

IN THE UNITED STATES PATENT TRIAL AND APPEAL BOARD

In re <i>Inter Partes</i> Review of:)	
)	
U.S. Patent No. RE 44,453)	
)	
Issued: August 27, 2013)	
)	
Inventors: Alexander Virr et al.)	
)	
Application No. 13/100,783)	
)	
Filed: May 4, 2011)	
)	FILED ELECTRONICALLY
For: HUMIDIFIER WITH STRUCTURE)	PER 37 C.F.R. § 42.6(b)(1)
TO PREVENT BACKFLOW OF)	
LIQUID THROUGH THE)	
HUMIDIFIER INLET)	

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PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. RE 44,453

BMC Medical Co. Ltd. (“BMC”) requests *inter partes* review of claims 1-7 of U.S. Patent No. RE 44,453 (“the ’453 patent”) (Ex. 1001), now assigned to ResMed Limited (“ResMed”), in accordance with 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.100 *et seq.*

An electronic payment in the amount of \$23,000.00 for the *inter partes* review fee specified by 37 C.F.R. § 42.15(b)(1)—comprising the \$9,000.00 request fee and \$14,000.00 post-institution fee—is being paid at the time of filing this petition. If

there are any additional fees due in connection with the filing of this paper, please charge the required fees to our Deposit Account No. 06-0916.

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LIST OF EXHIBITS

Petition Exhibit 1001:	U.S. Patent No. RE 44,453 to Virr et al. (“ <i>Virr</i> ”).
Petition Exhibit 1002:	DE 199 36 499 to Schatzl et al. (“ <i>Schatzl</i> ”) with certified translation.
Petition Exhibit 1003:	REMstar Manual (“ <i>Manual</i> ”).
Petition Exhibit 1004:	Declaration of Steve Bordewick.
Petition Exhibit 1005:	IPR2014-00551, Paper No. 1, “Petition for <i>Inter Partes</i> Review of U.S. Patent No. RE44,453.”
Petition Exhibit 1006:	IPR2014-00551, Paper No. 7, “Patent Owner ResMed Limited’s Preliminary Response.”
Petition Exhibit 1007:	ITC Investigation No. 337-TA-890: Initial Determination Granting Complainants’ Motion to Amend Complaint and Notice of Investigation and Granting Respondents’ Motion to Terminate the Investigation With Respect to U.S. Patent No. 7,614,398.
Petition Exhibit 1008:	Case No. 13-cv-1246-CAB: Order on Motion to Stay, Motion to Dismiss, and Related Discovery Request.
Petition Exhibit 1009:	Case No. SACV 13-00498: Order Granting Defendants’ Motion to Stay Litigation Pending <i>Inter Partes</i> Review.
Petition Exhibit 1010:	Patent Prosecution History of Reissue Patent Application 13/944,960.
Petition Exhibit 1011:	Patent Prosecution History of U.S. Patent No. 7,614,398.
Petition Exhibit 1012:	Patent Prosecution History of U.S. Patent Reissue No. RE44,453.
Petition Exhibit 1013:	Proof of Service of 3B Medical, Inc. in Civil Action No. 13-cv-1246-MMA-WMC.
Petition Exhibit 1014:	Australian Application No. PR3117.
Petition Exhibit 1015:	ITC Investigation No. 337-TA-890: Order No. 8: Construing Terms of the Asserted Patents.

- Petition Exhibit 1016: ITC Investigation No. 337-TA-890: Denying Respondents' Motion for Summary Determination of Invalidity of U.S. Patent No. RE44,453.
- Petition Exhibit 1017: U.S. Patent No. 6,050,260 to Daniell et al. ("*Daniell*").
- Petition Exhibit 1018: PCT International Publication No. WO 00/21602 to *Prime*.
- Petition Exhibit 1019: U.S. Patent No. 5,673,687 to Dobson et al. ("*Dobson*").
- Petition Exhibit 1020: Australian Application No. PR7288.
- Petition Exhibit 1021: International Publication No. WO 02/066106A1.
- Petition Exhibit 1022: ITC Investigation No. 337-TA-890: Notice of Commission Determination Not to Review an Initial Determination Granting the Complainants' Motion to Amend the Complaint and Notice of Investigation to Substitute U.S. Patent No. RE 44,453 for U.S. Patent No. 7,614,398 and Granting Respondents' Motion to Terminate the Investigation with Respect to U.S. Patent No. 7,614,398.

I. PRELIMINARY STATEMENT

The '453 patent is a reissue of U.S. Patent No. 7,614,398 (“the '398 patent”). Although the patent claims priority to two Australian applications filed in 2001, the subject matter of claims 1-7 was not disclosed until PCT application PCT/AU02/00155 was filed on February 14, 2002, long after others had already disclosed such subject matter.

Claims 1-7 are directed to a humidifier assembly for use with a Continuous Positive Airway Pressure (CPAP) apparatus. Ex. 1001 at 1:25-28. The patent specification acknowledges humidifiers and CPAP devices as well-known. The only purported development in claims 1-7 is thus a humidifier assembly with “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.”

But more than one year before the PCT filing, DE 199 36 499 to Schatzl et al. (“*Schatzl*”) (Ex. 1002) already disclosed a humidification appliance with a connecting structure (mountable housing 4) for use with a CPAP device. *See e.g.*, Ex. 1002 at (57); 1:1-4, 33-41. Indeed, before the PCT filing, Respironics sold a REMstar heated humidifier embodying the claimed connecting structure. The REMstar Manual (“*Manual*”) (Ex. 1003) explains that the heated humidifier includes a removable base plate and water chamber that connects to a CPAP device via a humidifier platform, in the same fashion as claims 1-7 of the '453 patent require.

As discussed in more detail below, the disclosures of *Schatz*¹ and the *Manual*, as well as those of other patents and publications, warrant the cancellation of claims 1-7.

II. MANDATORY NOTICES

A. Real Party-in-Interest

The real parties-in-interest are BMC Medical Co. Ltd.; 3B Products, L.L.C.; and 3B Medical Inc.

B. Related Matters

The '453 patent is a reissue of U.S. Patent No. 7,614,398 (“the '398 patent”). The '398 patent was initially asserted in *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 patent¹.

ResMed also asserted the '398 patent in *ResMed Inc. v. BMC Medical Co., Ltd., et al.*, 313-cv-01246 (CASD), and *ResMed Inc. et al v. Apex Medical Corporation et al.*, 8:13-cv-00498 (CACD), but has not asserted the reissued '453 patent. These district court cases have been stayed pending the outcome of ITC Investigation Nos. 337-TA-890 and 337-TA-879, respectively.²

¹ See Ex. 1007, Ex. 1022.

² See Ex. 1008, Ex. 1009.

ResMed has filed a second reissue application of the '398 patent, U.S. Patent Application No. 13/944,960, which has also been stayed pending the outcome of the related litigations.³

The '453 patent is being challenged in an *inter partes* review, IPR2014-00551, filed March 27, 2014⁴. Regardless of whether the Board institutes trial on any grounds in IPR2014-00551, the Board should grant this petition and institute trial on all grounds because the primary references relied on here are prior art under 35 U.S.C. §§ 102(a) and/or 102(b), not § 102(e), and also disclose features of the claims ResMed argued the references in IPR2014-00551 lacked.⁵

C. Lead and Back-Up Counsel, and Service Information

Lead Counsel: E. Robert Yoches (Reg. No. 30,120) can be reached at Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, 901 New York Avenue, NW, Washington, DC 20001-4413 (phone: 202.408.4039; e-mail: bob.yoches@finnegan.com; fax: 202.408.4400).

³ See Ex. 1010, Interview Summary at 70.

⁴ See Ex. 1005.

⁵ ResMed argued in its preliminary response in IPR 2014-00551 that the petition failed to properly articulate how *Meyer* discloses the claimed seal and *Dobson* discloses the claimed heating element. See Ex. 1006 at 18-19 and 26-27. As explained below in Section VII, the primary references relied on here disclose those features.

Backup Counsel: Joshua L. Goldberg (Reg. No. 59,369) can be reached at Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, 901 New York Avenue, NW, Washington, DC 20001-4413 (phone: 202.408.6092; e-mail: joshua.goldberg@finnegan.com; fax: 202.408.4400).

Petitioner consents to e-mail service at BMC-ResMed-IPR@finnegan.com.

III. THE '453 PATENT

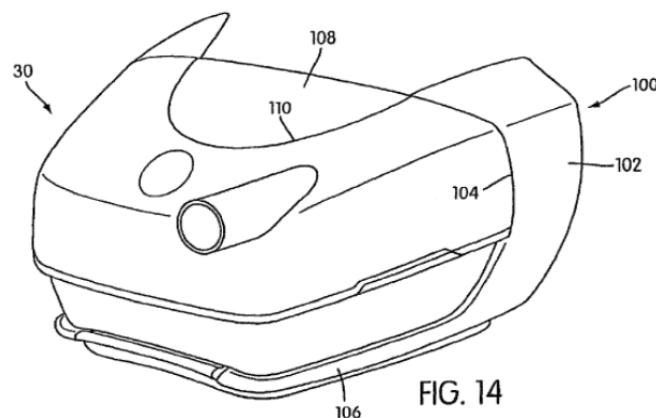
A. Overview of the Disclosure

The '453 patent describes humidifiers for use with devices that supply breathable gas, such as Continuous Positive Airway Pressure (CPAP) devices. Ex. 1001, at 1:25-28. Conventional CPAP devices included a blower to supply gas to a patient, and it was known to use a humidifier to add humidity to the breathable gas for the comfort of the patients. *Id.* at 1:29-39. The humidifier and blower were typically separate components either connected via a flexible conduit or rigidly connected together. *Id.* at 1:40-44. These known arrangements presented a problem that “water may run or spill from the humidifier into the blower outlet.” *Id.* at 1:46-50.

To address this issue, the patent discloses humidifiers intended to prevent liquid from leaving an inlet of the humidifier when the humidifier is not upright. *See e.g., id.* at 1:53-56; 2:3-7. A humidifier 10 (Fig. 1) with a fluid passage includes an inlet 22, an outlet 24, an orifice 20, and portions of chambers 14 and 16. *See e.g., id.* at 4:39-43. The patent alleges that the configuration of the chambers, size and placement of

the inlet and outlet, and size and placement of the orifice between the chambers
“decrease the possibility of liquid exiting the inlet of the humidifier.” *Id.* at 5:23-29.

The '453 patent also discloses a humidifier 30 having an inlet 32 and outlet 34 in a top cover 36. *See e.g., id.* at 6:15-30; Figs. 6 and 7. Humidifier 30 includes a base 40 and a gasket 38 between top cover 36 and base 40. *See id.* at 6:41-43. Humidifier 30 is removably attachable to a CPAP apparatus through the use of a connecting structure. *See e.g., id.* at 9:25-29. Figure 14 shows humidifier 30 and connecting structure 100:



Connecting structure 100 includes conventional components such as housing 102 with a base portion 106 to support humidifier 30, a heater 152 to heat humidifier 30, a retaining portion 108 to secure connecting structure 100 to humidifier 30, and a retaining mechanism 140 to secure a CPAP apparatus to connecting structure 100. *See e.g., id.* at 9:30-35, 10:4-9, 34; 11:23-25.

B. Prosecution History

The '453 patent is a reissue of U.S. Patent No. 7,614,398. The application that led to the '398 patent was filed with two independent claims, including an independent claim directed to a humidifier assembly for a CPAP apparatus. *See* Ex. 1011, 7/15/2005 Preliminary Amendment at p. 8. That claim recited, among other things, “a humidifier . . . and a connecting structure configured to connect between [a] CPAP apparatus and [the] humidifier.” *Id.* The PTO rejected the claim several times. In response, the Patent Owner amended the claim to require that the connecting structure “allow communication of an outlet of [a] CPAP apparatus with [an] inlet of the humidifier.” *See id.*, 3/27/2009 Response at p. 7, 6/26/2009 Examiner’s Amendment at 2. That claim and its dependent claims were allowed and issued as claims 1-7 of the '398 patent.

On March 4, 2011, the Patent Owner filed a reissue application for the '398 patent. In the application, the inventors alleged that:

[T]he original patent (U.S. Patent No. 7,614,398) is partially inoperative or invalid by reasons of the patentees claiming less than they had a right to claim in the original patent. . . . In particular, we believe we had a right to claim a humidifier not limited by a connecting structure configured to connect between the humidifier and a CPAP apparatus as recited in claim 1 of the issued patent.

Ex. 1012, Reissue Declaration at ¶¶ 9-10. The application was ultimately allowed with only a minor amendment to claim 1 and the addition of 91 new claims. *Id.*, Response of 5/13/2013 at p. 2-17, Notice of Allowability at 3.

C. Claims of the '453 Patent

The '453 patent includes 98 claims, but this petition only requests review of claims 1-7, which define a humidifier assembly for use with a CPAP apparatus.

Independent claim 1, in full, reads:

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.

IV. GROUNDS FOR STANDING

Pursuant to 37 C.F.R. § 42.104(a), Petitioner certifies the '453 patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting *inter partes* review of the '453 patent challenging the patent claims on the grounds identified in this petition. To the extent service of a complaint alleging infringement of the '398 patent is relevant to this proceeding involving the '453 patent, BMC notes that this petition is filed within one year of service of a complaint on BMC, its real parties-in-interest, or its privies alleging infringement of the '398 patent. *See, e.g.*, Ex. 1013.

V. STATEMENT OF PRECISE RELIEF REQUESTED FOR EACH CLAIM CHALLENGED

A. Claims for Which Review is Requested

Petitioner respectfully requests review under 35 U.S.C. § 311 of claims 1-7 of the '453 patent, and the cancellation of these claims as unpatentable.

B. Statutory Grounds of Challenge

Claims 1-7 are unpatentable under 35 U.S.C. §§ 102 and/or 103. The claim construction, reasons for unpatentability, and specific evidence supporting this request are detailed below.

C. Claim Construction - Broadest Reasonable Interpretation

Claim terms are given their ordinary and accustomed meaning as understood by one of ordinary skill in the art.⁶ *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc). A claim in an unexpired patent subject to *inter partes* review receives the “broadest reasonable construction in light of the specification of the patent in which it appears.” 37 C.F.R. § 42.100(b). And as such, the constructions in this proceeding may differ from the constructions in any district court or ITC litigation, including ITC Investigation No. 337-TA-890. The following phrase from the claims of the ’453 patent requires construction.⁷

a. “a retaining mechanism configured to secure the connecting structure to the CPAP apparatus”

Independent claim 1 recites “a retaining mechanism configured to secure the connecting structure to the CPAP apparatus.” Ex. 1001 at 11:52-53. In light of the specification, this phrase should be construed to mean “a structure that holds the

⁶ The ALJ in the 890 Investigation found that a person of ordinary skill in the art 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. *See* Ex. 1015 at 5. Petitioner applies this level of ordinary skill in this petition.

⁷ The broadest reasonable interpretation should be applied to any claim terms not addressed below.

CPAP apparatus in position on the connecting structure when in its normal orientation.” *See e.g.*, Ex. 1001, 10:7-9 (“The rearward side of the connecting structure 100 provides a retaining mechanism 140 to secure the connecting structure 100 to the CPAP apparatus.”); *id.* at 10:10-13 (“the retaining mechanism 140 may include a series of apertures 142 within the rearward portion of the housing 102. The apertures 142 may receive therein, for example, prongs or tabs (not shown) provided by the CPAP apparatus.”); and *id.* at 10:13-16 (“a locking member 144 may be provided”).

VI. CLAIMS 1-7 OF THE ’453 PATENT ARE NOT ENTITLED TO ANY PRIORITY DATE EARLIER THAN FEBRUARY 14, 2002

The ’453 patent is a reissue of the ’398 patent, which was filed on July 15, 2005, as a continuation of U.S. Patent Application No. 10/467,382, a National Stage entry of PCT/AU02/00155, filed on February 14, 2002⁸. The ’453 patent claims priority to Australian Application No. PR3117, filed February 16, 2001, and Australian Application No. PR7288, filed August 27, 2001, but claims 1-7 are not entitled to the filing dates of these Australian applications.

For a claim in a later application to be entitled to the filing date of an earlier application under 35 U.S.C. § 119, the earlier application must comply with 35 U.S.C. § 112, ¶ 1 as applied to such claim. *See In re Ziegler*, 992 F.2d 1197, 1200 (Fed. Cir. 1993). Section 112, paragraph 1, requires that the specification “contain a written description of the invention, and of the manner and process of making and using it.”

⁸ *See* Ex. 1021.

Thus, the priority application must reasonably convey to one of skill in the art that the inventor possessed the later-claimed subject matter at the time the parent application was filed. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991).

Australian Application Nos. PR3117⁹ and PR7288¹⁰ do not provide written-description support for claims 1-7 of the '453 patent. Neither application discloses “a connecting structure configured to connect between the CPAP apparatus and [a] humidifier,” as required by claim 1.¹¹ *See also* Ex. 1004 at ¶26-27. In fact, the figures and corresponding disclosure of the connecting structure and its components were first introduced in the PCT filing. Compare Ex. 1021 at 34-42 with Ex. 1014 and Ex. 1020, for example. Accordingly, claims 1-7 are not entitled to any priority date earlier than the PCT filing date, i.e., February 14, 2002.

VII. CLAIMS 1-7 OF THE '453 PATENT ARE UNPATENTABLE

A. Ground 1: *Schatzl* anticipates claims 1 and 4-7

DE 199 36 499 to *Schatzl* was published on February 8, 2001. Because the earliest effective priority date of claims 1-7 of the '453 patent is February 14, 2002, *Schatzl* is prior art under 35 U.S.C. § 102(b).

⁹ *See* Ex. 1014.

¹⁰ *See* Ex. 1020.

¹¹ In the related ITC litigation, ResMed did not dispute that the Australian Applications lack this disclosure. *See* Ex. 1016 at 15-16.

Schatz describes a humidification appliance for use with a CPAP apparatus. See e.g., Ex. 1002 at (57); 1:1-4. The humidification appliance includes a refill unit 3 positioned in and “easily removed from a mountable housing 4.” *Id.* at 4:34-36. Fig. 1 of *Schatz*, reproduced here, is a sectional view of the humidification appliance with refill unit 3 positioned in mountable housing 4:

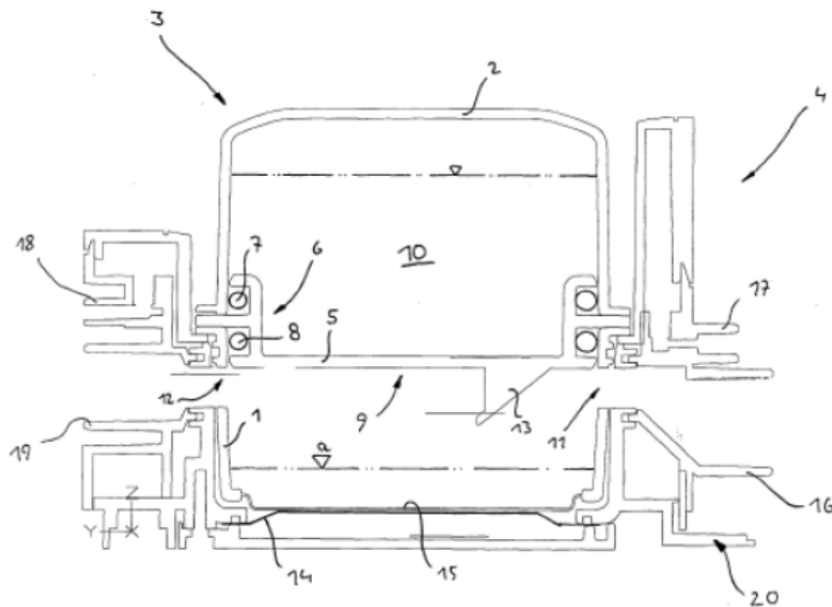


Fig.1

As shown, refill unit 3 includes a tub element 1 and a pot part 2, which “are coupled with each other by means of a seal.” See *id.* at 4:39-40 and Fig. 1. *Schatz* discloses that the coupling of the tub element 1 and the pot part 2 is achieved with a sealing structure 6, comprising a first sealing ring 7 and a second sealing ring 8. *Id.* at 4:40-43 and Fig. 1. Also, *Schatz* discloses that the two sealing rings 7 and 8 are incorporated in circumferential grooves formed in a dividing element 9. *Id.* at 4:43-45. Additionally,

*Schatz*l discloses that the dividing element 9 comprises a dividing wall 5 that separates the interior area of the pot part 2 from the interior area of the tub element 1. *Id.* at 4:45-48.

*Schatz*l describes the tub element 1 as having “an essentially bowl-shaped design,” to retain humidification fluid. *See id.* at 5:1; 4:52-54. In order to heat the fluid, *Schatz*l discloses that “the bottom area 15 of tub element 1 is made of a material with high thermal conductivity, for example metal.” *Id.* at 5:19-21.

*Schatz*l teaches “tub element 1 is designed such that it can be inserted in self-positioning fashion in the mountable housing 4 with an easy fit.” *Id.* at 5:24-26. In position, “[t]he respiratory gas inlet opening [of refill unit 3] and the respiratory gas outlet opening [of refill unit 3] are aligned with corresponding complementary openings and conduits formed in the mountable housing 4.” *Id.* at 5:26-29. Further, mountable housing 4 includes a connector peg 16 adjacent to the respirator gas inlet opening, which is configured to be coupled to a corresponding portion of a CPAP apparatus. *See e.g., id.* at 5:30-34.

As shown in the figure above, mountable housing 4 includes a base portion that supports refill unit 3. Mountable housing 4 also includes a fastening appliance 20 “via which the humidification applicant can be coupled with a CPAP apparatus in a mechanically relatively rigid manner.” *See id.* at 6:1-3, Fig. 1. *Schatz*l discloses that mountable housing 4 includes a heating device 14 closely contacting the material with high thermal conductivity of bottom area 15 of tub element 1. *See id.* at 5:13-21, Fig. 1.

A plug-in adapter is provided to facilitate an electrical connection between heating device 14 and a power supply provided by the CPAP apparatus. *See e.g., id.* at 5:52-56, 6:55-59. As further detailed in the claim chart below, *Schatzl* discloses all elements of claims 1 and 4-7 of the '453 patent.

Claims	Exemplary Disclosure of <i>Schatzl</i>
1. A humidifier assembly for a CPAP apparatus, comprising	<p><i>Schatzl</i> discloses a humidification appliance (the claimed “humidifier assembly”) for use with a CPAP apparatus. <i>See</i> Ex. 1002 at 1:3-6, 1:25-41, 3:47-50, 4:32-36, 5:30-34.</p> <p>“The invention relates to an appliance for the humidification of respiratory gas.” <i>Id.</i> at (57), 1:3-6;</p> <p>“[T]he object of the invention is to create an easy-to-handle appliance for the humidification of a respiratory gas . . . by means of which a uniform humidification of the respiratory gas can be achieved.” <i>Id.</i> at 1:25-29;</p> <p>“[According to the invention, said object is solved with the appliance for the humidification of a respiratory gas having a fluid storage chamber for storing a fluid, a humidification area for loading the respiratory gas with a fluid, whereby the respiratory gas comes into contact with the fluid in the humidification area, a respiratory gas supply appliance for supplying the respiratory gas to the humidification area and a respiratory removal appliance for removing the humidified respiratory gas from the humidification area.” <i>Id.</i> at 1:30-41; and</p> <p>“According to a particularly preferred embodiment of the invention, the humidification appliance comprises connectors, which enable the direct coupling of the humidification appliance on a corresponding CPAP apparatus.” <i>Id.</i> at 3:52-55.</p>

Claims	Exemplary Disclosure of <i>Schatz</i>
a humidifier including	<p><i>Schatz</i> discloses the humidification appliance includes a refill unit 3 (the claimed “humidifier”). <i>See</i> Ex. 1002 at 4:30-48.</p> <p>“The representation according to Fig. 1 shows a longitudinal sectional view through an appliance for the humidification of a respiratory gas.” <i>Id.</i> at 4:30-32;</p> <p>“The illustrated embodiment of the humidification appliance in this case comprises a refill unit 3 . . . compris[ing] a plurality of parts, said refill unit being formed with a tub element 1 and a pot part 2 coupled with the tub element.” <i>Id.</i> at 4:34-38; and</p> <p>“A separate humidification area is formed in the tub element 1 arranged underneath the pot part 2.” <i>Id.</i> at 4:52-53.</p>
a base configured to retain a body of liquid therein, at least a portion of the base being constructed of a heat conducting material,	<p><i>Schatz</i> discloses refill unit 3 includes a tub element 1 having a bowl-shaped design (the claimed “base”) that is configured to retain a body of humidification fluid (the claimed “liquid”). <i>See</i> Ex. 1002 at 4:53-56 (“[a] . . . humidification area is formed in the tub element 1 . . . in which only a partial quantity of the humidification fluid is retained. The level of the fluid retained in the tub element is kept at a predefined filling level by means of a dosing apparatus.”); <i>see also id.</i> at 2:54, 5:1-2, Fig. 1. <i>Schatz</i> discloses that a “bottom area 15 of tub element 1 is made of a material with high thermal conductivity, for example metal” (the claimed “at least a portion of the base being constructed of a heat conducting material”). <i>See id.</i> at 5:19-21, Fig. 1.</p>
a top cover, and	<p><i>Schatz</i> discloses that refill unit 3 also includes a pot part 2 (the claimed “top cover”) coupled to the tub element 1. <i>See</i> Ex. 1002 at 4:37-38, Fig. 1. <i>See also id.</i> at 2:47-48 (“[t]he fluid</p>

Claims	Exemplary Disclosure of <i>Schatzl</i>
	storage chamber is preferably formed by a pot-shaped housing part.”).
a seal disposed between the top cover and the base; and	<i>Schatzl</i> discloses a seal structure 6 (the claimed “seal”) disposed between pot part 2 and tub element 1. <i>See</i> Ex. 1002 at 4:39-48 and Fig. 1 (“The tub element 1 and pot part 2 are coupled with each other by means of a seal. The coupling of the tub element 1 and the pot part 2 is achieved with a sealing structure 6, comprising a first sealing ring 7 and a second sealing ring 8. The two sealing rings 7 and 8 are incorporated in circumferential grooves formed in a dividing element 9. The dividing element 9 comprises a dividing wall 5 that separates the interior area of the pot part 2 from the interior area of the tub element 1.”)
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	<i>Schatzl</i> discloses a mountable housing 4 (the claimed “connecting structure”) that is equipped with a fastening appliance 20, Ex. 1002 at 5:59-6:3, including a connector peg 16 to couple refill unit 3 to a complimentary structure on a CPAP apparatus, <i>id.</i> at 5:30-33, thereby allowing communication of an outlet of the CPAP apparatus with a respirator inlet opening 11 of refill unit 3. <i>Id.</i> at 5:26-29.
a housing providing a base portion to support the humidifier thereon, and	<i>Schatzl</i> discloses mountable housing 4 includes a base portion that supports the refill unit 3. <i>See</i> Ex. 1002 at 4:34-36, Fig. 1.
a retaining mechanism configured to	<i>Schatzl</i> discloses that mountable housing 4 “is equipped with a fastening appliance 20, via which the humidification

Claims	Exemplary Disclosure of <i>Schatzl</i>
secure the connecting structure to the CPAP apparatus,	appliance can be coupled with a CPAP apparatus in a mechanically relatively rigid manner.” ¹² Ex. 1002 at 5:59-6:3; <i>see also id.</i> at 6:51-55 (“[t]he fastening appliance labeled with the reference number 20 in Fig. 1, with which a particularly rigid coupling of the humidification appliance with the corresponding CPAP apparatus can be achieved, is provided below the mentioned connector pegs.”).
wherein the base portion includes a heating element in contact with the heat conducting material of the base of the humidifier.	<i>Schatzl</i> discloses that the base portion of mountable housing 4 includes a heating device 14 closely contacting the material with high thermal conductivity of bottom area 15 of tub element 1. <i>See</i> Ex. 1002 at 5:13-21, Fig. 1.
4. A humidifier assembly according to claim 1, wherein the connecting structure includes	<i>Schatzl</i> discloses that mountable housing 4 includes a plug-in adapter to provide an electrical connection between heating device 14 and a power supply provided by the CPAP

¹² Fastening appliance 20 is a structure that holds the CPAP apparatus in position on mountable housing 4 when in its normal orientation, because the fastening appliance is coupled to a bottom of the CPAP apparatus “in a mechanically rigid manner.” Ex. 1004 at ¶42 (citing Ex. 1002 at 5:58 - 6:3; 6:50-54).

Claims	Exemplary Disclosure of <i>Schatzl</i>
contact elements that communicate with a power supply within the CPAP apparatus.	<p>apparatus. <i>See</i> Ex. 1002 at 5:52-56, 6:55-59.¹³</p> <p>“Below the connector labeled with the reference number 16, a plug-in adapter . . . is provided, via which an electrical connection between the heating device 14 and a power supply provided by the CPAP apparatus can be established.” Ex. 1002 at 5:52-56; and</p> <p>“An electrical plug-in connector . . . for the creation of an electrical connection between the heating device and the associated CPAP apparatus is provided in a retaining trough provided underneath the connector peg 16.” <i>Id.</i> at 6:55-59.</p>
5. A humidifier assembly according to claim 1, wherein the connecting structure is configured to allow removable attachment of the CPAP apparatus to the humidifier.	<p><i>Schatzl</i> discloses mountable housing 4 with connectors to removably couple refill unit 3 to the CPAP apparatus. <i>See Schatzl</i> at 5:30 - 6:3. For example, <i>Schatzl</i> teaches that “mountable housing 4 is equipped with a connector peg 16, which can be directly put on a corresponding complementary connecting section of a CPAP apparatus . . . [a]n additional connector peg 17 [] can be . . . provided near the connector peg 16.” <i>Id.</i> at 5:31-36. Pegs 16 and 17 can be “put on or plugged in directly” into connector pegs 32 and 33 on the CPAP apparatus. <i>Id.</i> at 7:16-23, Fig. 1, Fig. 3. <i>Schatzl</i> teaches that “[a] modularly expandable CPAP system is created hereby in an advantageous fashion, which can</p>

¹³ In order for the plug-in adapter on mountable housing 4 of *Schatzl* to provide an electrical connection between the heating device 14 and a power supply provided by the CPAP apparatus, the plug-in adapter must necessarily include contact elements that communicate with the power supply within the CPAP apparatus. Ex. 1004 at ¶44 (citing Ex. 1002 at 5:51-55).

Claims	Exemplary Disclosure of <i>Schatzl</i>
	<p>easily and quickly be configured as needed, including by laypersons.” <i>Id.</i> at 4:8-11.¹⁴</p> <p>Additionally, <i>Schatzl</i> teaches that the refill unit 3 is positioned in and “easily removed from a mountable housing 4.” <i>Id.</i> at 4:34-36.</p>
6. A humidifier assembly according to claim 1, wherein the heat conducting material is a metallic material.	<p><i>Schatzl</i> discloses “the bottom area 15 of tub element 1 is made of a material with high thermal conductivity, for example [sic] metal.” Ex. 1002 at 5:19-21. <i>See also id.</i> at 3:10-12.</p>
7. A CPAP apparatus including a humidifier assembly according to claim 1.	<p><i>Schatzl</i> discloses a CPAP apparatus for use with the humidification appliance. <i>See</i> Ex. 1002 at 1:3-6, 1:25-38, 3:47-53, 4:32-36, and 5:30-34.</p> <p>“The invention relates to an appliance for the humidification of respiratory gas, in particular for the conduct of CPAP therapy as well as a CPAP apparatus for use with said type of appliance.” Ex. 1002 at (57), 1:3-6;</p> <p>“[T]he object of the invention is to create an easy-to-handle appliance for the humidification of a respiratory gas as well as a CPAP apparatus intended for use with it, by means of which a uniform humidification of the respiratory gas can be achieved.” <i>Id.</i> at 1:25-29;</p> <p>“According to the invention, said object is solved with</p>

¹⁴ Mountable housing 4 is configured to allow removable attachment of the CPAP apparatus to the refill unit 3 because the CPAP system is modular and expandable, which can easily and quickly be configured as needed, including by laypersons. Ex. 1004 at ¶45 (citing Ex. 1002 at 4:8-11).

Claims	Exemplary Disclosure of <i>Schatzl</i>
	<p>the appliance for the humidification of a respiratory gas having a fluid storage chamber for storing a fluid, a humidification area for loading the respiratory gas with a fluid, whereby the respiratory gas comes into contact with the fluid in the humidification area, a respiratory gas supply appliance for supplying the respiratory gas to the humidification area and a respiratory removal appliance for removing the humidified respiratory gas from the humidification area.” <i>Id.</i> at 1:30-38; and</p> <p>“According to a particularly preferred embodiment of the invention, the humidification appliance comprises connectors, which enable the direct coupling of the humidification appliance on a corresponding CPAP apparatus. According to a particularly referred embodiment of the invention, the CPAP apparatus and the humidification appliance are designed for this purpose.” <i>Id.</i> at 3:52-58.</p>

B. Ground 2: *Schatzl* in combination with *Daniell* renders claim 3 obvious

Claim 3 depends from claim 1 and requires that “the connecting structure includes a control knob to control a heat setting of the heating element.” *Schatzl* discloses all of the features of claim 1. *Supra*, *Schatzl* also discloses a mountable housing 4 which includes a switching means 27 on an exterior of mountable housing 4 “by way of which the temperature of the fluid in the tub element . . . can be set.” Ex. 1002 at 7:1-4. It would have been obvious to one of ordinary skill in the art to implement the switching means as a control knob.

The use of a control knob for temperature setting was well known in the industry. For example, *Daniell*, which issued on April 18, 2000, and is prior art under 35 U.S.C. § 102(b), discloses a dial 10 to control the temperature of a heater plate 7. *See* Ex. 1017 at 4:2-6. “In response to the user set humidity or temperature value input via dial 10 and other inputs, controller 9 determines when (or to what level) to energise heater plate 7 to heat the water 6 within humidification chamber 5.” *Id.*

At the very least, one of ordinary skill in the art would have been motivated to substitute the dial of *Daniell* for the switching means 27 of *Schatz*l in order to provide a patient with easy control over the temperature setting of the heater. Ex. 1004 at ¶52. Such a modification of *Schatz*l would constitute no more than an obvious design choice – one of a “finite number of identified, predictable solutions” – to one skilled in the art at the time the ’453 patent was filed. Ex. 1004 at ¶52; *see also* *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 402-3 (2007) (“When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.”), 416 (“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.”).

Indeed, such a modification would simply improve the apparatus disclosed by *Schatz*l in the same way as it improves the apparatus in *Daniell* (e.g., by providing a

patient with easy control over the temperature setting of the heater) and would not have been beyond the ordinary skill in the art. Ex. 1004 at ¶52; *see KSR*, 550 U.S. at 417 (“[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.”).

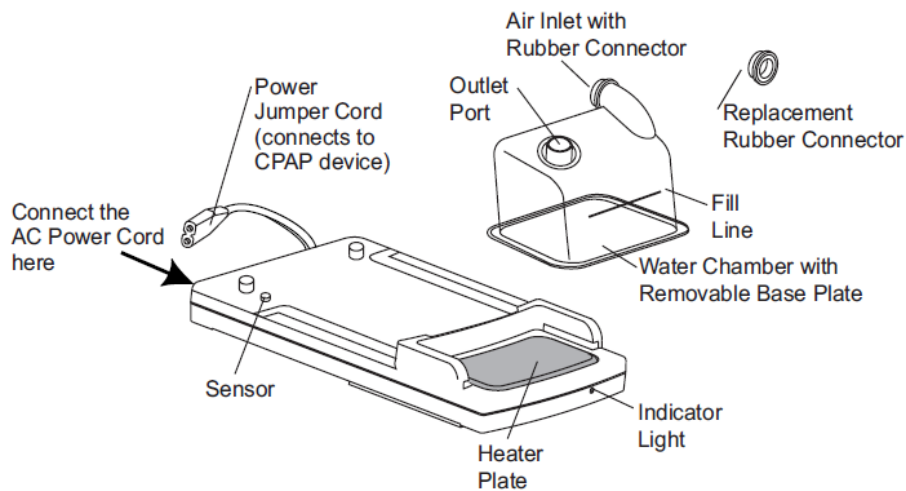
As further detailed in the claim chart below, *Schatzl* in combination with *Daniell* renders claim 3 of the ’453 patent obvious.

Claims	Exemplary Disclosure of <i>Schatzl</i> and <i>Daniell</i>
3. A humidifier assembly according to claim 1, wherein the connecting structure includes a control knob to control a heat setting of the heating element.	<p><i>Schatzl</i> discloses that mountable housing 4 includes a heating device 14 closely contacting the material with high thermal conductivity of bottom area 15 of tub element 1. <i>See Schatzl</i> at 5:13-18 and Fig. 1. <i>Schatzl</i> discloses that mountable housing 4 includes a switching means 27 on an exterior of mounting housing 4 “by way of which the temperature of the fluid in the tub element . . . can be set.” Ex. 1002 at 7:1-4.</p> <p><i>Daniell</i> teaches this feature. More specifically, <i>Daniell</i> discloses a dial 10 to control the temperature of a heater plate 7. <i>See</i> Ex. 1017, at 4:2-6 (“In response to the user set humidity or temperature value input via dial 10 and other inputs, controller 9 determines when (or to what level) to energise heater plate 7 to heat the water 6 within humidification chamber 5.”)</p>

C. Ground 3: Claims 1, 2, 4, 5, and 7 are anticipated by the REMstar *Manual*

The REMstar Manual (“*Manual*”) was published on March 15, 2001, and is prior art under 35 U.S.C. § 102(a)¹⁵.

The *Manual* discloses a “Heated Humidifier [] for use with certain Respiration CPAP devices.” *See* Ex. 1003 at 1. Components of the Heated Humidifier are shown in the Figure reproduced below:



¹⁵ The *Manual* can be accessed, for example, at:

<http://www.thecpappeople.com/Files/UserGuideREMstarHeatedHumidifier.pdf>

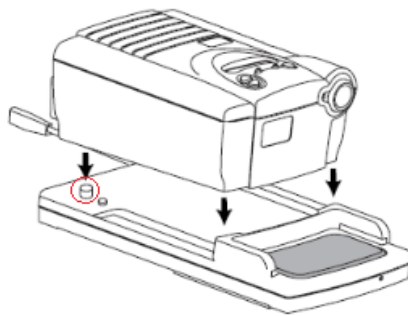
and [http://www.apria.com/wps/wcm/connect/e684f137-c6be-4f96-97ed-](http://www.apria.com/wps/wcm/connect/e684f137-c6be-4f96-97ed-d89858a6dd1e/REMstar+Heated+Humidifier+User+Guide.pdf?MOD=AJPERES)

[d89858a6dd1e/REMstar+Heated+Humidifier+User+Guide.pdf?MOD=AJPERES](http://www.apria.com/wps/wcm/connect/e684f137-c6be-4f96-97ed-d89858a6dd1e/REMstar+Heated+Humidifier+User+Guide.pdf?MOD=AJPERES),

and indicates that it was published on “3/15/01.” Ex. 1003 at bottom of 8.

The Heated Humidifier includes a removable base plate and water chamber to “hold[] the water for humidification.” *See id.* at 3. The *Manual* discloses that the Heated Humidifier includes a rubber seal. *See id.* at 6 (“Gently remove the base of the chamber with your hands being careful not to damage the rubber seal.”).

The Heated Humidifier also includes a humidifier platform for connecting a CPAP device to the removable base plate and water chamber. *Id.* at 5. In order to assemble the Heated Humidifier for use, the CPAP device is placed on and retained by the humidifier platform. *See id.* at 4, and the figure reproduced below:



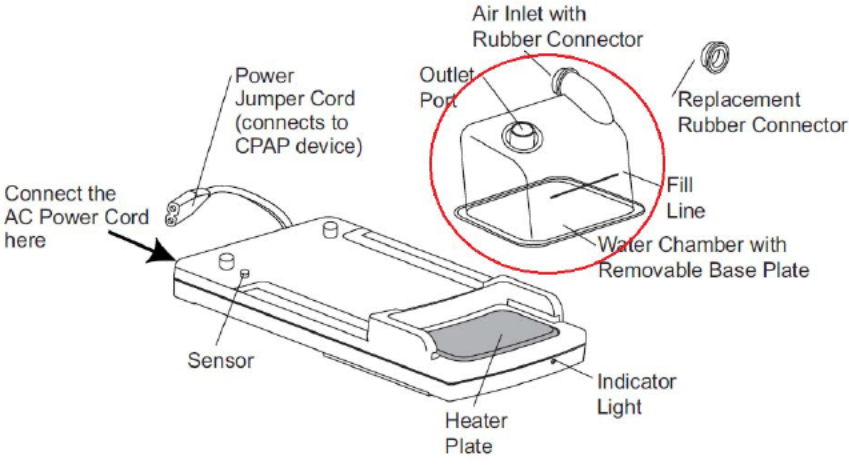
A power-cord jumper of the humidifier platform is connected to an AC inlet on the CPAP device. *See id.* (“Connect the humidifier’s power jumper cord to the AC inlet on the device. Plug the CPAP device’s power cord into the AC connector on the humidifier. Plug the remaining end of the power cord into an AC outlet.”). The *Manual* instructs a user to “[p]ress down the spring loaded heater plate with the water chamber and slide the chamber into place” to position the water chamber on the heater plate. *Id.* at 5. The Heated Humidifier is fully assembled when “the rubber connector on the inlet port [of the water chamber] fits securely over the CPAP

device's air outlet.” *Id.* Disassembly involves “[d]isconnecting the tubing from the water chamber,” and “[p]ress[ing] down on the water chamber and slid[ing] it out of the humidifier platform.” *Id.* at 6.

The heater plate of the humidifier platform warms the water in the water chamber. *Id.* at 3. According to Mr. Bordewick, one of ordinary skill in the art would recognize that the base plate must be constructed of a heat conducting material, for otherwise the humidifier platform would be unable to effectively transfer heat to (and thus warm) the water in the water chamber. Ex. 1004 at ¶56; *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991) (“To serve as anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.”).

An air inlet and an outlet port are provided on the water chamber and in communication with an interior of the assembled chamber. *See id.* at 3 and above (water chamber is an open interior). The *Manual* discloses that the air inlet is for “connect[ing] to [an] outlet port on the CPAP device” for receiving the gas requiring humidity. *Id.* Further, the outlet port “connect[s] [a] flexible tubing,” to deliver the pressurized gas with the added humidifier to a patient. *Id.*; *see also id.* at 7.

As further detailed in the claim chart below, the *Manual* discloses all elements of claims 1, 2, 4, 5, and 7 of the '453 patent.

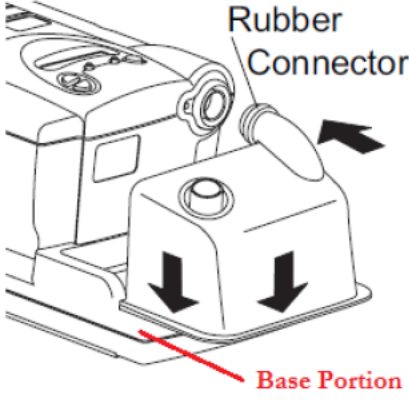
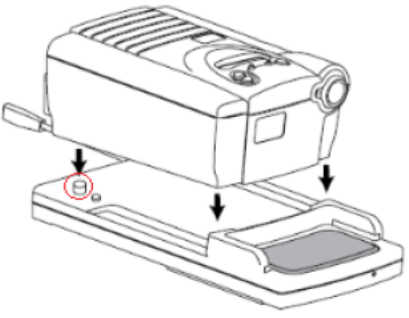
Claims	Exemplary Disclosure of Respironics' REMstar <i>Manual</i>
1. A humidifier assembly for a CPAP apparatus, comprising	The <i>Manual</i> discloses a humidifier assembly for a CPAP apparatus. For example, the title page of the <i>Manual</i> states that “[t]he REMstar Heated Humidifier is for use with certain Respironics CPAP devices. The humidifier moistens the air delivered by the Respironics CPAP devices.” <i>See</i> Ex. 1003 at 1.
a humidifier including	<p>The <i>Manual</i> discloses that the REMstar Heated Humidifier includes a humidifier. <i>See</i> Ex. 1003, at p. 1 (“the REMstar Heated Humidifier . . .”); <i>see also id.</i> at p. 2 (“read all instructions before using the humidifier”). The humidifier is identified in the annotated Figure included below:</p>  <p><i>Manual</i> at 3.</p>
a base configured to retain a body of liquid therein, at least a portion of the base being constructed of a heat conducting material,	The REMstar humidifier includes a water chamber with a removable base plate (the claimed “base”) configured to retain water (the claimed “body of liquid”) therein. For example, the <i>Manual</i> discloses that “[t]he removable water chamber holds the water for humidification. It has a removable base plate for ease in cleaning.” <i>See</i> Ex. 1003 at 3. The “base” is identified in the annotated Figure included below:

Claims	Exemplary Disclosure of Respironics' REMstar <i>Manual</i>
	<div data-bbox="860 367 1169 640" data-label="Image"> </div> <p data-bbox="560 672 763 714">Ex. 1003 at 6.</p> <p data-bbox="560 735 1396 829">The <i>Manual</i> discloses that the base plate is positioned on a heater plate, identified in the annotated Figure below:</p> <div data-bbox="576 871 1429 1354" data-label="Image"> </div> <p data-bbox="560 1396 1437 1585">Ex. 1003 at 3. For example, the <i>Manual</i> discloses that a user is to “[p]ress down the spring loaded heater plate with the water chamber and slide the chamber into place” to position the base plate on the heater plate. <i>Id.</i> at 5. In position, the</p>

Claims	Exemplary Disclosure of Respironics' REMstar <i>Manual</i>
	heater plate warms the water in the “humidifier,” so it is constructed of a heat conducting material. ¹⁶ <i>See</i> Ex. 1003 at 5.
a top cover, and	<p>The REMstar humidifier includes a water chamber (the claimed “top cover”). <i>See</i> Ex. 1003 at 3. “The removable water chamber holds the water for humidification.” <i>Id.</i></p> <p>The “top cover” is identified in the annotated Figure included below:</p> <div data-bbox="863 800 1170 1071" data-label="Image"> </div> <p>Ex. 1003 at 6.</p>
a seal disposed between the top cover and the base; and	The REMstar humidifier includes a seal disposed between the “top cover” and “base.” <i>See</i> Ex. 1003 at 6 (“3. . . . Gently remove the base of the chamber with your hands being careful not to damage the rubber seal.”)
a connecting structure configured to connect between the CPAP apparatus and humidifier and allow communication of an outlet of the CPAP	The <i>Manual</i> discloses a humidifier platform (the claimed “connecting structure”) that is configured to connect between the CPAP apparatus and the “humidifier.” <i>See Manual</i> at 3. The humidifier platform is identified in the annotated Figure included below:

¹⁶ For the heater plate to warm the water, the “base” must be constructed of a heat conducting material. Ex.1004 at ¶¶56, 63.

Claims	Exemplary Disclosure of Respironics' REMstar <i>Manual</i>
<p>apparatus with an inlet of the humidifier, the connecting structure including</p>	<div data-bbox="560 325 1421 787" data-label="Image"> </div> <p>Ex. 1003 at 3.</p> <p>The <i>Manual</i> discloses that the humidifier platform allows for communication between an inlet port on the humidifier and the CPAP device's air outlet. For example, the <i>Manual</i> discloses:</p> <p><i>id.</i> at 4 (“[p]lace the CPAP device on the humidifier platform.”);</p> <p><i>id.</i> at 5 (“[i]mmediately install the chamber into the humidifier (step 2)”); and</p> <p><i>id.</i> (“[step] 2. Press down the spring loaded heater plate with the water chamber and slide the chamber into place. Make sure the rubber connector on the inlet port fits securely over the CPAP device’s air outlet.”).</p>
<p>a housing providing a base portion to support the humidifier thereon, and</p>	<p>The humidifier platform in the <i>Manual</i> includes a housing having a base portion to support the humidifier. <i>See Manual</i> at 5. The base portion is identified in the annotated Figure included below:</p>

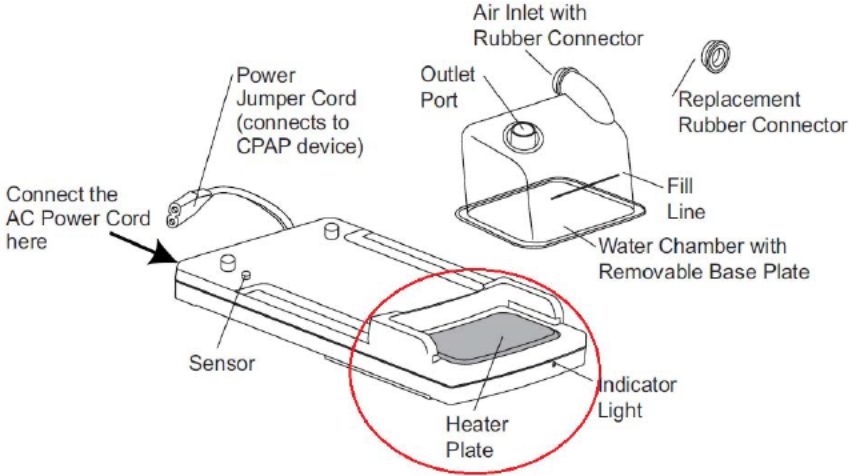
Claims	Exemplary Disclosure of Respironics' REMstar <i>Manual</i>
	 <p style="text-align: center;">Ex. 1003 at 5.</p>
<p>a retaining mechanism configured to secure the connecting structure to the CPAP apparatus,</p>	<p>The humidifier platform in the <i>Manual</i> includes a plurality of pegs (the claimed “retaining mechanism”) configured to secure the humidifier platform to the CPAP apparatus.¹⁷ The “retaining mechanism” is identified in the annotated Figure included below:</p>  <p style="text-align: center;">Ex. 1003 at 4. As shown, a peg is provided which can be received by the CPAP device to help prevent the CPAP</p>

¹⁷ The plurality of pegs are a structure that holds the CPAP in position on the humidifier platform when in its normal orientation, because they prevent movement of the CPAP device after the device has been placed on the humidifier platform. Ex. 1004 at ¶69 (citing Ex. 1003 at 4).

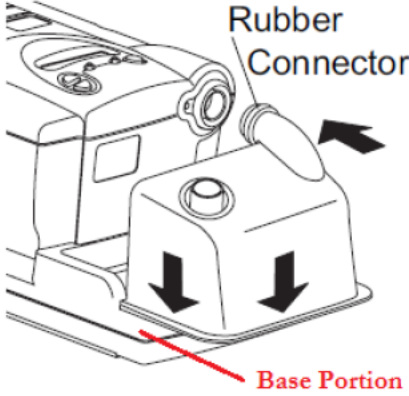
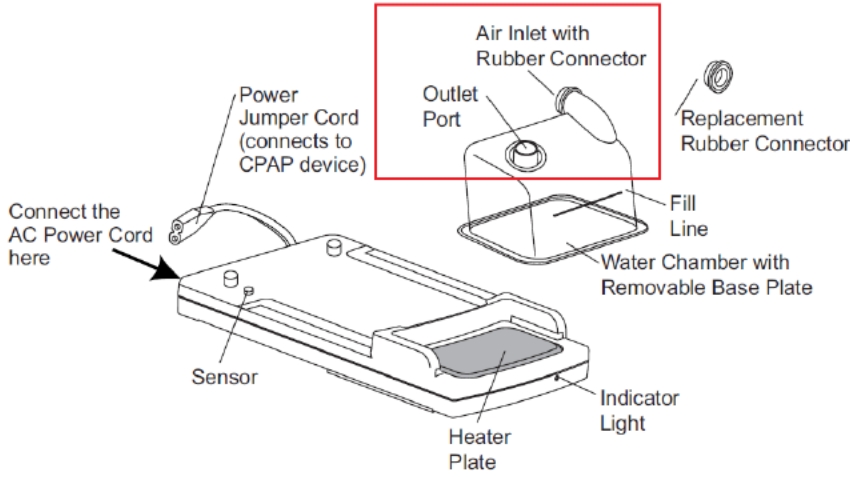
Claims	Exemplary Disclosure of Respironics' REMstar <i>Manual</i>
	<p>from moving around on the humidifier platform. The <i>Manual</i> also teaches that the CPAP device is positioned so “that the four feet match up with the humidifier base.” <i>Id.</i></p> <p>Additionally, the <i>Manual</i> instructs a user to “[p]ress down the spring loaded heater plate with the water chamber and slide the chamber into place” to position the water chamber on the heater plate. Ex. 1003 at 5. The Heated Humidifier is fully assembled when “the rubber connector on the inlet port [of the water chamber] fits securely over the CPAP device’s air outlet.”¹⁸ <i>Id.</i></p> <p>Additionally, the <i>Manual</i> discloses that a power-cord jumper of the humidifier platform is connected to an AC inlet on the CPAP device. <i>See id.</i> at 4. (“Connect the humidifier’s power jumper cord to the AC inlet on the device. Plug the CPAP device’s power cord into the AC connector on the humidifier. Plug the remaining end of the power cord into an AC outlet.”).¹⁹</p>

¹⁸ This connection is also a “retaining mechanism configured to secure the connecting structure to the CPAP apparatus,” as it helps hold the CPAP in position on the humidifier platform when in its normal orientation by providing retention of the CPAP device at the point of engagement between the CPAP outlet and humidifier inlet via the rubber connector. Ex. 1004 at ¶69 (citing *Manual* at 5).

¹⁹ This connection is also a “retaining mechanism configured to secure the connecting structure to the CPAP apparatus,” as it helps hold the CPAP in position on the humidifier platform when in its normal orientation by providing retention of the

Claims	Exemplary Disclosure of Respironics' REMstar <i>Manual</i>
<p>wherein the base portion includes a heating element in contact with the heat conducting material of the base of the humidifier.</p>	<p>The <i>Manual</i> discloses the “base portion” of the humidifier platform includes a heater plate (the claimed “heating element”). <i>See</i> Ex. 1003, at p. 3. The “heating element” is identified in the annotated Figure below:</p>  <p>Ex. 1003 at 3.</p> <p>The <i>Manual</i> discloses that a user is to “[p]ress down the spring loaded heater plate with the water chamber and slide the chamber into place” to position the “humidifier” on the “heating element.” <i>See id.</i> at 5. In position, the “heating element” contacts the “heat conducting material” of the “base” as shown in the annotated Figure below:</p>

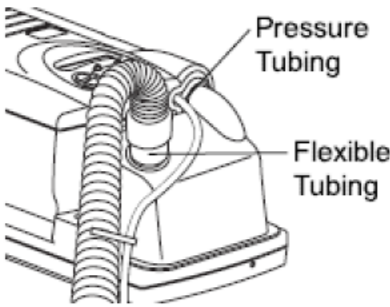
CPAP device to the humidifier platform via the power-cord jumper tethered between the back of the CPAP device and the humidifier platform after the CPAP device has been placed on the humidifier platform. Ex. 1004 at ¶69 (citing *Manual* at 4).

Claims	Exemplary Disclosure of Respironics' REMstar Manual
	 <p>Ex. 1003 at 5.</p> <p>The <i>Manual</i> discloses that the “heating element” warms the water in the “humidifier.” See Ex. 1003 at 3 (“Heater Plate: Warms the water in the water chamber”).</p>
<p>2. A humidifier assembly according to claim 1, wherein the top cover defines both an inlet and an outlet communicated with an interior of the base, the inlet configured to receive pressurized breathable gas and the outlet configured to deliver the pressurized breathable gas with added humidity.</p>	<p>The <i>Manual</i> discloses that the water chamber defines both an air inlet (the claimed “inlet”) and an outlet port (the claimed “outlet”) communicated with an interior of the base plate. The “inlet” and “outlet” are identified in the annotated Figure included below:</p>  <p>Ex. 1003 at 3.</p>

Claims	Exemplary Disclosure of Respironics' REMstar <i>Manual</i>
	<p>The <i>Manual</i> discloses that the “inlet” is for “connect[ing] to the outlet port on the CPAP device.” <i>Id.</i> The “inlet” receives pressurized gas from the CPAP device. <i>Id.</i> The <i>Manual</i> further discloses that the “outlet” is for “connect[ing] [a] flexible tubing.” <i>Id.</i>; <i>See also id.</i> at 5 (“Connect the flexible tubing to the outlet port on the water chamber.”). The outlet is configured to deliver the pressurized gas with the added humidity from the “humidifier.” <i>See, e.g., id.</i> at 7 (defining the pressure drop “over the range of operating pressures”).</p>
<p>4. A humidifier assembly according to claim 1, wherein the connecting structure includes contact elements that communicate with a power supply within the CPAP apparatus.</p>	<p>The <i>Manual</i> discloses that the humidifier platform includes a power jumper cord (the claimed “contact elements”). <i>See</i> Ex. 1003 at 3–4. The cord is identified in the annotated Figure included below:</p> <div data-bbox="784 1020 1195 1413" data-label="Image"> </div> <p>Ex. 1003 at 4.</p> <p>The <i>Manual</i> teaches that the humidifier platform communicates with an AC inlet on the CPAP device. <i>See</i> Ex. 1003 at 4. For example, the <i>Manual</i> discloses “[c]onnecting the humidifier’s power jumper cord to the AC inlet on the [CPAP] device.” <i>Id.</i> The <i>Manual</i> further discloses plugging “the CPAP device’s power cord into the AC connector on the humidifier” and plugging “the</p>

Claims	Exemplary Disclosure of Respironics' REMstar <i>Manual</i>
	remaining end of the power cord into an AC outlet.” ²⁰ <i>Id.</i>
5. A humidifier assembly according to claim 1, wherein the connecting structure is configured to allow removable attachment of the CPAP apparatus to the humidifier.	The <i>Manual</i> discloses that the “connecting structure” is configured to allow removable attachment of the CPAP apparatus to the humidifier. For example, the <i>Manual</i> discloses that the “humidifier” can be attached to the CPAP apparatus by “[p]ressing down the spring loaded heater plate with the water chamber and slide the chamber into place [on the humidifier platform]. Make sure the rubber connector on the inlet port fits securely over the CPAP device’s air outlet.” Ex. 1003 at 5. For removing the humidifier from the CPAP apparatus, the <i>Manual</i> discloses “[d]isconnecting the tubing from the water chamber” and “[p]ress[ing] down on the water chamber and slide it out of the humidifier platform.” <i>Id.</i> at 6.
7. A CPAP apparatus including a humidifier assembly according to claim 1.	<p>The <i>Manual</i> discloses a CPAP apparatus including a humidifier assembly. For example, the <i>Manual</i> discloses that “[t]he REMstar Heated Humidifier is for use with certain Respironics CPAP devices. The humidifier moistens the air delivered by the Respironics CPAP devices.” <i>See</i> Ex. 1003 at 1. Further the <i>Manual</i> discloses placing “the CPAP device on the humidifier platform,” of the humidifier assembly. <i>See id.</i> at 4.</p> <p>The “CPAP apparatus” is identified in the Figure included below:</p>

²⁰ There must be a power supply in the CPAP device that receives electricity from the main electricity source via the power jumper cord and provides the electricity to the CPAP device. Ex. 1004 at ¶75 (citing Ex. 1003 at 4).

Claims	Exemplary Disclosure of Respironics' REMstar <i>Manual</i>
	 <p data-bbox="560 657 760 688">Ex. 1003 at 5.</p>

D. Ground 4: Claim 3 is obvious over the REMstar *Manual* in view of *Daniell*

Claim 3 depends from claim 1 and requires “the connecting structure includes a control knob to control a heat setting of the heating element.” The *Manual* discloses or renders obvious all of the features of claim 1. Further, the *Manual* teaches a user interface to control a heat setting of the heater plate. *See* Ex. 1003 at p. 5 (“Press and hold the humidifier button on the CPAP device until the humidifier screen appears. Press the humidifier or ram buttons to change the setting.”). The Heater Humidifier includes heat settings 1 to 5 (104 to 149 °F/40 °C to 65 °C). *See id.*, at p. 7. It would have been obvious to one of ordinary skill in the art to implement the humidifier platform of the Heated Humidifier with a control knob to control the heat setting of the heater plate.

The use of a control knob on a heated humidifier for temperature setting was well known in the industry. For example, *Daniell* discloses a dial 10 to control the

temperature of a heater plate 7. *See* Ex. 1017 at 4:2-6. *Daniell* teaches that “[i]n response to the user set humidity or temperature value input via dial 10 and other inputs, controller 9 determines when (or to what level) to energise heater plate 7 to heat the water 6 within humidification chamber 5.” *Id.*

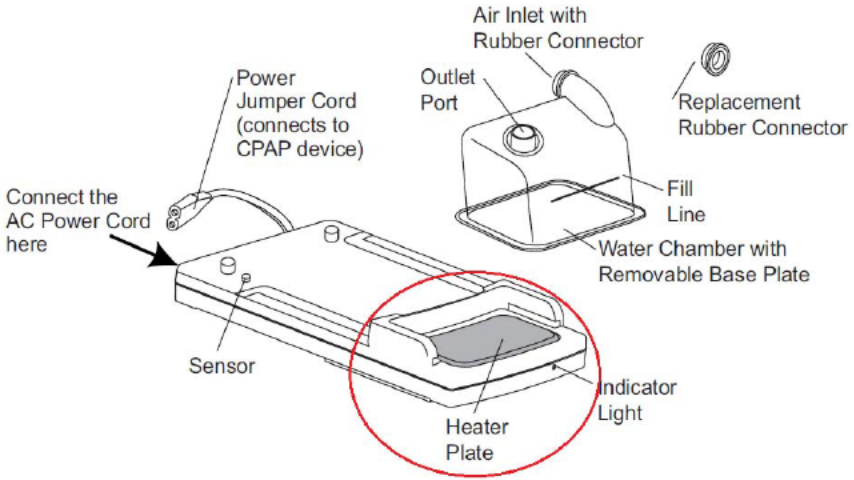
At the very least, one of ordinary skill in the art would have been motivated to provide the dial of *Daniell* onto the humidifier platform of the Heated Humidifier described in the *Manual*, to provide a patient with easy control over the temperature setting of the Heated Humidifier when the water chamber is placed on the heater plate of the humidifier platform. Indeed, such a modification of the *Manual* would constitute no more than an obvious design choice – one of a “finite number of identified, predictable solutions” – to one skilled in the art at the time the ’453 patent was filed. Ex. 1004 at ¶79; *see also* KSR, 550 U.S. at 402-3 (“When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.”), 416 (“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.”). Ex. 1004 at ¶79.

Moreover, it would have been obvious to one of ordinary skill in the art to incorporate the dial of *Daniell* onto the humidifier platform of the Heated Humidifier

as the heat setting of the heater plate would only need to be adjusted when the water chamber is positioned on the heater plate of the humidifier platform. Indeed, according to Mr. Bordewick, it would have been obvious to one of ordinary skill in the art to incorporate the dial of *Daniell* onto the humidifier platform of the Heated Humidifier described in the *Manual* as the heat setting of the heater plate would only need to be adjusted when the water chamber is positioned on the humidifier platform (i.e., there is no need for water temperature adjustment without the water chamber which holds the water). Thus, one having ordinary skill in the art would readily appreciate that the dial should be tied in together with the Heated Humidifier described in the *Manual*. Ex. 1004 at ¶80; see *KSR*, 550 U.S. at 417 (“[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.”). Ex. 1004 at ¶80.

As further detailed in the claim chart below, *Manual* in combination with *Daniell* renders all of the elements of claim 3 of the '453 patent obvious.

Claims	Exemplary Disclosure of Respironics' REMstar <i>Manual</i> and <i>Daniell</i>
3. A humidifier assembly according to claim 1, wherein the connecting structure includes a control knob to control a heat setting of the heating element.	The <i>Manual</i> discloses that the humidifier platform includes a heater plate (the claimed “heating element”). See <i>Manual</i> , at p. 3. The “heating element” is identified in the annotated Figure below:

Claims	Exemplary Disclosure of Respironics' REMstar <i>Manual</i> and <i>Daniell</i>
	 <p>See Ex. 1003, at p. 3.</p> <p>The <i>Manual</i> discloses a user interface to control a heat setting of the heater plate. See <i>Manual</i>, at p. 5 (“Press and hold the humidifier button on the CPAP device until the humidifier screen appears. Press the humidifier or ram buttons to change the setting.”). The <i>Manual</i> discloses heater settings 1 to 5 (104 to 149 °F/40 °C to 65 °C). See Ex. 1003, at p. 7.</p> <p>To the extent the <i>Manual</i> does not disclose a “control knob” on the humidifier platform to control a heat setting of the heater plate, <i>Daniell</i> teaches this feature. More specifically, <i>Daniell</i> discloses a dial 10 to control the temperature of a heater plate 7. See Ex. 1017, at 4:2-6 (“In response to the user set humidity or temperature value input via dial 10 and other inputs, controller 9 determines when (or to what level) to energise heater plate 7 to heat the water 6 within humidification chamber 5.”)</p>

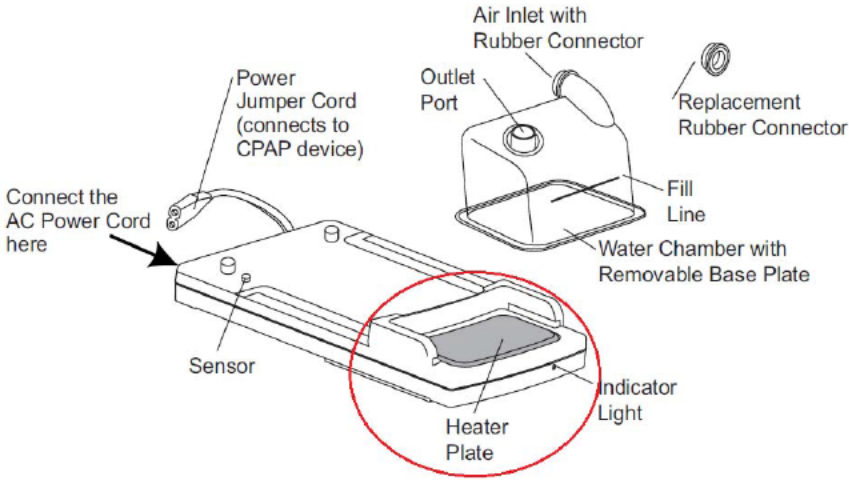
E. Ground 5: Claim 6 is obvious over the REMstar *Manual* in view of *Schatzl*

Claim 6 depends from claim 1 and requires “the heat conducting material [of the base] is a metallic material.” As discussed above, the *Manual* describes a humidifier platform having a heater plate for warming water in a water chamber. *See* Ex. 1003 at 3. In order for the heater plate to warm the water, the base plate must necessarily be constructed of a heat conducting material. Ex. 1004 at ¶¶56, 81.

Schatzl discloses “the bottom area 15 of tub element 1 is made of a material with high thermal conductivity, for example[,] metal.” Ex. 1002 at 5:19-21; *see also id.* at 3:10-12. It would have been obvious for one of ordinary skill in the art to have utilized a metallic material as taught in *Schatzl* for the heat conducting material of the base plate disclosed in the *Manual* to facilitate more effective heat transfer between the heater plate and the water located in the water chamber, as metal provides effective heat transfer and durability for repeated heat transfers (metal better withstands heat related age degradation allowing for repeated heating cycles over time). Ex. 1004 at ¶82. *See also KSR*, 550 U.S. at 417.

As further detailed in the claim chart below, the *Manual* in combination *Schatzl* renders all elements of claim 6 of the '453 patent obvious.

Claims	Exemplary Disclosure of Respironics' REMstar <i>Manual</i> and <i>Schatzl</i>
6. A humidifier assembly according to claim 1, wherein the heat	The <i>Manual</i> discloses that the “humidifier” is positioned on a heater plate, identified in the annotated Figure below:

Claims	Exemplary Disclosure of Respironics' REMstar <i>Manual</i> and <i>Schatzl</i>
conducting material is a metallic material.	 <p>See Ex. 1003, at p. 3. For example, the <i>Manual</i> discloses that a user is to “[p]ress down the spring loaded heater plate with the water chamber and slide the chamber into place” to position the “humidifier” on the heater plate. <i>Id.</i>, p. 5. In position, the heater plate warms the water in the “humidifier,” so it is constructed of a heat conducting material.²¹ See Ex. 1003, at p. 5.</p> <p><i>Schatzl</i> recognizes that one type of heat conducting material is metallic material. More specifically, <i>Schatzl</i> discloses that “the bottom area 15 of tub element 1 is made of a material with high thermal conductivity, for example[,] metal.” Ex. 1002 at 5:19-21. See also <i>id.</i> at 3:10-12.</p>

²¹ In order for the heater plate to warm the water, the “base” must be constructed of a heat conducting material. Ex. 1004 at ¶¶56, 81.

F. Ground 6: Claims 1 and 2 are obvious over *Prime* in view of *Schatzl* and further in view of *Dobson*

WO 00/21602 to Prime (“*Prime*”) published on April 20, 2000, and is prior art under 35 U.S.C. § 102(b). U.S. Patent No. 5,673,687 to Dobson (“*Dobson*”) issued on October 7, 1997, and is thus also prior art under 35 U.S.C. § 102(b).

Prime discloses a respiratory humidification system having a respiratory humidification chamber 1 for use with a breathing assistance apparatus. *See* Ex. 1018 at Abstract (“The humidification chamber is designed to be used in a breathing assistance apparatus in order to provide pressurised humidified gases to a user.”). The humidifier chamber 1 includes a dome 2 and a base 3. *Id.* at 3:21-22. *Prime* discloses that base 3 has a flat disk shape and a raised circular flange for retaining liquid. *See e.g., id.* at 4:3-6, Abstract.

As shown in Fig. 5 of *Prime*, dome 2 defines a gases inlet 4 and a gases outlet 5, “both of which protrude from the upper surface 6” of dome 2. Gases inlet 4 and gases outlet 5 are in communication with an interior of chamber 1 “such that the gases passing through the top of the dome will be humidified.” *See id.* at 3:28-29, Abstract. As detailed in the claim chart below, *Prime* discloses a respiratory humidification system, which includes the claimed humidifier, for use with a CPAP apparatus of claim 1.

Claim 1 also requires 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.” To the extent *Prime* does not explicitly disclose the claimed “connecting structure,” *Schatz* teaches this feature.

Schatz, like *Prime*, discloses a humidifier for use with a CPAP apparatus. Further, *Schatz* discloses a mountable housing 4 that is equipped with a fastening appliance 20 including a connector peg 16 to couple a humidifier (e.g., refill unit 3) to a CPAP apparatus and allow for fluid communication between an outlet of the CPAP apparatus and a respiratory gas inlet opening 11 of the humidifier. *See* Ex. 1002 at 5:58 - 6:3; 5:26-33. According to *Schatz*,

[T]he mountable housing, into which at least the tube element can be inserted, is provided to retain the desired humidification unit. . . . In an advantageous fashion, the design of the connecting structure for the breathing tube and preferably also the one for the secondary, in particular the pressure measuring tube provided on the side of the humidification appliance coincides with the corresponding connection structure provided on a CPAP apparatus. Thus, compatibility of the tube connectors both with the CPAP apparatus as well as the optionally interconnected humidification appliance is achieved in an advantageous fashion.

In so doing, a robust and advantageous embodiment under manufacturing aspects is achieved with the fact that the secondary tube adapter and the breathing tube adapter are integrally formed with the tube element or the mountable housing.”

Id. at 3:25-51.

Schatz explains, “[A]n object of the invention is to create an easy-to-handle appliance for the humidification of a respiratory gas as well as a CPAP apparatus intended for use with it.” *Id.* at 1:25-29.

It would have been obvious to one having ordinary skill in the art to have modified the respiratory humidification system of *Prime* to incorporate a connecting structure, such as the mountable housing 4 of *Schatz*, to connect the humidifier of *Prime* to its gases supply or breathing assistance apparatus, creating an integral and easier-to-handle respiratory humidification system for a patient. *Schatz* stresses the advantageous effects of using a connecting structure, such as the mountable housing 4, to connect its tub element 1 together with a CPAP apparatus: an integrally formed and easy-to-handle humidification appliance and CPAP apparatus. Indeed, by forming an integral connection and minimizing the distance between the CPAP apparatus and the humidification appliance, *Schatz* is quick to highlight the resulting manufacturing efficiencies and user-friendly nature achieved by such a system. *Id.* at 3:25-49. As such, a modification of *Prime* to include the mountable housing 4 would have been obvious.

Given the disclosures of *Prime* and *Schatz*, one having ordinary skill in the art would have recognized that CPAP apparatuses, humidifiers, and connecting structures (for connecting a humidifier to a CPAP apparatus) were familiar elements before the earliest priority date of claims 1-7 and that modifying the respiratory humidification system of *Prime* to incorporate the connecting structure of *Schatz* would have done

nothing more than combine familiar elements according to known methods. Ex. 1004 at ¶89; *see KSR* 550 U.S. at 416. Such a modification would yield the predictable results of superior inventory management and manufacturing of the respiratory humidification system for manufacturers, superior patient friendliness through enhanced aesthetics (e.g., system does not look as much like a “medical device” to others), as well as increased safety and mobility (e.g., a patient is less likely entangled with extraneous components while using or in transit with the system). Ex. 1004 at ¶90; *see KSR*, 550 U.S. at 416.

The patient-friendly features discussed above, as well as additional benefits of such an integrated system between a CPAP apparatus and a humidifier is further evidenced by *Dobson*. *Dobson* discusses the disadvantages of a flexible hose between a ventilator for sleep apnea and humidifier in home environments. *See* Ex. 1019 at 1:24-29. *Dobson* also teaches a flexible hose between a ventilator and humidifier is undesirable. *Id.* The hose “can easily be accidentally snagged or struck by the patient as he or she manipulates the various controls or moves the unit.” *See id.* at 1:29-33. Moreover, the hose “is [] an additional part that must be disconnected from both the ventilator and humidifier to be periodically cleaned.” *Id.* at 1:34-36. Further, “[s]uch hoses can [] be cut or torn in use.” *Id.* at 1:38.

Therefore, in light of the disadvantages of a flexible hose itemized in *Dobson*, it would have been obvious to one having ordinary skill in the art, at the time of the filing of the alleged invention, to modify the respiratory humidification system of

Prime to use a connecting structure such as the mountable housing 4 of *Schatz*, instead of a flexible hose, to connect the humidifier to a CPAP apparatus. This modification would have addressed the problems with a flexible hose taught by *Dobson*, and would have increased the safety and mobility of the patient while using and in transit with the system. Ex. 1004 at ¶92. Such a modification of *Prime* to include mountable housing 4 of *Schatz*, as suggested by *Dobson*, would have been an obvious combination of familiar elements to yield predictable results. *See KSR*, at 416; *see also* Ex. 1004 at ¶92.

As further detailed in the claim chart below, *Prime*, in combination with *Schatz*, as evidenced by *Dobson*, renders claims 1-2 of the '453 patent obvious.

Claims	Exemplary Disclosures of <i>Prime</i> , <i>Schatz</i> , and <i>Dobson</i>
1. A humidifier assembly for a CPAP apparatus, comprising	<i>Prime</i> discloses a respiratory humidification chamber 1 (the claimed “humidifier assembly”) for use with a breathing assistance apparatus (the claimed “CPAP apparatus”) ²² . <i>See</i> Ex. 1018 at Abstract, 3:19-22, 6:23-25, and Figs. 1-2 and 5.

²² One having ordinary skill in the art would recognize that a breathing assistance apparatus which provides pressurized humidified gases to a user, as disclosed by *Prime*, is a CPAP apparatus. Ex. 1004 at ¶95. Furthermore, the '453 patent acknowledges that conventional CPAP devices included a blower to supply gas to a patient, and that it was known to use a humidifier to add humidity to the breathable gas for the comfort of the patients. Ex. 1001 at 1:29-39. *See also* Ex. 1004 at ¶95

Claims	Exemplary Disclosures of <i>Prime, Schatzl, and Dobson</i>
	<p>“With reference to the drawings, and in particular Figures 1 and 2 initially, a respiratory humidification chamber 1 is shown.” <i>Id.</i> at 3:19-20 and Figs. 1-2;</p> <p>“The dome and the base together form a humidification chamber which holds a body of water which is heated through the metallic base such that gases passing through the top of the dome will be humidified.” <i>Id.</i> at Abstract;</p> <p>“The humidification chamber is designed to be used in a breathing assistance apparatus in order to provide pressurized humidified gases to a user.” <i>Id.</i></p>
a humidifier including	<p><i>Prime</i> discloses that humidification chamber 1 is a humidifier. <i>See</i> Ex. 1018, at 3: 19-26 and abstract and Figs. 1-2.</p> <p>“With reference to the drawings, and in particular Figures 1 and 2 initially, a respiratory humidification chamber 1 is shown.” <i>Id.</i> at 3:19-20; Figs. 1-2</p> <p>“The dome and the base together form a humidification chamber which holds a body of water which is heated through the metallic base such that gases passing through the top of the dome will be humidified. The humidification chamber is designed to be used in a breathing assistance apparatus in order to provide pressurized humidified gases to a user.” <i>Id.</i> at Abstract.</p>
a base configured to retain a body of liquid therein, at least a portion of the base being constructed of a heat conducting	<p><i>Prime</i> discloses the “humidifier” includes a base means or base 3 (the claimed “base”) configured to retain a body of water (the claimed “liquid”) therein. <i>See Prime</i>, at 3: 19-26, Abstract, and Figs. 1-2.</p> <p>“The respiratory humidification chamber 1 substantially comprises two parts, a chamber means or dome 2 and a base means or base 3.” <i>Id.</i> at 3:21-22 and Figs. 1-2.</p>

Claims	Exemplary Disclosures of <i>Prime, Schatzl, and Dobson</i>
material,	<p>“The dome and the base together form a humidification chamber which holds a body of water which is heated through the metallic base such that gases passing through the top of the dome will be humidified. The humidification chamber is designed to be used in a breathing assistance apparatus in order to provide pressurized humidified gases to a user.” <i>Id.</i> at Abstract.</p> <p>Further, <i>Prime</i> discloses that at least a portion of the base 3 is constructed of a heat conducting material. <i>See, id.</i> at 1:5-7; 4:7-10; Abstract.</p> <p>“This invention relates to seals and more particularly though not solely to humidification apparatus in which a water tight seal between a plastics chamber and a metallic base is provided.” <i>Id.</i> at 1: 5-7.</p> <p>“As will be described below, it is necessary for base 3 to possess good thermal conductivity properties and we have found that a good material from which base 3 may be formed is anodized aluminum.” <i>Id.</i> at 4:7-10.</p> <p>“The dome and the base together form a humidification chamber which holds a body of water which is heated through the metallic base such that gases passing through the top of the dome will be humidified.” <i>Id.</i> at Abstract.</p>
a top cover, and	<p><i>Prime</i> discloses that the “humidifier” also includes a chamber means or dome 2 (the claimed “top cover”). <i>See</i> Ex. 1018 at 3:19-26, Abstract, and Figs. 1-2.</p> <p>“The respiratory humidification chamber 1 substantially comprises two parts, a chamber mans or dome 2 and a base means or base 3.” <i>Id.</i> at 3: 21-22, Figs. 1-2; and</p> <p>“The dome and the base together form a humidification</p>

Claims	Exemplary Disclosures of <i>Prime, Schatzl, and Dobson</i>
	<p>chamber which holds a body of water which is heated through the metallic base such that gases passing through the top of the dome will be humidified. The humidification chamber is designed to be used in a breathing assistance apparatus in order to provide pressurized humidified gases to a user.” <i>Id.</i> at Abstract.</p>
<p>a seal disposed between the top cover and the base; and</p>	<p><i>Prime</i> discloses a layer of adhesive means or glue 12 (the claimed “seal”) disposed between dome 2 and the base 3. <i>See</i> Ex. 1018 at 1:5-7; 4:6-7 and Figs. 1-2.</p> <p>“This invention relates to seals and more particularly though not solely to humidification apparatus in which a water tight seal between a plastics chamber and a metallic base is provided.” <i>Id.</i> at 1: 5-7.</p>
<p>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</p>	<p><i>Prime</i> discloses that its “humidifier” can be used with a breathing assistance apparatus (e.g., a CPAP apparatus). <i>See Prime</i>, at Abstract, 3:19-22, 6:23-25, and Figs. 1-2 and 5.</p> <p>“With reference to the drawings, and in particular Figures 1 and 2 initially, a respiratory humidification chamber 1 is shown.” <i>Prime</i>, 3:19-20 and Figs. 1-2;</p> <p>“The dome and the base together form a humidification chamber which holds a body of water which is heated through the metallic base such that gases passing through the top of the dome will be humidified.” <i>Id.</i> at Abstract; and</p> <p>“The humidification chamber is designed to be used in a breathing assistance apparatus in order to provide pressurized humidified gases to a user.” <i>Id.</i></p> <p>To the extent that <i>Prime</i> does not disclose “a connecting structure configured to connect between the CPAP apparatus and humidifier and allow communication of an</p>

Claims	Exemplary Disclosures of <i>Prime</i> , <i>Schatz</i> , and <i>Dobson</i>
	<p>outlet of the CPAP apparatus with an inlet of the humidifier,” <i>Schatz</i> discloses these features.</p> <p>For example, <i>Schatz</i> discloses a mountable housing 4 (the claimed “connecting structure”) that is equipped with a fastening appliance 20 including a connector peg 16 to couple refill unit 3 (a “humidifier”) to a complimentary structure on a CPAP apparatus, thereby allowing communication of an outlet of the CPAP apparatus with a respirator inlet opening 11 of refill unit 3. <i>See</i> Ex. 1002 at 5:58 - 6:3; 5:26-33. <i>See also</i> above discussion of <i>Schatz</i> in Section VII.A. at 16.</p> <p><i>Dobson</i> describes motivation for using the “connecting structure” described in <i>Schatz</i> with the “humidifier” of <i>Prime</i>. In particular, <i>Dobson</i> discloses that in home environments, where ventilators are widely used to treat sleep apnea, a flexible hose between a ventilator and humidifier is undesirable. <i>See</i> Ex. 1019, at 1:24-29. The hose “can easily be accidentally snagged or struck by the patient as he or she manipulates the various controls or moves the unit.” <i>See id.</i> at 1:29-33. Moreover, the hose “is [] an additional part that must be disconnected from both the ventilator and humidifier to be periodically cleaned.” <i>Id.</i> at 1:34-36. Further, “[s]uch hoses can [] be cut or torn in use.” <i>Id.</i> at 1:38.</p>
a housing providing a base portion to support the humidifier thereon, and	<p>As shown in Fig. 1, <i>Schatz</i> discloses that mountable housing 4 includes a base portion that supports the refill unit 3. <i>See</i> Ex. 1002 at 4:34-38. <i>See also</i> above discussion of <i>Schatz</i> in Section VII.A. at 16.</p>
a retaining mechanism	<p><i>Schatz</i> discloses that mountable housing 4 “is equipped with</p>

Claims	Exemplary Disclosures of <i>Prime, Schatzl, and Dobson</i>
configured to secure the connecting structure to the CPAP apparatus,	a fastening appliance 20, via which the humidification appliance can be coupled with a CPAP apparatus in a mechanically relatively rigid manner.” ²³ <i>See</i> Ex. 1002 at 5:59-6:3; <i>see also id.</i> at 6:51-55 (“[t]he fastening appliance labeled with the reference number 20 in Fig. 1, with which a particularly rigid coupling of the humidification appliance with the corresponding CPAP apparatus can be achieved, is provided below the mentioned connector pegs.”). <i>See also</i> above discussion of <i>Schatzl</i> in Section VII.A. at 16-17.
wherein the base portion includes a heating element in contact with the heat conducting material of the base of the humidifier.	<i>Schatzl</i> discloses that mountable housing 4 includes a heating device 14 closely contacting the material with high thermal conductivity of bottom area 15 of tub element 1 of refill unit 3. <i>See</i> Ex. 1002 at 5:13-18 and Fig. 1. <i>See also</i> above discussion of <i>Schatzl</i> in Section VII.A. at 17.
2. A humidifier assembly according to claim 1, wherein the top cover defines both an inlet and an outlet communicated	<i>Prime</i> discloses that the dome 2 defines both a gases inlet 4 (the claimed “inlet”) and a gases outlet 5 (the claimed “outlet”) communicated with an interior of the base 3. <i>Prime</i> teaches that the “inlet” is configured to receive pressurized

²³ Fastening appliance 20 is a structure that holds the CPAP apparatus in position on mountable housing 4 when in its normal orientation, because the fastening appliance is coupled to a bottom of the CPAP apparatus “in a mechanically rigid manner.” Ex. 1004 at ¶105 (citing Ex. 1002 at 5:58 - 6:3; 6:50-54).

Claims	Exemplary Disclosures of <i>Prime, Schatzl, and Dobson</i>
<p>with an interior of the base, the inlet configured to receive pressurized breathable gas and the outlet configured to deliver the pressurized breathable gas with added humidity.</p>	<p>breathable gas²⁴, and the “outlet” is configured to deliver the pressurized breathable gas with added humidity. <i>See, e.g.</i>, Ex. 1018 at 3:28-30, 4:1, 6:15-27, Abstract, Fig. 5.</p> <p>“Dome 2 is preferably provided with a gases inlet 4 and a gases outlet 5, both of which protrude from the upper surface 6 thereof.” <i>Id.</i> at 3:28-29, and Figs. 1-2, 5;</p> <p>“The dome and the base together form a humidification chamber which holds a body of water which is heated through the metallic base such that gases passing through the top of the dome will be humidified. The humidification chamber is designed to be used in a breathing assistance apparatus in order to provide pressurized humidified gases to a user.” <i>Id.</i> at Abstract; and</p> <p>“A gases supply or ventilator 18 provides a flow of gases to the gases inlet 4 of the humidification chamber 1. As the water within the chamber is heated it will release water vapor to the gases flow producing humidified gases at the gases outlet 5 which are carried to a patient 19 by an inspiratory conduit 21.” <i>Id.</i> at 6:23-27, and Fig. 5.</p>

²⁴ The gases inlet 4 of *Prime* must receive pressurized breathable gas, for otherwise the breathable gas would not flow into the respiratory humidification chamber. Ex. 1004 at ¶108.

VIII. CONCLUSION

For the reasons set forth above, the challenged claims 1-7 are unpatentable and should be cancelled. Petitioner respectfully requests that the Board grant this petition for *inter partes* review and institute trial.

Petitioner reserves the right to apply additional prior art and arguments, depending on what arguments and/or amendments Patent Owner might present. Petitioner also reserves the right to cite and apply any additional art it might discover as relevant to the issued claims or any amended claims, as the *inter partes* review proceeds.

The undersigned attorneys welcome a telephone call should the Office have any requests or questions. If there are any additional fees due in connection with the filing of this paper, please charge the required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

Dated: July 23, 2014

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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing Petition for Inter Partes Review was served on July 23, 2014, by Federal Express at the following addresses of record for the subject patent. The associated Power of Attorney and Exhibits 1001 through 1022 were also served on July 23, 2014.

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