

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of

**CERTAIN SLEEP-DISORDERED
BREATHING TREATMENT SYSTEMS
AND COMPONENTS THEREOF**

Inv. No. 337-TA-890

ORDER NO. 8: CONSTRUING TERMS OF THE ASSERTED PATENTS

(January 16, 2014)

The claim terms construed in this Order are done so for the purposes of this Investigation. Hereafter, discovery and briefing in this Investigation shall be governed by the construction of the claim terms in this Order. Those terms not in dispute need not be construed. *See Vanderlande Indus. Nederland BV v. Int'l Trade Comm'n*, 366 F.3d 1311, 1323 (Fed. Cir. 2004) (noting that the administrative law judge need only construe disputed claim terms) Any claim terms not discussed herein shall be deemed undisputed and shall be interpreted by the undersigned in accordance with "their ordinary meaning as viewed by one of ordinary skill in the art." *Apex Inc. v. Raritan Computer, Inc.*, 325 F.3d 1364, 1371 (Fed. Cir. 2003), cert. denied, 540 U.S. 1073 (2003).

Table of Abbreviations

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|------|--|
| CMIB | Complainant's Initial Markman Brief |
| CMRB | Complainant's Reply Markman Brief |
| CMSB | Complainant's Supplemental Markman Brief |
| RMIB | Respondents' Initial Markman Brief |
| RMRB | Respondents' Reply Markman Brief |
| RMSB | Respondents' Supplemental Markman Brief |
| SMIB | Staff's Initial Markman Brief |
| SMSB | Staff's Supplemental Markman Brief |
| Tr. | Transcript of the Markman Hearing |

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I. INTRODUCTION

By publication of notice in the Federal Register, this Investigation was instituted by the Commission on August 23, 2013, to determine whether certain sleep-disordered breathing treatment systems and components thereof infringe one or more of claims 32-37, 53, 79, 80, and 88 of U.S. Patent No. 7,997,267; claims 1-7 of U.S. Patent No. 7,614,398;¹ claim 1 of U.S. Patent No. 7,938,116; claims 30, 37, and 38 of U.S. Patent No. 7,341,060; claims 1, 3, 5, 11, 28, 30, 31, and 56 of U.S. Patent No. 8,312,883; claims 1, 3, 6, 7, 9, 29, 32, 35, 40, 42, 45, 50, 51, 56, 59, 89, 92, 94, and 96 of U.S. Patent No. 7,178,527; claims 19-24, 26, 29-36, and 39-41 of U.S. Patent No. 7,950,392; and claims 13, 15, 16, 26-28, 51, 52, and 55 of U.S. Patent No. 7,926,487; and whether an industry in the United States exists as required by subsection (a)(2) of section 337. 78 Fed. Reg. 52564 (August 23, 2013.) The Complainants are ResMed Corporation of San Diego, California; ResMed Incorporated of San Diego, California; and ResMed Limited of New South Wales, Australia (collectively “ResMed”). *Id.* The Respondents are BMC Medical Co., Ltd. of Beijing, China; 3B Medical, Inc. of Lake Wales, Florida; and 3B Products, L.L.C., of Lake Wales, Florida (collectively “Respondents”). *Id.* The Commission Investigative Staff (“Staff”) is also a party. *Id.*

On December 11-12, 2013, a *Markman* hearing and tutorial was held in this Investigation, where the parties presented technology tutorials, (Tr. at 9:24-67:16), and participated in oral argument on several disputed claim terms. (Tr. at 74:1-322:12). Prior to the *Markman* hearing, the parties submitted several briefs setting forth their claim construction positions. ResMed and Respondents submitted their initial *Markman* briefs on November 13, 2013. The private parties attached declarations from their designated experts, Neil Sheehan for ResMed (CMIB Exh. 4) and

¹ Pursuant to Order No. 7, an initial determination issued on January 9, 2013, U.S. Patent No. 7,614,398 (“the ’398 Patent”) has been terminated from this Investigation and replaced with U.S. Patent No. RE44,453 (“the ’453 Patent”).

Steven S. Bordewick for Respondents (RMIB Exh. 1). The Staff submitted its initial *Markman* brief on November 20, 2013. ResMed and Respondents each filed reply *Markman* briefs on November 26, 2013. After the *Markman* hearing, ResMed, Respondents, and the Staff each submitted supplemental *Markman* briefs on December 30, 2013. The parties filed an Amended Final Joint Claim Construction Chart on January 14, 2014.²

II. RELEVANT LAW

“An infringement analysis entails two steps. The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device accused of infringing.” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (*en banc*) (internal citations omitted), *aff’d*, 517 U.S. 370 (1996). Claim construction is a “matter of law exclusively for the court.” *Id.* at 970-71. “The construction of claims is simply a way of elaborating the normally terse claim language in order to understand and explain, but not to change, the scope of the claims.” *Embrex, Inc. v. Serv. Eng’g Corp.*, 216 F.3d 1343, 1347 (Fed. Cir. 2000).

Claim construction focuses on the intrinsic evidence, which consists of the claims themselves, the specification, and the prosecution history. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (*en banc*); *see also Markman*, 52 F.3d at 979. As the Federal Circuit in *Phillips* explained, courts must analyze each of these components to determine the “ordinary and customary meaning of a claim term” as understood by a person of ordinary skill in art at the time of the invention. 415 F.3d at 1313. “Such intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language.” *Bell Atl. Network Servs., Inc. v. Covad Commc’ns Grp., Inc.*, 262 F.3d 1258, 1267 (Fed. Cir. 2001).

² This order only addresses the terms that the parties identified as disputed in the Final Claim Construction Chart. Terms where the parties have agreed to a construction or no longer dispute are not addressed in this order.

“It is a ‘bedrock principle’ of patent law that ‘the claims of a patent define the invention to which the patentee is entitled the right to exclude.’” *Phillips*, 415 F.3d at 1312 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). “Quite apart from the written description and the prosecution history, the claims themselves provide substantial guidance as to the meaning of particular claims terms.” *Id.* at 1314; *see also Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001) (“In construing claims, the analytical focus must begin and remain centered on the language of the claims themselves, for it is that language that the patentee chose to use to ‘particularly point [] out and distinctly claim [] the subject matter which the patentee regards as his invention.’”). The context in which a term is used in an asserted claim can be “‘highly instructive.” *Phillips*, 415 F.3d at 1314. Additionally, other claims in the same patent, asserted or unasserted, may also provide guidance as to the meaning of a claim term. *Id.*

The specification “is always highly relevant to the claim construction analysis. Usually it is dispositive; it is the single best guide to the meaning of a disputed term.” *Id.* at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). “[T]he specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor’s lexicography governs.” *Id.* at 1316. “In other cases, the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor.” *Id.* As a general rule, however, the particular examples or embodiments discussed in the specification are not to be read into the claims as limitations. *Id.* at 1323. In the end, “[t]he construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be ... the correct construction.” *Id.* at 1316 (quoting *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998)).

In addition to the claims and the specification, the prosecution history should be examined, if in evidence. *Id.* at 1317; *see also Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 913 (Fed. Cir. 2004). The prosecution history can “often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Phillips*, 415 F.3d at 1317; *see also Chimie v. PPG Indus. Inc.*, 402 F.3d 1371, 1384 (Fed. Cir. 2005) (“The purpose of consulting the prosecution history in construing a claim is to exclude any interpretation that was disclaimed during prosecution.”).

When the intrinsic evidence does not establish the meaning of a claim, then extrinsic evidence (*i.e.*, all evidence external to the patent and the prosecution history, including dictionaries, inventor testimony, expert testimony, and learned treatises) may be considered. *Phillips*, 415 F.3d at 1317. Extrinsic evidence is generally viewed as less reliable than the patent itself and its prosecution history in determining how to define claim terms. *Id.* at 1317. “The court may receive extrinsic evidence to educate itself about the invention and the relevant technology, but the court may not use extrinsic evidence to arrive at a claim construction that is clearly at odds with the construction mandated by the intrinsic evidence.” *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 977 (Fed. Cir. 1999).

If, after a review of the intrinsic and extrinsic evidence, a claim term remains ambiguous, the claim should be construed so as to maintain its validity. *Phillips*, 415 F.3d at 1327. Claims, however, cannot be judicially rewritten in order to fulfill the axiom of preserving their validity. *See Rhine v. Casio, Inc.*, 183 F.3d 1342, 1345 (Fed. Cir. 1999). Thus, “if the only claim construction that is consistent with the claim’s language and the written description renders the claim invalid, then the axiom does not apply and the claim is simply invalid.” *Id.*

III. LEVEL OF ORDINARY SKILL IN THE ART

The private parties have each proposed one standard for a person of ordinary skill in the art for all of the asserted patents. ResMed proposes that a person of ordinary skill in the art “would be a person with a mechanical engineering degree, industrial design degree, or similar technical degree, or equivalent work experience, and 5-10 years of working in the area of medical product design including CPAP masks and devices.” (CMIB at Ex. 4, Sheehan Decl. at ¶ 15).

Respondents propose that a person of ordinary skill in the art would have had “either (1) a bachelor’s degree in mechanical engineering, biomedical engineering, or the like and at least five (5) years of relevant product design experience; or (2) an advanced degree in mechanical engineering, biomedical engineering, or the like and at least two (2) years of relevant product design experience.” (RMIB at 7). The Staff found no material difference between the parties’ proposed levels of ordinary skill and identified a “person with a mechanical engineering degree and five years of CPAP mask and device design experience” as someone who would satisfy both parties’ descriptions. (SMIB at 6).

The parties’ proposed educational qualifications are similar, but ResMed’s proposal requires more specific work experience including product design of CPAP masks and devices. Based on my reading of the asserted patents, the technology tutorial presented by the parties, and the Markman hearing and briefs, I find that ResMed’s proposal is too restrictive, and relevant product design experience would be sufficient for one of ordinary skill in the art. Accordingly, I find that a person of ordinary skill in the art for the asserted patents in this Investigation would have a degree in mechanical engineering, biomedical engineering, or a similar technical field, and at least five (5) years of relevant product design experience or equivalent advanced education.

IV. THE '527 AND '392 PATENTS

A. Overview

U.S. Patent No. 7,178,527 (“the '527 Patent”) and U.S. Patent No. 7,950,392 (“the '392 Patent”) relate to nasal masks used to treat obstructive sleep apnea. The patents describe structures that help to create a more comfortable mask and effective seal on a patient’s face. ('527 Patent at 2:34-3:44; '392 Patent at 2:9-3:14). The features of these inventions purportedly reduce mask-to-face pressure for greater patient comfort and a reduction in the likelihood of skin irritation. *Id.*

The '527 Patent is entitled “Nasal Mask and Mask Cushion Therefor,” and it issued on February 20, 2007 with 96 claims, naming inventors Philip Rodney Kwok and Robert Edward Styles. Exemplary independent claims 3 and 9 are set forth below:

3. A nasal mask cushion assembly to sealingly connect a nasal mask to a wearer’s face, the cushion assembly comprising:
 - a generally triangularly shaped frame of resilient material, the frame including a first side adapted to contact a mask body of the nasal mask, a second side opposite the first side, **an aperture extending from the first side to the second side**, a rim on the second side extending around at least a portion of the perimeter of the aperture, and a **notch** in the rim in a region adapted to receive the bridge of the wearer's nose; and
 - a generally triangularly shaped membrane of resilient material, the membrane including an aperture adapted to receive the wearer's nose, an edge defining the perimeter of the aperture, a **notch** in a region adapted to receive the bridge of the wearer's nose, a first surface including a seal forming portion disposed around the perimeter of the aperture adapted to deform and form a seal over a portion of the wearer’s face in a region between the base of the nose and the upper lip and around the sides and over the bridge of the wearer's nose when the mask is in use, a second surface opposite the first surface that surrounds and is spaced a first distance from the rim of the frame in at least the region adapted to receive the bridge of the wearer’s nose when the mask is in use, wherein the membrane is more flexible than the frame.
- (’527 Patent at 5:60-6:19).
9. A nasal mask cushion assembly to sealingly connect a nasal mask to a wearer’s face, the cushion assembly comprising:

a generally triangularly shaped frame of resilient material, the frame including a first side adapted to contact a mask body of the nasal mask, a second side opposite the first side, **an aperture extending from the first side to the second side**, an inwardly oriented rim extending along at least a portion of a perimeter of the frame and a **notch** in a region adapted to receive the bridge of the wearer's nose; and

a generally triangularly shaped membrane of resilient material, the membrane including an aperture adapted to receive the wearer's nose, an edge defining the perimeter of the aperture, a **notch** in a region adapted to receive the bridge of the wearer's nose, a first surface including a seal forming portion disposed around the perimeter of the aperture adapted to deform and form a seal over a portion of the wearer's face in a region between the base of the nose and the upper lip and around the sides and over the bridge of the wearer's nose when the mask is in use, a second surface opposite the first surface that is spaced a first distance from the rim in at least the region adapted to receive the bridge of the wearer's nose when the mask is in use, wherein

the membrane is more flexible than the frame;

the aperture of the membrane is smaller than the aperture of the frame; and

the edge of the membrane is spaced a second distance from the rim, the second distance being variable.

('527 Patent at 6:61-7:23).

The '392 Patent is entitled "Cushion and Mask Therefor," and it issued on May 31, 2011, naming inventors Philip Rodney Kwok and Robert Edward Styles. The '392 Patent has 45 claims, and claims 19-21 are set forth below:

19. A mask cushion for sealingly connecting a mask to a patient's face during the administration of positive airway pressure, the cushion including:

a frame of resilient material, said frame having a rim for substantially surrounding a portion of the patient's face;

a membrane of resilient material and fixed to and extending away from the frame so as to have an outer surface spaced from the rim, in at least one region of the frame, to define a gas-filled gap between the membrane and the frame before the cushion is in use, said membrane being longer than and/or fully covering or overlying the rim as seen in cross section,

a seal forming portion of said outer surface forming a face contacting seal, said seal forming portion being provided only on said membrane, said seal forming portion presenting a convex sealing surface to the patient's face; the membrane being pre-shaped to 1) generally match the contours of the patient's face; and 2) have the same general shape as said rim, wherein said seal forming portion is resiliently deformable into the gap towards the rim in use of the cushion, and wherein the face contacting seal portion is structured

such that it is not required to turn in on itself to conform with the wearer's face, in use.

20. A mask cushion as claimed in claim 19, wherein said frame defines a nose receiving cavity, and the membrane includes a contoured **notch** to accommodate the bridge of the patient's nose.

21. A mask cushion as claimed in claim 20, wherein said rim has a preformed and contoured notch, co-located relative to the **notch** of the membrane, also to accommodate the bridge of the patient's nose.

('392 Patent at 7:16-47).

B. Disputed Claim Terms

1. "notch"

The parties dispute the proper construction of the term "notch," which appears in claims 1, 3, 7 and 9 of the '527 Patent and claims 20 and 21 of the '392 Patent. Respondents have proposed "a narrow cutout region" while ResMed and the Staff have proposed "indentation, depression, recess or cutout region:"

| ResMed | Respondents | Staff |
|--|------------------------|--|
| indentation, depression, recess or cutout region | a narrow cutout region | indentation, depression, recess or cutout region |

Respondents argue that the alleged purpose of the "notch" in the inventions of the '527 and '392 Patents was to overcome the problems of prior art rolling-edge seals, and they thus propose a construction limiting this term to the cutout region described in the specification of the patents. (RMRB at 2-5). Respondents also rely heavily on the declaration of their expert, Steven S. Bordewick to explain that a notch must be formed by removing material in these devices. (RMIB at 9-11; RMRB at 5-6). Respondents cite several dictionary definitions that define a "notch" as a cut-out region and argue that relying on extrinsic evidence is appropriate here because the intrinsic record does not conclusively establish the meaning of the term. (RMIB at 10-11).

ResMed contends that “notch” is an ordinary English word that does not require construction and, in its reply brief, ResMed adopted the Staff’s broad construction that included an indentation, depression, recess, or a cutout region.³ (RMIB at 9-10; RMRB at 2-3). ResMed cites one of the dictionaries relied upon by Respondents to show that the word “notch” can mean an “indentation” as well as a “cutout.” (RMIB at 10). ResMed asserts that the patent does not use the term “cut out” and does not describe the invention’s “notch” as a removal of material; ResMed argues that Respondents rely entirely on an expert declaration to import these limitations. (RMRB at 3). The Staff agrees with ResMed that “notch” has its ordinary meaning in the context of these patents, which broadly includes an indentation, depression, recess or cutout region. (SMIB at 6-7). The Staff further argues that there is nothing in the specification or the prosecution history that requires the claimed “notch” to be narrow. (SMIB at 8).

I agree with ResMed and the Staff that the intrinsic evidence does not support a construction of “notch” as a cut out region, and there is no support for requiring the “notch” to be narrow. As used in the context of these patents, the term “notch” has an ordinary meaning that is readily apparent, and “claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words.” *Phillips*, 415 F.3d at 1316.

Accordingly, I find that the term “notch” shall be construed to have its plain and ordinary meaning, which is an “indentation, depression, recess or cutout region.”

2. “an aperture extending from the first side to the second side”

The parties dispute the proper construction of the term “an aperture extending from the first side to the second side,” which appears in claims 3 and 9 of the ’527. Respondents have

³ The “cutout region” was adopted from Respondents’ proposed construction.

proposed “an opening having substantially the same shape on both sides” while ResMed and the Staff have proposed “an opening extending from the first side to the second side:”

| ResMed | Respondents | Staff |
|---|--|---|
| an opening extending from the first side to the second side | an opening having substantially the same shape on both sides | an opening extending from the first side to the second side |

The parties agree that an “aperture” is an “opening.” (SMIB at 8). Respondents contend that an opening “extending” from one side to another must have “substantially the same shape on both sides.” (RMRB at 10; Tr. at 263-264). Respondents argue that the objective of the ’527 patent was to provide an alternative to the rolling-edge seal of prior art nasal masks by using a cushion with apertures that are generally triangular to match the facial contours around the nose of the patient, as shown in Figures 4, 5, and 6 of the patent specification. (RMIB at 12-13; RMRB at 9). ResMed and the Staff disagree with Respondents’ argument and find no requirement for symmetry between the first and second sides of the aperture. (CMRB at 4-5; SMIB at 9; Tr. at 267-279, 272). ResMed concedes that the figures in the ’527 Patent show the same general shape on either side of the aperture, but there are no explicit requirements in the patent regarding regarding the shape of both sides of the aperture. (CMIB at 12; CMRB at 4-5). ResMed points out that the claim explicitly defines the frame as “generally triangular” but is silent regarding the shape of the aperture. (CMIB at 11; CMRB at 5).

I agree with ResMed and the Staff, and I find that the ’527 Patent does not require that the aperture have the same shape on both sides. The Federal Circuit considered a similar dispute in *Acumed LLC v. Stryker Corp.*, where the parties disputed the construction of the term “transverse holes” in a patent related to orthopedic surgical nails. 483 F.3d 800, 807-809 (Fed.Cir.2007). In *Acumed*, the defendant argued for a narrow construction of the term based on the fact that all the

embodiments disclosed in the patent depicted holes perpendicular to the nail shaft. *Id.* at 807.

The Federal Circuit disagreed, noting that the plain meaning of “transverse” was broader than the defendants’ proposed construction of “perpendicular,” and there was “very little indication that the patentees considered perpendicularity important to their invention.” *Id.* The same analysis applies to Respondents’ proposed construction for the claimed aperture. Although all of the disclosed embodiments depict an aperture having a triangular shape on both sides, Respondents have not identified any language in the patent indicating why having the same shape on both sides of the aperture would be important to the invention. In addition, while claims 3 and 9 explicitly require that the frame and membrane be “generally triangularly shaped,” there are no limitations specifying the shape of the sides of the aperture.

Accordingly, I find that the term “an aperture extending from the first side to the second side” shall be construed as “an opening extending from the first side to the second side.”

V. THE ’060 AND ’116 PATENTS

A. Overview

U.S. Patent No. 7,341,060 (“the ’060 Patent”) and U.S. Patent No. 7,938,116 (“the ’116 Patent”) are both continuations from a common application and share the same specification, which describes a respiratory mask assembly for delivering breathable gas to a patient. The assembly comprises a frame that can attach to cushions to protect a patient’s face (’060 Patent at 8:4-9:33, Fig. 5; ’116 Patent at 7:51-9:8), a rotatable elbow that carries gas in and out of the mask (’060 Patent at 9:34-67, 17:48-18:52 Fig. 6; ’116 Patent at 9:9-42, 17:15-18:7), a headgear assembly that can be used to secure the mask on the patient’s head (’060 Patent at 10:54-58, Fig. 1; ’116 Patent at 10:25-29), and connectors that attach these components together (’060 Patent at 9:34-10:52; ’116 Patent at 9:9-10:24).

The '060 Patent is entitled "Ergonomic and Adjustable Respiratory Mask Assembly with Headgear Assembly" and it issued on March 11, 2008 with 48 claims, naming inventors Anthony Michael Ging and Saad Nasr. Asserted claims 30, 37 and 38 are set forth below:

30. A nasal mask assembly for nasal CPAP therapy of a patient comprising:
- (i) a frame including a first alignment indicator, an aperture and a **channel having an inner wall, an outer wall and a channel floor**;
 - (ii) a silicone nasal seal selectively and repeatedly attachable to and detachable from the frame, the seal having a face-contacting side and a non-face contacting side, the non-face contacting side being engagable between the inner and outer walls of the frame, the nasal seal including a second alignment indicator on an outer surface of the nasal seal adapted to align with the first alignment indicator on the frame as the seal and frame are engaged with one another;
 - (iii) a rotatable elbow provided to the frame and including one or more vent openings open to atmosphere for gas washout of exhaled carbon dioxide, the elbow being adapted to connect to a gas delivery tube in order to supply pressurized air to the entrance of the patient's airway;
 - (iv) a headgear assembly including relatively flexible headstraps; and
 - (v) a stiffening support structure extending from the frame to assist in the stabilization of the nasal seal, the stiffening support structure being formed of a relatively more rigid material in comparison to the relatively flexible headstraps, said stiffening support structure having a degree of flexibility in one direction such that variations in patient physiology can be accommodated, said stiffening support structure being stiffer in another direction generally orthogonal to the one direction to resist vertical rotation of the frame due to the weight of the mask frame and/or components supported by the frame, said stiffening support structure arranged to be positioned adjacent the cheek regions in use, said stiffening support structure having on an inside surface thereof, a layer of relatively soft and flexible material arranged between the patient's cheek and the stiffening support structure in use, and said layer of relatively soft and flexible material having the same general shape as the stiffening support structure.
37. The nasal mask assembly of claim 36 wherein the free end of the headstrap is adapted for lengthwise adjustment by threading through the connector element of the stiffening support structure.
38. The nasal mask assembly of claim 30, wherein the silicone nasal seal comprises nasal pillows.

('060 Patent at 38:51-39:24, 39:44-49).

The '116 Patent is also entitled “Ergonomic and Adjustable Respiratory Mask Assembly with Headgear Assembly” and it issued on May 10, 2011 with 73 claims, also naming inventors Anthony Michael Ging and Saad Nasr. Asserted claim 1 is set forth below:

1. A **respiratory mask assembly** for delivering breathable gas to a patient, comprising:
 - a frame having a main body and a side frame member provided on each lateral side of the main body, each side frame member including an integrally formed first connector portion, and
 - a headgear assembly removably attachable to the frame, the headgear assembly having a second connector portion adapted to be removably coupled with the first connector portion provided on the frame,
 wherein one of the first connector portion and the second connector portion includes at least one tooth and the other of the first connector portion and the second connector portion includes a plurality of teeth configured for rotationally locking engagement with the at least one tooth in a plurality of different rotationally locked positions in which the first and second connector portions may not rotate relative to one another, such that the headgear assembly is rotationally adjustable with respect to the frame.

('116 Patent at 34:38-57).

B. Disputed Claim Terms

3. “channel having an inner wall, an outer wall, and a channel floor”

The parties dispute the proper construction of the term “channel having an inner wall, an outer wall, and a channel floor,” which appears in claim 30 of the '060 Patent. Respondents have proposed “channel extending around the aperture of the frame which has an inner wall, an outer wall, and a floor” while ResMed contends that no construction is necessary and the Staff submits that this term has its plain and ordinary meaning.

| ResMed | Respondents | Staff |
|---------------------------|--|---|
| No construction necessary | channel extending around the aperture of the frame which has an inner wall, an outer wall, and a floor | Plain and ordinary meaning, which is the claim language |

Respondents contend that the “channel” in claim 30 is ambiguous and that, when read in the context of the ’060 Patent, this term refers to a channel extending around the aperture of the frame described in the specification. (RMRB at 20-22). Respondents identify this claimed channel as feature 26 in Figure 5c of the ’060 Patent and argue that this channel must extend around the frame’s aperture to ensure a secure seal between the silicone nasal seal and the frame. (RMIB at 23-24; RMRB at 21-23). Respondents argue that this channel extends around the aperture of the frame in every disclosed embodiment of the invention. (RMIB at 23-24; RMRB at 22-23).

ResMed disagrees with Respondents’ interpretation of the specification, pointing to language identifying the disclosed channel as part of a “preferred embodiment,” “an embodiment,” or “one embodiment.” (CMIB at 18 citing ’060 Patent at 5:19-21, 5:36-37, 6:55, 6:63, 7:3-13, 7:23-32, 7:37-41, 29:36, 30:8-9, 33:1). While every embodiment discloses a channel as described by the Respondents, ResMed argues that the fact that the channel surrounds the aperture is never identified as a critical feature of the invention. (CMIB at 18; CMRB at 6).

The Staff agrees with ResMed’s arguments and submits that the correct claim construction of this term is its plain and ordinary meaning. (SMIB at 14-16). The Staff disagrees with Respondents’ characterization of the purpose of the channel, identifying the disclosed purpose of the channel as not creating a seal itself, but “for connecting to the cushion,” specifically: “the engagement of the cushion 40 to the frame 20 is facilitated” because the inner wall of the channel “provides a visual and/or tactile cue to cushion alignment and then will facilitate the continuance of the engagement process.” (SMIB at 15 citing ’060 Patent at 9:30, 10:18-22).

I agree with ResMed and the Staff and find that the proper construction of this term does not include a requirement that the channel extend around the frame. Respondents cite *Alloc, Inc. v. International Trade Commission* for the principle that claims may be limited to disclosed

embodiments where “the specification read as a whole suggests that the very character of the invention requires the limitation be a part of every embodiment.” 342 F.3d 1361, 1370 (Fed. Cir. 2003). But in *Alloc*, the Federal Circuit identified parts of the specification that distinguished the prior art on the basis of the disputed limitation and statements in the prosecution history identifying that limitation as “important.” *Id.* at 1369-1371. Respondents have not identified any such statements here, and I find that it is appropriate to apply the “general rule” that “it is improper to read limitations from a preferred embodiment described in the specification—even if it is the only embodiment—into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited.” *Dealertrack, Inc. v. Huber*, 674 F.3d 1315, 1327 (Fed. Cir. 2012) (citing *Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1342 (Fed.Cir.2010)).

Accordingly, I find that the term “channel having an inner wall, an outer wall, and a channel floor” shall be construed to have its plain and ordinary meaning.

4. “respiratory mask assembly”

The parties dispute the proper construction of the term “respiratory mask assembly,” which appears in claim 1 of the ’116 Patent. Respondents and the Staff propose “a patient interface assembly that surrounds the nose or nose and mouth of a patient” while ResMed contends that no construction is necessary:

| ResMed | Respondents | Staff |
|---------------------------|---|---|
| No construction necessary | a patient interface assembly that surrounds the nose or nose and mouth of a patient | a patient interface assembly that surrounds the nose or nose and mouth of a patient |

The parties had initially disputed whether the claim preamble containing this term was limiting, but at the Markman hearing, ResMed conceded that the preamble was limiting. (Tr. at

78:10-79:19; RMSB at 6; SMSB at 6). The parties' dispute regarding this term focuses on the interpretation of one paragraph in the specification:

The patient interface for NPPV therapy may take many forms, such as a nasal mask assembly, a nose and mouth mask assembly, nasal cushions or a nasal prongs or pillows assembly. A mask assembly typically includes a rigid shell, a soft face-contacting cushion, a forehead support and headgear for securing the mask to the head.

('116 Patent at 1:60-65). ResMed argues that this paragraph should be read to include all of the listed assemblies ("a nasal mask assembly, a nose and mouth mask assembly, nasal cushions or a nasal prongs or pillows assembly") within the definition of "respiratory mask assembly." (Tr. at 80:14-84:8; CMRB at 15; CMSB at 1-2). ResMed reads the second sentence of this paragraph as a broad definition of "mask assembly" that would include nasal pillows, which have "a soft face-contacting cushion." (CMSB at 1). Respondents and the Staff, however, read this paragraph as distinguishing nasal cushions, prongs, and pillows from mask assemblies. (RMIB at 40; SMIB at 27; RMRB at 32). Their interpretation of this paragraph defines a "patient interface" as a broad category that includes "mask assemblies" and nasal pillows as distinct forms. (SMIB at 27; RMRB at 32).

ResMed further supports its broad construction of this term by presenting evidence that the ordinary meaning of "respiratory mask assembly" includes nasal pillows. ResMed has identified two prior art references cited on the face of the '116 Patent that described nasal pillows as "masks." (CMIB at 22 citing U.S. Patent No. 4,782,832 at 3:36-38, 5:29-30, 5:57; "Specification Sheet for Opus Nasal Pillows Mask, Fisher & Paykel Healthcare). ResMed also cites a patent filed by Respondents' expert, Steven Bordewick, referring to nasal pillows as a "nasal mask," a slide from Mr. Bordewick's tutorial referring to nasal pillows as a "mask," and the website for one of Respondents' products that refers to a nasal pillow as a mask. (Tr. at 86:16-88:20; CMIB at 23; CMSB at 3-4). ResMed also identifies one of its own products comprising a mask assembly that

surrounds a patient's mouth but incorporates "nasal pillows" that do not surround the patient's nose. (CMRB at 16-17).

Respondents and the Staff support their interpretation of the specification by pointing to the different preambles of other claims in the '116 Patent as evidence that "respiratory mask assembly" has a different meaning from "patient interface device." (Tr. at 99:5-105:3; RMIB at 41; SMIB at 26; RMSB at 7-8). Respondents further point out that the dependent claims of the '116 Patent that reference nasal pillows and prongs all depend on independent claims with preambles specifying a "patient interface device." (RMSB at 7). The Staff acknowledges that prior art references refer to nasal pillows as masks but argues that this is not dispositive of how the '116 Patent's inventors described their invention. (SMIB at 26).

I agree with Respondents and the Staff that the '116 Patent makes a clear distinction between a "respiratory mask assembly" and a "patient interface device." Recognizing this distinction accounts for the fact that claims 1-4 of the '116 Patent have the preamble "[a] respiratory mask assembly for delivering breathable gas to a patient" while claims 5-73 have the preamble "[a] patient interface device for delivering breathable gas to a patient." ('116 Patent at 34:38-42:17). It is the claims of a patent that define the invention, *Phillips*, 415 F.3d at 1312, and there is a presumption "that different claim terms have different meanings." *Chicago Bd. Options Exchange, Inc. v. Int'l Securities Exchange, LLC*, 677 F.3d 1361, 1369 (Fed. Cir. 2012); *see also Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006) ("claims are interpreted with an eye toward giving effect to all terms in the claim"); *CAE Screenplates, Inc. v. Heinrich Fiedler GmbH & Co. KG*, 224 F.3d 1308, 1317 (Fed. Cir. 2000) ("In the absence of any evidence to the contrary, we must presume that the use of these different terms in the claims connotes different meanings."). Although claim differentiation arguments are typically applied between independent and dependent claims, the Federal Circuit has held that the same principles can differentiate

between independent claims. *Hologic, Inc. v. SenoRx, Inc.*, 639 F.3d 1329, 1336-37 (Fed. Cir. 2011) (“Hologic wrongly asserts that looking to other terms is only appropriate when the comparison is between an independent claim and the claims that depend from it.”); *Digital-Vending Servs. Int’l, LLC v. Univ. of Phoenix, Inc.*, 672 F.3d 1270, 1274-75 (Fed. Cir. 2012) (applying claim differentiation between several independent claims). The claims of the ’116 Patent use two distinct preambles, and I must presume that the language of these preambles have different meanings.

I am mindful of the cases cited by ResMed, which warn that “claims that are written in different words may ultimately cover substantially the same subject matter,” *Kraft Foods, Inc. v. Int’l Trading Co.*, 203 F.3d 1362, 1365-69 (Fed. Cir. 2000), and “[i]t is not unusual that separate claims may define the invention using different terminology, especially where (as here) independent claims are involved.” *Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1380-81 (Fed. Cir. 2006) (citing *Hormone Research Found. v. Genentech, Inc.*, 904 F.2d 1558, 1567 n. 15 (Fed.Cir.1990)); see also *Tandon Corp. v. U.S. International Trade Commission*, 831 F.2d 1017, 1021-24 (Fed. Cir. 1987) (“two claims which read differently can cover the same subject matter.”). But in those cases, there was evidence from the specification and file history that suggested that the invention was more narrow than the claim differentiation argument would imply, and the courts were understandably cautious not to “interpret a claim to be broader than what is contained in the specification and claims as filed.” *Tandon*, 831 F.2d at 1024; see also *Curtiss-Wright*, 438 F.3d at 1381 (“Any construction to the contrary is not consistent with the overall context of this invention and this field of art as described in the specification”); *Kraft Foods*, 203 F.3d at 1368 (“the written description and prosecution history overcome any presumption arising from the doctrine of claim differentiation”). That is not the case here, where distinguishing between the different preamble language narrows the scope of the claim in

question, and as discussed below, the specification is consistent with the more narrow construction for the disputed term.

The disputed paragraph in the specification describing a “patient interface” and “mask assembly” is also consistent with different meanings for these terms, and I find that Respondents’ and the Staff’s interpretation of this paragraph is the correct one. In the first sentence of the disputed paragraph, the patent describes a broad category of “patient interface” devices and only identifies a subset of those as “mask assembl[ies].” (’116 Patent at 1:60-63). The other devices are identified as “nasal cushions or a nasal prongs or pillows assembly.” (*Id.* at 1:62-63). The second sentence of the paragraph is wholly consistent with this interpretation, identifying typical components of a mask assembly. (*Id.* at 1:63-65). While ResMed asserts that this second sentence could refer to the cushions used with nasal pillows, (CMSB at 1), I find that the reference to a “face-contacting cushion” is more consistent with a mask structure covering more of a patient’s face. ResMed also identifies cited prior art using the term “nasal mask” more broadly, U.S. Pat. No. 4,782,832 and a Specification Sheet for Opus Nasal Pillows Mask by Fisher & Paykel Healthcare, but ResMed does not identify anything in the ’116 Patent itself or its prosecution history contradicting a more narrow construction for this term. While there is apparent ambiguity in the use of the term “mask” among those of ordinary skill in the art at the time of the invention, the drafters of the specification and claims of the ’116 Patent used the terms “mask assembly” and “respiratory mask assembly” consistently to refer to a subset of “patient interface” devices that does not include nasal cushions, nasal prongs, or nasal pillows.

The dependent claims of the ’116 Patent are also consistent with this distinction between mask assemblies and nasal pillows, cushions, and prongs. There is no reference to nasal pillows or prongs in the claims with “respiratory mask assembly” preambles. (’116 Patent at 34:38-35:51). But dependent claim 55 reads: “The patient interface device according to claim 47,

wherein the sealing member comprises nasal pillows.” (’116 Patent at 39:66-67). And claim 66 reads: “The patient interface device according to claim 62, wherein the sealing member comprises nasal pillows.” (’116 Patent at 40:47-48). Similarly, claims 56 and 62 refer to “a nasal cushion, an oro-nasal cushion, or nasal prongs.” (’116 Patent at 40:1-3, 40:49-51).

The claims and specification are thus consistent with a construction of “respiratory mask assembly” as a subset of “patient interface device” that does not include nasal pillows, cushions, and prongs. I thus agree with Respondents’ and the Staff’s proposed construction, which is based on the two explicit examples of mask assemblies provided in the specification: “a nasal mask assembly” and “a nose and mouth mask assembly.” (’116 Patent at 1:61-62).

Accordingly, I find that the term “respiratory mask assembly” in the ’116 Patent shall be construed as “a patient interface assembly that surrounds the nose or nose and mouth of a patient.”

VI. THE ’267 PATENT

A. Overview

U.S. Patent No. 7,997,267 (“the ’267 Patent”) is entitled “Ergonomic and Adjustable Respiratory Mask Assembly with Elbow Assembly,” and it issued on August 16, 2011 with 89 claims, naming inventors Anthony Michael Ging, Saad Nasr, Rachael Elizabeth Moore, and Andrew Martin Price. The ’267 Patent is related to the ’060 and ’116 Patent, claiming priority to the same Australian patent application and U.S. provisional applications. While there are some minor differences, the specification of the ’267 Patent is largely the same as the specification for the ’060 and ’116 Patent. The claims of the ’267 Patent are focused on the connection between the mask’s frame and an “elbow assembly” that carries gas in and out of the mask. (’267 Patent at 17:7-19:34). Exemplary claims 32-37 and 53 are set forth below:

32. A respiratory mask assembly for delivering breathable gas to a patient, comprising:

a frame having a front surface and a rear surface adapted in use to face the patient, the frame including a main body providing an aperture therethrough for the introduction of breathable gas into a nasal breathing cavity; and

a **quick-release elbow assembly** swivelably coupled to the front surface of the frame, the elbow assembly including a swivel elbow,

wherein the swivel elbow includes an end portion that allows **quick release attachment to and detachment from the frame** while allowing the elbow to swivel.

33. A respiratory mask assembly according to claim 32, wherein the swivel elbow is **quickly releasable from the frame** while the frame is in use on the patient's head.
34. A respiratory mask assembly according to claim 33, wherein the swivel elbow can be attached to and released from the frame with one hand.
35. A respiratory mask assembly according to claim 34, wherein the aperture is sized to permit the patient to breathe comfortably upon release of the swivel elbow from the frame.
36. A respiratory mask assembly according to claim 35, wherein a diameter of the aperture is larger than at least one of a diameter of an air delivery tube connectable to the swivel elbow and a second elbow end configured to be connected to the air delivery tube.
37. A respiratory mask assembly according to claim 36, wherein the aperture has an area of at least 180 mm².

('267 Patent at 37:4-33).

53. A **respiratory mask assembly** for delivering CPAP therapy to patient at a pressure of 4 to 20 cm H₂O, the **respiratory mask assembly** comprising:
 - a rigid frame;
 - a soft cushion attached to the frame; and
 - an elbow assembly, the elbow assembly including
 - an elbow,
 - a **quick-release mechanism** accessible from a front side of the frame to selectively couple and decouple the elbow assembly to the frame while allowing the elbow to rotate in a secured position.

('267 Patent at 38:16-26).

B. Disputed Claim Terms

5. “respiratory mask assembly”

The parties dispute the proper construction of the term “respiratory mask assembly,” which appears in claim 53 of the ’267 Patent.⁴ Respondents and the Staff propose “a patient interface assembly that surrounds the nose or nose and mouth of a patient” while ResMed contends that no construction is necessary:

| ResMed | Respondents | Staff |
|---------------------------|---|---|
| No construction necessary | a patient interface assembly that surrounds the nose or nose and mouth of a patient | a patient interface assembly that surrounds the nose or nose and mouth of a patient |

The parties had initially disputed whether the claim preamble of claim 53 was limiting, but at the Markman hearing, ResMed conceded that the preamble was limiting. (Tr. at 78:10-79:19; RMSB at 6; SMSB at 6). The parties’ dispute regarding this term is identical to their dispute regarding the construction of this term in ’116 Patent, and the ’267 Patent contains the same identical disputed paragraph in its specification:

The patient interface for NPPV therapy may take many forms, such as a nasal mask assembly, a nose and mouth mask assembly, nasal cushions or a nasal prongs or pillows assembly. A mask assembly typically includes a rigid shell, a soft face-contacting cushion, a forehead support and headgear for securing the mask to the head.

(’267 Patent at 1:57-62). The parties’ briefs raised the same arguments regarding this paragraph in the context of the ’267 Patent as the ’116 Patent. (RMIB at 45-46; CMRB at 21-22; RMRB at 34-35; SMSB at 7-8). All of the claim preambles in the ’267 Patent use the term “respiratory mask assembly,” however, so there is no basis for distinguishing “patient interface” from “mask assembly” based on the claim language of the ’267 Patent alone. But the Federal Circuit has held that “unless otherwise compelled ... the same claim term in the same patent or related patents

⁴ The parties previously disputed the construction of “respiratory mask assembly” in claims 32-37, 79, 80, and 88 but have agreed that the preamble is not limiting in those claims.

carries the same construed meaning.” *Omega Engineering, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1334 (Fed.Cir.2003); *see also In re Rambus Inc.*, 694 F.3d 42, 48 (Fed. Cir. 2012) (applying a claim differentiation argument from a related patent where the patent at issue did not have the relevant dependent claims). It is thus appropriate to apply the same construction from the ’116 Patent to the same term in the related ’267 Patent. But even without the arguments based on claim language in the ’116 Patent, I find that excluding nasal cushions, prongs, and pillows from the definition of “respiratory mask assembly” is the best reading of the disputed paragraph in the specification, and the construction proposed by Respondents and the Staff is the one that “most naturally aligns with the patent’s description of the invention.” *Phillips*, 415 F.3d at 1316. As with the ’116 Patent, ResMed has not identified any evidence in the claims or specification of the ’267 Patent to contradict this construction. For the same reasons as discussed above, I therefore agree with Respondents’ and the Staff’s proposed construction for this term.

Accordingly, I find that the term “respiratory mask assembly” in the ’267 Patent shall be construed as “a patient interface assembly that surrounds the nose or nose and mouth of a patient.”

6. “quick-release elbow assembly”

The parties dispute the proper construction of the term “quick-release elbow assembly,” which appears in claim 32 of the ’267 Patent. ResMed contends that no construction is necessary while Respondents propose “an elbow assembly that is quickly and easily attached to the frame and detached from the frame by flexing each side of the elbow’s collar towards one another in order to raise protrusions on the collar radially outwardly to allow passage of a flange on the wall of the frame’s aperture.” The Staff believes that this term should have its plain and ordinary meaning:

| ResMed | Respondents | Staff |
|---------------------------|---------------------------|-----------------------------|
| No construction necessary | an elbow assembly that is | Plain and ordinary meaning, |

| | | |
|--|---|------------------------------------|
| | quickly and easily attached to the frame and detached from the frame by flexing each side of the elbow's collar towards one another in order to raise protrusions on the collar radially outwardly to allow passage of a flange on the wall of the frame's aperture | which is the claim language itself |
|--|---|------------------------------------|

The dispute between the parties is the same for all of the “quick release” terms: “quick-release elbow assembly,” “quick release attachment to and detachment from the frame,” “quickly releasable from the frame,” and “quick-release mechanism.”

Respondents contend that the patentees distinguished the “quick release” mechanisms claimed in the '267 Patent from prior art mechanisms and that the patent should therefore be limited to the embodiments disclosed in the specification. (Tr. at 283-287; RMIB at 48-49; RMRB at 36; RMSB at 9-11). Specifically, Respondents identify passages in the specification recognizing that quick release mechanisms already existed in the prior art. ('267 Patent at 2:4-23, 19:27-30). Respondents then point to specific statements in the specification that “[a] flexible quick release mechanism includes a collar and an apron,” ('267 Patent at 17:50-51), and “[t]o release the elbow from the frame, portions on each side of the collar are flexed towards one another in order to raise the protrusions radially outwardly to allow passage of the flange. In this manner, the elbow can be quickly and easily removed from the frame without accessing the interior portion of the nasal cavity, as would be the case with an elbow connected using a C-clip.” (*Id.* at 18:28-33). Respondents assert that these disclosures define a single mechanism for quickly and easily detaching the elbow assembly and thus propose constructions for the “quick release” terms that reflect this description from the specification. (Tr. at 283-287; RMIB at 48-49; RMRB at 36; RMSB at 9-11).

ResMed and the Staff both criticize Respondents' constructions for reading limitations from the specification into the claims. (CMIB at 30; SMIB at 32-33). ResMed argues that there is no clear disavowal of claim scope in any of the passages cited by Respondents, and the mechanism cited by Respondent is only one embodiment of the invention. (CMRB at 24; CMSB at 4). The Staff notes that Respondents' constructions substitute the term "easy" for "quick" without any justification and sees no reason to construe these terms beyond their plain and ordinary meaning. ResMed argues that the prior art was distinguished on other grounds, such as a shorter elbow assembly ('267 Patent at 8:45-51), narrower apertures (*id.* at 19:30-32), or a need for an intermediate swivel connector (*id.* at 8:45-50, 3:28-32), and not solely on the basis of the quick-release mechanism. (Tr. at 288-298; RMRB at 24; SMSB at 8-9). At the *Markman* hearing, Respondents argued that these portions of the specification referred to other specific aspects of the invention rather than the claimed quick release mechanism. (Tr. at 298-300; CMSB at 9-10).

I agree with ResMed and the Staff and find that the patentees did not limit the claimed quick release mechanism to the embodiment disclosed in the specification. Respondents cite the Federal Circuit's decision in *Honeywell* to support a narrow construction where a patentee distinguishes the prior art. *Honeywell Int'l, et al. v. ITT Indus., et al.*, 452 F.3d 1312 (Fed. Cir. 2006). But in *Honeywell*, the court described the disputed limitation in the context of a "detailed discussion of the prior art problem addressed by the patented invention." *Id.* at 1318. Respondents only identify general discussion of prior art in the '267 Patent, and the '267 Patent does not contain the type of "clear statement[]" referenced by the court in *Honeywell*. *Id.* The evidence here is more similar to cases cited by ResMed, such as *Ventana Medical Systems, Inc. v. Biogenex Laboratories, Inc.*, where the court declined to limit the invention to the preferred embodiment where the specification included "only general statements by the inventors indicating that the invention is intended to improve upon prior art automated staining methods." 473 F.3d

1173, 1180 (Fed. Cir. 2006). To limit an invention to the disclosed embodiment generally “requires expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope.” *Epistar Corp. v. International Trade Commission*, 566 F.3d 1321, 135 (Fed. Cir. 2009); *see also Spine Solutions, Inc. v. Medtronic Sofamor Danek USA, Inc.*, 620 F.3d 1305, 1315 (rejecting defendant’s argument that the asserted patent “actively disparages” a prior art design because “this does not rise to the level of an express disclaimer sufficient to limit the scope of the claims.”). The Respondents have failed to identify any such disclaimers in the ’267 Patent, while ResMed and the Staff have identified plausible distinctions between the invention and the prior art that do not require the limitations that Respondents seek to impose on this claim term.

Accordingly, I find that the term “quick-release elbow assembly” shall be construed to have its plain and ordinary meaning.

7. “quick-release attachment to and detachment from the frame”

The parties dispute the proper construction of the term “quick release attachment to and detachment from the frame,” which appears in claim 32 of the ’267 Patent. ResMed contends that no construction is necessary while Respondents propose “quick and easy attachment to the frame and detachment from the frame by flexing each side of the elbow’s collar towards one another in order to raise protrusions on the collar radially outwardly to allow passage of a flange on the wall of the frame’s aperture.” The Staff believes that this term should have its plain and ordinary meaning:

| ResMed | Respondents | Staff |
|---------------------------|--|--|
| No construction necessary | quick and easy attachment to the frame and detachment from the frame by flexing each side of the elbow’s collar towards one another in order to raise protrusions on the collar radially | Plain and ordinary meaning, which is the claim language itself |

| | | |
|--|--|--|
| | outwardly to allow passage of a flange on the wall of the frame's aperture | |
|--|--|--|

The parties' arguments regarding all of the "quick release" terms are the same, and I find that the same analysis applies to "quick release attachment to and detachment from the frame" as discussed above for "quick-release elbow assembly."

Accordingly, I find that the term "quick release attachment to and detachment from the frame" shall be construed to have its plain and ordinary meaning.

8. "quickly releasable from the frame"

The parties dispute the proper construction of the term "quickly releasable from the frame," which appears in claim 33 of the '267 Patent. ResMed contends that no construction is necessary while Respondents propose quickly and easily releasable from the frame by flexing each side of the elbow's collar towards one another in order to raise protrusions on the collar radially outwardly to allow passage of a flange on the wall of the frame's aperture." The Staff believes that this term should have its plain and ordinary meaning:

| ResMed | Respondents | Staff |
|---------------------------|---|--|
| No construction necessary | quickly and easily releasable from the frame by flexing each side of the elbow's collar towards one another in order to raise protrusions on the collar radially outwardly to allow passage of a flange on the wall of the frame's aperture | Plain and ordinary meaning, which is the claim language itself |

The parties' arguments regarding all of the "quick release" terms are the same, and I find that the same analysis applies to "quickly releasable from the frame" as discussed above for "quick-release elbow assembly."

Accordingly, I find that the term “quickly releasable from the frame” shall be construed to have its plain and ordinary meaning.

9. “quick-release mechanism”

The parties dispute the proper construction of the term “quick-release mechanism,” which appears in claim 53 of the '267 Patent. ResMed contends that no construction is necessary while Respondents propose “an elbow assembly mechanism that is quickly and easily attached to the frame and detached from the frame by flexing each side of the elbow’s collar towards one another in order to raise protrusions on the collar radially outwardly to allow passage of a flange on the wall of the frame’s aperture.” The Staff believes that this term should have its plain and ordinary meaning:

| ResMed | Respondents | Staff |
|---------------------------|---|--|
| No construction necessary | an elbow assembly mechanism that is quickly and easily attached to the frame and detached from the frame by flexing each side of the elbow’s collar towards one another in order to raise protrusions on the collar radially outwardly to allow passage of a flange on the wall of the frame’s aperture | Plain and ordinary meaning, which is the claim language itself |

The parties’ arguments regarding all of the “quick release” terms are the same, and I find that the same analysis applies to “quick-release mechanism” as discussed above for “quick-release elbow assembly.”

Accordingly, I find that the term “quick-release mechanism” shall be construed to have its plain and ordinary meaning.

VII. THE '487 PATENT

A. Overview

U.S. Patent No. 7,926,487 (“the ‘487 Patent”) is entitled “Respiratory Mask having Gas Washout Vent and Gas Washout Vent Assembly for a Respiratory Mask” and it issued on April 19, 2011 with 92 claims, naming inventors Joanne Elizabeth Drew, Alexander Virr, and Geoffrey Crumblin. The ‘487 Patent is directed to a gas washout vent for a respiratory mask for venting the patient’s exhaled gases to the atmosphere. (‘487 Patent at 1:62-65). The patent describes several considerations in the design of these gas washout vents, emphasizing the importance of minimizing noise and weight for patient comfort. (*Id.* at 1:66-2:15). It is also desirable to maximize the elimination of exhaled carbon dioxide and the inhalation of breathable gas. (*Id.* at 2:6-13). Compatibility with humidifiers is also a consideration, and it is desirable that a vent be easily cleaned or economically disposable. (*Id.* at 2:16-20). Exemplary claims 13, 26, and 51 are set forth below:

13. A respiratory mask comprising:

a cushion;

a breathable gas inlet to provide pressurized gas at a pressure elevated above atmospheric pressure to the patient via the cushion when the mask is in use; and

at least one **gas washout vent** to allow gas to exit from the mask, wherein the washout vent has at least twenty through holes each having a length and a diameter that are selected to help eliminate or reduce noise while maintaining sufficient CO₂ washout during patient breathing, and

wherein each of the holes has a first end positioned on an inside surface of the mask and a second end positioned on an outer surface of the mask, and wherein the first end has a **diameter** that is larger than a **diameter** of the second end

(‘487 Patent at 8:8-23).

26. A respiratory mask comprising:

a patient interface having a cushion;

a breathable gas inlet to provide pressurized gas at a pressure elevated above atmospheric pressure to a breathing cavity formed at least in part by the patient interface when the mask is in use; and a **gas washout vent** having a plurality of holes, said holes being structured and arranged to allow gas to be exhausted from the breathing cavity substantially without gas jetting, wherein:

the vent has a thickness of less than 3 mm, and

the vent includes at least 20 of said holes, said holes being arranged in a plurality of rows;

wherein each of the holes has a first end positioned on an inside surface of the mask and a second end positioned on an outer surface of the mask, and wherein the first end has a different **diameter** than a **diameter** of the second end.

(’487 Patent at 9:5-22).

51. A respiratory mask comprising:

a cushion;

a breathable gas inlet to provide pressurized gas at a pressure elevated above atmospheric pressure to the patient via the cushion when the mask is in use; and

at least one **gas washout vent** to allow gas to exit from the mask, wherein the washout vent has an array of at least 20 through holes grouped to avoid or reduce air jetting;

wherein each of the holes has a first end positioned on an inside surface of the mask and a second end positioned on an outer surface of the mask, and wherein the first end has a different **diameter** than a **diameter** of the second end.

(’487 Patent at 11:3-16).

B. Disputed Claim Terms

10. “gas washout vent”

The parties dispute the proper construction of the term “gas washout vent,” which appears in claims 13, 26, and 51 of the ’487 Patent. ResMed contends that no construction is necessary or, in the alternative, proposes “vent for exhausting gas to the atmosphere.” Respondents and the Staff have proposed “a vent comprising a thin air permeable membrane extending across an opening for exhausting gas to the atmosphere.”

| ResMed | Respondents | Staff |
|--|--|--|
| No construction necessary. Otherwise: “vent for exhausting gas to the atmosphere” | a vent comprising a thin air permeable membrane extending across an opening for exhausting gas to the atmosphere | a vent comprising a thin air permeable membrane extending across an opening for exhausting gas to the atmosphere |

The construction proposed by Respondents and the Staff limits the “gas washout vent” to a thin air permeable membrane and seeks to exclude vents that are comprised of holes in the mask itself, without a separate membrane. (Tr. at 187-191; RMSB at 6). Respondents point to the Summary of the Invention for the ’487 Patent, which begins with the sentence: “The present invention provides a vent assembly suitable for use with a mask used in CPAP treatment wherein the vent assembly is a thin air permeable membrane.” (’487 Patent at 3:3-5) (Tr. at 187:19-190:10; RMIB at 29; RMRB at 25-26; RMSB at 5). Respondents and Staff note that every embodiment disclosed in the ’487 Patent uses an air permeable membrane. (Tr. at 194; RMIB at 29-31; RMRB at 25-26; RMSB at 5-6; SMSB at 4). (See ’487 Patent at 4:40-44, 5:6-8, 5:19-23, 5:24-29, 5:34-37, 5:46-50, 6:1-3, 6:15-17, Figs. 1-9). And they contend that the ’487 Patent distinguishes its air permeable membrane from prior art vents, including vents “formed from the same polycarbonate material that is used to form the elbow and the mask frame.” (’487 Patent at 2:29-33) (Tr. at 190:11-192:13; RMIB at 31; SMIB at 18-19; RMSB at 6’ SMSB at 4-5). The ’487 Patent states that “[i]t is an object of the present invention to provide an alternative form of vent that is suitable for use in a respiratory mask.” (’487 Patent at 2:65-67). Respondents and the Staff thus read these statements in the specification to limit the “gas washout vent” to the “thin air permeable membrane” disclosed in the patent.

ResMed disagrees with this reading of the ’487 Patent, finding no disclaimer or disavowal in the specification that would narrow the “gas washout vent” to a thin air permeable membrane. (CMSB at 7). ResMed also points to language in the Abstract stating that “[i]n one embodiment

the vent is made of a thin air permeable membrane.” (’487 Patent at Abstract) (CMIB at 38). And ResMed highlights the language of dependent claims 34, 41, and 62, which add a limitation “wherein the vent is formed on a membrane,” and argues that application of the doctrine of claim differentiation would not read this limitation into the independent claims. (Tr. at 185:1-10; CMIB at 37-38; CMRB at 25). These dependent claims read:

34. A respiratory mask according to claim 26, wherein the vent is formed on a membrane that is mounted to the patient interface.

41. A respiratory mask according to claim 39, wherein the vent is formed on a membrane that is mounted on the patient interface.

62. A respiratory mask according to claim 56, wherein the plurality of holes is formed on a membrane attached to the elbow.

(’487 Patent at 9:47-49, 10:27-29, 11:65-67). Independent claim 8 also explicitly claims “a gas washout vent including an air permeable portion.” (’487 Patent at 7:54). ResMed further argues that the prosecution history is consistent with a broad construction for “gas washout vent” because the examiner cited prior art using a vent in the mask frame without protest from the patentee, and the notice of allowability recognized an “air permeable material” as only one embodiment. (CMIB at 39; CMSB at 7-8).

ResMed had also argued that Respondents’ construction would read out an embodiment using stainless steel for the washout vent, (CMRB at 25-26), but Respondents explained at the *Markman* hearing that the patentees had acted as their own lexicographers to refer to stainless steel as an air permeable membrane. (Tr. at 193-204; RMSB at 4). Respondents also counter ResMed’s claim differentiation arguments by arguing that the claims with an “air permeable membrane” limitation also contain additional limitations to differentiate them from the independent claims. (RMIB at 31-33; RMRB at 26). Respondents argue that the reference to a membrane in claim 8 is used to describe specific characteristics of the membrane, while claims 34 and 41 specify that the membrane is “mounted to the patient interface” and claim

62 specifies that the membrane is “attached to the elbow.” (Tr. at 223-24; RMRB at 26-27; SMIB at 19-20; SMSB at 5). But ResMed criticizes the Staff’s interpretation of the dependent claims, arguing that the Staff’s construction would render the dependent claim language superfluous. (CMRB at 28-29).

I find that the reference to membranes in dependent claims 34, 42, and 62 creates a presumption that a membrane limitation is not present in the independent claims. *Phillips*, 415 at 1315. While Respondents and the Staff have sought to minimize the significance of the membrane limitations in these dependent claims, I do not find their arguments convincing. They contend that claims 34 and 41 add a limitation that the gas washout vent is located on the patient interface, while claim 62 adds a limitation where the gas washout vent is located on the elbow. The Staff illustrated this point by citing Figures 6 and 9 of the ’487 Patent, showing vents located on different parts of the device. (Tr. at 223-24; SMIB at 19-20). But these limitations on vent location are not added by the dependent claims; they are part of the independent claims from which these claims depend.

Claims 34 and 41 are dependent on claims 26 and 39, respectively, and these independent claims both refer to a “patient interface” with “a gas washout vent having a plurality of holes,” “wherein each of the holes has a first end positioned on an inside surface of the mask and a second end positioned on an outer surface of the mask.” (’467 Patent at 9:5-22, 10:8-24). Claims 26 and 39 thus already require that the gas washout vent be “positioned” on the “surface of the mask.” The only additional limitation added by claims 34 and 41 is that “the vent is formed on a membrane.” (*Id.* at 9:47-49, 10:27-29). Similarly, independent claim 56 claims “a gas washout vent having an array of through holes extending from an inside of the elbow to an outside of the elbow.” (*Id.* at 11:31-50). The only additional limitation added by claim 62 is that “the plurality of holes is formed on a membrane.” (*Id.* at 11:65-67). Since the sole difference between these

independent and dependent claims is the “membrane” limitation that Respondents and the Staff are proposing to read into the “gas washout vent” term, this is a situation where “the doctrine of claim differentiation is at its strongest.” *SanDisk Corp. v. Kingston Technology Co., Inc.* 695 F.3d 1348, 1361 (Fed. Cir. 2012) (citing *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed. Cir. 2004); *Phillips*, 415 F.3d at 1315).

Claim differentiation only creates a rebuttal presumption, however, which “will be overcome by a contrary construction dictated by the written description or prosecution history.” *Seachange Int’l, Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1369 (Fed. Cir. 2005); *Retractable Technologies, Inc. v. Becton, Dickinson and Co.*, 653 F.3d 1296, 1305 (Fed. Cir. 2011); *Kraft Foods, Inc. v. International Trading Co.*, 203 F.3d 1362, 1368 (Fed. Cir. 2000). Respondents and the Staff argue for rebuttal of the presumption in this case because the ’487 Patent describes an air permeable membrane in every embodiment in the specification, but I find that the evidence in the intrinsic record is not as strong here as in the cases cited by Respondents.

In *Seachange*, the Federal Circuit analyzed a similar specification, finding that “it is unclear whether these references ... are simply the consistent description of one possible embodiment or a description of the invention itself.” 413 F.3d at 1370. The court was only able to rebut the claim differentiation presumption after finding evidence in the prosecution history of that patent to conclude that the patentee had narrowed the meaning of the term. *Id.* at 1370-75. Similarly, the court in *Kraft Foods* found a statement from the patent examiner supporting the disputed limitation and relied on the prosecution history to rebut the presumption of claim differentiation. 203 F.3d at 1367-69. Respondents and the Staff have not cited any such evidence in the prosecution history here, and ResMed has identified statements from the examiner and the applicant that appear to be consistent with a broader construction of “gas washout mask.” (CMIB at 39; CMSB at 8-9).

In *Retractable Techs.*, the Federal Circuit identified a statement in the specification stating “that the prior art had failed to recognize a retractable syringe that can be molded as one piece outer body.” 653 F.3d at 1305. But there is no such disclaimer or criticism of the prior art in the ’487 Patent. While Respondents and the Staff identify many different prior art vent configurations listed in the ’487 Patent, there is no indication that a thin air permeable membrane was the critical feature distinguishing the invention from the prior art. To the contrary, some of the listed prior art vents appear to include a thin air permeable membrane extending across an opening. (’487 Patent at 2:42-47 (“A known vent ... includes a window which is covered with a porous sintered material of approximately 3-4mm thickness.”), 2:55-64 (“The MIRAGE® mask has a crescent shaped opening in the mask shell in which is located a complementary shaped crescent elastomeric insert with six holes therein which constitutes the vent. The elastomeric inset has a cross-sectional thickness of 3 to 4mm.”)). The patent states that “[i]t is an object of the present invention to provide an alternative form of vent,” but it is not clear that it is a thin permeable membrane that distinguishes the ’487 Patent from the prior art. This discussion of prior art appears to be “only general statements by the inventors indicating that the invention is intended to improve upon prior art [] methods.” *Ventana Medical Systems*, 473 F.3d at 1180. These statements are not sufficient to rebut the presumption of claim differentiation here.⁵

Respondents also cite a line of cases restricting claims to the preferred embodiment where the specification describes a limitation as “the invention.” *Honeywell Intern., Inc. v. ITT Industries, Inc.*, 452 F.3d 1312, 1318 (Fed. Cir. 2006); *Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1330 (Fed. Cir. 2009). The ’487 Patent does describe “[t]he present invention” as

⁵ Respondents also cite *Curtiss Wright Flow Control Corp. v. Velan, Inc.*, but that case was related to claim differentiation between two independent claims. 438 F.3d 1374, 1381 (Fed. Cir. 2006). *Multiform Desiccants, Inc. v. Medzam, Ltd.* is also distinguishable because the claim at issue in that case was construed in accordance with 35 U.S.C. § 112 ¶ 6. 133 F.3d 1473, 1479 (Fed. Cir. 1998).

a vent assembly “wherein the vent assembly is a thin air permeable membrane,” (’487 Patent at 3:3-5), but the Abstract of the ’487 Patent states that “[i]n one embodiment the vent is made of a thin air permeable membrane.” (’487 Patent at Abstract). While every disclosed embodiment of the gas washout vent is a thin air permeable membrane, there is no evidence that the patentee used these terms interchangeably, as the Federal Circuit found in *Edwards Lifesciences*, 582 F.3d at 1329-1330. The specification describes the membrane as one part of the gas washout vent: “The mask includes a gas washout vent constituted by an opening in the shell across which extends a thin air permeable membrane.” (’487 Patent at 4:40-42). And claim 8 explicitly describes “a gas washout vent including an air permeable portion.” (*Id.* at 7:54-60). As discussed above, there is no discussion in the ’487 Patent of how using a thin air permeable membrane overcomes the problems in the prior art, which was a critical piece of evidence relied upon by the Federal Circuit in *Honeywell*. 452 F.3d at 1318.⁶ I therefore find that the references to the “present invention” and “this invention” in the ’487 Patent are not definitive enough to overcome the presumption of claim differentiation discussed above.

I thus decline to construe “gas washout vent” to be restricted to a thin permeable membrane and find that this term has its plain and ordinary meaning, which can be understood from the claim language of the ’487 Patent. Claims 13 and 51 describe a “gas washout vent to allow gas to exit from the mask.” (’487 Patent at 8:13-14, 11:8-9). Claim 26 describes the holes of the vent being structured and arranged “to allow gas to be exhausted from the breathing cavity.” (*Id.* at 9:11-14). The Background of the Invention describes “a gas washout vent for venting

⁶ In other cases, the Federal Circuit has found that the phrases “present invention” and “this invention” are not so limiting, “such as where the references to a certain limitation as being the ‘invention’ are not uniform, or where other portions of the intrinsic evidence do not support applying the limitation to the entire patent.” *Absolute Software, Inc. v. Stealth Signal, Inc.*, 659 F.3d 1121, 1136-37 (Fed. Cir. 2011) (citing *Voda v. Cordis Corp.*, 536 F.3d 1311, 1320-22 (Fed. Cir. 2008); *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1326 (Fed. Cir. 2008); *Rambus, Inc. v. Infineon Techs. AG*, 318 F.3d 1081, 1094-95 (Fed. Cir. 2003)).

exhaled gases to atmosphere.” (*Id.* at 1:62-63). And the specification describes “the gas washout vent for venting exhaled gases to the atmosphere.” (*Id.* at 7:1-2). The parties do not appear to dispute that the vent is for exhausting gas to the atmosphere.

Accordingly, I find that the term “gas washout vent” shall be construed to have its plain and ordinary meaning, which is “vent for exhausting gas to the atmosphere.”

11. “diameter”

The parties dispute the proper construction of the term “diameter,” which appears in claims 13, 26, 51 and 52 of the ’487 Patent. Respondents propose “a straight line segment passing through the center of a circle” while ResMed and the Staff propose “a straight line segment passing through the center of a circle or ellipse.”

| ResMed | Respondents | Staff |
|---|--|---|
| Plain and ordinary meaning, which is: “a straight line segment passing through the center of a circle or ellipse” | a straight line segment passing through the center of a circle | Plain and ordinary meaning, which is: “a straight line segment passing through the center of a circle or ellipse” |

The term “diameter” appears in each claim of the ’487 Patent to describe the relative size of the holes in the gas washout vent. The limitations related to these holes generally require that “the first end has a diameter that is larger than a diameter of the second end” or that “the first end has a different diameter than a diameter of the second end.” (*See, e.g.* ’487 Patent at 8:19-23, 9:18-22, 11:12-16). Respondents argue that the plain and ordinary meaning of “diameter” is a straight line segment passing through the center of a circle. (RMIB at 35-36). This definition is based on a mathematical definition of diameter that limits this term to circles. (Tr. at 245-246). ResMed and the Staff propose a broader construction that would apply to both circles and ellipses. (Tr. at 255-258; CMIB at 40-41; SMIB at 24-25). ResMed points out that the word “circle” does not appear anywhere in the ’487 Patent; the claims only describe the shape as a “hole.” (CMIB at

41). Both ResMed and the Staff view the word “diameter” as a commonly understood word that does not require a highly technical construction. (Tr. at 258-259; CMIB at 39-40; SMIB at 24-25). ResMed points out that when a hole is drilled at an angle, the result will be elliptical. (CMIB at 41). Respondents’ expert concedes that line segments through the centers of ellipses can be referred to as diameters but argues that including ellipses would be imprecise. (RMIB at 36-37). Respondents contend that construing this term as ResMed and the Staff propose would lead to an indefiniteness problem, because ellipses have many different diameters of varying lengths. (Tr. at 247-251; RMIB at 37; RMRB at 29-31).

I find that Respondents’ precise mathematical definition is not consistent with the language of the ’487 Patent. As discussed at the *Markman* hearing, the asserted patents in this Investigation are not generally written with precise mathematical language. (Tr. at 246:5-247:7). The term “diameter” in the asserted claims is not used to convey a precise mathematical concept but only to limit the claims to vent holes where one end of the hole is a different size from the other end of the hole. As the Staff said at the *Markman* hearing, “it probably doesn’t even need to be an ellipse, it can be regularly shaped or a square. The point is that the opening is bigger on the one end than the other.” (Tr. at 258). The patent does not specify any particular shape for its holes, and several figures appear to depict square or rectangular holes in a mesh. (See ’487 Patent at Figs. 2, 3, 6, 7, 8, 9). I thus find that it is inappropriate to limit the construction of “diameter” to circles or ellipses in the context of this invention. ResMed cited Webster’s Online Dictionary in its Reply Brief defining “diameter” as “a straight line from one side of something (such as a circle) to the other side that passes through the center point” or “the distance through the center of something from one side to the other.” (CMRB at 30). I find that this general definition more closely aligns with the use of the term diameter in the ’487 Patent, where the diameter is only used to compare the size of two ends of a hole. Also, I find that the term diameter is used in the claims to refer to a

length or distance rather than to a line segment itself. (*See, e.g.* '487 Patent at 9:18-22 (“the first end has a different diameter than a diameter of the second end.”))

Respondents’ argument that a broad construction would render the term indefinite is not well founded. A claim is indefinite only if “one of ordinary skill in the art could not discern the boundaries of the claim based on the claim language, the specification, the prosecution history, and the knowledge in the relevant art.” *Haemonetics Corp. v. Baxter Healthcare Corp.*, 607 F.3d 776, 783 (Fed. Cir. 2010). In this case, one of ordinary skill in the art would know that to compare the size of two ends of a hole, one would choose corresponding diameters, whether that is the shortest distance through the center, the longest distance through the center, or some other convenient measurement.

Accordingly, I find that the term “diameter” shall be construed to have its plain and ordinary meaning, which is “distance through the center from one side to the other.”

VIII. THE '453 PATENT

A. Overview

U.S. Patent No. RE44,453 (“the '453 Patent”) is entitled “Humidifier with Structure to Prevent Backflow of Liquid through the Humidifier Inlet” and it reissued on August 27, 2013 with 98 claims, naming inventors Alexander Virr, Ian Malcolm Smith, Perry David Lithgow, Richard Llewelyn Jones, and Andrew Cheung. The '453 Patent is a reissue of U.S. Pat. No. 7,614,398 (“the '398 Patent”), which originally issued on November 10, 2009.

The patent describes a humidifier for a CPAP apparatus that is adapted to prevent liquid from undesirably exiting an inlet of the humidifier. ('453 Patent at 1:53-56). The '453 Patent has 98 claims, with claim 1 provided below:

1. A humidifier assembly for a CPAP apparatus, comprising
a humidifier including

a base configured to retain a body of liquid therein, at least a portion of the base being constructed of a heat conducting material,

a top cover, and

a seal disposed between the top cover and the base; and

a connecting structure configured to connect between the CPAP apparatus and humidifier and allow communication of an outlet of the CPAP apparatus with an inlet of the humidifier, the connecting structure including

a housing providing a base portion to support the humidifier thereon, and

a retaining mechanism configured to secure the connecting structure to the CPAP apparatus,

wherein the base portion includes a heating element in contact with the heat conducting material of the base of the humidifier.

(’453 Patent at 1:38-56).

B. Disputed Claim Terms

12. “base configured to retain a body of liquid therein”

The parties dispute the proper construction of the term “base configured to retain a body of liquid therein,” which appears in claim 1 of the ’453 Patent. Respondents have proposed “base capable of retaining the body of liquid used with the humidifier” while ResMed contends that no construction is necessary and the Staff submits that this term has its plain and ordinary meaning, which is the claim language:

| ResMed | Respondents | Staff |
|----------------------------|---|---|
| No construction necessary. | base capable of retaining the body of liquid used with the humidifier | Plain and ordinary meaning, which is the claim language |

Respondents argue that the term “a body of liquid” should be construed to refer to the “body of liquid used with the humidifier,” not just any amount of liquid. (Tr. at 117; RMSB at 1-2). This construction seeks to distinguish the claim from Respondents’ products, where water fills a top chamber and only a small amount of liquid reaches the bottom. (Tr. at 112-113, 127-130; RMIB at 14-15). Respondents contend that the patentees defined the term “a body of liquid” as

having “a maximum volume V_{max} ” in the specification, and that the claim language should be read in light of the specification. (Tr. at 116-117, 131-137; RMRB at 12; RMSB at 1-2).

Respondents assert that retaining the entire body of liquid is necessary to achieve the overall object of the invention and that this feature overcame disadvantages in the prior art related to backflow of water into the apparatus. (RMRB at 13-14). Further, Respondents suggest that ResMed intentionally worded the claim as “a body of liquid” rather than “the body of liquid” to avoid antecedent basis issues during prosecution, and that ResMed is attempting to expand the scope of the claim to cover products it did not invent. (RMSB at 3). Finally, Respondents argue that it is necessary to construe this term because under ResMed’s construction, “a body of” would not add meaning to the claim. (RMRB at 11; RMSB at 3).

ResMed adopted the Staff’s construction of plain and ordinary meaning. (CMRB at 34). ResMed contends that the claim language “a body of liquid” does not impose any limitations on the amount or purpose of the liquid. (CMRB at 35; CMSB at 8). ResMed argues that Respondents have confused the “base” and the “receptacle” in the patent specification. (CMRB at 35). In ResMed’s view, adopting Respondents’ construction would improperly read in limitations from the specification that are not required by the claim. (CMRB at 34-35; CMSB at 8). ResMed argues that the term “a body of liquid” is clear and that the specification contains no specific requirement that the base hold all of the water. (CMSB at 8). ResMed further argues that Respondents’ suggested construction of “used with the humidifier” is superfluous, and that the claim does not focus on how the liquid is used but rather on the structure of the humidifier. (CMSB at 9). At the *Markman* hearing, ResMed also responded to Respondents’ arguments regarding the alleged purpose of the invention, characterizing the “no-spill feature” described in the specification as another invention that is claimed in a parent of the ’453 Patent. (Tr. at 138-141).

The Staff has consistently argued that the plain and ordinary meaning of the term is the correct construction for this term. (SMIB at 9; SMSB at 1). In particular, the Staff disagrees with Respondents' interpretation of column 4 of the specification, which the Staff interprets as referring to the maximum volume of liquid in the humidifier, not the base. (Tr. at 119; SMSB at 2). The Staff also agreed with ResMed that the phrase "used with the humidifier" in Respondents' construction is superfluous. (Tr. at 119).

I agree with ResMed and the Staff that the term should be interpreted according to its plain and ordinary meaning. "Though understanding the claim language may be aided by explanations contained in the written description, it is important not to import into a claim limitations that are not part of the claim." *Superguide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004). The claim language is "*a* body of liquid," not *the* body of liquid, and adopting Respondents' proposed construction would improperly impart a meaning to the word "*a*" that is inconsistent with its plain meaning. While Respondents raised various arguments regarding the alleged "overall object" of the invention, the only support they identified in the specification was related to a goal of "prevent[ing] liquid from exiting through the inlet at orientations of the humidifier up to an angle of about 90° from the working upright orientation." ('453 Patent at 9:1-6). This object does not appear to be related to the claims of the '453 Patent, and as the Federal Circuit has held: "An invention may possess a number of advantages or purposes, and there is no requirement that every claim directed to that invention be limited to encompass all of them." *E-Pass Technologies, Inc. v. 3Com Corp.*, 343 F.3d 1364, 1370 (Fed. Cir. 2003). I agree with ResMed and the Staff that the references to a maximum volume of liquid in the specification refer to the entire humidifier or the receptacle, and not to the base. (See '453 Patent at 4:42-43 ("The humidifier is designed to carry a body of liquid having maximum volume, V_{max} .")).

While Respondents correctly cite case law supporting a general rule that “all claim terms are presumed to have meaning in a claim,” *Innova/Pure Water*, 381 F.3d at 1119, construing “a body” as “the body” does not provide any additional meaning to this term; it merely attempts to rewrite the claim language. Moreover, any speculation as to ResMed’s strategic avoidance of antecedent basis issues during prosecution has no bearing on the claim construction of this term. The claim language is “a body of liquid,” and there is no support in the patent specification for rewriting this term.

Accordingly, I find that the term “base configured to retain a body of liquid therein” shall be construed to have its plain and ordinary meaning.

13. “a seal disposed between the top cover and base”

The parties dispute the proper construction of the term “a seal disposed between the top cover and the base,” which appears in claim 1 of the ’453 Patent. Respondents have proposed “a seal which separates the top cover and the base into two chambers” while ResMed contends that no construction is necessary and the Staff submits that this term has its plain and ordinary meaning, which is the claim language:

| ResMed | Respondents | Staff |
|----------------------------|---|---|
| No construction necessary. | a seal which separates the top cover and the base into two chambers | Plain and ordinary meaning, which is the claim language |

Respondents associate the claimed seal with the “sealing gasket” in the ’453 Patent specification. (Tr. at 149-151; RMIB at 18-19; RMRB at 16; RMSB at 4-5). This gasket is labeled as item 38 in the specification, which states: “The gasket 38 is disposed between the top cover 36 and base 40.” (’453 Patent at 42-43). Respondents point to figures 7 and 8 as showing that this sealing gasket divides the top cover and base into two chambers. (RMIB at 19).

Respondents argue that this gasket is the claimed “seal” because it is described as “the *sealing* gasket” and because of the matching “disposed between” language in the claims and specification. (RMRB at 16). Respondents also cite inventor testimony referring to the gasket as a seal. (RMRB at 16; RMSB at 5). In Respondents’ view, dividing the chamber between the top cover and base achieves a purpose of the invention to prevent backflow into the apparatus. (RMRB at 17-18; RMSB at 5).

ResMed does not believe that this term requires construction and disagrees with Respondents’ importation of additional limitations from the specification. (CMIB at 49; CMSB at 9). ResMed points out that the specification uses the word “divider” to describe a structure that separates the top cover from the base. (CMIB at 50; CMRB at 38-39). ResMed cites a parent patent, U.S. Pat. No. 6,935,337, where a “divider” was explicitly claimed and argues that this is evidence that “seal” and “divider” have different meanings. (Tr. at 161-163; CMRB at 39). ResMed also cites a dependent claim that was withdrawn during prosecution that included a limitation separating the top cover and base into separate chambers. (CMIB at 51). ResMed strongly disputes Respondents’ reading of the specification as conflating the claimed seal with the gasket in the specification. (CMIB at 50-51; CMRB at 38). ResMed argues that the “sealing flange 58,” which is “formed about the periphery” of the gasket, forms the seal recited in the claim. (Tr. at 157-160; CMSB at 10). ResMed argues that the ordinary meaning of this term should be applied, and “disposed” simply means “to put in place,” which does not suggest separation. (CMSB at 9-10). And ResMed argues that its construction is consistent with the rest of the claim, which is focused on preventing liquid from leaking out of the apparatus all together, rather than leaking between chambers. (CMSB at 10).

The Staff proposes that the term should be construed according to its plain and ordinary meaning. (SMIB at 11-12; SMSB at 3). The Staff argues that Respondents’ construction confuses

the term “seal” with the “divider” in the specification. (SMSB at 11-12; SMSB at 3). In particular, the Staff notes that while the gasket may serve as both the claimed seal and a divider, the specification clarifies that the seal need not necessarily divide. (SMSB at 3).

I agree with ResMed and the Staff and find that the proper construction of the term is its plain and ordinary meaning. The ’453 Patent clearly describes both a sealing gasket and a divider, but does not equate the two: “The top cover 36 may also include a divider wall structure 56 (FIG. 8) which corresponds to and is received within the channel structure 46 of the gasket 38. The gasket 38 includes a sealing flange 58 formed about a periphery thereof.” (’453 Patent at 6:61-65). Respondents’ arguments linking the term “disposed between” to a “separation” are unpersuasive because, although “disposed” is used to describe the relationship between the top cover, base and divider (*Id.* at 2:37-38), “disposed” is also used to describe many other spatial relationships between components in the specification (*See, e.g., id.* at 2:18-20 (“the humidifier is disposed in the working upright orientation”), at 3:31-33 (“the volume of a second portion of the second chamber, which is disposed to the side of the first chamber”), 6:5-6 (“the inlet 22 is disposed below the level of the liquid body 26”)). As discussed at the *Markman* hearing, “disposed between” just means positioned between, which does not imply any separation. (Tr. at 146-148).

While Respondents cite language from the specification emphasizing the importance of separating the top cover and base for the purpose of the invention, none of this evidence ties to the claimed seal. Even if Respondents were correct that a divider between the top cover and base was an important feature of the invention, “each claim need not include every feature of an invention.” *AllVoice Computing PLC v. Nuance Communications, Inc.*, 504 F.3d 1236, 1248 (Fed. Cir. 2007). The disputed term is a seal, and as discussed at the *Markman* hearing, a seal can be formed around the edge of a connection, like a head gasket on a car engine, which does not separate two

chambers but allows air to flow between the chambers without leaking. (Tr. at 147-154). As ResMed and the Staff point out, the '453 Patent discloses such a seal: "a sealing flange formed about a periphery thereof." ('453 Patent at 6:64-65). Respondents have not identified sufficient evidence in the '453 Patent to read a separation limitation into the claims, and I therefore find that the claimed seal may be disposed between the top cover and the base without separating the two.

Accordingly, I find that the term "a seal disposed between the top cover and the base" shall be construed to have its plain and ordinary meaning.

IX. CONCLUSION

I find that the disputed terms of the asserted patents shall be construed as follows:

- The term "notch" in the '392 and '527 Patents shall be construed to have its plain and ordinary meaning, which is an "indentation, depression, recess or cutout region."
- The term "an aperture extending from the first side to the second side" in the '527 Patent shall be construed as "an opening extending from the first side to the second side."
- The term "channel having an inner wall, an outer wall, and a channel floor" in the '060 Patent shall be construed to have its plain and ordinary meaning.
- The term "respiratory mask assembly" in the '116 Patent shall be construed as "a patient interface assembly that surrounds the nose or nose and mouth of a patient."
- The term "respiratory mask assembly" in the '267 Patent shall be construed as "a patient interface assembly that surrounds the nose or nose and mouth of a patient."
- The term "quick-release elbow assembly" in the '267 Patent shall be construed to have its plain and ordinary meaning.

- The term “quick release attachment to and detachment from the frame” in the ’267 Patent shall be construed to have its plain and ordinary meaning.
- The term “quickly releasable from the frame” in the ’267 Patent shall be construed to have its plain and ordinary meaning.
- The term “quick-release mechanism” in the ’267 Patent shall be construed to have its plain and ordinary meaning.
- The term “gas washout vent” in the ’487 Patent shall be construed to have its plain and ordinary meaning, which is “vent for exhausting gas to the atmosphere.”
- The term “diameter” in the ’487 Patent shall be construed to have its plain and ordinary meaning, which is “distance through the center from one side to the other.”
- The term “base configured to retain a body of liquid therein” in the ’453 Patent shall be construed to have its plain and ordinary meaning.
- The term “a seal disposed between the top cover and the base” in the ’453 Patent shall be construed to have its plain and ordinary meaning.

SO ORDERED.

A handwritten signature in black ink, reading "Thomas B. Pender", with a long horizontal line extending to the right.

Thomas B. Pender
Administrative Law Judge

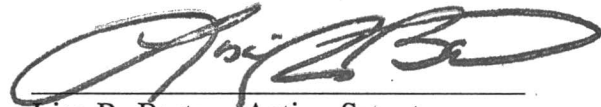
**IN THE MATTER OF CERTAIN SLEEP-DISORDERED
BREATHING TREATMENT SYSTEMS AND COMPONENTS
THEREOF**

337-TA-890

CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **PUBLIC ORDER NO. 8** has been served upon, **The Office of Unfair Import Investigations** and the following parties on

JAN 17 2014



Lisa R. Barton, Acting Secretary
U.S. International Trade Commission
500 E Street, S.W., Room 112A
Washington, DC 20436

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