 3036

23117
NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

PUBLICATION NOTICE



Title:MASK SYSTEM

Publication No.US-2014-0338672-A1

Publication Date:11/20/2014

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently <http://www.uspto.gov/patft/>.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently <http://pair.uspto.gov/>. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101



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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO.	TOT CLAIMS	IND CLAIMS
14/447,673	07/31/2014	3649	1680	PTB-4398-1485	21	1

CONFIRMATION NO. 3036

CORRECTED FILING RECEIPT



OC000000072039310

23117
NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

Date Mailed: 11/28/2014

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

Errol Savio Alex D'SOUZA, Sydney, AUSTRALIA;
Matthew EVES, Sydney, AUSTRALIA;
David James LOCKWOOD, Gosford, AUSTRALIA;
Zoran VALCIC, Sydney, AUSTRALIA;
Jamie Graeme WEHBEH, Sydney, AUSTRALIA;

Applicant(s)

ResMed Limited, Bella Vista, AUSTRALIA

Power of Attorney: The patent practitioners associated with Customer Number 23117

Domestic Priority data as claimed by applicant

This application is a CON of 13/964,280 08/12/2013
which is a CON of 13/745,077 01/18/2013 PAT 8528561
which is a CON of 12/736,024 09/02/2010 PAT 8550084
which is a 371 of PCT/AU2009/000241 02/27/2009
which claims benefit of 61/064,406 03/04/2008
and claims benefit of 61/071,893 05/23/2008
and claims benefit of 61/136,617 09/19/2008

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see <http://www.uspto.gov> for more information.) - None.

Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

If Required, Foreign Filing License Granted: 08/08/2014

page 1 of 3

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 14/447,673**

Projected Publication Date: Not Applicable

Non-Publication Request: No

Early Publication Request: No
Title

MASK SYSTEM

Preliminary Class

128

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

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Title 37, Code of Federal Regulations, 5.11 & 5.15

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The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

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The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop technology, manufacture products, deliver services, and grow your business, visit <http://www.SelectUSA.gov> or call +1-202-482-6800.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

D'SOUZA et al.

Atty. Ref.: PTB-4398-1485

Confirmation No. 3036

Appln. No. 14/447,673

Art Unit: 3649

Filed: 07/31/2014

Examiner: Matter, Kristen Clarette

For: MASK SYSTEM

* * * * *

December 1, 2014

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

PRELIMINARY AMENDMENT

In order to place the above-identified application in better condition for examination,
please amend the application as follows:

AMENDMENTS TO THE DRAWINGS

The attached sheet of drawing includes changes to Fig. 22. This sheet, which includes Fig. 22, replaces the original sheet including Fig. 22. In Fig. 22, the lead lines to elements “1145(1)” and “1149(1)” have been corrected.

D'SOUZA et al.
Appl. No. 14/447,673

REMARKS/ARGUMENTS

Claims 1-21 are pending in this application. By this Amendment, the drawings have been amended to correct Fig. 22 and make the drawing consistent with the specification.

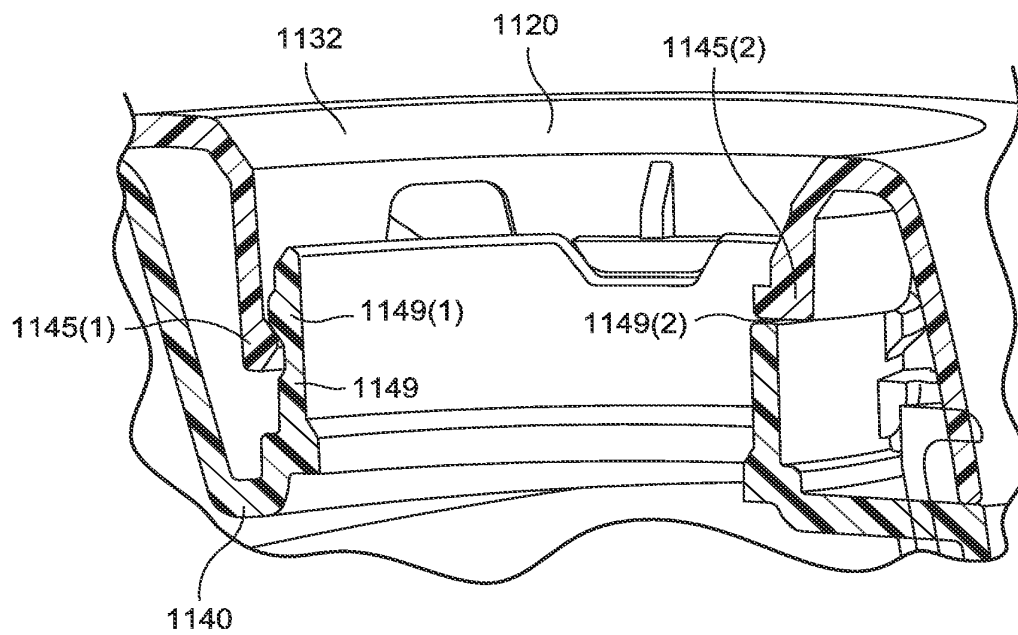
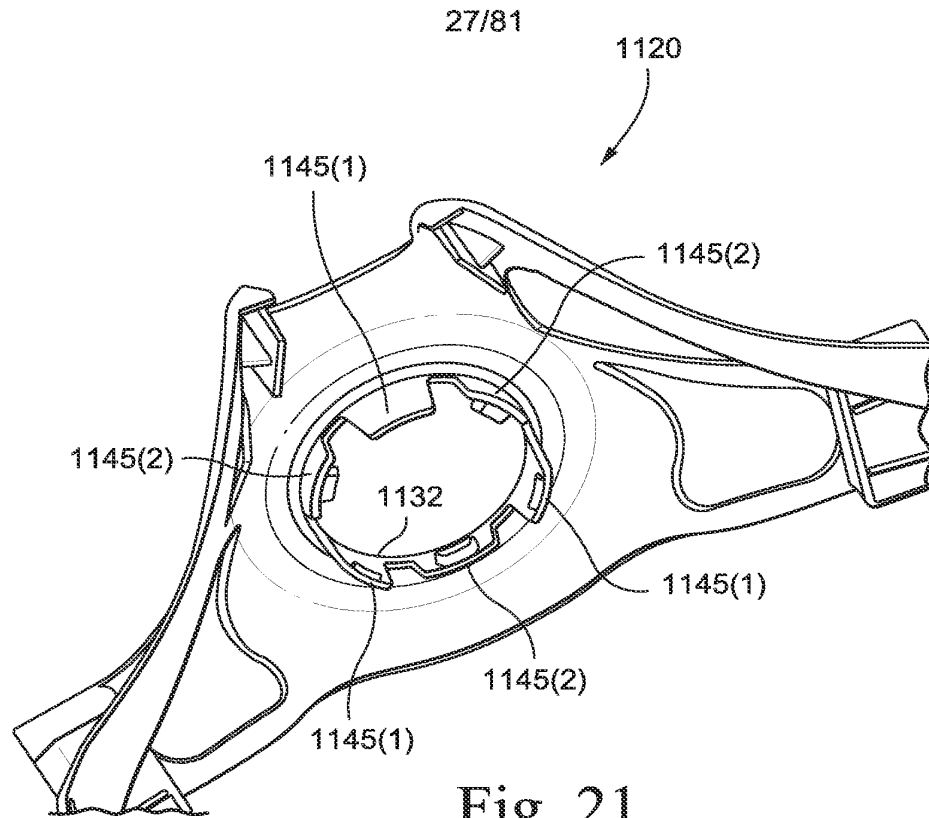
The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: /Paul T. Bowen/
Paul T. Bowen
Reg. No. 38,009

PTB:tlm
901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100



Electronic Acknowledgement Receipt	
EFS ID:	20824897
Application Number:	14447673
International Application Number:	
Confirmation Number:	3036
Title of Invention:	MASK SYSTEM
First Named Inventor/Applicant Name:	Errol Savio Alex D'SOUZA
Customer Number:	23117
Filer:	Paul Thomas Bowen/Tanja Majca
Filer Authorized By:	Paul Thomas Bowen
Attorney Docket Number:	PTB-4398-1485
Receipt Date:	01-DEC-2014
Filing Date:	31-JUL-2014
Time Stamp:	13:06:28
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
------------------------	----

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		4398-1485_Preliminary_Amen dment.pdf	82529 bf875b0322359bf712aa53ce8460e8b4772182a9	yes	3

	Multipart Description/PDF files in .zip description								
	Document Description		Start	End					
	Preliminary Amendment		1	1					
	Applicant Arguments/Remarks Made in an Amendment		2	3					
Warnings:									
Information:									
2	Drawings-only black and white line drawings	4398-1485_ReplacementSheet.pdf	50386	no	1				
			71c21f3ca64e0f851f6ff3baafb903fa0286fd30						
Warnings:									
Information:									
Total Files Size (in bytes):			132915						
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>									



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/447,673	07/31/2014	Errol Savio Alex D'SOUZA	PTB-4398-1485	3036

23117	7590	12/08/2014
NIXON & VANDERHYE, PC		
901 NORTH GLEBE ROAD, 11TH FLOOR		
ARLINGTON, VA 22203		

EXAMINER	
MATTER, KRISTEN CLARETTE	

ART UNIT	PAPER NUMBER
3649	

NOTIFICATION DATE	DELIVERY MODE
12/08/2014	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTOMAIL@nixonvan.com
pair_nixon@firsttofile.com

Office Action Summary	Application No. 14/447,673	Applicant(s) D'SOUZA ET AL.	
	Examiner KRISTEN MATTER	Art Unit 3649	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 7/31/2014.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☒ Claim(s) 1-21 is/are pending in the application.
5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☒ Claim(s) 1-21 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10) ☐ The specification is objected to by the Examiner.

11) ☒ The drawing(s) filed on 7/31/2014 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some** c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date 7/31/14, 8/27/14, 9/11/14, 10/1/14, 11/21/14.

3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

4) ☐ Other: _____.

The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

Drawings

The drawings are objected to because Figures 41-3 and 41-4 should include a connector mechanism showing how the components in the exploded view fit together or are related.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 3 is objected to because of the following informalities: In lines 1-2, the claim reads “one or more folds...has a...” and in lines 2-3 the claim reads “one or more folds...have a...” Examiner suggests using “has” in both instances or using “have” in both instances instead of one of each.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13 and 19-21 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Ho et al. (US 2006/0272646, herein referred to as “Ho”) in view of Lieberman et al. (US 2008/0178886, herein referred to as “Lieberman”) and Schegerin (US 5,349,949).

Regarding claims 1-3 and 20, Ho discloses a mask system comprising: a shroud module (10); wherein the shroud module includes headgear connectors (e.g., 16) adapted to removably attach to respective headgear straps of headgear (see Figure 10); and a cushion module comprising: a frame (102 - the element with wall 108) defining a breathing chamber (see Figure 13); and a cushion (the cushion on 102) 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 face (see Figure 10), wherein the shroud

module and the cushion module are configured to be removably coupled to one another (see paragraph 59 and Figure 5).

Ho is silent as to the materials of the mask. However, Lieberman discloses another face mask with a cushion formed of silicone (see claim 12), a first, relatively soft elastomeric material and a mask frame/body constructed of polycarbonate (see claim 12), a second material that is more rigid than the cushion. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the frame of Ho from polycarbonate and the cushion from silicone as taught by Lieberman in order to use a rigid enough structure to allow connecting of the elbow and shroud to the frame and a soft material for create a soft comfortable seal on the patient's face. See also *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960), in which the selection of a known material based on its suitability for its intended use supported a prima facie case of obviousness.

Ho lacks the cushion having one or more folds as claimed. However, Schegerin discloses a breathing mask with folds (26) in the nasal and lower lip/chin region (see Figure 1) to provide a higher level of adaptability, the fold(s) in the nasal bridge region having a relatively higher degree of flexibility than those in the lower lip/chin region (see column 2, lines 10-20). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Ho's cushion to include folds as taught by Schegerin in order to provide additional adaptability and maintain a good seal even as the applied force to the mask changes, for example, as a patient moves.

Regarding claim 4, Schegerin discloses that the folds comprise adjacent first walls (e.g., the flat portions seen in Figure 7) interconnected by a second wall (26).

Regarding claim 5, Ho discloses full-face cushions (paragraph 12 - although a nasal mask is shown in the Figures Ho discloses Full face masks as interchangeable with nasal masks) as does Lieberman and Schegerin as is well known in the art.

Regarding claim 6, Ho discloses the shroud module includes upper and lower headgear connectors on each side of the shroud module (see Figures 9 and 10).

Regarding claim 7, the upper headgear connectors are slots adapted to receive a strap in use (see Figures 9 and 10).

Regarding claims 8 and 9, Ho discloses that the slots can be replaced by the arrangement seen in US 2004/0025883 (see paragraph 56), and as seen in US 2004/0025883 Figures 11 and 13, the headgear connectors are removably interlocked with a headgear clip (76) associated with a headgear strap via snap-fit.

Regarding claim 10, Ho discloses that the shroud module provides an open construction that provides an annular or part annular cushion retaining portion (40) structured to retain the cushion module.

Regarding claim 11, Ho discloses an elbow module (118) adapted to be connected to a delivery tube that delivers breathable air to the patient.

Regarding claim 12, Ho discloses that the elbow module is provided to the shroud module (see Figure 13).

Regarding claim 13, Ho is silent as to the material of the elbow module. However, polycarbonate is a well-known and commonly used material for facemask components. Absent a critical teaching and/or showing of unexpected results from making the elbow module of polycarbonate examiner contends that it would have been obvious to one of ordinary skill in the

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art at the time the invention was made to have made Ho's elbow module from polycarbonate in order to provide a rigid, biocompatible material for the elbow module. See also *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960), in which the selection of a known material based on its suitability for its intended use supported a prima facie case of obviousness.

Regarding claim 19, Ho discloses that the shroud can be made from a variety of materials (see paragraph 51) but does not expressly state polycarbonate. However, polycarbonate is a well-known and commonly used material for facemask components. Absent a critical teaching and/or showing of unexpected results from making the shroud module of polycarbonate examiner contends that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made Ho's shroud module from polycarbonate in order to provide a rigid, biocompatible material for the shroud module. See also *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960), in which the selection of a known material based on its suitability for its intended use supported a prima facie case of obviousness.

Regarding claim 21, “Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)(citations omitted). Here, Ho does not expressly disclose “co-mold[ing]” the frame and cushion. However, the process by which the frame and cushion are joined is not required for a product by process claim. Since ho discloses a frame connected to a

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cushion, and which are fully capable of being joined by co-molding, the instant claim language is met.

Claims 14-16 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Ho in view of Lieberman and Schegerin, as applied to claims 1-13 and 19-21 above, and further in view of Smart (US 2006/0107960).

Regarding claim 14, Ho discloses that the elbow module and shroud module are connected with a mechanical interlock (see Figure 13) but Ho is silent as to allowing 360 degree rotation of the elbow module. However, Smart discloses another elbow module that is mechanically connected to a frame while allowing 360 degree rotation (via swivels 30 and 41) as is well known and common practice in the art. Therefore, it would have been obvious to one of ordinary skill in the art to allow Ho's elbow to swivel as taught by Smart in order to allow even more freedom of movement to the patient while maintaining a good seal. Having the swivel be 360 degrees is obvious as being an optimal value within a well-known workable range.

Regarding claims 15 and 16, Ho lacks a valve on the elbow as claimed. Smart discloses an elbow module with an anti-asphyxia valve (see abstract) that includes a flap portion (27) adapted to selectively close a port (44) provided in the elbow module. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Ho's elbow module with a valve as taught by Smart in order to prevent accidental suffocation as is well known in the art.

Claims 17 and 18 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Ho in view of Lieberman and Schegerin, as applied to claims 1-13 and 19-21 above, and further in view of Geist (US 2006/0042629).

Ho discloses the shroud module is attachable to a variety of prior art masks (see paragraph 59) but does not expressly state different masks. Geist discloses that the prior art is replete with masks of different sizes and structures (paragraph 2). Therefore, it would have been obvious, if not inherent, that the masks could come in a small, medium and large module, all of which are coupleable to the same shroud module (and which can already have or obviously be modified to have “folds” in the cushion module) in order to accommodate patients of different sizes as is well known in the art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van*

Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit <http://www.uspto.gov/forms/>. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to <http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp>.

Claims 1-21 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 7 of U.S. Patent No. 8,528,561. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the patented claim and the instant claims are minor and obvious from each other. For example, the instant claim 1 is a broader version of the patented claim 7 (i.e. the instant claim 1 does not include the structural element of elbow, headgear, specific materials, valve, etc. as in the patented claim 7). In the instant claim 1, the structural elements are included in the patented claim 7. Similar arguments exist for the remaining claims -- the structural elements are included

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or obvious variants from material choice and remaining claims (e.g., different sizes of masks).

Any infringement over the patent would also infringe over the instant claims. Hence, the instant claims 1-21 do not differ from the scope of the patented claim 7.

Claims 1-21 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 3-6 and 32-36 of U.S. Patent No. 8,550,084. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the patented claims and the instant claims are minor and obvious from each other. For example, the instant claim 1 is a broader version of the patented claim 3 (i.e. the instant claim 1 does not include the structural element of elbow, headgear, specific materials, valve, etc. as in the patented claim 3). In the instant claim 1, the structural elements are included in the patented claim 3. Similar arguments exist for the remaining claims -- the structural elements are included or obvious variants from material choice and remaining claims (e.g., different sizes of masks). Any infringement over the patent would also infringe over the instant claims. Hence, the instant claims 1-21 do not differ from the scope of the patented claims 3-6 and 32-36.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTEN MATTER whose telephone number is (571)272-5270. The examiner can normally be reached on Monday - Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Darnell Jayne can be reached on (571) 272-7723. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kristen C. Matter
Primary Examiner
Art Unit 3649

/KRISTEN MATTER/
Primary Examiner, Art Unit 3649

Notice of References Cited	Application/Control No. 14/447,673	Applicant(s)/Patent Under Reexamination D'SOUZA ET AL.	
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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2006/0042629	03-2006	Geist, Leroy D.	128/206.24
*	B	US-2006/0107960	05-2006	Smart, Gregory S.	128/206.24
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
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	M	US-			


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	O					
	P					
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	S					
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NON-PATENT DOCUMENTS

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	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Search Notes 	Application/Control No. 14447673	Applicant(s)/Patent Under Reexamination D'SOUZA ET AL.
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CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
128	205.25, 206.21, 206.24, 206.28, 207.11	11/24/14	KCM

SEARCH NOTES		
Search Notes	Date	Examiner
Inventor name search	11/24/14	KCM

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

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CONFIRMATION NO. 3036

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.		
14/447,673	07/31/2014	128	3649	PTB-4398-1485		
RULE						
APPLICANTS ResMed Limited, Bella Vista, AUSTRALIA, Assignee (with 37 CFR 1.172 Interest); INVENTORS Errol Savio Alex D'SOUZA, Sydney, AUSTRALIA; Matthew EVES, Sydney, AUSTRALIA; David James LOCKWOOD, Gosford, AUSTRALIA; Zoran VALCIC, Sydney, AUSTRALIA; Jamie Graeme WEHBEH, Sydney, AUSTRALIA; ** CONTINUING DATA ***** /KCM/ This application is a CON of 13/964,280 08/12/2013 which is a CON of 13/745,077 01/18/2013 PAT 8528561 which is a CON of 12/736,024 09/02/2010 PAT 8550084 which is a 371 of PCT/AU2009/000241 02/27/2009 which claims benefit of 61/064,406 03/04/2008 and claims benefit of 61/071,893 05/23/2008 9/19/2008 and claims benefit of 61/136,117 08/13/2008 61/136,617 (see ADS and spec) /KCM/ (*) Data provided by applicant is not consistent with PTO records. ** FOREIGN APPLICATIONS ***** ** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** 08/08/2014						
Foreign Priority claimed <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	35 USC 119(a-d) conditions met <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Met after Allowance	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
Verified and /KRISTEN CLARETTE	MATTER/	Initials	AUSTRALIA	81	21	1
Acknowledged	Examiner's Signature					
ADDRESS						
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203 UNITED STATES						
TITLE						
MASK SYSTEM						
FILING FEE RECEIVED 1680	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:			<input type="checkbox"/> All Fees <input type="checkbox"/> 1.16 Fees (Filing) <input type="checkbox"/> 1.17 Fees (Processing Ext. of time) <input type="checkbox"/> 1.18 Fees (Issue) <input type="checkbox"/> Other _____ <input type="checkbox"/> Credit		

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	Notice of Opposition to Grant of Patent (Section 21) to New Zealand Patent Application No. 622665, filed September 1, 2014, 7 pages.
	Notice of Opposition to Grant of Patent (Section 21) to New Zealand Patent Application No. 622666, filed September 1, 2014, 7 pages.
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	FILING DATE 07/31/2014	GROUP 3649

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Petition Info

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*Examiner	/Kristen Matter/	Date Considered	11/24/2014
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	FILING DATE	GROUP
	Herewith	Unassigned

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	Herewith	Unassigned

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	2,415,846	02/1947	RANDALL			
	2,428,451	10/1947	EMERSON			
	2,433,565	12/1947	KORMAN			
	2,438,058	03/1948	KINCHELOE			
	2,473,518	06/1949	GARRARD et al			
	2,540,567	02/1951	BENNETT			
	2,578,621	12/1951	YANT			
	2,590,006	03/1952	GORDON			
	2,625,155	01/1953	ENGELDER			
	2,641,253	06/1953	ENGELDER			
	2,693,178	11/1954	GILROY			
	2,706,983	04/1955	MATHESON et al.			
	2,749,910	06/1956	FAULCONER, JR.			
	2,820,651	01/1958	PHILLIPS			
	2,837,090	06/1958	BLOOM et al.			
	2,868,196	01/1959	STAMPE			
	2,875,757	03/1959	GALLEHER, JR.			
	2,875,759	03/1959	GALLEHER, JR.			
	2,881,444	04/1959	FRESH et al.			
	2,882,895	04/1959	GALEAZZI			
	2,902,033	09/1959	GALLEHER, JR.			
	2,917,045	12/1959	SCHILDKNECHT et al.			
	2,931,356	04/1960	SCHWARZ			
	2,939,458	06/1960	LUNDQUIST			
	3,013,556	12/1961	GALLEHER, JR.			
	3,042,035	07/1962	COANDA			
	3,117,574	01/1964	REPLOGLE			
	3,182,659	05/1965	BLOUNT			
	3,189,027	06/1965	BARTLETT, JR.			
	3,193,624	07/1965	WEBB et al.			
	3,238,943	03/1966	HOLLEY			
	3,288,138	11/1966	SACHS			
	3,315,672	04/1967	CUNNINGHAM et al.			
	3,315,674	04/1967	BLOOM et al.			
	3,330,273	07/1967	BENNETT			
	3,330,274	07/1967	BENNETT			
	3,362,420	01/1968	BLACKBURN et al.			
*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

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		3,363,833	01/1968	LAERDAL			
		3,545,436	12/1970	HOLLOWAY			
		3,556,122	01/1971	LAERDAL			
		3,580,051	05/1971	BLEVINS			
		3,670,726	03/1972	MAHON et al.			
		3,682,171	08/1972	DALI et al.			
		3,700,000	10/1972	HESSE, Deceased et al.			
		3,720,235	03/1973	SCHROCK			
		3,725,953	04/1973	JOHNSON et al.			
		3,739,774	06/1973	GREGORY			
		3,750,333	08/1973	VANCE			
		3,752,157	08/1973	MALMIN			
		3,754,552	08/1973	KING			
		3,796,216	03/1974	SCHWARZ			
		3,799,164	03/1974	ROLLINS			
		3,830,230	08/1974	CHESTER			
		3,861,385	01/1975	CARDEN			
		3,902,486	09/1975	GUICHARD			
		3,905,361	09/1975	HEWSON et al.			
		3,910,261	10/1975	RAGSDALE et al.			
		3,938,614	02/1976	AHS			
		3,972,321	08/1976	PROCTOR			
		3,978,854	09/1976	MILLS, JR.			
		4,006,744	02/1977	STEER			
		4,062,357	12/1977	LAERDAL			
		4,069,516	01/1978	WATKINS, JR.			
		4,077,404	03/1978	ELAM			
		4,120,302	10/1978	ZIEGLER			
		4,142,527	03/1979	GARCIA			
		4,153,051	05/1979	SHIPPERT			
		4,156,426	05/1979	GOLD			
		4,167,185	09/1979	LEWIS			
		4,201,205	05/1980	BARTHOLOMEW			
		4,226,234	10/1980	GUNDERSON			
		4,231,363	11/1980	GRIMES			
		4,233,972	11/1980	HAUFF et al.			
		4,239,038	12/1980	HOLMES			
		4,245,632	01/1981	HOUSTON			

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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	4,248,218	02/1981	FISCHER			
	4,263,908	04/1981	MIZERAK			
	4,264,743	04/1981	MARUYAMA et al.			
	4,265,239	05/1981	FISCHER, JR. et al.			
	4,266,540	05/1981	PANZIK et al.			
	4,267,845	05/1981	ROBERTSON, JR. et al.			
	4,273,124	06/1981	ZIMMERMAN			
	4,304,229	12/1981	CURTIN			
	4,312,359	01/1982	OLSON			
	4,328,797	05/1982	ROLLINS et al.			
	4,337,767	07/1982	YAHATA			
	4,347,205	08/1982	STEWART			
	4,354,488	10/1982	BARTOS			
	4,367,735	01/1983	DALI			
	4,367,816	01/1983	WILKES			
	4,369,284	01/1983	CHEN			
	4,402,316	09/1983	GADBERRY			
	4,406,283	09/1983	BIR			
	4,412,537	11/1983	TIGER			
	4,414,973	11/1983	MATHESON et al.			
	4,417,575	11/1983	HILTON et al.			
	4,422,456	12/1983	TEIP			
	4,446,576	05/1984	HISATAKA			
	4,449,526	05/1984	ELAM			
	4,454,880	06/1984	MUTO et al.			
	4,454,881	06/1984	HUBER et al.			
	4,455,675	06/1984	BOSE et al.			
	4,458,679	07/1984	WARD			
	4,467,799	08/1984	STEINBERG			
	4,493,614	01/1985	CHU et al.			
	4,522,639	06/1985	ANSITE et al.			
	4,548,200	10/1985	WAPNER			
	4,549,542	11/1985	CHEIN			
	4,558,710	12/1985	EICHLER			
	4,572,323	02/1986	RANDALL			
	4,579,113	04/1986	McCREADIE et al.			
	4,587,967	05/1986	CHU et al.			
	4,593,688	06/1986	PAYTON			

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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	4,601,465	07/1986	ROY			
	4,616,647	10/1986	McCREADIE			
	4,617,637	11/1986	CHU et al.			
	4,622,964	11/1986	FLYNN			
	4,630,604	12/1986	MONTESI			
	4,641,645	02/1987	TAYEBI			
	4,641,647	02/1987	BEHAN			
	4,655,213	04/1987	RAPOPORT et al.			
	4,657,010	04/1987	WRIGHT			
	4,660,555	04/1987	PAYTON			
	4,665,570	05/1987	DAVIS			
	4,671,267	06/1987	STOUT			
	4,671,271	06/1987	BISHOP et al.			
	4,674,134	06/1987	LUNDIN			
	4,676,241	06/1987	WEBB et al.			
	4,677,975	07/1987	EDGAR et al.			
	4,677,977	07/1987	WILCOX			
	4,686,977	08/1987	COSMA			
	4,699,139	10/1987	MARSHALL et al.			
	4,706,664	11/1987	SNOOK et al.			
	4,707,863	11/1987	McNEAL			
	4,711,636	12/1987	BIERMAN			
	4,713,844	12/1987	WESTGATE			
	4,739,755	04/1988	WHITE et al.			
	4,753,233	06/1988	GRIMES			
	4,767,411	08/1988	EDMUNDS			
	4,770,169	09/1988	SCHMOEGNER et al.			
	4,772,760	09/1988	GRAHAM			
	4,774,941	10/1988	COOK			
	4,774,946	11/1988	ACKERMAN et al.			
	4,782,832	11/1988	TRIMBLE et al.			
	4,790,829	12/1988	BOWDEN et al.			
	4,799,477	01/1989	LEWIS			
	4,802,857	02/1989	LAUGHLIN			
	4,803,981	02/1989	VICKERY			
	4,807,617	02/1989	NESTI			
	4,809,692	03/1989	NOWACKI et al.			
	4,811,730	03/1989	MILANO			

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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	4,819,629	04/1989	JONSON			
	4,821,713	04/1989	BAUMAN			
	4,827,924	05/1989	JAPUNTICH			
	4,830,138	05/1989	PALMAER et al.			
	4,832,017	05/1989	SCHNOOR			
	4,838,878	06/1989	KALT et al.			
	4,841,953	06/1989	DODRILL			
	4,848,334	07/1989	BELLM			
	4,848,366	07/1989	AITA et al.			
	4,850,346	07/1989	MICHEL et al.			
	4,856,118	08/1989	SAPIEJEWSKI			
	4,886,058	12/1989	BROMSTROM et al.			
	4,899,740	02/1990	NAPOLITANO			
	4,905,683	03/1990	CRONJAEGER			
	4,907,584	03/1990	MCGINNIS			
	4,910,806	03/1990	BAKER et al.			
	4,914,957	04/1990	DOUGHERTY			
	4,915,105	04/1990	LEE			
	4,915,106	04/1990	AULGUR et al.			
	4,919,128	04/1990	KOPALA et al.			
	4,919,654	04/1990	KALT			
	4,938,210	07/1990	SHENE			
	4,938,212	07/1990	SNOOK et al.			
	4,941,476	07/1990	FISHER			
	4,944,310	07/1990	SULLIVAN			
	4,945,907	08/1990	TAYEBI			
	4,947,860	08/1990	FISHER			
	4,960,121	10/1990	NELSON et al.			
	4,966,590	10/1990	KALT			
	4,969,880	11/1990	ZAMIEROWSKI			
	4,971,051	11/1990	TOFFOLON			
	4,976,698	12/1990	STOKLEY			
	4,986,269	01/1991	HAKKINEN			
	4,989,271	02/1991	SAPIEJEWSKI et al.			
	4,989,596	02/1991	MACRIS et al.			
	4,989,599	02/1991	CARTER			
	4,996,983	03/1991	AMRHEIN			

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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,000,173	03/1991	ZALKIN et al.			
	5,003,631	04/1991	RICHARDSON			
	5,003,633	04/1991	ITOHI			
	5,005,568	04/1991	LOESCHER et al.			
	5,005,571	04/1991	DIETZ			
	5,018,519	05/1991	BROWN			
	5,020,163	06/1991	AILEO et al.			
	5,022,900	06/1991	BAR-YONA et al.			
	5,023,955	06/1991	MURPHY, II et al.			
	5,025,805	06/1991	NUTTER			
	5,027,809	07/1991	ROBINSON			
	5,038,772	08/1991	KOLBE et al.			
	5,038,776	08/1991	HARRISON et al.			
	5,042,473	08/1991	LEWIS			
	5,042,478	08/1991	KOPALA et al.			
	5,046,200	09/1991	FEDER			
	5,046,491	09/1991	DERRICK			
	5,062,421	11/1991	BURNS et al.			
	5,063,922	11/1991	HAKKINEN			
	5,069,205	12/1991	URSO			
	5,074,297	12/1991	VENEGAS			
	5,080,092	01/1992	TENNA			
	5,093,940	03/1992	NISHIYAMA			
	5,109,839	05/1992	BLASDELL et al.			
	5,109,840	05/1992	DALEIDEN			
	5,113,857	05/1992	DICKERMAN et al.			
	5,117,818	06/1992	PALFY			
	5,121,745	06/1992	ISRAEL			
	5,121,746	06/1992	SIKORA			
	5,123,677	06/1992	KRECZKO et al.			
	5,127,397	07/1992	KOHNKE			
	5,133,347	07/1992	HUENNEBECK			
	5,137,017	08/1992	SALTER			
	5,138,722	08/1992	URELLA et al.			
	5,140,980	08/1992	HAUGHEY et al.			
	5,140,982	08/1992	BAUMAN			
	5,146,914	09/1992	STURROCK			

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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,159,938	11/1992	LAUGHLIN			
	5,178,138	01/1993	WALSTROM et al.			
	5,181,506	01/1993	TARDIFF, JR. et al.			
	5,188,101	02/1993	TUMOLO			
	5,199,424	04/1993	SULLIVAN et al.			
	5,207,665	05/1993	DAVIS et al.			
	5,220,699	06/1993	FARRIS			
	5,222,478	06/1993	SCARBERRY et al.			
	5,231,983	08/1993	MATSON et al.			
	5,233,978	08/1993	CALLAWAY			
	5,243,709	09/1993	SHEEHAN et al.			
	5,243,971	09/1993	SULLIVAN et al.			
	5,245,995	09/1993	SULLIVAN et al.			
	5,263,939	11/1993	WORTRICH			
	5,265,592	11/1993	BEAUSSANT			
	5,265,595	11/1993	RUDOLPH			
	5,267,557	12/1993	HER-MOU			
	5,269,296	12/1993	LANDIS			
	5,271,391	12/1993	GRAVES			
	5,279,289	01/1994	KIRK			
	5,280,784	01/1994	KOHLER			
	5,291,880	03/1994	ALMOVIST et al.			
	5,299,448	04/1994	MARYYANEK			
	5,299,579	04/1994	GEDEON et al.			
	5,299,599	04/1994	FARMER et al.			
	5,301,689	04/1994	WENNERHOLM			
	5,304,146	04/1994	JOHNSON et al.			
	5,311,862	05/1994	BLASDELL et al.			
	5,322,057	06/1994	RAABE et al.			
	5,322,059	06/1994	WALTHER			
	5,331,691	07/1994	RUNCKEL			
	5,334,646	08/1994	CHEN			
	5,335,656	08/1994	BOWE et al.			
	5,343,878	09/1994	SCARBERRY et al.			
	5,349,949	09/1994	SCHEGERIN			
	5,353,789	10/1994	SCHLOBOHM			
	5,355,878	10/1994	GRIFFITHS et al.			
	5,355,893	10/1994	MICK et al.			

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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,357,945	05/2002	MESSINA			
	5,357,951	10/1994	RATNER			
	5,364,367	11/1994	BANKS et al.			
	5,372,130	12/1994	STERN et al.			
	5,372,388	12/1994	GARGIULO			
	5,372,389	12/1994	TAM et al.			
	5,372,390	12/1994	CONWAY et al.			
	5,372,391	12/1994	BAST et al.			
	5,375,593	12/1994	PRESS			
	5,385,141	01/1995	GRANATIERO			
	5,388,571	02/1995	ROBERTS et al.			
	5,390,373	02/1995	FLORY			
	5,391,248	02/1995	BRAIN			
	5,394,568	03/1995	BROSTROM et al.			
	5,396,885	03/1995	NELSON			
	5,398,676	03/1995	PRESS et al.			
	5,400,776	03/1995	BARTHOLOMEW			
	5,400,781	03/1995	DAVENPORT			
	5,404,871	04/1995	GOODMAN et al.			
	5,419,317	05/1995	BLASDELL et al.			
	5,419,318	05/1995	TAYEBI			
	5,425,359	06/1995	LIQU			
	5,429,126	07/1995	BRACKEN			
	5,429,683	07/1995	LE MITOUARD			
	5,431,158	07/1995	TIROTTA			
	5,437,267	08/1995	WEINSTEIN et al.			
	5,438,981	08/1995	STARR et al.			
	5,441,046	08/1995	STARR et al.			
	5,462,528	10/1995	ROEWER			
	5,477,852	12/1995	LANDIS et al.			
	5,479,920	01/1996	PIPER et al.			
	5,481,763	01/1996	BROSTROM et al.			
	5,485,837	01/1996	SOLES BEE et al.			
	5,488,948	02/1996	DUBRUILLE et al.			
	5,492,116	02/1996	SCARBERRY et al.			
	5,501,214	03/1996	SABO			
	5,503,147	04/1996	BERTHEAU			
	5,509,404	04/1996	LLOYD et al.			

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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,509,409	04/1996	WEATHERHOLT			
	5,511,541	04/1996	DEARSTINE			
	5,513,634	05/1996	JACKSON			
	5,513,635	05/1996	BEDI			
	5,517,986	05/1996	STARR et al.			
	5,522,382	06/1996	SULLIVAN et al.			
	5,526,806	06/1996	SANSONI			
	5,533,506	07/1996	WOOD			
	5,538,000	07/1996	RUDOLPH			
	5,538,001	07/1996	BRIDGES			
	5,540,223	07/1996	STARR et al.			
	5,542,128	08/1996	LOMAS			
	5,546,936	08/1996	VIRAG et al.			
	5,558,090	09/1996	JAMES			
	5,560,354	10/1996	BERTHON-JONES et al.			
	5,568,946	10/1996	JACKOWSKI			
	5,570,682	11/1996	JOHNSON			
	5,570,684	11/1996	BEHR			
	5,570,689	11/1996	STARR et al.			
	5,575,278	11/1996	BONHOMME et al.			
	5,592,937	01/1997	FREUND			
	5,592,938	01/1997	SCARBERRY et al.			
	5,608,647	03/1997	RUBSAMEN et al.			
	5,617,849	04/1997	SPRINGETT et al.			
	5,623,923	04/1997	BERTHEAU et al.			
	5,642,726	07/1997	OWENS et al.			
	5,642,730	07/1997	BARAN			
	5,645,054	07/1997	COTNER et al.			
	5,647,355	07/1997	STARR et al.			
	5,647,356	07/1997	BARNETT et al.			
	5,647,357	07/1997	BARNETT et al.			
	5,649,532	07/1997	GRIFFITHS			
	5,649,533	07/1997	OREN			
	5,653,228	08/1997	BYRD			
	5,655,520	08/1997	HOWE et al.			
	5,655,527	08/1997	SCARBERRY et al.			
	5,657,493	08/1997	FERRERO et al.			
	5,657,752	08/1997	LANDIS et al.			

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Continuation of 13/964,280APPLICANT
D'SOUZA et al.

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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,660,171	08/1997	KIMM et al.			
	5,660,174	08/1997	JACOBELLI			
	5,662,101	09/1997	OGDEN et al.			
	5,666,946	09/1997	LANGENBACK			
	5,676,133	10/1997	HICKLE et al.			
	5,682,881	11/1997	WINTHROP et al.			
	5,685,296	11/1997	ZDROJKOWSKI et al.			
	5,687,715	11/1997	LANDIS et al.			
	5,704,345	01/1998	BERTHON-JONES			
	5,707,342	01/1998	TANAKA			
	5,709,204	01/1998	LESTER			
	5,715,814	02/1998	EBERS			
	5,724,964	03/1998	BRUNSON et al.			
	5,724,965	03/1998	HANDKE et al.			
	5,735,272	04/1998	DILLON et al.			
	5,740,799	04/1998	NIELSON			
	5,746,201	05/1998	KIDD			
	5,752,509	05/1998	LACHMANN et al.			
	5,752,511	05/1998	SIMMONS et al.			
	5,778,872	07/1998	FUKUNAGA et al.			
	5,782,774	07/1998	SHMULEWITZ			
	5,794,615	08/1998	ESTES			
	5,794,617	08/1998	BRUNELL et al.			
	5,794,619	08/1998	EDEIMAN et al.			
	5,807,341	09/1998	HEIM			
	5,813,423	09/1998	KIRCHGEORG			
	5,832,918	11/1998	PANTINO			
	5,842,469	12/1998	RAPP et al.			
	5,884,624	03/1999	BARNETT et al.			
	5,887,587	03/1999	GROENKE			
	5,896,857	04/1999	HELY et al.			
	5,906,203	05/1999	KLOCKSETH et al.			
	5,909,732	06/1999	DIESEL et al.			
	5,918,598	07/1999	BELFER et al.			
	5,935,136	08/1999	HULSE et al.			
	5,937,445	08/1999	RAVO et al.			
	5,937,851	08/1999	SEROWSKI et al.			
	5,954,049	09/1999	FOLEY et al.			

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	APPLICANT	
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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,964,485	10/1999	HAME et al.			
	5,966,745	10/1999	SCHWARTZ et al.			
	5,970,975	10/1999	ESTES et al.			
	5,975,079	11/1999	HELLINGS et al.			
	6,003,511	12/1999	FUKUNAGA et al.			
	6,006,748	12/1999	HOLLIS			
	6,016,804	01/2000	GLEASON et al.			
	6,019,101	02/2000	COTNER et al.			
	6,026,811	02/2000	SETTLE			
	6,029,660	02/2000	CALLUAUD et al.			
	6,029,665	02/2000	BERTHON-JONES			
	6,039,044	03/2000	SULLIVAN			
	6,044,844	04/2000	KWOK et al.			
	6,082,360	07/2000	RUDOLPH et al.			
	6,086,118	07/2000	McNAUGHTON et al.			
	6,091,973	07/2000	COLLA et al.			
	6,095,996	08/2000	STEER et al.			
	6,102,040	08/2000	TAYEBI et al.			
	6,109,263	08/2000	FEUCHTGRUBER			
	6,112,746	09/2000	KWOK et al.			
	6,119,693	09/2000	KWOK et al.			
	6,119,694	09/2000	CORREA et al.			
	6,123,071	09/2000	BERTHON-JONES et al.			
	6,123,082	09/2000	BERTHON-JONES			
	6,139,787	10/2000	HARRISON			
	6,152,137	11/2000	SCHWARTZ et al.			
	6,155,253	12/2000	GAMBERINI			
	6,192,886	02/2001	RUDOLPH			
	6,193,914	02/2001	HARRISON			
	6,196,223	03/2001	BELFER et al.			
	6,211,263	04/2001	CINELLI et al.			
	6,213,125	04/2001	REESE et al.			
	6,231,548	05/2001	BASSETT			
	6,241,930	06/2001	HARRISON			
	6,257,237	07/2001	SUZUKI			
	6,257,626	07/2001	CAMPAU			
	6,258,066	07/2001	URICH			
	6,279,573	08/2001	JOHNSON et al.			

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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	6,295,366	09/2001	BALLER et al.			
	6,328,031	12/2001	TISCHER et al.			
	6,328,038	12/2001	KESSLER et al.			
	6,340,024	01/2002	BROOKMAN et al.			
	6,341,606	01/2002	BORDEWICK et al.			
	6,345,618	02/2002	HAYEK			
	6,347,631	02/2002	HANSEN et al.			
	6,357,440	03/2002	HANSEN et al.			
	6,357,441	03/2002	KWOK et al.			
	6,358,279	03/2002	TAHI et al.			
	6,371,110	04/2002	PETERSON et al.			
	6,374,826	04/2002	GUNARATNAM et al.			
	6,388,640	05/2002	CHIGIRA et al.			
	6,397,847	06/2002	SCARBERRY et al.			
	6,412,487	07/2002	GUNARATNAM et al.			
	6,412,488	07/2002	BARNETT et al.			
	6,412,593	07/2002	JONES			
	6,418,928	07/2002	BORDEWICK et al.			
	6,419,660	07/2002	RUSSO			
	6,422,238	07/2002	LITHGOW			
	6,423,036	07/2002	VAN HUZEN			
	6,425,395	07/2002	BREWER et al.			
	6,427,694	08/2002	HECKER et al.			
	6,431,172	08/2002	BORDEWICK			
	6,434,796	08/2002	SPEIRS			
	6,439,230	08/2002	GUNARATNAM et al.			
	6,439,234	08/2002	CURTI et al.			
	6,448,303	09/2002	PAUL			
	6,463,931	10/2002	KWOK et al.			
	6,467,482	10/2002	BOUSSIGNAC			
	6,467,483	10/2002	KOPACKO et al.			
	6,470,887	10/2002	MARTINEZ			
	6,478,026	11/2002	WOOD			
	6,482,178	11/2002	ANDREWS et al.			
	6,491,034	12/2002	GUNARATNAM et al.			
	6,513,526	02/2003	KWOK et al.			
	6,520,182	02/2003	GUNARATNAM			
	6,530,373	03/2003	PATRON et al.			

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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	6,532,961	03/2003	KWOK et al.			
	6,536,435	03/2003	FECTEAU et al.			
	6,557,556	05/2003	KWOK et al.			
	6,561,188	05/2003	ELLIS			
	6,561,190	05/2003	KWOK			
	6,561,191	05/2003	KWOK			
	6,561,192	05/2003	PALMER			
	6,561,193	05/2003	NOBLE			
	6,571,798	06/2003	THORNTON			
	6,579,267	06/2003	LYNCH et al.			
	6,581,601	06/2003	ZIAEE			
	6,581,602	07/2003	KWOK et al.			
	6,584,975	07/2003	TAYLOR			
	6,595,214	07/2003	HECKER et al.			
	6,595,215	07/2003	WOOD			
	6,607,516	08/2003	CINELLI et al.			
	6,615,830	09/2003	SEROWSKI et al.			
	6,615,832	09/2003	CHEN			
	6,626,177	09/2003	ZIAEE			
	6,627,289	09/2003	DILNIK et al.			
	6,631,718	10/2003	LOVELL			
	6,634,358	10/2003	KWOK et al.			
	6,637,434	10/2003	NOBLE			
	6,644,315	11/2003	ZIAEE			
	6,651,663	11/2003	BARNETT et al.			
	6,655,385	12/2003	CURTI et al.			
	6,663,600	12/2003	BIERMAN et al.			
	6,669,712	12/2003	CARDOSO			
	6,679,257	01/2004	ROBERTSON et al.			
	6,679,261	01/2004	LITHGOW			
	6,679,265	01/2004	STRICKLAND et al.			
	6,691,707	02/2004	GUNARATNAM et al.			
	6,691,708	02/2004	KWOK et al.			
	6,701,535	03/2004	DOBBIE et al.			
	6,701,926	03/2004	OLSEN et al.			
	6,701,927	03/2004	KWOK et al.			
	6,710,099	03/2004	CINELLI et al.			

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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	7,207,335	04/2007	KWOK et al			
	6,712,072	03/2004	LANG (corres. to WO 99/43375)			
	6,729,333	05/2004	BARNETT et al.			
	6,766,800	07/2004	CHU et al.			
	6,766,817	07/2004	da SILVA			
	6,772,760	08/2004	FRATER et al.			
	6,776,162	08/2004	WOOD			
	6,776,163	08/2004	DOUGILL et al.			
	6,789,543	09/2004	CANNON			
	6,796,308	09/2004	GUNARATNAM et al.			
	6,805,117	10/2004	HO et al.			
	6,807,967	10/2004	WOOD			
	6,817,362	11/2004	GELINAS et al.			
	6,820,617	11/2004	ROBERTSON et al.			
	6,823,865	11/2004	DREW et al.			
	6,823,869	11/2004	RAJE et al.			
	6,834,650	12/2004	FINI			
	6,851,425	02/2005	JAFFRE			
	6,851,428	02/2005	DENNIS			
	6,851,429	02/2005	BISHOP			
	6,860,269	03/2005	KWOK et al.			
	6,860,270	03/2005	SNIADICH			
	6,871,649	03/2005	KWOK et al.			
	6,892,729	05/2005	SMITH et al.			
	6,895,965	05/2005	SCARBERRY et al.			
	6,907,882	06/2005	GING			
	6,914,091	07/2005	DONALD et al.			
	6,918,404	07/2005	DIAS da SILVA			
	6,926,004	08/2005	SCHUMACHER			
	6,938,620	09/2005	PAYNE, JR.			
	6,959,710	11/2005	BARNETT et al.			
	6,968,844	11/2005	LILAND			
	6,972,003	12/2005	BIERMAN et al.			
	6,986,352	01/2006	FRATER et al.			
	6,997,177	02/2006	WOOD			
	7,000,614	02/2006	LANG et al.			
	7,007,696	03/2006	PALKON et al.			

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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	7,011,090	03/2006	DREW et al.			
	7,018,362	03/2006	BIERMAN et al.			
	7,040,321	05/2006	GOEBEL			
	7,052,127	05/2006	HARRISON			
	7,059,326	06/2006	HEIDMANN et al.			
	7,066,586	06/2006	da SILVA			
	7,069,932	07/2006	EATON et al.			
	7,076,282	07/2006	MUNRO et al.			
	7,076,822	07/2006	PEARCE			
	7,080,645	07/2006	GENGER et al.			
	7,093,599	08/2006	CHEN			
	7,100,610	09/2006	BIENER et al.			
	7,101,359	09/2006	KLINE et al.			
	7,107,989	09/2006	FRATER et al.			
	7,114,497	10/2006	AYLSWORTH et al.			
	7,146,976	12/2006	McKOWN			
	7,152,599	12/2006	THOMAS			
	7,152,601	12/2006	BARAKAT et al.			
	7,178,525	02/2007	MATULA, JR. et al.			
	7,185,652	03/2007	GUNARATNAM et al.			
	7,191,781	03/2007	WOOD			
	7,207,328	04/2007	ALTEMUS			
	7,210,481	05/2007	LOVELL et al.			
	7,216,647	05/2007	LANG et al.			
	7,237,551	07/2007	HO et al.			
	7,243,723	07/2007	SURJAATMADJA			
	7,285,255	10/2007	KADLEC et al.			
	7,302,950	12/2007	BERTHON-JONES et al.			
	7,308,895	12/2007	WIXEY et al.			
	7,318,437	01/2008	GUNARATNAM			
	7,318,439	01/2008	RAJE et al.			
	7,320,323	01/2008	LANG et al.			
	7,341,060	03/2008	GING et al.			
	7,353,826	04/2008	SLEEPER et al.			
	7,441,618	12/2006	LUBKE et al.			
	7,461,656	12/2008	GUNARATNAM et al.			
	7,470,256	12/2008	LAMPROPOULOS et al.			
	7,481,220	01/2009	MEYER et al.			

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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	7,487,772	02/2009	GING et al.			
	7,503,327	03/2009	GUNARATNAM			
	7,509,958	03/2009	AMARASINGHE et al.			
	7,520,869	04/2009	LAMPROPOULOS et al.			
	7,523,754	04/2009	LITHGOW			
	7,562,658	07/2009	MADAUS et al.			
	7,614,400	11/2009	LITHGOW et al.			
	7,614,401	11/2009	THOMPSON			
	7,621,274	11/2009	SPRINKLE et al.			
	7,624,735	12/2009	HO et al.			
	7,640,934	01/2010	ZOLLINGER et al.			
	7,654,263	02/2010	LANG et al.			
	7,658,189	02/2010	DAVIDSON et al.			
	7,665,464	02/2010	KOPACKO et al.			
	7,699,808	04/2010	MARRS et al.			
	7,703,457	04/2010	BARNETT et al.			
	7,708,017	05/2010	DAVIDSON			
	7,743,767	06/2010	GING et al.			
	7,775,209	08/2010	BIENER et al.			
	7,762,259	07/2010	GUNARATNAM			
	7,779,832	08/2010	HO			
	7,798,144	09/2010	KWOK et al.			
	7,814,911	10/2010	BORDEWICK et al.			
	7,819,119	10/2010	HO			
	7,827,990	11/2010	MELIDIS et al.			
	7,841,345	11/2010	GUNEY et al.			
	7,856,980	12/2010	LANG et al.			
	7,856,982	12/2010	MATULA, JR. et al.			
	7,861,715	01/2011	JONES et al.			
	7,874,293	01/2011	GUNARATNAM et al.			
	7,878,199	02/2011	GING et al.			
	7,900,631	03/2011	PERSSON			
	7,900,635	03/2011	GUNARATNAM et al.			
	7,931,024	04/2011	HO et al.			
	7,958,893	06/2011	LITHGOW et al.			
	7,967,013	06/2011	GING et al.			
	7,967,014	06/2011	HEIDMANN et al.			
	7,971,590	07/2011	FRATER et al.			

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(Use several sheets if necessary)	D'SOUZA et al.	
	FILING DATE	TC/A.U.
	Herewith	Unassigned

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	7,992,559	08/2011	LANG et al.			
	7,997,267	08/2011	GING et al.			
	8,042,538	10/2011	GING et al.			
	8,042,541	10/2011	AMARASINGHE et al.			
	8,042,542	10/2011	GING et al.			
	8,042,546	10/2011	GUNARATNAM et al.			
	8,051,850	11/2011	KWOK et al.			
	8,091,553	01/2012	BORDEWICK et al.			
	8,096,301	01/20012	SMITH et al.			
	8,136,524	03/2012	GING et al.			
	8,136,525	03/2012	LUBKE et al.			
	8,186,352	05/2012	GUNARATNAM et al.			
	8,210,180	07/2012	GUNARATNAM			
	8,220,459	07/2012	DAVIDSON et al.			
	H397	01/1988	STARK			
	US 2001/0020474	09/2001	HECKER et al.			
	US 2002/0020416	02/2002	NAMEY			
	US 2002/0029780	03/2002	FRATER et al.			
	US 2002/0046755	04/2002	DEVOSS			
	US 2002/0066452	06/2002	KESSLER et al.			
	US 2002/0069872	06/2002	GRADON et al.			
	US 2002/0124849	09/2002	BILLETTE de VILLEMEUR			
	US 2002/0143296	10/2002	RUSSO			
	US 2002/0157673	10/2002	KESSLER et al.			
	US 2002/0174868	11/2002	KWOK et al.			
	US 2003/0019495	01/2003	PALKON et al.			
	US 2003/0062048	04/2003	GRADON et al.			
	US 2003/0089373	05/2003	GRADON et al.			
	US 2003/0168063	09/2003	GAMBONE et al.			
	US 2003/0196656	10/2003	MOORE et al.			
	US 2003/0196658	10/2003	GING et al.			
	US 2004/0025883	02/2004	EATON et al.			
	US 2004/0094157	05/2004	DANTANARAYANA et al.			
	US 2004/0106891	06/2004	LANGAN et al.			
	US 2004/0111104	06/2004	SCHEIN et al.			
	US 2004/0112384	06/2004	LITHGOW et al.			
	US 2004/0112385	06/2004	DREW et al.			

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D'SOUZA et al.

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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	US 2004/0127856	07/2004	JOHNSON			
	US 2004/0177850	09/2004	GRADON et al.			
	US 2004/0182398	09/2004	SPRINKLE et al.			
	US 2004/0211428	10/2004	JONES			
	US 2004/0226566	11/2004	GUNARATNAM et al.			
	US 2005/0051171	03/2005	BOOTH			
	US 2005/0051176	03/2005	RIGGINS			
	US 2005/0056286	03/2005	HUDDART et al.			
	US 2005/0061326	03/2005	PAYNE, JR.			
	US 2005/0098183	05/2005	NASH et al.			
	US 2005/0150495	07/2005	RITTNER et al.			
	US 2005/0155604	07/2005	GING et al.			
	US 2005/0211252	09/2005	LANG et al.			
	US 2005/0241644	11/2005	GUNARATNAM et al.			
	US 2006/0076017	04/2006	WALKER et al.			
	US 2006/0272646	12/2006	HO et al.			
	US 2006/0124131	06/2006	CHANDRAN et al.			
	US 2006/0137690	06/2006	GUNARATNAM et al.			
	US 2006/0174887	08/2006	CHANDRAN et al.			
	US 2006/0207597	09/2006	WRIGHT			
	US 2006/0213520	09/2006	FRATER et al.			
	US 2006/0283461	12/2006	LUBKE et al.			
	US 2007/0137653	06/2007	WOOD			
	US 2007/0144525	06/2007	DAVIDSON et al.			
	US 2007/0215161	09/2007	FRATER et al.			
	US 2007/0272249	11/2007	CHANDRAN et al.			
	US 2007/0282272	12/2007	BANNON et al.			
	US 2008/0004573	01/2008	KAUFMANN et al.			
	US 2008/0006277	01/2008	WORBOYS et al.			
	US 2008/0047560	02/2008	VELISS et al.			
	US 2008/0060649	03/2008	VELISS et al.			
	US 2008/0065022	03/2008	KYVIK et al.			
	US 2008/0110464	05/2008	DAVIDSON et al.			
	US 2008/0110469	05/2008	WEINBERG			
	US 2008/0178886	07/2008	LIEBERMAN et al.			
	US 2008/0200880	08/2008	KYVIK et al.			
	US 2008/0257354	10/2008	DAVIDSON et al.			
	US 2008/0314389	12/2008	THOMAS et al.			

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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	US 2009/0044808	02/2009	GUNEY et al.			
	US 2009/0126739	05/2009	NG. et al			
	US 2009/0139526	06/2009	MELIDIS et al.			
	US 2009/0138527	06/2009	NG et al.			
	US 2009/0173343	07/2009	OMURA et al.			
	US 2009/0217929	09/2009	KWOK et al.			
	US 2009/0223518	09/2009	KWOK et al.			
	US 2009/0223521	09/2009	HOWARD et al.			
	US 2010/0000534	01/2010	KOOIJ et al.			
	US 2010/0000543	01/2010	BERTHON-JONES et al.			
	US 2010/0018534	01/2010	VELISS et al.			
	US 2010/0089401	04/2010	LANG et al.			
	US 2010/0132717	06/2010	DAVIDSON et al.			
	US 2010/0192955	08/2010	BIENER et al.			
	US 2010/0282265	11/2010	MELIDIS et al.			
	US 2010/0300447	12/2010	BIENER et al.			
	US 2010/0319700	12/2010	NG et al.			
	US 2011/0030692	02/2011	JONES et al.			
	US 2011/0056497	03/2011	SCHEINER et al.			
	US 2011/0220110	09/2011	FRATER et al.			
	US 2011/0220114	09/2011	LITHGOW et al.			
	US 2011/0226254	09/2011	LANG et al.			
	US 2011/0259337	10/2011	HITCHCOCK et al.			
	US 2012/0174928	07/2012	RAJE et al.			
	US 2012/0266886	10/2012	DAVIDSON et al.			
	US 2013/0133658	05/2013	NG et al.			
	US 2013/0133660	05/2013	NG et al.			
	D156,060	11/1949	WADE			
	D161,337	12/1950	HILL			
	D188,084	05/1960	GARELICK			
	D231,803	06/1974	HUDDY			
	D248,497	07/1978	SLOSEK			
	D250,131	10/1978	LEWIS et al.			
	D262,322	12/1981	MIZERAK			
	D285,496	09/1986	BERMAN			
	D289,238	04/1987	ARTHUR, JR.			
	D293,613	01/1988	WINGLER			
	D304,384	10/1989	DEROBERT			

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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	D310,431	09/1990	BELLM			
	D313,277	12/1990	HAINING			
	D323,908	02/1992	HOLLISTER et al.			
	D333,015	02/1993	FARMER et al.			
	D334,633	04/1993	RUDOLPH			
	D335,322	05/1993	JONES			
	D349,586	08/1994	HANDKE			
	D362,061	09/1995	McGINNIS et al.			
	D377,089	12/1996	STARR et al.			
	D385,960	11/1997	RUDOLPH			
	D389,238	01/1998	KIRK, III et al.			
	D398,987	09/1998	COTNER et al.			
	D402,755	12/1998	KWOK			
	D412,745	08/1999	SCHEU			
	D419,658	01/2000	MATCHETT et al.			
	D421,298	02/2000	KENYON et al.			
	D423,096	04/2000	KWOK			
	D428,987	08/2000	KWOK			
	D439,326	03/2001	HECKER et al.			
	D443,355	06/2001	GUNARATNAM et al.			
	D468,823	01/2003	SMART			
	D484,237	12/2003	LANG et al.			
	D485,905	01/2004	MOORE et al.			
	D492,992	07/2004	GUNEY et al.			
	D493,521	07/2004	GUNEY			
	D550,836	09/2007	CHANDRAN et al.			
	D552,733	10/2007	CRISCUOLO et al.			
	RE 24,193	08/1956	EMERSON			
	RE 35,339	10/1996	RAPOPORT			
	RE 36,165	03/1999	BEHR			
	8,297,283	10/2012	HITCHCOCK et al.			
	8,397,728	03/2013	D'SOUZA et al.			
	US-13/834,189	03/2013	HITCHCOCK et al.			
	US-13/870,678	04/2013	KWOK et al.			
	US-2007/0044804	03/2007	MATULA, JR. et al.			
	US-2007/0221226	09/2007	HANSEN et al.			
	US-2008/0178875	07/2008	HENRY			
	US-2008/0302365	12/2008	COHEN et al.			

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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	US-2012/0138063	06/2012	EVES et al.			
	US-2013/0037033	02/2013	HITCHCOCK et al.			
	US-2013/0081628	04/2013	DAVIDSON et al.			
	US-2013/0081629	04/2013	DAVIDSON et al.			
	US-2013/0081630	04/2013	DAVIDSON et al.			
	US-2013/0081631	04/2013	DAVIDSON et al.			
	US-2013/0081632	04/2013	DAVIDSON et al.			
	US-2013/0086795	04/2013	DAVIDSON et al.			
	US-2013/0086796	04/2013	DAVIDSON et al.			
	US-2013/0087147	04/2013	DAVIDSON et al.			
	US-2013/0087148	04/2013	DAVIDSON et al.			
	US-2013/0087149	04/2013	DAVIDSON et al.			
	US-2013/0092168	04/2013	DAVIDSON et al.			
	US-2013/0092170	04/2013	DAVIDSON et al.			

FOREIGN PATENT DOCUMENTS

DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
					YES	NO
AU 91/77110	11/1991	AUSTRALIA				
AU 94/64816	12/1994	AUSTRALIA				
AU 95/16178	07/1995	AUSTRALIA				
AU 94/59430	10/1995	AUSTRALIA				
AU 95/32914	02/1996	AUSTRALIA				
AU 96/51130	10/1996	AUSTRALIA				
AU 97/41018	04/1998	AUSTRALIA				
AU 98/89312	01/1999	AUSTRALIA				
AU 2005100738	11/2005	AUSTRALIA				
AU 2006/00031 (WO 2007/045008)	01/2006 (04/2007)	AUSTRALIA				
CA 618807	04/1961	CANADA				
CA 623129	07/1961	CANADA				
CA 1039144	09/1978	CANADA				
CN 2464353	12/2001	CHINA				
CN 1219883	06/1999	CHINA				
CN 1735439	02/2006	CHINA				
DD 146 688	01/1981	EAST GERMANY				
DD 159 396	03/1983	EAST GERMANY				
EP 0 054 154	06/1982	EUROPE				

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		DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
		EP 0 252 052	01/1988	EUROPE				
		EP 0 264 772	04/1988	EUROPE				
		EP 0 288 937	11/1988	EUROPE				
		EP 0 334 555	09/1989	EUROPE				
		EP 0 386 605	09/1990	EUROPE				
		EP 0 427 474	05/1991	EUROPE				
		EP 0 462 701	12/1991	EUROPE				
		EP 0 466 960	01/1992	EUROPE				
		EP 0 303 090 B1	04/1992	EUROPE				
		EP 0 549 299	06/1993	EUROPE				
		EP 0 602 424	06/1994	EUROPE				
		EP 0 608 684	08/1994	EUROPE				
		EP 0 658 356	06/1995	EUROPE				
		EP 0 697 225	02/1996	EUROPE				
		EP 0 178 925 A2	04/1996	EUROPE				
		EP 0 747 078	12/1996	EUROPE				
		EP 0 776 679	06/1997	EUROPE				
		EP 0 821 978	02/1998	EUROPE				
		EP 0 853 962	07/1998	EUROPE				
		EP 1 027 905	08/2000	EUROPE				
		EP 1 057 494	12/2000	EUROPE				
		EP 1 099 452	05/2001	EUROPE				
		EP 1 118 346	07/2001	EUROPE				
		EP 1 163 923	12/2001	EUROPE				
		EP 1 205 205	05/2002	EUROPE				
		EP 1 258 266	11/2002	EUROPE				
		EP 1 356 843	10/2003	EUROPE				
		EP 1 360 971	11/2003	EUROPE				
		EP 1 481 702	12/2004	EUROPE				
		EP 2 471 566	07/2012	EUROPE				
		EP 2 471 567	07/2012	EUROPE				
		FR 780018	04/1935	FRANCE				
		FR 2 574 657	06/1986	FRANCE				
		FR 2 658 725	08/1991	FRANCE				
		FR 2 720 280	12/1995	FRANCE				
		FR 2 749 176	12/1997	FRANCE				
		FR 2 823 122	10/2002	FRANCE				

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	APPLICANT	
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		DE 185 017	05/1907	GERMANY				
		DE 284 800	11/1913	GERMANY				
		DE 459 104	04/1928	GERMANY				
		DE 701 690	01/1941	GERMANY				
		DE 30 11 900	10/1980	GERMANY				
		DE 30 15 279	10/1981	GERMANY				
		DE 31 49 449	10/1982	GERMANY				
		DE 33 45 067	06/1984	GERMANY				
		DE 37 07 952	03/1987	GERMANY				
		DE 35 37 507	04/1987	GERMANY				
		DE 35 39 073	05/1987	GERMANY				
		DE 37 19 009	12/1988	GERMANY				
		DE 39 27 038	02/1991	GERMANY				
		DE 40 04 157	04/1991	GERMANY				
		DE 42 12 259	01/1993	GERMANY				
		DE 42 33 448	04/1993	GERMANY				
		DE 43 43 205	06/1995	GERMANY				
		DE 195 48 380	07/1996	GERMANY				
		DE 196 03 949	08/1997	GERMANY				
		DE 297 15 718	10/1997	GERMANY				
		DE 197 35 359	01/1998	GERMANY				
		DE 297 23 101	07/1998	GERMANY				
		DE 197 03 526	08/1998	GERMANY				
		DE 298 10 846	08/1998	GERMANY				
		DE 198 17 332	01/1999	GERMANY				
		DE 198 07 961	08/1999	GERMANY				
		DE 198 08 105	09/1999	GERMANY				
		DE 198 40 760	03/2000	GERMANY				
		DE 200 05 346	05/2000	GERMANY				
		DE 299 23 141	05/2000	GERMANY				
		DE 200 17 940	02/2001	GERMANY				
		DE 199 44 242	03/2001	GERMANY				
		DE 199 54 517	06/2001	GERMANY				
		DE 199 62 515	07/2001	GERMANY				
		DE 100 02 571	07/2001	GERMANY				
		DE 100 45 183	05/2002	GERMANY				
		DE 102 13 905	10/2002	GERMANY				
		DE 10 2004 055 433	11/2004	GERMANY				

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					CLASS	SUBCLASS	TRANSLATION	
							YES	NO
		DE 103 31 837	01/2005	GERMANY				
		DE 20 2004 018 108	02/2005	GERMANY				
		DE 103 38 169	03/2005	GERMANY				
		GB 532 214	01/1941	GREAT BRITAIN				
		GB 649 689	01/1951	GREAT BRITAIN				
		GB 823 887	11/1959	GREAT BRITAIN				
		GB 1 395 391	05/1975	GREAT BRITAIN				
		GB 1 467 828	03/1977	GREAT BRITAIN				
		GB 2 145 335	03/1985	GREAT BRITAIN				
		GB 2 147 506	05/1985	GREAT BRITAIN				
		GB 2 164 569	03/1986	GREAT BRITAIN				
		GB 2 176 404	12/1986	GREAT BRITAIN				
		GB 2 186 801	08/1987	GREAT BRITAIN				
		GB 2 267 648	12/1993	GREAT BRITAIN				
		GB 2 368 533	05/2002	GREAT BRITAIN				
		GB 2 385 533	05/2003	GREAT BRITAIN				
		JP S39-13991	07/1964	JAPAN				
		JP S51-142793	11/1976	JAPAN				
		JP H03-007173	01/1991	JAPAN				
		JP H09-216240	08/1997	JAPAN				
		JP H11-000397	01/1999	JAPAN				
		JP H11-104256	04/1999	JAPAN				
		JP H11-508159	07/1999	JAPAN				
		JP 2000-279520	10/2000	JAPAN				
		JP 2000-325481	11/2000	JAPAN				
		JP 2000-515784	11/2000	JAPAN				
		JP 2003-535657	12/2003	JAPAN				
		JP 2002-028240	04/2002	JAPAN				
		JP 2002-543943	12/2002	JAPAN				
		JP 2003-175106	06/2003	JAPAN				
		JP 2004-000570	01/2004	JAPAN				
		JP 2005-337371	12/2005	JAPAN				
		JP 3802872	07/2006	JAPAN				
		WO 00/35525	06/2000	PCT				
		WO 80/01044	05/1980	PCT				
		WO 82/03548	10/1982	PCT				
		WO 86/06969	12/1986	PCT				
		WO 87/01950	04/1987	PCT				

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	APPLICANT	
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		WO 91/03277	03/1991	PCT				
		WO 92/15353	09/1992	PCT				
		WO 92/20392	11/1992	PCT				
		WO 92/20395	11/1992	PCT				
		WO 93/01854	02/1993	PCT				
		WO 93/24169	12/1993	PCT				
		WO 94/02190	02/1994	PCT				
		WO 94/16759	08/1994	PCT				
		WO 94/20051	09/1994	PCT				
		WO 95/02428	01/1995	PCT				
		WO 96/17643	06/1996	PCT				
		WO 96/25983	08/1996	PCT				
		WO 96/28207	09/1996	PCT				
		WO 96/39206	12/1996	PCT				
		WO 97/00092	01/1997	PCT				
		WO 97/07847	03/1997	PCT				
		WO 97/09090	03/1997	PCT				
		WO 97/41911	11/1997	PCT				
		WO 98/03145	01/1998	PCT				
		WO 98/04310	02/1998	PCT				
		WO 98/11930	03/1998	PCT				
		WO 98/12965	04/1998	PCT				
		WO 98/18514	05/1998	PCT				
		WO 98/23305	06/1998	PCT				
		WO 98/24499	06/1998	PCT				
		WO 98/26829	06/1998	PCT				
		WO 98/26830	06/1998	PCT				
		WO 98/34665	08/1998	PCT				
		WO 98/48878	11/1998	PCT				
		WO 99/16327	04/1999	PCT				
		WO 99/25410	05/1999	PCT				
		WO 99/43375	09/1999	PCT				
		WO 99/58181	11/1999	PCT				
		WO 99/61088	12/1999	PCT				
		WO 99/65554	12/1999	PCT				
		WO 00/20072	04/2000	PCT				
		WO 00/21600	04/2000	PCT				
		WO 00/38772	07/2000	PCT				

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					CLASS	SUBCLASS	TRANSLATION	
							YES	NO
		WO 00/50121	08/2000	PCT				
		WO 00/57942	10/2000	PCT				
		WO 00/69521	11/2000	PCT				
		WO 00/72905	12/2000	PCT				
		WO 00/74758	12/2000	PCT				
		WO 00/76568	12/2000	PCT				
		WO 00/78381	12/2000	PCT				
		WO 00/78384	12/2000	PCT				
		WO 01/62326	08/2001	PCT				
		WO 01/95965	12/2001	PCT				
		WO 01/97892	12/2001	PCT				
		WO 01/97893	12/2001	PCT				
		WO 02/11804	02/2002	PCT				
		WO 02/32491	04/2002	PCT				
		WO 02/38221	05/2002	PCT				
		WO 02/45784	06/2002	PCT				
		WO 03/005931	01/2003	PCT				
		WO 03/059427	07/2003	PCT				
		WO 03/082406	10/2003	PCT				
		WO 03/090827	11/2003	PCT				
		WO 03/105921	12/2003	PCT				
		WO 2004/007010	01/2004	PCT				
		WO 2004/022144	03/2004	PCT				
		WO 2004/022145	03/2004	PCT				
		WO 2004/022146	03/2004	PCT				
		WO 2004/022147	03/2004	PCT				
		WO 2004/041342	05/2004	PCT				
		WO 2004/073778	09/2004	PCT				
		WO 2004/078228	09/2004	PCT				
		WO 2004/078230	09/2004	PCT				
		WO 2004/096332	11/2004	PCT				
		WO 2005/002656	01/2005	PCT				
		WO 2005/018523	03/2005	PCT				
		WO 2005/021075	03/2005	PCT				
		WO 2005/028010	03/2005	PCT				
		WO 2005/053781	06/2005	PCT				
		WO 2005/063326	07/2005	PCT				
		WO 2005/063328	07/2005	PCT				

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Form PTO-FB-A820 (Also PTO/SB/08A)

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**INFORMATION DISCLOSURE
CITATION**ATTY. DOCKET NO.
PTB-4398-1485SERIAL NO.
Continuation of 13/964,280APPLICANT
D'SOUZA et al.

(Use several sheets if necessary)

FILING DATE

TC/A.U.

Herewith

Unassigned

					CLASS	SUBCLASS	TRANSLATION	
							YES	NO
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	D'SOUZA et al.	
	FILING DATE	TC/A.U.
	Herewith	Unassigned

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	D'SOUZA et al.	
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*EXAMINER INITIAL	OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)
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	APPLICANT	
	D'SOUZA et al.	
(Use several sheets if necessary)	FILING DATE	TC/A.U.
	Herewith	Unassigned

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*Examiner		Date Considered	
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	APPLICANT	
	D'SOUZA et al.	
(Use several sheets if necessary)	FILING DATE	TC/A.U.
	Herewith	Unassigned

*EXAMINER INITIAL	OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)
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*Examiner		Date Considered	
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	PTB-4398-1485	Continuation of 13/964,280
(Use several sheets if necessary)	APPLICANT	
	D'SOUZA et al.	
	FILING DATE	TC/A.U.
	Herewith	Unassigned

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	Herewith	Unassigned

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	D'SOUZA et al.	
(Use several sheets if necessary)	FILING DATE	TC/A.U.
	Herewith	Unassigned

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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	2006/0118117	06/2006	BERTHON-JONES et al.			
	2013/0327333 A1	12/2013	NG et al.			

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DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
					YES	NO

OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)


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*Examiner	/Kristen Matter/	Date Considered	11/24/2014
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<i>Index of Claims</i> 	Application/Control No. 14447673	Applicant(s)/Patent Under Reexamination D'SOUZA ET AL.
	Examiner KRISTEN MATTER	Art Unit 3649

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

<input type="checkbox"/> Claims renumbered in the same order as presented by applicant			<input type="checkbox"/> CPA			<input type="checkbox"/> T.D.			<input type="checkbox"/> R.1.47		
CLAIM		DATE									
Final	Original	11/24/2014									
	1	✓									
	2	✓									
	3	✓									
	4	✓									
	5	✓									
	6	✓									
	7	✓									
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	16	✓									
	17	✓									
	18	✓									
	19	✓									
	20	✓									
	21	✓									



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/447,673	07/31/2014	Errol Savio Alex D'SOUZA	PTB-4398-1485	3036

23117 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203	7590 12/23/2014
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EXAMINER	
MATTER, KRISTEN CLARETTE	

ART UNIT	PAPER NUMBER
3649	

NOTIFICATION DATE	DELIVERY MODE
12/23/2014	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTOMAIL@nixonvan.com
pair_nixon@firsttofile.com

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Examiner indicated that the proposed amendment to claim 1, making the shroud and cushion module "non-rotatably coupleable" to one another is sufficient to overcome the Ho reference since Ho teaches away from having the shroud be non-rotatably coupled to the cushion but that an updated search would need to be performed before a final determination on allowability is made. Regarding claim 22, examiner maintained that without further limiting structure the shroud of Ho has an "annular portion structured to retain the cushion module" at least by virtue of the elbow connector but that if the claim was amended to make it clear that the cushion module and frame are connectable without an additional structure such as the elbow and/or that the shroud has a cushion module facing projection that that might be sufficient to overcome the Ho reference. Regarding claim 26, examiner maintained that Ho teaches using the shroud with a variety of well-known masks and that it is well known that masks come in different sizes to accommodate different sizes of patients so the proposed amendment to claim 26 is not likely to be held allowable. Applicant indicated he would take the examiner's comments into consideration and file a formal response to the outstanding office action .

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Atty Docket No.: PTB-4398-1485

AMENDMENTS TO THE CLAIMS:

PROPOSED AMENDMENT FOR DISCUSSION ONLY. /KCM/

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Currently Amended) A mask system, comprising:
 - (i) a shroud module; wherein the shroud module includes headgear connectors adapted to removably attach to respective headgear straps of headgear; and
 - (ii) a cushion module, comprising:
 - a 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,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, and 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 the shroud module and the cushion module are configured to be removably and non-rotatably coupleable to one another.
2. (Original) The mask system of claim 1 wherein the cushion comprises one or more folds in a lower lip/chin region of the cushion.
3. (Currently Amended) The mask system of claim 2, wherein the one or more folds in the nasal bridge region has a relatively high degree of flexibility and the one or more folds in the lower lip/chin region ~~have~~ has a relatively low degree of flexibility.
4. (Original) The mask system of claim 1, wherein each of said one or more folds comprises adjacent first side walls interconnected by a second side wall.
5. (Original) The mask system of claim 1, wherein the cushion is a full-face cushion.

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Appl. No. 14/447,673

Atty Docket No.: PTB-4398-1485

6. (Original) The mask system of claim 1, wherein the shroud module includes upper and lower headgear connectors on each side of the shroud module.
7. (Original) The mask system of claim 6, wherein each upper headgear connector includes a slot adapted to receive a respective headgear strap in use.
8. (Original) The mask system of claim 6, wherein each lower headgear connector is adapted to be removably interlocked with a headgear clip associated with a respective headgear strap.
9. (Original) The mask system of claim 8, further comprising headgear including respective headgear clips, wherein each said headgear clip is adapted to snap-fit with the respective lower headgear connector.
10. (Original) The mask system of claim 1, wherein the shroud module includes an open construction that provides an annular or part annular cushion retaining portion structured to retain the cushion module.
11. (Original) The mask system of claim 1, further comprising an elbow module adapted to be connected to an air delivery tube that delivers breathable gas to the patient.
12. (Original) The mask system according to claim 11, wherein the elbow module is provided to the shroud module.
13. (Original) The mask system of claim 11, wherein the elbow module comprises polycarbonate.
14. (Original) The mask system of claim 11, wherein the elbow module and the shroud module are connected with a mechanical interlock while allowing 360 degree rotation of the elbow module.

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Appl. No. 14/447,673

Atty Docket No.: PTB-4398-1485

15. (Original) The mask system of claim 11, wherein the elbow module includes an anti-asphyxia valve.
16. (Original) A mask system of claim 15, wherein the anti-asphyxia valve includes a flap portion adapted to selectively close a port provided in the elbow module.
17. (Original) The mask system of claim 1, 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.
18. (Original) The mask system of claim 1 comprising 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.
19. (Original) The mask system of claim 1, wherein the shroud module comprises polycarbonate.
20. (Original) The mask system of claim 1, wherein the cushion comprises silicone.
21. (Original) The mask system of claim 1, wherein the frame and the cushion are co-molded.
22. (New) The mask system, comprising:
 (i) a shroud module; wherein the shroud module includes headgear connectors adapted to removably attach to respective headgear straps of headgear; and
 (ii) a cushion module, comprising:
 a 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,

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Atty Docket No.: PTB-4398-1485

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, and 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;

wherein the shroud module and the cushion module are configured to be removably coupleable to one another, and

wherein the shroud module includes an open construction that provides an annular or part annular cushion retaining portion structured to retain the cushion module.

23. (New) The mask system of claim 22, wherein the elbow module and the shroud module are mechanically interlocked while allowing 360 degree rotation of the elbow module.

24. (New) The mask system of claim 22, wherein the shroud module includes upper and lower headgear connectors on each side of the shroud module;

wherein each upper headgear connector includes a slot adapted to receive a respective headgear strap in use; and

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

25. (New) The mask system of claim 22, further comprising an elbow module adapted to be connected to an air delivery tube that delivers breathable gas to the patient, wherein the retaining portion is structured to retain the elbow module, as well as the cushion module.

26. (New) The mask system, comprising:

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

(ii) a cushion module, comprising:

a 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,

D'SOUZA et al.
Appl. No. 14/447,673

Atty Docket No.: PTB-4398-1485

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, and 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;

wherein the shroud module and the cushion module are configured to be removably coupleable to one another, and

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.

27. (New) The mask system of claim 26 comprising 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.

28. (New) The mask system of claim 26, wherein the shroud module includes upper and lower headgear connectors on each side of the shroud module;

wherein each upper headgear connector includes a slot adapted to receive a respective headgear strap in use; and

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

29. (New) The mask system of claim 26, wherein the shroud module includes an open construction that provides an annular or part annular cushion retaining portion structured to retain the cushion module, wherein the elbow module and the shroud module are mechanically interlocked while allowing 360 degree rotation of the elbow module.

30. (New) The mask system of claim 26, wherein the shroud module is configured to snap-fit with the frame of the first cushion module and configured to snap-fit with the frame of the second cushion module.

Doc Code: DIST.E.FILE Document Description: Electronic Terminal Disclaimer - Filed		PTO/SB/26 U.S. Patent and Trademark Office Department of Commerce
Electronic Petition Request	TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT	
Application Number	14447673	
Filing Date	31-Jul-2014	
First Named Inventor	Errol D'SOUZA	
Attorney Docket Number	PTB-4398-1485	
Title of Invention	MASK SYSTEM	
<input checked="" type="checkbox"/> Filing of terminal disclaimer does not obviate requirement for response under 37 CFR 1.111 to outstanding Office Action <input checked="" type="checkbox"/> This electronic Terminal Disclaimer is not being used for a Joint Research Agreement.		
Owner	Percent Interest	
ResMed Limited	100%	
<p>The owner(s) with percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of prior patent number(s)</p> <p>8550084 8528561</p> <p>as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.</p> <p>In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later:</p> <ul style="list-style-type: none"> - expires for failure to pay a maintenance fee; - is held unenforceable; - is found invalid by a court of competent jurisdiction; - is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321; - has all claims canceled by a reexamination certificate; - is reissued; or - is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer. 		

- ☒ Terminal disclaimer fee under 37 CFR 1.20(d) is included with Electronic Terminal Disclaimer request.
- ☐ I certify, in accordance with 37 CFR 1.4(d)(4), that the terminal disclaimer fee under 37 CFR 1.20(d) required for this terminal disclaimer has already been paid in the above-identified application.

Applicant claims the following fee status:

- ☐ Small Entity
- ☐ Micro Entity
- ☒ Regular Undiscounted

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES

I certify, in accordance with 37 CFR 1.4(d)(4) that I am:

- ☒ An attorney or agent registered to practice before the Patent and Trademark Office who is of record in this application

Registration Number 38009

- ☐ A sole inventor
- ☐ A joint inventor; I certify that I am authorized to sign this submission on behalf of all of the inventors as evidenced by the power of attorney in the application
- ☐ A joint inventor; all of whom are signing this request

Signature	/Paul T. Bowen/
Name	Paul T. Bowen

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).
Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

Electronic Patent Application Fee Transmittal				
Application Number:		14447673		
Filing Date:		31-Jul-2014		
Title of Invention:		MASK SYSTEM		
First Named Inventor/Applicant Name:		Errol Savio Alex D'SOUZA		
Filer:		Paul Thomas Bowen/Tanja Majca		
Attorney Docket Number:		PTB-4398-1485		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Statutory or Terminal Disclaimer	1814	1	160	160
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				160

Doc Code: DISQ.E.FILE

Document Description: Electronic Terminal Disclaimer – Approved

Application No.: 14447673

Filing Date: 31-Jul-2014

Applicant/Patent under Reexamination: D'SOUZA et al.

Electronic Terminal Disclaimer filed on December 23, 2014

☒ APPROVED

This patent is subject to a terminal disclaimer

☐ DISAPPROVED

Approved/Disapproved by: Electronic Terminal Disclaimer automatically approved by EFS-Web

U.S. Patent and Trademark Office

Electronic Acknowledgement Receipt	
EFS ID:	21047117
Application Number:	14447673
International Application Number:	
Confirmation Number:	3036
Title of Invention:	MASK SYSTEM
First Named Inventor/Applicant Name:	Errol Savio Alex D'SOUZA
Customer Number:	23117
Filer:	Paul Thomas Bowen/Tanja Majca
Filer Authorized By:	Paul Thomas Bowen
Attorney Docket Number:	PTB-4398-1485
Receipt Date:	23-DEC-2014
Filing Date:	31-JUL-2014
Time Stamp:	12:29:30
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$ 160
RAM confirmation Number	11621
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Electronic Terminal Disclaimer-Filed	eTerminal-Disclaimer.pdf	33507 e9cea08cd89cfaeea324c666861ebffb287b977d	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30532 9defd604592fa3319592d071a01143e0c9dfc3c2	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			64039		
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

D'SOUZA et al.

Atty. Ref.: PTB-4398-1485

Appl. No. 14/447,673

Confirmation No. 3036

Filed: 07/31/2014

Art Unit: 3649

Examiner: Matter, Kristen Clarette

For: MASK SYSTEM

* * * * *

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

December 23, 2014

Sir:

AMENDMENT

Responsive to the Official Action dated December 8, 2014, please amend the above-identified application as follows:

AMENDMENTS TO THE SPECIFICATION:

Please amend the heading before paragraph [00169] as follows:

4.1 Elbow Connection to Frame/Shroud

Please add the following paragraphs after the heading and before paragraph [00169] as follows:

[00168.1] As shown in Figs. 27-30, the shroud module 20 is structured to maintain the elbow module 70 in an operative position with respect to the patient's face. That is, the shroud module 20 acts as a carrier and bearing surface for the elbow module 70. The shroud module 20 and elbow module 70 may connect with a friction fit, snap-fit, mechanical interlock, or other suitable attachment mechanism. However, other suitable arrangements for attaching the elbow module to the frame module are possible.

Please add the following paragraph after paragraph [00168.1] as follows:

[00168.2] In Figs. 27-30, the elbow module 70 may be rotatably attached to the shroud module 20 so that the elbow module 70 may be rotated relative to the shroud module 20 in use, e.g., 360° rotation.

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Currently Amended) A mask system, comprising:
 - (i) a shroud module; wherein the shroud module includes headgear connectors adapted to removably attach to respective headgear straps of headgear; and
 - (ii) a cushion module, comprising:
 - a 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,
 - 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, and 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 the shroud module and the cushion module are configured to be removably and non-rotatably coupleable to one another.
2. (Original) The mask system of claim 1 wherein the cushion comprises one or more folds in a lower lip/chin region of the cushion.
3. (Currently Amended) The mask system of claim 2, wherein the one or more folds in the nasal bridge region has a relatively high degree of flexibility and the one or more folds in the lower lip/chin region ~~have~~ has a relatively low degree of flexibility.
4. (Original) The mask system of claim 1, wherein each of said one or more folds comprises adjacent first side walls interconnected by a second side wall.
5. (Currently Amended) The mask system of claim 1, wherein the frame includes an opening and the frame further includes a collar surrounding said opening, and wherein the

shroud includes a retaining portion with one or more snap fingers structured to engage the collar with a snap-fit~~the cushion is a full face cushion.~~

6. (Original) The mask system of claim 1, wherein the shroud module includes upper and lower headgear connectors on each side of the shroud module.

7. (Original) The mask system of claim 6, wherein each upper headgear connector includes a slot adapted to receive a respective headgear strap in use.

8. (Original) The mask system of claim 6, wherein each lower headgear connector is adapted to be removably interlocked with a headgear clip associated with a respective headgear strap.

9. (Currently Amended) The mask system of claim 68, ~~further comprising headgear including respective headgear clips, wherein each said headgear clip is adapted to snap-fit with the respective lower headgear connector, wherein the upper headgear connectors and the lower headgear connectors define a fulcrum point or moment of pivoting that is positioned between the upper headgear connectors and the lower headgear connectors.~~

10. (Currently Amended) The mask system of claim 1, wherein the shroud module includes ~~an open construction that provides~~ an annular or part annular cushion retaining portion structured to retain the cushion module.

11. (Original) The mask system of claim 1, further comprising an elbow module adapted to be connected to an air delivery tube that delivers breathable gas to the patient.

12. (Currently Amended) The mask system ~~according to~~ of claim 11, wherein the elbow module is provided to the shroud module.

13. (Original) The mask system of claim 11, wherein the elbow module comprises polycarbonate.

14. (Original) The mask system of claim 11, wherein the elbow module and the shroud module are connected with a mechanical interlock while allowing 360 degree rotation of the elbow module.

15. (Currently Amended) The mask system of claim 11, 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.

16. Canceled.

17. (Original) The mask system of claim 1, 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.

18. (Original) The mask system of claim 1 comprising 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.

19. (Currently Amended) The mask system of claim 1, wherein the shroud module comprises polycarbonate and the cushion comprises silicone.

20-21. Cancelled.

22. (New) A mask system, comprising:

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

(ii) a cushion module, comprising:

a 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,

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, and 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;

wherein the shroud module and the cushion module are configured to be removably coupleable to one another, and

wherein the shroud module includes a front opening and a retaining portion extending rearwardly from the front opening and structured to retain the cushion module.

23. (New) The mask system of claim 22, further comprising an elbow module mechanically interlocked with the shroud module while allowing 360 degree rotation of the elbow module.

24. (New) The mask system of claim 22, wherein the shroud module includes upper and lower headgear connectors on each side of the shroud module;

wherein each upper headgear connector includes a slot adapted to receive a respective headgear strap in use; and

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

25. (New) The mask system of claim 22, further comprising an elbow module adapted to be connected to an air delivery tube that delivers breathable gas to the patient, wherein the shroud module is structured to retain and carry the elbow module.

26. (New) The mask system of claim 1, wherein:

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,

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,

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, 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.

27. (New) The mask system of claim 26, wherein the upper straps provide padding to the respective headgear connectors of the shroud module on the patient's face in use.

28. (New) The mask system of claim 26, 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.

29. (New) The mask system of claim 1, the frame including a protruding vent arrangement having a plurality of holes, wherein the shroud module includes a first opening to accommodate said protruding vent arrangement, further wherein the shroud module includes a second opening to accommodate an elbow.

30. (New) A mask system for delivery of a supply of air at positive pressure to a patient's airway, the mask system comprising:

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, 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, the frame including a washout vent;

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, 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, 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 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;

a shroud module including headgear connectors adapted to removably attach to the headgear, wherein the headgear connectors include two upper connectors associated with the upper headgear straps and two lower connectors associated with the lower headgear straps, each said upper headgear connector including a slot or receiving hole adapted to receive one of the upper headgear straps, 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; 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, the elbow including a swivel adapted to connect to an air delivery tube, the elbow including an anti-asphyxia valve (AAV) and a port that is selectively closed by a flap portion of the AAV.

31. (New) The mask system of claim 30, wherein:

each upper headgear connector includes a laterally elongated arm and the slot or receiving hole is positioned at a free end of the arm,

each arm is contoured to extend along the patient's cheek, curving below the patient's field of vision or eyes, and then curves upwards at an angle relative to a horizontal axis in use,

the arms are at least semi-rigid to help prevent up and down movement of the arms relative to the face of the patient,

the top straps are integral with one another,

the frame, the shroud module and the headgear are structured to control rotation of the mask system in the sagittal and coronal planes of the patient in use, without a forehead support, and

the elbow is rotatably snap-fit to the frame of the cushion module.

32. (New) The mask system of claim 30, wherein:

each upper headgear connector includes a laterally extending arm and the slot or receiving hole is positioned at a free end of the arm,

the arms are at least semi-rigid to help prevent up and down movement of the arms relative to the face of the patient,

the elbow is rotatably snap-fit to the frame of the cushion module,

the top straps are integral with one another, and

the frame includes a co-molded ring-shaped lip seal to seal against the elbow when connected.

33. (New) The mask system of claim 30, wherein:

the elbow is rotatably attached the shroud module,

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

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

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

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

AMENDMENTS TO THE DRAWINGS:

The attached sheet of drawing includes changes to Figs. 41-3 and 41-4. This sheet replaces the original sheet including those figures. In the replacement figures, arrows have been added.

REMARKS/ARGUMENTS

Claims 1-33 are pending. By this Amendment, claims 1, 3, 5, 9, 10, 12, 15 and 19 have been amended, claims 16, 20 and 21 have been canceled and claims 22-33 are added. Reconsideration in view of the above amendments and the following remarks is respectfully requested.

Examiner Matter is thanked for the courtesies extended to Applicant's representative during a telephone interview conducted on 16 December 2014. The substance of the interview is discussed below.

It is respectfully requested that the Examiner enter and consider the Preliminary Amendment filed on December 1, 2014, in which Fig. 22 was amended

On page 2 of the Office Action, the Examiner objects to the drawings based on Figs. 41-3 and 41-4. As described in paragraph [00207] of the present specification, the connecting portion 528 is received in the groove 535 of the frame 542, and the clip structures 525 releaseably interlock with respect to retaining members 533. While Figs. 41-3 and 41-4 show exploded views, Figs. 41-1 and 41-2 show complete or at least nearly complete assembly where the clips 525 are received within the retaining members 533. Attached hereto is an amendment adding arrows to Figures 41-3 and 41-4, as discussed with the examiner during the interview.

Reconsideration and withdrawal of the drawing objection are respectfully requested.

Claim 3 was objected to based on a minor informality which is corrected by amendment to claim 3, to adopt the Examiner's helpful suggestion.

Reconsideration and withdrawal of the objection is respectfully requested.

Claims 1-13 and 19-21 are rejected under 35 U.S.C. §103(a) over Ho et al. (US 2006/0272646) in view of Lieberman et al. (US 2008/0178886) and Schegerin (US 5,349,949). This rejection is respectfully traversed.

Ho does not teach or suggest the claimed shroud module and cushion module, wherein the shroud module and the cushion module are configured to be removably and non-rotatably coupleable to one another. Important to Ho's disclosure is the ability to allow the mounting member 10 to rotate relative to the cushion assembly, to allow for different types of headgear configurations.

The tertiary references to Lieberman and Schegerin do not make up for these deficiencies, nor are they relied upon for such.

Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 14-16 are rejected under 35 U.S.C. §103(a) over the combination of Ho, Lieberman and Schegerin, and further in view of Smart (US 2006/0107960). This rejection is respectfully traversed as Smart does not make up for the deficiencies noted above.

Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 17 and 18 were rejected under 35 U.S.C. §103(a) over the Ho, Lieberman and Schegerin combination, and further in view of Geist (US 2006/0042629). This rejection is respectfully traversed because claims 17 and 18 depend from claim 1, either directly or indirectly, and are patentable by virtue of that dependency.

Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1-21 stand rejected under obviousness-type double patenting over commonly owned U.S. Patent No. 8,528,561 and 8,550,084. Submitted contemporaneously herewith is a Terminal Disclaimer to obviate the rejection. The filing of a Terminal Disclaimer is not an admission as to the propriety of the rejection. See M.P.E.P. §802.04.

Reconsideration and withdrawal of the rejection is respectfully requested.

New claims 22-33 have been added for the Examiner's consideration.

In view of the above amendments and remarks, Applicants respectfully submit that all the claims are patentable and that the entire application is in condition for allowance.

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140 under Order No. PTB-4398-1485.

Should the Examiner believe that anything further is desirable to place the application in better condition for allowance, he is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

NIXON & VANDERHYE P.C.

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68/81

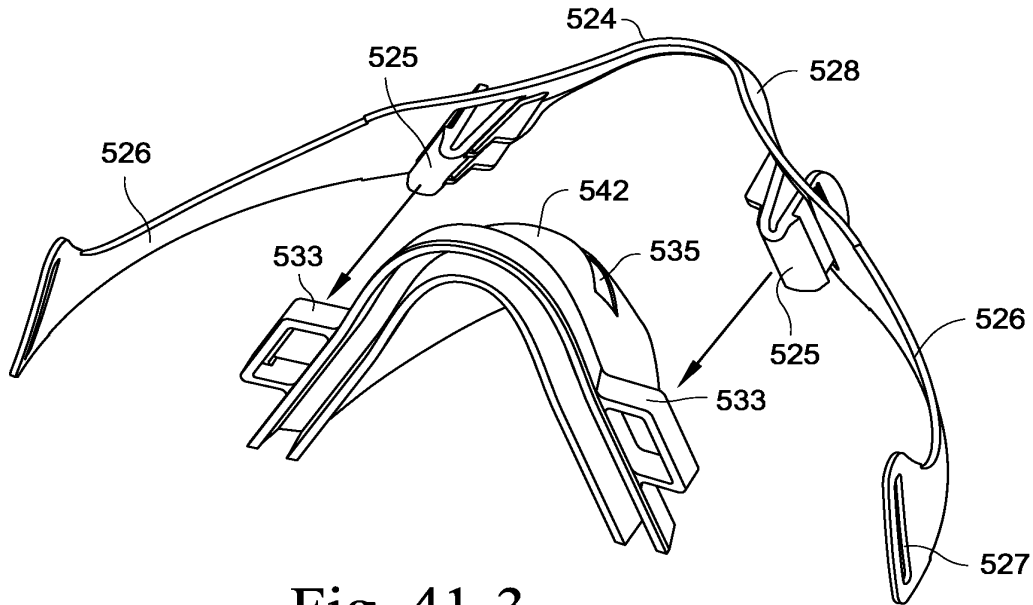


Fig. 41-3

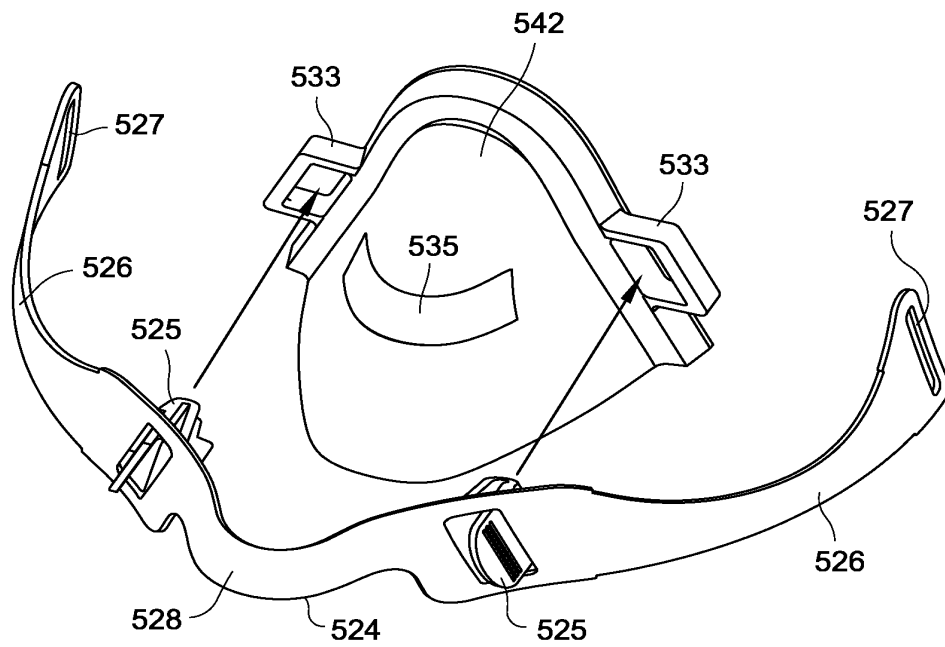


Fig. 41-4

Electronic Patent Application Fee Transmittal				
Application Number:		14447673		
Filing Date:		31-Jul-2014		
Title of Invention:		MASK SYSTEM		
First Named Inventor/Applicant Name:		Errol Savio Alex D'SOUZA		
Filer:		Paul Thomas Bowen/Tanja Majca		
Attorney Docket Number:		PTB-4398-1485		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
Total in USD (\$)				180

Electronic Acknowledgement Receipt	
EFS ID:	21047822
Application Number:	14447673
International Application Number:	
Confirmation Number:	3036
Title of Invention:	MASK SYSTEM
First Named Inventor/Applicant Name:	Errol Savio Alex D'SOUZA
Customer Number:	23117
Filer:	Paul Thomas Bowen/Tanja Majca
Filer Authorized By:	Paul Thomas Bowen
Attorney Docket Number:	PTB-4398-1485
Receipt Date:	23-DEC-2014
Filing Date:	31-JUL-2014
Time Stamp:	12:44:07
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$180
RAM confirmation Number	11844
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		4398-1485_AMD_to_12_8_2014_OA.pdf	105291 b9023cad5c283a2b10f256613805f799361c784	yes	13
	Multipart Description/PDF files in .zip description				
	Document Description		Start		End
	Amendment/Req. Reconsideration-After Non-Final Reject		1		1
	Specification		2		2
	Claims		3		9
	Applicant Arguments/Remarks Made in an Amendment		10		13
Warnings:					
Information:					
2	Drawings-only black and white line drawings	4398-1485_ReplacementSheet.pdf	60296 7ce547aa3dbf5b16e647d1ebbeede70ea59a3902	no	1
Warnings:					
Information:					
3	Information Disclosure Statement (IDS) Form (SB08)	4398-1485_Information_Disclosure_Statement.pdf	140545 c4db4c2ed4d595a8ab867c388ec88a257940fcbcd	no	6
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
4	Non Patent Literature	4398-1485_NPL01_Photos.pdf	7760749 46fa3a4cd832844302bdb39d32afe7fa716a42f7	no	6
Warnings:					
Information:					
5	Non Patent Literature	4398-1485_NPL02_JP_OA.pdf	251177 fadf8781619df509cb107d7dbd9007eb3acd7d6	no	8
Warnings:					
Information:					

6	Fee Worksheet (SB06)	fee-info.pdf	30741 6673ea0a64239c475b71fe1df1b336c87ca937ce	no	2
Warnings:					
Information:					
Total Files Size (in bytes):				8348799	
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					

Document code: WFEE

United States Patent and Trademark Office
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RHARMON	SALE	#00000001	Mailroom Dt:	12/23/2014	141140	14447673
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875				Application or Docket Number 14/447,673		Filing Date 07/31/2014		<input type="checkbox"/> To be Mailed	
ENTITY: <input checked="" type="checkbox"/> LARGE <input type="checkbox"/> SMALL <input type="checkbox"/> MICRO									
APPLICATION AS FILED – PART I									
(Column 1)		(Column 2)							
FOR	NUMBER FILED	NUMBER EXTRA		RATE (\$)		FEE (\$)			
<input type="checkbox"/> BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A					
<input type="checkbox"/> SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A		N/A					
<input type="checkbox"/> EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A					
TOTAL CLAIMS (37 CFR 1.16(j))	minus 20 =	*		X \$ =					
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		X \$ =					
<input type="checkbox"/> APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).								
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))									
* If the difference in column 1 is less than zero, enter "0" in column 2.						TOTAL			
APPLICATION AS AMENDED – PART II									
(Column 1)		(Column 2)		(Column 3)					
AMENDMENT	12/23/2014	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	* 30	Minus	** 21	= 9	X \$80 =		720	
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0	X \$420 =		0	
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))								
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
						TOTAL ADD'L FEE		720	
(Column 1)		(Column 2)		(Column 3)					
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =			
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =			
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))								
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
						TOTAL ADD'L FEE			
<p>* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.</p> <p>** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".</p> <p>*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".</p> <p>The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.</p>									

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/447,673	07/31/2014	Errol Savio Alex D'SOUZA	PTB-4398-1485	3036

23117	7590	02/03/2015
NIXON & VANDERHYE, PC		
901 NORTH GLEBE ROAD, 11TH FLOOR		
ARLINGTON, VA 22203		

EXAMINER	
MATTER, KRISTEN CLARETTE	

ART UNIT	PAPER NUMBER
3649	

NOTIFICATION DATE	DELIVERY MODE
02/03/2015	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTOMAIL@nixonvan.com
pair_nixon@firsttofile.com

Office Action Summary	Application No. 14/447,673	Applicant(s) D'SOUZA ET AL.	
	Examiner KRISTEN MATTER	Art Unit 3649	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/23/2014.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 1-15, 17-19 and 22-33 is/are pending in the application.
5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-15, 17-19, 22-28 and 30-32 is/are rejected.
- 8) ☒ Claim(s) 29 and 33 is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 3) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) | Paper No(s)/Mail Date. ____. |
| Paper No(s)/Mail Date <u>7/31/2014, 12/23/2014</u> . | 4) <input type="checkbox"/> Other: ____. |

The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

This Action is in response to the amendment filed 12/23/2014. Claims 1, 3, 5, 9, 10, 12, 15, and 19 have been amended, claims 16, 20 and 21 have been cancelled, and claims 22-33 have been added. Thus, claims 1-15, 17-19 and 22-33 are currently pending in the instant application.

Information Disclosure Statement

Applicant noted that the IDS of 7/31/2014 contained some typographical errors during a phone interview for co-pending case 13/747,701. Examiner agreed to reconsider the IDS and include corrections to the mistakes.

Claim Rejections - 35 USC § 103

The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 10-14, 19, 22, 23, and 25 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Geist (US 2006/0042629) in view of Lieberman et al. (US 2008/0178886, herein referred to as “Lieberman”) and Schegerin (US 5,349,949).

Regarding claims 1-3, Geist discloses a mask system comprising: a shroud module (20); wherein the shroud module includes headgear connectors (75, 76) adapted to removably attach to respective headgear straps of headgear (see Figure 18); and a cushion module comprising: a

frame (12) defining a breathing chamber (see Figure 2B); and a cushion (14) 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 face (see Figure 17), wherein the shroud module and the cushion module are configured to be removably and non-rotatably coupled to one another (see paragraph 46 and Figure 18 - the ridge 39/recess 73 prevents rotation).

Geist is silent as to the materials of the mask although it seems readily apparent that the mask frame 12 is more rigid than the cushion 14. However, Lieberman discloses another face mask with a cushion formed of silicone (see claim 12), a first, relatively soft elastomeric material and a mask frame/body constructed of polycarbonate (see claim 12), a second material that is more rigid than the cushion. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the frame of Geist from polycarbonate and the cushion from silicone as taught by Lieberman in order to use a rigid enough structure to allow connecting of the elbow and shroud to the frame and a soft material for create a soft comfortable seal on the patient's face. See also *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960), in which the selection of a known material based on its suitability for its intended use supported a prima facie case of obviousness.

Geist lacks the cushion having one or more folds as claimed. However, Schegerin discloses a breathing mask with folds (26) in the nasal and lower lip/chin region (see Figure 1) to provide a higher level of adaptability, the fold(s) in the nasal bridge region having a relatively higher degree of flexibility than those in the lower lip/chin region (see column 2, lines 10-20). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Geist's cushion to include folds as taught by Schegerin in order to

provide additional adaptability and maintain a good seal even as the applied force to the mask changes, for example, as a patient moves.

Regarding claim 4, Schegerin discloses that the folds comprise adjacent first walls (e.g., the flat portions seen in Figure 7) interconnected by a second wall (26).

Regarding claim 10, Geist's shroud module includes an annular or part annular cushion retaining portion (72 - see Figures 14-16) structured to retain the cushion module.

Regarding claim 11, Geist discloses an elbow module (23-25) adapted to be connected to an air delivery tube that delivers breathable gas to the patient as is well known in the art.

Regarding claim 12, as seen in Figures 6 and 9 of Geist, the elbow module is "provided" to the shroud module. Note that provided does not have any definite structural limitation.

Regarding claim 13, Geist is silent as to the material of the elbow module. However, polycarbonate is a well-known and commonly used material for facemask components (see also Lieberman). Absent a critical teaching and/or showing of unexpected results from making the elbow module of polycarbonate examiner contends that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made Geist's elbow module from polycarbonate in order to provide a rigid, biocompatible material for the elbow module. See also *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960), in which the selection of a known material based on its suitability for its intended use supported a prima facie case of obviousness.

Regarding claim 14, Geist's elbow and shroud module are connected with a mechanical interlock (see Figure 6) while allowing for 360 degree rotation of the elbow module as is well known in the art (see paragraph 35 and Figure 2A).

Regarding claim 19, Geist as modified by Lieberman discloses that the cushion comprises silicone as discussed above but is silent as to the shroud being made of polycarbonate. However, polycarbonate is a well-known and commonly used material for facemask components. Absent a critical teaching and/or showing of unexpected results from making the shroud module of polycarbonate examiner contends that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made Geist's shroud module from polycarbonate in order to provide a rigid, biocompatible material for the shroud module. See also *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960), in which the selection of a known material based on its suitability for its intended use supported a prima facie case of obviousness.

Regarding claim 22, Geist discloses a mask system comprising: a shroud module (20); wherein the shroud module includes headgear connectors (75, 76) adapted to removably attach to respective headgear straps of headgear (see Figure 18); and a cushion module comprising: a frame (12) defining a breathing chamber (see Figure 2B); and a cushion (14) 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 face (see Figure 17), wherein the shroud module and the cushion module are configured to be removably and non-rotatably coupled to one another (see paragraph 46 and Figure 18). Geist further discloses that the shroud module has a front opening and a retaining portion (74) extending rearward from the front opening and structured to retain the cushion module.

Geist is silent as to the materials of the mask although it seems readily apparent that the mask frame 12 is more rigid than the cushion 14. However, Lieberman discloses another face mask with a cushion formed of silicone (see claim 12), a first, relatively soft elastomeric material

and a mask frame/body constructed of polycarbonate (see claim 12), a second material that is more rigid than the cushion. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the frame of Geist from polycarbonate and the cushion from silicone as taught by Lieberman in order to use a rigid enough structure to allow connecting of the elbow and shroud to the frame and a soft material for create a soft comfortable seal on the patient's face. See also *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960), in which the selection of a known material based on its suitability for its intended use supported a prima facie case of obviousness.

Geist lacks the cushion having one or more folds as claimed. However, Schegerin discloses a breathing mask with folds (26) in the nasal and lower lip/chin region (see Figure 1) to provide a higher level of adaptability, the fold(s) in the nasal bridge region having a relatively higher degree of flexibility than those in the lower lip/chin region (see column 2, lines 10-20). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Geist's cushion to include folds as taught by Schegerin in order to provide additional adaptability and maintain a good seal even as the applied force to the mask changes, for example, as a patient moves.

Regarding claim 23, Geist's elbow and shroud module are connected with a mechanical interlock (see Figure 6) while allowing for 360 degree rotation of the elbow module as is well known in the art (see paragraph 35 and Figure 2A).

Regarding claim 25, Geist discloses an elbow module (23-25) adapted to be connected to an airway tube and that the shroud module is structured to help retain and carry the elbow module (see Figure 9 - the elbow module abuts the shroud and can be carried by it).

Claim 5 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Geist in view of Lieberman and Schegerin, as applied to claim 1 above, and further in view of Lubke et al. (US 2006/0283461, herein referred to as "Lubke").

Regarding claim 5, Geist discloses that the frame includes an opening surrounded by a collar (38 - see Figure 3) and wherein the shroud includes a retaining portion (73) to engage the collar. The two elements are press-fit together but Geist does not expressly state they create a "snap-fit" even though examiner believes this is readily apparent/obvious. In addition, Lubke discloses a similar releasable connection with a peg/finger that is snap fit into a retaining member (see Figure 16 and paragraph 173). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Geist to include a snap fit connection as taught by Lubke between the collar and retaining member in order to make sure the two pieces were securely but releasably held together as is well known in the art. Such a modification involves the mere substitution of one well-known fastening means for another yielding predictable results that do not patentably distinguish an invention over the prior art. Which element of the two the "fingers" are on is obvious to try from two finite possible configurations and does not patentably distinguish the invention over the prior art.

Claims 6, 7, 9 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Geist in view of Lieberman and Schegerin, as applied to claim 1 above, and further in view of Ogden et al. (US 5,662,101, herein referred to as "Ogden").

Regarding claim 6, Geist lacks the shroud module having upper and lower headgear connectors on each side. However, Ogden discloses another mask with a shroud module having upper (27) and lower (25) headgear connectors on each side of the shroud module (see Figure 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Geist to include upper and lower headgear connectors as taught by Ogden in order to more evenly distribute the force over the patient's head. Furthermore, CPAP masks commonly have upper and lower headgear straps and adding them to Geist appears to involve the mere use of a well-known headgear arrangement in a well-known device to yield predictable results that do not patentably distinguish an invention over the prior art.

Regarding claim 7, both Geist and Ogden disclose slots for receiving respective headgear straps in use (see Figure 2 of Ogden for upper headgear connector slot).

Regarding claim 9, the upper headgear connectors and the lower headgear connectors of Ogden would define a fulcrum point or moment of pivoting that is positioned between the upper and lower headgear connectors in the same manner as the instant invention (i.e., the narrowest portion of the shroud would pivot some when enough force was applied to the headgear connector portions -- see Figure 2).

Claims 8 and 24 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Geist in view of Lieberman, Schegerin, and Ogden, as applied to claims 6 and 22 above, and further in view of Ho et al. (US 2006/0272646, herein referred to as "Ho").

Regarding claims 8 and 24, motivation for providing Geist with upper and lower straps as taught by Ogden remains the same as above. The modified Geist device lacks the lower headgear

connector being removably interlocked with a headgear clip. However, Ho discloses that slotted headgear connectors can be replaced by the arrangement seen in US 2004/0025883 (see paragraph 56), and as seen in US 2004/0025883 Figures 11 and 13, the headgear connectors are removably interlocked with a headgear clip (76) associated with a headgear strap via snap-fit. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have replaced the lower headgear slots of the modified Geist device with a headgear clip as taught by make them faster to take on/off or so that a patient need not readjust the length each time a strap is removed.

Claim 15 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Geist in view of Lieberman and Schegerin, as applied to claims 1 and 11 above, and further in view of Smart (US 2006/0107960).

Regarding claim 15, Geist lacks a valve on the elbow as claimed. Smart discloses an elbow module with an anti-asphyxia valve (see abstract) that includes a flap portion (27) adapted to selectively close a port (44) provided in the elbow module. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Geist's elbow module with a valve as taught by Smart in order to prevent accidental suffocation as is well known in the art.

Claims 17 and 18 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Geist in view of Lieberman and Schegerin, as applied to claim 1 above, and further in view of Kwok et al. (US 2005/0022820, herein referred to as "Kwok").

Geist discloses that the prior art is replete with masks of different sizes and structures (paragraph 2) but does not expressly state that the cushion module includes first and second cushion modules that are different. However, Kwok discloses making a mask frame different sizes such as small, medium and large, the different sized mask frames being attachable to the same component (see paragraph 149). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the modified mask of Geist in various sizes all attachable to the same shroud module component as taught by Kwok in order to better accommodate patient's with different sizes of faces as is well known in the art.

Claims 26-28 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Geist in view of Lieberman and Schegerin, as applied to claim 1 above, and further in view of Lubke and Gunaratnam et al. (US 2005/0241644, herein referred to as "Gunaratnam").

Regarding claims 26 and 28, Geist lacks the mask system headgear having upper and lower straps. However, Lubke discloses another mask having upper headgear straps (218) that extend above a patient's ears in use (see Figure 1) and lower headgear straps (232) that extend below the patient's ears in use (see Figure 1). Each free end of the upper and lower straps includes a hook tab (228, 238) structured to engage a remainder of the respective strap to secure the straps in place in a length adjustable manner as is well known in the art. Further, the upper straps split to form a pair of top straps (224) and a pair of rear straps (226), the top straps being configured to extend over the ears/head and the rear straps passing behind the patient's head in use and wherein the top and rear straps form a closed loop to encircle a rear portion of the

patient's head when in use (see Figures 1 and 6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Geist to include upper, lower, top and rear headgear straps as taught by Lubke in order to more evenly distribute the force over the patient's head. Furthermore, CPAP masks commonly have upper and lower headgear straps and adding them to Geist appears to involve the mere use of a well-known headgear arrangement in a well-known device to yield predictable results that do not patentably distinguish an invention over the prior art. Obviously, the modified Geist/Lubke device would include two upper and two lower headgear connectors on the shroud to accommodate the number of straps being used. Both Geist (see Figure 18) and Lubke (see Figure 1) have headgear connectors with slots for receiving and attaching the straps.

The modified Geist device lacks a buckle for connecting the top straps and a hook tab threaded through the buckle on the top straps. However, Gunaratnam discloses, in another mask, a pair of straps that pass over the head and have ends with hook tabs (see paragraphs 75-78) for passing through a buckle (see Figure 17) to secure the straps in place in a length adjustable manner. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Geist's modified device with a buckle for the top straps as taught by Gunaratnam in order to allow the device to be even more customizable and to help keep the device centered on a person's head as needed.

Regarding claim 27, the upper straps would provide padding to the upper headgear connectors in the modified device when the device was in use. The claim does not appear to positively require the padding touch the face. However, even if required, examiner notes that it would have been obvious to include headgear connectors such as those taught by Lubke (i.e., a

semi-rigid arm 250) in Geist's modified device, which would touch the patient's face in use and also provide for padding.

Claim 30 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Geist in view of Lieberman, Schegerin, Smart, and Lubke.

Regarding 30, Geist discloses a mask system for delivery of positive pressure air to a patient comprising: a shroud module (20) including headgear connectors (75, 76) adapted to removably attach to respective headgear straps of headgear to maintain the mask system in a desired position on the patient's face (see Figures 17-18); and a cushion module comprising a frame (12) defining a breathing chamber for receiving the pressurized air (see Figure 2B); and a cushion (14) 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 face (see Figure 17), wherein the shroud module and the frame of the cushion module are configured to be removably and non-rotatably coupled to one another (see paragraph 46 and Figure 18).

Geist is silent as to the materials of the mask although it seems readily apparent that the mask frame 12 is more rigid than the cushion 14. However, Lieberman discloses another face mask with a cushion formed of silicone (see claim 12), a first, relatively soft elastomeric material and a mask frame/body constructed of polycarbonate (see claim 12), a second material that is more rigid than the cushion. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the frame of Geist from polycarbonate and the cushion from silicone as taught by Lieberman in order to use a rigid enough structure to allow connecting of the elbow and shroud to the frame and a soft material for create a soft

comfortable seal on the patient's face. See also *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960), in which the selection of a known material based on its suitability for its intended use supported a prima facie case of obviousness.

Geist disclose an elbow that includes a swivel (25) adapted to connect to an air delivery tube, the elbow being configured for delivering the air to the breathing chamber and being rotatably attached to and carried by the shroud module or frame. Geist lacks a valve on the elbow as claimed. Smart discloses an elbow with an anti-asphyxia valve (see abstract) that includes a flap portion (27) adapted to selectively close a port (44) provided in the elbow module. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Geist's elbow with a valve as taught by Smart in order to prevent accidental suffocation as is well known in the art.

Geist lacks the mask system having upper and lower headgear straps as claimed. However, Lubke discloses another mask having upper headgear straps (218) that extend above a patient's ears in use (see Figure 1) and lower headgear straps (232) that extend below the patient's ears in use (see Figure 1). Each free end of the upper and lower straps includes a hook tab (228, 238) structured to engage a remainder of the respective strap to secure the straps in place in a length adjustable manner as is well known in the art. Further, the headgear includes a pair of top straps (224) and a pair of rear straps (226), the top straps being configured to extend over the ears/head and the rear straps passing behind the patient's head in use and wherein the top and rear straps form a closed loop to encircle a rear portion of the patient's head when in use (see Figures 1 and 6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Geist to include upper, lower, top and rear

headgear straps as taught by Lubke in order to more evenly distribute the force over the patient's head. Furthermore, CPAP masks commonly have upper and lower headgear straps and adding them to Geist appears to involve the mere use of a well-known headgear arrangement in a well-known device to yield predictable results that do not patentably distinguish an invention over the prior art. Obviously, the modified Geist/Lubke device would include two upper and two lower headgear connectors on the shroud to accommodate the number of straps being used. Both Geist (see Figure 18) and Lubke (see Figure 1) have headgear connectors with slots for receiving and attaching the straps.

Geist discloses that the frame includes an opening surrounded by a collar (38 - see Figure 3) and wherein the shroud includes a retaining portion (73) to engage the collar. The two elements are press-fit together but Geist does not expressly state they create a "snap-fit" even though examiner believes this is readily apparent/obvious. In addition, Lubke discloses a similar releasable connection with a peg/finger that is snap fit into a retaining member (see Figure 16 and paragraph 173). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Geist to include a snap fit connection as taught by Lubke between the collar and retaining member in order to make sure the two pieces were securely but releasably held together as is well known in the art. Such a modification involves the mere substitution of one well-known fastening means for another yielding predictable results that do not patentably distinguish an invention over the prior art.

Geist also lacks a gas washout vent on the frame. However, Lubke discloses having a gas washout vent (281) on the frame of the mask. Therefore, it would have been obvious to one of

ordinary skill in the art to have added a gas washout vent on the mask frame in Geist as taught by Lubke for carbon dioxide gas washout as is well known in the art.

Claim 31 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Geist in view of Lieberman, Schegerin, Smart, and Lubke as applied to claim 30 above, and further in view of Gunaratnam (US 2004/0226566, herein referred to as “Gunaratnam ‘566”).

Regarding claim 31, the Geist as modified by Lubke includes upper headgear connectors that include semi-rigid laterally elongated arms (244 - see paragraph 166) with a slot (254) positioned at a free end of the arm (see Figure 9). Lubke’s top straps (224) are integral with one another (see for example Figure 2). Further both Geist (see Figure 6) and Lubke (see paragraph 304) disclose the elbow connected to a mask frame collar member via snap fit. However, the modified Geist/Lubke device lacks the arms being contoured as claimed. Gunaratnam ‘566 discloses another similar elongated arm attached to a mask that is contoured to extend along the patient’s cheek, curving below the patient’s field of vision and then curves upwards at an angle relative to a horizontal axis in use (see Figure 84). Therefore, it would have been obvious to one of ordinary skill in the art to have provided Geist with semi-rigid elongated arms that are contoured below the eye as taught by Gunaratnam ‘566 in order to be less intrusive on a patients face and/or to avoid blocking their vision. The frame, the shroud module and the headgear would be structured to control rotation of the mask system in the sagittal and coronal planes of the patient in use, without a forehead support in the same manner as the instant invention in the modified Geist device.

Claim 32 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Geist in view of Lieberman, Schegerin, Smart, and Lubke as applied to claim 30 above, and further in view of Gunaratnam '566 and Gunaratnam.

Regarding claim 32, Geist as modified by Lieberman, Schegerin, Smart, Lubke and Gunaratnam '566 disclose the limitations of claim 32 as discussed above for claim 31 (same reasoning applies). The modified reference lacks a co-molded ring-shaped lip seal on the frame to seal against the elbow. However, Gunaratnam discloses a similar device with a co-molded ring-shaped lip seal (614 - see paragraph 70) on a mask frame to seal against an elbow when connected. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Geist's modified device with a co-molded ring-shaped lip seal on the mask frame as taught by Gunaratnam in order to create a better air tight seal between the components.

Response to Arguments

Applicant's arguments with respect to claims 1-19 have been considered but are moot in view of the new grounds of rejection necessitated by applicant's amendment.

Allowable Subject Matter

Claims 29 and 33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTEN MATTER whose telephone number is (571)272-5270. The examiner can normally be reached on Monday - Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Darnell Jayne can be reached on (571) 272-7723. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kristen C. Matter
Primary Examiner
Art Unit 3649

/KRISTEN MATTER/
Primary Examiner, Art Unit 3649

Notice of References Cited	Application/Control No. 14/447,673	Applicant(s)/Patent Under Reexamination D'SOUZA ET AL.	
	Examiner KRISTEN MATTER	Art Unit 3649	Page 1 of 1

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2005/0022820	02-2005	Kwok et al.	128/206.21
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
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	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
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	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

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INFORMATION DISCLOSURE CITATION	ATTY. DOCKET NO.	SERIAL NO.
	PTB-4398-1485	Continuation of 13/964,280
	APPLICANT	
(Use several sheets if necessary)	D'SOUZA et al.	
	FILING DATE	GROUP
	Herewith	Unassigned

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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
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	428,592	05/1890	CHAPMAN			
	443,191	12/1890	ILLING			
	781,516	01/1905	GUTHRIE, JR.			
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Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /K.M./

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**INFORMATION DISCLOSURE
CITATION**ATTY. DOCKET NO.
PTB-4398-1485SERIAL NO.
Continuation of 13/964,280APPLICANT
D'SOUZA et al.

(Use several sheets if necessary)

FILING DATE

TC/A.U.

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	2,875,759	03/1959	GALLEHER, JR.			
	2,881,444	04/1959	FRESH et al.			
	2,882,895	04/1959	GALEAZZI			
	2,902,033	09/1959	GALLEHER, JR.			
	2,917,045	12/1959	SCHILDKNECHT et al.			
	2,931,356	04/1960	SCHWARZ			
	2,939,458	06/1960	LUNDQUIST			
	3,013,556	12/1961	GALLEHER, JR.			
	3,042,035	07/1962	COANDA			
	3,117,574	01/1964	REPLOGLE			
	3,182,659	05/1965	BLOUNT			
	3,189,027	06/1965	BARTLETT, JR.			
	3,193,624	07/1965	WEBB et al.			
	3,238,943	03/1966	HOLLEY			
	3,288,138	11/1966	SACHS			
	3,315,672	04/1967	CUNNINGHAM et al.			
	3,315,674	04/1967	BLOOM et al.			
	3,330,273	07/1967	BENNETT			
	3,330,274	07/1967	BENNETT			
	3,362,420	01/1968	BLACKBURN et al.			
*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

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Continuation of 13/964,280APPLICANT
D'SOUZA et al.

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		3,363,833	01/1968	LAERDAL			
		3,545,436	12/1970	HOLLOWAY			
		3,556,122	01/1971	LAERDAL			
		3,580,051	05/1971	BLEVINS			
		3,670,726	03/1972	MAHON et al.			
		3,682,171	08/1972	DALI et al.			
		3,700,000	10/1972	HESSE, Deceased et al.			
		3,720,235	03/1973	SCHROCK			
		3,725,953	04/1973	JOHNSON et al.			
		3,739,774	06/1973	GREGORY			
		3,750,333	08/1973	VANCE			
		3,752,157	08/1973	MALMIN			
		3,754,552	08/1973	KING			
		3,796,216	03/1974	SCHWARZ			
		3,799,164	03/1974	ROLLINS			
		3,830,230	08/1974	CHESTER			
		3,861,385	01/1975	CARDEN			
		3,902,486	09/1975	GUICHARD			
		3,905,361	09/1975	HEWSON et al.			
		3,910,261	10/1975	RAGSDALE et al.			
		3,938,614	02/1976	AHS			
		3,972,321	08/1976	PROCTOR			
		3,978,854	09/1976	MILLS, JR.			
		4,006,744	02/1977	STEER			
		4,062,357	12/1977	LAERDAL			
		4,069,516	01/1978	WATKINS, JR.			
		4,077,404	03/1978	ELAM			
		4,120,302	10/1978	ZIEGLER			
		4,142,527	03/1979	GARCIA			
		4,153,051	05/1979	SHIPPERT			
		4,156,426	05/1979	GOLD			
		4,167,185	09/1979	LEWIS			
		4,201,205	05/1980	BARTHOLOMEW			
		4,226,234	10/1980	GUNDERSON			
		4,231,363	11/1980	GRIMES			
		4,233,972	11/1980	HAUFF et al.			
		4,239,038	12/1980	HOLMES			
		4,245,632	01/1981	HOUSTON			

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INFORMATION DISCLOSURE CITATION	ATTY. DOCKET NO.	SERIAL NO.
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(Use several sheets if necessary)	FILING DATE	TC/A.U.
	Herewith	Unassigned

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	4,248,218	02/1981	FISCHER			
	4,263,908	04/1981	MIZERAK			
	4,264,743	04/1981	MARUYAMA et al.			
	4,265,239	05/1981	FISCHER, JR. et al.			
	4,266,540	05/1981	PANZIK et al.			
	4,267,845	05/1981	ROBERTSON, JR. et al.			
	4,273,124	06/1981	ZIMMERMAN			
	4,304,229	12/1981	CURTIN			
	4,312,359	01/1982	OLSON			
	4,328,797	05/1982	ROLLINS et al.			
	4,337,767	07/1982	YAHATA			
	4,347,205	08/1982	STEWART			
	4,354,488	10/1982	BARTOS			
	4,367,735	01/1983	DALI			
	4,367,816	01/1983	WILKES			
	4,369,284	01/1983	CHEN			
	4,402,316	09/1983	GADBERRY			
	4,406,283	09/1983	BIR			
	4,412,537	11/1983	TIGER			
	4,414,973	11/1983	MATHESON et al.			
	4,417,575	11/1983	HILTON et al.			
	4,422,456	12/1983	TEIP			
	4,446,576	05/1984	HISATAKA			
	4,449,526	05/1984	ELAM			
	4,454,880	06/1984	MUTO et al.			
	4,454,881	06/1984	HUBER et al.			
	4,455,675	06/1984	BOSE et al.			
	4,458,679	07/1984	WARD			
	4,467,799	08/1984	STEINBERG			
	4,493,614	01/1985	CHU et al.			
	4,522,639	06/1985	ANSITE et al.			
	4,548,200	10/1985	WAPNER			
	4,549,542	11/1985 10/1985	CHEIN			
	4,558,710	12/1985	/KCM/ EICHLER			
	4,572,323	02/1986	RANDALL			
	4,579,113	04/1986	McCREADIE et al.			
	4,587,967	05/1986	CHU et al.			
	4,593,688	06/1986	PAYTON			

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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	4,601,465	07/1986	ROY			
	4,616,647	10/1986	McCREADIE			
	4,617,637	11/1986 10/1986	CHU et al.			
	4,622,964	11/1986	/KCM/ FLYNN			
	4,630,604	12/1986	MONTESI			
	4,641,645	02/1987	TAYEBI			
	4,641,647	02/1987	BEHAN			
	4,655,213	04/1987	RAPOPORT et al.			
	4,657,010	04/1987	WRIGHT			
	4,660,555	04/1987	PAYTON			
	4,665,570	05/1987	DAVIS			
	4,671,267	06/1987	STOUT			
	4,671,271	06/1987	BISHOP et al.			
	4,674,134	06/1987	LUNDIN			
	4,676,241	06/1987	WEBB et al.			
	4,677,975	07/1987	EDGAR et al.			
	4,677,977	07/1987	WILCOX			
	4,686,977	08/1987	COSMA			
	4,699,139	10/1987	MARSHALL et al.			
	4,706,664	11/1987	SNOOK et al.			
	4,707,863	11/1987	McNEAL			
	4,711,636	12/1987	BIERMAN			
	4,713,844	12/1987	WESTGATE			
	4,739,755	04/1988	WHITE et al.			
	4,753,233	06/1988	GRIMES			
	4,767,411	08/1988	EDMUNDS			
	4,770,169	09/1988	SCHMOEGNER et al.			
	4,772,760	09/1988	GRAHAM			
	4,774,941	10/1988	COOK			
	4,774,946	11/1988 10/1988	ACKERMAN et al.			
	4,782,832	11/1988	/KCM/ TRIMBLE et al.			
	4,790,829	12/1988	BOWDEN et al.			
	4,799,477	01/1989	LEWIS			
	4,802,857	02/1989	LAUGHLIN			
	4,803,981	02/1989	VICKERY			
	4,807,617	02/1989	NESTI			
	4,809,692	03/1989	NOWACKI et al.			
	4,811,730	03/1989	MILANO			

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	D'SOUZA et al.	
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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	4,819,629	04/1989	JONSON			
	4,821,713	04/1989	BAUMAN			
	4,827,924	05/1989	JAPUNTICH			
	4,830,138	05/1989	PALMAER et al.			
	4,832,017	05/1989	SCHNOOR			
	4,838,878	06/1989	KALT et al.			
	4,841,953	06/1989	DODRILL			
	4,848,334	07/1989	BELLM			
	4,848,366	07/1989	AITA et al.			
	4,850,346	07/1989	MICHEL et al.			
	4,856,118	08/1989	SAPIEJEWSKI			
	4,886,058	12/1989	BROMSTROM et al.			
	4,899,740	02/1990	NAPOLITANO			
	4,905,683	03/1990	CRONJAEGER			
	4,907,584	03/1990	MCGINNIS			
	4,910,806	03/1990	BAKER et al.			
	4,914,957	04/1990	DOUGHERTY			
	4,915,105	04/1990	LEE			
	4,915,106	04/1990	AULGUR et al.			
	4,919,128	04/1990	KOPALA et al.			
	4,919,654	04/1990	KALT			
	4,938,210	07/1990	SHENE			
	4,938,212	07/1990	SNOOK et al.			
	4,941,476	07/1990	FISHER			
	4,944,310	07/1990	SULLIVAN			
	4,945,907	08/1990	TAYEBI			
	4,947,860	08/1990	FISHER			
	4,960,121	10/1990	NELSON et al.			
	4,966,590	10/1990	KALT			
	4,969,880	11/1990	ZAMIEROWSKI			
	4,971,051	11/1990	TOFFOLON			
	4,976,698	12/1990	STOKLEY			
	4,986,269	01/1991	HAKKINEN			
	4,989,271	02/1991	SAPIEJEWSKI et al.			
	4,989,596	02/1991	MACRIS et al.			
	4,989,599	02/1991	CARTER			
	4,996,983	03/1991	AMRHEIN			

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	FILING DATE	TC/A.U.
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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,000,173	03/1991	ZALKIN et al.			
	5,003,631	04/1991	RICHARDSON			
	5,003,633	04/1991	ITOHI			
	5,005,568	04/1991	LOESCHER et al.			
	5,005,571	04/1991	DIETZ			
	5,018,519	05/1991	BROWN			
	5,020,163	06/1991	AILEO et al.			
	5,022,900	06/1991	BAR-YONA et al.			
	5,023,955	06/1991	MURPHY, II et al.			
	5,025,805	06/1991	NUTTER			
	5,027,809	07/1991	ROBINSON			
	5,038,772	08/1991	KOLBE et al.			
	5,038,776	08/1991	HARRISON et al.			
	5,042,473	08/1991	LEWIS			
	5,042,478	08/1991	KOPALA et al.			
	5,046,200	09/1991	FEDER			
	5,046,491	09/1991	DERRICK			
	5,062,421	11/1991	BURNS et al.			
	5,063,922	11/1991	HAKKINEN			
	5,069,205	12/1991	URSO			
	5,074,297	12/1991	VENEGAS			
	5,080,092	01/1992	TENNA			
	5,093,940	03/1992	NISHIYAMA			
	5,109,839	05/1992	BLASDELL et al.			
	5,109,840	05/1992	DALEIDEN			
	5,113,857	05/1992	DICKERMAN et al.			
	5,117,818	06/1992	PALFY			
	5,121,745	06/1992	ISRAEL			
	5,121,746	06/1992	SIKORA			
	5,123,677	06/1992	KRECZKO et al.			
	5,127,397	07/1992	KOHNKE			
	5,133,347	07/1992	HUENNEBECK			
	5,137,017	08/1992	SALTER			
	5,138,722	08/1992	URELLA et al.			
	5,140,980	08/1992	HAUGHEY et al.			
	5,140,982	08/1992	BAUMAN			
	5,146,914	09/1992	STURROCK			

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(Use several sheets if necessary)	D'SOUZA et al.	
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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,159,938	11/1992	LAUGHLIN			
	5,178,138	01/1993	WALSTROM et al.			
	5,181,506	01/1993	TARDIFF, JR. et al.			
	5,188,101	02/1993	TUMOLO			
	5,199,424	04/1993	SULLIVAN et al.			
	5,207,665	05/1993	DAVIS et al.			
	5,220,699	06/1993	FARRIS			
	5,222,478	06/1993	SCARBERRY et al.			
	5,231,983	08/1993	MATSON et al.			
	5,233,978	08/1993	CALLAWAY			
	5,243,709	09/1993	SHEEHAN et al.			
	5,243,971	09/1993	SULLIVAN et al.			
	5,245,995	09/1993	SULLIVAN et al.			
	5,263,939	11/1993	WORTRICH			
	5,265,592	11/1993	BEAUSSANT			
	5,265,595	11/1993	RUDOLPH			
	5,267,557	12/1993	HER-MOU			
	5,269,296	12/1993	LANDIS			
	5,271,391	12/1993	GRAVES			
	5,279,289	01/1994	KIRK			
	5,280,784	01/1994	KOHLER			
	5,291,880	03/1994	ALMOVIST et al.			
	5,299,448	04/1994	MARYYANEK			
	5,299,579	04/1994	GEDEON et al.			
	5,299,599	04/1994	FARMER et al.			
	5,301,689	04/1994	WENNERHOLM			
	5,304,146	04/1994	JOHNSON et al.			
	5,311,862	05/1994	BLASDELL et al.			
	5,322,057	06/1994	RAABE et al.			
	5,322,059	06/1994	WALTHER			
	5,331,691	07/1994	RUNCKEL			
	5,334,646	08/1994	CHEN			
	5,335,656	08/1994	BOWE et al.			
	5,343,878	09/1994	SCARBERRY et al.			
	5,349,949	09/1994	SCHEGERIN			
	5,353,789	10/1994	SCHLOBOHM			
	5,355,878	10/1994	GRIFFITHS et al.			
	5,355,893	10/1994	MICK et al.			

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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,357,945	05/2002	10/1994 MESSINA			
	5,357,951	10/1994	/KCM/ RATNER			
	5,364,367	11/1994	BANKS et al.			
	5,372,130	12/1994	STERN et al.			
	5,372,388	12/1994	GARGIULO			
	5,372,389	12/1994	TAM et al.			
	5,372,390	12/1994	CONWAY et al.			
	5,372,391	12/1994	BAST et al.			
	5,375,593	12/1994	PRESS			
	5,385,141	01/1995	GRANATIERO			
	5,388,571	02/1995	ROBERTS et al.			
	5,390,373	02/1995	FLORY			
	5,391,248	02/1995	BRAIN			
	5,394,568	03/1995	BROSTROM et al.			
	5,396,885	03/1995	NELSON			
	5,398,676	03/1995	PRESS et al.			
	5,400,776	03/1995	BARTHOLOMEW			
	5,400,781	03/1995	DAVENPORT			
	5,404,871	04/1995	GOODMAN et al.			
	5,419,317	05/1995	BLASDELL et al.			
	5,419,318	05/1995	TAYEBI			
	5,425,359	06/1995	LIQU			
	5,429,126	07/1995	BRACKEN			
	5,429,683	07/1995	LE MITOUARD			
	5,431,158	07/1995	TIROTTA			
	5,437,267	08/1995	WEINSTEIN et al.			
	5,438,981	08/1995	STARR et al.			
	5,441,046	08/1995	STARR et al.			
	5,462,528	10/1995	ROEWER			
	5,477,852	12/1995	LANDIS et al.			
	5,479,920	01/1996	PIPER et al.			
	5,481,763	01/1996	BROSTROM et al.			
	5,485,837	01/1996	SOLES BEE et al.			
	5,488,948	02/1996	DUBRUILLE et al.			
	5,492,116	02/1996	SCARBERRY et al.			
	5,501,214	03/1996	SABO			
	5,503,147	04/1996	BERTHEAU			
	5,509,404	04/1996	LLOYD et al.			

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	D'SOUZA et al.	
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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,509,409	04/1996	WEATHERHOLT			
	5,511,541	04/1996	DEARSTINE			
	5,513,634	05/1996	JACKSON			
	5,513,635	05/1996	BEDI			
	5,517,986	05/1996	STARR et al.			
	5,522,382	06/1996	SULLIVAN et al.			
	5,526,806	06/1996	SANSONI			
	5,533,506	07/1996	WOOD			
	5,538,000	07/1996	RUDOLPH			
	5,538,001	07/1996	BRIDGES			
	5,540,223	07/1996	STARR et al.			
	5,542,128	08/1996	LOMAS			
	5,546,936	08/1996	VIRAG et al.			
	5,558,090	09/1996	JAMES			
	5,560,354	10/1996	BERTHON-JONES et al.			
	5,568,946	10/1996	JACKOWSKI			
	5,570,682	11/1996	JOHNSON			
	5,570,684	11/1996	BEHR			
	5,570,689	11/1996	STARR et al.			
	5,575,278	11/1996	BONHOMME et al.			
	5,592,937	01/1997	FREUND			
	5,592,938	01/1997	SCARBERRY et al.			
	5,608,647	03/1997	RUBSAMEN et al.			
	5,617,849	04/1997	SPRINGETT et al.			
	5,623,923	04/1997	BERTHEAU et al.			
	5,642,726	07/1997	OWENS et al.			
	5,642,730	07/1997	BARAN			
	5,645,054	07/1997	COTNER et al.			
	5,647,355	07/1997	STARR et al.			
	5,647,356	07/1997	BARNETT et al. OSENDORF et al. /KCM/			
	5,647,357	07/1997	BARNETT et al.			
	5,649,532	07/1997	GRIFFITHS			
	5,649,533	07/1997	OREN			
	5,653,228	08/1997	BYRD			
	5,655,520	08/1997	HOWE et al.			
	5,655,527	08/1997	SCARBERRY et al.			
	5,657,493	08/1997	FERRERO et al.			
	5,657,752	08/1997	LANDIS et al.			

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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,660,171	08/1997	KIMM et al.			
	5,660,174	08/1997	JACOBELLI			
	5,662,101	09/1997	OGDEN et al.			
	5,666,946	09/1997	LANGENBACK			
	5,676,133	10/1997	HICKLE et al.			
	5,682,881	11/1997	WINTHROP et al.			
	5,685,296	11/1997	ZDROJKOWSKI et al.			
	5,687,715	11/1997	LANDIS et al.			
	5,704,345	01/1998	BERTHON-JONES			
	5,707,342	01/1998	TANAKA			
	5,709,204	01/1998	LESTER			
	5,715,814	02/1998	EBERS			
	5,724,964	03/1998	BRUNSON et al.			
	5,724,965	03/1998	HANDKE et al.			
	5,735,272	04/1998	DILLON et al.			
	5,740,799	04/1998	NIELSON			
	5,746,201	05/1998	KIDD			
	5,752,509	05/1998	LACHMANN et al.			
	5,752,511	05/1998	SIMMONS et al.			
	5,778,872	07/1998	FUKUNAGA et al.			
	5,782,774	07/1998	SHMULEWITZ			
	5,794,615	08/1998	ESTES			
	5,794,617	08/1998	BRUNELL et al.			
	5,794,619	08/1998	EDEIMAN et al.			
	5,807,341	09/1998	HEIM			
	5,813,423	09/1998	KIRCHGEORG			
	5,832,918	11/1998	PANTINO			
	5,842,469	12/1998	RAPP et al.			
	5,884,624	03/1999	BARNETT et al.			
	5,887,587	03/1999	GROENKE			
	5,896,857	04/1999	HELY et al.			
	5,906,203	05/1999	KLOCKSETH et al.			
	5,909,732	06/1999	DIESEL et al.			
	5,918,598	07/1999	BELFER et al.			
	5,935,136	08/1999	HULSE et al.			
	5,937,445	08/1999	RAVO et al.			
	5,937,851	08/1999	SEROWSKI et al.			
	5,954,049	09/1999	FOLEY et al.			

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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,964,485	10/1999	HAME et al.			
	5,966,745	10/1999	SCHWARTZ et al.			
	5,970,975	10/1999	ESTES et al.			
	5,975,079	11/1999	HELLINGS et al.			
	6,003,511	12/1999	FUKUNAGA et al.			
	6,006,748	12/1999	HOLLIS			
	6,016,804	01/2000	GLEASON et al.			
	6,019,101	02/2000	COTNER et al.			
	6,026,811	02/2000	SETTLE			
	6,029,660	02/2000	CALLUAUD et al.			
	6,029,665	02/2000	BERTHON-JONES			
	6,039,044	03/2000	SULLIVAN			
	6,044,844	04/2000	KWOK et al.			
	6,082,360	07/2000	RUDOLPH et al.			
	6,086,118	07/2000	McNAUGHTON et al.			
	6,091,973	07/2000	COLLA et al.			
	6,095,996	08/2000	STEER et al.			
	6,102,040	08/2000	TAYEBI et al.			
	6,109,263	08/2000	FEUCHTGRUBER			
	6,112,746	09/2000	KWOK et al.			
	6,119,693	09/2000	KWOK et al.			
	6,119,694	09/2000	CORREA et al.			
	6,123,071	09/2000	BERTHON-JONES et al.			
	6,123,082	09/2000	BERTHON-JONES			
	6,139,787	10/2000	HARRISON			
	6,152,137	11/2000	SCHWARTZ et al.			
	6,155,253	12/2000	GAMBERINI			
	6,192,886	02/2001	RUDOLPH			
	6,193,914	02/2001	HARRISON			
	6,196,223	03/2001	BELFER et al.			
	6,211,263	04/2001	CINELLI et al.			
	6,213,125	04/2001	REESE et al.			
	6,231,548	05/2001	BASSETT			
	6,241,930	06/2001	HARRISON			
	6,257,237	07/2001	SUZUKI			
	6,257,626	07/2001	CAMPAU			
	6,258,066	07/2001	URICH			
	6,279,573	08/2001	JOHNSON et al.			

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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	6,295,366	09/2001	BALLER et al.			
	6,328,031	12/2001	TISCHER et al.			
	6,328,038	12/2001	KESSLER et al.			
	6,340,024	01/2002	BROOKMAN et al.			
	6,341,606	01/2002	BORDEWICK et al.			
	6,345,618	02/2002	HAYEK			
	6,347,631	02/2002	HANSEN et al.			
	6,357,440	03/2002	HANSEN et al.			
	6,357,441	03/2002	KWOK et al.			
	6,358,279	03/2002	TAHI et al.			
	6,371,110	04/2002	PETERSON et al.			
	6,374,826	04/2002	GUNARATNAM et al.			
	6,388,640	05/2002	CHIGIRA et al.			
	6,397,847	06/2002	SCARBERRY et al.			
	6,412,487	07/2002	GUNARATNAM et al.			
	6,412,488	07/2002	BARNETT et al.			
	6,412,593	07/2002	JONES			
	6,418,928	07/2002	BORDEWICK et al.			
	6,419,660	07/2002	RUSSO			
	6,422,238	07/2002	LITHGOW			
	6,423,036	07/2002	VAN HUZEN			
	6,425,395	07/2002	BREWER et al.			
	6,427,694	08/2002	HECKER et al.			
	6,431,172	08/2002	BORDEWICK			
	6,434,796	08/2002	SPEIRS			
	6,439,230	08/2002	GUNARATNAM et al.			
	6,439,234	08/2002	CURTI et al.			
	6,448,303	09/2002	PAUL			
	6,463,931	10/2002	KWOK et al.			
	6,467,482	10/2002	BOUSSIGNAC			
	6,467,483	10/2002	KOPACKO et al.			
	6,470,887	10/2002	MARTINEZ			
	6,478,026	11/2002	WOOD			
	6,482,178	11/2002	ANDREWS et al.			
	6,491,034	12/2002	GUNARATNAM et al.			
	6,513,526	02/2003	KWOK et al.			
	6,520,182	02/2003	GUNARATNAM			
	6,530,373	03/2003	PATRON et al.			

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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	6,532,961	03/2003	KWOK et al.			
	6,536,435	03/2003	FECTEAU et al.			
	6,557,556	05/2003	KWOK et al.			
	6,561,188	05/2003	ELLIS			
	6,561,190	05/2003	KWOK			
	6,561,191	05/2003	KWOK			
	6,561,192	05/2003	PALMER			
	6,561,193	05/2003	NOBLE			
	6,571,798	06/2003	THORNTON			
	6,579,267	06/2003	LYNCH et al.			
	6,581,601	06/2003	ZIAEE			
	6,581,602	07/2003	6/2003 KWOK et al.			
	6,584,975	07/2003	/KCM/ TAYLOR			
	6,595,214	07/2003	HECKER et al.			
	6,595,215	07/2003	WOOD			
	6,607,516	08/2003	CINELLI et al.			
	6,615,830	09/2003	SEROWSKI et al.			
	6,615,832	09/2003	CHEN			
	6,626,177	09/2003	ZIAEE			
	6,627,289	09/2003	DILNIK et al.			
	6,631,718	10/2003	LOVELL			
	6,634,358	10/2003	KWOK et al.			
	6,637,434	10/2003	NOBLE			
	6,644,315	11/2003	ZIAEE			
	6,651,663	11/2003	BARNETT et al.			
	6,655,385	12/2003	CURTI et al.			
	6,663,600	12/2003	BIERMAN et al.			
	6,669,712	12/2003	CARDOSO			
	6,679,257	01/2004	ROBERTSON et al.			
	6,679,261	01/2004	LITHGOW			
	6,679,265	01/2004	STRICKLAND et al.			
	6,691,707	02/2004	GUNARATNAM et al.			
	6,691,708	02/2004	KWOK et al.			
	6,701,535	03/2004	DOBBIE et al.			
	6,701,926	03/2004	OLSEN et al.			
	6,701,927	03/2004	KWOK et al.			
	6,710,099	03/2004	CINELLI et al.			

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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	7,207,335	04/2007	KWOK et al			
	6,712,072	03/2004	LANG (corres. to WO 99/43375)			
	6,729,333	05/2004	BARNETT et al.			
	6,766,800	07/2004	CHU et al.			
	6,766,817	07/2004	da SILVA			
	6,772,760	08/2004	FRATER et al.			
	6,776,162	08/2004	WOOD			
	6,776,163	08/2004	DOUGILL et al.			
	6,789,543	09/2004	CANNON			
	6,796,308	09/2004	GUNARATNAM et al.			
	6,805,117	10/2004	HO et al.			
	6,807,967	10/2004	WOOD			
	6,817,362	11/2004	GELINAS et al.			
	6,820,617	11/2004	ROBERTSON et al.			
	6,823,865	11/2004	DREW et al.			
	6,823,869	11/2004	RAJE et al.			
	6,834,650	12/2004	FINI			
	6,851,425	02/2005	JAFFRE			
	6,851,428	02/2005	DENNIS			
	6,851,429	02/2005	BISHOP			
	6,860,269	03/2005	KWOK et al.			
	6,860,270	03/2005	SNIADICH			
	6,871,649	03/2005	KWOK et al.			
	6,892,729	05/2005	SMITH et al.			
	6,895,965	05/2005	SCARBERRY et al.			
	6,907,882	06/2005	GING			
	6,914,091	07/2005	DONALD et al.			
	6,918,404	07/2005	DIAS da SILVA			
	6,926,004	08/2005	SCHUMACHER			
	6,938,620	09/2005	PAYNE, JR.			
	6,959,710	11/2005	BARNETT et al.			
	6,968,844	11/2005	LILAND			
	6,972,003	12/2005	BIERMAN et al.			
	6,986,352	01/2006	FRATER et al.			
	6,997,177	02/2006	WOOD			
	7,000,614	02/2006	LANG et al.			
	7,007,696	03/2006	PALKON et al.			

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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	7,011,090	03/2006	DREW et al.			
	7,018,362	03/2006	BIERMAN et al.			
	7,040,321	05/2006	GOEBEL			
	7,052,127	05/2006	HARRISON			
	7,059,326	06/2006	HEIDMANN et al.			
	7,066,586	06/2006	da SILVA			
	7,069,932	07/2006	EATON et al.			
	7,076,282	07/2006	MUNRO et al.			
	7,076,822	07/2006	PEARCE			
	7,080,645	07/2006	GENGER et al.			
	7,093,599	08/2006	CHEN			
	7,100,610	09/2006	BIENER et al.			
	7,101,359	09/2006	KLINE et al.			
	7,107,989	09/2006	FRATER et al.			
	7,114,497	10/2006	AYLSWORTH et al.			
	7,146,976	12/2006	McKOWN			
	7,152,599	12/2006	THOMAS			
	7,152,601	12/2006	BARAKAT et al.			
	7,178,525	02/2007	MATULA, JR. et al.			
	7,185,652	03/2007	GUNARATNAM et al.			
	7,191,781	03/2007	WOOD			
	7,207,328	04/2007	ALTEMUS			
	7,210,481	05/2007	LOVELL et al.			
	7,216,647	05/2007	LANG et al.			
	7,237,551	07/2007	HO et al.			
	7,243,723	07/2007	SURJAATMADJA			
	7,285,255	10/2007	KADLEC et al.			
	7,302,950	12/2007	BERTHON-JONES et al.			
	7,308,895	12/2007	WIXEY et al.			
	7,318,437	01/2008	GUNARATNAM			
	7,318,439	01/2008	RAJE et al.			
	7,320,323	01/2008	LANG et al.			
	7,341,060	03/2008	GING et al.			
	7,353,826	04/2008	SLEEPER et al.			
	7,441,618	12/2006	LUDKE et al.			
	7,461,656	12/2008	GUNARATNAM et al.			
	7,470,256	12/2008	LAMPROPOULOS et al.			
	7,481,220	01/2009	MEYER et al.			

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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	7,487,772	02/2009	GING et al.			
	7,503,327	03/2009	GUNARATNAM			
	7,509,958	03/2009	AMARASINGHE et al.			
	7,520,869	04/2009	LAMPROPOULOS et al.			
	7,523,754	04/2009	LITHGOW			
	7,562,658	07/2009	MADAUS et al.			
	7,614,400	11/2009	LITHGOW et al.			
	7,614,401	11/2009	THOMPSON			
	7,621,274	11/2009	SPRINKLE et al.			
	7,624,735	12/2009	HO et al.			
	7,640,934	01/2010	ZOLLINGER et al.			
	7,654,263	02/2010	LANG et al.			
	7,658,189	02/2010	DAVIDSON et al.			
	7,665,464	02/2010	KOPACKO et al.			
	7,699,808	04/2010	MARRS et al.			
	7,703,457	04/2010	BARNETT et al.			
	7,708,017	05/2010	DAVIDSON			
	7,743,767	06/2010	GING et al.			
	7,775,209	08/2010	BIENER et al.			
	7,762,259	07/2010	GUNARATNAM			
	7,779,832	08/2010	HO			
	7,798,144	09/2010	KWOK et al.			
	7,814,911	10/2010	BORDEWICK et al.			
	7,819,119	10/2010	HO			
	7,827,990	11/2010	MELIDIS et al.			
	7,841,345	11/2010	GUNEY et al.			
	7,856,980	12/2010	LANG et al.			
	7,856,982	12/2010	MATULA, JR. et al.			
	7,861,715	01/2011	JONES et al.			
	7,874,293	01/2011	GUNARATNAM et al.			
	7,878,199	02/2011	GING et al.			
	7,900,631	03/2011	PERSSON			
	7,900,635	03/2011	GUNARATNAM et al.			
	7,931,024	04/2011	HO et al.			
	7,958,893	06/2011	LITHGOW et al.			
	7,967,013	06/2011	GING et al.			
	7,967,014	06/2011	HEIDMANN et al.			
	7,971,590	07/2011	FRATER et al.			

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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	7,992,559	08/2011	LANG et al.			
	7,997,267	08/2011	GING et al.			
	8,042,538	10/2011	GING et al.			
	8,042,541	10/2011	AMARASINGHE et al.			
	8,042,542	10/2011	GING et al.			
	8,042,546	10/2011	GUNARATNAM et al.			
	8,051,850	11/2011	KWOK et al.			
	8,091,553	01/2012	BORDEWICK et al.			
	8,096,301	01/20012	SMITH et al.			
	8,136,524	03/2012	GING et al.			
	8,136,525	03/2012	LUBKE et al.			
	8,186,352	05/2012	GUNARATNAM et al.			
	8,210,180	07/2012	GUNARATNAM			
	8,220,459	07/2012	DAVIDSON et al.			
	H397	01/1988	STARK			
	US 2001/0020474	09/2001	HECKER et al.			
	US 2002/0020416	02/2002	NAMEY			
	US 2002/0029780	03/2002	FRATER et al.			
	US 2002/0046755	04/2002	DEVOSS			
	US 2002/0066452	06/2002	KESSLER et al.			
	US 2002/0069872	06/2002	GRADON et al.			
	US 2002/0124849	09/2002	BILLETTE de VILLEMEUR			
	US 2002/0143296	10/2002	RUSSO			
	US 2002/0157673	10/2002	KESSLER et al.			
	US 2002/0174868	11/2002	KWOK et al.			
	US 2003/0019495	01/2003	PALKON et al.			
	US 2003/0062048	04/2003	GRADON et al.			
	US 2003/0089373	05/2003	GRADON et al.			
	US 2003/0168063	09/2003	GAMBONE et al.			
	US 2003/0196656	10/2003	MOORE et al.			
	US 2003/0196658	10/2003	GING et al.			
	US 2004/0025883	02/2004	EATON et al.			
	US 2004/0094157	05/2004	DANTANARAYANA et al.			
	US 2004/0106891	06/2004	LANGAN et al.			
	US 2004/0111104	06/2004	SCHEIN et al.			
	US 2004/0112384	06/2004	LITHGOW et al.			
	US 2004/0112385	06/2004	DREW et al.			

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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	US 2004/0127856	07/2004	JOHNSON			
	US 2004/0177850	09/2004	GRADON et al.			
	US 2004/0182398	09/2004	SPRINKLE et al.			
	US 2004/0211428	10/2004	JONES			
	US 2004/0226566	11/2004	GUNARATNAM et al.			
	US 2005/0051171	03/2005	BOOTH			
	US 2005/0051176	03/2005	RIGGINS			
	US 2005/0056286	03/2005	HUDDART et al.			
	US 2005/0061326	03/2005	PAYNE, JR.			
	US 2005/0098183	05/2005	NASH et al.			
	US 2005/0150495	07/2005	RITTNER et al.			
	US 2005/0155604	07/2005	GING et al.			
	US 2005/0211252	09/2005	LANG et al.			
	US 2005/0241644	11/2005	GUNARATNAM et al.			
	US 2006/0076017	04/2006	WALKER et al.			
	US 2006/0272646	12/2006	HO et al.			
	US 2006/0124131	06/2006	CHANDRAN et al.			
	US 2006/0137690	06/2006	GUNARATNAM et al.			
	US 2006/0174887	08/2006	CHANDRAN et al.			
	US 2006/0207597	09/2006	WRIGHT			
	US 2006/0213520	09/2006	FRATER et al.			
	US 2006/0283461	12/2006	LUBKE et al.			
	US 2007/0137653	06/2007	WOOD			
	US 2007/0144525	06/2007	DAVIDSON et al.			
	US 2007/0215161	09/2007	FRATER et al.			
	US 2007/0272249	11/2007	CHANDRAN et al.			
	US 2007/0282272	12/2007	BANNON et al.			
	US 2008/0004573	01/2008	KAUFMANN et al.			
	US 2008/0006277	01/2008	WORBOYS et al.			
	US 2008/0047560	02/2008	VELISS et al.			
	US 2008/0060649	03/2008	VELISS et al.			
	US 2008/0065022	03/2008	KYVIK et al.			
	US 2008/0110464	05/2008	DAVIDSON et al.			
	US 2008/0110469	05/2008	WEINBERG			
	US 2008/0178886	07/2008	LIEBERMAN et al.			
	US 2008/0200880	08/2008	KYVIK et al.			
	US 2008/0257354	10/2008	DAVIDSON et al.			
	US 2008/0314389	12/2008	THOMAS et al.			

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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	US 2009/0044808	02/2009	GUNEY et al.			
	US 2009/0126739	05/2009	NG. et al			
	US 2009/0139526	06/2009	MELIDIS et al.			
	US 2009/0138527	06/2009	NG et al.			
	US 2009/0173343	07/2009	OMURA et al.			
	US 2009/0217929	09/2009	KWOK et al.			
	US 2009/0223518	09/2009	KWOK et al.			
	US 2009/0223521	09/2009	HOWARD et al.			
	US 2010/0000534	01/2010	KOOIJ et al.			
	US 2010/0000543	01/2010	BERTHON-JONES et al.			
	US 2010/0018534	01/2010	VELISS et al.			
	US 2010/0089401	04/2010	LANG et al.			
	US 2010/0132717	06/2010	DAVIDSON et al.			
	US 2010/0192955	08/2010	BIENER et al.			
	US 2010/0282265	11/2010	MELIDIS et al.			
	US 2010/0300447	12/2010	BIENER et al.			
	US 2010/0319700	12/2010	NG et al.			
	US 2011/0030692	02/2011	JONES et al.			
	US 2011/0056497	03/2011	SCHEINER et al.			
	US 2011/0220110	09/2011	FRATER et al.			
	US 2011/0220114	09/2011	LITHGOW et al.			
	US 2011/0226254	09/2011	LANG et al.			
	US 2011/0259337	10/2011	HITCHCOCK et al.			
	US 2012/0174928	07/2012	RAJE et al.			
	US 2012/0266886	10/2012	DAVIDSON et al.			
	US 2013/0133658	05/2013	NG et al.			
	US 2013/0133660	05/2013	NG et al.			
	D156,060	11/1949	WADE			
	D161,337	12/1950	HILL			
	D188,084	05/1960	GARELICK			
	D231,803	06/1974	HUDDY			
	D248,497	07/1978	SLOSEK			
	D250,131	10/1978	LEWIS et al.			
	D262,322	12/1981	MIZERAK			
	D285,496	09/1986	BERMAN			
	D289,238	04/1987	ARTHUR, JR.			
	D293,613	01/1988	WINGLER			
	D304,384	10/1989	DEROBERT			

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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	D310,431	09/1990	BELLM			
	D313,277	12/1990	HAINING			
	D323,908	02/1992	HOLLISTER et al.			
	D333,015	02/1993	FARMER et al.			
	D334,633	04/1993	RUDOLPH			
	D335,322	05/1993	JONES			
	D349,586	08/1994	HANDKE			
	D362,061	09/1995	McGINNIS et al.			
	D377,089	12/1996	STARR et al.			
	D385,960	11/1997	RUDOLPH			
	D389,238	01/1998	KIRK, III et al.			
	D398,987	09/1998	COTNER et al.			
	D402,755	12/1998	KWOK			
	D412,745	08/1999	SCHEU			
	D419,658	01/2000	MATCHETT et al.			
	D421,298	02/2000	KENYON et al.			
	D423,096	04/2000	KWOK			
	D428,987	08/2000	KWOK			
	D439,326	03/2001	HECKER et al.			
	D443,355	06/2001	GUNARATNAM et al.			
	D468,823	01/2003	SMART			
	D484,237	12/2003	LANG et al.			
	D485,905	01/2004	MOORE et al.			
	D492,992	07/2004	GUNEY et al.			
	D493,521	07/2004	GUNEY			
	D550,836	09/2007	CHANDRAN et al.			
	D552,733	10/2007	CRISCUOLO et al.			
	RE 24,193	08/1956	EMERSON			
	RE 35,339	10/1996	RAPOPORT			
	RE 36,165	03/1999	BEHR			
	8,297,283	10/2012	HITCHCOCK et al.			
	8,397,728	03/2013	D'SOUZA et al.			
	US-13/834,189	03/2013	HITCHCOCK et al.			
	US-13/870,678	04/2013	KWOK et al.			
	US-2007/0044804	03/2007	MATULA, JR. et al.			
	US-2007/0221226	09/2007	HANSEN et al.			
	US-2008/0178875	07/2008	HENRY			
	US-2008/0302365	12/2008	COHEN et al.			

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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	US-2012/0138063	06/2012	EVES et al.			
	US-2013/0037033	02/2013	HITCHCOCK et al.			
	US-2013/0081628	04/2013	DAVIDSON et al.			
	US-2013/0081629	04/2013	DAVIDSON et al.			
	US-2013/0081630	04/2013	DAVIDSON et al.			
	US-2013/0081631	04/2013	DAVIDSON et al.			
	US-2013/0081632	04/2013	DAVIDSON et al.			
	US-2013/0086795	04/2013	DAVIDSON et al.			
	US-2013/0086796	04/2013	DAVIDSON et al.			
	US-2013/0087147	04/2013	DAVIDSON et al.			
	US-2013/0087148	04/2013	DAVIDSON et al.			
	US-2013/0087149	04/2013	DAVIDSON et al.			
	US-2013/0092168	04/2013	DAVIDSON et al.			
	US-2013/0092170	04/2013	DAVIDSON et al.			

FOREIGN PATENT DOCUMENTS

DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
					YES	NO
AU 91/77110	11/1991	AUSTRALIA				
AU 94/64816	12/1994	AUSTRALIA				
AU 95/16178	07/1995	AUSTRALIA				
AU 94/59430	10/1995	AUSTRALIA				
AU 95/32914	02/1996	AUSTRALIA				
AU 96/51130	10/1996	AUSTRALIA				
AU 97/41018	04/1998	AUSTRALIA				
AU 98/89312	01/1999	AUSTRALIA				
AU 2005100738	11/2005	AUSTRALIA				
AU 2006/00031 (WO 2007/045008)	01/2006 (04/2007)	AUSTRALIA				
CA 618807	04/1961	CANADA				
CA 623129	07/1961	CANADA				
CA 1039144	09/1978	CANADA				
CN 2464353	12/2001	CHINA				
CN 1219883	06/1999	CHINA				
CN 1735439	02/2006	CHINA				
DD 146 688	01/1981	EAST GERMANY				
DD 159 396	03/1983	EAST GERMANY				
EP 0 054 154	06/1982	EUROPE				

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		DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
		EP 0 252 052	01/1988	EUROPE				
		EP 0 264 772	04/1988	EUROPE				
		EP 0 288 937	11/1988	EUROPE				
		EP 0 334 555	09/1989	EUROPE				
		EP 0 386 605	09/1990	EUROPE				
		EP 0 427 474	05/1991	EUROPE				
		EP 0 462 701	12/1991	EUROPE				
		EP 0 466 960	01/1992	EUROPE				
		EP 0 303 090 B1	04/1992	EUROPE				
		EP 0 549 299	06/1993	EUROPE				
		EP 0 602 424	06/1994	EUROPE				
		EP 0 608 684	08/1994	EUROPE				
		EP 0 658 356	06/1995	EUROPE				
		EP 0 697 225	02/1996	EUROPE				
		EP 0 178 925 A2	04/1996	EUROPE				
		EP 0 747 078	12/1996	EUROPE				
		EP 0 776 679	06/1997	EUROPE				
		EP 0 821 978	02/1998	EUROPE				
		EP 0 853 962	07/1998	EUROPE				
		EP 1 027 905	08/2000	EUROPE				
		EP 1 057 494	12/2000	EUROPE				
		EP 1 099 452	05/2001	EUROPE				
		EP 1 118 346	07/2001	EUROPE				
		EP 1 163 923	12/2001	EUROPE				
		EP 1 205 205	05/2002	EUROPE				
		EP 1 258 266	11/2002	EUROPE				
		EP 1 356 843	10/2003	EUROPE				
		EP 1 360 971	11/2003	EUROPE				
		EP 1 481 702	12/2004	EUROPE				
		EP 2 471 566	07/2012	EUROPE				
		EP 2 471 567	07/2012	EUROPE				
		FR 780018	04/1935	FRANCE				
		FR 2 574 657	06/1986	FRANCE				
		FR 2 658 725	08/1991	FRANCE				
		FR 2 720 280	12/1995	FRANCE				
		FR 2 749 176	12/1997	FRANCE				
		FR 2 823 122	10/2002	FRANCE				

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					CLASS	SUBCLASS	TRANSLATION	
							YES	NO
		DE 185 017	05/1907	GERMANY				
		DE 284 800	11/1913	GERMANY				
		DE 459 104	04/1928	GERMANY				
		DE 701 690	01/1941	GERMANY				
		DE 30 11 900	10/1980	GERMANY				
		DE 30 15 279	10/1981	GERMANY				
		DE 31 49 449	10/1982	GERMANY				
		DE 33 45 067	06/1984	GERMANY				
		DE 37 07 952	03/1987	GERMANY				
		DE 35 37 507	04/1987	GERMANY				
		DE 35 39 073	05/1987	GERMANY				
		DE 37 19 009	12/1988	GERMANY				
		DE 39 27 038	02/1991	GERMANY				
		DE 40 04 157	04/1991	GERMANY				
		DE 42 12 259	01/1993	GERMANY				
		DE 42 33 448	04/1993	GERMANY				
		DE 43 43 205	06/1995	GERMANY				
		DE 195 48 380	07/1996	GERMANY				
		DE 196 03 949	08/1997	GERMANY				
		DE 297 15 718	10/1997	GERMANY				
		DE 197 35 359	01/1998	GERMANY				
		DE 297 23 101	07/1998	GERMANY				
		DE 197 03 526	08/1998	GERMANY				
		DE 298 10 846	08/1998	GERMANY				
		DE 198 17 332	01/1999	GERMANY				
		DE 198 07 961	08/1999	GERMANY				
		DE 198 08 105	09/1999	GERMANY				
		DE 198 40 760	03/2000	GERMANY				
		DE 200 05 346	05/2000	GERMANY				
		DE 299 23 141	05/2000	GERMANY				
		DE 200 17 940	02/2001	GERMANY				
		DE 199 44 242	03/2001	GERMANY				
		DE 199 54 517	06/2001	GERMANY				
		DE 199 62 515	07/2001	GERMANY				
		DE 100 02 571	07/2001	GERMANY				
		DE 100 45 183	05/2002	GERMANY				
		DE 102 13 905	10/2002	GERMANY				
		DE 10 2004 055 433	11/2004	GERMANY				

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					CLASS	SUBCLASS	TRANSLATION	
							YES	NO
		DE 103 31 837	01/2005	GERMANY				
		DE 20 2004 018 108	02/2005	GERMANY				
		DE 103 38 169	03/2005	GERMANY				
		GB 532 214	01/1941	GREAT BRITAIN				
		GB 649 689	01/1951	GREAT BRITAIN				
		GB 823 887	11/1959	GREAT BRITAIN				
		GB 1 395 391	05/1975	GREAT BRITAIN				
		GB 1 467 828	03/1977	GREAT BRITAIN				
		GB 2 145 335	03/1985	GREAT BRITAIN				
		GB 2 147 506	05/1985	GREAT BRITAIN				
		GB 2 164 569	03/1986	GREAT BRITAIN				
		GB 2 176 404	12/1986	GREAT BRITAIN				
		GB 2 186 801	08/1987	GREAT BRITAIN				
		GB 2 267 648	12/1993	GREAT BRITAIN				
		GB 2 368 533	05/2002	GREAT BRITAIN				
		GB 2 385 533	05/2003	GREAT BRITAIN				
		JP S39-13991	07/1964	JAPAN				
		JP S51-142793	11/1976	JAPAN				
		JP H03-007173	01/1991	JAPAN				
		JP H09-216240	08/1997	JAPAN				
		JP H11-000397	01/1999	JAPAN				
		JP H11-104256	04/1999	JAPAN				
		JP H11-508159	07/1999	JAPAN				
		JP 2000-279520	10/2000	JAPAN				
		JP 2000-325481	11/2000	JAPAN				
		JP 2000-515784	11/2000	JAPAN				
		JP 2003-535657	12/2003	JAPAN				
		JP 2002-028240	04/2002	JAPAN				
		JP 2002-543943	12/2002	JAPAN				
		JP 2003-175106	06/2003	JAPAN				
		JP 2004-000570	01/2004	JAPAN				
		JP 2005-337371	12/2005	JAPAN				
		JP 3802872	07/2006	JAPAN				
		WO 00/35525	06/2000	PCT				
		WO 80/01044	05/1980	PCT				
		WO 82/03548	10/1982	PCT				
		WO 86/06969	12/1986	PCT				
		WO 87/01950	04/1987	PCT				

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	APPLICANT	
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		WO 91/03277	03/1991	PCT				
		WO 92/15353	09/1992	PCT				
		WO 92/20392	11/1992	PCT				
		WO 92/20395	11/1992	PCT				
		WO 93/01854	02/1993	PCT				
		WO 93/24169	12/1993	PCT				
		WO 94/02190	02/1994	PCT				
		WO 94/16759	08/1994	PCT				
		WO 94/20051	09/1994	PCT				
		WO 95/02428	01/1995	PCT				
		WO 96/17643	06/1996	PCT				
		WO 96/25983	08/1996	PCT				
		WO 96/28207	09/1996	PCT				
		WO 96/39206	12/1996	PCT				
		WO 97/00092	01/1997	PCT				
		WO 97/07847	03/1997	PCT				
		WO 97/09090	03/1997	PCT				
		WO 97/41911	11/1997	PCT				
		WO 98/03145	01/1998	PCT				
		WO 98/04310	02/1998	PCT				
		WO 98/11930	03/1998	PCT				
		WO 98/12965	04/1998	PCT				
		WO 98/18514	05/1998	PCT				
		WO 98/23305	06/1998	PCT				
		WO 98/24499	06/1998	PCT				
		WO 98/26829	06/1998	PCT				
		WO 98/26830	06/1998	PCT				
		WO 98/34665	08/1998	PCT				
		WO 98/48878	11/1998	PCT				
		WO 99/16327	04/1999	PCT				
		WO 99/25410	05/1999	PCT				
		WO 99/43375	09/1999	PCT				
		WO 99/58181	11/1999	PCT				
		WO 99/61088	12/1999	PCT				
		WO 99/65554	12/1999	PCT				
		WO 00/20072	04/2000	PCT				
		WO 00/21600	04/2000	PCT				
		WO 00/38772	07/2000	PCT				

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					CLASS	SUBCLASS	TRANSLATION	
							YES	NO
		WO 00/50121	08/2000	PCT				
		WO 00/57942	10/2000	PCT				
		WO 00/69521	11/2000	PCT				
		WO 00/72905	12/2000	PCT				
		WO 00/74758	12/2000	PCT				
		WO 00/76568	12/2000	PCT				
		WO 00/78381	12/2000	PCT				
		WO 00/78384	12/2000	PCT				
		WO 01/62326	08/2001	PCT				
		WO 01/95965	12/2001	PCT				
		WO 01/97892	12/2001	PCT				
		WO 01/97893	12/2001	PCT				
		WO 02/11804	02/2002	PCT				
		WO 02/32491	04/2002	PCT				
		WO 02/38221	05/2002	PCT				
		WO 02/45784	06/2002	PCT				
		WO 03/005931	01/2003	PCT				
		WO 03/059427	07/2003	PCT				
		WO 03/082406	10/2003	PCT				
		WO 03/090827	11/2003	PCT				
		WO 03/105921	12/2003	PCT				
		WO 2004/007010	01/2004	PCT				
		WO 2004/022144	03/2004	PCT				
		WO 2004/022145	03/2004	PCT				
		WO 2004/022146	03/2004	PCT				
		WO 2004/022147	03/2004	PCT				
		WO 2004/041342	05/2004	PCT				
		WO 2004/073778	09/2004	PCT				
		WO 2004/078228	09/2004	PCT				
		WO 2004/078230	09/2004	PCT				
		WO 2004/096332	11/2004	PCT				
		WO 2005/002656	01/2005	PCT				
		WO 2005/018523	03/2005	PCT				
		WO 2005/021075	03/2005	PCT				
		WO 2005/028010	03/2005	PCT				
		WO 2005/053781	06/2005	PCT				
		WO 2005/063326	07/2005	PCT				
		WO 2005/063328	07/2005	PCT				

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							YES	NO
		WO 2005/086943	09/2005	PCT				
		WO 2005/094928	10/2005	PCT				
		WO 2005/099801	10/2005	PCT				
		WO 2005/110220	11/2005	PCT				
		WO 2005/118040	12/2005	PCT				
		WO 2005/123166	12/2005	PCT				
		WO 2006/000046	01/2006	PCT				
		WO 2006/138416	12/2006	PCT				
		WO 2006/014630	02/2006	PCT				
		WO 2006/052653	05/2006	PCT				
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INFORMATION DISCLOSURE CITATION	ATTY. DOCKET NO.	SERIAL NO.
	PTB-4398-1485	Continuation of 13/964,280
	APPLICANT	
	D'SOUZA et al.	
(Use several sheets if necessary)	FILING DATE	TC/A.U.
	Herewith	Unassigned

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	Herewith	Unassigned

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	APPLICANT	
	D'SOUZA et al.	
(Use several sheets if necessary)	FILING DATE	TC/A.U.
	Herewith	Unassigned

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*Examiner		Date Considered	
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	D'SOUZA et al.	
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	Herewith	Unassigned

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	PTB-4398-1485	Continuation of 13/964,280
(Use several sheets if necessary)	APPLICANT	
	D'SOUZA et al.	
	FILING DATE	TC/A.U.
	Herewith	Unassigned

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*Examiner	Date Considered
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	Herewith	Unassigned

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(Use several sheets if necessary)	FILING DATE	TC/A.U.
	Herewith	Unassigned

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DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
					YES	NO

OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)


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*Examiner	/Kristen Matter/	Date Considered	01/26/2015
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Search Notes 	Application/Control No. 14447673	Applicant(s)/Patent Under Reexamination D'SOUZA ET AL.
	Examiner KRISTEN MATTER	Art Unit 3649

CPC- SEARCHED		
Symbol	Date	Examiner
A61M16/06, 16/0605, 16/0611, 16/0616, 16/0683	1/26/2015	KCM


CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
128	205.25, 206.21, 206.24, 206.28, 207.11	11/24/14	KCM
	Updated Search	1/26/2015	KCM

SEARCH NOTES		
Search Notes	Date	Examiner
Inventor name search	11/24/14	KCM

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

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<p><i>Index of Claims</i></p> 	<p>Application/Control No.</p> <p>14447673</p>	<p>Applicant(s)/Patent Under Reexamination</p> <p>D'SOUZA ET AL.</p>
	<p>Examiner</p> <p>KRISTEN MATTER</p>	<p>Art Unit</p> <p>3649</p>

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant
 ☐ CPA
 ☐ T.D.
 ☐ R.1.47

CLAIM		DATE									
Final	Original	11/24/2014	01/26/2015								
	1	✓	✓								
	2	✓	✓								
	3	✓	✓								
	4	✓	✓								
	5	✓	✓								
	6	✓	✓								
	7	✓	✓								
	8	✓	✓								
	9	✓	✓								
	10	✓	✓								
	11	✓	✓								
	12	✓	✓								
	13	✓	✓								
	14	✓	✓								
	15	✓	✓								
	16	✓	-								
	17	✓	✓								
	18	✓	✓								
	19	✓	✓								
	20	✓	-								
	21	✓	-								
	22		✓								
	23		✓								
	24		✓								
	25		✓								
	26		✓								
	27		✓								
	28		✓								
	29		O								
	30		✓								
	31		✓								
	32		✓								
	33		O								

[illegible][illegible][illegible]

*Examiner	/Kristen Matter/	Date Considered	01/22/2015
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Form PTO-FB-A820 (Also PTO/SB/08A)

244512

Electronic Patent Application Fee Transmittal				
Application Number:		14447673		
Filing Date:		31-Jul-2014		
Title of Invention:		MASK SYSTEM		
First Named Inventor/Applicant Name:		Errol Savio Alex D'SOUZA		
Filer:		Paul Thomas Bowen/Tanja Majca		
Attorney Docket Number:		PTB-4398-1485		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Claims in Excess of 20	1202	51	80	4080
Independent claims in excess of 3	1201	2	420	840
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
Request for Continued Examination	1801	1	1200	1200
Total in USD (\$)				6120

Electronic Acknowledgement Receipt	
EFS ID:	22247152
Application Number:	14447673
International Application Number:	
Confirmation Number:	3036
Title of Invention:	MASK SYSTEM
First Named Inventor/Applicant Name:	Errol Savio Alex D'SOUZA
Customer Number:	23117
Filer:	Paul Thomas Bowen/Tanja Majca
Filer Authorized By:	Paul Thomas Bowen
Attorney Docket Number:	PTB-4398-1485
Receipt Date:	04-MAY-2015
Filing Date:	31-JUL-2014
Time Stamp:	16:11:13
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$6120
RAM confirmation Number	2945
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Request for Continued Examination (RCE)	4398-1485_RCE_Transmittal.pdf	102405 57737e8faec93a389139f39cde8fb8dbe9db70e9	no	1
Warnings:					
This is not a USPTO supplied RCE SB30 form.					
Information:					
2	Miscellaneous Incoming Letter	4398-1485_Amendment_Transmittal.pdf	66240 32f3c6d8c88cac8521c6f9d467a8a009f666065f	no	1
Warnings:					
Information:					
3		4398-1485_AMD_with_RCE.pdf	137839 efcee7801ea5eace0ddca0d8ef0d81eac0f66314	yes	23
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Amendment Submitted/Entered with Filing of CPA/RCE		1	1	
	Claims		2	19	
	Applicant Arguments/Remarks Made in an Amendment		20	23	
Warnings:					
Information:					
4	Information Disclosure Statement (IDS) Form (SB08)	4398-1485_Information_Disclosure_Statement.pdf	134674 b751ca7267ca83eb58a426f899e4839fda225bfe	no	7
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
5	Foreign Reference	4398-1485_EP0830180.pdf	492110 769cdc11e52b7deb6780bdba2cba23804f25bc1c	no	8
Warnings:					
Information:					

6	Foreign Reference	4398-1485_WO9640370.pdf	563194	no	16
			f99ace47f456d1c3fdae32ccd21cccaed5c9a36		
Warnings:					
Information:					
7	Foreign Reference	4398-1485_CN2902337.pdf	447541	no	7
			8e7e925fcd0853cf69c3a1960b02b0ddc6a82d34		
Warnings:					
Information:					
8	Non Patent Literature	4398-1485_NPL01_EP_Communication.pdf	229768	no	4
			d52851dd61c0a6cc9d1d6d9e2e5f3154dac6c603		
Warnings:					
Information:					
9	Non Patent Literature	4398-1485_NPL02_NZ_Ntc_of_Oppos_NZ701136.pdf	637789	no	9
			01db21baf52578b5ab3c2d6386c35caeed620dbb		
Warnings:					
Information:					
10	Non Patent Literature	4398-1485_NPL03_NZ_Ntc_of_Oppos_NZ701183.pdf	632564	no	9
			d35d5fbc3fe2cb090bc1355c7d826213749c3e1d		
Warnings:					
Information:					
11	Non Patent Literature	4398-1485_NPL04_NZ_Decline_for_Counterstatement.pdf	2352501	no	39
			c0a14fbc4ef6f8c5fbf09881537e65fcdaf4a5f		
Warnings:					
Information:					
12	Non Patent Literature	4398-1485_NPL05_Statutory_Decl_of_Nightingale.pdf	77910	no	1
			5905ba054627473b351b9c8e071c7486b728b2df		
Warnings:					
Information:					
13	Non Patent Literature	4398-1485_NPL06_Statutory_Decl_of_McAuley.pdf	2834619	no	39
			a8b910066d81f3e61aaed1dcbd73f3536a9bf369		
Warnings:					
Information:					
14	Non Patent Literature	4398-1485_NPL07_2nd_Statutory_Decl_of_McAuley.pdf	362334	no	6
			8139bfcd925d1741c2f2d5f71bd44b7d813aae3		
Warnings:					
Information:					

15	Non Patent Literature	4398-1485_NPL08_3rd_Statutory_Decl_of_McAuley.pdf	739886	no	11
			20e02507b3d6aae3d5eae0edbf5f835a9238013		
Warnings:					
Information:					
16	Non Patent Literature	4398-1485_NPL09_Statutory_Decl_of_Baker.pdf	5123333	no	36
			2153ef644e7b69de7c269d4060712f80687b86b7		
Warnings:					
Information:					
17	Non Patent Literature	4398-1485_NPL10_Statutory_Decl_of_Rapoport.pdf	5114048	no	45
			761cda7c04d2f7138f20eabe21faa9034d7f36be		
Warnings:					
Information:					
18	Non Patent Literature	4398-1485_NPL11_Statement_of_Case_NZ701136.pdf	926917	no	14
			0dd9d96286510d6b924a6b82ee98c47c0bb2da1d		
Warnings:					
Information:					
19	Non Patent Literature	4398-1485_NPL12_Statement_of_Case_NZ701183.pdf	903841	no	13
			3d04fdcd9795098e4cbd1595156020d266a9b77a		
Warnings:					
Information:					
20	Fee Worksheet (SB06)	fee-info.pdf	34139	no	2
			9701248f3f34eb60952321d07ff296294e9bf445		
Warnings:					
Information:					
Total Files Size (in bytes):			21913652		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.



REQUEST FOR CONTINUED EXAMINATION (RCE) TRANSMITTAL Address to: Mail Stop RCE Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	<i>Application Number</i>			14/447,673		
	<i>Filing Date</i>			07/31/2014		
	<i>First Named Inventor</i>			NG, Eva		
	<i>Group Art Unit</i>			<i>Conf. No.</i>	3036	
	<i>Examiner Name</i>			Matter, Kristen Clarette		
	<i>Attorney Docket Number</i>			PTB-4398-1485		

This is a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114 of the above-identified application. Request for continued Examination (RCE) practice under 37 C.F.R. § 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. **Submission required under 37 C.F.R. § 1.114.**

a. ☐ Previously submitted (Note: Any previously filed unentered amendments will be entered unless applicant instructs otherwise. If applicant does not wish to have previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).)

i. ☐ Consider the amendment(s)/reply under 37 C.F.R. § 1.116 previously filed on _____

ii. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

iii. ☐ Other _____

b. ☒ Enclosed

i. ☒ Amendment/Reply

ii. ☐ Affidavit(s)/Declaration(s)

iii. ☒ Information Disclosure Statement (IDS)

iv. ☒ Other Response/Amendment/Letter _____

2. **Miscellaneous**

a. ☐ Suspension of action on the above-identified application is requested under 37 C.F.R. § 1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months; Fee under 37 C.F.R. § 1.17(i) required)

b. ☐ Other _____

3. **Fees** The RCE fee under 37 C.F.R. § 1.17(e) is required by 37 C.F.R. § 1.114 when the RCE is filed.

a. ☐ Applicant claims "small entity" status.

☐ Applicant claims "micro entity" status. ☐ Micro entity certification statement filed herewith.

b. ☒ Fees are attached as calculated below:

i. ☒ RCE fee required under 37 C.F.R. § 1.17(e)(1) \$1200.00 (1801)/\$600.00 (2801)/\$300.00 (3801) \$ 1200.00

☐ RCE fee required under 37 C.F.R. § 1.17(e)(2) \$1700.00 (1820)/\$850.00 (2820)/\$425.00 (3820) \$

ii. ☐ Petition is made to extend the due date _____ months (less _____ months previously paid) \$

iii. ☒ Other Claims (Codes 1201 and 1202) \$ 4920.00

c. ☒ CREDIT CARD OR DEPOSIT ACCOUNT PAYMENT (CREDIT CARD FORM ATTACHED IF PAPER FILING) in the amount of \$6120.00

d. ☒ The Director is hereby authorized to charge any deficiency in the fee(s) filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm), to Deposit Account No. 14-1140.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED			
<i>Name (Print Type)</i>	Paul T. Bowen	<i>Registration No. (Attorney/Agent)</i>	38,009
<i>Signature</i>	/Paul T. Bowen/	<i>Date</i>	May 4, 2015

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

2498232

In re Patent Application of	Atty Dkt.: PTB-4398-1485
D'SOUZA et al.	TC/A.U.: 3649
Appln. No. 14/447,673	Examiner: Matter, Kristen Clarette
Filed: 07/31/2014	Date: May 4, 2015

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE/AMENDMENT/LETTER

☐ Correspondence Address Indication Form attached.

Total effective claims after amendment					79	minus highest number		
previously paid for	28	(at least 20) =	51	x	\$80.00 =	\$4080.00 (1202)	\$2040.00 (2202)	\$ 4,080.00
Independent claims after amendment					5	minus highest number		
previously paid for	3	(at least 3) =	2	x	\$420.00=	\$840.00 (1201)	\$420.00 (2201)/\$210.00 (3201)	\$ 840.00

Petition is hereby made to extend the current due date so as to cover the filing date of this paper and attachment(s)

One Month Extension	\$200.00 (1251)/	\$100.00 (2251)/	\$50.00 (3251)
Two Month Extensions	\$600.00 (1252)/	\$300.00 (2252)/	\$150.00 (3252)
Three Month Extensions	\$1400.00 (1253)/	\$700.00 (2253)/	\$350.00 (3253)
Four Month Extensions	\$2200.00 (1254)/	\$1100.00 (2254)/	\$550.00 (3254)
Five Month Extensions	\$3000.00 (1255)/	\$1500.00 (2255)/	\$750.00 (3255)

☐ Applicant claims "small entity" status. ☐ Statement filed herewith

☐ Applicant claims "micro entity" status ☐ Micro entity certification statement filed herewith

Assignment Recordation Fee	\$40.00 (8021)/ \$0 if filed electronically	\$
Other: Request for Continued Examination		\$ 1,200.00

☒ CREDIT CARD PAYMENT (FORM ATTACHED IF PAPER FILING).

901 North Glebe Road, 11th Floor
Arlington, Virginia 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100
PTB:tlm

Signature: /Paul T. Bowen/

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

D'SOUZA et al.

Atty. Ref.: PTB-4398-1485

Appl. No. 14/447,673

Confirmation No. 3036

Filed: 07/31/2014

Art Unit: 3649

Examiner: Matter, Kristen Clarette

For: MASK SYSTEM

* * * * *

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

May 4, 2015

Sir:

AMENDMENT WITH RCE

Responsive to the Official Action dated February 3, 2015, please amend the
above-identified application as follows:

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Currently Amended) A mask system, comprising:
 - (i) a shroud module; wherein the shroud module includes headgear connectors adapted to removably attach to respective headgear straps of headgear; and
 - (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,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, ~~and 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 the shroud module and the cushion module are configured to be removably and non-rotatably coupleable to one another; and
 - 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 further wherein the shroud module includes a second opening positioned to align with a frame opening of the frame leading to the breathing chamber.
2. (Previously Presented) The mask system of claim 1 wherein the cushion comprises one or more folds in a lower lip/chin region of the cushion.
3. (Currently Amended) The mask system of claim 2, 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 the one or more folds in the nasal bridge region has a relatively high degree of flexibility and the one or more folds in the lower lip/chin region has a relatively low degree of flexibility.

4. (Currently Amended) The mask system of claim 1, 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.

5. (Currently Amended) The mask system of claim 1, wherein the frame ~~includes an opening and the frame further~~ includes a collar surrounding said frame opening, and wherein the shroud includes a retaining portion with ~~one or more~~ a plurality snap fingers structured to engage the collar with a snap-fit.

6. (Original) The mask system of claim 1, wherein the shroud module includes upper and lower headgear connectors on each side of the shroud module.

7. (Original) The mask system of claim 6, wherein each upper headgear connector includes a slot adapted to receive a respective headgear strap in use.

8. (Currently Amended) The mask system of claim ~~6~~ 7, wherein each lower headgear connector is adapted to be removably interlocked with a headgear clip associated with a respective headgear strap.

9. (Currently Amended) The mask system of claim 6, ~~[[,]]~~ wherein the upper headgear connectors and the lower headgear connectors define a fulcrum point or moment of pivoting that is positioned between the upper headgear connectors and the lower headgear connectors.

10. (Previously Presented) The mask system of claim 1, wherein the shroud module includes an annular or part annular cushion retaining portion structured to retain the cushion module.
11. (Original) The mask system of claim 1, further comprising an elbow module adapted to be connected to an air delivery tube that delivers breathable gas to the patient.
12. (Previously Presented) The mask system of claim 11, wherein the elbow module is provided to the shroud module.
13. (Original) The mask system of claim 11, wherein the elbow module comprises polycarbonate.
14. (Currently Amended) The mask system of claim 11, wherein the elbow module and the shroud module are directly connected with a mechanical interlock while allowing 360 degree rotation of the elbow module.
15. (Previously Presented) The mask system of claim 11, 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.
16. Canceled.
17. (Original) The mask system of claim 1, 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.
18. (Original) The mask system of claim 1 comprising 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.

19. (Currently Amended) The mask system of claim 1, wherein the shroud module ~~comprises~~ and the frame comprise polycarbonate and the cushion comprises silicone.

20.-21. Cancelled.

22. (Currently Amended) A mask system, comprising:

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

(ii) a cushion module, comprising:

a frame defining a breathing chamber; and

a cushion to form a seal with the patient's face in at least a nasal bridge region and; a cheek region ~~and a lower lip/chin region~~ of the patient's face,

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, and 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;

wherein the shroud module and the cushion module are configured to be removably coupleable to one another, and

wherein the shroud module includes a front opening of substantively circular shape and a retaining portion extending rearwardly from the front opening, towards the frame, and structured to ~~retain~~ snap-fit with the cushion module.

23. (Currently Amended) The mask system of claim 22, further comprising an elbow module directly mechanically interlocked with the shroud module while allowing 360 degree rotation of the elbow module.

24. (Previously Presented) The mask system of claim 22, wherein the shroud module includes upper and lower headgear connectors on each side of the shroud module;

wherein each upper headgear connector includes a slot adapted to receive a respective headgear strap in use; and

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

25. (Currently Amended) The mask system of claim 22, further comprising an elbow module adapted to be connected to an air delivery tube that delivers breathable gas to the patient, wherein the shroud module is structured to directly retain and carry the elbow module.

26. (Previously Presented) The mask system of claim 1, wherein:

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,

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,

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, 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.

27. (Previously Presented) The mask system of claim 26, wherein the upper straps provide padding to the respective headgear connectors of the shroud module on the patient's face in use.

28. (Previously Presented) The mask system of claim 26, 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.

29. (Canceled)

30. (Currently Amended) A mask system for delivery of a supply of air at positive pressure to a patient's airway, the mask system comprising:

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, 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, the frame including a washout vent, the frame including an opening;

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, 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, 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 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;

a shroud module including headgear connectors adapted to removably attach to the headgear, wherein the headgear connectors include two upper connectors associated with the upper headgear straps and two lower connectors associated with the lower headgear straps, each said upper headgear connector including a slot or receiving hole adapted to receive one of the upper headgear straps, 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 the opening of the frame; 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, the elbow including a swivel adapted to connect to an air delivery tube, the elbow including an anti-asphyxia valve (AAV) and a port that is selectively closed by a flap portion of the AAV.

31. (Previously Presented) The mask system of claim 30, wherein:
each upper headgear connector includes a laterally elongated arm and the slot or receiving hole is positioned at a free end of the arm,
each arm is contoured to extend along the patient's cheek, curving below the patient's field of vision or eyes, and then curves upwards at an angle relative to a horizontal axis in use,
the arms are at least semi-rigid to help prevent up and down movement of the arms relative to the face of the patient,
the top straps are integral with one another,
the frame, the shroud module and the headgear are structured to control rotation of the mask system in the sagittal and coronal planes of the patient in use, without a forehead support, and
the elbow is rotatably snap-fit to the frame of the cushion module.

32. (Previously Presented) The mask system of claim 30, wherein:
each upper headgear connector includes a laterally extending arm and the slot or receiving hole is positioned at a free end of the arm,
the arms are at least semi-rigid to help prevent up and down movement of the arms relative to the face of the patient,
the elbow is rotatably snap-fit to the frame of the cushion module,
the top straps are integral with one another, and
the frame includes a co-molded ring-shaped lip seal to seal against the elbow when connected.

33. (Previously Presented) The mask system of claim 30, wherein:
the elbow is rotatably attached the shroud module,
the upper headgear straps provide padding to the respective headgear connectors of the shroud on the patient's face in use,
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, further wherein the shroud module includes a second opening to accommodate the elbow,

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

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

34. (New) A mask system for delivery of a supply of air at positive pressure to a patient's airway, the mask system comprising:

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, 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, the frame including a washout vent;

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, 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, 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 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;

a shroud module including headgear connectors adapted to removably attach to the headgear, wherein the headgear connectors include two upper connectors associated with the upper headgear straps and two lower connectors associated with the lower headgear straps, each said upper headgear connector including a slot or receiving hole adapted to receive one of the upper headgear straps, 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; 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, the elbow including a swivel adapted to connect to an air delivery tube, the elbow including an anti-asphyxia valve (AAV) and a port that is selectively closed by a flap portion of the AAV;

the elbow is rotatably attached the shroud module,

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

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

the frame includes a frame opening and the frame further includes a collar surrounding said frame 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

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

35. (New) The mask system of claim 34, wherein the mask system is adapted to pivot about a fulcrum point or moment of pivoting that is positioned between the upper connectors and the lower connectors.

36. (New) The mask system of claim 34, 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.

37. (New) The mask system of claim 30, wherein the mask system is configured and arranged to pivot about a fulcrum point or moment of pivoting that is positioned between the upper connectors and the lower connectors.

38. (New) The mask system of claim 22, 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.

39. (New) The mask system of claim 38, wherein the headgear connectors are configured and arranged to allow pivoting of the cushion module, when attached with the shroud module, about a fulcrum point or moment of pivoting that is positioned between the upper connectors and the lower connectors.

40. (New) The mask system of claim 26, 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.

41. (New) The mask system of claim 40, wherein the headgear connectors are configured and arranged to allow pivoting of the cushion module, when attached with the shroud module, about a fulcrum point or moment of pivoting that is positioned between the upper connectors and the lower connectors.

42. (New) The mask system of claim 1, wherein the second opening of the shroud module and the frame opening of the frame are aligned along a common longitudinal axis, and 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.

43. (New) The mask system of claim 42, wherein the headgear connectors are configured and arranged to allow pivoting of the cushion module, when attached with the shroud module, about a fulcrum point or moment of pivoting that is positioned between the upper connectors and the lower connectors.

44. (New) The mask system of claim 1, wherein:

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,

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

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

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

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

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

45. (New) The mask system of claim 44, wherein each of the shroud module and the frame comprises polycarbonate, and the cushion comprises silicone.

46. (New) A mask system for treating a patient with sleep disordered breathing with a supply of air at positive pressure, comprising:

headgear including headgear straps;

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, the shroud module having a front opening;

a rotatable elbow directly attached to the shroud; and

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

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 and structured to snap fit with the cushion module.

47. (New) The mask system of claim 46, wherein the shroud module and the cushion module are structured and arranged to be detached from one another by moving the shroud module and the cushion module away from one another along the longitudinal axis.

48. (New) The mask system of claim 46, wherein the upper and lower headgear connectors are configured and arranged to allow pivoting of the cushion module, when attached with the shroud module, about a fulcrum point or moment of pivoting that is positioned between the upper headgear connectors and the lower headgear connectors.

49. (New) The mask system of claim 46, wherein each upper headgear connector includes a slot adapted to receive a respective headgear strap in use; and

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

50. (New) The mask system of claim 46, wherein the elbow is adapted to be connected to an air delivery tube that delivers breathable gas to the patient.

51. (New) The mask system of claim 46, wherein:
the headgear includes upper straps and lower straps,

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,

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, 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.

52. (Previously Presented) The mask system of claim 51, wherein the upper straps provide padding to the respective headgear connectors of the shroud module on the patient's face in use.

53. (Previously Presented) The mask system of claim 51, 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.

54. (New) The mask system of claim 46, 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.

55. (New) The mask system of claim 46, wherein the cushion comprises one or more folds in a lower lip/chin region of the cushion.

56. (New) The mask system of claim 55, 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 the one or more folds in the nasal bridge region has a relatively high degree of flexibility and the one or more folds in the lower lip/chin region has a relatively low degree of flexibility.

57. (New) The mask system of claim 46, 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.

58. (New) The mask system of claim 46, wherein the frame includes a collar surrounding said frame opening, and wherein the shroud includes a retaining portion with a plurality snap fingers structured to engage the collar with a snap-fit.

59. (New) The mask system of claim 46, wherein the elbow 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.

60. (New) The mask system of claim 46, wherein each of the shroud module and the frame comprises polycarbonate and the cushion comprises silicone.

61. (New) The mask system of claim 46, wherein:

the shroud module and the cushion module are structured and arranged to be detached from one another by moving the shroud module and the cushion module away from one another along the longitudinal axis,

wherein each upper headgear connector includes a slot adapted to receive a respective headgear strap in use, and wherein each lower headgear connector is adapted to be removably interlocked with a headgear clip associated with a respective headgear strap,

the elbow is adapted to be connected to an air delivery tube that delivers breathable gas to the patient,

the headgear includes upper straps and lower straps, 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, 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, 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,

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

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

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,

the cushion comprises one or more folds in a lower lip/chin region of the cushion,

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,

the frame includes a collar surrounding said frame opening, and wherein the shroud includes a retaining portion with a plurality snap fingers structured to engage the collar with a snap-fit,

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

62. (New) The mask system of claim 61, wherein the upper and lower headgear connectors are configured and arranged to allow pivoting of the cushion module, when attached with the shroud module, about a fulcrum point or moment of pivoting that is positioned between the upper headgear connectors and the lower headgear connectors.

63. (New) The mask system of claim 61, wherein the elbow 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.

- 64. (New) The mask system of claim 61, wherein the frame is semi-rigid or rigid.
- 65. (New) The mask system of claim 64, wherein the frame is rigid.
- 66. (New) The mask system of claim 46, wherein the frame is semi-rigid or rigid.
- 67. (New) The mask system of claim 66, wherein the frame is rigid.
- 68. (New) The mask system of claim 1, wherein the frame is rigid.
- 69. (New) The mask system of claim 44, wherein the frame is rigid.
- 70. (New) The mask system of claim 22, wherein the frame is semi-rigid or rigid.
- 71. (New) The mask system of claim 70, wherein the frame is rigid.
- 72. (New) The mask system of claim 26, wherein the frame is rigid.
- 73. (New) The mask system of claim 39, wherein the frame is rigid.
- 74. (New) The mask system of claim 41, wherein the frame is rigid.
- 75. (New) The mask system of claim 30, wherein the frame is semi-rigid or rigid.
- 76. (New) The mask system of claim 75, wherein the frame is rigid.
- 77. (New) The mask system of claim 34, wherein the frame is semi-rigid or rigid.
- 78. (New) The mask system of claim 77, wherein the frame is rigid.

79. (New) A system for treating a patient with sleep disordered breathing, comprising:
the mask system of claim 1;
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.
80. (New) A system for treating a patient with sleep disordered breathing, comprising:
the mask system of claim 22;
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.
81. (New) A system for treating a patient with sleep disordered breathing, comprising:
the mask system of claim 30; 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.
82. (New) A system for treating a patient with sleep disordered breathing, comprising:
the mask system of claim 34; 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.
83. (New) A system for treating a patient with sleep disordered breathing, comprising:
the mask system of claim 46;

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.

REMARKS/ARGUMENTS

Claims 1-15, 17-19 and 22-83 are pending. By this Amendment, claims 1, 3-5, 8, 9, 14, 19, 22, 23 and 30 have been amended, claim 29 has been canceled and claims 34-83 are added for the Examiner's consideration. Reconsideration in view of the above amendments and the following remarks is respectfully requested.

Claims 1-4, 10-14, 19, 22, 23 and 25 were rejected under 35 U.S.C. §103(a) over Geist (U.S. 2006/0042629) in view of Lieberman et al. (US 2008/0178886) and Schegerin (US 5,349,949). This rejection is respectfully traversed.

In regard to independent claim 1, Applicants note the Examiner's indication that claim 29 would define patentable subject matter. As such, the subject matter of claim 29 has been added into claim 1. At the same time, the feature regarding "the nasal bridge portion of the cushion including one or more folds" has been moved from claim 1 to claims 3 and 4 since it is not believed to form the basis of the Examiner's indication of allowability. Furthermore, the last phrase of claim 29 (now canceled) which read "further wherein the shroud module includes a second opening to accommodate an elbow" has been changed to --further wherein the shroud module includes a second opening positioned to align with a frame opening of the frame leading to the breathing chamber--. Again, it is not believed that the Examiner's indications of allowability regarding claim 29 was based on the above noted original language.

In regard to independent claim 22, it is not believed that the Geist/Lieberman/Schegerin combination teaches a shroud module includes a front opening and a retaining portion extending rearwardly from the front opening and is structured to retain the cushion module. In the Office Action (page 5) the Examiner points to element 74 as the claimed retaining portion. Element 74 is labeled in Fig. 14 of Geist. However, as is evident, that retaining portion does not extend rearwardly from the front opening, rather it extends forwardly from the front opening. For example, compare the retaining portion, shown, e.g., in Figs. 23 and 28 of the present application which extends rearwardly rather than forwardly of the opening.

Nonetheless, claim 22 has been updated in minor respects to even more particularly distinguish over Geist. For example, claim 22 species that the shroud module includes a front opening of substantially circular shape and that the retaining portion extends rearwardly from the front opening, towards the frame, and structured to snap-fit with the cushion module. One of ordinary skill would not have any motivation to provide Geist's shroud module with a

substantially circular shaped front opening since this would prevent the assembly of the shroud to the cushion module as taught by Geist, see e.g. Fig. 18 of Geist. In particular, the retaining portion 74 must be in the shape of a "U" in order to allow assembly of the shroud 20 to the cushion module in a direction that is transverse to the longitudinal axis of element 38 as shown for example in Fig. 18 of Geist. Moreover, the Geist disclosure appears to be focused on a mask removably mounted to adjustable headgear straps which permits the mask to be removed from the headstraps - while the headstraps remain on the person's head. See paragraph [0008] of Geist.

In addition, the Amendment makes even more clear that the retaining portion extends towards the frame. Geist teaches the opposite arrangement, whereby the retaining portion extends away from the frame.

In regard to dependent claims 23 and 25, these have been amended so as to even more clearly distinguish over Geist by specifying direct mechanical interlock or direct retaining of the elbow module to the shroud module. Close inspection and clear understanding of Geist shows that there is no connection, or direct connection, between the shroud module and the elbow module in Geist. In Geist, the shroud module only makes contact with the cushion module, not the elbow module.

Reconsideration and withdrawal of the rejection are respectfully requested.

Dependent claims 5-9, 15, 17, 18, 24 and 26-28 were rejected under 35 U.S.C. §103(a) based on the basic Geist/Lieberman/Schegerin combination and further in view of various secondary references. However, because all of these claims depend from either claim 1 or claim 22, they were patentable by virtue of that dependency and the further features recited therein.

Reconsideration and withdrawal of the rejection are respectfully requested.

Claim 30 was rejected under 35 U.S.C. §103(a) over Geist/Lieberman/Schegerin/Smart and Lubke. This rejection is respectfully traversed.

At the outset, Applicants note that the Examiner's reliance based on no less than five references tends to indicate non-obviousness.

While there is no *per se* rule against the number of references, the fact that so many references have been applied leads to any number of arguments regarding their (in)combinability, (lack of) motivation to combine, their individual teachings, etc. For example, the Examiner recognizes that Geist does not teach a valve on the elbow as claimed and seeks to

rely on the teachings of Smart for such deficiencies. However, because Geist is a nasal mask, there is no motivation to look to Smart's full face mask to make up for this deficiency. Should a patient wearing the nasal mask of Geist for some reason experience a power failure with regard to delivery of pressurized gas, such user would simply open his or her mouth in order to breathe in ambient air. Thus, there is no reason to complicate Geist with unnecessary anti-asphyxia valves as taught by Smart.

In addition, the Examiner recognizes that Geist does not teach upper and lower headgear straps as claimed, and looks to Lubke to resolve such deficiency. However, Geist specifically teaches a nasal mask which uses a three-point headgear connection including two lateral connectors and one "over the top" type connector. There is simply no teaching or suggestion that one of ordinary skill in the art would have replaced Geist's three point connection with a four point connection.

In addition, the Examiner states that Geist does not expressly state the frame and collar create a snap-fit, even though the Examiner believes this is readily apparent/obvious. To make up for this deficiency, the Examiner points to the teachings of Lubke as allegedly disclosing a similar releasable connection with a peg finger that is snap-fit into the retaining mechanism, pointing to Fig. 16 in paragraph 173. However, the Lubke disclosure referred to by the Examiner is directed toward a headgear to frame connection, not a shroud to frame connection, which are very different type connections located on different parts of the mask having different types of requirements. One of ordinary skill in the art simply would not have looked at Fig. 16 of Lubke and decide to somehow adapt a snap-fit teaching to the connection between the frame and the shroud.

Moreover, independent claim 30 is amended so as to specify that the frame and 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 the opening of the frame. As described above, Fig. 18 of Geist clearly shows that any such snap-fit between the shroud and the frame of the cushion module is achieved by pushing the shroud along an axis that is transverse to the longitudinal axis of the opening of the frame, not along a longitudinal axis, as claimed. Moreover, one of ordinary skill in the art would not modify Geist in a manner inconsistent with the teachings of Geist. Geist requires a mask to be removable from the

headstraps while the headstraps remain on the person's head, tightened and still individually adjusted to the patient's head. See paragraph [0008] of Geist.

Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 31 and 32 were rejected under the same five way combination used to reject claim 30, and further in view of additional references. Because claims 31 and 32 are dependent on claim 30, these claims are also patentable by virtue of their dependence, and for the further features recited therein.

Reconsideration and withdrawal of the rejection is respectfully requested.

Applicants appreciate the indication that claim 33 defines allowable subject matter, and thus new claim 34 is added which is unamended claim 30, combined with claim 33.

In view of the above amendments and remarks, Applicants respectfully submit that all the claims are patentable and that the entire application is in condition for allowance.

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140 under Order No. PTB-4398-1485.

Should the Examiner believe that anything further is desirable to place the application in better condition for allowance, she is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875				Application or Docket Number 14/447,673		Filing Date 07/31/2014		<input type="checkbox"/> To be Mailed	
ENTITY: <input checked="" type="checkbox"/> LARGE <input type="checkbox"/> SMALL <input type="checkbox"/> MICRO									
APPLICATION AS FILED – PART I									
(Column 1)		(Column 2)							
FOR	NUMBER FILED	NUMBER EXTRA		RATE (\$)		FEE (\$)			
<input type="checkbox"/> BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A					
<input type="checkbox"/> SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A		N/A					
<input type="checkbox"/> EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A					
TOTAL CLAIMS (37 CFR 1.16(j))	minus 20 =	*		X \$ =					
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		X \$ =					
<input type="checkbox"/> APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).								
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))									
* If the difference in column 1 is less than zero, enter "0" in column 2.						TOTAL			
APPLICATION AS AMENDED – PART II									
(Column 1)		(Column 2)		(Column 3)					
AMENDMENT	05/04/2015	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	* 79	Minus	** 30	= 49	X \$80 =		3920	
	Independent (37 CFR 1.16(h))	* 5	Minus	*** 3	= 2	X \$420 =		840	
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))								
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
						TOTAL ADD'L FEE		4760	
(Column 1)		(Column 2)		(Column 3)					
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =			
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =			
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))								
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
						TOTAL ADD'L FEE			
<p>* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.</p> <p>** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".</p> <p>*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".</p> <p>The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.</p>									

LIE
/SANDRA F. GARNETT/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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International Application Number:	
Confirmation Number:	3036
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First Named Inventor/Applicant Name:	Errol Savio Alex D'SOUZA
Customer Number:	23117
Filer:	Paul Thomas Bowen/Tanja Majca
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Application Type:	Utility under 35 USC 111(a)

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Information:					
7	Non Patent Literature	4398-1485_NPL06_Stat_Decl_McAuley.pdf	2949737 f485c2b8a6db25a023aa4d413587544041f8235f	no	38
Warnings:					
Information:					
8	Non Patent Literature	4398-1485_NPL07_2nd_Stat_Decl_McAuley.pdf	178433 27be4371f257a9698d2ee0710bd0383989fbbe1d	no	3
Warnings:					
Information:					
9	Non Patent Literature	4398-1485_NPL08_AU_Exam_Report.pdf	1031957 b4c67db19bb86b1dfdc7ced89f633ab3bc99166	no	8
Warnings:					
Information:					
Total Files Size (in bytes):			24525340		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/447,673	07/31/2014	Errol Savio Alex D'SOUZA	PTB-4398-1485	3036
23117 7590 07/10/2015 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			EXAMINER MATTER, KRISTEN CLARETTE	
			ART UNIT 3649	PAPER NUMBER
			NOTIFICATION DATE 07/10/2015	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTOMAIL@nixonvan.com
pair_nixon@firsttofile.com

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Examiner indicated that amendment/RCE filed 5/4/2015 is sufficient to overcome the rejections of claims 1, 22, and 34, which examiner would indicate as allowable. Examiner also noted that claim 46 would be allowable if amended to better define "rearwardly" as being "towards the frame" as was done in other claims.

Examiner noted that the prior art would be maintained for claim 30 because one would be capable of snap-fitting the shroud and frame by pulling away from the face on a longitudinal axis as claimed. Applicant noted one of ordinary skill would not do this because the straps are to be maintained in a fitted position with Geist even with mask removal. Examiner noted that even if not completely desirable, the capability to do so is all that matters and that she wasn't convinced one could not remove the shroud from the frame by pulling them apart in a longitudinal direction as claimed.

Applicant suggested amending claim 30 to have the shroud module have a circular opening as opposed to the substantially circular/horseshoe/semi-circular opening of Geist. Examiner agreed Geist lacked motivation for such an opening and that such an amendment would be sufficient to overcome the Geist reference as applied.

Applicant indicated he would check with his client and if the changes are approved either provide a supplemental amendment or authorize an examiner's amendment making the above changes.



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UNITED STATES DEPARTMENT OF COMMERCE
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NOTICE OF ALLOWANCE AND FEE(S) DUE

23117 7590 07/15/2015
NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER

MATTER, KRISTEN CLARETTE

ART UNIT

PAPER NUMBER

3649

DATE MAILED: 07/15/2015

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/447,673	07/31/2014	Errol Savio Alex D'SOUZA	PTB-4398-1485	3036

TITLE OF INVENTION: MASK SYSTEM

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$960	\$0	\$0	\$960	10/15/2015

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail** **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax **(571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

23117 7590 07/15/2015
NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/447,673	07/31/2014	Errol Savio Alex D'SOUZA	PTB-4398-1485	3036

TITLE OF INVENTION: MASK SYSTEM

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$960	\$0	\$0	\$960	10/15/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS
MATTER, KRISTEN CLARETTE	3649	128-206280

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) The names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____
- (2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____
- 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
- ☐ Applicant asserting small entity status. See 37 CFR 1.27
- ☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/447,673	07/31/2014	Errol Savio Alex D'SOUZA	PTB-4398-1485	3036

23117	7590	07/15/2015
NIXON & VANDERHYE, PC		
901 NORTH GLEBE ROAD, 11TH FLOOR		
ARLINGTON, VA 22203		

EXAMINER	
MATTER, KRISTEN CLARETTE	

ART UNIT	PAPER NUMBER
3649	

DATE MAILED: 07/15/2015

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 14/447,673 Examiner KRISTEN MATTER	Applicant(s) D'SOUZA ET AL. Art Unit 3649 AIA (First Inventor to File) Status No
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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the RCE filed 5/4/2015.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are 1-15, 17-19, 22-28, 30-83. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
Certified copies:
 a) ☐ All b) ☐ Some *c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date <u>See Continuation Sheet</u> 3. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material 4. <input type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date _____.	5. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 6. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance 7. <input type="checkbox"/> Other _____.
--	--

/KRISTEN MATTER/ Primary Examiner, Art Unit 3649	
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Continuation of Attachment(s) 2. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date: 2/9/2015, 5/4/2015 and 7/2/2015.

The present application is being examined under the pre-AIA first to invent provisions.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Paul Bowen on July 3, 2015.

The application has been amended as follows:

In claim 30, line 25, "upper headgear straps," has been changed to --upper headgear straps, the shroud module having an opening of circular shape--.

In claim 30, lines 27-28, "along a longitudinal axis of the opening of the frame" has been changed to --along a longitudinal axis of both the opening of the frame and the opening of the shroud--.

In claim 46, second to last line, "rearwardly of the front opening" has been changed to --rearwardly of the front opening, towards the frame--.

In claim 58, lines 2-3, "the shroud includes a retaining portion with a plurality snap fingers" has been changed to --the retaining portion of the shroud includes ~~a retaining portion~~ with a plurality of snap fingers--.

In claim 61, lines 30-31, “the shroud includes a retaining portion with a plurality snap fingers” has been changed to --the retaining portion of the shroud includes ~~a retaining portion~~ with a plurality of snap fingers--.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTEN MATTER whose telephone number is (571)272-5270. The examiner can normally be reached on Monday - Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Darnell Jayne can be reached on (571) 272-7723. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kristen C. Matter
Primary Examiner
Art Unit 3649


/KRISTEN MATTER/
Primary Examiner, Art Unit 3649

Issue Classification 	Application/Control No. 14447673	Applicant(s)/Patent Under Reexamination D'SOUZA ET AL.	
	Examiner KRISTEN MATTER	Art Unit 3649	

CPC						
Symbol					Type	Version
A61M		16		0683	F	2013-01-01
A61M		16		06	I	2013-01-01
A61M		16		0066	I	2013-01-01
A61M		16		0816	I	2013-01-01
A61M		16		0875	I	2013-01-01
A61M		16		20	I	2013-01-01
A61M		16		0057	I	2013-01-01
A61M		16		0616	I	2014-02-04
A61M		16		0611	I	2014-02-04
A61M		16		0622	I	2014-02-04
A61M		16		0694	I	2014-02-04
A61M		2016		0661	A	2013-01-01

CPC Combination Sets						
Symbol			Type	Set	Ranking	Version

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	79	
/KRISTEN MATTER/ Primary Examiner.Art Unit 3649	7/6/2015	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	3

Issue Classification 	Application/Control No. 14447673	Applicant(s)/Patent Under Reexamination D'SOUZA ET AL.
	Examiner KRISTEN MATTER	Art Unit 3649

<input type="checkbox"/> Claims renumbered in the same order as presented by applicant <input type="checkbox"/> CPA <input type="checkbox"/> T.D. <input type="checkbox"/> R.1.47															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1	16	17	46	33	60	49	76	65	50	81				
2	2	17	18	51	34	61	50	77	66	56	82				
3	3	18	19	52	35	62	51	78	67	79	83				
4	4		20	53	36	63	52	31	68						
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8	8	35	24	22	40	67	56	25	72						
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12	12	21	28	28	44	71	60	49	76						
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14	14	43	30	57	46	73	62	55	78						
15	15	44	31	58	47	74	63	32	79						
	16	45	32	59	48	75	64	42	80						

NONE		Total Claims Allowed:	
		79	
(Assistant Examiner)	(Date)		
/KRISTEN MATTER/ Primary Examiner.Art Unit 3649	7/6/2015	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	3




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BIB DATA SHEET

CONFIRMATION NO. 3036

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.		
14/447,673	07/31/2014	128	3649	PTB-4398-1485		
APPLICANTS ResMed Limited, Bella Vista, AUSTRALIA; INVENTORS Errol Savio Alex D'SOUZA, Sydney, AUSTRALIA; Matthew EVES, Sydney, AUSTRALIA; David James LOCKWOOD, Gosford, AUSTRALIA; Zoran VALCIC, Sydney, AUSTRALIA; Jamie Graeme WEHBEH, Sydney, AUSTRALIA; ** CONTINUING DATA ***** /KCM/ This application is a CON of 13/964,280 08/12/2013 which is a CON of 13/745,077 01/18/2013 PAT 8528561 which is a CON of 12/736,024 09/02/2010 PAT 8550084 which is a 371 of PCT/AU2009/000241 02/27/2009 which claims benefit of 61/064,406 03/04/2008 and claims benefit of 61/071,893 05/23/2008 and claims benefit of 61/136,617 09/19/2008 ** FOREIGN APPLICATIONS ***** None /KCM/ ** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** 08/08/2014						
Foreign Priority claimed <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No 35 USC 119(a-d) conditions met <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Verified and /KRISTEN CLARETTE MATTER/ Acknowledged Examiner's Signature		<input type="checkbox"/> Met after Allowance Initials	STATE OR COUNTRY AUSTRALIA	SHEETS DRAWINGS 81	TOTAL CLAIMS 21	INDEPENDENT CLAIMS 1
ADDRESS NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203 UNITED STATES						
TITLE MASK SYSTEM						
FILING FEE RECEIVED 7320	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:			<input type="checkbox"/> All Fees <input type="checkbox"/> 1.16 Fees (Filing) <input type="checkbox"/> 1.17 Fees (Processing Ext. of time) <input type="checkbox"/> 1.18 Fees (Issue) <input type="checkbox"/> Other _____ <input type="checkbox"/> Credit		

Search Notes 	Application/Control No. 14447673	Applicant(s)/Patent Under Reexamination D'SOUZA ET AL.
	Examiner KRISTEN MATTER	Art Unit 3649

CPC- SEARCHED		
Symbol	Date	Examiner
A61M16/06, 16/0605, 16/0611, 16/0616, 16/0683	1/26/2015	KCM
Updated Search	7/6/2015	KCM

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
128	205.25, 206.21, 206.24, 206.28, 207.11	11/24/14	KCM
	Updated Search	1/26/2015	KCM

SEARCH NOTES		
Search Notes	Date	Examiner
Inventor name search	11/24/14	KCM

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
	See attached EAST Search	7/6/2015	KCM

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INFORMATION DISCLOSURE CITATION	ATTY. DOCKET NO.	APPLICATION NO.
	PTB-4398-1485	14/447,673
(Use several sheets if necessary)	INVENTOR(S)	
	D'SOUZA et al.	
	FILING DATE	ART UNIT
	07/31/2014	3649

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	2009/0151729 A1	06/2009	Judson et al.			
	5,921,239	07/1999	McCall et al.			
	6,435,181 B1	08/2002	Jones, Jr. et al.			
	6,457,473 B1	10/2002	Brostrom et al.			

FOREIGN PATENT DOCUMENTS

DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	NO
EP 0 830 180 B1	03/2002	EP (corres. to WO 96/40370)				
WO 96/40370 A1	12/1996	WO (corres. to EP 0 830 180)				
CN 2902337Y	05/2007	CN			ABSTRACT	

OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)

	Communication Pursuant to Article 94(3) EPC mailed February 11, 2015 in European Application No. 13 197 251.5 (4 pages)
	Extension of Time Granted (1 page) mailed March 2, 2015 in New Zealand Application No. 701136, together with a Notice of Opposition to Grant of Patent (Section 21) (8 pages)
	Extension of Time Granted (1 page) mailed March 2, 2015 in New Zealand Application No. 701183, together with a Notice of Opposition to Grant of Patent (Section 21) (8 pages)
	Deadline for Counterstatement (1 page) mailed March 27, 2015 in New Zealand Application No. 624599, together with Amended Notice of Opposition to Grant of Patent (Section 21) (9 pages) and Statement of Case (29 pages)
	Statutory Declaration of Christopher Earl Nightingale executed April 17, 2015 for submission in the Opposition of Australian Application No. 2009221630 (1 page)
	Statutory Declaration of Alistair Edwin McAuley executed April 9, 2015 for submission in the Opposition of Australian Application No. 2009221630 (39 pages)
	Second Statutory Declaration of Alistair Edwin McAuley executed April 14, 2015 for submission in the Opposition of Australian Application No. 2009221630 (6 pages)
	Third Statutory Declaration of Alistair Edwin McAuley executed April 17, 2015 for submission in the Opposition of Australian Application No. 2009221630 (11 pages)
	Statutory Declaration of Troy Alan Baker executed April 16, 2015 for submission in the Opposition of Australian Application No. 2009221630 (36 pages)
	Statutory Declaration of Dr. David Maurice Rapoport executed April 2, 2015 for submission in the Opposition of Australian Application No. 2009221630 (45 pages)
	Statement of Case dated April 28, 2015 and filed by Fisher & Paykel Healthcare Limited in New Zealand Opposition No. 701136 (14 pages)
	Statement of Case dated April 28, 2015 and filed by Fisher & Paykel Healthcare Limited in New Zealand Opposition No. 701183 (13 pages)

*Examiner	/Kristen Matter/	Date Considered	07/06/2015
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Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-FB-A820 (Also PTO/SB/08A)

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /K.M./

2487004

INFORMATION DISCLOSURE CITATION	ATTY. DOCKET NO.	APPLICATION NO.
	PTB-4398-1485	14/447,673
(Use several sheets if necessary)	INVENTOR(S)	
	D'SOUZA et al.	
	FILING DATE	ART UNIT
	07/31/2014	3649

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	2005/0011521 A1	01/2005	Sprinkle et al.			

FOREIGN PATENT DOCUMENTS

DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO

OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)

	Communication mailed January 5, 2015 (Extension of Time Granted), with Notice of Opposition filed December 23, 2014, in New Zealand Application No. 624599 (9 pages).
	Extended European Search Report mailed January 15, 2015 in European Application No. 14182823.6 (6 pages)
	IP Australian Official Receipt dated January 19, 2015, with Statement of Grounds and Particulars, filed in Australian Application No. 2009221630 (21 pages)

*Examiner	/Kristen Matter/	Date Considered	02/14/2015
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Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-FB-A820 (Also PTO/SB/08A)

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /K.M./

2461503

EAST Search History**EAST Search History (Prior Art)**

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	5	(shroud and module and cushion and frame and vent and elbow and material and rigid and opening).clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/07/06 08:27

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L2	5	(shroud and module and cushion and frame and vent and elbow and material and rigid and opening).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2015/07/06 08:28

7 / 6 / 2015 8:28:37 AM

[illegible][illegible]

	Proceeding Correspondence mailed June 17, 2015 in New Zealand Appln. No. 622670 (2 pages)
	Proceeding Correspondence mailed June 17, 2015 in New Zealand Appln. No. 607032 (2 pages)
	Affirmation of Chun Cui executed June 12, 2015 for submission in the Opposition of New Zealand Application Nos. 607032 (51 pages)
	Statutory Declaration of Troy Alan Baker executed April 16, 2015 for submission in the Opposition of New Zealand Application Nos. 607032, 622666 and 622670 (36 pages)
	Statutory Declaration of Dr. David Maurice Rapoport executed April 2, 2015 for submission in the Opposition of New Zealand Application Nos. 607032, 622666 and 622670 (46 pages)
	Statutory Declaration of Alistair Edwin McAuley executed April 9, 2015 for submission in the Opposition of New Zealand Application Nos. 607032, 622666 and 622670 (38 pages)
	Second Statutory Declaration of Alistair Edwin McAuley executed April 14, 2015 for submission in the Opposition of New Zealand Application Nos. 607032, 622666 and 622670 (3 pages)
	Patent Examination Report No. 1 mailed May 29, 2015 in Australian Application No. 2014218465 (8 pages)

*Examiner	/Kristen Matter/	Date Considered	07/06/2015
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Form PTO-FB-A820 (Also PTO/SB/08A)

2520889

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail** **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax **(571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

23117 7590 07/15/2015
NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/447,673	07/31/2014	Errol Savio Alex D'SOUZA	PTB-4398-1485	3036

TITLE OF INVENTION: MASK SYSTEM

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$960	\$0	\$0	\$960	10/15/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS
MATTER, KRISTEN CLARETTE	3649	128-206280

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☒ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Nixon & Vanderhye P.C.

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

ResMed Limited

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Bella Vista, Australia

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

☒ Issue Fee

☐ Publication Fee (No small entity discount permitted)

☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

☐ A check is enclosed.

☒ Payment by credit card. ~~From PTO-2003-000000~~

☒ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number 14-1140 (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Paul T. Bowen/

Date July 15, 2015

Typed or printed name Paul T. Bowen

Registration No. 38,009

"FEE ADDRESS" INDICATION FORM

Address to:
Mail Stop M Correspondence
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Fax to:
571-273-6500

- OR -

Please recognize as the "Fee Address" under the provisions of 37 CFR 1.363 the address associated with the following customer number

☒ Customer Number

000197

Type Customer Number here

OR

☐ Request for Customer Number (PTO/SB/125) attached hereto

in the following listed application(s) for which the Issue Fee has been paid or patent(s).

PATENT NUMBER (if known)	APPLICATION NUMBER
	14/447,673

(check one)

☐ Applicant/Inventor

☒ Attorney or Agent of record

38,009

(Reg. No.)

☐ Assignee of record of the entire interest. See 37 C.F.R. § 3.71. Statement under 37 C.F.R. § 3.73(b) is enclosed.

☐ Assignment recorded at Reel

Frame

/Paul T. Bowen/

Signature

Paul T. Bowen

Typed or printed name

703-816-4019

Requester's telephone number

July 15, 2015

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.*

☒ *Total of 1 form/s are submitted.

Electronic Patent Application Fee Transmittal				
Application Number:		14447673		
Filing Date:		31-Jul-2014		
Title of Invention:		MASK SYSTEM		
First Named Inventor/Applicant Name:		Errol Savio Alex D'SOUZA		
Filer:		Paul Thomas Bowen/Tanja Majca		
Attorney Docket Number:		PTB-4398-1485		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl Issue Fee	1501	1	960	960


Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				960

Electronic Acknowledgement Receipt	
EFS ID:	22925262
Application Number:	14447673
International Application Number:	
Confirmation Number:	3036
Title of Invention:	MASK SYSTEM
First Named Inventor/Applicant Name:	Errol Savio Alex D'SOUZA
Customer Number:	23117
Filer:	Paul Thomas Bowen/Tanja Majca
Filer Authorized By:	Paul Thomas Bowen
Attorney Docket Number:	PTB-4398-1485
Receipt Date:	15-JUL-2015
Filing Date:	31-JUL-2014
Time Stamp:	14:47:48
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$960
RAM confirmation Number	1037
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	


File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	4398-1485_Issue_Fee_Transmit tal.PDF	127287 f263dcfdbe0eb9bc9c7d0d42ac63694b9612852c	no	1
Warnings:					
Information:					
2	Post Allowance Communication - Incoming	4398-1485_Fee_Address_Indication_Form.pdf	85772 cb7bafd85570bfc2e144cd38b73448240b16b00f	no	1
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30766 0604f7c725be941d4557cee32cf78914dfce3a7	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			243825		
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					

Issue Classification 	Application/Control No. 14447673	Applicant(s)/Patent Under Reexamination D'SOUZA ET AL.	
	Examiner KRISTEN MATTER	Art Unit 3649	

CPC						
Symbol					Type	Version
A61M		16		0683	F	2013-01-01
A61M		16		06	I	2013-01-01
A61M		16		0066	I	2013-01-01
A61M		16		0816	I	2013-01-01
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A61M		16		0611	I	2014-02-04
A61M		16		0622	I	2014-02-04
A61M		16		0694	I	2014-02-04
A61M		2016		0661	A	2013-01-01


CPC Combination Sets							
Symbol				Type	Set	Ranking	Version

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	79	
/KRISTEN MATTER/ Primary Examiner.Art Unit 3649	7/23/2015	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	3

Issue Classification 	Application/Control No. 14447673	Applicant(s)/Patent Under Reexamination D'SOUZA ET AL.
	Examiner KRISTEN MATTER	Art Unit 3649

US ORIGINAL CLASSIFICATION						INTERNATIONAL CLASSIFICATION														
CLASS		SUBCLASS				CLAIMED					NON-CLAIMED									
						A	6	2	B	18 / 02 (2006.01.01)										
CROSS REFERENCE(S)																				
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)																			

NONE		Total Claims Allowed:	
		79	
(Assistant Examiner)	(Date)		
/KRISTEN MATTER/ Primary Examiner.Art Unit 3649	7/23/2015	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	3

Issue Classification 	Application/Control No. 14447673	Applicant(s)/Patent Under Reexamination D'SOUZA ET AL.
	Examiner KRISTEN MATTER	Art Unit 3649

<input type="checkbox"/> Claims renumbered in the same order as presented by applicant <input type="checkbox"/> CPA <input type="checkbox"/> T.D. <input type="checkbox"/> R.1.47															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
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2	2	17	18	51	34	61	50	77	66	56	82				
3	3	18	19	52	35	62	51	78	67	79	83				
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5	5		21	47	37	64	53	30	69						
6	6	33	22	37	38	65	54	40	70						
7	7	34	23	38	39	66	55	41	71						
8	8	35	24	22	40	67	56	25	72						
9	9	36	25	23	41	68	57	39	73						
10	10	19	26	26	42	69	58	24	74						
11	11	20	27	27	43	70	59	48	75						
12	12	21	28	28	44	71	60	49	76						
13	13		29	29	45	72	61	54	77						
14	14	43	30	57	46	73	62	55	78						
15	15	44	31	58	47	74	63	32	79						
	16	45	32	59	48	75	64	42	80						

NONE (Assistant Examiner) _____ (Date) _____		Total Claims Allowed: 79	
/KRISTEN MATTER/ Primary Examiner. Art Unit 3649 (Primary Examiner) _____ (Date) _____		O.G. Print Claim(s) 1	O.G. Print Figure 3

Sheet 3 of 35

INFORMATION DISCLOSURE
CITATION

ATTY. DOCKET NO.

SERIAL NO.

PTB-4398-1485

Continuation of 13/964,280

APPLICANT

D'SOUZA et al.

(Use several sheets if necessary)

FILING DATE

TC/A.U.

Herewith

Unassigned

Change(s) applied
to document,
/S.X.R./
7/29/2015

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	4,245,632	01/1981	HOUSTON			

*Examiner

Date Considered

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-FB-A820 (Also PTO/SB/08A)

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /K.M./

Sheet 20 of 35

**INFORMATION DISCLOSURE
CITATION**ATTY. DOCKET NO.
PTB-4398-1485SERIAL NO.
Continuation of 13/964,280

APPLICANT

D'SOUZA et al.

(Use several sheets if necessary)

FILING DATE

Herewith

TC/A.U.

Unassigned

Change(s) applied
to document,
/S.X.R./
7/31/2015

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	US 2009/0044808	02/2009	GUNEY et al.			
	US 2009/0126739	05/2009	NG. et al			
	US 2009/0139526	06/2009	MELIDIS et al.			
	US 2009/0138527	06/2009	NG et al.	20090139527		
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	US 2010/0000534	01/2010	KOOIJ et al.			
	US 2010/0000543	01/2010	BERTHON-JONES et al.			
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	US 2010/0192955	08/2010	BIENER et al.			
	US 2010/0282265	11/2010	MELIDIS et al.			
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	D188,084	05/1960	GARELICK			
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	D289,238	04/1987	ARTHUR, JR.			
	D293,613	01/1988	WINGLER			
	D304,384	10/1989	DEROBERT			

*Examiner

Date Considered

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-FB-A820 (Also PTO/SB/08A)

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /K.M./



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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/447,673	09/01/2015	9119931	PTB-4398-1485	3036

23117 7590 08/12/2015
NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional applicants):

Errol Savio Alex D'SOUZA, Sydney, AUSTRALIA;
ResMed Limited, Bella Vista, AUSTRALIA;
Matthew EVES, Sydney, AUSTRALIA;
David James LOCKWOOD, Gosford, AUSTRALIA;
Zoran VALCIC, Sydney, AUSTRALIA;
Jamie Graeme WEHBEH, Sydney, AUSTRALIA;

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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 IPR2017-00061
Patent 9,119,931 B2

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

RICE, *Administrative Patent Judge*.

DECISION
Instituting Inter Partes Review
37 C.F.R. § 42.108

I. INTRODUCTION

A. Background

Fisher & Paykel Healthcare Limited (“Petitioner”) filed a Petition (Paper 1, “Pet.”) requesting an *inter partes* review of claims 1, 4–8, 10–22, 25, 26, 28–37, and 40–42 of U.S. Patent No. 9,119,931 B2 (Ex. 1001, “the ’931 Patent”). Petitioner supported the Petition with a declaration from Jason Eaton, P.E. (Ex. 1013). ResMed Limited (“Patent Owner”) did not file a preliminary response to the Petition.¹

Under 35 U.S.C. § 314, an *inter partes* review may not be instituted “unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). Upon considering the Petition and the evidence filed therewith, we determine that Petitioner has shown a reasonable likelihood that it would prevail with respect to claims 33–37 and 40–42, but not claims 1, 4–8, 10–22, 25, 26, 28–32.

Accordingly, we institute an *inter partes* review of claims 33–37 and 40–42.

B. Related Matters

The parties identify a related federal district court case involving the ’931 Patent: *Fisher & Paykel Healthcare Ltd. v. ResMed Corp.*, Case No. 3:16-cv-02068-GPC-WVG (S.D. Cal.). Pet. 7–8; Paper 4, 2. The parties also indicate that the ’931 Patent is involved in U.S. International Trade Commission Investigation No. 337–TA–1022. Pet. 7; Paper 4, 2.

¹ See 37 C.F.R. § 42.107 (providing that filing a preliminary response to the petition is not obligatory).

Petitioner has filed three additional petitions for *inter partes* review of the '931 Patent. See IPR2017-00062, IPR2017-00064, IPR2017-00065; Pet. 8; Paper 4, 2.

C. The '931 Patent

The '931 Patent, titled “Mask System,” issued on September 1, 2015, and claims priority based on a series of applications dating back to February 27, 2009, as well as several provisional applications dating back to September 19, 2008. Ex. 1001, 1:6–17. The '931 Patent relates generally to a mask system for treatment of “Sleep Disordered Breathing” using “Continuous Positive Airway Pressure [‘CPAP’]” or “Non-Invasive Positive Pressure Ventilation.” *Id.* at 1:21–24.

Figure 3 of the '931 Patent is reproduced below.

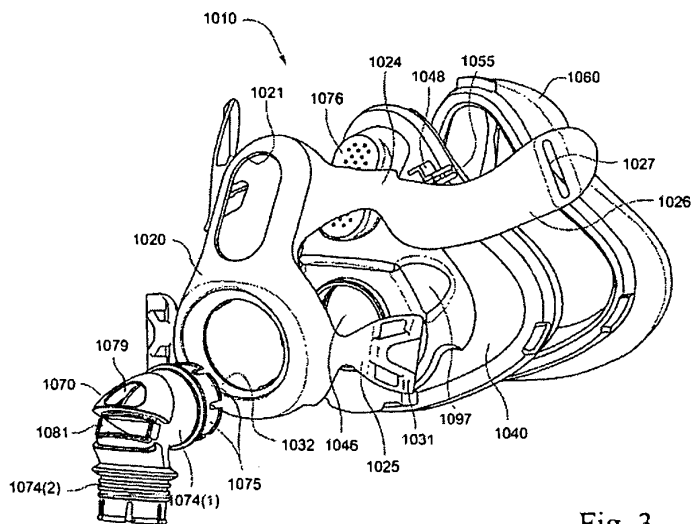
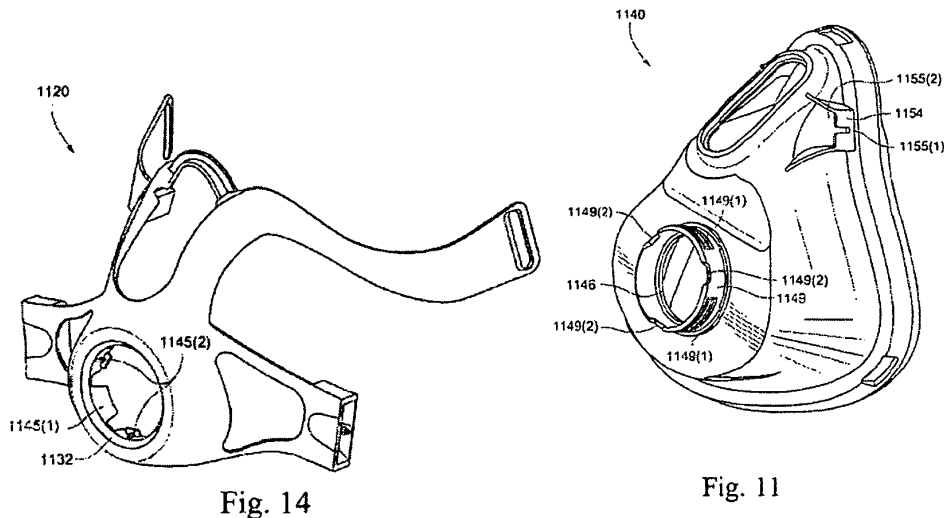


Fig. 3

Figure 3 depicts mask system 1010 comprising frame 1040, mask cushion 1060, shroud 1020, and elbow 1070. *Id.* at 6:51–53. The frame

defines a breathing chamber adapted to receive the patient's nose and mouth and includes an opening 1046 that communicates with elbow 1070. *Id.* at 6:60–64. The frame 1040 also includes vent arrangement 1076, shown in Figure 3, that protrudes from frame 1040. *Id.* at 7:22–23. Opening or vent receiving hole 1021 in shroud 1020 accommodates the protruding vent arrangement. *Id.* at 7:21–23.

Petitioner's annotated versions of Figures 14 and 11 of the '931 Patent are reproduced below:



Pet. 20. According to Petitioner, the annotated Figure 14 above depicts a retaining mechanism at opening 1132 of shroud 1120. *Id.* (citing Ex. 1001, 18:48–53). The retaining mechanism includes snap fingers 1145(1) that engage collar 1149 of frame 1140 (depicted in annotated Figure 11 above). *See id.* (citing Ex. 1001, 18:62–67).

Of the challenged claims, claims 1 and 33 are independent. Claims 4–8, 10–22, 25, 26, and 28–32 depend, directly or indirectly, from claim 1.

Claims 34–37, and 40–42 depend, directly or indirectly, from claim 33.

Claims 1 and 33 are reproduced below:

1. A mask system, comprising:
 - (i) a shroud module; wherein the shroud module includes headgear connectors adapted to removably attach to respective headgear straps of headgear; and
 - (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,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,wherein the shroud module and the cushion module are configured to be removably and non-rotatably coupleable to one another; and
- 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 further wherein the shroud module includes a second opening positioned to align with a frame opening of the frame leading to the breathing chamber.

Ex. 1001, 24:6–29.

33. A mask system, comprising:
 - (i) a shroud module; wherein the shroud module includes headgear connectors adapted to removably attach to respective headgear straps of headgear; and
 - (ii) a cushion module, comprising:
 - a frame defining a breathing chamber; and

a cushion to form a seal with the patient's face in at least a nasal bridge region and a cheek region of the patient's face,

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, and 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;

wherein the shroud module and the cushion module are configured to be removably coupleable to one another, and

wherein the shroud module includes a front opening of substantively circular shape and a retaining portion extending rearwardly from the front opening, towards the frame, and structured to snap-fit with the cushion module.

Id. at 26:54–27:11.

D. Overview of Prosecution History

During prosecution of the '931 Patent, the Examiner issued a final rejection of all pending claims, except claims 29 and 33. Ex. 1014, 343–61. The Examiner indicated that application claims 29 and 33 (each of which recited “a protruding vent arrangement”) would be allowable if rewritten in independent form. *Id.* at 359. In response, the applicant, *inter alia*, added the subject matter of claim 29 to claim 1, canceled claim 29, and added new claims 34–83. *Id.* at 447. With respect to application claim 22 (which issued as claim 33), Petitioner argued that the combination of references applied by the Examiner did not satisfy the claim requirement for “a shroud module [that] includes a front opening and a retaining portion extending rearwardly from the front opening and [] structured to retain the cushion

module.” *Id.* After a subsequent telephonic interview, the Examiner allowed the claims subject to an Examiner’s Amendment. *Id.* at 462–72.

E. The Asserted Grounds

Petitioner challenges claims 1, 4–8, 10–22, 25, 26, 28–37, and 40–42 on the following grounds (Pet. 14–16):

Reference(s)	Basis	Claims Challenged
D’Souza ² and Ultra Mirage ³	§ 103(a)	1, 6, 10, 11, 18, 31, and 32
D’Souza, Ultra Mirage, and Matula-II ⁴	§ 103(a)	4, 5, 26, 33, 37, and 40–42
D’Souza, Ultra Mirage, and FlexiFit ⁵	§ 103(a)	7 and 8
D’Souza, Ultra Mirage, and Barnett ⁶	§ 103(a)	12, 14, 16, and 17
D’Souza, Ultra Mirage, and Lovell ⁷	§ 103(a)	13
D’Souza, Ultra Mirage, and Jaffre ⁸	§ 103(a)	15

² WO 2007/041751 A1, pub. Apr. 19, 2007 (Ex. 1002, “D’Souza”).

³ ResMed product brochure describing the “Ultra Mirage™ Full Face Mask” (Ex. 1003, “Ultra Mirage”). Petitioner has proffered evidence to establish that the brochure was publicly available by September 1, 2006. Pet. 11–12 (citing Ex. 1003, 1–2, 7–8; Ex. 1013 ¶¶ 55–56).

⁴ US 2007/0044804 A1, pub. Mar. 1, 2007 (Ex. 10054, “Matula-II”).

⁵ Fisher & Paykel Healthcare Corporation Limited product brochure describing the “FlexiFit™431 Full Face Mask” (Ex. 1006, “FlexiFit”). Petitioner has proffered evidence to establish that the brochure was publicly available by October 16, 2006. Pet. 12–13 (citing Ex. 1006, 1–2, 5, 8, 11; Ex. 1013 ¶¶ 55, 57; 1016, 1–4).

⁶ US 6,412,488 B1, iss. July 2, 2002 (Ex. 1007, “Barnett”).

⁷ US 6,631,718 B1, iss. Oct. 14, 2003 (Ex. 1008, “Lovell”).

⁸ US 6,851,425 B2, iss. Feb. 8, 2005 (Ex. 1012, “Jaffre”).

Reference(s)	Basis	Claims Challenged
D'Souza, Ultra Mirage, FlexiFit, and Gunaratnam-II ⁹	§ 103(a)	19–21 and 25
D'Souza, Ultra Mirage, FlexiFit, Gunaratnam-II, and Matula-II	§ 103(a)	22
D'Souza, Ultra Mirage, Matula-II, FlexiFit, and Barnett	§ 103(a)	28–30
D'Souza, Ultra Mirage, Matula-II, and Barnett	§ 103(a)	34 and 36
D'Souza, Ultra Mirage, Matula-II, and FlexiFit	§ 103(a)	35

II. ANALYSIS

A. Level of Skill in the Art

Petitioner asserts that a person having ordinary skill in the art (“PHOSITA”) “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.” Pet. 21 (citing Ex. 1013 ¶ 27). Based on our review of the Petition and evidence, including Mr. Eaton’s testimony, we find that Petitioner’s asserted level of skill in the art is reasonable and, for the purposes of this Decision, we adopt that definition.

B. Claim Construction

In an *inter partes* review, the Board gives claim terms in an unexpired patent their broadest reasonable interpretation in light of the specification of

⁹ US 2004/0226566 A1, pub. Nov. 18, 2004 (Ex. 1010, “Gunaratnam-II”).

the patent in which they appear. 37 C.F.R. § 42.100(b); *see Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under that standard, a claim term generally is given its ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). While our claim interpretation cannot be divorced from the specification and the record evidence, *see Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015) (quoting *In re NTP, Inc.*, 654 F.3d 1279, 1288 (Fed. Cir. 2011)), we must be careful not to import limitations from the specification that are not part of the claim language. *See SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

1. “*a protruding vent arrangement having a plurality of holes*” (claim 1)

Claim 1 recites “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” (emphasis added). Petitioner does not propose an explicit construction for this or any other claim term, but rather contends generally that all claim terms should “have their ordinary and customary meaning[s] in light of the Specification, as commonly understood by those of ordinary skill in the art at the time of the invention.” Pet 16.

In its obviousness analysis, Petitioner argues, however, that the “protruding vent arrangement” claim term would be satisfied by adding a

plurality of vent holes to a portion of D'Souza's frame 414 that extends through an opening in shroud 412. *Id.* at 28–29, 33–34; *see* Ex. 1013 ¶¶ 72–73. As such, Petitioner contends, implicitly, that the “protruding vent arrangement” claim term broadly encompasses vent holes in a portion of the frame that extends through an opening in the shroud module.

We disagree. Petitioner's implicit claim construction is contrary to the plain language of claim 1, which requires the frame to have a “vent arrangement” that is “protruding” (rather than reciting that the frame has a protruding portion that includes a vent arrangement having a plurality of holes). Petitioner's construction also is inconsistent with the Specification. As described in the Specification and depicted in Figure 3 (reproduced above on page 3), protruding vent arrangement 1076 is a discrete vent structure that extends above the surrounding surface of frame 1040 and contains a plurality of vent holes. Ex. 1001, 7:18–23 (“The top end of the shroud 1020 . . . includes an opening or vent receiving hole 1021 to accommodate *the vent arrangement 1076 that protrudes from the frame 1040*” (emphasis added)), Fig. 3. Contrary to Petitioner's implicit claim construction, protruding vent arrangement 1076 is described in the Specification as extending from the surface of the frame, and not merely as extending through an opening in shroud 1020. *See id.*

Further, claim 1 separately recites that “the shroud module includes a first opening to accommodate said protruding vent arrangement.” That language would be rendered “merely superfluous” under Petitioner's implicit construction that “a protruding vent arrangement” is a portion of the frame with vent holes that extends through an opening in the shroud. *See Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006) (stating

that “claims are interpreted with an eye toward giving effect to all terms in the claim,” so that physical structures and characteristics specifically described in a claim are not rendered “merely superfluous”).

We determine that the broadest reasonable interpretation consistent with the Specification of “a protruding vent arrangement having a plurality of vent holes” is a discrete vent structure that extends above the surrounding surface of the frame and contains a plurality of vent holes.

2. Other Claim Terms

We determine that no other explicit claim interpretation is required for the purposes of this Decision. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

C. Asserted Obviousness

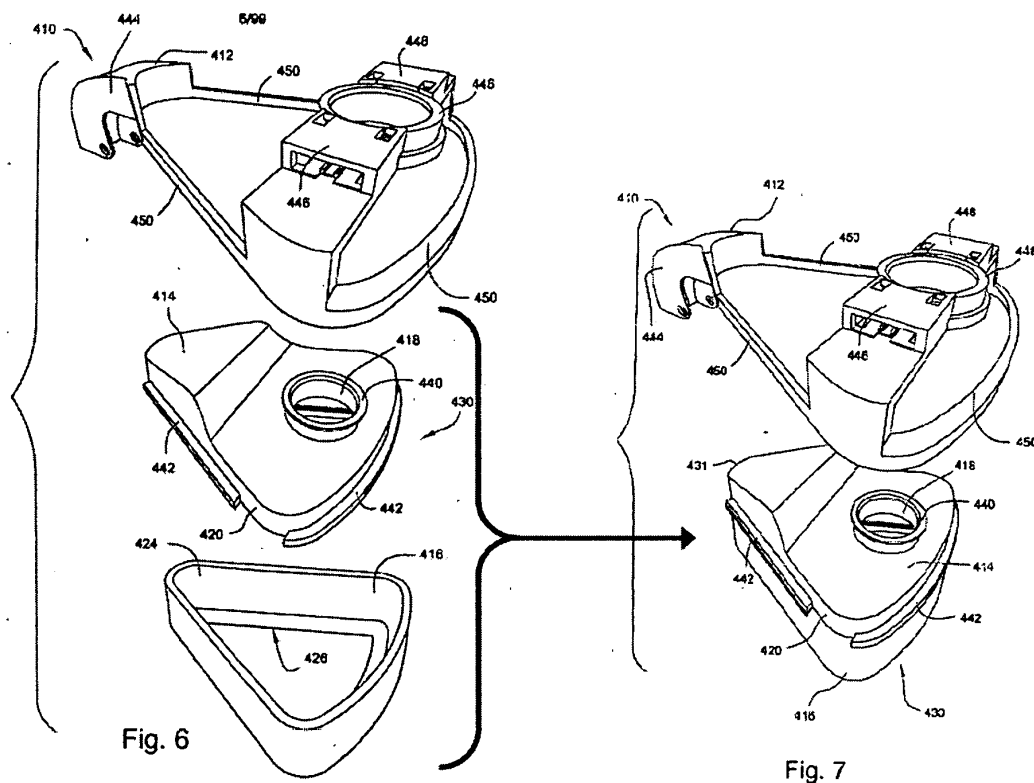
A claim is unpatentable for obviousness under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). In analyzing the obviousness of a combination of prior art elements, it can be important to identify a reason that would have prompted one of skill in the art to combine the elements in the way the claimed invention does. *Id.* The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness, i.e., secondary considerations, if in evidence. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

Petitioner challenges claims 1, 6, 10, 11, 18, 31, and 32 as obvious over D'Souza and Ultra Mirage. Petitioner challenges claims 4, 5, 7, 8, 12–16, 17, 19–21, 22, 25, 26, and 28–30 as obvious over D'Souza and Ultra Mirage in view of one or more of Matula-II, Flexi-Fit, Barnett, Lovell, Jaffe, and Gunaratnam-II.

1. D'Souza and Ultra Mirage

a. Overview of D'Souza

Petitioner's annotated versions of Figures 6 and 7 of D'Souza are reproduced below.



See Pet. 23; Ex. 1002, Figs. 6, 7. The figures above depict D'Souza's mask assembly 410 comprising skeleton frame 412 (asserted "shroud module"),

frame 414 (asserted “frame”), and cushion 416. *Id.* at 25; Ex. 1002 ¶ 97. As illustrated in the figures, frame 414 interlocks with cushion 416 to form cushion/frame sub-assembly 430 (asserted “cushion module”). Pet. 25; Ex. 1002 ¶ 97.

b. Overview of Ultra Mirage

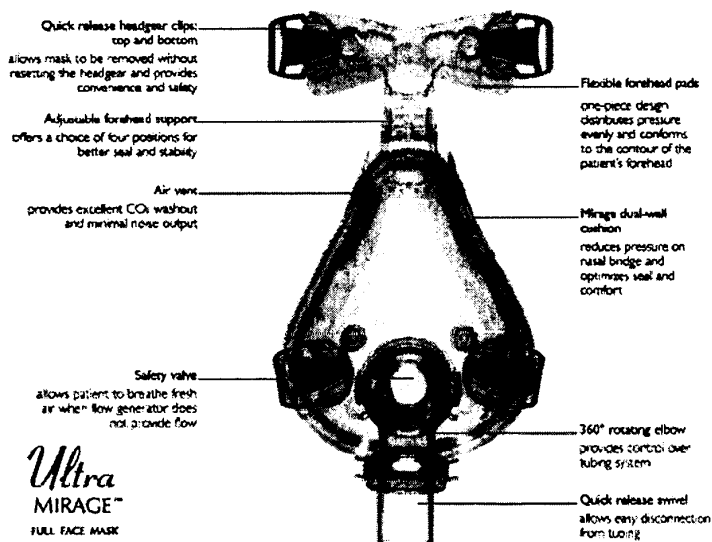
Ultra Mirage discloses a full face CPAP mask with top and bottom removable headgear clips, an air vent to provide CO₂ washout, and a rotating elbow with a quick release swivel. *See* Pet. 24–25; Ex. 1003, 6. A figure in Ultra Mirage, which is reproduced below, illustrates the mask.

Ultra Mirage™ Full Face Mask

The ultimate solution for mouth leak

Mouth breathing and leak are common problems for CPAP and bilevel therapy users. These problems result in ineffective therapy, discomfort and disrupted sleep—all of which can cause patients to be noncompliant or to abandon therapy altogether.

ResMed's Ultra Mirage™ Full Face Mask covers both the nose and mouth so patients receive effective therapy even in the presence of mouth breathing and leak.

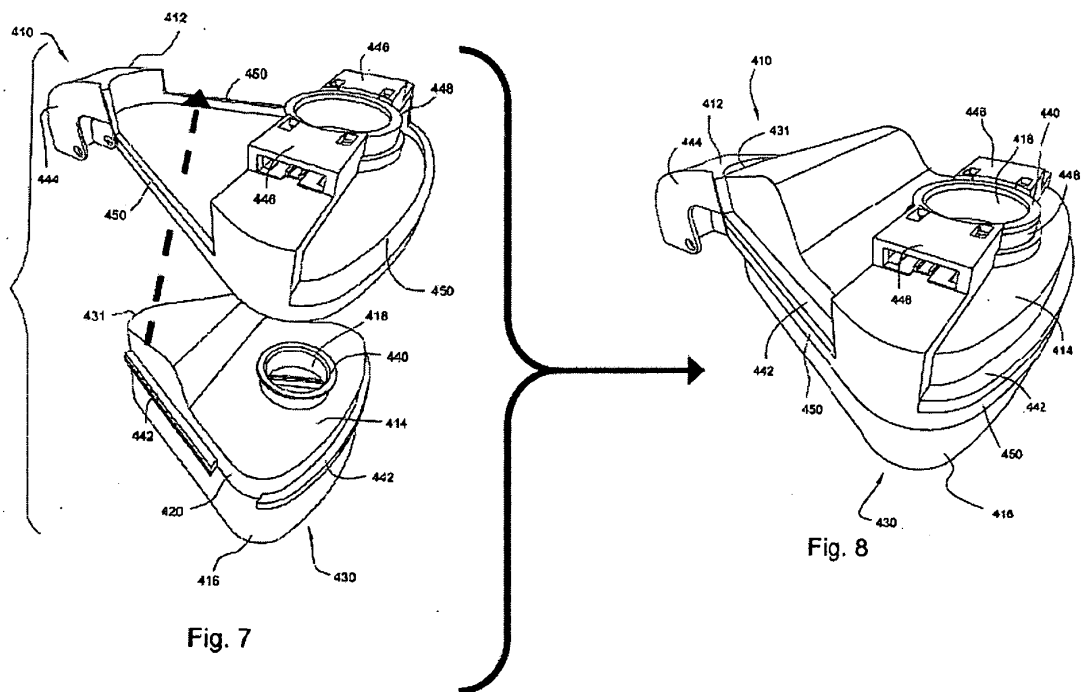


See id. at 24–25; Ex. 1003, 6. Various elements of the mask, including the air vent, are identified in the Ultra Mirage figure.

c. Analysis of Claims 1, 4–8, 10–22, 25, 26, 28–32

Claim 1 recites, *inter alia*, that “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” (emphasis added).

With respect to this claim requirement, Petitioner asserts: “As shown in Figs. 7–8 of D’Souza [reproduced below], when the mask assembly 410 is assembled, the top portion 431 (nasal bridge region) of the frame 414 protrudes through the opening (between the elongated frame members 450) in the shroud 412.” Pet. 28 (citing Ex. 1002 ¶ 101); Ex. 1002, Figs. 7, 8.



Petitioner acknowledges that D’Souza “does not expressly disclose a vent on the protrusion,” but argues that “vents positioned in the region of the D’Souza protrusion (nasal bridge region) were common in prior art CPAP

masks.” *Id.* at 29 (citing Ex. 1013 ¶¶ 64, 72–73). Petitioner further argues that “Ultra Mirage teaches an air vent positioned in the nasal bridge region to provide CO₂ washout and minimize noise output,” and “a skilled artisan would have been motivated to provide the vent of Ultra Mirage in the same nasal bridge region of D’Souza, and thus on the protruding portion of D’Souza.” *Id.* (citing Ex. 1003, 6; Ex. 1013 ¶¶ 64, 72–73).

Petitioner’s argument, that adding a plurality of vent holes to a portion of D’Souza’s frame 414 that extends through an opening in shroud 412 would satisfy the claim requirement, is based on an improper claim construction, as discussed above. *See supra* Section II.B.1. Under our claim interpretation, the claim term requires a discrete vent structure that extends above the surrounding surface of the frame and contains a plurality of vent holes. *See id.* Petitioner does not contend that Ultra Mirage teaches or suggests “a protruding vent arrangement having a plurality of vent holes.” Rather, Petitioner contends that Ultra Mirage teaches positioning a plurality of vent holes in the nasal bridge region of a mask. Merely positioning a plurality of vent holes in the nasal bridge region of D’Souza’s mask would not result in a discrete vent structure that extends above the surrounding surface of the frame and contains a plurality of vent holes, as required under our claim interpretation. The vent holes would be flush with the surrounding surface of the nasal bridge region. We are unpersuaded, therefore, that the combination of D’Souza and Ultra Mirage teaches or suggests “a protruding vent arrangement having a plurality of holes.”

For the reasons given, we determine that Petitioner has not established a reasonable likelihood of prevailing on its challenge to independent claim 1 as obvious over D’Souza and Ultra Mirage. For the same reasons, Petitioner

has not shown a reasonable likelihood of prevailing on its challenge to claims 6, 10, 11, 18, 31, and 32, which depend, directly or indirectly, from claim 1.

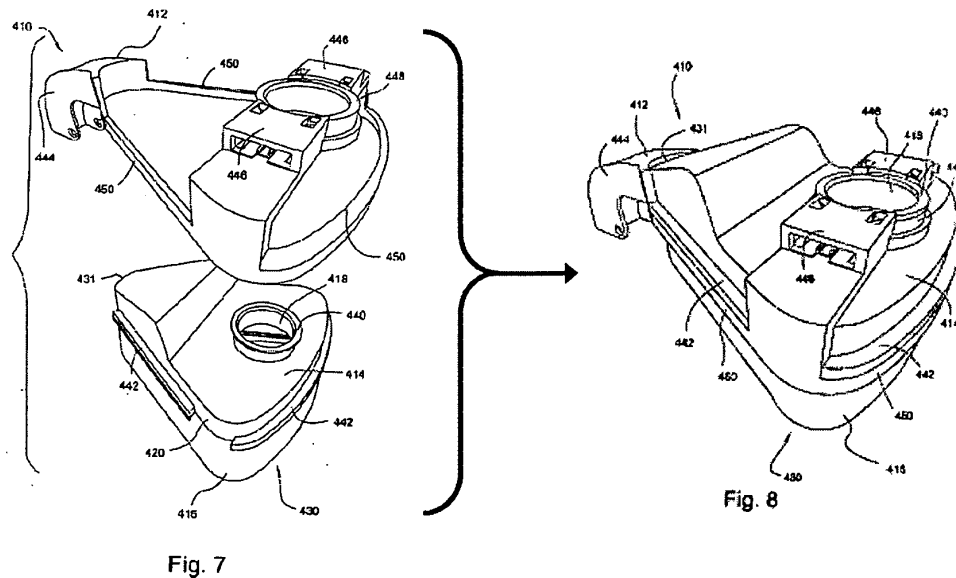
Claims 4, 5, 7, 8, 12–16, 17, 19–21, 22, 25, 26, and 28–30 also depend, directly or indirectly, from independent claim 1. For its challenges to those claims, Petitioner relies on D’Souza and Ultra Mirage in view of one or more of Matula-II, Flexi-Fit, Barnett, Lovell, Jaffe, and Gunaratnam-II. *See* Pet. 34–86. As Petitioner does not argue that any of those references remedies the deficiency with respect to independent claim 1, discussed above, we also determine that Petitioner has not established a reasonable likelihood of prevailing on its challenges to dependent claims 4, 5, 7, 8, 12–16, 17, 19–21, 22, 25, 26, and 28–30.

2. D’Souza, Ultra Mirage, and Matula-II

Petitioner contends that claims 33, 37, and 40–42 would have been obvious over D’Souza, Ultra Mirage, and Matula-II.

a. Overview of D’Souza

As shown in Petitioner’s annotated versions of Figures 7 and 8 of D’Souza, reproduced below, skeleton frame 412 interlocks with cushion/frame sub-assembly 430 (asserted “cushion module”). *See* Pet. 38; Ex. 1002 ¶ 96, Figs. 7, 8.



Figures 7 and 8 of D'Souza illustrate that frame 414 of the asserted cushion module includes an opening 418, which is surrounded by an annular wall 440; and skeleton frame 412 (asserted "shroud module") includes "an annular elbow connection seal 448 adapted to engage an inlet conduit, e.g., elbow." Ex. 1002 ¶¶ 98, 100. To assemble and interlock the shroud module and cushion module, the large-diameter collar on the end of annular wall 440 must be passed through the opening in annular seal 448 to rest against the front/top edge of annular seal 448 to rest against the front/top edge of annular seal 448. *See id.* ¶ 101, Figs. 7, 8; Pet. 38.

b. Overview of Matula-II

Petitioner asserts that Matula-II discloses a CPAP mask including faceplate 36 coupled to seal member 38. Pet. 35 (citing Ex. 1005 ¶¶ 52–53). Petitioner provides an annotated version of Figure 4 of Matula-II (reproduced below).

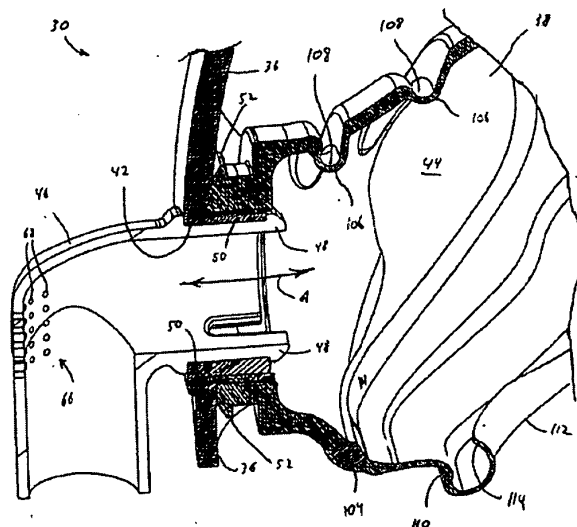


Fig. 4

As shown in Figure 4, Matula-II discloses coupling member or elbow piece 46, which has a pair of prongs 48 that define a channel (channel 50). Ex. 1005 ¶¶ 49, 53. Petitioner explains that channel 50 receives the wall of faceplate 36 and the end of seal member 38. Pet. 35 (citing Ex. 1005 ¶ 53).

c. Analysis of Claims 33, 37, and 40–42

Claim 33 recites, *inter alia*, that “the shroud module includes . . . a retaining portion extending rearwardly from the front opening, towards the frame, and structured to snap-fit with the cushion module” (“the rearwardly extending retaining portion” requirement).

Petitioner contends that “D’Souza teaches a shroud module having an annular opening 448 with a retaining portion extending rearwardly from the opening 448.” *Id.* at 40 (citing Ex. 1002 ¶ 101). As discussed below, Petitioner has not persuaded us that the asserted retaining portion is structured to snap-fit with the cushion module, as required by claim 33.

Petitioner argues:

The shroud 412 includes a retaining portion 448 structured to engage the collar 440. [Ex. 1002] ¶ 101. The shroud and frame are constructed from plastic and their assembly would require elastic deformation of the collar 440 or the retaining portion 448 for the larger diameter collar 440 to pass through the retaining portion 448. Thus, the retaining portion 448 engages the collar 440 with a snap-fit. *Id.* ¶¶ 98, 100; Ex. 1013 ¶¶ 85–86. As shown in Fig. 8 of D’Souza (above), *the collar 440 snaps over the front/top edge of the retaining portion 448.* Ex. 1013 ¶ 86.

Pet. 38 (emphasis added). At most, this argument explains how the large-diameter collar on the end of annular wall 440 is structured to interlock or snap-fit with the shroud module. This argument does not explain how the rearwardly extending portion of annular seal 448 is structured to snap-fit with the cushion module, as the claim requires.

Alternatively, Petitioner argues that “to the extent D’Souza provides insufficient teachings for a removable snap-fit, Matula-II teaches a plurality of snap fingers 48 that elastically deform to mechanically and removably couple the seal member 38 to the faceplate 36.” *Id.* at 41 (citing Ex. 1005 ¶ 53). As a reason to modify D’Souza’s interlock mechanism to satisfy the “rearwardly extending retaining portion” requirement, Petitioner argues: “Based on the teachings of Matula-II, a skilled artisan would have been motivated to incorporate such snap fingers into the removable interlocking arrangement of D’Souza.” *Id.* (citing Ex. 1013 ¶ 91). Petitioner additionally argues:

A skilled artisan would have also been motivated to modify the rearward extending retaining portion of D’Souza to include the plurality of rearward extending snap fingers, as taught by Matula-II, to facilitate formation of the removable snap-fit of D’Souza. Ex. 1013 ¶¶ 94–95. Although the Matula-II snap

fingers are on the elbow, incorporating such snap fingers into the retaining portion of D'Souza would have involved a simple substitution of one known feature for another to obtain predictable results and achieve the same purpose of providing a removable mechanical interlock between the shroud and the cushion module.

Id. at 42 (citing Ex. 1002 ¶ 96).

At this stage of the proceeding, we are persuaded by the cited testimony of Mr. Eaton that a PHOSITA would have modified D'Souza's interlock mechanism by removing the large diameter collar from the end of annular wall 440 and substituting snap fingers, as taught by Matula-II, on the rearwardly extending portion of annular seal 448 (asserted retaining portion). We set forth below Mr. Eaton's testimony explaining that a reason for the substitution would have been the well-known advantages of axially oriented snap fingers over radially oriented compression/expansion features such as D'Souza's large diameter collar:

94. As I have explained above, D'Souza describes a CPAP mask assembly with a snap-fit between the cushion frame and shroud. A person of skill in the art seeking to practice the arrangement described in D'Souza would have recognized that the degree of deformation required to allow assembly of the collar and the rearward extending retaining portion, as shown in the figures, appears to exceed acceptable material strain limits of commonly used rigid plastics such as polycarbonate, and thus could have made it difficult or even impossible to assemble these components. A well-known solution to the problem of snap-fit features exceeding material strain limits was to create slots that segment the interfering features on one or both mating parts into one or more fingers or beams. These fingers or beams can deform along the length of the finger or beam by bending, and allow greater deflection than could be achieved by the radial compression/expansion of cylindrical features, such as those depicted in D'Souza.

95. A person skilled in the art would have known to look to other mask assembly designs where mating cylindrical features were intended to axially engage in a snap fit. This type of an arrangement of snap fingers is taught by Matula-II, where engaging geometry on the elbow is segmented to create a plurality of snap fingers that permit deflection during assembly to the shroud, then elastically recover to an assembled and interlocked position. A person of skill in the art at the time of the invention would have been motivated to modify the rearward extending retaining portion of D'Souza to include a plurality of rearward extending snap fingers on the retaining portion, based on the teaching of Matula-II. While the snap fingers of Matula-II are located in the elbow, incorporating such snap fingers into the retaining portion of D'Souza would have involved simply substituting one known feature for another with a predictable result. Although the location of the snap fingers would have been a matter of design preference, one of skill in the art would have recognized that it would have been advantageous to add snap fingers to the shroud rather than the mask frame based on the simplicity of molding the required snap finger geometry without compromising the airtight surfaces of the mask frame.

Ex. 1013 ¶¶ 94–95.

Claim 33 also recites, *inter alia*, that “the shroud module includes headgear connectors adapted to removably attach to respective headgear straps of headgear.” Petitioner argues that a PHOSITA “would have been motivated to provide removable headgear straps to the mask assembly of D'Souza to enable quick and easy mask fitting and removal (e.g., for cleaning or replacement).” Pet. 33 (citing Ex. 1013 ¶ 71; Ex. 1003, 6). At this stage of the proceeding, we are persuaded that a PHOSITA would have combined the teachings of D'Souza and Ultra Mirage to provide removable headgear straps to D'Souza's mask assembly.

Petitioner provides arguments and a claim chart identifying where all of the limitations of claims 33, 37, and 40–42 are taught by D'Souza, Ultra

Mirage, and Matula-II. Pet. 34–42, 86–90. We have reviewed Petitioner’s arguments and the underlying evidence cited in support and are persuaded at this stage of the proceeding that Petitioner sufficiently establishes that claims 33, 37, and 40–42 would have been obvious over D’Souza, Ultra Mirage, and Matula-II.

For the reasons given, we determine that Petitioner has established a reasonable likelihood of prevailing on its challenge to claims 33, 37, and 40–42 as obvious over D’Souza, Ultra Mirage, and Matula-II.

3. *D’Souza, Ultra Mirage, Matula-II, and Barnett*

Petitioner contends that claims 34 and 36 would have been obvious over D’Souza, Ultra Mirage, Matula-II, and Barnett. Claim 34 recites: “The mask system of claim 33, further comprising an elbow module directly mechanically interlocked with the shroud module while allowing 360 degree rotation of the elbow module.” Claim 36 recites: “The mask system of claim 33, further comprising an elbow module adapted to be connected to an air delivery tube that delivers breathable gas to the patient, wherein the shroud module is structured to directly retain and carry the elbow module.”

Petitioner sufficiently establishes at this stage of the proceeding that “D’Souza discloses an elbow adapted to engage the mask assembly (Ex. 1002 ¶ 100) and Ultra Mirage discloses that the elbow rotates 360° (Ex. 1003 at 6).” *Id.* at 48. While D’Souza and Ultra Mirage do not disclose an elbow that directly connects to the shroud module, Petitioner establishes sufficiently at this stage of the proceeding that “Barnett discloses an elbow 36 that is mounted to the shroud 34 and freely rotates 360°.” *Id.* (citing Ex. 1007, 3:52–57). At this stage of the proceeding, we determine that Petitioner also has provided adequate reasoning with rational

underpinning to show that a PHOSITA would have been motivated to combine the teachings of D’Souza, Ultra Mirage, Matula-II, and Barnett to arrive at the features of claims 34 and 36. *See id.* at 50 (citing Ex. 1013 ¶¶ 110–111), 63 (citing Ex. 1013 ¶ 138).

For the reasons given, we determine that Petitioner has established a reasonable likelihood of prevailing on its challenge to claims 34 and 36 as obvious over D’Souza, Ultra Mirage, Matula-II, and Barnett.

4. *D’Souza, Ultra Mirage, Matula-II, and FlexiFit*

Claim 35 recites:

The mask system of claim 33, wherein the shroud module includes upper and lower headgear connectors on each side of the shroud module; wherein each upper headgear connector includes a slot adapted to receive a respective headgear strap in use; and wherein each lower headgear connector is adapted to be removably interlocked with a headgear clip associated with a respective headgear strap.

Petitioner argues that “D’Souza does not expressly disclose upper headgear connectors, but Ultra Mirage teaches a shroud having a forehead support with headgear connectors.” Pet. 30 (citing Ex. 1013 ¶¶ 65–66). Petitioner additionally asserts that “a skilled artisan would have known to add upper headgear connectors as taught by Ultra Mirage to the forehead support of D’Souza to secure the upper portion of the mask assembly and to stabilize the mask assembly.” *Id.* at 33 (citing Ex. 1013 ¶ 71).

Petitioner also argues that “D’Souza does not expressly disclose upper headgear connector slots and Ultra Mirage shows the slots on headgear clips, but . . . FlexiFit discloses attaching upper horizontal straps to corresponding slots in the mask base.” *Id.* at 44 (citing Ex. 1006, 10; Ex. 1013 ¶ 98). As a

reason to modify the headgear connector configuration of D’Souza and Ultra Mirage, Petitioner asserts:

When headgear is pulled over a user’s head, lower headgear straps undergo tension, making it difficult to position the lower headgear straps. [Ex. 1013 ¶¶ 100–101.] A skilled artisan would have been motivated to provide removable lower headgear clips as taught by FlexiFit, so that the user would not have to force the lower headgear straps over his/her head. *Id.* Since upper headgear straps undergo less tension than lower headgear straps when positioning the headgear, a skilled artisan would have known that a simpler design option would have been to provide upper headgear connectors with slots as taught by FlexiFit and that such an alternative arrangement would simplify manufacturing and reduce parts. *Id.*

Id. at 45–46.

Petitioner sufficiently establishes at this stage of the proceeding that D’Souza, Ultra Mirage, and FlexiFit teach or suggest the limitations added by claim 35. Further, at this stage of the proceeding, we determine that Petitioner has provided adequate reasoning with rational underpinning to show that a PHOSITA would have been motivated to combine the teachings of D’Souza, Ultra Mirage, Matula-II, and FlexiFit to arrive at the features of claim 35. *See id.* at 63 (citing Ex. 1013 ¶¶ 139–140), 88–89; *see* Ex. 1013 ¶¶ 96–101, 130–132.

For the reasons given, we determine that Petitioner has established a reasonable likelihood of prevailing on its challenge to claim 35 as obvious over D’Souza, Ultra Mirage, Matula-II, and FlexiFit.

III. CONCLUSION

For the reasons give, Petitioner has shown a reasonable likelihood that it would prevail in establishing unpatentability of claims 33–37 and 40–42,

but not claims 1, 4–8, 10–22, 25, 26, 28–32. At this stage of the proceeding, the Board has not made a final determination with respect to the patentability of any of the challenged claims, nor with respect to claim construction.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is hereby instituted based on the following grounds:

- A. claims 33, 37, and 40–42 of U.S. Patent No. 9,119,931 B2 as obvious over D’Souza, Ultra Mirage, and Matula-II;
- B. claims 34 and 36 of U.S. Patent No. 9,119,931 B2 as obvious over D’Souza, Ultra Mirage, Matula-II, and Barnett; and
- C. claim 35 of U.S. Patent No. 9,119,931 B2 as obvious over D’Souza, Ultra Mirage, Matula-II, and FlexiFit;

FURTHER ORDERED that no other ground of unpatentability asserted in the Petition is authorized for this *inter partes* review; and

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

IPR2017-00061
Patent 9,119,931 B2

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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 IPR2017-00062
Patent 9,119,931 B2

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

GROSSMAN, *Administrative Patent Judge*.

DECISION
Instituting Inter Partes Review
37 C.F.R. § 42.108

I. INTRODUCTION

A. Background

Fisher & Paykel Healthcare Limited (“Petitioner”) filed a Petition (Paper 1, “Pet.”) requesting an *inter partes* review of claims 43, 46, 48–51, 53–58, 60–65, 68–71, and 77–79 of U.S. Patent No. 9,119,931 B2 (Ex. 1101, “the ’931 Patent”). ResMed Limited (“Patent Owner”) did not file a preliminary response to the Petition.¹

Under 35 U.S.C. § 314, an *inter partes* review may not be instituted “unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). The Board considers the Petition on behalf of the Director. 37 C.F.R. § 42.4(a).

Upon considering the Petition and the evidence filed therewith, we determine that Petitioner has shown a reasonable likelihood that it would prevail with respect to claims 43, 48–50, 57, 58, 60, 61–64, 68, 69, 70, 71, and 77–79. Petitioner has *not* shown a reasonable likelihood that it would prevail with respect to claims 46, 51, and 53–56, and 65. Accordingly, we institute an *inter partes* review of claims 43, 48–50, 57, 58, 60, 61–64, 68, 69, 70, 71, and 77–79.

B. Related Matters

The parties identify a related federal district court case involving the ’931 Patent: *Fisher & Paykel Healthcare Ltd. v. ResMed Corp.*, Case No. 3:16-cv-02068-GPC-WVG (S.D. Cal.). Pet. 7–8; Paper 4, 2. The parties

¹ See 37 C.F.R. § 42.107 (providing that filing a preliminary response to the petition is not obligatory).

IPR2017-00062
Patent 9,119,931 B2

also indicate that the '931 Patent is involved in U.S. International Trade Commission Investigation No. 337-TA-1022. Pet. 7; Paper 4, 2.

Petitioner has filed three additional petitions for *inter partes* review of the '931 Patent. See IPR2017-00061, IPR2017-00064, IPR2017-00065; Pet. 8; Paper 4, 2. The reviews sought in the four petitions by Petitioner challenging the '931 Patent are summarized in the chart below.

Case No.	IPR2017-00061	IPR2017-00062	IPR2017-00064	IPR2017-00065
Challenged Claims	1, 4–8, 10–22, 25, 26, 28–37, and 40–42	43, 46, 48–51, 53–58, 60–65, 68–71, and 77–79	33–37, 40–43, 48–50, 57, 58, 60–64, 68–71, and 77–79	1, 4–8, 10–22, 25, 26, 28–32, 46, 51, 53–56, and 65
References Asserted ²	D'Souza, Ultra Mirage, Matula-II, FlexiFit, Barnett, Lovell, Jaffre, and Gunaratnam-II	D'Souza, Ultra Mirage, Matula-II, FlexiFit, Barnett, Jaffre, and Gunaratnam-II	Barnett, Ogden, Gunaratnam-I, Gunaratnam-II, Worboys, Matula-II,	Barnett, Ogden, Gunaratnam-I, Gunaratnam-II, Worboys, Matula-II, Matula-I, and Lovell

C. The '931 Patent

The '931 Patent, titled “Mask System,” issued on September 1, 2015, and claims priority based on a series of applications dating back to February 27, 2009, as well as several provisional applications dating back to

² We use the shorthand identification used in each Petition to identify the references asserted. Not all references are asserted against all claims in each case. As necessary, in other sections of this Decision, we provide complete citations of the specific references asserted against each claim.

September 19, 2008. Ex. 1101, 1:6–17. The '931 Patent relates generally to a mask system for treatment of “Sleep Disordered Breathing” using “Continuous Positive Airway Pressure [‘CPAP’]” or “Non-Invasive Positive Pressure Ventilation.” *Id.* at 1:21–24. This is a highly-developed technology, as represented by the eleven pages of references cited in the patent. *Id.* at 2–12.

Figure 3 of the '931 Patent, as annotated by Petitioner (Pet. 3), is reproduced below.

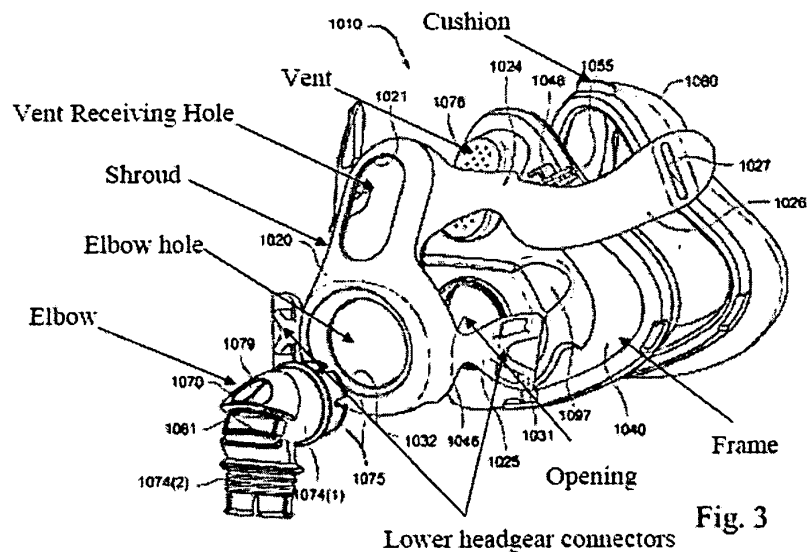


Figure 3 is an exploded perspective view of the disclosed mask system showing the frame, cushion, shroud, and elbow, as annotated by Petitioner.

Figure 3 depicts mask system 1010 comprising frame 1040, mask cushion 1060, shroud 1020, and elbow 1070. *Id.* at 6:51–53. The frame defines a breathing chamber adapted to receive the patient’s nose and mouth and includes an opening 1046 that communicates with elbow 1070. *Id.* at 6:60–64. The frame 1040 also includes vent arrangement 1076, shown in

Figure 3, which protrudes from frame 1040. *Id.* at 7:22–23. Opening or vent receiving hole 1021 in shroud 1020 accommodates the protruding vent arrangement. *Id.* at 7:21–23. Upper headgear connectors 1024 extend from each side of the top portion of the shroud and lower headgear connectors 1025 extend from each side of the lower portion. *Id.* at 7:28–30. Each lower headgear connector 1025 includes clip receptacle 1031 at the free end that interlocks with a headgear clip on a headgear strap (*see* Figure 9 showing headgear strap 1090). *Id.* at 8:29–32.

Of the challenged claims, claims 43, 51, and 57 are independent.

Representative claims 43 and 57 are reproduced below:

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

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, 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, the frame including a washout vent, the frame including an opening;

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, 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, 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 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;

a shroud module including headgear connectors adapted to removably attach to the headgear, wherein the headgear connectors include two upper connectors associated with the upper headgear straps, the shroud module having an opening of circular shape, and two lower connectors associated with the lower headgear straps, each said upper headgear connector including a slot or receiving hole adapted to receive one of the upper headgear straps, 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; 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, the elbow including a swivel adapted to connect to an air delivery tube, the elbow including an anti-asphyxia valve (AAV) and a port that is selectively closed by a flap portion of the AAV.

Ex. 1101, 27:55–28:39.

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

headgear including headgear straps;

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, the shroud module having a front opening;

a rotatable elbow directly attached to the shroud; and

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, wherein the cushion comprises a first,

relatively soft, elastomeric material and the frame comprises a second material that is more rigid than the cushion;

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.

Id. at 30:52–31:11.

Independent claim 51 includes the limitations of claim 43 and its dependent claim 46, reciting additional details of the straps and frame.

D. The Asserted Grounds

Petitioner challenges claims 43, 46, 48–51, 53–58, 60–65, 68–71, and 77–79 on the following five grounds (Pet. 15–16):

Reference(s)	Basis	Claims Challenged
D’Souza ³ , Ultra Mirage ⁴ , Barnett ⁵ , and Matula-II ⁶	§ 103(a)	57, 58, 61, 65, 68, 69, 71, and 77–79

³ WO 2007/041751 A1, pub. Apr. 19, 2007 (Ex. 1102, “D’Souza”).

⁴ ResMed product brochure describing the “Ultra Mirage™ Full Face Mask” (Ex. 1103, “Ultra Mirage”). Petitioner has proffered evidence to establish that the brochure was publicly available by September 1, 2006. Pet. 11–12 (citing Ex. 1103, 1–2, 7–8; Ex. 1113 ¶¶ 48–50).

⁵ US 6,412,488 B1, iss. July 2, 2002 (Ex. 1107, “Barnett”).

⁶ US 2007/0044804 A1, pub. Mar. 1, 2007 (Ex. 1105, “Matula-II”).

Reference(s)	Basis	Claims Challenged
D'Souza, Ultra Mirage, Barnett, Matula-II, and FlexiFit ⁷	§ 103(a)	60
D'Souza, Ultra Mirage, Barnett, Matula-II, FlexiFit, and Gunaratnam-II ⁸	§ 103(a)	62–64
D'Souza, Ultra Mirage, FlexiFit, Barnett, Jaffre ⁹ , and Matula-II	§ 103(a)	43, 48–50, and 70
D'Souza, Ultra Mirage, FlexiFit, Barnett, Jaffre, Matula-II, and Gunaratnam-II	§ 103(a)	46, 51, and 53–56

II. ANALYSIS

A. Level of Skill in the Art

Petitioner asserts that a person having ordinary skill in the art (“PHOSITA”) “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.” Pet. 20 (citing Ex. 1113 ¶ 27). Based on our review of the Petition and evidence, including Mr. Eaton’s testimony, we find that

⁷ Fisher & Paykel Healthcare Corporation Limited product brochure describing the “FlexiFit™431 Full Face Mask” (Ex. 1106, “FlexiFit”). Petitioner has proffered evidence to establish that the brochure was publicly available by October 16, 2006. Pet. 12–14 (citing Ex. 1106, 5, 8, 11; Ex. 1113 ¶¶ 48–50; Ex. 1116, 1–4).

⁸ US 2004/0226566 A1, pub. Nov. 18, 2004 (Ex. 1110, “Gunaratnam-II”).

⁹ US 6,851,425 B2, iss. Feb. 8, 2005 (Ex. 1112, “Jaffre”).

Petitioner's asserted level of skill in the art is reasonable and, for the purposes of this Decision, we adopt that definition.

B. Claim Construction

In an *inter partes* review, the Board gives claim terms in an unexpired patent their broadest reasonable interpretation in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *see Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under that standard, a claim term generally is given its ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

Petitioner does not assert any specific construction for the claims. Pet. 16. Petitioner states the claims should be given 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. *Id.* We determine that it will be helpful to our analysis and decision to construe one claim phrase, which we do below.

1. "a protruding vent arrangement having a plurality of holes" (claim 1)

Claim 65 recites "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." Ex. 1101, 31:55–59 (emphasis added).

In its obviousness analysis, Petitioner argues that the "protruding vent arrangement" claim term would be satisfied by adding the vent of Ultra Mirage in the nasal bridge region of D'Souza and thus on the protruding

portion of D'Souza. Pet. 34–35. As such, Petitioner contends, implicitly, that the “protruding vent arrangement” claim term broadly encompasses vent holes in a portion of the frame that extends through an opening in the shroud module.

We disagree. Petitioner’s implicit claim construction is contrary to the plain language of claim 65, which requires the frame to have a “vent arrangement” that is “protruding” (rather than reciting that the frame has a protruding portion that includes a vent arrangement having a plurality of holes). Petitioner’s implicit construction also is inconsistent with the Specification. As described in the Specification and depicted in Figure 3 (reproduced above), protruding vent arrangement 1076 is a discrete vent structure that extends above the surrounding surface of frame 1040 and contains a plurality of vent holes. Ex. 1001, 7:18–23 (“The top end of the shroud 1020 . . . includes an opening or vent receiving hole 1021 to accommodate *the vent arrangement 1076 that protrudes from the frame 1040*” (emphasis added)), Fig. 3. Contrary to Petitioner’s implicit claim construction, protruding vent arrangement 1076 is described in the Specification as extending from the surface of the frame, and not merely as extending through an opening in shroud 1020. *See id.*

Further, claim 65 also recites that “the shroud module” includes an upper opening to accommodate the protruding vent arrangement. That language would be rendered superfluous under Petitioner’s implicit construction that “a protruding vent arrangement” is a portion of the frame with vent holes that extends through an opening in the shroud. *See Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006) (stating that “claims are interpreted with an eye toward giving effect to all terms in the

claim,” so that physical structures and characteristics specifically described in a claim are not rendered “merely superfluous”).

We determine that the broadest reasonable interpretation consistent with the Specification of the “a protruding vent arrangement having a plurality of gas washout holes,” as recited in claim 65 is a discrete vent structure that extends above the surrounding surface of the frame and contains a plurality of vent holes.¹⁰

The parties are hereby given notice that claim construction, in general, is an issue to be addressed at trial. Claim construction will be determined at the close of all the evidence and after any hearing. The parties are expected to assert all their claim construction arguments and evidence in the Petition, Patent Owner’s Response, Petitioner’s Reply, or otherwise during trial, as permitted by our rules.

*C. Patentability of Claims 57, 58, 61, 65, 68, 69, 71, and 77–79
in view of D’Souza, Ultra Mirage, Barnett, and Matula-II*

1. Scope and Content of the Prior Art

a. Overview of D’Souza

Petitioner’s annotated versions (Pet. 28) of Figures 6 and 7 of D’Souza are reproduced below.

¹⁰ We note that this consistent with the claim interpretation of a substantially similar phrase in claim 1 of the ’931 Patent construed in IPR2017-00061.

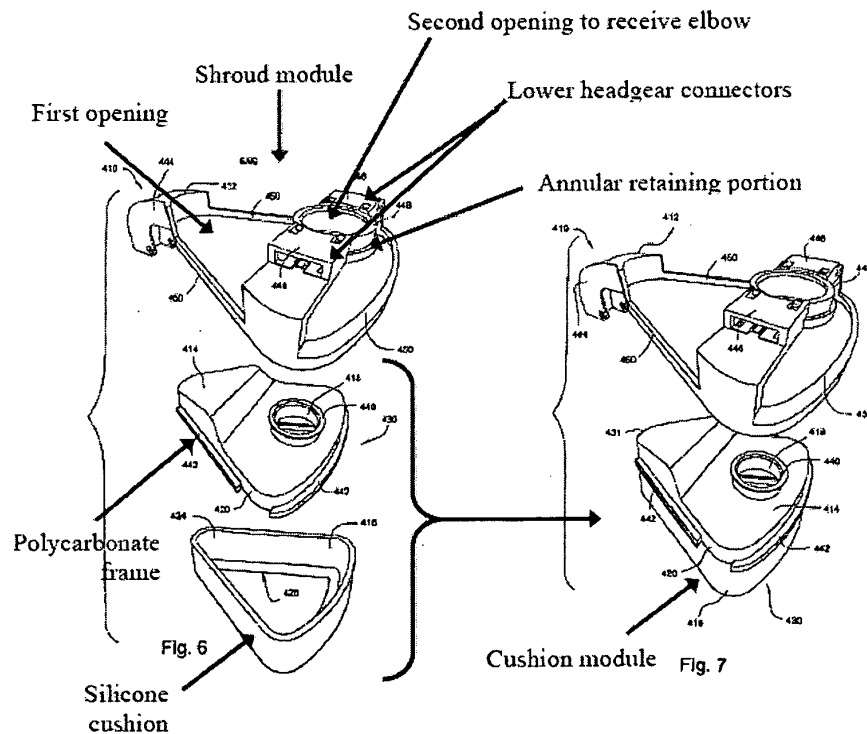


Fig. 6 is a top perspective view of a mask assembly
Fig. 7 is the mask assembly in a partially assembled condition,
as annotated by Petitioner.

See Ex. 1102, Figs. 6, 7. The figures above depict D’Souza’s mask assembly 410 comprising skeleton frame 412 (asserted “shroud module”), frame 414, and cushion 416. Ex. 1102 ¶¶ 96–97. As illustrated in the figures, frame 414 interlocks with cushion 416 to form cushion/frame sub-assembly 430. *Id.* D’Souza discloses that cushion 416 is constructed of liquid silicone rubber (*id.* ¶ 97), whereas frame 414 is constructed of polycarbonate (*id.* ¶ 98).

b. Overview of Ultra Mirage

Ultra Mirage discloses a full face CPAP mask with top and bottom removable headgear clips, an air vent to provide CO₂ washout, and a rotating

elbow with a quick release swivel. *See* Pet. 23–24; Ex. 1103, 6. A figure in Ultra Mirage, which is reproduced below, illustrates the mask.

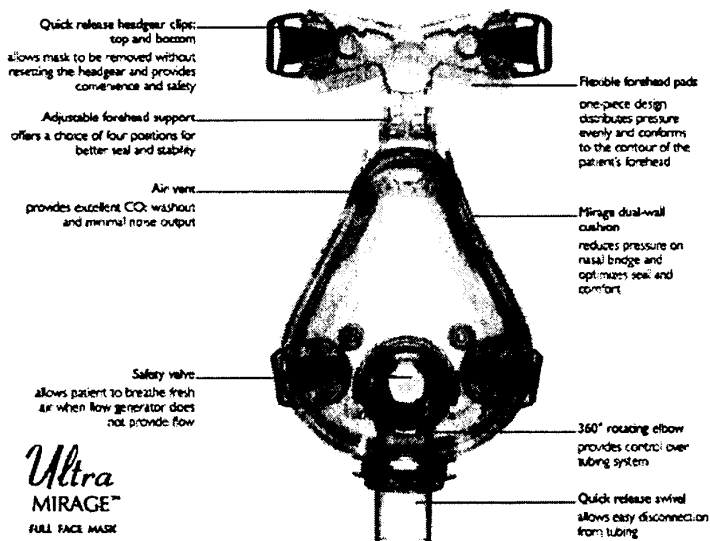
Ultra Mirage™ Full Face Mask

The ultimate solution for mouth leak



Mouth breathing and leak are common problems for CPAP and bi-level therapy users. These problems result in ineffective therapy, discomfort and disrupted sleep—all of which can cause patients to be noncompliant or to abandon therapy altogether.

ResMed's Ultra Mirage™ Full Face Mask covers both the nose and mouth so patients receive effective therapy even in the presence of mouth breathing and leak.



Front view of the Ultra Mirage mask, with components identified.

See Pct. 23–24; Ex. 1103, 6. Various elements of the mask, including the air vent, are identified in the Ultra Mirage figure.

c. Overview of Barnett

Petitioner's annotated Figure 6 from Barnett (Pet. 24) is reproduced below.

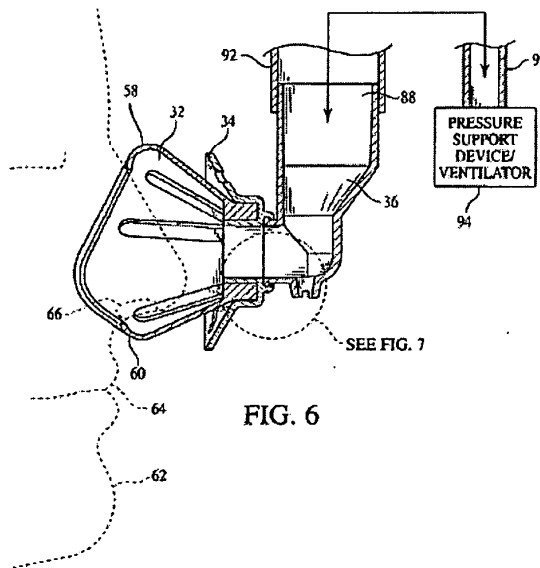


FIG. 6

FIG. 6 is a side sectional view of a nasal mask assembly schematically illustrating the nasal mask assembly in a system for delivering a gas to a patient, as annotated by Petitioner.

As shown above in Petitioner's annotated Figure 6, Barnett discloses nasal mask assembly 30 with seal member 32 that contacts the patient's face and collar 34 that is fixed and not movable relative to seal member 32. *Id.* at 25 (citing Ex. 1107, 3:48–52). Conduit coupling member or elbow 36 is rotatably mounted to collar 34 and freely rotates 360° about a central axis of collar 34. *Id.* (citing Ex. 1107, 3:52–56).

d. Overview of Matula-II

Petitioner's annotated Figure 4 from Barnett (Pet. 25) is reproduced below.

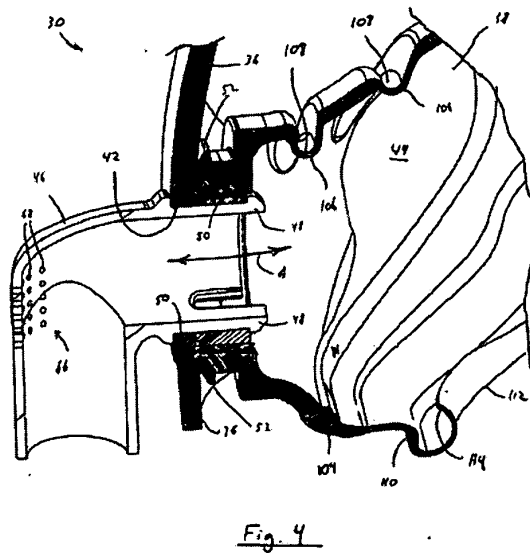


Fig. 4 is a sectional view of a seal member and faceplate coupling configuration in a patient interface, as annotated by Petitioner.

Matula-II discloses a CPAP interface including faceplate 36 mechanically coupled to seal member 38. Pet. 25 (citing Ex. 1105 ¶¶ 52–53). As shown in Figure 4, according to Petitioner, coupling member 46 includes a pair of prongs 48 that define channel 50 to receive the wall of faceplate 36 and the end of seal member 38. *Id.* at 26 (citing Ex. 1105 ¶ 53). Petitioner also asserts that Matula-II discloses seal member 38 having at least one fold 106 provided at an upper portion of the seal member “so that the seal member has the desired degree of flexibility.” *Id.* (citing Ex. 1105 ¶ 66).

2. Differences Between Prior Art and Challenged Claims, and Analysis

Petitioner asserts “D’Souza discloses nearly all of the limitations of Claims 57, 58, 61, 65, 71, 77–79.” Pet. 26. It is Petitioner’s position that

any differences between the challenged claims and the disclosure of D'Souza are “minor, well-known, and disclosed in other prior art CPAP masks.” *Id.* (citing Ex. 1113 ¶ 59). Mr. Eaton’s cited testimony supports Petitioner’s position.

a. Snap Fit

Independent claims 57 and 79 recite that “the shroud module and the cushion module are structured and arranged to be removably snap-fit attached to one another.” *E.g.* Ex. 1101, 31:4–6.

As shown in Figure 8 of D'Souza, reproduced below, skeleton frame 412 is engaged with cushion/frame sub-assembly 430 such that annular elbow connection seal 448 interlocks with annular wall 440 of the cushion/frame sub-assembly 430, upper support member 444 interlocks with top portion 431 of cushion/frame sub-assembly 430, and elongated frame members 450 interlock with respective protrusions 442 provided around the perimeter of cushion/frame sub-assembly 430. Ex. 1105 ¶ 101.

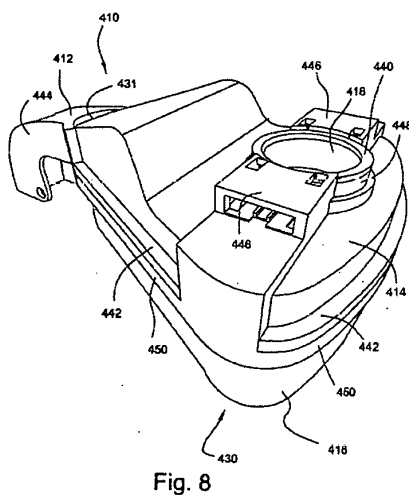


Fig. 8 is a top perspective view of the D'Souza mask
in an assembled condition;

Alternatively, Petitioner asserts Matula-II teaches a plurality of snap fingers 48 that facilitate elastic deformation to mechanically and removably couple seal member 38 to faceplate 36. Pet. 33 (citing Ex. 1105 ¶ 53).

Based on the record before us, for purposes of this Decision, we are persuaded that each of D'Souza and Matula-II disclose a snap-fit as recited in the claims.

b. Upper Headgear Connectors

Claims 57 and 79 recite “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.” *E.g.*, Ex. 1101, 30:56–59. As disclosed in the '931 Patent, and as shown generally in Figure 3 of the patent, upper headgear connectors 1024 extend from each side of the top portion of the shroud and lower headgear connectors 1025 extend from each side of the lower portion. Ex. 1101, 7:28–30. Each lower headgear connector 1025 includes clip receptacle 1031 at the free end that interlocks with a headgear clip on a headgear strap (*see* Figure 9 showing headgear strap 1090). *Id.* at 8:29–32.

D'Souza discloses that skeleton frame 412 provides attachment points for a forehead support, a headgear assembly, and an inlet conduit. Ex. 1102 ¶ 101. As best shown in Figures 6 and 7 of D'Souza (*see* Section II(C)(1)(a) above), skeleton frame 412 includes upper support member 444 adapted to support a forehead support, lower headgear clip receptacles 446 adapted to be engaged with clips provided to straps of a headgear assembly (not shown). *Id.*

Petitioner acknowledges that D'Souza “does not expressly disclose upper headgear connectors.” Pet. 29. Petitioner asserts, however, that Ultra

Mirage discloses “a shroud having a forehead support with upper and lower headgear connectors. *Id.* (citing Ex. 1103, 6) (*see* figure with identification of “Quick release headgear clips: top and bottom”). As stated in Ultra Mirage, the headgear clips allow the mask “to be removed without resetting the headgear and provides convenience and safety.” Ex. 1106, 6

Petitioner asserts that “to the extent the removability of the headgear in D’Souza is unclear, Ultra Mirage discloses this feature.” Pet. 30. Based on the record before us, for purposes of this Decision, we are persuaded that Ultra Mirage discloses upper and lower headgear connectors as recited in the claims.

As a rationale for the proposed modification, Petitioner asserts a person of ordinary skill in the art at the time of the invention would have been motivated to modify D’Souza to add upper headgear connectors as taught by Ultra Mirage to provide stability to the mask assembly. Pet. 48 (citing Ex. 1113 ¶ 86). Mr. Eaton testifies that the proposed modification also would have been obvious to provide ease in manufacturing, assembly, and ease of use. Ex. 1113 ¶ 86.

For purposes of this Decision, on the record before us, we agree with Petitioner.

c. “a rotatable elbow directly attached to the shroud”

Claims 57 and 79 include “a rotatable elbow directly attached to the shroud.” *E.g.* Ex. 1101, 30:60.

Petitioner acknowledges that D’Souza “does not expressly disclose a rotatable elbow directly attached to the shroud or the elbow being connected to an air delivery tube [*see* claim 61]”. Pet. 30–31. Petitioner asserts, however, that D’Souza “discloses mask assemblies for use with a flow

generator and adapted to engage an elbow.” *Id.* at 30 (citing Ex. 1102 ¶ 3 (disclosing use with flow generators); Ex. 1102 ¶ 100 (disclosing an annular elbow connection seal 448 adapted to engage an inlet conduit, e.g., elbow”).

Petitioner asserts Ultra Mirage discloses a “360° rotating elbow” on a CPAP mask to provide control over a tubing system. Pet. 31 (citing Ex. 1103, 6; Ex. 1113 ¶ 66). Petitioner also asserts Barnett discloses a rotatable elbow as claimed. *Id.* (citing Ex. 1107, 3:52–57).

Based on the record before us, for purposes of this Decision, we are persuaded that Ultra Mirage and Barnett each disclose a rotatable elbow directly attached to the shroud as recited in the claims.

As a rationale for the proposed modification, Petitioner asserts a person of skill in the art at the time of the invention would have been motivated to modify the references as proposed to allow the wearer to position the tubing to provide the most convenient, comfortable, and low force mask connection. *Id.* at 31 (citing Ex. 1113 ¶ 87). Petitioner also asserts a skilled person would have been motivated to directly attach the elbow to the shroud as taught in Barnett to make it easier to detach the elbow without affecting the engagement of the mask components. *Id.* (citing Ex. 1113 ¶ 89). According to Petitioner, attaching the elbow directly to the shroud instead of the frame would also have provided more design flexibility. *Id.*

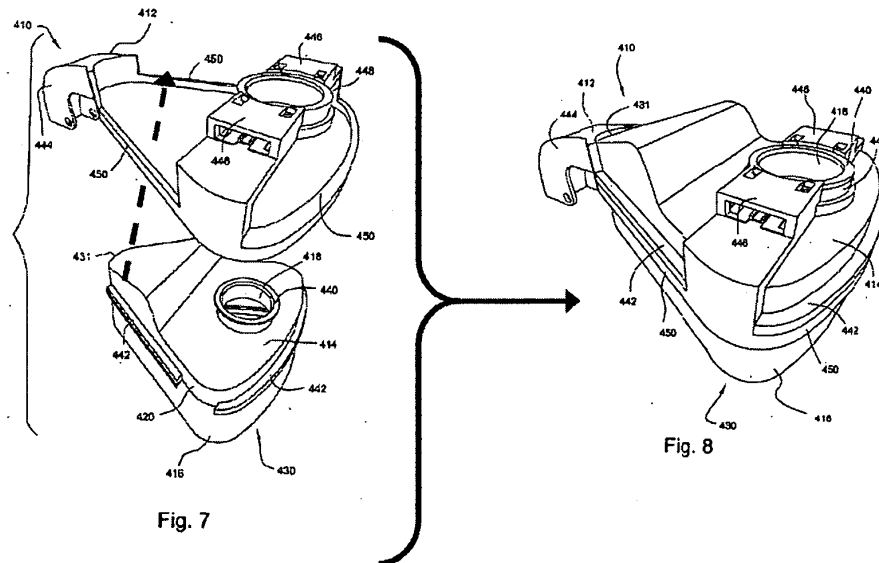
For purposes of this Decision, on the record before us, we agree with Petitioner.

d. “Protruding Vent Arrangement”

Claim 65 depends from Claim 57 and further recites that “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.” Ex. 1101, 31:55–59.

With respect to this claim requirement, Petitioner asserts: “As shown in Figs. 7–8 of D’Souza, reproduced below with Petitioner’s annotations, when the mask assembly 410 is assembled, the top portion 431 (nasal bridge region) of the frame 414 protrudes through the opening (between the elongated frame members 450) in the shroud 412.” Pet. 34 (citing Ex. 1102 ¶ 101); Ex. 1102, Figs. 7, 8.



Figures 7 and 8 are a top perspective views of the D’Souza mask.

Figure 7 is partially assembled; Figure 8 is fully assembled,
as annotated by Petitioner.

Petitioner acknowledges that D’Souza “does not expressly disclose a vent on the protrusion.” Pet. 34. Petitioner asserts, however, that “vents positioned in the region of the D’Souza protrusion (nasal bridge region) were common in prior art CPAP masks.” *Id.* (citing Ex. 1113 ¶ 74).

Petitioner further argues that “Ultra Mirage teaches an air vent positioned in

the nasal bridge region to provide CO₂ washout and minimize noise output.” *Id.* 34–35 (citing Ex. 1103, 6). Petitioner concludes a skilled artisan “would have been motivated to provide the vent of Ultra Mirage in the same nasal bridge region of D’Souza, and thus on the protruding portion of D’Souza.” *Id.* (citing Ex. 1113 ¶¶ 74, 90). We disagree with Petitioner’s analysis, as discussed below.

Petitioner’s argument, that adding a plurality of vent holes to a portion of D’Souza’s frame 414 that extends through an opening in shroud 412 would satisfy the claim requirement, is based on an improper claim construction, as discussed above. *See supra* Section II.B.1. Under our claim interpretation, the claim term requires a discrete vent structure that extends above the surrounding surface of the frame and contains a plurality of vent holes. *See id.* Petitioner does not contend that Ultra Mirage teaches or suggests “a protruding vent arrangement having a plurality of vent holes.” Rather, Petitioner contends that Ultra Mirage teaches positioning a plurality of vent holes in the nasal bridge region of a mask. Merely positioning a plurality of vent holes in the nasal bridge region of D’Souza’s mask would not result in a discrete vent structure that extends above the surrounding surface of the frame and contains a plurality of vent holes, as required under our claim interpretation. The vent holes would be flush with the surrounding surface of the nasal bridge region. We are unpersuaded, therefore, that the combination of D’Souza and Ultra Mirage teaches or suggests “a protruding vent arrangement having a plurality of holes.”

For the reasons given, we determine that Petitioner has not established a reasonable likelihood of prevailing on its challenge that claim 65 would have been obvious based on D’Souza, Ultra Mirage, Barnett, and Matula-II.

e. “One or More Folds”

Claim 68 depends from Claim 57 and further recites “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.” Ex. 1101, 32, 5–9. Claim 68 also recites that each of the one or more folds comprises adjacent first side walls interconnected by a second side wall.

The Specification of the ’931 Patent states that, as best shown in Figures 30 and 33, a “concertina” section 50 may be provided in a nasal bridge region of the cushion and/or frame “to enhance the flexibility of the cushion in use.” Ex. 1101, 14:19–25. Concertina section 50 includes a bellows structure with one or more folds 52 that provide a higher degree of flexibility, movement, or adaptability to the nasal bridge region of the cushion/frame. *Id.* at 14:25–32. In one disclosed embodiment, as shown in Figure 32-3, each fold 52 includes first side wall 52(1) and second side wall 52(2) that interconnect adjacent side walls 52(1). *Id.* at 14:40–42.

Petitioner acknowledges that “D’Souza does not expressly disclose a fold” as claimed. Pet. 36. Petitioner relies on Matula-II for the disclosure of fold 106 in the nasal bridge portion of the cushion 38 to provide “the desired degree of flexibility.” *Id.* (citing Ex. 1105 ¶ 66).

Petitioner asserts a skilled artisan would have known to incorporate the folds taught by Matula-II with the D’Souza cushion to provide a higher degree of flexibility in the delicate nose bridge region compared to other regions. Pet. 42 (citing Ex. 1113 ¶ 92).

For purposes of this Decision, on the record before us, we agree with Petitioner.

f. “Plurality of Snap Fingers”

Claim 69 depends from Claim 57 and further recites “the frame includes a collar surrounding said frame opening” and “the retaining portion of the shroud includes a plurality of snap fingers structured to engage the collar with a snap-fit.” Ex. 1101, 32:14–18.

The ’951 patent discloses that, as shown in Figures 14, 15, 17, and 21, opening 1132 of shroud 1120 may include snap fingers 1145(1) adapted to engage the collar 1149 surrounding the frame opening 1146 with a snap-fit. Ex. 1101, 18:54–58.

Petitioner acknowledges that D’Souza does not expressly disclose a plurality of snap fingers. Pet. 39. According to Petitioner, however, snap fingers “were common in prior art CPAP masks.” *Id.* (citing Ex. 1113 ¶ 82). As an example of the common snap fingers, Petitioner asserts Matula-II discloses prongs, or snap fingers, 48 that mechanically couple seal member 38 to the faceplate. *Id.*

As a rationale for the proposed modification, Petitioner asserts it would have been obvious to a person of ordinary skill to facilitate repeated insertion of the collar 440 through the rigid retaining portion 448 without destroying the parts. *Id.* at 42–43. According to Petitioner, this would provide a more effective removable mechanical interlock between the shroud and the cushion module. *Id.* at 43.

For purposes of this Decision, on the record before us, we agree with Petitioner.

g. Polycarbonate Frame

Claim 71 depends from Claim 57 and further recites that the shroud module and the frame comprise polycarbonate. Ex. 1101, 32:23–25.

Petitioner states that D’Souza discloses a plastic shroud being formed of plastic, but acknowledges that D’Souza “does not expressly disclose polycarbonate. Pet. 49. According to Petitioner, however, it was common at the time of the invention to construct CPAP components, including the shroud, from polycarbonate. *Id.* (citing Ex. 1113 ¶ 84). Mr. Eaton’s testimony supports Petitioner’s argument.

For purposes of this Decision, on the record before us, we agree with Petitioner.

3. Conclusion

In summary, based on the analysis above and the record before us, we determine that it is reasonably likely Petitioner will prevail on its challenge to the patentability of Claims 57, 58, 61, 68, 69, 71, and 77–79 in view of D’Souza, Ultra Mirage, Barnett, and Matula-II. Accordingly, we institute trial on this ground. Based on the analysis above and the record before us, we determine that it is *not* reasonably likely Petitioner will prevail on its challenge to claim 65. Accordingly, we do *not* institute trial on claim 65.

D. Patentability of Claim 60 in View of D’Souza Ultra Mirage, Barnett, Matula-II, and FlexiFit

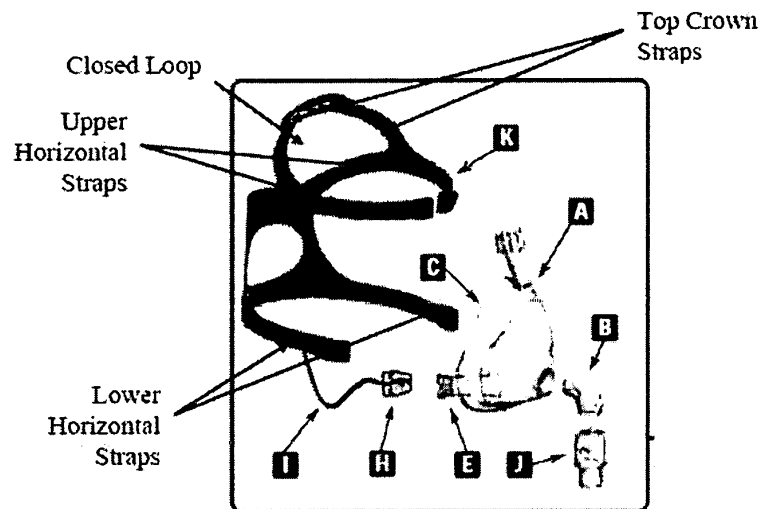
Claim 60 depends from claim 57 and further recites that “each upper headgear connector includes a slot adapted to receive a respective headgear strap in use; and wherein each lower headgear connector is adapted to be removably interlocked with a headgear clip associated with a respective headgear strap.”

As disclosed in the Specification, and as shown in Figure 3, each upper headgear connector 1024 includes elongated arm 1026 and slot or receiving hole 1027 at the free end of arm 1026 adapted to receive a

respective headgear strap. Ex. 1101, 7:34–37. Each lower headgear connector 1025 includes an abbreviated arm and a clip receptacle 1031 at the free end of the arm adapted to be removably interlocked with a headgear clip associated with a respective headgear strap. *Id.* at 8:29–32. The clips allow for easier positioning or donning/removal of the mask system. *Id.* at 8:32–34.

Figures 27–30 illustrate lower headgear clip 33 adapted to be removably interlocked with clip receptacle 31. *Id.* at 8:37–38. As best shown in Figure 28, clip 33 includes spring arms 35 adapted to interlock with clip receptacle 31 with a snap-fit, and slot 37 adapted to receive a respective headgear strap in use. *Id.* at 8:39–42.

Petitioner provides (Pet. 44) an annotated figure from FlexiFit, reproduced below.



Petitioner's annotated figure of an exploded view of a mask and headgear from FlexiFit.

According to Petitioner, FlexiFit shows headgear (K), which can be coupled to mask base (A). Pet. 43 (citing Ex. 1106, 10). As shown in the figure and identified by Petitioner's annotations, Headgear (K) has upper horizontal straps and lower horizontal straps. *Id.*

As explained in the "Fitting Your Mask" instructions for FlexiFit, a user fits the mask by unclipping headgear (K) from Glider™ strap (E) by pulling release cord (I) downwardly. Ex. 1106, 10. The user then fits the mask comfortably over the user's head. *Id.* The user re-attaches headgear clip (H) to the Glider™ strap, and adjusts the top and lower horizontal straps, and the top crown straps. *Id.*

Petitioner asserts D'Souza discloses lower headgear connectors adapted to engage clips, but argues that to the extent D'Souza provides insufficient teachings for the "removability" of the clips, Ultra Mirage and FlexiFit both disclose removable lower headgear clips. Pet. 46 (citing Ex. 1102 ¶ 100; Ex. 1103, 6; Ex. 1106, 10). Why would it have been obvious to a person of ordinary skill to make the proposed modification? Petitioner's answer to this question is that at the time of the invention, a skilled artisan would have been motivated to provide removable lower headgear clips, as disclosed in FlexiFit, "so that the user would not have to force the lower headgear straps over his/her head," and "a simpler design option" of upper headgear connectors with slots, as taught by FlexiFit, to "simplify manufacturing and reduce parts." *Id.* at 46–47 (citing Ex. 1113 ¶ 101). Mr. Eaton testifies that the proposed modification:

improves ease of donning/doffing, as a user would not have to overcome strap tension while holding the mask away from the face and sliding it down from the top of the head. This advantage would have been minimal at the top headgear connection because

those straps are only brought into tension as they near the worn position. Thus, as an alternative design option, a skilled artisan would have known to provide slots at the upper headgear connectors, instead of clips. Although clip attachments have their own advantages, such as quick release, a person of skill in the art would have also recognized simple slots on the frame as a design option with its own advantages.

Ex. 1113 ¶ 101.

Based on the analysis above and the record before us, we determine that it is reasonably likely Petitioner will prevail on its challenge to the patentability of claim 60 based on D'Souza Ultra Mirage, Barnett, Matula-II, and FlexiFit.

E. Patentability of Claims 62–64 in view of D'Souza, Ultra Mirage, Barnett, Matula-II, FlexiFit, and Gunaratnam-II

Claim 62 depends from independent claim 57. Claims 63 and 64 depend from claim 62. All three claims concern specific structure for the upper and lower straps and for the top and rear straps of the headgear.

Claim 62 recites:

the headgear includes upper straps and lower straps,
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,
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, 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.

Claim 63 recites that the upper straps provide padding to the headgear connectors of the shroud module on the patient's face.

Claim 64 recites that the rear straps and the top straps form a closed loop to encircle a rear portion of the patient's head.

As disclosed in the Specification, and as shown in Figure 9, headgear 1090 includes a pair of upper and lower straps 1092, 1094. Ex. 1101, 10:41–42. Upper straps 1092 removably attached to upper headgear connectors 1024 and lower straps 1094 removably attached to lower headgear connectors 1025. *Id.* at 10:42–45. The free end of each strap may include a VELCRO® tab structured to engage the remainder of the strap to secure the strap in place. *Id.* at 10:45–47. Upper straps 1092 split at the crown of the patient's head to form top straps 1096 adapted to pass over the top of the patient's head and rear straps 1098 adapted to pass behind the patient's head. *Id.* at 10:52–57.

Petitioner relies on FlexiFit for the strap system recited in claim 62 (Pet. 48–49), and on Gunaratnam-II for the specific disclosure of a buckle connector for the top straps, as shown in Figure 135 of Gunaratnam-II (*id.* at 50) (citing Ex. 1110 ¶ 316; Ex. 1113 ¶ 107).

Concerning claim 63, Petitioner asserts that FlexiFit discloses that the flexible headgear strap between the upper headgear connector and the user's face provides padding. *Id.* at 51 (citing Ex. 1113 ¶ 110).

Petitioner relies on FlexiFit for the disclosure of the “closed loop” recited in claim 64. *Id.* at 52.

Petitioner's rationale for the proposed combination is that a person of skill in the art would have recognized the comfort benefits, without adding additional parts, of using the FlexiFit headgear in connection with upper

headgear connectors to provide padding between the upper headgear connectors and the user's face. *Id.* at 53–54 (citing Ex. 1113 ¶¶ 110, 114). Petitioner also asserts it would have been obvious to a person of ordinary skill to use a rear loop for stability and a buckle for adjustability based on the prior art disclosures. *Id.* at 54 (citing Ex. 1113 ¶¶ 114, 115).

Based on the analysis above and the record before us, we determine that it is reasonably likely Petitioner will prevail on its challenge to the patentability of claims 62–64 based on D'Souza, Ultra Mirage, Barnett, Matula-II, FlexiFit, and Gunaratnam-II

F. Patentability of Claims 43, 48–50, and 70 Based on D'Souza, Ultra Mirage, FlexiFit, Barnett, Jaffre, and Matula-II

Independent claim 43 is similar to independent claim 57, discussed above, in that both claims are directed to a mask system including a cushion module, headgear, a shroud module, and an elbow assembly. Claim 43 includes substantial additional structure not recited in claim 57.

In claim 57, the frame of the cushion module includes a “frame opening” leading to the breathing chamber, which is not recited in claim 43. In claim 57, the headgear is recited very broadly, as merely including “headgear straps,” whereas claim 43 recites the headgear in detail, incorporating substantial portions from dependent claims 62 and 64 discussed above. In claim 57, the shroud module is recited broadly, as merely including upper and lower headgear connectors, whereas claim 43 recites the shroud module in additional detail, such as including a slot in the headgear connector similar to dependent claim 60 discussed above. Claim 57 also recites the rotatable elbow attached to the frame very broadly, whereas claim 43 also recites that the elbow includes a swivel adapted to

connect to an air delivery tube and also includes an anti-asphyxia valve (AAV) and a port that is selectively closed by a flap portion of the AAV. This list of differences between independent claim 43 and independent claim 57 is exemplary, not exhaustive.

As described in the '931 Patent, and as shown generally in Figure 3, elbow 1070 includes slot 1081, which receives an anti-asphyxia valve (AAV). Ex. 1101, 16:42–43. Anti-asphyxia valve 85 is shown generally in Figure 27 of the '931 Patent. Elbow 1070 also includes port 1079 that is selectively closed by flap 86 of the AAV depending on the presence of pressurized gas. *Id.* at 16:43–45; 65–67.

Jaffre is newly asserted in this ground of unpatentability. We first discuss its scope and content. Petitioner relies on Jaffre for its disclosure of an exhaust port assembly. Pet. 55.

Jaffre discloses an exhaust port assembly with enhanced noise reduction and gas diffusion capabilities, while also minimizing size. Ex. 1112, 1:15–17. It has particular applicability to a patient interface mask in a CPAP machine. *Id.* at 7:8–12; 1:20–28. Exhaust port assembly 62 is shown in detail in Figures 4–9 and described in the related text. Figures 7, 8, and 9 from Jaffre are reproduced below.

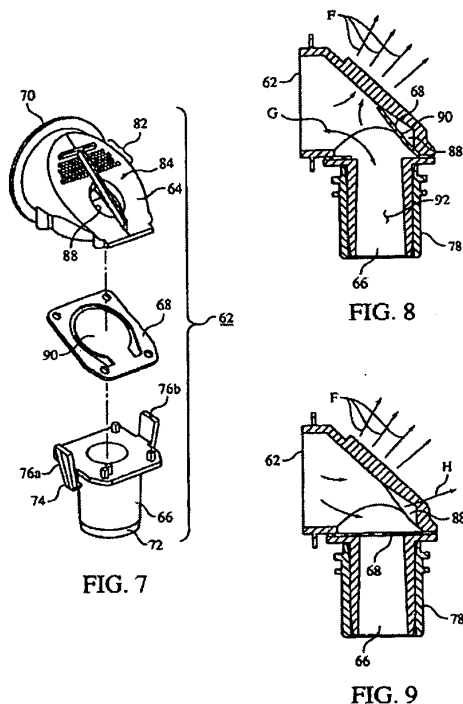


Figure 7 is an exploded view of exhaust port assembly 62. Figures 8 and 9 are cross-sectional views of the exhaust port assembly.

As shown in Figures 7–9, exhaust port assembly 62 includes vent 64, conduit coupling member 66, and valve 68. Ex. 1112, 7:21–23. Vent 64 and conduit coupling member 66 define a conduit having first end 70 that is coupled to patient interface device, or mask, 46 (*see id.* Figure 3) and a second end 72 that is coupled to patient circuit 52 (*id.*). *Id.* at 7:35–38. Patient circuit 52 is connected to pressure generating system 32, 32'. *Id.* at 7:8–15; Figure 3. First end 70 is rotateably and permanently attached to patient interface device 46 using any conventional technique. *Id.* at 7:38–41. Second end 72 is selectively attachable to patient circuit 52. *Id.* at 41–42.

To provide automatic access to the ambient atmosphere, exhaust port assembly 62 includes auxiliary opening 88 defined in the conduit and having a relatively large diameter. *Id.* at 10:11–14. During normal use, cantilever member 90 of valve 68 flexes, as shown to Figure 8, to block auxiliary opening 88, so that gas is able to flow between the patient and the pressure generating system, as indicated by arrow G in Figure 8. *Id.* at 10:14–22. If, however, the pressure of the gas in interior 92 is not greater than ambient atmosphere, cantilever member 90 returns to its normal, undeflected position shown in Figure 9 and unblocks auxiliary opening 88 so that the patient has access to the ambient atmosphere as indicated by arrow H in Figure 9. *Id.* at 10:23–27. In this Figure 9 position, cantilever member 90 also blocks gas from flowing through the conduit toward the pressure support system. *Id.* at 10:28–30. The spring force of cantilever member 90 tends to urge it toward the unflexed position shown in Figure 9 to ensure that auxiliary opening 88 becomes unblocked if the pressure support system fails to provide an adequate supply of breathing gas. *Id.* at 10:30–33.

The operation of valve 68 to block and unblock auxiliary opening 88 and the patient circuit does not affect the operation of holes 82 allowing a continuous flow F of gas from the patient circuit, as shown in Figures 8 and 9. *Id.* at 10:35–38.

Petitioner asserts D’Souza discloses “nearly all” of the limitations of claims 43, 48–50, and 70. Pet. 55. According to Petitioner, “[a]ny differences were well-known at the time of the invention and taught by other prior art CPAP masks.” *Id.* (citing Ex. 1113 ¶ 117). Petitioner relies on D’Souza, Ultra Mirage, FlexiFit, Barnett, and Matula-II, as discussed above in our analysis of claims 57, 60–62, and 65, for “most of the features of”

claims 43, 48–50, and 70. We agree with Petitioner that our analysis above addresses most of the elements recited in challenged claims 43, 48–50, and 70. Claim 48 recites that the frame is semi-rigid or rigid. Claim 49 recites that the frame is rigid. Claim 50 adds a flow generator and delivery tube to the mask of claim 43. These limitations have been addressed above.

We discuss below the two elements of claims 43, 48–50, and 70 that Petitioner acknowledges are not disclosed in D’Souza, Ultra Mirage, FlexiFit, Barnett, and Matula-II – an “elbow including a swivel” and an anti-asphyxia valve.

*1. Differences Between Prior Art
and Challenged Claims, and Analysis*

Independent claim 43 recites “the elbow including a swivel adapted to connect to an air delivery tube.” D’Souza discloses an elbow adapted to engage the mask, but, as acknowledged by Petitioner, D’Souza “does not expressly disclose the elbow including a swivel.” Pet. 56 (citing Ex. 1102 ¶ 100). Petitioner correctly asserts that Ultra Mirage discloses a 360° rotating elbow. *Id.* (citing Ex. 1103, 6).

Independent claim 43, and claim 70, dependent from claim 57, each recite that the elbow includes an AAV and a port that is selectively closed by a flap portion of the AAV. Petitioner correctly asserts that Jaffre discloses an AAV as recited in claims 43 and 70. Pet. 57.

As a reason why the proposed modifications would have been obvious to a person of ordinary skill, Petitioner asserts the swivel elbow facilitates easy adjustment and disconnection from tubing. Pet. 58 (citing Ex. 1103, 6; Ex. 1113 ¶ 123). Regarding the AAV, Petitioner asserts would have been obvious to a person of ordinary skill to adapt the AAV of Jaffre to the D’Souza modified elbow “to allow patients to breathe fresh air when the

flow generator does not provide flow.” Pet. 58 (citing Ex. 1103, 6; Ex. 1109 ¶ 106¹¹; Ex. 1113 ¶ 124). Mr. Eaton testifies that one skilled in the art would have recognized that a safety valve such as the AAV in Jaffre “would be a requirement of the full-face mask of D’Souza” and “would have been motivated to include this structure.” Ex. 1113 ¶ 124.

Based on the analysis above and the record before us, we determine that it is reasonably likely Petitioner will prevail on its challenge to the patentability of claims 43, 48–50, and 70 based on D’Souza, Ultra Mirage, FlexiFit, Barnett, Jaffre, and Matula-II.

G. Patentability of Claims 46, 51, and 53–56 Based on D’Souza, Ultra Mirage, FlexiFit, Barnett, Jaffre, Matula-II, and Gunaratnam-II

Claim 46 depends from claim 43 and adds details about the elbow, headgear straps, and frame. In particular, it recites that the frame includes a “protruding vent arrangement” having holes, and that the shroud module includes an opening to accommodate the protruding vent. Independent claim 51 combines independent claim 43 and dependent claim 46. As such, claim 51 recites the same “protruding vent arrangement” limitations as are recited in claim 46. Claims 53–56 depend directly or indirectly from claim 51. Thus, all the claims in this group include the “protruding vent arrangement” limitations recited in claim 46.

The “protruding vent arrangement” limitations in claims 46, 51, and 53–56 are substantially identical to the “protruding vent arrangement” limitations in claim 65 discussed above. Claim 65 refers to the “holes” in

¹¹ Ex. 1109 is PCT Publication No. WO 2007/045008, published April 26, 2007. It is not relied on as a reference in the asserted ground of unpatentability.

the protruding vent as “gas washout” holes, and refers to the opening in the shroud module as an “upper” opening. These are distinctions without a substantive difference based on the record before us.

Petitioner relies on its analysis of claim 65 to assert that the “protruding vent arrangement” limitations of claims 46, 51, and 53–56 would have been obvious based on the cited references. *E.g.*, Pet. 73–74. We rely on our analysis of claim 65 in rejecting that assertion. For the reasons discussed above in connection with claim 65, we are unpersuaded that the combination of D’Souza and Ultra Mirage teaches or suggests “a protruding vent arrangement having a plurality of holes,” as recited in claims 46, 51, and 53–56.

Accordingly, we determine that Petitioner has not established a reasonable likelihood of prevailing on its challenge that claims 46, 51, and 53–56 would have been obvious based on D’Souza, Ultra Mirage, FlexiFit, Barnett, Jaffre, Matula-II, and Gunaratnam-II.

III. CONCLUSION

For the reasons give, Petitioner has shown a reasonable likelihood that it would prevail in establishing unpatentability of claims 43, 48–50, 57, 58, 60, 61–64, 68, 69, 70, 71, and 77–79. Accordingly, as set out in the Order below, we institute a trial of these claims.

Petitioner has *not* shown a reasonable likelihood of prevailing in establishing unpatentability of claims 46, 51, and 53–56, and 65. Accordingly, we do *not* institute a trial of these claims.

This is a decision to institute an *inter partes* review under 35 U.S.C. § 314. Our factual findings and determinations at this stage of the proceeding are preliminary, and based on the evidentiary record developed

thus far. This is not a final decision as to the patentability of claims for which *inter partes* review is instituted. Our final decision will be based on the record as fully developed during trial.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review is hereby instituted based on the following grounds:

- A. claims 57, 58, 61, 68, 69, 71, and 77–79 would have been obvious in view of D’Souza, Ultra Mirage, Barnett, and Matula-II;
 - B. claim 60 would have been obvious in view of D’Souza Ultra Mirage, Barnett, Matula-II, and FlexiFit;
 - C. claims 62–64 would have been obvious in view of D’Souza, Ultra Mirage, Barnett, Matula-II, FlexiFit, and Gunaratnam-II;
 - D. claims 43, 48–50, and 70 would have been obvious in view of D’Souza, Ultra Mirage, FlexiFit, Barnett, Jaffre, and Matula-II;
- and

FURTHER ORDERED that no other ground of unpatentability asserted in the Petition is authorized for this *inter partes* review; and

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

IPR2017-00062
Patent 9,119,931 B2

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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 IPR2017-00064
Patent 9,119,931 B2

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

RICE, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Background

Fisher & Paykel Healthcare Limited (“Petitioner”) filed a Petition (Paper 1, “Pet.”) requesting an *inter partes* review of claims 33–37, 40–43, 48–50, 57, 58, 60–64, 68–71, and 77–79 of U.S. Patent No. 9,119,931 B2 (Ex. 1201, “the ’931 Patent”). Petitioner supported the Petition with a declaration from Jason Eaton, P.E. (Ex. 1211). ResMed Limited (“Patent Owner”) did not file a preliminary response to the Petition.¹

Under 35 U.S.C. § 314, an *inter partes* review may not be instituted “unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). Upon considering the Petition and the evidence filed therewith, we determine that Petitioner has not shown a reasonable likelihood that it would prevail with respect to any of challenged claims 33–37, 40–43, 48–50, 57, 58, 60–64, 68–71, and 77–79.

Accordingly, we do not institute an *inter partes* review.

B. Related Matters

The parties identify a related federal district court case involving the ’931 Patent: *Fisher & Paykel Healthcare Ltd. v. ResMed Corp.*, Case No. 3:16-cv-02068-DMS-WVG (S.D. Cal.). Pet. 7; Paper 4, 2. The parties also indicate that the ’931 Patent is involved in U.S. International Trade Commission Investigation No. 337–TA–1022. Pet. 7; Paper 4, 2.

¹ See 37 C.F.R. § 42.107 (providing that filing a preliminary response to the petition is not obligatory).

Petitioner has filed three additional petitions for *inter partes* review of the '931 Patent. *See* IPR2017-00061, IPR2017-00062, IPR2017-00065; Pet. 7; Paper 4, 2.

C. The '931 Patent

The '931 Patent, titled “Mask System,” issued on September 1, 2015, and claims priority based on a series of applications dating back to February 27, 2009, as well as several provisional applications dating back to September 19, 2008. Ex. 1201, 1:6–16. The '931 Patent relates generally to a mask system for treatment of “Sleep Disordered Breathing” using “Continuous Positive Airway Pressure [‘CPAP’]” or “Non-Invasive Positive Pressure Ventilation.” *Id.* at 1:21–25.

Figure 3 of the '931 Patent is reproduced below.

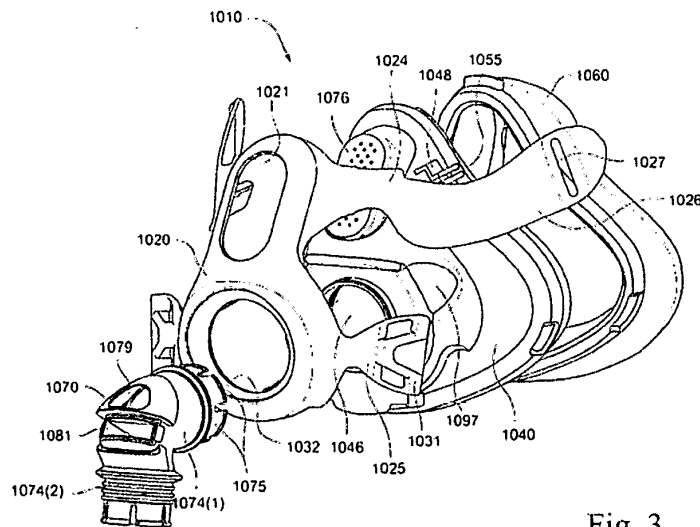
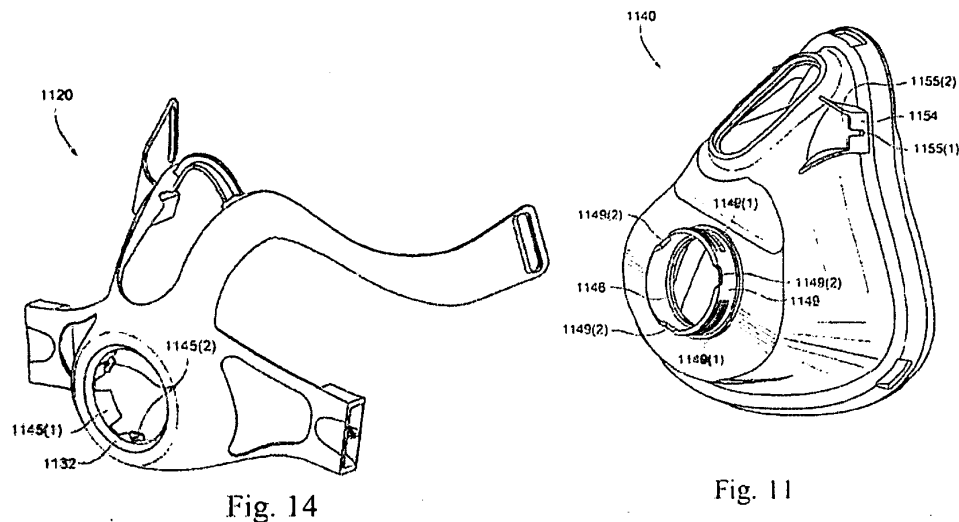


Fig. 3

Figure 3 depicts mask system 1010 comprising frame 1040, mask cushion 1060, shroud 1020, and elbow 1070. *Id.* at 6:51–53. The frame defines a breathing chamber adapted to receive the patient's nose and mouth

and includes an opening 1046 that communicates with elbow 1070. *Id.* at 6:60–64. The frame is constructed from a more rigid material (e.g., polyurethane) than the cushion (made of, e.g., silicone). *Id.* at 6:54–56.

Petitioner's annotated versions of Figures 14 and 11 of the '931 Patent are reproduced below:



Pet. 15. According to Petitioner, the annotated Figure 14 above depicts a retaining mechanism at opening 1132 of shroud 1120. *Id.* (citing Ex. 1201, 18:48–53). The retaining mechanism includes snap fingers 1145(1) that engage collar 1149 of frame 1140 (depicted in annotated Figure 11 above). *See id.* (citing Ex. 1201, 18:62–67).

Of the challenged claims, claims 33, 43, and 57 are independent. Claims 34–37 and 40–42 depend, directly or indirectly, from claim 33. Claims 48–50 depend, directly or indirectly, from claim 43. Claims 58, 60–64, 68–71, and 77–79 depend, directly or indirectly, from claim 57. Claims 33, 43, and 57 are reproduced below:

33. A mask system, comprising:
(i) a shroud module; wherein the shroud module includes headgear connectors adapted to removably attach to respective headgear straps of headgear; and
(ii) a cushion module, comprising:
a frame defining a breathing chamber; and
a cushion to form a seal with the patient's face in at least a nasal bridge region and a cheek region of the patient's face,
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, and 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;
wherein the shroud module and the cushion module are configured to be removably coupleable to one another, and
wherein the shroud module includes a front opening of substantively circular shape and a retaining portion extending rearwardly from the front opening, towards the frame, and structured to snap-fit with the cushion module.

Ex. 1201, 26:54–27:11.

43. A mask system for delivery of a supply of air at positive pressure to a patient's airway, the mask system comprising:
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, 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, the frame including a washout vent, the frame including an opening;
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, 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, 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 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;

a shroud module including headgear connectors adapted to removably attach to the headgear, wherein the headgear connectors include two upper connectors associated with the upper headgear straps, the shroud module having an opening of circular shape, and two lower connectors associated with the lower headgear straps, each said upper headgear connector including a slot or receiving hole adapted to receive one of the upper headgear straps, 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; 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, the elbow including a swivel adapted to connect to an air delivery tube, the elbow including an anti-asphyxia valve (AAV) and a port that is selectively closed by a flap portion of the AAV.

Id. at 27:55–28:39.

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

headgear including headgear straps;
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, the shroud module having a front opening;
a rotatable elbow directly attached to the shroud; and
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, wherein the cushion comprises a first, relatively soft, elastomeric material and the frame comprises a second material that is more rigid than the cushion;
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.

Id. at 30:52–31:11.

D. Overview of Prosecution History

During prosecution of the '931 Patent, the Examiner issued a final rejection of all pending claims, except claims 29 and 33. Ex. 1212, 343–61. The Examiner indicated that application claims 29 and 33 (each of which recited “a protruding vent arrangement”) would be allowable if rewritten in independent form. *Id.* at 359. In response, the applicant, *inter alia*, added the subject matter of claim 29 to claim 1, canceled claim 29, and added new claims 34–83. *Id.* at 447. With respect to application claim 22 (which issued as claim 33), Petitioner argued that the combination of references applied by the Examiner did not satisfy the claim requirement for “a shroud

module [that] includes a front opening and a retaining portion extending rearwardly from the front opening and [] structured to retain the cushion module.” *Id.* After a subsequent telephonic interview, the Examiner allowed the claims subject to an Examiner’s Amendment. *Id.* at 462–72.

E. The Asserted Grounds

Petitioner challenges claims 33–37, 40–43, 48–50, 57, 58, 60–64, 68–71, and 77–79 on the following grounds (Pet. 11):

Reference(s)	Basis	Claim(s) Challenged
Barnett ² and Ogden ³	§ 103(a)	57, 58, 61, 69, and 77–79
Barnett, Ogden, and Gunaratnam-I ⁴	§ 103(a)	60 and 71
Barnett, Ogden, and Gunaratnam-II ⁵	§ 103(a)	62–64
Barnett, Ogden, and Worboys ⁶	§ 103(a)	70
Barnett, Ogden, and Matula-II ⁷	§ 103(a)	33, 34, 36, 37, 40–42, and 68
Barnett, Ogden, Matula-II, and Gunaratnam-I	§ 103(a)	35
Barnett, Ogden, Gunaratnam-I, Gunaratnam-II, and Worboys	§ 103(a)	43 and 48–50

² US 6,412,488 B1, iss. July 2, 2002 (Ex. 1202, “Barnett”).

³ US 5,662,101, iss. Sept. 2, 1977 (Ex. 1203, “Ogden”).

⁴ US 6,796,308 B2, iss. Sept. 28, 2004 (Ex. 1207, “Gunaratnam-I”).

⁵ US 2004/0226566 A1, pub. Nov. 18, 2004 (Ex. 1208, “Gunaratnam-II”).

⁶ WO 2007/045008 A1, pub. Apr. 26, 2007 (Ex. 1206, “Worboys”).

⁷ US 2007/0044804 A1, pub. Mar. 1, 2007 (Ex. 1216, “Matula-II”).

II. ANALYSIS

A. Level of Skill in the Art

Petitioner asserts that a person having ordinary skill in the art (“PHOSITA”) “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.” Pet. 16 (citing Ex. 1211 ¶ 27). Based on our review of the Petition and evidence, including Mr. Eaton’s testimony, we find that Petitioner’s asserted level of skill in the art is reasonable and, for the purposes of this Decision, we adopt that definition.

B. Claim Construction

In an *inter partes* review, the Board gives claim terms in an unexpired patent their broadest reasonable interpretation in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *see Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under that standard, a claim term generally is given its ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). While our claim interpretation cannot be divorced from the specification and the record evidence, *see Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015) (quoting *In re NTP, Inc.*, 654 F.3d 1279, 1288 (Fed. Cir. 2011)), we must be careful not to import limitations from the specification that are not part of the claim language. *See SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004). Any special definition for a claim term must be set forth in the

specification with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Petitioner does not assert any specific construction for the claims, but rather asserts that the claims should be given “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.” Pet. 12. We determine that no explicit claim interpretation is required for the purposes of this Decision. *See Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

C. Asserted Obviousness

A claim is unpatentable for obviousness under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). In analyzing the obviousness of a combination of prior art elements, it can be important to identify a reason that would have prompted one of skill in the art to combine the elements in the way the claimed invention does. *Id.* The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness, i.e., secondary considerations, if in evidence. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

Petitioner challenges claims 57, 58, 61, 69, and 77–79 as obvious over Barnett and Ogden. Petitioner challenges claims 33–37, 40–43, 48–50, 60,

62–64, 68, 70, and 71 as obvious over Barnett and Ogden in view of one or more of Gunaratnam-I, Gunaratnam II, Matula-II, and Worboys.

1. Barnett and Ogden—Claims 57, 58, 61, 69, and 77–79

Independent claim 57 recites “a cushion module . . . comprising a frame defining a breathing chamber . . . and a cushion to form a seal with the patient’s face, wherein the cushion comprises a first, relatively soft, elastomeric material and *the frame comprises a second material that is more rigid than the cushion*” (emphasis added) (the “more rigid frame material” limitation). Claim 57 also recites the “removably snap-fit” limitation shown in italics below:

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.

(Emphasis added). Petitioner asserts that Barnett and Ogden teach the “more rigid frame material” and “removably snap-fit” limitations.

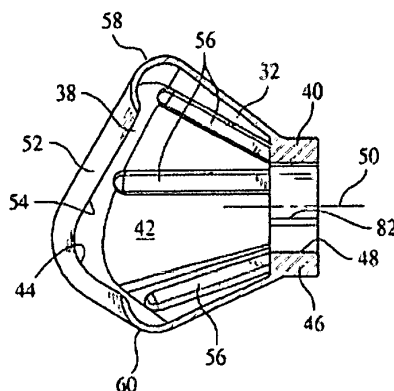
a. Overview of Barnett

Barnett “pertains . . . to a low contact nasal mask that includes a *one-piece*, lightweight seal member defining a nose receiving cavity, a collar coupled to the seal member, and a conduit coupling member.” Ex. 1202, 1:9–11 (emphasis added). In the “Summary of the Invention” section, Barnett describes the seal member as “defined from a *unitary* piece of elastomeric material” that “includes a nose receiving cavity.” *Id.* at 1:58–60

(emphasis added); *see id.* at 2:24–27 (“The nasal mask assembly includes a seal member defined from a *unitary piece* of elastomeric material. The seal member includes a nose receiving cavity.” (emphasis added)).

An exemplary embodiment disclosed in Barnett includes seal member 32, collar 34, and conduit coupling 36. *Id.* at 3:48–50. As described in Barnett, “seal member 32 is preferably defined from a *unitary piece* of elastomeric material that is *relatively flexible* when a deformation force is applied thereto, yet returns to its original shape when the deformation force is removed.” *Id.* at 3:62–66 (emphases added). “Seal member 32 has a first end portion 38 and a second end portion 40 generally opposite first end portion 38 with a nose receiving cavity 42 defined therebetween.” *Id.* at 3:67–4:3. “A first opening 44 is defined in first end portion 38 to allow passage of at least a portion of the patient’s nose into nose receiving cavity 42.” *Id.* at 4:3–5. At opposite ends of seal member 32 are neck portion 46 and lip 52. *Id.* at 4:11–12, 66–67. An exposed surface of lip 52 contacts the patient’s face. *Id.* at 5:1–2.

Petitioner’s annotated version of Figure 2A of Barnett (*see* Pet. 26) is reproduced below.



In the annotated figure above, Petitioner highlights seal member 32 and neck portion 46 in Barnett's Figure 2A.

Barnett discloses that "neck portion 46 is relatively thick as compared to a remainder of the seal member to provide a solid mounting base for the seal member." *Id.* at 4:17–19. In the illustrated embodiment, neck portion 46 is formed from the same material as the remainder of the seal member; however, Barnett discloses that "neck portion 46 can be made from a substance different from that of the remainder of the seal member and bonded thereto to define the illustrated seal member." *Id.* at 4:19–26.

As shown above in annotated Figure 2A of Barnett, seal member 32 includes a plurality of ribs 56 on the side walls of the seal member. *Id.* at 5:8–11. The ribs "provide structural support for the sides of the seal member." *Id.* at 5:12–15. In a preferred embodiment, ribs 56 are integrally formed with the seal member and are approximately twice as thick as the remaining side wall portions of seal member 32. *Id.* at 5:18–22. Barnett discloses that "ribs 56 can be made from substances that differ from that used to define seal member 32 and preferably fixedly secured thereto," and that "the ribs can have other thicknesses so long as they provide sufficient support for the side walls of the seal member." *Id.* at 5:22–29. Barnett also discloses that the ribs can be eliminated in favor increasing the thickness of the entire side wall:

The present invention also contemplates that the ribs can be eliminated in favor of increasing the thickness of the entire side wall, or a major portion of the side wall, of the seal member to provide the side wall support function. However, the weight of the seal member of this configuration, in which the thickness of the entire side wall is increased to prevent collapse of the side

walls, is believed to be greater than the illustrated seal member having a plurality of ribs, and, therefore, is not preferred.

Id. at 5:33–41.

Barnett discloses that collar 34 is “relatively rigid” and includes first mounting member 76, which is sized and configured to insert within opening 48 of neck portion 46 of seal member 32, such that friction prevents the seal member from being readily pulled-off of the collar. *Id.* at 7:14, 17–21. Barnett also discloses that “a tongue and groove or other coupling structure can be provided on neck portion 46 . . . and mounting member 76 . . . to maintain the neck portion in an engaged relation with the mounting member.” *Id.* at 7:29–33.

Petitioner’s annotated versions of Barnett’s Figures 3A and 4A (*see* Pet. 19) are reproduced below.

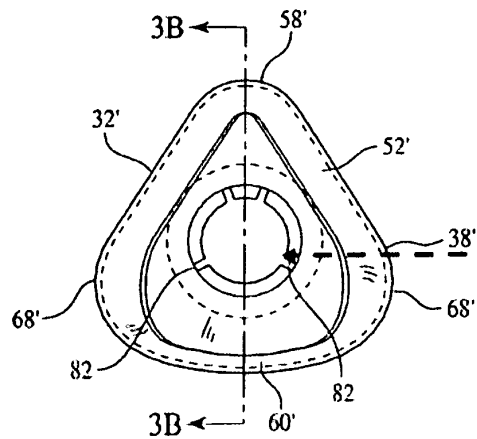


FIG. 3A

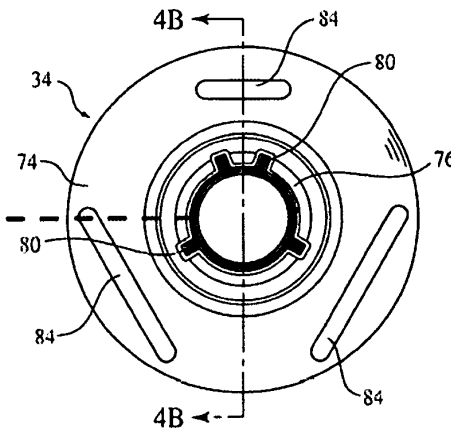


FIG. 4A

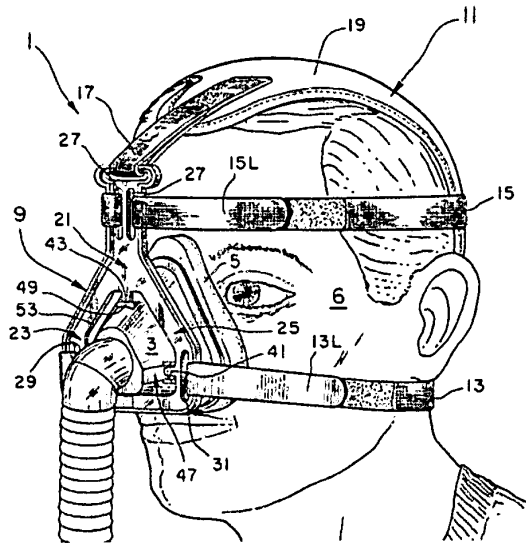
Figure 3A of Barnett is a front view of alternative seal member 32', and Figure 4A of Barnett is a rear view of collar 34. Ex. 1202, 3:6–8, 11–12; in the annotated figures, Petitioner illustrates that channels 82 in neck

portion 46 receive protrusions 80 of mounting member 76 (shown in red) of collar 34. *See id.* at 7:34–39. Barnett discloses that channels 82 and protrusions 80 prevent rotational movement of seal member 32 relative to collar 34. *Id.*

b. Overview of Ogden

Petitioner asserts that “Ogden discloses a nasal mask for respiratory care, but the disclosure is equally applicable to full-face masks.” Pet. 20 (citing Ex. 1203, 1:6–10, 2:44–50). Petitioner’s annotated version of Figure 1 of Ogden is reproduced below.

Fig. 1



Id. Petitioner’s annotated Figure 1 highlights elements of Ogden’s mask assembly 1, including “rigid, cup-shaped shell 3 made of hard plastic [that] encloses the patient’s nose” and “soft, pliable seal 5.” *Id.* (citing Ex. 1203, 2:50–57). As noted by Petitioner:

A soft, pliable seal 5 is attached to the rear perimeter 7 of the rigid shell 3 and seals against the patient’s face. *Id.* at col. 2:54–

57. A rigid plate 9 is attached to the rigid shell 3 at three locations A, B, C by detents 39, 41 and 43 being received in channels 45, 47, and 49. *Id.* at col. 3:26–29. The detents and channels are dimensioned to snap together to hold or maintain the rigid plate 9 on the rigid shell 3. *Id.* at col. 5:15–18.

Id. at 20–21.

c. Petitioner's Arguments

Petitioner asserts that “Barnett discloses nearly all of the limitations of independent Claim 57” and “[a]ny differences were minor and well-known at the time of the invention and taught by Ogden.” *Id.* at 22 (citing Ex. 1211 ¶¶ 54–73). According to Petitioner, Barnett does not disclose expressly that “the frame comprises a second material that is more rigid than the cushion” (the “more rigid frame material” limitation), but “Ogden discloses that the rigid frame 3 is made of hard plastic and the cushion 5 is made of a soft pliable material such as elastomer, urethane foam, or rubber.” *Id.* at 26 (citing Ex. 1203, 2:50–57). Petitioner argues that “a person of ordinary skill in the art would have been motivated to provide a cup-shaped rigid frame, as taught by Ogden, that is formed from a material more rigid than the cushion *to provide a solid mounting base for the cushion module and prevent movement of the cushion module.*” *Id.* at 32 (emphasis added) (citing Ex. 1202, 3:62—4:19; Ex. 1211 ¶¶ 71–72).

In support of this rationale, Mr. Eaton testifies: “Regarding the rigid frame material, Barnett discloses that the neck portion 46 and plurality of ribs 56 may be formed of a different substance than the rest of the seal member, which indicates that the cushion module of Barnett could take on a *well-known cushion/frame construction.*” Ex. 1211 ¶ 71 (emphasis added) (citing 1202, 7:28–36, Fig. A). Mr. Easton further testifies: “A person of

ordinary skill in the art would have known to modify the mask of Barnett based on the teaching of Ogden to make a cup-shaped frame out of a rigid material to provide structure to the cushion module and provide an effective attachment structure for the shroud.” *Id.* Mr. Eaton also testifies that “a skilled artisan would have recognized the need for additional structure in the cushion module to hold the cushion in place,” and further explains:

The internal positive air pressure would cause a cushion module of a unitary soft material to deform under pressure, thus leading to undesired displacement of the mask assembly and its seal. This would be especially problematic with a flow generator designed to provide more than a single level of pressure, as the displacement of the mask would be dynamic based on breathing and delivered pressure over time. One skilled in the art would have known that the rigid frame of Ogden would resist such displacement and provide a suitable and predictable solution.

Id. ¶ 72.

With respect to the requirement of claim 57 for the shroud module and the cushion module to be “removably snap-fit attached to one another” (the “removably snap-fit” limitation), Petitioner argues that Barnett teaches “a tongue and groove snap-fit.” Pet. 28 (citing Ex. 1211 ¶ 63). Petitioner further argues that, “[t]o the extent Barnett does not sufficiently disclose a snap-fit between the shroud and cushion module, such connections between CPAP frames and cushions were well-known at the time of the invention.” *Id.* (citing Ex. 1211 ¶¶ 64–65). Petitioner argues that a PHOSITA would have been motivated to provide such a snap-fit connection “to ensure that the collar and cushion member are fully attached and engaged correctly.” *Id.* at 32 (citing Ex. 1211 ¶ 73; Ex. 1202, 7:28–33; Ex. 1203, col. 5:14–19).

In support of Petitioner’s rationale, Mr. Eaton testifies: “Given the rigid frame of Barnett in view of Ogden, which I describe above [i.e., in

paragraphs 71 and 72 of his declaraton], a person of skill in the art would have known to provide a snap-fit connection between the frame and the shroud.” Ex. 1211 ¶ 73. Mr. Eaton states that Barnett “anticipates the use of coupling structures between the cushion module and the shroud” and “Ogden teaches the specifics of a removable snap-fit arrangement.” *Id.* Mr. Eaton further testifies:

Thus, a skilled artisan would have looked to Ogden and included the snap fingers on the attachment portion of the shroud (collar) of Barnett. A person of skill would have been motivated to make this modification because the snap fingers and removable snap-fit would provide assurance to the user that the collar and cushion member were fully attached and engaged correctly. Additionally, one skilled in the art would have recognized that such a snap-fit arrangement would be advantageous over a friction-fit alone, because the snap-fit provides consistent fit and function, regardless of surface condition or contaminants, which could adversely affect the retention of a joint based on friction alone.

Id.

d. *Analysis of Claims 57, 58, 61, 69, and 77–79*

Petitioner has not persuaded us that a PHOSITA would have substituted Barnett’s unitary seal member with Ogden’s separate cushion/frame construction. *See* Pet 32 (citing Ex. 1202, 3:62–4:19; Ex. 1211 ¶¶ 71–72). Ogden’s rigid shell 3 is made of hard plastic and encloses the patient’s nose and nares, and Ogden’s separate seal 5 is made of a soft and pliable material such as urethane foam, attaches to the rear perimeter portion of shell 3, and seals against the patient’s face. Ex. 1203, 2:50–57. In contrast, Barnett teaches that the seal member, including its nose receiving cavity, is “defined from a *unitary* piece of elastomeric material.” Ex. 1202, 1:58–60 (emphasis

added); *see also id.* at 2:24-27 (“The nasal mask assembly includes a seal member defined from a *unitary piece* of elastomeric material. The seal member includes a nose receiving cavity.” (emphasis added)); *id.* at 3:62–66 (“[S]eal member 32 is preferably defined from a *unitary piece* of elastomeric material that is *relatively flexible* when a deformation force is applied thereto, yet returns to its original shape when the deformation force is removed.” (emphases added); *id.* at 3:67–4:3 (“Seal member 32 has a first end portion 38 and a second end portion 40 generally opposite first end portion 38 with a nose receiving cavity 42 defined therebetween.”).

Barnett describes mechanisms for supporting the sides of the nose receiving cavity of the seal member while using a single piece of material to form both the portion of the seal member that contacts the patient’s face and the portion of the seal member that encloses the patient’s nose. For example, Barnett describes increasing the thickness of the side walls, integrally forming ribs in the side walls, increasing the number or thickness of the ribs, and making ribs from a different substance than the side walls and then fixedly securing them to the side walls. Barnett also describes forming the neck portion of the seal member from a thicker or different substance than the remainder of the seal member. *Barnett does not, however, teach making the portion of the seal member that encloses the patient’s nose from a different substance than the portion of the seal member that contacts the patient’s face.*

We do not agree, therefore, with Mr. Eaton’s opinion that Barnett’s disclosure “that neck portion 46 and plurality of ribs 56 may

be formed of a different substance than the rest of the seal member . . . indicates that the cushion module of Barnett could take on a well-known cushion/frame construction.” See Ex. 1211 ¶11 (citing 1202, 7:28–36, Fig. A). Mr. Eaton’s reading of Barnett does not account sufficiently for the description of the invention as “a one-piece, light-weight seal member defining a nose receiving cavity.” Ex. 1202, 1:9–11; see *id.* at 2:24–27; see also *id.* at 3:62–4:3 (describing an exemplary embodiment in similar terms).

Moreover, Mr. Eaton’s testimony that “a skilled artisan would have recognized the need for additional structure in the cushion module to hold the cushion in place” (Ex. 1211 ¶ 72) is conclusory and unpersuasive.⁸ Neither Petitioner nor Mr. Eaton explains why a PHOSITA would have concluded that the side-wall support mechanisms described in Barnett do not provide adequate structure to hold the cushion in place. More specifically, Mr. Eaton asserts that “a cushion module of a unitary soft material [would] deform under pressure, thus leading to undesired displacement of the mask assembly and its seal” (Ex. 1211 ¶ 72), but fails to explain why the side-wall support mechanisms described in Barnett would not prevent such distortion and displacement. As such, Mr. Eaton’s testimony does not appear to take into account Barnett’s disclosure with respect to ribs 56, for example, that

⁸ Petitioner’s similar assertion—that “a person of ordinary skill in the art would have been motivated to provide a cup-shaped rigid frame, as taught by Ogden, that is formed from a material more rigid than the cushion *to provide a solid mounting base for the cushion module and prevent movement of the cushion module*” (Pet. 32 (emphasis added))—is also conclusory and unpersuasive.

“ribs 56 . . . provide structural support for the sides of the seal member so that the seal member does not collapse when a strapping force⁹ sufficient to minimize[] leaks at the mask-patient interface is applied on second end portion 40.” Ex. 1202, 5:12–18; *see also id.* at 5:20–21, 27–29 (stating that the ribs are approximately twice as thick as the remaining side wall portions of seal member 32, but can have other thicknesses so long as they provide sufficient support for the side walls of the seal member).¹⁰ Nor does Mr. Eaton explain why or how a PHOSITA would have known that Ogden’s cushion/frame construction would resist displacement more effectively than Barnett’s unitary seal member with ribs. *See* Ex. 1211 ¶ 72.

Petitioner’s assertion that incorporating Ogden’s rigid frame in Barnett’s seal member would have provided a solid mounting base for the cushion module (*see* Pet. 32) is similarly conclusory and unpersuasive. “[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (quoted in

⁹ Barnett defines “strapping force” as the force by which the nasal mask assembly is pressed against the patient’s face. Ex. 1202, 5:4–7.

¹⁰ Mr. Eaton states that the problem of internal positive air pressure caused by a flow generator designed to provide more than a single level of pressure would be particularly problematic, because the displacement of the mask would be dynamic based on breathing and delivered pressure over time. Ex. 1211 ¶ 72. However, Mr. Eaton does not explain whether that problem would be more severe, or require a different solution, than the problem of a “strapping force sufficient to minimize[] leaks at the mask-patient interface,” as described in Barnett. *See* Ex. 1202, 5:12–18.

KSR, 550 U.S. at 418). Petitioner does not explain with sufficient specificity why a PHOSITA would have substituted Barnett's neck portion 46 with Ogden's rigid cup-shaped frame to provide a solid mounting base for the seal member. The general goal of providing a solid mounting base for the cushion module is not enough. Indeed, Barnett expressly discloses that "neck portion 46 is relatively thick as compared to a remainder of the seal member *to provide a solid mounting base for the seal member.*" Ex. 1202, 4:17–19 (emphasis added).

Finally, we are not persuaded by Mr. Eaton's testimony that a PHOSITA would have modified Barnett's mask based on the teaching of Ogden "to make a cup-shaped frame out of a rigid material to provide . . . an effective attachment structure for the shroud." Ex. 1211 ¶ 71. This testimony appears to be directed at both the "removably snap-fit" limitation as well as the "more rigid frame material" limitation. Indeed, in paragraph 73 of Mr. Eaton's declaration discussing the "removably snap fit" limitation, Mr. Eaton assumes, referring to his opinions relating to the "more rigid frame material" limitation, that "Barnett in view of Ogden" has a "rigid frame." *Id.* ¶ 73.¹¹ However, Mr. Eaton's opinion that "a skilled artisan would have looked to Ogden and included [] snap fingers on the attachment portion of the shroud (collar) of Barnett" (*id.*) does not provide sufficient articulated reasoning, with some rational underpinning, to establish that a PHOSITA would have incorporated Ogden's cup-shaped frame in Barnett's

¹¹ Specifically, Mr. Eaton states: "*Given the rigid frame of Barnett in view of Ogden*, which I describe above [i.e., in paragraphs 71 and 72 of his declaration], a person of skill in the art would have known to provide a snap-fit connection between the frame and the shroud." Ex. 1211 ¶ 73 (emphasis added).

seal member. *See Kahn*, 441 F.3d at 988. In particular, Mr. Eaton does not explain why a PHOSITA would have modified the flexible side walls forming the nose receiving cavity of Barnett's seal member 32 in order to include snap fingers on Barnett's collar 34.

Petitioner has provided no persuasive evidence, moreover, to show that including snap fingers on mounting member 76 of collar 34 reasonably would have required modifying any portion of seal member 32 other than (possibly) neck portion 46. Indeed, Barnett explicitly describes providing a "coupling structure . . . on neck portion 46 of seal member 32 and mounting member 76 of collar 34 to maintain the neck portion in an engaged relation with the mounting member in addition to or in place of the friction engagement," but does not teach or suggest modifying any portion of seal member 32 other than neck portion 46 to provide such a coupling. *See Ex. 1202*, 7:29–33. Accordingly, we are not persuaded that a PHOSITA would have substituted the flexible side walls defining the nose receiving cavity of Barnett's seal member with the rigid cup-shaped frame of Ogden in order to include snap fingers on Barnett's collar.

For the reasons given, we determine that Petitioner has not established a reasonable likelihood of prevailing on its challenge to claim 57 as obvious over Barnett and Ogden. For the same reasons, Petitioner has not shown a reasonable likelihood of prevailing on its challenge to claims 58, 61, 69, and 77–79, which depend, directly or indirectly, from claim 57.

2. *Analysis of Claims 33–37, 40–43, 48–50, 60, 62–64, 68, 70, and 71*

For its challenges to claims 33–37, 40–43, 48–50, 60, 62–64, 68, 70, and 71, Petitioner relies on Barnett and Ogden in view of one or more of

Gunaratnam-I, Gunaratnam II, Worboys, and Matula-II. *See* Pet. 32–89. Claims 33 and 43 each recite “the frame is constructed of a second material that is more rigid than the cushion.” That limitation is essentially identical to the “more rigid frame material” limitation of claim 57. For each of these claim limitations, Petitioner relies on Barnett and Ogden. *See* Pet. 18–32, 57–62, 70, 77, 80–82. As claims 34–37, 40–42, 48–50, 60, 62–64, 68, 70, and 71 each depend, directly or indirectly, from claim 33, 43, or 57, we determine, for the reasons discussed above in connection with our analysis of claim 57 over Barnett and Ogden, that Petitioner has not established a reasonable likelihood of prevailing on its challenges to claims 33–37, 40–43, 48–50, 60, 62–64, 68, 70, and 71.

III. CONCLUSION

For the reasons given, Petitioner has not shown a reasonable likelihood that it would prevail in establishing unpatentability of any of challenged claims 33–37, 40–43, 48–50, 57, 58, 60–64, 68–71, and 77–79.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner’s Petition for an *inter partes* review of claims 33–37, 40–43, 48–50, 57, 58, 60–64, 68–71, and 77–79 of U.S. Patent No. 9,119,931 B2 is *denied*.

IPR2017-00064
Patent 9,119,931 B2

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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 IPR2017-00065
Patent 9,119,931 B2

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

RICE, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Background

Fisher & Paykel Healthcare Limited (“Petitioner”) filed a Petition (Paper 1, “Pet.”) requesting an *inter partes* review of claims 1, 4–8, 10–22, 25, 26, 28–32, 46, 51, 53–56, and 65 of U.S. Patent No. 9,119,931 B2 (Ex. 1301, “the ’931 Patent”). Petitioner supported the Petition with a declaration from Jason Eaton, P.E. (Ex. 1312). ResMed Limited (“Patent Owner”) did not file a preliminary response to the Petition.¹

Under 35 U.S.C. § 314, an *inter partes* review may not be instituted “unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). Upon considering the Petition and the evidence filed therewith, we determine that Petitioner has not shown a reasonable likelihood that it would prevail with respect to any of challenged claims 1, 4–8, 10–22, 25, 26, 28–32, 46, 51, 53–56, and 65.

Accordingly, we do not institute an *inter partes* review.

B. Related Matters

The parties identify a related federal district court case involving the ’931 Patent: *Fisher & Paykel Healthcare Ltd. v. ResMed Corp.*, Case No. 3:16-cv-02068-DMS-WVG (S.D. Cal.). Pet. 6; Paper 4, 2. The parties also indicate that the ’931 Patent is involved in U.S. International Trade Commission Investigation No. 337–TA–1022. Pet. 6; Paper 4, 2.

¹ See 37 C.F.R. § 42.107 (providing that filing a preliminary response to the petition is not obligatory).

and includes an opening 1046 that communicates with elbow 1070. *Id.* at 6:60–64. The frame 1040 also includes vent arrangement 1076, shown in Figure 3, that protrudes from frame 1040. *Id.* at 7:22–23. Opening or vent receiving hole 1021 in shroud 1020 accommodates the protruding vent arrangement. *Id.* at 7:21–23.

Of the challenged claims, claims 1 and 51 are independent. Claims 4–8, 10–22, 25, 26, and 28–32 depend, directly or indirectly, from claim 1. Claims 53–56 depend, directly or indirectly, from claim 51. Claim 46 depends from independent claim 43, which is unchallenged. Claim 65 depends from independent claim 57, which is unchallenged. Claim 1 is reproduced below:

1. A mask system, comprising:
 - (i) a shroud module; wherein the shroud module includes headgear connectors adapted to removably attach to respective headgear straps of headgear; and
 - (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,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,wherein the shroud module and the cushion module are configured to be removably and non-rotatably coupleable to one another; and
- 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 further wherein the shroud module includes a second opening positioned to align with a frame opening of the frame leading to the breathing chamber.

Ex. 1001, 24:6–29.

D. Overview of Prosecution History

During prosecution of the '931 Patent, the Examiner issued a final rejection of all pending claims, except claims 29 and 33. Ex. 1313, 343–61. The Examiner indicated that application claims 29 and 33 (each of which recited “a protruding vent arrangement”) would be allowable if rewritten in independent form. *Id.* at 359. In response, the applicant, *inter alia*, added the subject matter of claim 29 to claim 1, canceled claim 29, and added new claims 34–83. *Id.* at 447. After a subsequent telephonic interview, the Examiner allowed the claims subject to an Examiner’s Amendment. *Id.* at 462–72.

E. The Asserted Grounds

Petitioner challenges claims 1, 4–8, 10–22, 25, 26, 28–32, 46, 51, 53–56, and 65 on the following grounds (Pet. 11–12):

Reference(s)	Basis	Claims Challenged
Matula-I, ² Ogden, ³ and Gunaratnam-I ⁴	§ 103(a)	1, 6–8, 11, 12, 26, and 31–32
Matula-I, Ogden, Gunaratnam-I, and Matula-II ⁵	§ 103(a)	4, 5, 10, and 65

² WO 2007/147088 A2, pub. Dec. 21, 2007 (Ex. 1302, “Matula-I”).

³ US 5,662,101, iss. Sept. 2, 1977 (Ex. 1310, “Ogden”).

⁴ US 6,796,308 B2, iss. Sept. 28, 2004 (Ex. 1303, “Gunaratnam-I”).

⁵ US 2007/0044804 A1, pub. Mar. 1, 2007 (Ex. 1319, “Matula-II”).

Reference(s)	Basis	Claims Challenged
Matula-I, Ogden, Gunaratnam-I, and Lovell ⁶	§ 103(a)	13, 14, and 18
Matula-I, Ogden, Gunaratnam-I, Matula-II, and Lovell	§ 103(a)	28–30
Matula-I, Ogden, Gunaratnam-I, and Worboys ⁷	§ 103(a)	15
Matula-I, Ogden, Gunaratnam-I, and Barnett ⁸	§ 103(a)	16 and 17
Matula-I, Ogden, Gunaratnam-I, and Gunaratnam-II ⁹	§ 103(a)	19–22 and 25
Matula-I, Ogden, Gunaratnam-I, Matula-II, Gunaratnam-II, and Worboys	§ 103(a)	46, 51, and 53–56

II. ANALYSIS

A. Level of Skill in the Art

Petitioner asserts that a person having ordinary skill in the art (“PHOSITA”) “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.” Pet. 16–17 (citing Ex. 1312 ¶ 27). Based on our review of the Petition and evidence, including Mr. Eaton’s testimony, we find that

⁶ US 6,631,718 B1, iss. Oct. 14, 2003 (Ex. 1311, “Lovell”).

⁷ WO 2007/045008 A1, pub. Apr. 26, 2007 (Ex. 1306, “Worboys”).

⁸ US 6,412,488 B1, iss. July 2, 2002 (Ex. 1309, “Barnett”).

⁹ US 2004/0226566 A1, pub. Nov. 18, 2004 (Ex. 1304, “Gunaratnam-II”).

Petitioner's asserted level of skill in the art is reasonable and, for the purposes of this Decision, we adopt that definition.

B. Claim Construction

In an *inter partes* review, the Board gives claim terms in an unexpired patent their broadest reasonable interpretation in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *see Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under that standard, a claim term generally is given its ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). While our claim interpretation cannot be divorced from the specification and the record evidence, *see Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015) (quoting *In re NTP, Inc.*, 654 F.3d 1279, 1288 (Fed. Cir. 2011)), we must be careful not to import limitations from the specification that are not part of the claim language. *See SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

1. a protruding vent arrangement having a plurality of holes or gas washout holes (claims 1, 46, 51, and 65)

Claims 1, 46, and 51 each recite “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” (emphasis added). Claim 65 similarly recites “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” (emphasis added). Petitioner does not propose an explicit construction for “a protruding vent arrangement having a plurality of holes” or any other claim term, but rather contends generally that all claim terms should “have their ordinary and customary meaning[s] in light of the specification, as commonly understood by those of ordinary skill in the art at the time of the invention.” Pet 13.

In its obviousness analysis, Petitioner argues, however, that the “protruding vent arrangement” claim term would be satisfied by adding a vent to a portion of Matula-I’s cushion frame 1260 that extends through opening 1250 of body portion 1240. *Id.* at 27–28, 33–34, 69–71; *see* Ex. 1312 ¶¶ 63–67. As such, Petitioner contends, implicitly, that the “protruding vent arrangement” claim term broadly encompasses a vent in a portion of the frame that extends through an opening in the shroud module. We disagree with Petitioner’s implicit claim construction.

Petitioner’s construction is contrary to the plain language of the claim term, which requires the frame to have a “vent arrangement” that is “protruding” (rather than reciting that the frame has a protruding portion that includes a vent arrangement having a plurality of holes). Petitioner’s construction also is inconsistent with the Specification. As described in the Specification and depicted in Figure 3 (reproduced above on page 3), protruding vent arrangement 1076 is a discrete vent structure that extends above the surrounding surface of frame 1040 and contains a plurality of vent holes. Ex. 1301, 7:18–23 (“The top end of the shroud 1020 . . . includes an opening or vent receiving hole 1021 to accommodate *the vent arrangement 1076 that protrudes from the frame 1040.*” (emphasis added)), Fig. 3.

Contrary to Petitioner's implicit claim construction, protruding vent arrangement 1076 is described in the Specification as extending from the surface of the frame, and not merely as extending through an opening in shroud 1020. *See id.*

Further, claims 1, 46, 51, and 65 each separately recite that "the shroud module includes a first opening to accommodate said protruding vent arrangement," or similar language. That language would be rendered "merely superfluous" under Petitioner's implicit construction that "a protruding vent arrangement" is a portion of the frame with vent holes that extends through an opening in the shroud. *See Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006) (stating that "claims are interpreted with an eye toward giving effect to all terms in the claim," so that physical structures and characteristics specifically described in a claim are not rendered "merely superfluous").

We determine that the broadest reasonable interpretation consistent with the Specification of "a protruding vent arrangement having a plurality of holes" is a discrete vent structure that extends above the surrounding surface of the frame and contains a plurality of vent holes. Similarly, we determine that the broadest reasonable interpretation consistent with the Specification of "a protruding vent arrangement having a plurality of gas washout holes" is a discrete vent structure that extends above the surrounding surface of the frame and contains a plurality of gas washout holes.

2. Other Claim Terms

We determine that no other explicit claim interpretation is required for the purposes of this Decision. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

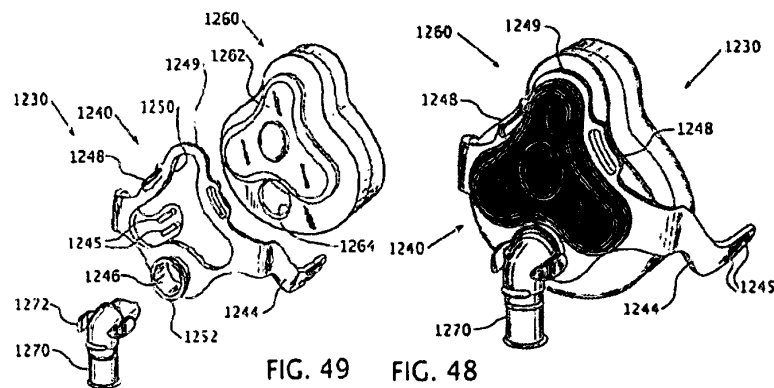
C. Asserted Obviousness

A claim is unpatentable for obviousness under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). In analyzing the obviousness of a combination of prior art elements, it can be important to identify a reason that would have prompted one of skill in the art to combine the elements in the way the claimed invention does. *Id.* The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness, i.e., secondary considerations, if in evidence. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

Challenged claims 1, 4–8, 10–22, 25, 26, 28–32, 46, 51, 53–56, and 65 each require a frame that includes a protruding vent arrangement having a plurality of holes or gas washout holes (“the protruding vent arrangement limitation”). As to each of those claims, Petitioner asserts that the combination of Matula-I and Gunaratnam-I teaches the protruding vent arrangement limitation. *See* Pet. 26–27, 33–34, 69–71, 107, 115–17, 123.

1. Overview of Matula-I

Petitioner asserts that Matula-I discloses CPAP mask assembly 1230 including body portion 1240 and patient interface 1260. Pet. 18 (citing Ex. 1302 ¶ 101). Petitioner further asserts that, as shown in Figure 49 of Matula-I, body portion 1240 includes opening 1262 “sized and configured to fit snugly into opening 1250.” *Id.* (citing Ex. 1302 ¶ 104). Petitioner’s annotated versions of Figures 49 and 48 of Matula-I are reproduced below.



See id. at 27; Ex. 1302, Figs. 49, 48. The figures above depict mask assembly 1230 including body portion 1240 and patient interface 1260. According to Petitioner, “the cushion frame 1260 includes a protrusion 1262 (highlighted in red [as shown in annotated Figure 48 above]) that protrudes through the opening 1250 of the body portion 1240.” Pet. 27; Ex. 1302 ¶ 106).

Matula-I discloses that an exhaust assembly (not shown in any of the figures) can be provided “on patient circuit coupling 1270 . . . [or] at other locations, such as in the patient interface portion, the body member, or in any combination of locations.” Ex. 1302 ¶ 106.

2. Overview of *Gunaratnam-I*

Petitioner asserts that *Gunaratnam-I* discloses a full-face mask system that includes mask frame 160, cushion 180, and clip 800. Pet. 22 (citing Ex. 1303, 6:3–7, Fig. 15). As shown in Petitioner’s annotated version of *Gunaratnam-I*’s Figure 15, reproduced below, mask frame 160 includes aperture 930 for receiving air vent 940. *Id.* (citing Ex. 1303, 6:25–29).

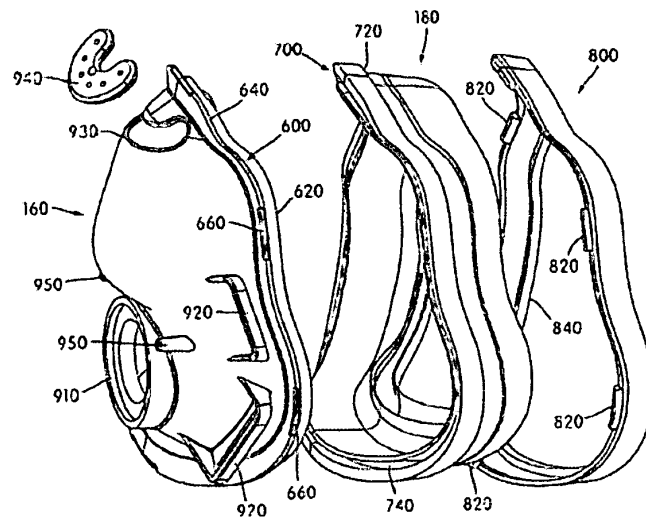


FIG. 15

See id. In the annotated figure above, Petitioner shows, in yellow, elements 930 and 940 of frame 160.

3. Analysis

With respect to the protruding vent arrangement limitation, Petitioner argues:

Matula-I [] discloses that an exhaust vent assembly can be provided on the cushion frame 1260. [Ex. 1302 ¶ 104]. To the extent *Matula-I* provides insufficient teaching for a vent on the protruding portion, *Gunaratnam-I* discloses an air vent (940) in the nasal bridge region, as shown in Figure 15 []. Ex. 1303 at col. 6:25–29. . . . [A] skilled artisan at the time of the invention

would have been motivated to provide the vent of Gunaratnam-I in the same nasal bridge region of Matula-I, and thus on the protruding portion of Matula-I. Ex. 1312 ¶ 65.

Pet. 27–28. Petitioner also argues:

A person of skill in the art also would have been motivated to modify Matula-I to include a vent for CO₂ washout. [Ex. 1312 ¶ 83]. A skilled artisan would have recognized the benefits in positioning the vent on the protruding portion of the frame to minimize noise output. *Id.* Additionally, it was well-known to place the vent in the nasal bridge region to minimize dead space and because air from the inlet would flow by the patient's nose and exit the vent to flush exhaled air effectively and minimize re-breathing of exhaled air. *Id.*

Id. at 33–34.

Petitioner, thus, argues that a POSITA would have modified Matula-I's mask, so as to include the protruding vent arrangement limitation, by adding a vent to a portion of Matula-I's cushion frame 1260 that protrudes through opening 1250 of body portion 1240. Petitioner's analysis, however, is based on an improper claim construction, as discussed above. *See supra* Section II.B.1. Under a proper claim interpretation, the limitation requires a discrete vent structure that extends above the surrounding surface of the frame and contains a plurality of vent holes or gas washout holes. *See id.* Petitioner does not contend that either Matula-I or Gunaratnam-I specifically teaches or suggests a protruding vent arrangement having a plurality of vent holes or gas washout holes. Rather, Petitioner contends that both references teach positioning a vent in the nasal bridge region of a mask. Merely positioning a vent in a portion of Matula-I's mask that protrudes through opening 1250 of body portion 1240, such as the nasal bridge region, would not result in a discrete vent structure that extends above the surrounding surface of the frame and contains a plurality of vent holes or gas

washout holes, as required under our claim interpretation. The vent would be flush with the surrounding surface of the frame, for example, in the nasal bridge region of the frame. We are unpersuaded, therefore, that the combination of Matula-I and Gunaratnam-I teaches or suggests the protruding vent arrangement limitation.

For the reasons given, we determine that Petitioner has not established a reasonable likelihood of prevailing on its challenges to claims 1, 4–8, 10–22, 25, 26, 28–32, 46, 51, 53–56, and 65, each of which requires the protruding vent arrangement limitation.

III. CONCLUSION

For the reasons give, Petitioner has not shown a reasonable likelihood that it would prevail in establishing unpatentability of any claim.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner's Petition for an *inter partes* review of claims 1, 4–8, 10–22, 25, 26, 28–32, 46, 51, 53–56, and 65 of U.S. Patent No. 9,119,931 B2 is *denied*.

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Patent 9,119,931 B2

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