

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FISHER & PAYKEL HEALTHCARE LIMITED,
Petitioner,

v.

RESMED LIMITED,
Patent Owner.

Case IPR2017-00504
Patent 9,027,556 B2

Before BARRY L. GROSSMAN, BEVERLY M. BUNTING, and
JAMES J. MAYBERRY, *Administrative Patent Judges*.

MAYBERRY, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

Petitioner, Fisher & Paykel Healthcare Ltd. (“Fisher”), filed a Petition (Paper 1, “Pet.”) requesting *inter partes* review of claims 1–66 (the “Challenged Claims”) of U.S. Patent No. 9,027,556 B2 (Ex. 1101, the “’556 patent”). Patent Owner, ResMed Ltd. (“ResMed”), filed a Preliminary Patent Owner Response to the Petition. Paper 7 (“Prelim. Resp.”). We instituted trial on all Challenged Claims and all grounds. See Paper 8, 49–50 (instituted trial on claims 1–66 on ten grounds) (“Dec. on Inst.”); cf. Pet. 8–10 (listing the ten asserted grounds).

After we instituted trial, ResMed filed a Patent Owner Response. Paper 13 (“PO Resp.”). Fisher filed a Reply to ResMed’s Patent Owner Response. Paper 16 (“Reply”). Oral hearing was conducted for this proceeding on February 21, 2018, and the record contains a transcript of the hearing. Paper 24 (“Tr.”).

Fisher relies on the declaration testimony of Mr. Richard Lordo. Ex. 1109. ResMed relies on the declaration testimony of Mr. Geoffrey Sleeper. Ex. 2005.

The Board has jurisdiction under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons that follow, we conclude that Fisher has not established, by a preponderance of the evidence, that claims 1–66 of the ’556 patent are unpatentable.

A. Related Matters

Fisher indicates that the ’556 patent is involved in district court litigation in the Southern District of California, in a case styled *Fisher & Paykel Healthcare Ltd. v. ResMed Corp.*, Case No. 3:16-cv-02068-DMS-

WVG (S.D. Cal.). Pet. 5; *see also* Paper 4, 2 (identifying the litigation). Fisher indicates that it has filed a second petition for *inter partes* review challenging claims 1–66 of the ’556 patent. Pet. 5; *see also* Paper 4, 2 (identifying the *inter partes* review as IPR2017–00501).

B. The ’556 Patent

The ’556 patent, titled “Mask System,” issued May 12, 2015, with claims 1–66. Ex. 1101, (54), (45), 9:65–20:40. The ’556 patent is generally directed “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).” *Id.* at 1:16–19. Figures 1, 2, and 4 of the ’556 patent depict an embodiment of the ’556 patent’s mask system and are reproduced below.

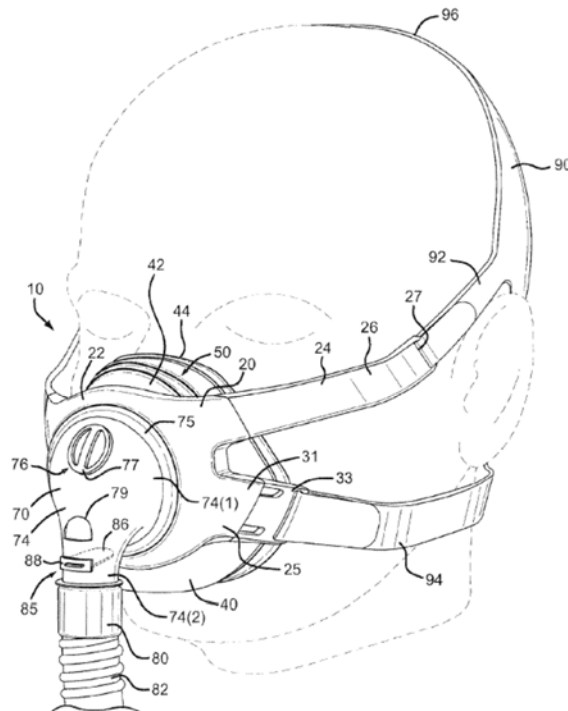


Fig. 1

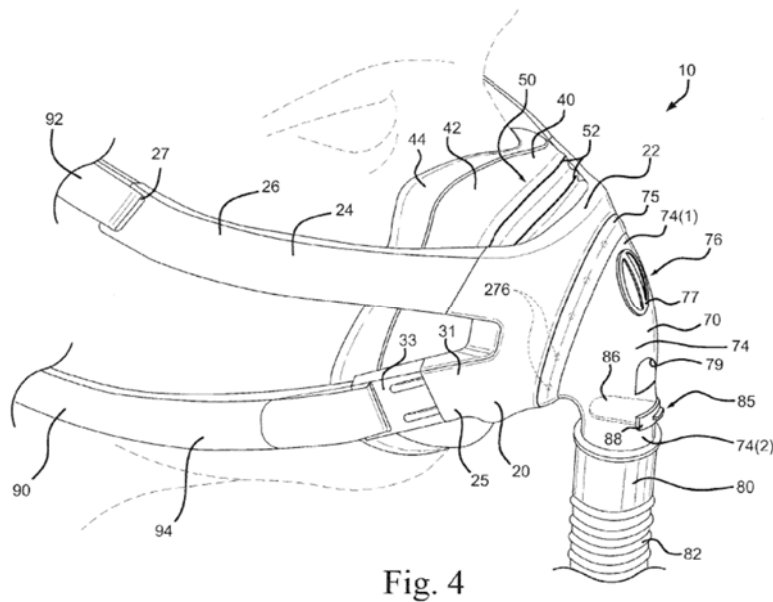
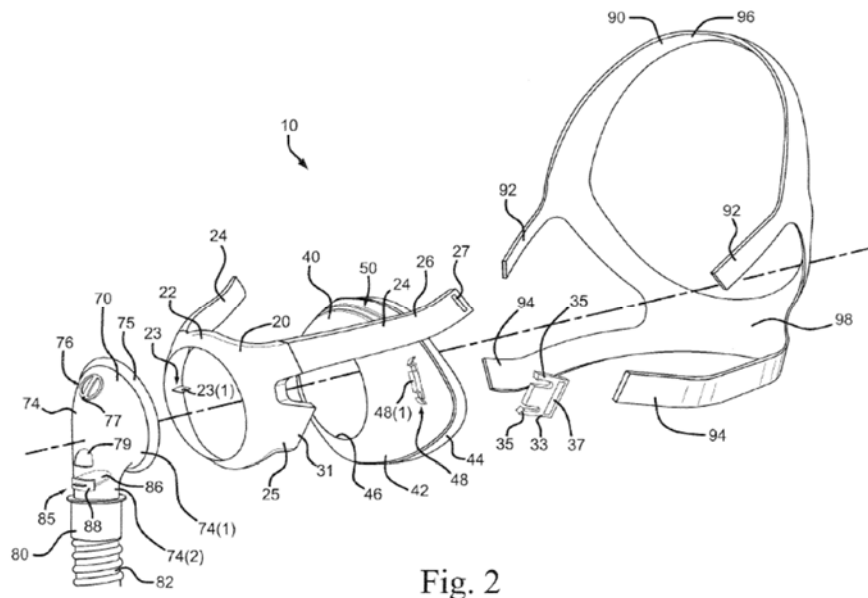


Figure 1 depicts “a front perspective view of a mask system according to an embodiment of the” ’556 patent, Figure 2 depicts “an exploded view of the mask system shown in [Figure] 1,” and Figure 4 depicts “a side view of the mask system shown in [Figure] 1.” Ex. 1101, 2:11–12, 2:13–14, 2:17. In the embodiment of Figures 1, 2, and 4, mask system 10 includes frame module 20, cushion module 40, elbow module 70, and headgear 90. *Id.* at 2:61–3:4. Cushion module 40 forms a seal with the wearer’s face, elbow 70

delivers breathing gas to the wearer, and headgear 90, which may be removably attached to frame module 20, maintains mask system 10 in position on the wearer's face. *Id.*

Cushion module 40 includes main body 42 and cushion 44. Ex. 1101, 4:1–2. Main body 42 attaches to frame 20. *Id.* at 4:2–4. Main body 42 and cushion 44 may form a one-piece, integrated component, such as by co-molding the two separate components. *Id.* at 5:2–4. Main body 42 may be molded from a material that is more rigid than the material used to mold cushion 44, so that main body 42 may interface with frame 20 and cushion 44 may be relatively soft to allow it to seal to a wearer's face. *Id.* at 5:5–12.

In the embodiment of Figures 1, 2, and 4, interfacing structure 23 of frame 20 removably connects to interfacing structure 48 of main body 42 to connect frame 20 to cushion module 40. Ex. 1101, 5:25–33. The '556 patent describes that alternative connections may be used, such as friction fit connections, snap-fit connections, and mechanical interlocks. *Id.* at 5:33–36.

C. Challenged Claims

Claims 1, 14, 22, 32, 54, and 61 of the '556 patent are independent. Claims 1, 14, and 32 are representative and are reproduced below:

1. A mask system for delivery of a supply of gas at positive pressure to a patient for medical treatment, the mask system comprising:
 - a frame module;
 - a cushion module provided to the frame module and adapted to form a seal with the patient's face;
 - an elbow module rotatably attached to the frame module such that the frame module acts as a carrier and bearing surface for the elbow module, the elbow module being rotatably attached

to the frame module such that the elbow module is rotatable 360° relative to the frame module in use, and the elbow module being adapted to be connected to an air delivery tube that delivers breathable gas to the patient; and

headgear removably attachable to the frame module to assist in maintaining the mask system in a desired adjusted position on the patient's face, wherein:

the cushion module includes a main body and a cushion, the main body at least partly defining a breathing chamber,

the frame module and the main body having shapes that prevent relative rotation when the frame module is attached to the main body,

an outer portion of the main body is exposed and remains uncovered by the frame module when the frame module and the main body are attached, and

the main body and cushion together comprise an integrated component, the main body comprising a molded material that interfaces with the frame module and the cushion comprises a molded silicone material adapted to interface with patient's face, and the molded material of the main body is a more rigid material than the molded silicone material of the cushion.

Ex. 1101, 9:65–10:31 (emphasis added).

14. A mask system for delivery of a supply of gas at positive pressure to a patient for medical treatment, the mask system comprising:

a frame module;

a cushion module snap-fit to the frame module and adapted to form a seal with the patient's face; and

an elbow module provided to the frame module, the frame module including a carrier having a bearing surface, the elbow module being rotatably attached to the bearing surface of the carrier such that, in use, the elbow module is rotatable 360° relative to the frame module, and adapted to be connected to an air delivery tube that delivers breathable gas to the patient,

wherein the cushion module includes a main body and a cushion, the main body at least partly defining a breathing chamber,

wherein the main body and the cushion together comprise an integrated component, the main body comprising a molded material adapted to directly contact the frame module and the cushion comprises a molded silicone material adapted to interface with patient's face,

wherein *the frame module and the main body have complementary shapes that provide for non-rotatable engagement relative to one another*, and

wherein the molded material of the main body is a more rigid material than the molded silicone material of the cushion.

Ex. 1101, 12:50–13:9 (emphasis added).

32. A mask system for a patient, the mask system comprising:

a cushion module comprising a cushion of one material adapted to form a seal with the patient's face, and a main body of a different, more rigid material, the main body having a main body opening to receive pressurized breathable gas;

an elbow module having an elbow adapted to be connected to an air delivery tube that delivers breathable gas to the patient via the cushion module; and

a frame module connected to the main body of the cushion module with a snap-fit connection,

wherein *the frame module and the cushion module are not rotatable relative to one another when connected*,

wherein the frame module retains the elbow module, and acts as a carrier and a bearing surface for the elbow module, and

wherein the elbow module is rotatably attached to the frame module so that the elbow module is rotatable 360 degrees relative to the frame module.

Ex. 1101, 16:9–28 (emphasis added).

D. The Prior Art

We instituted trial on ten (10) grounds of unpatentability for the Challenged Claims that rely on the following references:

Matula	US 2007/0044804 A1	Mar. 1, 2007	Ex. 1102
Jaffre	US 6,851,425 B2	Feb. 8, 2005	Ex. 1103 ¹
Ging	US 2005/0155604 A1	July 21, 2005	Ex. 1004
Lithgow	US 2004/0118406 A1	June 24, 2004	Ex. 1105
Gunaratnam	US 6,796,308 B2	Sept. 28, 2004	Ex. 1106
Namey	US 2002/0020416 A1	Feb. 21, 2002	Ex. 1107
Melidis	US 7,827,990 B1	Nov. 9, 2010	Ex. 1108

E. Alleged Grounds of Unpatentability

We instituted trial on ten (10) grounds of unpatentability for the Challenged Claims, each of which is based on 35 U.S.C. § 103(a)²:

References	Claims Challenged
(1) Matula	1, 2, and 4
(2) Matula and Ging	3, 5, 7, 14–16, 19, 22–26, 29, 32, 33, 36, 43, 45–52, 54, 55, 57, 58, 61–64, and 66
(3) Matula and Melidis	6
(4) Matula, Ging, and Melidis	8, 17, 18, 27, 28, 37, 38, 40, 41, 56, and 60
(5) Matula, Namey, and Gunaratnam	9–13
(6) Matula, Ging, Namey, and Gunaratnam	20, 21, 30, 31, 59, and 65

¹ Fisher contends that Jaffre is incorporated by reference into Matula. See Pet. 36; Ex. 1102 ¶ 59.

² The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, 125 Stat. 284, 296–307 (2011), took effect on September 16, 2012. Because the application for the patent at issue in this proceeding has an effective filing date before that date, we refer to the pre-AIA versions of the statute.

References	Claims Challenged
(7) Matula, Ging, and Gunaratnam	34 and 35
(8) Matula, Ging, Melidis, and Lithgow	39 and 42
(9) Matula, Ging, Gunaratnam, and Melidis	53
(10) Matula, Ging, and Namey	44

Pet. 9–10.

II. ANALYSIS

A. Level of Ordinary Skill in the Art

The level of skill in the art is “a prism or lens” through which we view the prior art and the claimed invention. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). Fisher asserts that the level of ordinary skill in the art to which the ’556 patent pertains is “at least a bachelor’s degree in mechanical engineering, biomedical engineering or other similar type of engineering degree combined with at least two years of experience in the field of masks, respiratory therapy, patient interfaces or relevant product design experience.” Pet. 13 (citing Ex. 1109 (Decl. of Richard Lordo) ¶ 25). Mr. Sleeper, ResMed’s declarant, states that a person having ordinary skill in the art “would have at least a bachelor’s degree in mechanical engineering, biomedical engineering, or a similar technical field, with at least two years of relevant product design experience. An increase in experience could compensate for less education, and an increase in education could likewise compensate for less experience.” Ex. 2005 (Decl. of Geoffrey Sleeper) ¶ 12.

Factual indicators of the level of ordinary skill in the art include “the various prior art approaches employed, the types of problems encountered in the art, the rapidity with which innovations are made, the sophistication of

the technology involved, and the educational background of those actively working in the field.” *Jacobson Bros., Inc. v. United States*, 512 F.2d 1065, 1071 (Ct. Cl. 1975); *see also Orthopedic Equip. Co., Inc. v. United States*, 702 F.2d 1005, 1011 (Fed. Cir. 1983) (quoting with approval *Jacobson Bros.*).

We find both parties assert very similar definitions of the level of ordinary skill in the art. Both definitions include a degreed engineer with two years of experience. Fisher identifies the fields of experience as “masks, respiratory therapy, patient interfaces or relevant product design” and ResMed, through Mr. Sleeper, defines the field of experience as “relevant product design.” Mr. Sleeper declares that additional experience may compensate for less education and additional education may compensate for less experience.

We find, based on our review of the complete record, that the evidence of record supports a level of ordinary skill in the art consistent with the parties’ definitions—a person having a bachelor’s degree in mechanical engineering, biomedical engineering, or other similar type of engineering degree combined with two years of experience in the field of masks, respiratory therapy, patient interfaces, or other relevant product design experience. We also find that additional experience may compensate for less education and additional education may compensate for less experience. Further, we note that our patentability analysis presented below would reach

the same findings and determinations under either party's definition of the level of ordinary skill in the art.

B. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b). Under the broadest reasonable construction standard, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Also, we are careful not to read a particular embodiment appearing in the written description into the claim if the claim language is broader than the embodiment. *See In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993) (“[L]imitations are not to be read into the claims from the specification.”).

In two situations, the proper interpretation of a claim term departs from the ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure—when the patentee acted as its own lexicographer or disavowed certain claim scope. *See Luminara Worldwide, LLC v. Liown Elecs. Co.*, 814 F.3d 1343, 1353 (Fed. Cir. 2016). “The standards for finding lexicography and disavowal are ‘*exacting*.’” *Id.* (emphasis added). “To act as a lexicographer, a patentee must ‘clearly set forth a definition of the disputed claim term’ and ‘clearly express an intent to redefine the term.’” *Id.* Disavowal (or disclaimer) requires that the patentee make it clear, either in the Specification or in the prosecution history, “that the invention does not include a particular

feature.” *Id.* “While such disavowal can occur either explicitly or implicitly, *it must be clear and unmistakable.*” *Id.* (emphasis added).

Fisher contends that the terms of the Challenged Claims should be “given their broadest reasonable interpretation in light of the [S]pecification of the ’556 [p]atent” and does not offer any express constructions for any term in the Challenged Claims. *See* Pet. 10. ResMed provides express constructions for four claim terms in its Patent Owner Response. *See* PO Resp. 19–30. Fisher responds to these constructions in its Reply. *See* Reply 2–10. We address the parties’ contentions below.

1. “prevent relative rotation;” “non-rotatable,” and “not rotatable”

Each independent claim of the ’556 patent includes a claim limitation that limits relative rotation between the recited “main body” of the “cushion module” (or just the “cushion module”) and the recited “frame module,” which we refer to herein as the “non-rotatable” claim limitations. These limitations are provided in the table below:

Independent Claim	“Non-rotatable” Limitation
1	“the frame module and the main body having shapes that prevent relative rotation when the frame module is attached to the main body”
14	“the frame module and the main body have complementary shapes that provide for non-rotatable engagement relative to one another”
22	“the main body being shaped complementary to the frame module such that the main body and the frame module are not rotatable relative to one another”
32	“wherein the frame module and the cushion module are not rotatable relative to one another when connected”
54	“the elbow module and the frame module are mechanically interlocked to form a combined elbow and frame module that

Independent Claim	“Non-rotatable” Limitation
	is releasably snap-fitted to the cushion module, in a non-rotatable manner, with a snap-fit attachment mechanism”
61	“the frame module and the main body having shapes that prevent relative rotation when the frame module is snap-fitted to the main body”

See Ex. 1101, 10:19–21, 13:4–6, 14:14–16, 16:21–22, 18:19–23, 19:23–25.

ResMed contends that the prosecution history and Specification informs the construction of the “non-rotatable” limitation for each of the independent claims. PO Resp. 19–20. ResMed offers a construction for each “non-rotatable” limitation, a construction that inserts the phrase “about all axes of rotation” into each claim limitation. That is, ResMed contends that we should construe the “non-rotatable” limitation to limit relative rotation between the frame module and main body of the cushion module (or cushion module) about all axes of rotation.

ResMed argues that its offered constructions “are consistent with the broadest reasonable interpretation of these terms as used in the claims, the specification of the ’556 patent, and the prosecution history of the ’556 patent.” PO Resp. 21. ResMed asserts that none of the “non-rotatable” limitations are “tethered to a particular axis of rotation” and that “any reasonable understanding of claimed non-rotation language applies to all axes of relative rotation between the frame module and the cushion module/main body.” *Id.* at 21–22.

ResMed further asserts that its claim interpretation is consistent with the disclosed embodiments of the ’556 patent. PO Resp. 22. ResMed explains that “the ’556 [S]pecification describes that ‘frame module 20 is structured to hold and secure the cushion module 40 in an operative position

with respect to the patient's face.” *Id.* (quoting Ex. 1101, 5:23–37) (emphasis added in PO Resp.). ResMed further explains that a person having ordinary skill in the art “would have readily understood from . . . this description of the interfacing structures and other complementary shapes of the frame module 20 and the cushion module 40 depicted in Figs. 1–4, that the frame module 20 and the cushion module 40 are non-rotatable relative to each other about all axes of rotation.” *Id.* (referencing Ex. 2005 ¶ 38); *see also* Tr. 22:26–23:2 (“MR. DENNING: . . . The frame module is structured to hold and secure the cushion module in an operative position with respect to patient's face. That hold and secure means it's not going to rotate. It's secured. It's held in position.”).

ResMed further asserts that the prosecution history “buttresse[s]” its position. PO Resp. 22. ResMed explains that the claims of the application that matured into the '556 patent were amended to add the “non-rotatable” limitations to overcome a rejection based on the Ho reference. *Id.*; *see also* Ex. 1110, 193–219 (providing an Amendment during prosecution that adds the “non-rotatable” limitations); Ex. 2007 (providing Ho). As ResMed explains, Ho permits relative rotation between a frame module and cushion module about the z-axis, that is, the axis parallel to the flow of gas into the mask. PO Resp. at 23–24. ResMed further explains that, as amended, the claims “required non-rotatable engagement about all axes of rotation,” something not present in Ho. *Id.* at 24. ResMed concludes that the subject claims were allowed over Ho because of this amendment. *Id.* at 24–25.

Fisher replies that, because the “non-rotatable” limitations are not “tethered to any axes of rotation,” the plain and ordinary meaning of the terms is that rotation is prevented about at least one axis of rotation,

specifically, the z-axis. Reply 2, 5. Fisher argues that the Specification of the '556 patent does not use the language of the “non-rotatable” limitation. *Id.* at 3. Fisher adds that the Specification “contemplates embodiments that do not prevent all relative rotation at the engagement.” *Id.* at 3 (citing Ex. 1101, 5:38–41 (“For example, the cushion module 40 may be coupled to the frame module 20 in a manner that allows the cushion module 40 to be locked in different angular positions with respect to the frame module 20, e.g., pivotally mounted.”)).

Fisher further contends that ResMed mischaracterizes the prosecution history with respect to the “non-rotatable” limitations. Reply 3. Fisher argues that any disavowal of claim scope resulting from amending the draft claims to include the “non-rotatable” limitations is ambiguous and, at most, the disavowal surrendered rotation about the z-axis only. *Id.* at 4–5.

Both parties recognize that certain portions of the main body or cushion module of the disclosed embodiments of the '556 patent move in a manner that could be characterized as rotation. *See, e.g.*, Reply 11 (“In fact, the '556 [p]atent itself does not exclude the possibility of rotation within the cushion module because it describes that the cushion module can include a soft elastomeric material and a flexible concertina section.”); Tr. 11:5–20 (“MR. SGANGA: . . . And we see in the '556 [patent] they claim in the independent claims anti[-]rotation and then in dependent claims from those very claims with the anti[-]rotation limitation, they specifically claim a concertina that allows some deflection in the main body of the cushion.”), 25:11–17 (“MR. DENNING: . . . When the claims talk about the concertina being able to fold in and out, that’s not relative movement either.”).

As we explain in greater detail below, we determine that the plain and ordinary meaning of the “non-rotatable” limitations is preventing relative rotation between the frame module and main body of the cushion module (or cushion module) about all points or axes of rotation. We further interpret the “non-rotatable” limitations to encompass those portions of the frame module and main body of the cushion module (or cushion module) that interface one another only. That is, certain portions of the frame module or main body of the cushion module (or cushion module)—portions that do not interface one another—may move in such a way as to be characterized as “rotation” and the structure still falls within the scope of the “non-rotatable” limitations. For example, a concertina section of the cushion module may move in a manner characterized as rotation, but the cushion module and frame module prevent relative rotation between these modules where the modules interface one another.

The plain reading of the claim language supports our construction. *See, e.g., Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc) (“[T]he context in which a term is used in the [claim at issue] can be highly instructive.”). As a starting point, we note that “rotation” describes a specific type of movement—movement around an axis or central point. *See, e.g., Ex. 2003, 2* (defining the verb “rotate” as “to turn about an axis or a center”). That is, the claims of the ’556 patent do not require there be no movement between the frame module and main body of the cushion module (or cushion module). Instead, the claims restrict a specific type of movement—rotation. The language of the claims tell us more. The movement that is to be prevented is the *relative* rotation between the frame

module and main body of the cushion module (or cushion module)—movement of one component relative to another.

As ResMed argues, none of the “non-rotatable” limitations expressly recites any spatial aspects of the relative rotation. See PO Resp. 21. The language of the “non-rotatable” limitation unambiguously state that relative rotation is prevented. See Ex. 1101, 10:19–21 (reciting “the frame module and the main body having shapes that prevent relative rotation”), 13:4–6 (reciting “the frame module and the main body have complementary shapes that provide for non-rotatable engagement relative to one another”), 14:14–16 (reciting “the main body being shaped complementary to the frame module such that the main body and the frame module are not rotatable relative to one another”), 16:21–22 (reciting “the frame module and the cushion module are not rotatable relative to one another”), 18:19–23 (reciting “a combined elbow and frame module that is releasably snap-fitted to the cushion module, in a non-rotatable manner”), 19:23–25 (reciting “the main body having shapes that prevent relative rotation”). That is, the plain language of the claims requires preventing any relative rotation, not just some relative rotation about certain arbitrary axes. See, e.g., Ex. 2005 ¶ 37 (“[T]he claim language here indicating that rotation is prevented generally between the frame module and the cushion module/main body, a [person having ordinary skill in the art] would have understood this language to mean that rotation about all axes of rotation (about x-axis, y-axis, and z-axis) is being prevented.”). Significantly, Fisher fails to explain adequately how the plain and ordinary meaning of preventing relative rotation means preventing some relative rotation only. Although we agree with Fisher that an interpretation where the “non-rotatable” limitations restrict relative

rotation about at least one axis is broader than an interpretation that restricts all relative rotation, such an interpretation is not necessarily the broadest *reasonable* interpretation when, as here, it does not comport with the plain and ordinary meaning of the limitation. *See, e.g., In re Smith Int'l, Inc.*, 871 F.3d 1375, 1383 (Fed. Cir. 2017) (concluding that the broadest *reasonable* interpretation differs from the broadest *possible* interpretation).

The language of other claims also informs our construction. *See Phillips*, 415 F.3d at 1314 (“Other claims of the patent in question . . . can also be valuable sources of enlightenment as to the meaning of a claim term.”). For example, independent claim 32 includes a “non-rotatable” claim limitation that recites “the frame module and the cushion module are not rotatable relative to one another.” Ex. 1101, 16:21–22. Dependent claim 41 depends indirectly from claim 32 through claim 37, with claim 37 reciting “wherein the cushion module includes a concertina section having one or more folds” and claim 41 reciting “wherein the concertina section is provided to a nasal bridge region *of the main body*.” *See id.* at 16:41–43, 57–58 (emphasis added). That is, claim 41 encompasses a structure that prevents relative rotation between the frame module and cushion module, yet the main body of the cushion module includes a concertina section, which allows movement of the main body relative to the frame module of the type that could be characterized as rotation, as the collapsing and expanding of folds cause the cushion module to articulate. *See id.* at 5:55–7:12 (describing the operation of the concertina section); *see, e.g., Tr.* 12:3–16 (MR. SGANGA: . . . “So I would not call [movement analogous to the concertina or folds in the ’556 patent] rotation as claimed, we’d call it . . . pivoting or articulation.”).

The Specification does not provide an express definition of the “non-rotatable” limitations nor does the Specification provide an expansive description of the relative movement (or lack of relative movement) between the frame module and cushion module.³ The limited disclosure in the Specification, however, is consistent with our construction. The single disclosed embodiment depicts frame module 20 with annular retaining portion 22 having interfacing structure 23. *See* Ex. 1101, Fig. 2, 5:23–30. Interfacing structure 23 interfaces with interfacing structure 48 located along the outer perimeter of main body 42 of cushion module 40. *See id.* “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 main body 42.” *Id.* at 5:30–33. We interpret this disclosure to indicate that, when interfacing structure 23 interlocks with interfacing structure 48, frame module 20 and main body 42 are locked into position relative to one another, such that the interfacing portions of frame module 20 and main body 42 do not rotate about any point or axis relative to one another. *See also id.* at 5:23–25 (“The frame module 20 is structured to hold and secure the cushion module 40 in an operative position with respect to the patient’s face.”).

Further, the Specification provides that main body 42 may include concertina section 50. Ex. 1101, 5:56–61, 6:57–59, 7:3–5. This concertina section includes folds that expand and collapse, which allows a portion of

³ This lack of expansive description in the Specification is not surprising. As the examiner recognized during the prosecution of the application that matured into the ’556 patent, the focus of the patentability of the claims shifted from “a co-molded connection to a previously unclaimed feature of the non-rotation.” Ex. 1110, 170.

main body 42 not connected to frame module 20 to articulate. *See, e.g., id.* at 6:18–26 (describing the movement of the folds), Fig. 4 (depicting a portion of main body 42 located between folds 52 of concertina section 50 and cushion 44, such that this portion of main body 42 does not interface frame module 20). As such, our construction of the “non-rotatable” limitations encompasses each depicted embodiment of the ’556 patent. *Cf. Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) (“[A]n interpretation [where ‘a preferred (and indeed only) embodiment in the specification would not fall within the scope of the patent claim’] is rarely, if ever, correct and would require highly persuasive evidentiary support.”). Accordingly, the claims must require preventing relative rotation between the frame module and main body of the cushion module (or cushion module) where these two structures interface or engage. *See* Reply 11 (“These claim limitations focus on preventing relative rotation **at the connection** between the main body/cushion module and the frame module.”).

Fisher’s reliance on the disclosure of cushion module 40 being pivotally mounted to frame module 20 is unavailing, as it does not undermine our construction. *See* Reply 3 (citing Ex. 1101, 5:38–41). The Specification states: “For example, the cushion module 40 may be coupled to the frame module 20 in a manner that allows the cushion module 40 *to be locked* in different angular positions with respect to the frame module 20, e.g., pivotally mounted.” Ex. 1101, 5:38–41 (emphasis added). That is, the cushion module is locked in position relative to the frame module, such that it may not rotate in any direction. In this embodiment, however, this locked position may be changed to a different angular position (where it is then

locked into position) by unlocking the two modules and pivoting the cushion module relative to the frame module. A claim, however, need not encompass every embodiment disclosed in the patent specification. *See Baran v. Med. Device Techs., Inc.*, 616 F.3d 1309, 1316 (Fed. Cir. 2010) (“It is not necessary that each claim read on every embodiment.”); *see also PPC Broadband, Inc. v. Corning Optical Commc’ns RF, LLC*, 815 F.3d 747, 755 (Fed. Cir. 2016) (“A construction which reads the preferred embodiment out of the scope of the claims would generally seem at odds with the intention of the patentee as expressed in the specification. This does not mean, however, that each and every claim ought to be interpreted to cover *each and every embodiment*.” (emphasis added)). Here, the embodiment Fisher identifies is an alternative (and non-depicted) embodiment to the preferred embodiment of the ’556 patent. Also, as originally drafted, the claims of the application that matured into the ’556 patent would have encompassed both of these embodiments. As discussed below, the claims were narrowed during prosecution to include an aspect of the preferred embodiment depicted in Figures 1–4.

The prosecution history is not inconsistent with our interpretation. We recognize that, to traverse a rejection over the Ho reference, which discloses rotation of a frame module relative to a cushion module about the z-axis only (the axis parallel to the flow of treatment gas into the mask), the applicants amended each independent claim to include the “non-rotatable” limitations. *See* Ex. 1110, 194–215. We do not read this amendment and the applicants’ accompanying arguments to *clearly and unambiguously* disavow relative rotation about the z-axis only. *See* Ex. 1110, 216–217. Instead, the applicants chose to narrow the scope of the claims to preclude

any relative rotation between the frame module and cushion module and, in doing so, avoided Ho.⁴ To the extent that the amendment constitutes a disclaimer of claim scope, we find the disclaimer ambiguous as to its scope.

Finally, we take this opportunity to explain that our claim interpretation is agnostic to any potential set of axes, including a set of x-, y-, and z-axes that intersect at a mask's opening for a gas conduit. *See, e.g.*, PO Resp. 33 (depicting two axes intersecting at the point where Matula's gas conduit enters the mask). The "non-rotatable" limitations recite preventing relative rotation between two structures, *not* preventing rotation about any arbitrary axis or point.

To summarize, based on the entire record, we construe the "non-rotatable" limitations to mean "preventing relative rotation between the frame module and main body of the cushion module (or cushion module) about all points or axes of rotation at those portions of the frame module and main body of the cushion module (or cushion module) that interface one another only." Accordingly, in applying our construction, we analyze the relative movement between portions of the frame module and main body of the cushion module (or cushion module) that interface or engage with one another and make findings as to whether that movement constitutes relative rotation.

⁴ As we identified, *supra*, each of the independent claims, except for claim 54, expressly limits *relative* rotation between the main body of the cushion module (or just the cushion module) and the frame module. Claim 54 recites a snap-fit connecting the cushion module and a combined elbow and frame module in a non-rotatable manner, which we interpret to limit relative rotation between the two modules at the snap fit interface.

2. *Additional claim terms*

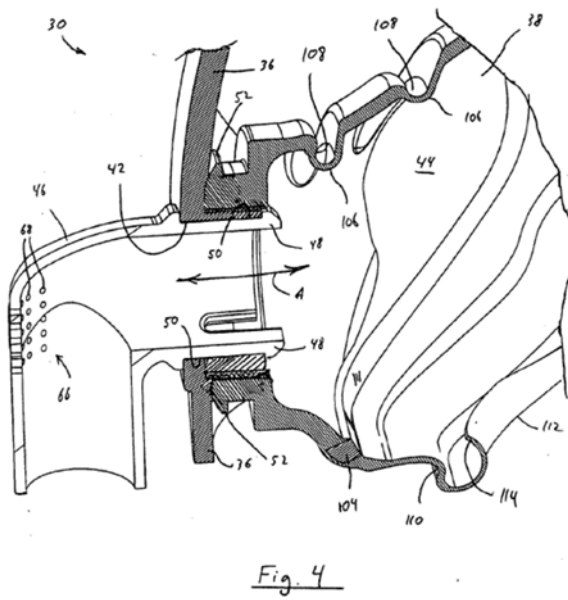
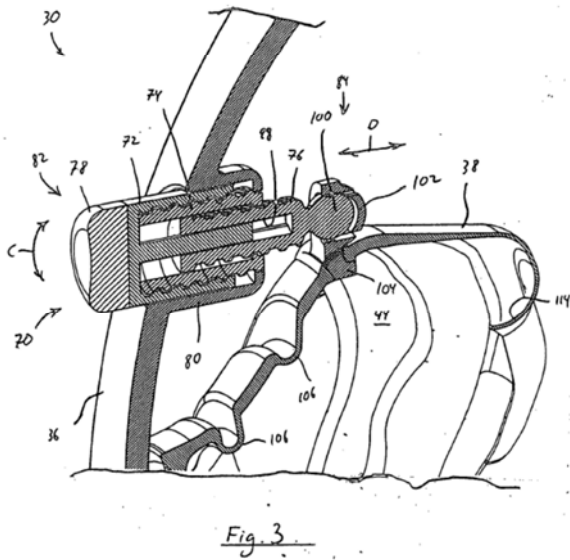
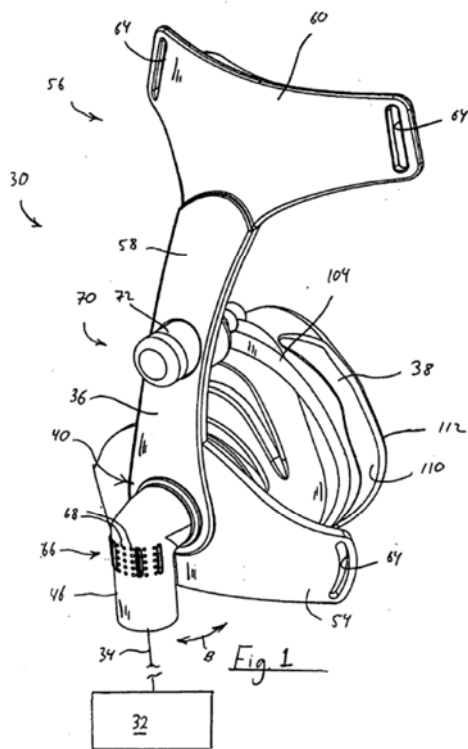
The parties also provide express constructions for the terms “snap-fit” between the “cushion module” and the “frame module”; “main body of a different, more rigid material”; and “open construction.” See PO Resp. 25–30; Reply 5–10. As will be apparent from our analysis below, we need not construe these terms to resolve the controversy between the parties. See *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (construing *explicitly* only those claim terms in controversy and only to the extent necessary to resolve the controversy).

C. *Overview of the Asserted Prior Art*

The Petition relies on seven prior art references (including Jaffre as incorporated into Matula) in its asserted grounds of unpatentability against the Challenged Claims. We provide an overview of these references below.

1. *Matula*

Matula, titled “Patient Interface with Adjustable Cushion,” published March 1, 2007. Ex. 1102, (54), (43). Matula is generally directed to “a patient interface for use in a non-invasive pressure support or ventilation system that supplies a flow of gas to the airway of a patient.” *Id.* ¶ 3. Matula’s Figures 1, 3, 4, and 5 are reproduced below.



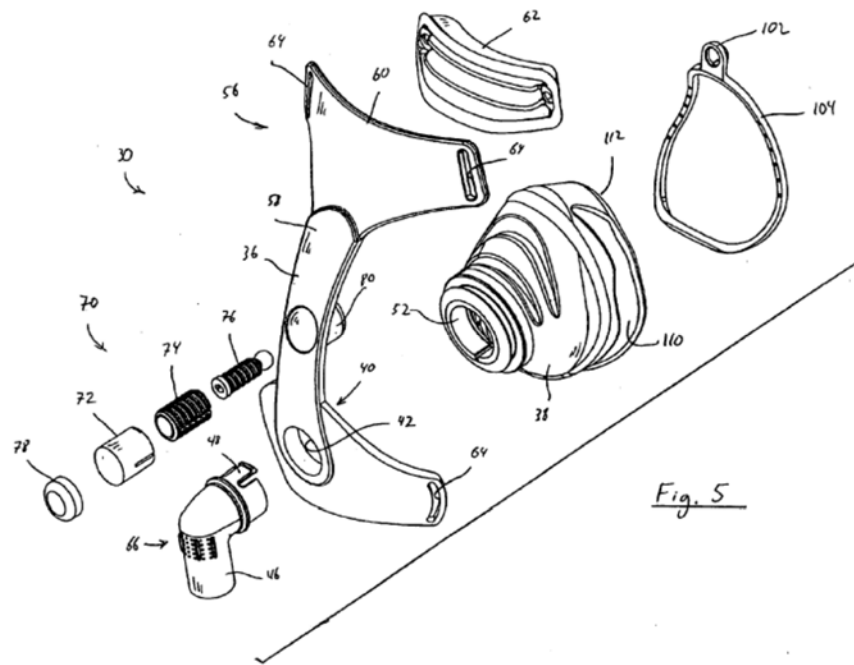


Figure 1 depicts “a front perspective view of a first embodiment of a patient interface according to the principles of” Matula’s invention. Ex. 1102 ¶ 13. Figure 3 depicts “a sectional view of the adjustment mechanism in the patient interface of [Figure] 1.” *Id.* ¶ 15. Figure 4 depicts “a sectional view of the seal member and faceplate coupling configuration in the patient interface of [Figure] 1.” *Id.* ¶ 16. Figure 5 depicts “an exploded view of the patient interface of [Figure] 1.” *Id.* ¶ 17.

Patient interface 30 includes faceplate 36 and seal member 38, with faceplate 36 being a substantially rigid member upon which seal member 38 is mounted. Ex. 1102 ¶ 51. Seal member 38 includes pleat 106 to provide the seal member with the desired degree of flexibility. *Id.* ¶ 66. Pleats 106 are provided at the upper portion of seal member 30 to allow the position of seal member 38 to be adjusted with adjustment mechanism 70. *Id.*

Faceplate 36 includes seal support portion 40, which includes orifice 42 to enable a flow of gas from patient circuit 34 to a breathing cavity. Ex.

1102 ¶ 52. Coupling member, or elbow, 46, connects the patient circuit to the interface device by way of orifice 42. *Id.* ¶ 53. “Coupling member 46 includes a pair of prongs 48 that define a channel 50 to receive the wall of the faceplate and the end of seal member 38.” *Id.* Coupling member 46 is able to rotate relative to faceplate 36. *Id.* The depicted embodiment includes exhaust assembly 66, such as that disclosed in Jaffre. *Id.* at ¶ 59.

Faceplate 36 includes lateral portions 54 and forehead support 56. Ex. 1102 ¶ 54. Forehead support 56 includes forehead pad support 60, and a forehead pad 62. *Id.* Lateral portions 54 and forehead pad support 60 include slots 64 to attach a headgear (not shown). *Id.*

Adjustment mechanism 70 is coupled to faceplate 36 and seal member 38 and moves at least an upper portion of the seal member relative to the faceplate. Ex. 1102 ¶ 63. Ball 100 of adjustment mechanism 70 interfaces with socket 102 on seal member 38, providing freedom of movement for seal member 38, allowing the upper portion of seal member 38 to move one way and the lower portion to move in the opposite way. *Id.* ¶¶ 63–64. “[S]eal member [38] is capable of being pivoted, articulated, or otherwise moved relative to the faceplate by this type of connection between the adjustment mechanism and the seal member . . . allow[ing] the seal member to move side-to-side so that the seal member is properly seated on the user.” *Id.* ¶ 64.

2. Jaffre

Jaffre, titled “Exhaust Port Assembly for a Pressure Support System,” issued February 8, 2005. Ex. 1103, (54), (45). Jaffre is generally directed to “to an exhaust port assembly with enhanced noise reduction and gas diffusion capabilities, while also minimizing size” such as those used in

mask systems used in non-invasive positive pressure support therapy. *Id.* at 1:13–17, 21–30. Jaffre’s Figures 7, 8, and 9 are reproduced below:

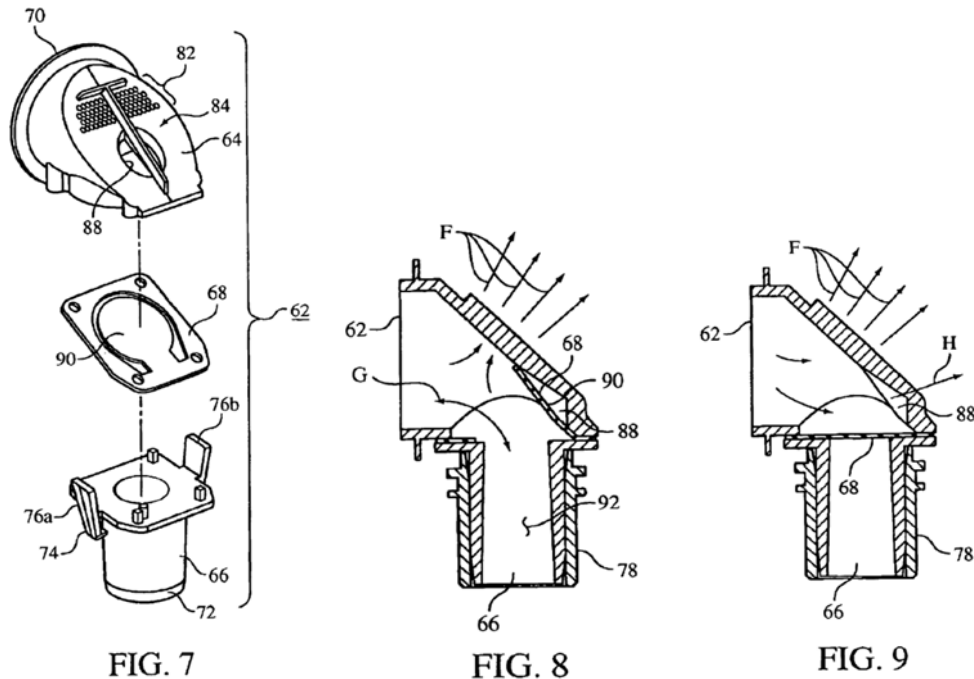


Figure 7 depicts an exploded view of [an] exhaust port assembly” of an embodiment of Jaffe’s invention. Ex. 1103, 6:45–46. Figure 8 depicts “a cross-sectional view of the exhaust port assembly showing a first position of the valve member” and Figure 9 depicts “a cross-sectional view of the exhaust port assembly showing a second position of the valve member.” *Id.* at 6:47–50. Exhaust port assembly 62 of Figures 7, 8, and 9 provides a patient access to ambient air when the patient wears a mask system employing the disclosed valve system. *Id.* at 10:11.

Exhaust port assembly 62 includes auxiliary opening 88 having a diameter greater than the diameter of holes 82, and valve member 68. Ex. 1103, 10:12–14. During normal use of a mask system employing exhaust assembly 62 (that is, when the pressure of the gas within interior 92 of the exhaust port assembly is greater than ambient atmospheric pressure),

cantilever member 90 associated with valve member 68 blocks auxiliary opening 88—it is deflected up against opening 88. *Id.* at 10:14–20. In this position, cantilever member 90 enables gas to flow between the patient and gas system. *Id.* at 10:20–22. If the pressure of the gas in interior 92 drops below the ambient air pressure, such as from a failure of the gas system, cantilever member 90 unblocks auxiliary opening 88 and blocks gas from flowing towards the gas system. *Id.* at 10:23–34.

3. *Ging*

Ging, titled “Respiratory Mask Assembly with Magnetic Coupling to Headgear Assembly,” published July 21, 2005. Ex. 1104, (54), (43). *Ging* is generally directed to “a nasal mask for use in the delivery of Non-invasive Positive Pressure Ventilation . . . and for nasal continuous positive airway pressure . . . therapy of sleep disordered breathing . . . conditions such as obstructive sleep apnea (OSA).” *Id.* ¶ 2. *Ging*’s Figure 1 is reproduced below.

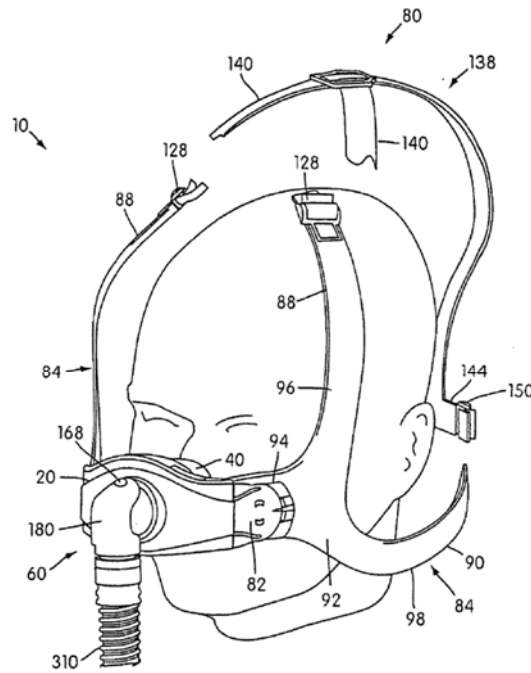


FIG. 1

Figure 1 depicts a perspective view of Ging's nasal mask assembly. Ex. 1103 ¶ 30. Nasal mask assembly 10 includes frame 20 and cushion 40, attached to frame 20, including by co-molding. *Id.* ¶ 110. Swivel elbow assembly 60 and a headgear assembly 80 are also attached to frame 20. *Id.* Frame 20 includes central bore 24 (not identified in Figure 1) to connect with swivel elbow assembly 60. *Id.* ¶ 112.

Ging's Figure 5c and Figures 27a, 27b, and 27c are reproduced below.

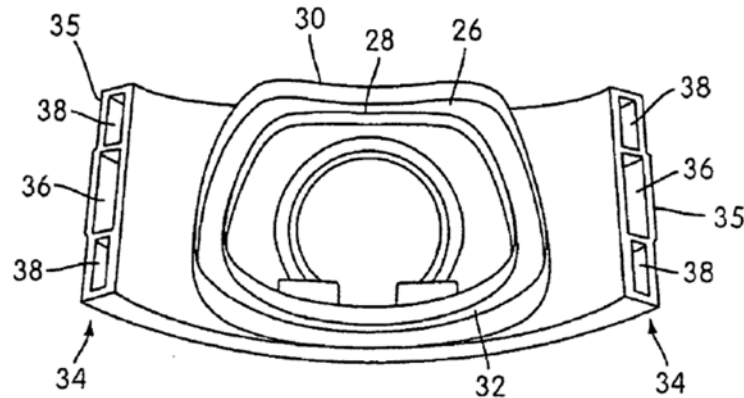


FIG. 5c

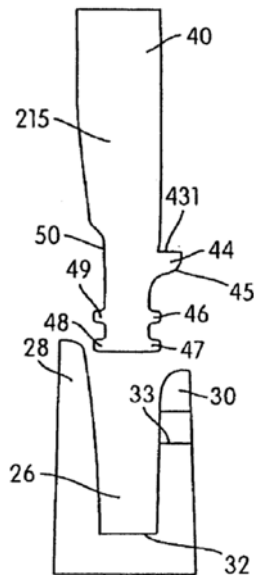


FIG. 27a

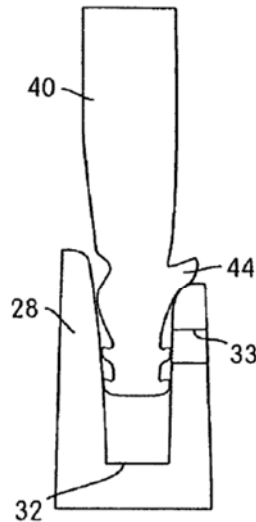


FIG. 27b

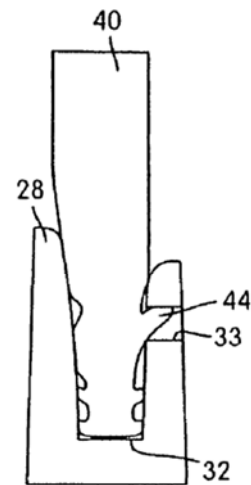


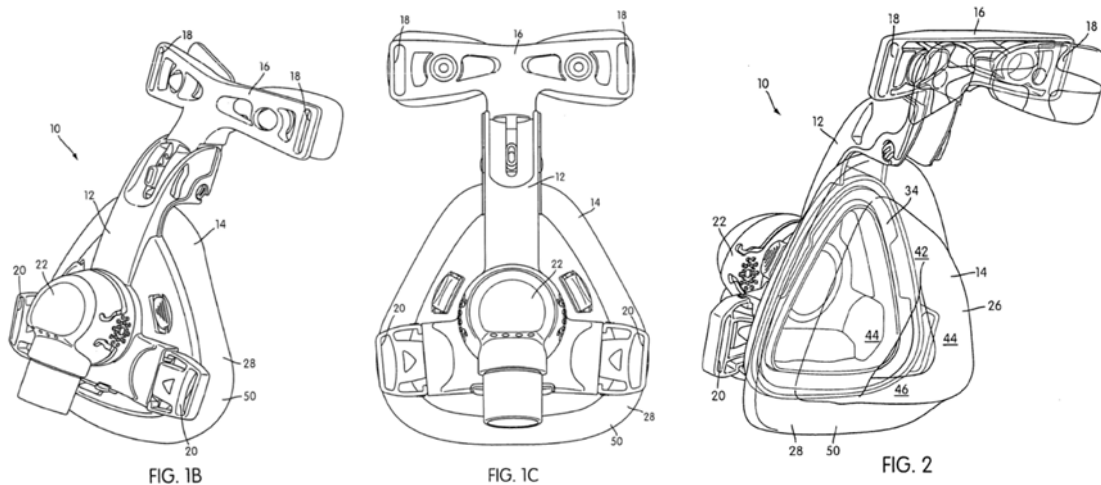
FIG. 27c

Figure 5c depicts a rear perspective view of frame 20. Ex. 1104 ¶ 38. Figures 27a, 27b, and 27c depict partial section views of frame 20 and cushion 40. *Id.* ¶ 88. As seen in Figure 5c, frame 30 connects with cushion 40 through channel 26, including inner wall 28 and outer wall 30. *Id.* ¶ 114. To connect cushion 40 with frame 20, leading edge 45 of retention lip 44 engages outer wall 30 and deforms. *Id.* ¶ 198. Cushion 40 is then further inserted into channel 26 until it contacts channel floor 32, with sealing lips

46–49 in full contact with inner and outer walls 28 and 30 retention lip 44 entered into undercut 33. *Id.*

4. *Lithgow*

Lithgow, titled “Cushion for a Respiratory Mask Assembly,” published June 24, 2004. Ex. 1105, (54), (43). Lithgow is generally directed to “a cushion for a respiratory mask assembly used for providing ventilator support, e.g., for treatment of Sleep Disordered Breathing . . . with Non-invasive Positive Pressure Ventilation.” *Id.* ¶ 2. Lithgow’s Figures 1B, 1C, and 2 are reproduced below:



Figures 1B, 1C, and 2 depict a front perspective view, a front view, and a rear perspective view of Lithow’s mask, respectively. Ex. 1105 ¶ 40–42. Respiratory mask assembly 10 includes frame 12, cushion 14, which may be removably connected to frame 12, and forehead support 16, movably mounted to frame 12. *Id.* ¶ 111. Intermediate portion 28 of cushion 14 includes gusset 50, which allows portion 26 to move relative to portion 28. *Id.* ¶ 124.

5. Gunaratnam

Gunaratnam, titled “Mask Cushion and Frame Assembly,” issued September 28, 2004. Ex. 1106, (54), (45). Gunaratnam is generally directed to connecting a mask used in the treatment of sleep disordered breathing with a nasal or full-face mask cushion. *Id.* at 1:21–25. Gunaratnam’s Figures 5a and 5c are reproduced below:

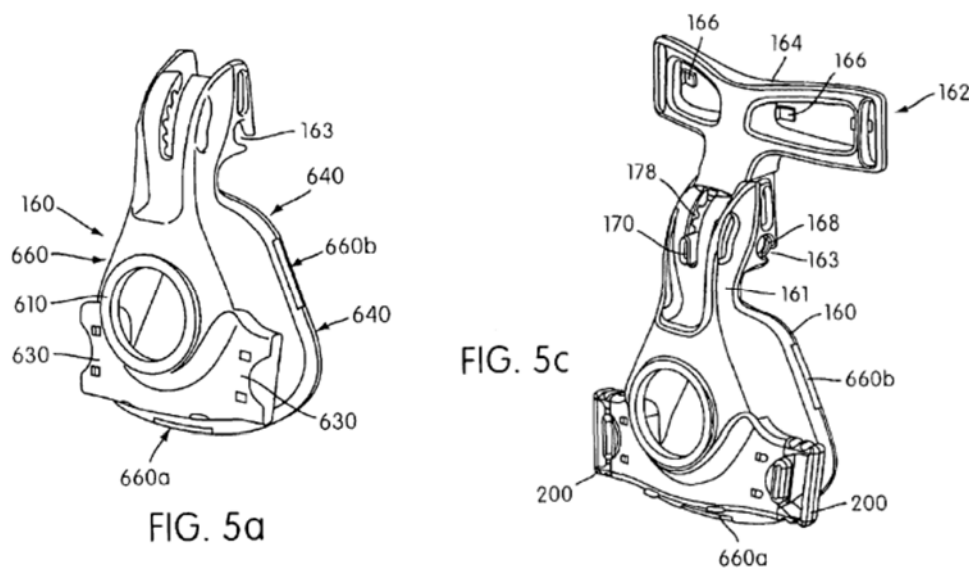


Figure 5a depicts “a front perspective view of a nasal mask frame,” and Figure 5c depicts “a front perspective view of a nasal mask frame and adjustable forehead support.” Ex. 1106, 3:6–12. Frame 160 is generally triangular and fits over a wearer’s nose and forms a breathing cavity. *Id.* at 4:26–30. Frame 160 includes gas inlet aperture 610, which connects to a conduit that delivers gas to the wearer. *Id.* at 4:21–25. The frame includes a front portion with connection points 630 for headgear.

The embodiment of Figure 5c includes adjustable forehead support 162 coupled to frame 160. Ex. 1106, 4:46–57. Figure 5c also depicts connector 200 for connecting the mask to a user’s headgear. *Id.* at 4:32–34.

Gunaratnam discloses that its frame may be made of polycarbonate material. *See, e.g.*, Ex. 1106, 4:22–24 (“The frame (160) is constructed as a substantially rigid shell of polycarbonate or similar transparent plastics material.”). Gunaratnam further discloses that “frame (160) is adapted to cover both the mouth and nose region of the patient’s face, and includes . . . aperture (930) for receiving an air vent (940).” *Id.* at 6:25–28.

6. Namey

Namey, titled “Two-Shot Injection Molded Nasal/Oral Mask,” published February 21, 2002. Ex. 1107, (54), (43). Namey is generally directed to “a mask in which both the mask body and at least a portion of a mask seal are formed and joined using a two-shot injection molding process.” *Id.* ¶ 2. Namey’s Figures 1 and 2 are reproduced below:

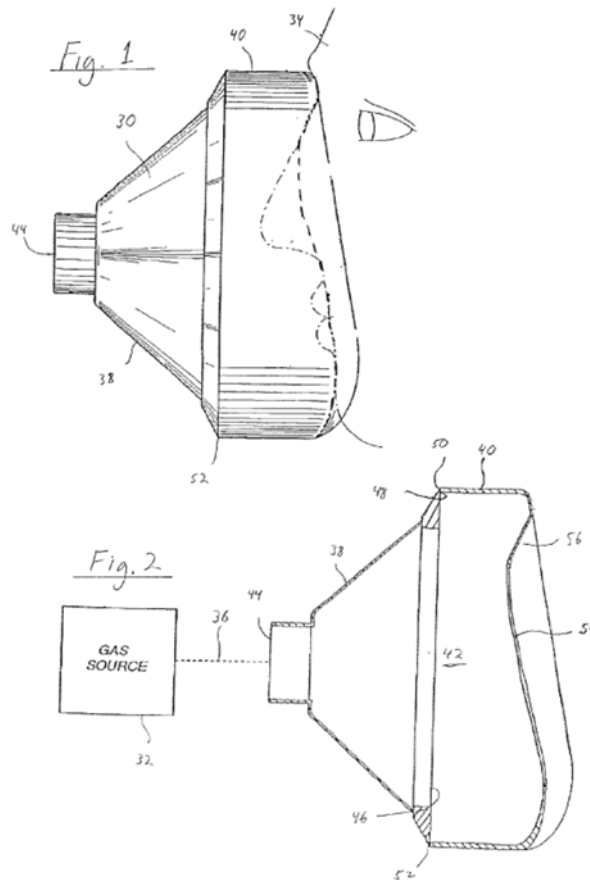


Figure 1 depicts “a side view of a mask manufactured in accordance with the two-shot injection molding technique of” Namey and Figure 2 depicts “a cross-sectional view of the mask of [Figure] 1.” Ex. 1107 ¶¶ 11–12. Mask 30, including main body 38 and mask seal member 40, is used to provide breathing gas to a patient. *Id.* ¶¶ 19–20. “Mask body 38 supports seal member 40 and is typically formed from a material that is more rigid than the seal member, such as a rigid or semi-rigid plastic.” *Id.* ¶ 21.

7. *Melidis*

Melidis, titled “Sealing Lip Device for a Respiratory Mask, Respiratory Mask and Method and a Mould for Producing the Same,” issued November 9, 2010. Ex. 1108, (54), (45). Melidis is generally directed to “breathing masks [that] can be fitted to the nose region in sealing relationship and [that] have a sealing device extending in the region of the upper lip of the mask wearer between the mouth and the nose.” *Id.* at 1:13–16. Melidis’s Figure 2 is reproduced below:

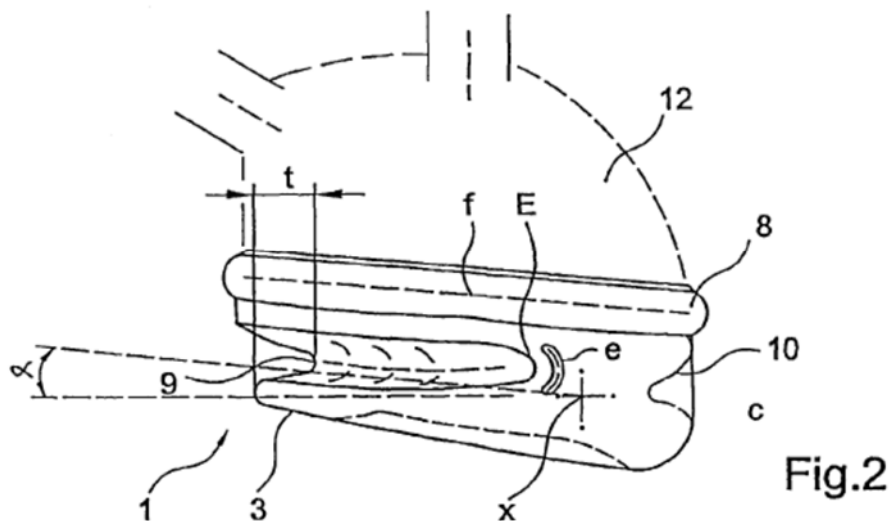


Figure 2 depicts “a simplified side view of a further breathing mask with a fold indentation and a frame portion.” Ex. 1108, 5:56–58. Mask

cushion or pad 1 is made from an elastomeric material, such as silicone rubber, and includes sealing lip 3 and folding bellows structure 9. *Id.* at 6:52–55, 8:1–3. Bellows structure 9 provides a flexible suspension of sealing lip 3. *Id.* at 8:1–3. Bellows structure 9 has the greatest indentation depth towards the bridge of the nose, with the indentation depth decreasing towards front end “E” of bellows structure 9. *Id.* at 8:18–21.

D. Grounds of Unpatentability

In *inter partes* reviews, a petitioner bears the burden of proving unpatentability of the challenged claims, and the burden of persuasion never shifts to the patent owner. *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail in this proceeding, Fisher must support its challenge by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). Accordingly, all of our findings and conclusions are based on a preponderance of the evidence.

We instituted trial on the ten grounds of unpatentability for the Challenged Claims presented in the Petition, each of which is based on 35 U.S.C. § 103(a).

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

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

The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) when available, secondary

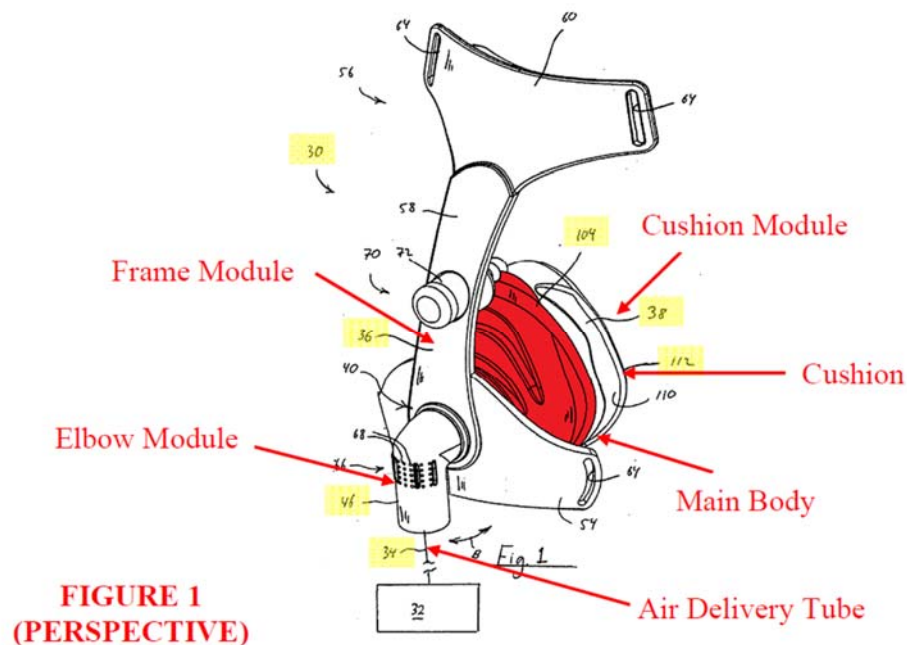
considerations, such as commercial success, long felt but unsolved needs, and failure of others. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). We address these underlying factual issues with respect to each asserted ground, below.⁵

1. Independent claim 1 and dependent claims 2–13

Fisher asserts that independent claim 1 is obvious over Matula alone. Pet. 9. Claim 1 recites, in relevant part, “[a] mask system for delivery of a supply of gas at positive pressure to a patient for medical treatment, the mask system comprising: a frame module.” Ex. 1101, 9:65–10:1 (the “frame module” limitation). Fisher contends that Matula’s faceplate 36 is the recited frame module. Pet. 15, 26; *see also* Ex. 1109 ¶¶ 41, 43 (identifying Matula’s faceplate 36 as corresponding to the recited frame module).

We find, based on the complete trial record, that the Petition makes the requisite showing that Matula discloses the recited frame module limitation, as we find that Matula’s faceplate 36 satisfies the frame module limitation of claim 1. We reproduce Fisher’s annotated version of Matula’s Figure 1, below.

⁵ We address the level of ordinary skill in the art in Section II.A., *supra*. ResMed does not argue or provide any evidence of secondary considerations.

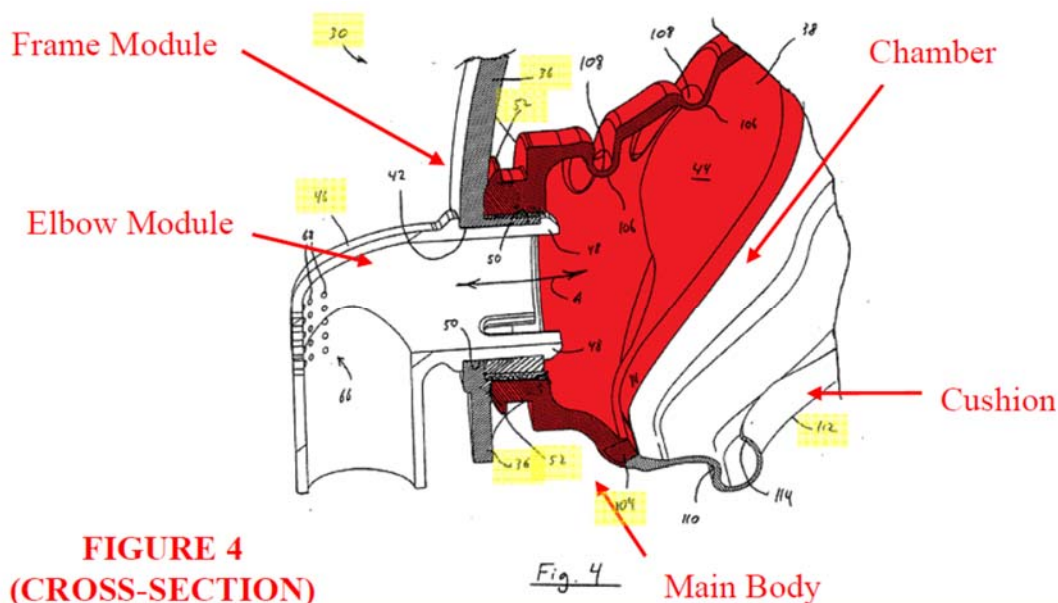


Fisher's annotated Figure 1 identifies a number of mask system components recited in claim 1, including the frame module. *See* Pet. 16; Ex. 1109 ¶ 46. Figure 1 depicts patient interface 30, which is “a front perspective view of a first embodiment of a patient interface according to the principles of [Matula's] invention shown schematically connected to a pressure support system.” Ex. 1102 ¶ 13. Matula discloses that “[p]atient interface 30 includes a faceplate 36 and a seal member 38, which is also referred to as a cushion or seal, coupled to the faceplate. . . . [F]aceplate 36 is a substantially rigid member that serves as a stable platform on which the seal member is mounted.” *Id.* ¶ 51.

ResMed does not dispute Fisher's contention that Matula's faceplate 36 satisfies the frame module limitation of claim 1.

Claim 1 further recites, in relevant part, “a cushion module provided to the frame module and adapted to form a seal with the patient's face.” Ex. 1101, 10:2–3 (the “cushion module” limitation). Claim 1 also recites “the cushion module includes a main body and a cushion, the main body at least

partly defining a breathing chamber.” *Id.* at 10:15–17 (the “breathing chamber” limitation). Fisher contends that Matula’s seal member 38, including rigid annular ring 104 and ring 52, is the recited cushion module. *See* Pet. 15, 16, 27. Fisher explains that “[s]eal member 38 is connected to the faceplate 36 at two molded ring portions 52, 104.” *Id.* at 15. Fisher further contends that seal member 38 is the cushion module, with ring 52 and ring 104 being part of the main body and contacting portion 112 as part of the cushion. Pet. 16, 27, 29. Fisher annotates Matula’s Figure 4 to indicate the asserted main body, cushion, and breathing chamber of the cushion module. *Id.* at 16. We reproduce annotated Figure 4 below.



Annotated Figure 4 provides a cross-section of a part of Matula’s mask, with the frame module, elbow module, breathing chamber, and the cushion and main body of the cushion module identified. Pet. 16; Ex. 1109 ¶ 46. As seen in the image reproduced above, the main body is shaded in red and includes the portion of seal member 38 between ring 52 and ring 104. *See* Pet. 16; Ex. 1109 ¶ 46; *see also* Pet. 31 (indicating the main body

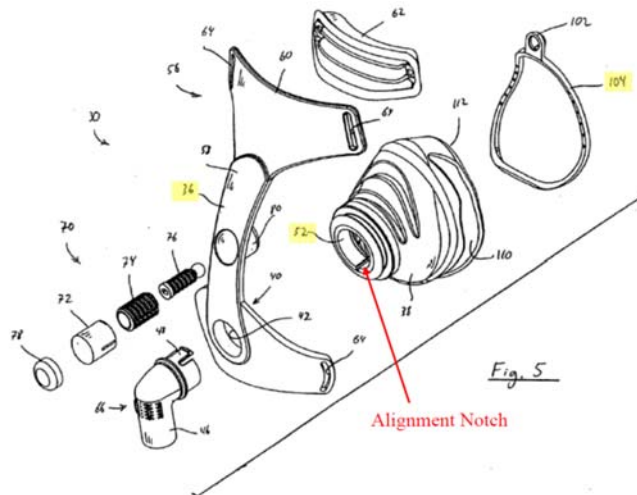
of the cushion module as a portion of seal member 38 located between ring 52 and ring 104 in connection with the analysis of a different limitation of claim 1).

We find, on the complete trial record, that the Petition makes the requisite showing that Matula discloses the recited “cushion module” and “breathing chamber” limitations. We find that Matula’s seal member 38, including rigid annular ring 104 and ring 52, corresponds to the recited cushion module. *See* Ex. 1102 ¶¶ 51, 52, 65, 66, 69. We find that, as defined in the Petition, the portion of Matula’s seal member 38 corresponding to the main body of the cushion module (the red-shaded portion of Matula’s seal member 38 and rigid annular ring 104 and ring 52) at least partly define a breathing chamber, as these identified components form a portion of chamber 44. *See* Pet. 16; *see also* Ex. 1102 ¶ 52 (“An orifice 42 is provided in seal support portion 40 of faceplate 36 to enable a flow of gas from patient circuit 34 to be communicated to a chamber 44 defined by the seal member of the patient interface.”); Ex. 1109 ¶¶ 43–46 (describing how Matula’s seal member 38 includes a main body and how the main body forms a portion of chamber 44).

ResMed does not dispute Fisher’s contention that Matula’s seal member 38, including rigid annular ring 104 and ring 52, satisfies the cushion module and breathing chamber limitations of claim 1.

Claim 1 also recites, in relevant part, “the frame module and the main body having shapes that prevent relative rotation when the frame module is attached to the main body.” Ex. 1101, 10:18–20 (the “non-rotatable” limitation of claim 1). Fisher asserts that two different structures of Matula’s mask satisfy this claim limitation. First, Fisher contends that

Matula's Figure 5 illustrates an alignment notch in ring 52 (part of the alleged main body of the cushion module), which corresponds to a shape that prevents rotation of the main body of the cushion module relative to the frame module (faceplate 36). Pet. 21 (referencing Ex. 1109 ¶ 55). Mr. Lordo testifies that "[a] person of ordinary skill in the art would have understood that this alignment notch in [ring] 52 of the cushion module is for aligning and rotationally fixing the cushion module with [faceplate] 36." Ex. 1109 ¶ 55. Fisher's annotated version of Matula's Figure 5 is reproduced below.



Fisher's annotated version of Matula's Figure 5 indicates the location of the alleged alignment notch in ring 52. Pet. 21; Ex. 1109 ¶ 55.

Fisher further contends that, in conjunction with the alignment notch of ring 52, ball 100 of attachment mechanism 70 (allegedly part of the frame module) engages socket 102 attached to annular ring 104 (allegedly part of the main body of the cushion module) to prevent relative rotation of the frame module and cushion module. Pet. 21–22 (referencing Ex. 1102 ¶ 63). Fisher explains that Matula discloses that ring 104 may be molded to seal member 38. *Id.* (referencing Ex. 1102 ¶ 65); *see also* Ex. 1102 ¶ 65 (“The

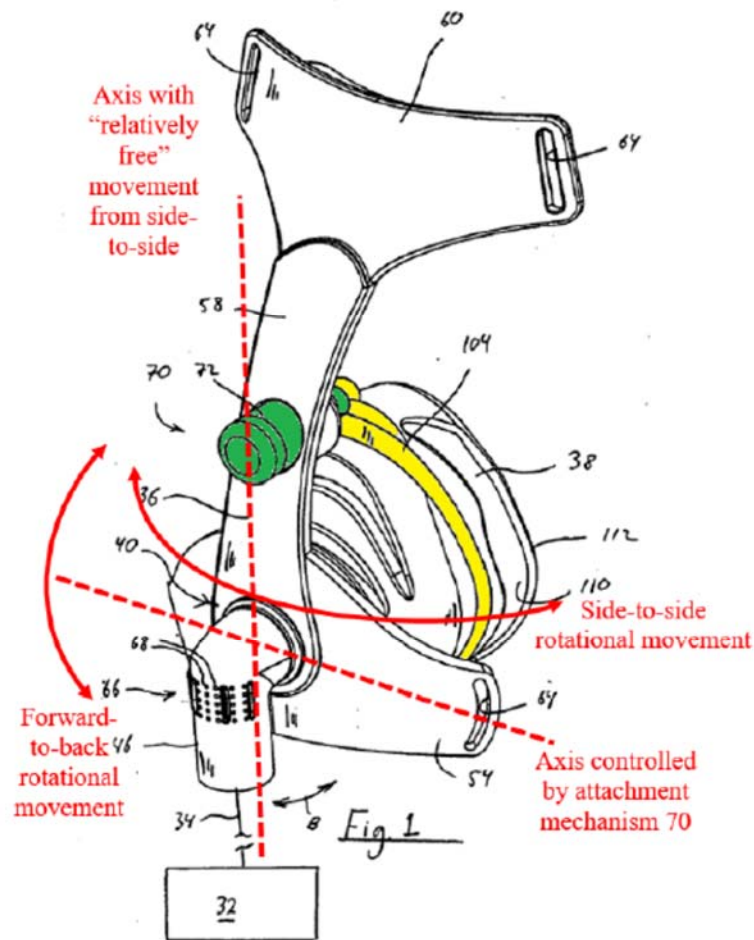
present invention contemplates attaching ring 104 to the seal member using any conventional technique, such as adhering, mechanically coupling, or two-shot molding the ring to the seal member.”). Fisher contends that “[t]he alignment notch in the main body of Matula provides shapes that prevent relative rotation. Also, Fisher asserts that a person of skill would have recognized that the ball-and-socket interface, as a second connection point, also *provides shapes that prevent relative rotation.*” Pet. 22 (referencing Ex. 1109 ¶ 54) (emphasis added).

Fisher’s declarant, Mr. Lordo, states that “Matula discloses a mask in which the cushion module 38 is attached to the frame module 36 at main body portions 52 and 104.” Ex. 1109 ¶ 54. Mr. Lordo explains that:

Because the main body portions 52, 104 of the cushion module and the frame module 36 are attached at two locations (at the opening and the ball-and socket), the ball-and-socket connection 100/102 includes interfacing shapes that prevent relative rotation when the frame module 36 is attached to main body portions 52, 104.

Id.

ResMed contends that it is undisputed that Matula discloses relative rotation between faceplate 36 and seal member 38 about the x-axis and y-axis. PO Resp. 32. To illustrate its position, ResMed annotates Matula’s Figure 1, which we reproduce below.



ResMed’s annotated version of Matula’s Figure 1 superimposes two axes onto Figure 1 intersecting at orifice 42 in seal support member 40 (to which coupling member (elbow) 46 is connected) and further illustrates forward-and-back and side-to-side rotational movement between faceplate 36 and seal member 38. See PO Resp. 33 (citing Ex. 2005 ¶ 54; Ex. 1102 ¶¶ 60, 64, 75).⁶ ResMed explains that Matula discloses that the seal member

⁶ The parties consider the depicted horizontal axis (“Axis controlled by attachment mechanism 70”) as the “x-axis” and the vertical axis as the “y-axis.” See Tr. 10:1–7. The parties also consider an axis perpendicular to both the x- and y-axes through orifice 42 as the “z-axis.” See *id.*; Ex. 1118, 79:20–80:9; Ex. 1119, 45.

38 is free to move side-to-side, that is, rotate about the y-axis relative to faceplate 36, and that attachment mechanism 70 allows for back and forth rotation of seal member 38 relative to faceplate 36 about the x-axis. *Id.* at 33–34. ResMed argues that Fisher’s declarant, Mr. Lordo, agrees with this interpretation of Matula. *Id.* at 32 (citing Ex. 2006, 96:1–5, 96:18–22⁷).

ResMed further contends that a person having ordinary skill in the art would have understood that Matula’s faceplate 36 would rotate about the z-axis relative to seal member 38. PO Resp. 35. ResMed argues that Matula discloses that seal member 38 is “relatively free floating” at ring 52, which would inform a person having ordinary skill in the art that ring 52 does not have an alignment notch that restricts z-axis rotation. *Id.* at 36 (citing Ex. 1102 ¶ 75; Ex. 2005 ¶ 58). ResMed also argues that the engagement at ball-and-socket 100/102 would also allow rotation about the z-axis, as that is the very nature of a ball-and-socket joint. *Id.* (referencing Ex. 2005 ¶ 59; Ex. 2006, 99:9–23).

ResMed further argues that the combined engagement of ball-and-socket joint 100/102 and the engagement faceplate 36 and seal member 38 at ring 52 still allows for rotation about the z-axis. PO Resp. 36–38; *see also* Ex. 2005 ¶ 60 (describing how the connection of faceplate 36 and seal member 38 at the two points still allows for some rotation about the z-axis).

Fisher replies that Matula prevents relative rotation between faceplate 36 and seal member 38 about the x- and y-axes. Reply 11. Fisher explains

⁷ The Patent Owner Response cites to page 95 of Ex. 2006, rather than page 96. *See* PO Resp. 32. We believe that this citation is a typographical error, as the testimony on page 96 of Mr. Lordo’s deposition transcript better aligns with ResMed’s contention. *Compare* Ex. 2006, 95:1–5, 95:18–22, *with id.* at 96:1–5, 96:18–22.

that the type of movement identified by ResMed is analogous to the concertina movement of main body 42 of the cushion module in the '556 patent's preferred embodiment. *Id.*

We find that the main body structure of Matula's cushion module (as alleged by Fisher) rotates relative to the alleged frame module at a point where the two structures interface, or engage. Specifically, we find that, when Matula's faceplate 36 is engaged with ring 52 and ring 104, ball 100 and socket 102 rotate relative to one another. That is, ball 100 and socket 102 do not prevent relative rotation between these two structures when Matula's mask is fully assembled. We base our finding on Matula's description of how adjustment mechanism 70 (which includes ball 100 and socket 102) operates. Ex. 1102 ¶¶ 60–64.

To be clear, our finding is not based on ball 100 being contained in socket 102 without faceplate 36 connected to ring 52. *Cf.* PO Resp. 36 (arguing that “ball-and-socket permits omnidirectional rotation of the adjustment mechanism 70 when engaged with the ring 104” without considering the engagement of faceplate 36 at ring 52). Also, our finding is not based on (1) the movement of the portion of Matula's cushion positioned between ring 52 and ring 104 as rotational movement, as this section of the alleged main body of Matula's cushion module does not interface with faceplate 36; or (2) the movement back-and-forth or side-to-side movement of ring 104 (except socket 102) relative to faceplate 36 (other than ball 100), as ring 104 does not interface with faceplate 36 except at ball 100/socket 102. *Cf.* PO Resp. 32–35 (describing certain movement of Matula's cushion relative to x- and y-axes).

We reproduce Matula's Figure 3, below:

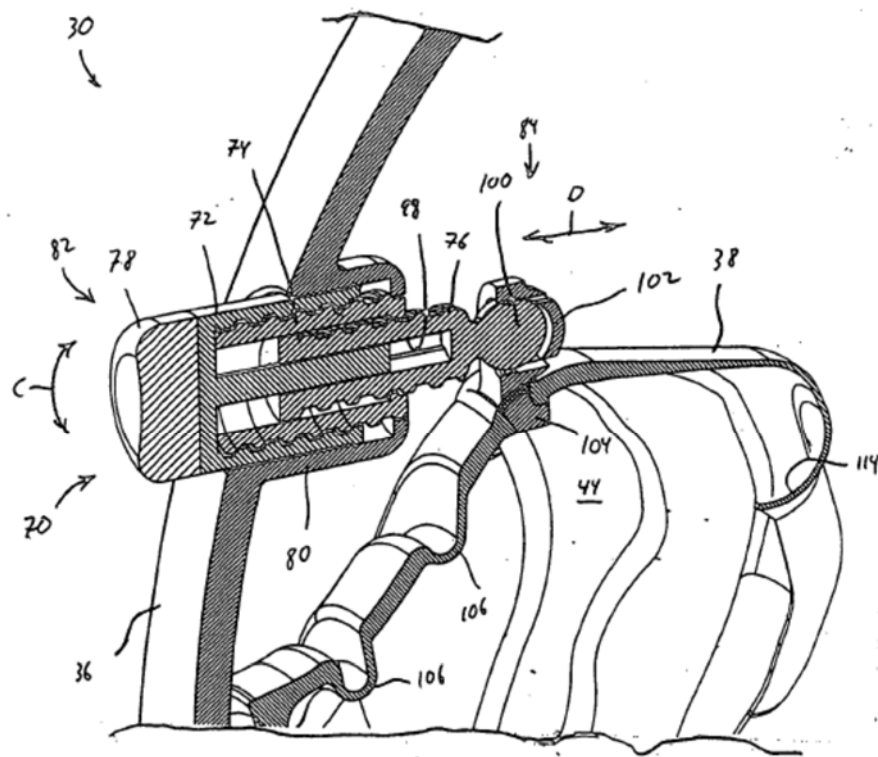


Fig. 3

Matula's Figure 3 depicts "a sectional view of the adjustment mechanism in the patient interface of [Matula's Figure] 1." Ex. 1102 ¶ 15. Matula discloses that "[p]atient interface 30 includes an adjustment mechanism 70 that allows the position of seal member 38 relative to faceplate 36 to be adjusted from a first position to a second position . . . [when] the user actuates the adjustment mechanism by rotating a knob portion 72." *Id.* ¶ 60. Matula continues that "this [rotating of knob 72] causes an upper portion of seal member 38 to be pushed away from or pulled toward faceplate 36, as indicated by arrow D [in Matula's Figure 3]." *Id.* "Adjustment mechanism 70 is coupled to seal member 38 such that the adjustment mechanism moves at least an upper portion of the seal member relative to the faceplate." *Id.* ¶ 63. "[A] ball-and-socket connection is used

to couple the adjustment mechanism to the seal member. More specifically, a ball 100 is provided on the end of stem 76 and a socket 102 is provided on seal member 38.” *Id.*

Significantly, Matula discloses that:

The use of this type of connection provides a high degree of freedom of movement for the seal member so that the whole seal member does not simply mover linearly with respect to the faceplate when the adjustment mechanism is actuated. Instead, this configuration allows the upper is allowed to move on one direction, e.g., to be pushed away from the faceplate, while the lower portion at the opposite end of the seal member is moves in an opposite direction, e.g., is pushed toward the faceplate. *In essence, the seal member is capable of being pivoted, articulated, or otherwise moved relative to the faceplate by this type of connection between the adjustment mechanism and the seal member.*

Id. ¶ 64 (emphasis added). For Matula’s seal member to pivot or articulate, socket 102 *must* move relative to ball 100 and the movement is a *rotational* movement. This function of a ball-and-socket joint is why Matula selected “this type of connection.” *See id.*; *see also* Ex. 2005 ¶¶ 54–56, 59 (describing the movement of Matula’s cushion module and adjustment mechanism 70). Specifically, when seal member 38 pivots or articulates, the point on seal member 38 where socket 102 connects to ring 104 will move in an arcuate path. Stem 76, on which ball 100 is connected, moves in a linear path. *See* Ex. 1102 ¶ 62. In order to transfer the linear movement of stem 76 and ball 100 to arcuate movement of ring 104, socket 102 rotates about ball 100. *See id.* ¶ 64.

Indeed, Matula explains that, in an alternative embodiment, the adjustment mechanism can have a rigid connection (that is, not a ball-and-socket connection) with the seal member, which would result in the seal

member moving linearly with respect to the faceplate.⁸ See Ex. 1102 ¶ 64. This description of the alternative embodiment further supports our finding that, with respect to the embodiment with ball 100 and socket 102, socket 102 rotates relative to ball 100. If this rotation did not take place, there would be no need for an alternative, rigid connection that would result in linear movement of the seal member. That is, if socket 102 did not rotate relative to ball 100, it would act identical to a rigid connection and result in linear movement of seal member 38, not articulating or pivoting (i.e., rotational) movement.

Accordingly, because Matula's ball 100 of its alleged frame module and socket 102 of its alleged main body of its cushion module interface or engage and because socket 102 rotates relative to ball 100 when knob 72 is actuated, we find that the embodiment of Matula that Petitioner relies on fails to satisfy the "non-rotatable" limitation of claim 1, as we have construed this term.⁹

For the reasons discussed above, we determine, based on the complete trial record, that Fisher has failed to demonstrate, by a preponderance of the evidence, that claim 1 is unpatentable under 35 U.S.C. § 103(a) over Matula.

Further, in asserting that dependent claims 2–13, which depend, directly or indirectly from claim 1, are unpatentable, Fisher relies on its

⁸ We recognize that this alternative embodiment described in Matula would not include the relative rotation that we find in Matula's ball-and-socket embodiment. The Petition, however, relies solely on Matula's ball-and-socket embodiment and not an alternative embodiment. See Pet. 22, 30.

⁹ Because we find that Matula's socket 102 rotates relative to ball 100 when knob 72 is actuated, we need not consider if any other movement asserted by ResMed takes Matula's structure outside the scope of the "non-rotatable" limitation of claim 1.

position that Matula discloses the “non-rotatable” limitation of claim 1. See Pet. 32–35 (addressing claims 2 and 4), 41 (addressing claims 3, 5, and 7), 94–97 (addressing claim 6), 98 (addressing claim 8), 105–109 (addressing claims 9–13). Accordingly, for the reasons discussed above in connection with our analysis of claim 1, we determine, based on the complete trial record, that Fisher has failed to demonstrate, by a preponderance of the evidence, that dependent claims 2–13 are unpatentable.

2. Claims 14–66

a. Independent claim 14 and dependent claims 15–21

Independent claim 14 recites, in relevant part, “the frame module and the main body have complementary shapes that provide for non-rotatable engagement relative to one another.” Ex. 1101, 13:4–6 (the “non-rotatable” claim limitation of claim 14). Fisher relies on Matula for disclosing the subject matter of the “non-rotatable” limitation of claim 14 similar to claim 1. See Pet. 68 (cross referencing Petition § VII(B)(2)(b), which is the analysis of the “non-rotatable” limitation of claim 1).

For the reasons discussed above, in connection with our analysis of claim 1, we determine, based on the complete trial record, that Fisher has failed to demonstrate, by a preponderance of the evidence, that independent claim 14 is unpatentable.

Further, in asserting that dependent claims 15–21, which depend, directly or indirectly from claim 14, are unpatentable, Fisher relies on its position that Matula discloses the “non-rotatable” limitation of claim 14. See Pet. 41 (addressing claims 15, 16, and 19), 98 (addressing claims 17 and 18), 109–110 (addressing claims 20 and 21). Accordingly, for the reasons discussed above in connection with our analysis of claims 1 and 14, we

determine, based on the complete trial record, that Fisher has failed to demonstrate, by a preponderance of the evidence, that dependent claims 15–21 are unpatentable.

b. Independent claim 22 and dependent claims 23–31

Independent claim 22 recites, in relevant part, “the main body being shaped complementary to the frame module such that the main body and the frame module are not rotatable relative to one another.” Ex. 1101, 14:14–16 (the “non-rotatable” claim limitation of claim 22). Fisher relies on Matula for disclosing the subject matter of the “non-rotatable” limitation of claim 22 similar to claim 1. *See* Pet. 72 (cross referencing Petition § VII(B)(2)(b), which is the analysis of the “non-rotatable” limitation of claim 1).

For the reasons discussed above, in connection with our analysis of claim 1, we determine, based on the complete trial record, that Fisher has failed to demonstrate, by a preponderance of the evidence, that independent claim 22 is unpatentable.

Further, in asserting that dependent claims 23–31, which depend, directly or indirectly from claim 22, are unpatentable, Fisher relies on its position that Matula discloses the “non-rotatable” limitation of claim 22. *See* Pet. 41 (addressing claims 23–26 and 29), 98 (addressing claims 27 and 28), 109, 111 (addressing claims 30 and 31). Accordingly, for the reasons discussed above in connection with our analysis of claims 1 and 22, we determine, based on the complete trial record, that Fisher has failed to demonstrate, by a preponderance of the evidence, that dependent claims 23–31 are unpatentable.

c. Independent claim 32 and dependent claims 33–53

Independent claim 32 recites, in relevant part, “the frame module and the cushion module are not rotatable relative to one another.” Ex. 1101, 16:21–22 (the “non-rotatable” claim limitation of claim 32). Fisher relies on Matula for disclosing the subject matter of the “non-rotatable” limitation of claim 32 similar to claim 1. See Pet. 78 (cross referencing Petition § VII(B)(2)(b), which is the analysis of the “non-rotatable” limitation of claim 1).

For the reasons discussed above, in connection with our analysis of claim 1, we determine, based on the complete trial record, that Fisher has failed to demonstrate, by a preponderance of the evidence, that independent claim 32 is unpatentable.

Further, in asserting that dependent claims 33–53, which depend, directly or indirectly from claim 32, are unpatentable, Fisher relies on its position that Matula discloses the “non-rotatable” limitation of claim 32. See Pet. 41 (addressing claims 33, 36, 43, and 45–52), 98 (addressing claims 37, 38, 40, and 41), 113–118 (addressing claims 34 and 35), 120–122 (addressing claims 39 and 42), 122 (addressing claim 53), 122–123 (addressing claim 44). Accordingly, for the reasons discussed above in connection with our analysis of claims 1 and 32, we determine, based on the complete trial record, that Fisher has failed to demonstrate, by a preponderance of the evidence, that dependent claims 33–53 are unpatentable.

d. Independent claim 54 and dependent claims 55–60

Independent claim 54 recites, in relevant part, “the elbow module and the frame module are mechanically interlocked to form a combined elbow

and frame module that is releasably snap-fitted to the cushion module, in a non-rotatable manner.” Ex. 1101, 18:19–23 (the “non-rotatable” claim limitation of claim 54). Fisher relies on Matula for disclosing the subject matter of the “non-rotatable” limitation of claim 54 similar to claim 1. See Pet. 86 (cross referencing Petition § VII(B)(2)(b), which is the analysis of the “non-rotatable” limitation of claim 1). Further, Fisher expressly identifies Matula’s ball 100 and socket 102 as providing the snap fit interface. See Pet. 51; Ex. 1109 ¶ 97.

Fisher also asserts that Matula’s prongs 48 of coupling member 46 (the alleged elbow module) serve to mechanically interlock the coupling member to faceplate 36 and snap-fit this interlocked structure to seal member 38. *Id.* at 52 (“Together, the elbow module 46 and the frame module 36 are mechanically interlocked to form a combined elbow and frame module that is releasably snap-fitted to the cushion module by the pair of prongs 48.”). We find, however, that the Petition fails to explain adequately how prongs 48 snap-fit *with seal member 38*, even indirectly, in a non-rotatable manner. See PO Resp. 62–62 (describing that prongs 48 snap-fits to faceplate 36 and not seal member 38); Ex. 2005 ¶ 22 (describing how coupling member 46 engages faceplate 36); Reply 22 (suggesting an indirect snap fit between the modules). Claim 54 requires the “combined elbow and frame module [to be] releasably *snap-fitted* to the cushion module, *in a non-rotatable manner*.” Ex. 1101, 18:19–23 (emphasis added). Although we agree with Fisher that prongs 48 would deflect then recover to connect coupling member 46 and faceplate 36 (that is, provide a snap-fit connection), Fisher fails to explain how this connection would snap-fit (even indirectly) these joined components to seal member 38, and do so in a non-rotatable

manner. *See* Pet. 52; Reply 22; Ex. 1109 ¶ 98. Instead, both the Petition and Mr. Lordo merely provide a conclusory assertion that the subject matter of the non-rotatable limitation of claim 54 is satisfied. *See id.* Such a conclusory assertion is insufficient to carry Fisher’s burden.

For these additional reasons discussed above (beyond those discussed in connection with our analysis of claim 1), we determine, based on the complete trial record, that Fisher has failed to demonstrate, by a preponderance of the evidence, that independent claim 54 is unpatentable.

Further, in asserting that dependent claims 55–60, which depend, directly or indirectly from claim 54, are unpatentable, Fisher relies on its position that Matula discloses the “non-rotatable” limitation of claim 54. *See* Pet. 41 (addressing claims 55, 57, and 58), 98 (addressing claims 56 and 60), 112 (addressing claim 59). Accordingly, for the reasons discussed above in connection with our analysis of claims 1 and 54, we determine, based on the complete trial record, that Fisher has failed to demonstrate, by a preponderance of the evidence, that dependent claims 55–60 are unpatentable.

e. Independent claim 61 and dependent claims 62–66

Independent claim 61 recites, in relevant part, “the main body having shapes that prevent relative rotation.” Ex. 1101, 19:23–25 (the “non-rotatable” claim limitation of claim 61). Fisher relies on Matula for disclosing the subject matter of the “non-rotatable” limitation of claim 61 similar to claim 1. *See* Pet. 78 (cross referencing Petition § VII(B)(2)(b), which is the analysis of the “non-rotatable” limitation of claim 1).

For the reasons discussed above, in connection with our analysis of claim 1, we determine, based on the complete trial record, that Fisher has

failed to demonstrate, by a preponderance of the evidence, that independent claim 61 is unpatentable.

Further, in asserting that dependent claims 62–66, which depend, directly or indirectly from claim 61, are unpatentable, Fisher relies on its position that Matula discloses the “non-rotatable” limitation of claim 61. *See* Pet. 41 (addressing claims 62–64 and 66), 112 (addressing claim 65), 113–118. Accordingly, for the reasons discussed above in connection with our analysis of claims 1 and 61, we determine, based on the complete trial record, that Fisher has failed to demonstrate, by a preponderance of the evidence, that dependent claims 62–66 are unpatentable.

III. CONCLUSION

For the foregoing reasons, we conclude that Fisher has not established, by a preponderance of the evidence, that claims 1–66 of the ’556 patent are unpatentable.

IV. ORDER

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

ORDERED claims 1, 2, and 4 have *not* been shown to be unpatentable under 35 U.S.C. § 103(a) over Matula;

FURTHER ORDERED that claims 3, 5, 7, 14–16, 19, 22–26, 29, 32, 33, 36, 43, 45–52, 54, 55, 57, 58, 61–64, and 66 have *not* been shown to be unpatentable under 35 U.S.C. § 103(a) over Matula in view of Ging;

FURTHER ORDERED that claim 6 has *not* been shown to be unpatentable under 35 U.S.C. § 103(a) over Matula and Melidis;

FURTHER ORDERED that claims 8, 17, 18, 27, 28, 37, 38, 40, 41, 56, and 60 have *not* been shown to be unpatentable under 35 U.S.C. § 103(a) over Matula in view of Ging and Melidis;

FURTHER ORDERED that claims 9–13 have *not* been shown to be unpatentable under 35 U.S.C. § 103(a) over Matula in view of Namey and Gunaratnam;

FURTHER ORDERED that claims 20, 21, 30, 31, 59, and 65 have *not* been shown to be unpatentable under 35 U.S.C. § 103(a) over Matula in view of Ging, Namey, and Gunaratnam;

FURTHER ORDERED that claims 34 and 35 have *not* been shown to be unpatentable under 35 U.S.C. § 103(a) over Matula in view of Ging and Gunaratnam;

FURTHER ORDERED that claims 39 and 42 have *not* been shown to be unpatentable under 35 U.S.C. § 103(a) over Matula in view of Ging, Melidis, and Lithgow;

FURTHER ORDERED that claim 53 has *not* been shown to be unpatentable under 35 U.S.C. § 103(a) over Matula in view of Ging, Gunaratnam, and Melidis; and

FURTHER ORDERED that claim 44 has *not* been shown to be unpatentable under 35 U.S.C. § 103(a) over Matula in view of Ging and Namey; and

FURTHER ORDERED because this is a Final Written Decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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