

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BMC MEDICAL CO. LTD., 3B PRODUCTS, L.L.C., and
3B MEDICAL INC.,
Petitioner,

v.

RESMED LIMITED,
Patent Owner.

Case IPR2014-01363
Patent RE 44,453 E

Before MEREDITH C. PETRAVICK, BARRY L. GROSSMAN, and
CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

Opinion for the Board filed by *Administrative Patent Judge* PAULRAJ.

Opinion Dissenting-in-Part filed by *Administrative Patent Judge*
PETRAVICK.

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

I. BACKGROUND

BMC Medical Co. Ltd., 3B Products, L.L.C., and 3B Medical Inc. (collectively “Petitioner”) filed a Petition for *inter partes* review of claims 9–19, 23–36, 40, and 63 of U.S. Patent No. RE 44,453 E (Ex. 1001, “the ’453 patent”) pursuant to 35 U.S.C. §§ 311–319 and 37 C.F.R. §§ 42.1–42.123. Paper 2 (“Pet.”). ResMed Limited (“Patent Owner”) filed a Preliminary Response. Paper 6. Taking into account the Petition and Patent Owner’s Preliminary Response, we determined that there was a reasonable likelihood that challenged claims 9–19, 23–36, 40, and 63 are unpatentable. Pursuant to 35 U.S.C. § 314, we instituted *inter partes* review, on January 21, 2015, as to claims 9–19, 23–36, 40, and 63 of the ’453 patent. Paper 7 (“Dec.”).

After institution, Patent Owner filed a Patent Owner Response (Paper 12, “PO Resp.”). Petitioner filed a reply to the Patent Owner Response. Paper 13 (“Pet. Reply”). Additionally, Petitioner filed a Motion to Exclude Evidence (Paper 14), to which Patent Owner filed an Opposition (Paper 18). Petitioner filed a Reply in Support of its Motion to Exclude (Paper 20).

A hearing was held on September 16, 2015, a transcript of which appears in the record. Record of Oral Hearing, Paper 24 (“Tr.”).

We have jurisdiction under 35 U.S.C. § 6(c). This decision is a final written decision under 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73 as to the patentability of the challenged claims. For the reasons discussed below, we determine that Petitioner has shown by a preponderance of the evidence that claims 9–19, 25–36, 40, and 63 are unpatentable. Petitioner’s Motion to Exclude Evidence is dismissed as moot.

A. Related Proceedings

In addition to this proceeding, we have instituted an *inter partes* review of claims 1–7 of the ’453 patent based on a separate petition filed by the same Petitioner. See Case IPR2014-01196, Decision on Institution of *Inter Partes* Review (PTAB Jan. 21, 2015) (Paper 7).

A separate petition for *inter partes* review challenging claims 1–7 of the ’453 patent was filed by Apex Medical Corp. in Case IPR2014-00551. That proceeding was terminated based on settlement prior to our decision on institution. See Case IPR2014-00551, Judgment (PTAB Sept. 12, 2014) (Paper 11).

The ’453 patent is a reissue of U.S. Patent No. 7,614,398 (“the ’398 patent”). Claims 8–98 were added in the reissue.

The ’398 patent was initially asserted in an investigation before the U.S. International Trade Commission (ITC), *In the Matter of Certain Sleep-Disordered Breathing Treatment Systems and Components Thereof*, ITC Investigation No. 337-TA-890, but was later substituted with the ’453 patent. Pet. 2; Ex. 1007; Ex. 1022. Patent Owner has also asserted the ’398 patent in *ResMed Inc. v. BMC Medical Co., Ltd., et al.*, 313-cv-01246 (S.D. Cal), and *ResMed Inc. et al v. Apex Medical Corporation et al.*, 8:13-cv-00498 (C.D. Cal), which have been stayed pending the outcome of the ITC investigation and the Board’s *inter partes* review. Pet. 2; Ex. 1008; Ex. 1009.

B. The ’453 Patent

The ’453 patent relates to a humidifier for use with a continuous positive airway pressure (CPAP) device. Ex. 1001, 1:25–28. As the ’453 patent explains, humidification of air delivered to CPAP patients may

increase comfort. *Id.* at 1:31–33. To this end, manufacturers often supply humidifiers which may be attached in the air circuit between the blower outlet and the patient interface of a CPAP device. *Id.* at 1:33–35.

In describing the prior art, the '453 patent explains that “[t]ypically, the blower and humidifier are separate components connected via a flexible conduit” wherein “[a]n air delivery conduit connects the humidifier outlet to a patient interface mask,” or “[a]lternatively, the blower and humidifier may be rigidly-connected together” wherein “[a]ir from the blower outlet passes into the humidifier inlet where it is humidified and then passes to the air delivery conduit.” *Id.* at 1:40–46. However, “[a] potential problem with either arrangement is that if the humidifier is tilted relative to its normal orientation, water may run or spill from the humidifier into the blower outlet which may damage the electrical circuits of the blower and potentially cause infection control problems.” *Id.* at 1:46–50.

The '453 patent seeks to address this problem with the humidifier embodiments disclosed therein. For example, one embodiment of a humidifier in a non-working, upright orientation is shown in Figure 10, reproduced below:

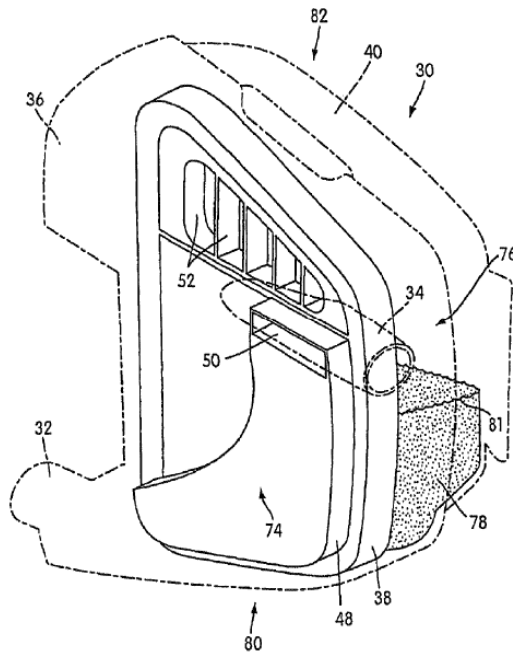


Figure 10 shows a humidifier 30 for a CPAP apparatus that “is rotated to an angle about 90° from the working upright orientation, such that a side 80 thereof corresponding to the side of the humidifier 30 adjacent the inlet 32, is oriented below a side 82 thereof corresponding to the side of the humidifier 30 adjacent the outlet 34.” *Id.* at 8:29–34. “Because the raised portion 48 of the gasket 38 increases the volume of the second chamber 76, the body of liquid 78 remains only in the second chamber 76 and the level 81 of the liquid body 78 remains below the first aperture 50. Thus, the liquid will not exit through the inlet 32.” *Id.* at 8:34–38.

The '453 patent contemplates that the humidifier “may be used as a retrofit or add-on component for a CPAP apparatus.” *Id.* at 9:25–26. To facilitate this usage, the '453 patent also discloses the use of “a connecting structure 100 that is configured to connect between the CPAP apparatus and humidifier 30.” *Id.* at 9:26–29. In certain embodiments illustrated in the patent, “the connecting structure 100 includes a housing 102, which provides

a generally horizontally extending receptacle 104 within which the humidifier 30 may be disposed. The housing 102 provides a base portion 106 that is configured to support the humidifier 310 thereon and a retaining portion 108 configured to secure the humidifier 30 in position.” *Id.* at 9:30–35.

C. Illustrative Claims

The challenged claims of the ’453 patent were added during the reissue proceeding. Reissued claims 9, 23, and 25 of the ’453 patent are illustrative, and reproduced below:

9. A humidifier for humidifying a flow of breathable gas to be delivered to a patient, the humidifier comprising:

a humidifier body configured to retain a body of liquid having a predetermined maximum volume, the humidifier body comprising:

a first chamber having a first chamber inlet configured to receive the flow of breathable gas, and

a second chamber in communication with the first chamber through a passage, the second chamber being structured to contain a predetermined maximum volume of liquid when the humidifier body is in a normal upright, operating position, the second chamber comprising a second chamber outlet configured to deliver the flow of breathable gas with added humidity,

wherein the first chamber, the second chamber, and the passage are arranged such that when liquid is contained in the second chamber in the upright, normal operating position, the possibility of liquid flowing from the second chamber through the passage is reduced or prevented, and liquid that flows from the second chamber and through the passage is collected in the first chamber such that

liquid is discouraged or prevented from spilling back from the first chamber inlet when the humidifier body is inadvertently rotated from the upright, normal operating position to a non-upright position.

23. An apparatus for supplying breathable gas under pressure, comprising:

- a blower to generate a flow of pressurized breathable gas;

- the humidifier according to claim 9 structured to reduce risk of or prevent spillback of liquid from the humidifier to the blower;

- a connecting structure configured to connect between the blower and the humidifier and allow communication of an outlet of the blower with the first chamber inlet of the humidifier; and

- an air delivery conduit in communication with output from the humidifier.

25. A humidifier assembly for a CPAP apparatus, comprising:

- a humidifier that defines a reservoir for a body of liquid, and a fluid passage between an inlet provided at a rear side of the humidifier and an outlet of the humidifier for exposure of a flow of breathable gas from the CPAP apparatus to the body of liquid, the humidifier comprising

- a base configured to retain the body of liquid therein and including a heat conducting material, and

- a top cover that covers the base, the top cover including the outlet; and

- a connecting structure configured to connect between the CPAP apparatus and humidifier and allow communication of an outlet of the CPAP apparatus with the inlet of the humidifier, the connecting structure comprising a housing, the housing providing a generally horizontal, open

receptacle within which the humidifier may be removably disposed by generally horizontally inserting the humidifier within and pulling it out of the receptacle, the housing comprising a base portion forming a lower surface of the receptacle and configured to support the humidifier thereon, a heating element positioned on the lower surface and in thermal contact with the heat conducting material of the base when the humidifier is disposed in the receptacle, and a retaining portion positioned adjacent the top cover of the humidifier and being spaced above the base portion, the retaining portion being configured to assist in retaining the humidifier in the generally horizontal receptacle.

D. Grounds for Unpatentability

We instituted *inter partes* review of the '453 patent based upon the following grounds of unpatentability:

- A. Anticipation of claims 9–19, 40, and 63 by Wilson;¹
- B. Obviousness of claims 23 and 24 over Wilson and Dobson;²
- C. Anticipation of claims 25–27 by HumidAire;³
- D. Obviousness of claim 28 Over HumidAire and Helot;⁴
- E. Obviousness of claims 29–31 Over HumidAire, Helot, and Maeda;⁵
- F. Obviousness of claim 32 Over HumidAire, Usry,⁶ and Prime;⁷

¹ U.S. Pat. No. 1,085,833, iss. Feb. 3, 1914 (Ex. 1002).

² U.S. Pat. No. 5,673,687, iss. Oct. 7, 1997 (Ex. 1019).

³ Instruction Manual for Sullivan® HumidAire Humidifier, 1998 (Ex. 1003).

⁴ U.S. Pat. No. 6,185,095 B1, iss. Feb. 6, 2001 (Ex. 1023).

⁵ U.S. Pat. No. 5,870,283, iss. Feb. 9, 1999 (Ex. 1013).

⁶ U.S. Pat. No. 4,588,425, iss. May 13, 1986 (Ex. 1017).

⁷ PCT Publication No. WO 00/21602, pub. Apr. 20, 2000 (Ex. 1018).

- G. Obviousness of Claim 33 Over HumidAire, Helot, Maeda, and Usry; and
- H. Obviousness of Claims 34–36 Over HumidAire, Helot, Maeda, Usry, and Glynn.⁸

Dec. 19.

II. DISCUSSION

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012). Claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

1. “Humidifier”

We determined, in our Decision to Institute, that that the preamble recitations of “humidifier” in all the challenged claims are merely statements of intended use and did not require any specific structure. Dec. 7. Although Patent Owner’s counsel indicated during the oral hearing that the term “humidifier” should be construed as “a device for regulating the amount of water vapor in a specific container or area” (Tr. 40:24–41:6), Patent Owner has not presented any any additional evidence or argument in its Patent Owner Response that would justify modification of our initial claim construction. *See Office Patent Trial Practice Guide*, 77 Fed. Reg. 48,756,

⁸ U.S. Pat. No. 2,780,708, iss. Feb. 5, 1957 (Ex. 1024).

48,768 (Aug. 14, 2012) (parties are not permitted to raise new arguments at oral hearing). There is no intrinsic evidence identified in support of Patent Owner's proposed construction. Nor does Patent Owner's construction impose any particular structural requirements for a "humidifier."

Accordingly, we maintain our determination that "humidifier" is not accorded patentable weight, beyond requiring that the prior-art structure be capable of the claimed use. *See In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

2. *"Connecting structure configured to connect between the CPAP apparatus and humidifier and allow communication of an outlet of the CPAP apparatus with the inlet of the humidifier"*

Patent Owner asserts that the phrase "connecting structure configured to connect between the CPAP apparatus and humidifier and allow communication of an outlet of the CPAP apparatus with the inlet of the humidifier," which is recited in claim 25, should be construed to require a "structure that connects a CPAP apparatus and a standalone humidifier to form an integrated assembly in which the outlet of the CPAP apparatus is allowed to communicate with the inlet of the humidifier without an intermediate hose which must be separately connected to the CPAP outlet and humidifier inlet." PO Resp. 7. Patent Owner asserts that, in order to establish communication between the CPAP outlet and humidifier inlet, "no intervening hose would be present in the circuit between a CPAP and a standalone humidifier." *Id.* at 7–8.

In support of its proposed construction, Patent Owner points out that "[e]very embodiment of the '453 specification that includes a connecting structure also relates to integrated assemblies of CPAP and humidifier

devices.” *Id.* at 8. Patent Owner further points to statements in the ’415 patent indicating that a blower and humidifier rigidly connected together is an alternative to a blower and humidifier connected via a flexible conduit, and that one aspect of the invention is “to provide a humidifier that is capable of directly connecting to a CPAP apparatus,” while another aspect of the invention is to “provide a humidifier that has an inlet that is directly connectable with a CPAP apparatus to effectively eliminate a supply tube.” *Id.* at 10 (citing Ex. 1001, 1:40–44, 57–61). Patent Owner further points to arguments and amendments made during the prosecution of both the original ’398 patent and the ’453 reissue where the applicants allegedly distinguished prior art structures with a “standalone humidifier.” *Id.* at 12–15.

Petitioner argues that neither the specification of the ’453 patent nor the prosecution history requires that the connecting structure in claim 25 lack an intermediate hose separately connected to the CPAP outlet and humidifier inlet. Pet. Reply 2–4. We agree with Petitioner.

The specification acknowledges that prior-art blower and humidifier combinations included both those connected via a flexible air delivery conduit as well as those connected rigidly. Ex. 1001, 1:40-44. There is nothing in the claim language that would distinguish between these two types of structures. Moreover, we find that the portions of the specification cited by Patent Owner referring to “aspects” of the invention where the humidifier is directly connected to the CPAP apparatus refer to only certain embodiments of the invention, but do not otherwise limit the claimed “connecting structure.” Although the preferred embodiments taught in the ’453 patent utilize rigid connecting structures rather than a flexible hose, the claims are not so limited. The Federal Circuit has “expressly rejected the

contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment.” *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004).

Furthermore, we do not find that applicants clearly disclaimed connecting structures utilizing a flexible hose during prosecution. Rather, applicants only argued that the “casing 28” in the structure of the prior art Grant reference did not meet the “connecting structure” requirement, but did not otherwise disavow the use of a connecting hose. Ex. 1011 (‘398 File History), 49-50.

We further note that claim 23 of the ’453 patent also recites “a connecting structure configured to connect between the blower and the humidifier and allow communication of an outlet of the blower with the first chamber inlet of the humidifier.” Although the language used is slightly different, we find no reason to distinguish the connecting structure of claim 25 from the structure of claim 23.

Accordingly, under a broadest reasonable interpretation, we decline to construe the claimed “connecting structure” to exclude the use of an intermediate hose.

3. *“generally horizontal, open receptacle within which [a] humidifier may be removably disposed by generally horizontally inserting the humidifier within and pulling it out of the receptacle”*

Patent Owner also asserts that the phrase “generally horizontal, open receptacle within which [a] humidifier may be removably disposed by generally horizontally inserting the humidifier within and pulling it out of the receptacle” in claim 25 should be construed to require that

the connecting structure housing has a generally horizontally extending opening that receives the humidifier and provides a resting place in which the humidifier is disposed, wherein the horizontal opening also is configured such that the humidifier is both inserted into the generally horizontally extending opening and pulled out of that opening by way of predominantly horizontal motion.

PO Resp. 17. Relying upon the Random House Webster's Dictionary, Patent Owner argues that "[t]he appropriate definition for 'generally' in the context of this phrase is 'with respect to the larger part; for the most part: a generally accurate interpretation of the facts.'" *Id.* at 18 (citing Ex. 2011, 795). As such, Patent Owner argues that "the words 'generally horizontal' requires that the receptacle be arranged for a humidifier to be inserted into the receptacle, or removed from the receptacle, in a predominantly horizontal manner," i.e., a "side-loading" humidifier. *Id.* at 18, 24. As further support, Patent Owner points to the embodiments illustrated in Figures 14 and 15 as showing a "connecting structure 100 [that] includes a housing 102, which provides a generally horizontally extending receptacle 104 within which the humidifier 30 may be disposed." *Id.* at 19 (citing Ex. 1001, 9:29–34)

We are unpersuaded by Patent Owner's arguments. The specification does not define "generally horizontal" as "predominantly horizontal," nor do we find any basis to limit the claims to the "side-loading" humidifiers described with respect to the the embodiments of Figures 14 and 15. In the context of the claims, the term "generally" is more akin to the modifier "about," and is thus intended to convey *less* precision when ascertaining whether the "open receptacle" and/or the act of inserting the humidifier is horizontal. See Ex. 2011, 795 (defining "generally" as "1. usually;

commonly, ordinarily: *He generally comes home at noon.* 2. with respect to the larger part; for the most part: *a generally accurate interpretation of the facts. . . .*”). Accordingly, we find nothing in the intrinsic evidence to suggest that a “generally horizontal, open receptacle” requires that the humidifier be inserted or received into the receptacle at any particular angle (e.g., 90 degrees). *See also* Tr. 59:15–61:6 (Patent Owner’s counsel declining to identify particular angle of insertion that qualifies as “generally horizontal.”) Furthermore, as we indicated in our Decision to Institute, the recitation “may be removably disposed” in this phrase indicates merely that the housing must be capable of allowing for a generally horizontal insertion and removal of the humidifier. Dec. 14. No particular structure is required to achieve this capability.

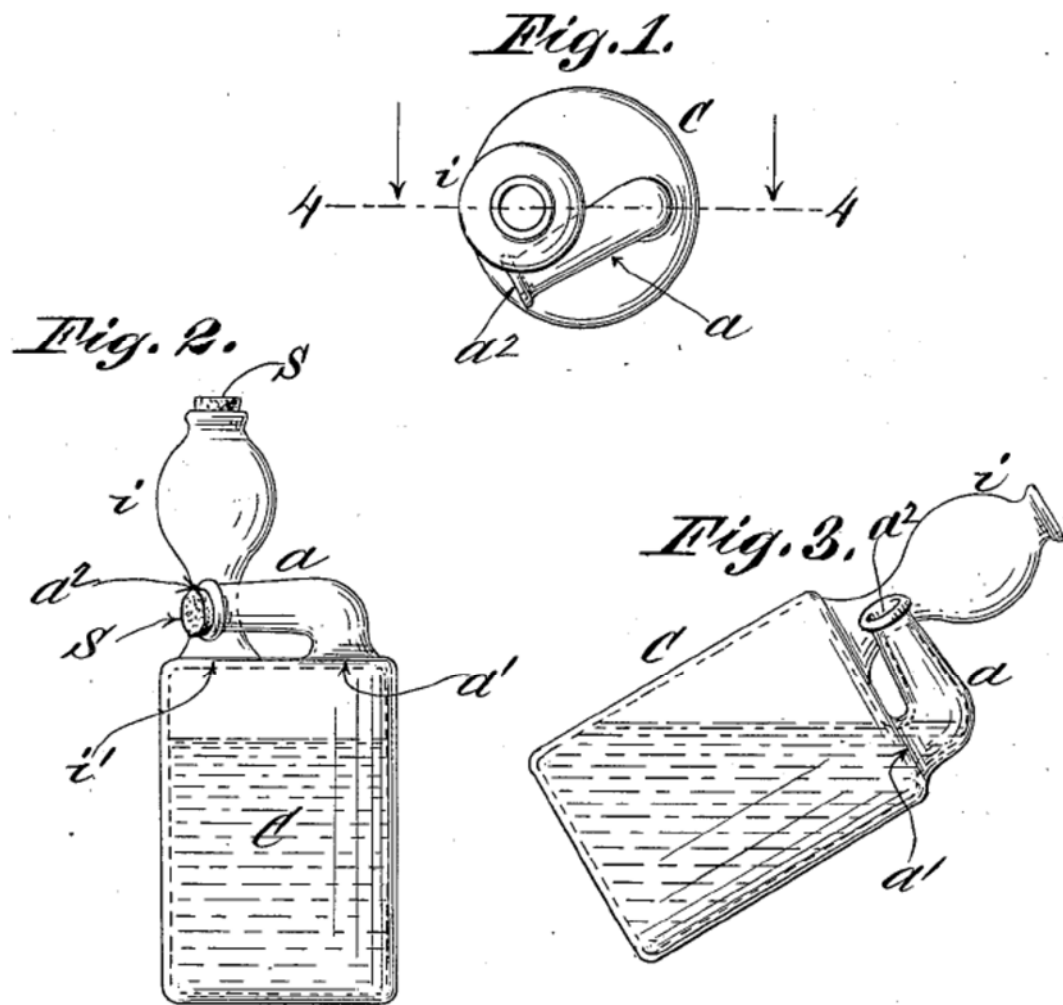
We therefore decline to adopt Patent Owner’s construction for this phrase, and otherwise apply the broadest reasonable interpretation of the claim language in our analysis.

4. *Other Claim Terms*

We determine that no express claim construction for any other term is required for purposes of this decision.

B. Anticipation of Claims 9–19, 40, and 63 by Wilson

Wilson, an early patent issued in 1914, discloses a vaporizing inhaler for delivering medication. Ex. 1002, 1:8–10. Wilson’s Figures 1, 2, and 3 are reproduced below.



Figures 1 and 2 show top and elevation views, respectively, of a vaporizing inhaler in an upright position, and Figure 3 shows an elevation view of the vaporizing inhaler in a tilted position. As shown in Wilson's Figure 2, the device includes container C, which contains a quantity of liquid, an air inlet duct a, which communicates with container C by air inlet port a^1 and draws in air from outside through exterior port a^2 . *Id.* at 1:40–52. There is also an inhalation nozzle I, which communicates with container C by vapor exhaust port i^1 . Wilson's Figure 1 indicates the relative positions of the inlets. In use, air sucked into the device is pulled over the liquid, which impregnates the air with medicinal vapor. *Id.* at 1:75–78. Fig. 3

illustrates an alternate mode of use, in which the device is tilted in order to pull air through the liquid. *Id.* at 1:70–74. When the device is tilted, the liquid is caught in air inlet duct *a* to prevent spillage. *Id.* at 1:54–61.

Petitioner argues that Wilson discloses all limitations of claims 9–19, 40, and 63 in the claimed arrangements. Pet. 8–12; 12–26 (chart). Patent Owner has not directed any arguments to this anticipation challenge. As we indicated in our Scheduling Order, “any arguments for patentability not raised in the [Patent Owner’s] response will be deemed waived.” Paper 8, 5. Upon consideration of the arguments and evidence made of record in this proceeding, we determine that Petitioner has demonstrated by a preponderance of the evidence that Wilson anticipates claims 9–19, 40, and 63.

C. Obviousness of Claims 23 and 24 over Wilson and Dobson

Claim 23 recites an “apparatus for supplying breathable gas under pressure,” comprising a blower, “the humidifier according to claim 9 structured to reduce risk of or prevent spillback of liquid from the humidifier to the blower,” a connecting structure, and an air delivery conduit. Claim 24 depends from claim 23, and further requires a “patient interface connected to the air delivery conduit.”

Petitioner contends that these claims are rendered obvious by the combination of Wilson and Dobson. As discussed above, Petitioner has demonstrated—without dispute from Patent Owner—that Wilson teaches the humidifier of claim 9. Petitioner contends that the other features of the apparatus of claims 23 and 24 are satisfied by Dobson. Pet. 27–28. In particular, Dobson discloses an apparatus for supplying breathable gas under pressure, comprising a ventilator 1 with a variable speed fan 3 to generate a

flow of pressurized breathable gas to a humidifier 2. Ex. 1019, 3:9-20, Figs. 1–3. Dobson also discloses a seal member 44' configured to connect between the ventilator 1/variable speed fan 3 and the humidifier 2 and allow communication of an air outlet 7 of the ventilator 1/ variable speed fan 3 with an air inlet 44 of the humidifier 2. *Id.* at 6:11–39, Fig. 16. Further, as shown in Fig. 1, Dobson discloses an air delivery conduit in communication with an output 48 from the humidifier 2, and a patient interface connected to the air delivery conduit. *Id.* 1019 at 4:52–54 and Figs. 1–3 (“the air A then flows around the divider 46 and exits through the outlet 48 and onto the patient”).

Petitioner contends that it would have been obvious for one of ordinary skill in the art to implement the inhaler of Wilson with Dobson's apparatus for supplying breathable gas under pressure. Pet. 28. More particularly, Petitioner asserts:

It also would have been obvious to one of ordinary skill in the art to implement the inhaler of *Wilson* with a seal member 44' configured to connect between the blower 1/variable speed fan 3 and the inhaler and allow communication of the air outlet 7 of the blower 1 with the exterior inlet port a^2 of the inhaler; resulting in reducing risk of or preventing spillback of liquid from the exterior inlet port a^2 of the inhaler to the blower 1/variable speed fan 3. Further, it would have been obvious to one of ordinary skill in the art to implement the inhaler of *Wilson* with an air delivery conduit, connected to a patient interface, in communication with output from the exhaust nozzle *i* of *Wilson*.

Id. at 28–29.

Petitioner asserts that a person of ordinary skill in the art would have been motivated to combine the structures of Wilson and Dobson “in order to provide an automated means by which to provide pressurized air to the inhaler for the treatment of various diseases.” *Id.* at 29. For example, Petitioner asserts that this would be beneficial to patients who “have shallow breathing and lack sufficient energy to produce and inhale adequate pressurized air through the inhaler.” *Id.* Furthermore, according to Petitioner, the combination would “ensure an optimum and effective delivery of the humidified air to the patient after exiting the inhaler” such that “the patient could simply lay in bed and allow the air delivery conduit and patient interface to help deliver the humidified air with or without the addition of medication.” *Id.* at 30. Petitioner also contends that “such a modification of *Wilson* would constitute no more than an obvious design choice.” *Id.*

We find that Petitioner has not demonstrated a sufficient basis to combine the structures of Dobson and Wilson to arrive at the apparatus of claims 23 and 24. We begin with the recognition that the devices taught by Wilson and Dobson are designed for fundamentally different purposes. “[C]ombinations that change the ‘basic principles under which the [prior art] was designed to operate,’ . . . or that render the prior art ‘inoperable for its intended purpose,’ . . . may fail to support a conclusion of obviousness.” *Plas-Pak Indus., Inc. v. Sulzer Mixpac AG*, 600 F. App'x 755, 758 (Fed. Cir. 2015) (citing *In re Gordon*, 733 F.2d 900, 902 (Fed.Cir.1984); *In re Ratti*, 270 F.2d 810, 813 (1959)). Wilson’s inhaler is designed to deliver medication when held to the patient’s mouth manually in one of two ways: 1) by holding the inhaler upright as indicated in Fig. 2, “the air and vapor

may be withdrawn through the inhalation nozzle *i*, from above the surface of the medicated fluid in the container C, without having passed the air through said fluid;” or 2) “by tilting the inhaler as indicated in Fig. 3, the exhaust through the inhalation nozzle will cause the inflow of air through the duct *a*, to pass through the medicated liquid before it can be inhaled.” See Ex. 1002, 2:64–74. It is therefore apparent that Wilson’s device is designed for a conscious patient who can control the amount of medication to be inhaled by tilting the device accordingly. By contrast, Dobson’s apparatus is designed for use on a patient who is sleeping or is otherwise unconscious of his or her breathing, as shown for example in Fig. 1 of Dobson. Contrary to the rationale supplied by Petitioner, there is an insufficient basis on this record to conclude that Wilson’s inhaler could be used properly in its intended manner by patients who are “sick, weak and barely able to get out of bed” and have “shallow breathing and lack sufficient energy to produce and inhale adequate pressurized air through an inhaler.” Pet. 29. For example, Petitioner has not demonstrated how such a patient would be able to tilt Wilson’s inhaler in order to control the amount of medication delivered when the device is connected to the blower 1/variable speed fan 3 taught by Dobson.

Additionally, we find that Dobson teaches away from the type of bottle arrangement used for Wilson’s inhaler. A reference teaches away from a claimed invention when a person of ordinary skill, “upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.” *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). In this case, Dobson teaches:

Early humidifying arrangements were simply bottles filled with water with air inlets and outlets. Later arrangements became more sophisticated but still presented many of the same fundamental problems as the earlier bottle ones.

More specifically, prior humidifying units as typified by the early bottle arrangements are somewhat clumsy to use and difficult to clean.

Ex. 1019, 1:15–22. The solution for this problem that is proposed in Dobson is to use a humidifier that “has a completely separable top and bottom,” which is not the type of arrangement taught in Wilson. *Id.* at 1:39–41. Petitioner acknowledges that Wilson’s inhaler is the type of early humidifying arrangement mentioned as prior art in Dobson, but does not otherwise address Dobson’s criticism and discouragement of using such a bottle arrangement. Pet. 27; Pet. Reply 9–12.

Finally, we find that Petitioner has not explained adequately the specific design considerations that are necessary to implement that apparatus taught by Dobson with Wilson’s inhaler. Rather, Petitioner asserts generally that “a modification of *Wilson* would constitute no more than an obvious design choice,” and “applying the blower providing pressurized breathable gas, air delivery conduit, and patient interface of *Dobson* to the inhaler of *Wilson* would have done nothing more than combine familiar elements according to known methods.” Pet. 30. However, a “design choice” rationale for obviousness is “precluded where the claimed structure and the function it performs are different from the prior art.” *In re Chu*, 66 F.3d 292, 299 (Fed. Cir. 1995) (citing *In re Gal*, 980 F.2d 717 (Fed. Cir. 1992)). The evidence of record shows that the inhalation of medication using Wilson’s inhaler functions differently from the supplying of humidified air to a patient using Dobson’s apparatus. For example, while Dobson’s humidifier consists

of a large-area, shallow tub of water for the blown air to pass over the water, the inhaler of Wilson, when tilted, would require the air coming in through the inlet port a^2 to pass *through* the medicated liquid in order to be withdrawn through the inhalation nozzle *i*. See Ex. 1002, Fig. 3; Ex. 1019, Fig. 3. There is no evidentiary basis to conclude that Dobson's blower 1/variable speed fan 3 could function in that manner when connected to the inlet port a^2 of Wilson's inhaler. See Pet. 28–29. As noted by Patent Owner, at least three design considerations must be taken into account to ensure that sufficient humidity is added to the pressurized air flow in a CPAP apparatus: 1) “the humidifier should provide sufficient water surface area that would be needed to generate the amount of evaporation required to achieve a desired humidity level;” 2) “the humidifier should provide sufficient storage capacity for at least the volume of water that would be needed for a full therapy session” (i.e., 6–8 hours for a night of CPAP therapy); and 3) “the structure of the humidifier should be adapted so that the pressurized air flow from the gas supply apparatus flows substantially over the entire surface of the water, rather than jetting across a portion of the surface area.” Pet. 33 (citing Ex. 2008 (Declaration of John Izuchukwu, Ph.D., P.E.), ¶ 128). Petitioner, however, does not address any of these design considerations in its analysis.

We therefore determine that Petitioner has not demonstrated by a preponderance of the evidence the obviousness of claims 23 and 24 based on a combination of Wilson and Dobson.

D. Anticipation of Claims 25–27 by HumidAire

Petitioner contends that the instruction manual for the Sullivan HumidAire, an earlier CPAP humidifier model sold by Patent Owner,

anticipates claims 25–27 of the '453 patent. Ex. 1003 (“HumidAire”).⁹ Patent Owner does not dispute that HumidAire qualifies as prior art under 25 U.S.C. § 102(b). See Ex. 1012, 1410.

The HumidAire instructions teach a CPAP humidifier, as shown in the annotated Figure below:



Ex. 1003, 2. The illustration above shows a front view of the Sullivan HumidAire humidifier with its various components labeled. According to the instructions, the HumidAire includes a water chamber (circled) that may be filled with water either through one of the first or second connector pipes or by removing the lid and filling the chamber base with water until it is

⁹ During the oral hearing for this proceeding, both Patent Owner and Petitioner sought to make arguments with respect to the physical Sullivan HumidAire device or photographs thereof. See, e.g., Tr. 56:7–24, 64:1–24. However, consistent with the statutory requirement in 35 U.S.C. § 311(b) that the scope of an *inter partes* review is limited to challenges “on the basis of prior art consisting of patents or printed publications,” our consideration of this anticipation challenge is limited to the actual teachings of the HumidAire instruction manual rather than the device itself or any photographs thereof.

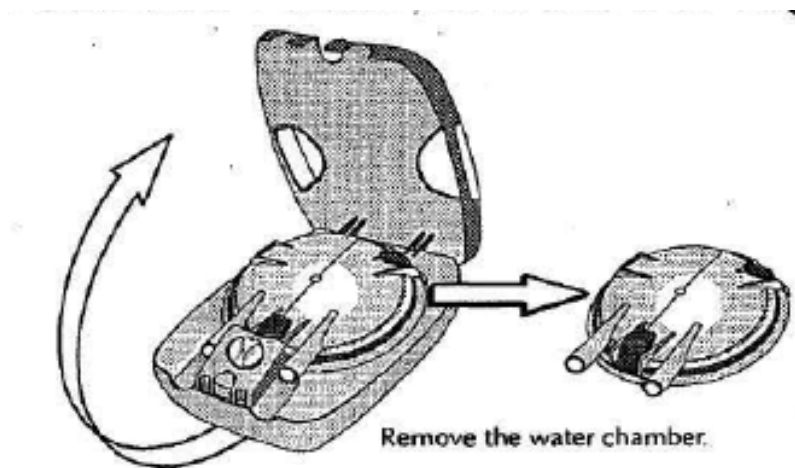
approximately 2/3 full. *Id.* at 3. Once filled with water, the water chamber is positioned over a heater plate within a circular recessed portion (labeled “concavity” in the illustration above) of the HumidAire housing. *Id.* One end of a “short tube” and one end of a “long tube” are each connected to the connector pipes, wherein the free end of the short tub is connected to a “flow generator” (i.e., a CPAP apparatus) while the free end of the long tube is connected to the patient’s mask. *Id.* at 3–4.

Petitioner has included claim charts showing how each of the limitations of claims 25–27 are taught by HumidAire. See Pet. 34–40 (claim chart). Patent Owner makes two arguments with respect to claim 25 regarding this challenge, neither of which we find persuasive.

First, Patent Owner argues that HumidAire does not anticipate claim 25 because it fails to expressly or inherently disclose a “connecting structure configured to connect between the CPAP apparatus and humidifier and allow communication of an outlet of the CPAP apparatus with the inlet of the humidifier.” PO Resp. 48–49. More particularly, Patent Owner asserts that “*HumidAire* does not anticipate claim 25 because it lacks the claimed connecting structure that excludes hose-type connections between the humidifier inlet and the CPAP outlet.” *Id.* at 48 (emphasis removed). We disagree. As noted above, we decline to construe the claimed “connecting structure” to exclude the use of an intermediate hose. Accordingly, the “short tube” used to connect the HumidAire to the CPAP apparatus may be properly considered as part of the claimed “connecting structure.”

Second, Patent Owner argues that “*HumidAire* does not anticipate claim 25 because it lacks a generally horizontal receptacle,” and that Petitioner “offers no evidence to show that *HumidAire*’s water chamber can

be ‘removably disposed by generally horizontally inserting the humidifier within and pulling it out of the receptacle.’” *Id.* at 52–59. Again, we disagree. With respect to the requirement for a “generally horizontal receptacle,” we find this to be taught by the illustrations included with the HumidAire instructions showing a circular recessed portion that is designed to receiver the water chamber. There is no basis to conclude that this recessed portion constitutes a “verticle” receptacle, rather than a “generally horizontal” receptacle as required. Furthermore, with respect to the requirement that “the humidifier may be removably disposed by generally horizontally inserting the humidifier within and pulling it out of the receptacle,” the HumidAire instructions also illustrate this capability, as shown in this Figure:



Ex. 1003, 3. In the illustration above, the presence of the arrow pointing to the right along with the instructions “[r]emove the water chamber” shows plainly that the water chamber may be inserted into and out of the HumidAire housing and receptacle in a generally horizontal fashion. We find this to hold true even assuming that the water chamber must be inserted or removed at an angle within the circular recessed portion (receptacle)

contained in the HumidAire housing. As noted in our claim construction discussion above, the term “generally horizontal” does not require any particular angle of insertion into or removal from the receptacle.

We therefore determine that Petitioner has shown by a preponderance of the evidence that HumidAire anticipates claims 25–27.

E. Obviousness of Claim 28 Over HumidAire and Helot

Claim 28 recites “[a] humidifier assembly according to claim 2 7, further comprising a retaining mechanism to secure the connecting structure to the CPAP apparatus.” With respect to this claim, Petitioner asserts that it would have been obvious to one of ordinary skill in the art to implement HumidAire with a retaining mechanism to secure the flow generator or CPAP on top of the HumidAire housing. Pet. 40–41. Petitioner further relies upon the teachings of Helot (Ex. 1023) for this limitation, and asserts that “[o]ne of ordinary skill in the art would have been motivated to implement the retaining mechanism of *Helot* to prevent the CPAP from falling off the top of the HumidAire housing.” *Id.* at 41

Other than the arguments with respect to independent claim 25 discussed above, Patent Owner does not direct any additional arguments to this obviousness challenge. Upon consideration of the arguments and evidence made of record in this proceeding, we determine that Petitioner has demonstrated by a preponderance of the evidence that claim 28 is unpatentable for obviousness over HumidAire and Helot.

F. Obviousness of Claims 29–31 Over HumidAire, Helot, and Maeda

Claim 29 recites “[a] humidifier assembly according to claim 28, wherein the retaining mechanism comprises a resiliently biased locking member configured to releasably engage a projection of the CPAP

apparatus.” Claim 30 recites “[a] humidifier assembly according to claim 29, further comprising a release member coupled to the resiliently biased locking member to move the resiliently biased locking member out of engagement with the projection of the CPAP apparatus.” Claim 31 recites “[a] humidifier assembly according to claim 30, wherein the release member is provided in the base portion of the housing.” Petitioner relies upon HumidAire combined with the teachings of Helot and Maeda (Ex. 1013) for these limitations. Pet. 47–49. Petitioner asserts that “[a]t the very least, one of ordinary skill in the art would have been motivated to implement the projection of *Maeda* to improve the connection between the flow generator or CP AP and the HumidAire housing,” and that “[b]y implementing the projection in the opening of *Maeda* in the aperture or slot of *Helot*, the connection between the engagement members 36 of docking station 22 with corresponding apertures or slots of the computer 24 could be better secured.” *Id.* at 47.

Other than the arguments with respect to independent claim 25 discussed above, Patent Owner does not direct any additional arguments to this obviousness challenge. Upon consideration of the arguments and evidence made of record in this proceeding, we determine that Petitioner has demonstrated by a preponderance of the evidence that claims 29–31 are unpatentable for obviousness over HumidAire, Helot, and Maeda.

G. Obviousness of Claim 32 Over HumidAire, Usry, and Prime

Claim 32 recites “[a] humidifier assembly according to claim 25, wherein the heat conducting material of the base of the humidifier is provided in an opening in a bottom wall of the base of the humidifier.” With respect to this claim, Petitioner relies upon HumidAire combined with the

teachings of Usry (Ex. 1017) and Prime (Ex. 1018). Pet. 49–52. According to Petitioner, “[i]t would have been obvious to one of ordinary skill in the art to have modified the base of the water chamber of the [HumidAire]

Instructions to incorporate heat conductive material panel of [Usry] in an opening in a bottom wall of the base of the water chamber such that the heat conductive material is positioned next to the heater plate.” *Id.* at 50. As a rationale to combine these teachings, Petitioner asserts that “only having the heat conductive material in an opening in a bottom portion of the base of the water chamber would increase the ability of the water chamber to retain heat for cost effective operation.” *Id.* Based on Prime’s teaching of the advantages of reducing the amount of heat conductive material in a humidifier, Petitioner further asserts that it would have been obvious “to modify the water chamber base of the Instructions to incorporate the flat cup 26 of [Usry], instead of making the entire base of the water chamber out of a heat conductive material” because “[t]his modification would have improved the heat retention at noted in *Prime*.” *Id.* at 51. Petitioner asserts that “[s]uch a modification of the water chamber base of the Instructions to include flat cup 26 of [Usry], as suggested by *Prime*, would have been an obvious combination of familiar elements to yield predictable results.” *Id.*

Other than the arguments with respect to independent claim 25 discussed above, Patent Owner does not direct any additional arguments to this obviousness challenge. Upon consideration of the arguments and evidence made of record in this proceeding, we determine that Petitioner has demonstrated by a preponderance of the evidence that claim 32 is unpatentable for obviousness over HumidAire, Usry, and Prime.

H. Obviousness of Claim 33 Over HumidAire, Helot, Maeda, and Usry

Claim 33 recites “[a] humidifier assembly according to claim 31, wherein the heating element is upwardly biased into engagement with the heat conducting material.” With respect to this claim, Petitioner relies upon HumidAire, combined with the teachings of Helot, Maeda, and Usry. Pet. 52–54. As a rationale for combining the references, Petitioner cites “the advantages of increasing the thermal contact between the heater plate and heat conducting material discussed in [Usry]” as reason why it would have been obvious to “modify the upwardly positioned heater plate of the [HumidAire] *Instructions* to include the spring-loaded heater plate of [Usry], so as to be upwardly biased into engagement with the heat conducting material of the water chamber base.” *Id.* at 53–54.

Other than the arguments with respect to independent claim 25 discussed above, Patent Owner does not direct any additional arguments to this obviousness challenge. Upon consideration of the arguments and evidence made of record in this proceeding, we determine that Petitioner has demonstrated by a preponderance of the evidence that claim 33 is unpatentable for obviousness over HumidAire, Helot, Maeda, and Usry.

I. Obviousness of Claims 34–36 Over HumidAire, Helot, Maeda, Usry, and Glynn

Claim 34 recites “[a] humidifier assembly according to claim 33, wherein the heating element is a resistance heater.” Claim 35 recites “[a] humidifier assembly according to claim 34, further comprising a seal between the heat conducting material and the bottom wall.” Claim 36 recites “[a] humidifier assembly according to claim 35, wherein the

connecting structure includes contact elements that communicate with a power supply, a controller, and/or sensors within the CPAP apparatus.” Petitioner relies upon HumidAire combined with the teachings of Helot, Maeda, Usry, and Glynn (Ex. 1024) for these limitations. Pet. 54–59. Petitioner asserts that the HumidAire’s “ heater plate must be a resistance heater because it operates on electricity, which creates heat through resistance,” but “[t]o the extent the Board finds otherwise, the use of a heater plate that uses a resistance heater is obvious in view of the teachings of *Glynn*.” *Id.* at 55. Petitioner further asserts that the the use of a seal between the heat conducting material and the wall in the bottom of the base would have been an obvious combination of familiar elements according to known methods, as taught by Usry, and “including a seal would prevent the leakage of water from the water chamber.” *Id.* at 56. Additionally, Petitioner asserts that the use of contact elements that communicate with a power supply of a CPAP apparatus would have been an obvious combination of familiar elements according to known methods, as taught by Helot, and “would enable power to be directed to the flow generator or CPAP through the HumidAire housing so that the flow generator or CPAP need not be manually plugged in before use.” *Id.* at 57.

Other than the arguments with respect to independent claim 25 discussed above, Patent Owner does not direct any additional arguments to this obviousness challenge. Upon consideration of the arguments and evidence made of record in this proceeding, we determine that Petitioner has demonstrated by a preponderance of the evidence that claims 34–36 are unpatentable for obviousness over HumidAire, Helot, Maeda, Usry, and Glynn.

III. PETITIONER'S MOTION TO EXCLUDE EVIDENCE

Petitioner moves to exclude certain portions of the Declarations submitted by Patent Owner (Ex. 2008; Ex. 2009), as well as Exhibits 2012–2018. Paper 14. Because our decision does not rely on any of the challenged portions of these exhibits, we dismiss Petitioner's Motion to Exclude Evidence as moot.

IV. CONCLUSION

We conclude that Petitioner has demonstrated by a preponderance of the evidence that claims 9–19, 40, and 63 are anticipated by Wilson, that claims 25–27 are anticipated by HumidAire, that claim 28 is rendered obvious by HumidAire and Helot, that claims 29–31 are rendered obvious by HumidAire, Helot, and Maeda, that claim 32 is rendered obvious by HumidAire, Usry, and Prime, that claim 33 is rendered obvious by HumidAire, Helot, Maeda, and Usry, and that claims 34–36 are rendered obvious by HumidAire, Helot, Maeda, Usry, and Glynn.

This is a final written decision of the Board under 35 U.S.C. § 318(a). Parties to the proceeding seeking judicial review of this decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

V. ORDER

Accordingly, it is

ORDERED that claims 9–19, 25–36, 40, and 63 of U.S. Patent RE 44,453 E are held to be unpatentable;

FURTHER ORDERED that Petitioner's Motion to Exclude Evidence is dismissed as moot;

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

PETRAVICK, *Administrative Patent Judge, joining-in-part and dissenting-in-part*

I join the majority opinion holding that claims 9–19, 25–36, 40, and 63 of the '453 are unpatentable, but I respectfully dissent from the majority regarding the patentability of claims 23 and 24. I determine that Petitioner establishes by a preponderance of the evidence that claims 23 and 24 are unpatentable over Wilson and Dobson.

A. Petitioner's Contentions

Petitioner contends that claims 23 and 24 would have been obvious to one of ordinary skill in the art based upon two alternative arguments to combine Wilson and Dobson. Petitioner first argues that “[i]t would have been obvious to one of ordinary skill in the art to implement the inhaler of *Wilson* with the apparatus for supplying breathable gas under pressure of *Dobson*.” Pet. 28. Under this theory, the resulting combination would be Dobson’s ventilator system with the humidifier replaced by Wilson’s inhaler.

Petitioner, however, alternatively argues that it would have been obvious to one of ordinary skill in the art to modify the inhaler of Wilson to include a blower as in Dobson, “to provide an automated means by which to provide pressurized air to the inhaler for the treatment of various diseases” because “in many cases, patients are sick, weak, and barely able to get out of bed” or “may also have shallow breathing and lack sufficient energy to produce and inhale adequate pressurized air through the inhaler.” Pet. 29 (citing Ex. 1004 ¶ 94). Petitioner further reasons that it would have been obvious to one of ordinary skill in the art to modify the inhaler of Wilson to

include “the air delivery conduit, connected to a patient interface of *Dobson*, to the inhaler of *Wilson* . . . to ensure an optimum and effective delivery of the humidified air to the patient after exiting the inhaler.” Pet. 30 (citing Ex. 1004 ¶ 95). Under this alternate theory, the resulting combination would be *Wilson*’s inhaler with a connected blower and air deliver conduit with a patient interface.

I am persuaded by Petitioner’s alternate combination that claims 23 and 24 are unpatentable over *Wilson* and *Dobson*.

B. Analysis

Claims 23 and 24 are reproduced below.

23. An apparatus for supplying breathable gas under pressure, comprising:
- a blower to generate a flow of pressurized breathable gas;
 - the humidifier according to claim 9 structured to reduce risk of or prevent spillback of liquid from the humidifier to the blower;
 - a connecting structure configured to connect between the blower and the humidifier and allow communication of an outlet of the blower with the first chamber inlet of the humidifier; and
 - an air delivery conduit in communication with output from the humidifier.

24. An apparatus according to claim 23, further comprising:
- a patient interface connected to the air delivery conduit.

As discussed above in the majority opinion, we determine that a preponderance of the evidence establishes that *Wilson* describes the humidifier of claim 9, and Patent Owner does not contest such. *See* Pet 12–16; Tr. 26–27.

Unlike the majority, however, I determine that a preponderance of the evidence establishes that it would have been obvious to one of

ordinary skill in the art to modify Wilson's inhaler to include a blower to generate a flow of pressurized breathable gas, to structure the humidifier to reduce risk of or prevent spillback of liquid from the humidifier to the blower, and to provide a connecting structure to connect the outlet of the blower to the inlet of the humidifier, as taught by Dobson.

Wilson discloses that its inhaler is used to treat diseases of the throat or nasal passages by inhaling medicated volatile fluids. Ex. 1002, 1:8–12. As discussed in the majority opinion above, Wilson's inhaler may be used in an upright position or a tilted position to change the amount of medication impregnated into the air. *Id.* at 1:24–30, 66–99. Wilson discloses that it is desirable to prevent the fluid from overflowing into the inhaler's inlet. *Id.* at 1:55–60. Regardless of whether Wilson's inhaler is used in an upright position or a tilted position, users must be able to inhale sufficiently to adequately pull air into the air inlet duct and out the vapor exhaust port. *See id.* 1:15–31, 66–96; Figs. 2–3.

Petitioner's declarant Mr. Steve Bordewick testifies that “[i]n many cases, patients are sick, weak, and barely able to get out of bed” and “may also have shallow breathing and lack sufficient energy to produce and inhale adequate pressurized air through the inhaler.” Ex. 1004 ¶ 94.

Dobson discloses early humidifiers that are similar to Wilson's inhaler. *See* Ex. 1019, 1:15–16 (disclosing bottle type humidifiers). Dobson discloses that these humidifiers are “commonly connected to [a] ventilator or other respiratory device by a flexible hose.” *Id.* at

1:13–15, 22–24. Dobson also discloses an embodiment of an apparatus that has a ventilator with a connected fan that generates an air flow through a humidifier to deliver humidified air to patient. Ex. 1009, 3:12–17, Fig. 1. Dobson does not limit its teachings to the disclosed ventilator embodiment, but suggests that a ventilator could be “any and all respiratory devices (including respirators) for generating air flow for use by a patient.” Ex. 1019, 6:55–64.

The ’435 patent similarly discloses that manufacturers of non-invasive positive pressure ventilation apparatus or CPAP apparatus “often supply humidifiers which may be attached in the air circuit between the blower outlet and the patient interface.” Ex. 1001, 1:29–35.

Given this evidence, I am persuaded that it would have been obvious to one of ordinary skill in the art to modify Wilson’s inhaler to include a blower to generate a flow of pressurized breathable gas, to structure the humidifier to reduce risk of or prevent spillback of liquid from the humidifier to the blower, and to provide a connecting structure to connect the outlet of the blower to the inlet of the humidifier as taught by Dobson. Such a modification is desirable because it helps diseased users produce an adequate air flow through the inhaler. See Ex. 1004 ¶¶ 94, 96.

In addition, I am persuaded by a preponderance of the evidence that it would have been obvious to one of ordinary skill in the art to modify Wilson’s inhaler to include an air delivery conduit with a patient interface. Dobson depicts the use of an air delivery conduit with a mask. Ex. 1019, Fig. 1. The ’435 patent similarly discloses

that non-invasive positive pressure ventilation or CPAP apparatus “typically comprises a blower whose output is connected to a patient interface, such as a mask, via an air delivery conduit.” Ex. 1001, 1:29–31. Petitioner’s declarant Mr. Bordewick testifies that such a modification would “ensure an optimum and effective delivery of the humidified air to the patient after exiting the inhaler.” Ex. 1004 ¶¶ 95, 96.

Given this evidence, I am persuaded that it would have been obvious to one of ordinary skill in the art to modify Wilson’s inhaler to include an air delivery conduit with a patient interface to facilitate delivery of medication impregnated air to the patient.

I determine that Petitioner establishes by a preponderance of the evidence that claims 23 and 24 are unpatentable over Wilson and Dobson.

C. Patent Owner’s Arguments

With respect to Petitioner’s alternate combination, Patent Owner argues that Petitioner’s alternate combination is unsupported by sufficient evidence. PO Resp. 38–40 (citing Ex. 2008 ¶¶ 137–139). For the reasons discussed above, however, I determine that the disclosures of Wilson and Dobson and the testimony of Petitioner’s declarant Mr. Bordewick sufficiently supports Petitioner’s alternate combination.

Patent Owner also argues that Mr. Bordewick is not qualified to testify because he is not a medical professional but an engineer. PO Resp. 39. Patent Owner’s argument, however, does not account for

the fact that Mr. Bordewick’s engineering experience includes designing and developing CPAP masks. Ex. 1004 ¶¶ 12–14.

With respect to Petitioner’s first combination, Patent Owner makes multiple arguments as to why Petitioner’s first combination would not have been obvious to one of ordinary skill in the art. PO Resp. 31–38, 40–45. For example, Patent Owner argues that implementing Wilson’s inhaler in the Dobson’s ventilator system would create practical problems because Wilson’s inhaler would not provide adequate humidity for Dobson’s clinical system (*id.* at 31–35), that Petitioner does not provide adequate evidence to establish how Wilson’s inhaler could be incorporated into Dobson’s ventilator (*id.* at 40), and that Dobson teaches away from incorporating Wilson’s inhaler into Dobson’s ventilator (*id.* at 44).

Each of these arguments are directed to whether Wilson’s inhaler could be bodily incorporated into Dobson’s ventilator. However, “[t]he test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference. . . . Rather, the test is what the combined teachings of those references would have suggested to those of ordinary skill in the art.” *In re Keller*, 642 F.2d 413, 425 (CCPA 1981); *see also In re Sneed*, 710 F.2d 1544, 1550 (Fed. Cir. 1983) (“[I]t is not necessary that the inventions of the references be physically combinable to render obvious the invention under review.”); *In re Nievelt*, 482 F.2d 965, 968 (CCPA 1973) (“Combining the *teachings* of references does not involve an ability to combine their specific structures.”).

Regardless, in the Petitioner's alternate combination, Wilson's inhaler is not being bodily incorporated into Dobson's ventilator. In Petitioner's alternate combination, Wilson's inhaler is being modified to include a blower to generate a flow of pressurized breathable gas, to structure the humidifier to reduce risk of or prevent spillback of liquid from the humidifier to the blower, to provide a connecting structure to connect the outlet of the blower to the inlet of the humidifier; and to include an air delivery conduit with a patient interface. Pet. 29–31.

D. Conclusion

I determine that Petitioner establishes by a preponderance of the evidence that claims 23 and 34 are unpatentable over Wilson and Dobson.

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