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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED LIMITED, RESMED INC., and RESMED CORP.,

Petitioners,

v.

FISHER & PAYKEL HEALTHCARE LIMITED,

Patent Owner.

Case No. IPR2016-01719
U.S. Patent No. 6,398,197

PATENT OWNER PRELIMINARY RESPONSE

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I. INTRODUCTION

Patent Owner Fisher & Paykel Healthcare Limited ("FPH") is a world leader and innovator in respiratory therapy devices for critical care and home care use. U.S. Patent No. 6,398,197 ("the '197 Patent") at issue in this IPR is directed to an improved humidifier apparatus for continuous positive airway pressure (CPAP) treatments. *See, e.g.*, Ex. 1001 at Abstract, 1:6-8.

FPH and Petitioners ResMed Inc., ResMed Corp, and ResMed Limited are presently engaged in a global patent dispute relating to CPAP machines and related products. As part of that dispute, Petitioners seek *inter partes* review of Claims 1-3, 6, and 13 of the '197 Patent. Before filing the present IPR petition, however, Petitioners filed a declaratory judgment action in district court challenging the validity of the '197 Patent. Petitioners' request to institute an IPR is therefore statutorily barred by 35 U.S.C. § 315(a).

Even if Petitioners were not barred, however, an IPR should not be instituted as to any claim. Petitioners have not met their burden of demonstrating a reasonable likelihood that the challenged claims are invalid as required by 35 U.S.C. § 314(a).

The '197 Patent invention includes an inlet extension tube, also referred to as a flow tube, extending from the horizontal inlet of a humidification chamber. Ex. 1001 at 2:25-28, Fig. 2. The flow tube design provides multiple advantages.

One benefit is that it reduces the noise caused by air blowing into the chamber by imparting an improved airflow pattern. *Id.* at 2:44-59. CPAP machines are utilized for treatment of sleep apnea and are used by patients during sleep. Prior art CPAP machine designs in which air flow was delivered directly to the humidifier chamber from the blower resulted in annoying noise levels within the chamber. *Id.* at 1:20-24. Noise from a CPAP machine can interfere with sleep, and thus noise reduction is an important benefit.

Another benefit of the flow tube design is that it prevents water from spilling out of the humidifier chamber air inlet and into the blower of the CPAP machine. *Id.* at 2:59-61. Positioning an inlet port on the side of the humidifier chamber increases the likelihood that water will spill out of the chamber if the chamber is tilted, which may result in water flowing into the blower of the CPAP machine and damaging the machine. *Id.* at 1:24-34. Figure 6 from the ’197 Patent (below) illustrates how the flow tube prevents water from spilling out of the inlet when the chamber is tipped.

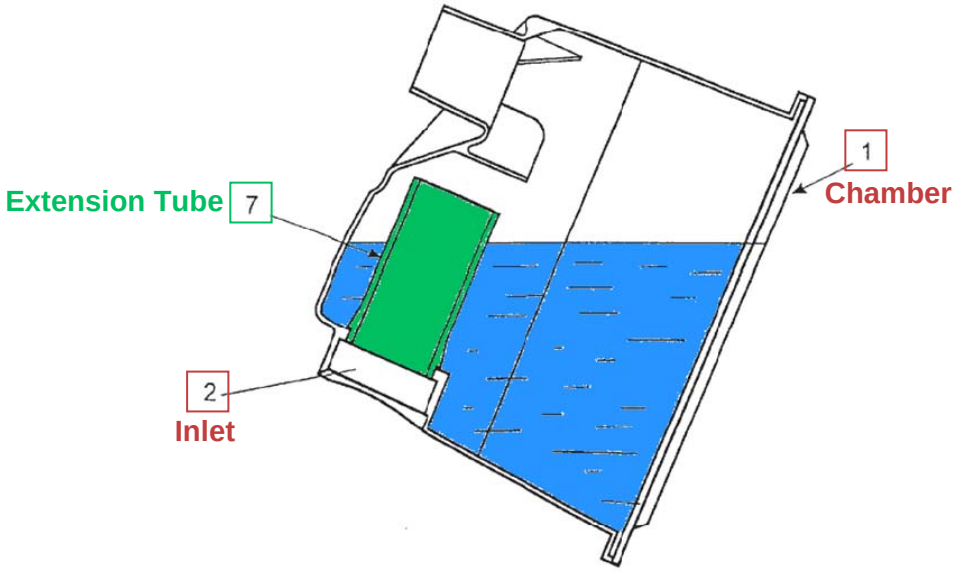
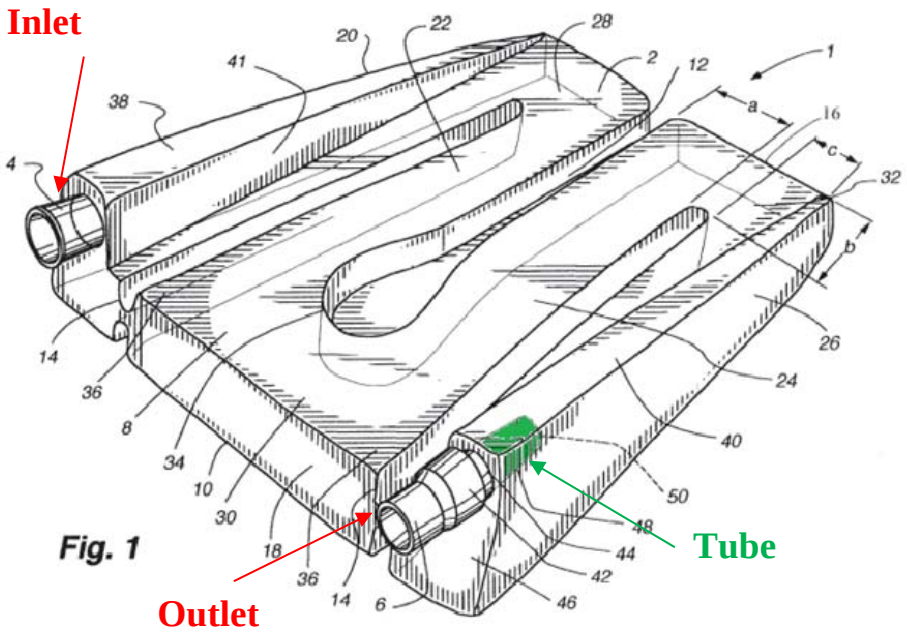


FIGURE 6

Id. at Fig. 6 (color and annotations added).

Claim 1 of the ’197 Patent claims, *inter alia*, a water chamber adapted for use in conjunction with a heater base, with a horizontally oriented gas inlet, and an elongate flow tube extending into the water chamber from the inner periphery of the gas inlet with the outlet end of the flow tube spaced apart from the wall of the chamber. Petitioners rely on Hebblewhite (Ex. 1004) as allegedly teaching or rendering obvious the claimed flow tube for all asserted grounds. But Hebblewhite, which describes a low profile humidifier, does not teach a flow tube extending from the air inlet. Rather, Hebblewhite’s tube extends from the air outlet, as shown in Figure 1 (below). Hebblewhite’s tube also serves a different purpose than the flow tube of the ’197 Patent.



Ex. 1004 at Fig. 1 (color and annotations added).

Hebblewhite's tube is not directed to either problem identified in the '197 Patent. Instead, Hebblewhite's tube purports to solve a specific problem created by Hebblewhite's low profile construction—splashing from waves at the ***outlet*** generated by air blowing from the inlet through the chamber and toward the outlet. *Id.* at 3:34-40. Waves would not be a problem at the inlet because air blows waves away from the inlet. Thus, there would be no reason to add a tube at Hebblewhite's inlet, and Hebblewhite does not teach locating a tube at the inlet.

Moreover, Petitioners rely on hindsight to argue why Hebblewhite would be combinable with the primary reference used in Ground 1—the HC200 Manual (Ex. 1015). Even without hindsight, Petitioners' argument fails because Hebblewhite is

directed to an entirely different problem—waves, not tipping. Spilling from waves is not a problem in the device shown in the HC200 Manual because the air inlet is located near the top of the water chamber and is spaced well above the water surface.

Also, combining Hebblewhite and the HC200 Manual as Petitioners urge would degrade the performance of the resulting humidifier. Due to the orientation of the air inlet and outlet of the device shown in the HC200 Manual, adding a flow tube to the air inlet would cause air to flow directly into the air outlet. As a result, the air circulation through the water chamber would be diminished which, in turn, would reduce air humidification.

Grounds 1-4 all rely upon the asserted combination of Hebblewhite and the HC200 Manual and therefore fail for the reasons described above and for additional reasons. For example, Grounds 2 and 4 also fail because they rely upon Gouget (Ex. 1006), which is directed to a portable urinal and is not analogous art. Grounds 2 and 4 suffer from yet another deficiency because Petitioners add another reference to their combination (Rose – Ex. 1008) in an attempt to remedy the degraded performance of the combination they have constructed. However, Petitioners' creation of, identification of, and solution to the performance problem rely on improper hindsight.

Grounds 5 and 6 again rely on Hebblewhite and replace the HC200 Manual with a different primary reference (Netzer – Ex. 1010). Petitioners again rely on hindsight to create an alleged motivation to combine Hebblewhite with the other relied upon references. Further, the combination would not have been obvious because Netzer already had a solution to Petitioners' asserted reason to combine it with Hebblewhite. And Petitioners' alleged obviousness grounds also ignore significant structure in Netzer making it incompatible with adding Smith to the hindsight-constructed combination. And finally, Ground 6 also fails because Petitioners rely upon the non-analogous portable urinal of Gouget.

II. THE STATUTE BARS INSTITUTION OF AN IPR

Petitioners' requested IPR may not be instituted because it is barred by statute. The statute is unequivocal:

> An inter partes review may not be instituted if, before the date on which the petition for such a review is filed, the petitioner or real party in interest filed a civil action challenging the validity of a claim of the patent.

35 U.S.C. § 315(a)(1). Before Petitioners filed the instant Petition, they filed a civil action in the United States District Court for the Southern District of California challenging the validity of the '197 Patent. Ex. 1023 (complaint filed August 16, 2016). The plain language of the statute bars the Petition.

The Board should not construe Section 315 in a manner contrary to its plain

meaning. As the Supreme Court has explained:

> If the statute is clear and unambiguous "that is the end of the matter, for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress."

Sullivan v. Stroop, 496 U.S. 478, 482 (1990) (quoting *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 291-92 (1988)); *accord Carcieri v. Salazar*, 555 U.S. 379, 387 (2009) (collecting cases). Here, Section 315 leaves no wiggle room. Petitioners are barred.

A. Petitioners' Contrary Construction Of Section 315 Is Meritless

Petitioners briefly acknowledge they had previously filed an action challenging validity of the '197 patent, and then note they dismissed the action without prejudice. Pet. at 4-5. Petitioners then argue that their "action for declaratory judgment regarding the invalidity of the ['197 Patent] has no effect under 35 U.S.C. § 315(a) because it was voluntarily dismissed without prejudice." *Id*.

Petitioners filed their declaratory judgment action apparently to ensure their home forum, the Southern District of California, would be the selected venue for the parties' U.S. patent dispute. Petitioners only dismissed their action after learning they obtained the desired forum because FPH also filed in that forum. Petitioners should not be permitted to escape the consequences of Section 315 that

flow from their procedural maneuvering.

Petitioners apparently contend Section 315(a)(1) includes an implicit, unstated exception for complaints that are dismissed without prejudice. This, however, is directly contrary to *Sullivan*, 496 U.S. at 482, *Carcieri*, 555 U.S. at 387, and a long line of Supreme Court cases holding that the unambiguous language of a statute must be faithfully applied. Indeed, Petitioners seek to completely rewrite Section 315(a)(1) under the apparent guise of interpretation. The plain language of Section 315(a)(1) unambiguously bars an IPR if the Petitioners previously "filed a civil action challenging the validity of a claim of the patent." 35 U.S.C. § 315(a)(1). Petitioners seek to rewrite this statute to declare that an IPR is barred if the Petitioners previously "filed a civil action challenging the validity of a claim of the patent, ***unless that civil action was dismissed without prejudice***." There is no legal basis for adding this non-statutory exception to the unambiguous language of the statute.

B. Petitioners' Cited Authorities Are Contrary To Two Lines of Supreme Court Precedents

In support of its strained statutory construction, Petitioners cite two unpublished, non-precedential Board decisions. *See* Pet. at 5 (citing *Macauto U.S.A. v. BOS GmbH & KG*, IPR2012-00004, Paper No. 18 at 15-16 (P.T.A.B. Jan. 24, 2013), and *Oracle Corp. v. Click-to-Call Techs. LP*, IPR2013-00312, Paper

No. 52 at 12-13 (P.T.A.B. Oct. 28, 2014)). These decisions reason that the Federal Rules of Civil Procedure and court precedent "treat a dismissal without prejudice as something that, *de jure*, never existed." *Oracle*, IPR2013-00312, Paper No. 52 at 12.[1] Thus, these decisions conclude, a dismissal without prejudice "leav[es] the parties in the same legal position as if the underlying complaint had never been served." *Id*. at 13; *see also Macauto*, IPR2012-00004, Paper No. 18 at 15-16.

These two non-precedential decisions are unpersuasive for at least two significant reasons. First, of course, they are both contrary to cases like *Sullivan*, 496 U.S. at 482, and *Carcieri*, 555 U.S. at 387, which hold that the plain language of statutory text must be followed by courts and agencies. The Board in *Oracle* and *Macauto* did not even address the statutory text, much less follow it.

Second, *Oracle* and *Macauto* err in assessing the significance of a dismissal without prejudice under Federal Rule of Civil Procedure 41(a). The Supreme Court clearly explained the effect of a Rule 41(a) dismissal without prejudice in *Semtek Int'l, Inc. v. Lockheed Martin Corp.*, 531 U.S. 497, 505 (2001), stating:

The primary meaning of "dismissal without prejudice," we think, is

[1] Following this reasoning, the district court in the parties' pending litigation also granted Petitioners' motion to stay over FHP's objection that the case should not be stayed because the IPR petitions were barred under 35 U.S.C. § 315(a)(1).

> dismissal without barring the [plaintiff] from returning later, to the same court, with the same underlying claim.

Id. The Court also quoted favorably the definition of "dismissal without prejudice" in Black's Law Dictionary – "removed from the court's docket in such a way that the plaintiff may refile the same suit on the same claim." *Id*.

In short, by designating their dismissal as being "without prejudice" under Rule 41(a), Petitioners merely reserved the right to refile the same claim in the same court at a later date. Petitioners did not and could not nullify the statutory right that had already accrued to FPH to be free from subsequent Petitions for IPR.

It is true that some lower court decisions have loosely described the effect of a dismissal without prejudice as to "leave the parties as if the action had never been brought." *Bonneville Assocs. v. Barram*, 165 F.3d 1360, 1364 (Fed. Cir. 1999). This dicta, however, if construed as broadly as Petitioners would do, is inconsistent with the Supreme Court's decision in *Semtek.* Moreover, *Bonneville* and the other courts employing this dicta were all merely addressing the procedural effect of a dismissal without prejudice within the federal court system. None of them was addressing the effect or lack of effect of a dismissal without prejudice on a substantive statutory right, such as FPH's rights under 35 U.S.C. § 315(a).

In addition, the broad dicta of *Bonneville*, if read in the sweeping fashion that Petitioners desire, would be plainly wrong on its face. Rule 41(a) itself

provides that a dismissal without prejudice does ***not*** "leave the parties as if the action had never been brought." Rule 41(a) states that a party who dismisses a claim without prejudice once may not thereafter dismiss the same claim without prejudice again. Fed. R. Civ. P. 41(a)(1)(B). Thus, the loose language of *Bonneville* cannot be taken to mean that a dismissal without prejudice leaves the parties as if the action had never been brought ***for all purposes***. Rather, consistent with *Semtek*, the language of *Bonneville* means only that a plaintiff is free to refile a claim that has been dismissed without prejudice. Indeed, the holding of *Bonneville* is that a dismissal without prejudice has no effect beyond this and thus does not operate to toll the time for refiling an action or an appeal. *Bonneville,* 165 F.3d at 1364-65.

Finally, the plain language of Rule 41(a) is about dismissal, not filing. Rule 41(a) declares that the ***dismissal*** of a complaint is without prejudice under some circumstances. It does not say that the ***filing*** of a complaint is ever without prejudice. To determine the effect of the filing of a complaint, one must look elsewhere, in this case to 35 U.S.C. § 315(a).

C. Petitioners' Cited Authorities Are Also Contrary To The Rules Enabling Act

The two lines of Supreme Court precedents cited above provided reason enough to reject *Oracle* and *Macauto.* Another cardinal principle of federal law,

however, provides an additional reason not to follow these non-precedential decisions. The Rules Enabling Act declares that the Federal Rules "shall not abridge, enlarge or modify any substantive right." 28 U.S.C. § 2072(b). Thus, any interpretation of the phrase "dismissal without prejudice" in Rule 41(a) to defeat a substantive right would violate the Rules Enabling Act.

Yet, that is precisely how *Oracle* and *Macauto* construe Rule 41(a). *Oracle* and *Macauto* both hold that the purported right of a plaintiff to dismiss its complaint without any consequence under Rule 41(a) trumps the substantive right of a patentee under 35 U.S.C. § 315(a) to be free from subsequent Petitions for *Inter Partes* Review. Such an interpretation of Rule 41(a) would abridge a substantive right of patentees under Section 315(a) and thus violate the Rules Enabling Act.

This is confirmed by the cases interpreting the Rules Enabling Act. For example, in *Semtek*, 531 U.S. 497, the issue was whether a Rule 41 dismissal "with prejudice" had *res judicata* effect. The defendant argued that the issue was governed by Rule 41, which specified that the dismissal "operates as an adjudication upon the merits." *Id*. at 501. Thus, the defendant argued, the dismissal was entitled to *res judicata* effect. The Supreme Court unanimously rejected this argument. *Id*. at 503. The Court concluded that the *res judicata* effect of a judgment was a substantive right, and that the defendant's interpretation of

Rule 41 therefore "would arguably violate the jurisdictional limitation of the Rules Enabling Act: that the Rules 'shall not abridge, enlarge or modify any substantive right.'" *Id*. (quoting 28 U.S.C. § 2072(b)). In short, Rule 41(a) did not trump substantive law regarding the *res judicata* effect of judgments.

Brennan v. Silvergate District Lodge No. 50, 503 F.2d 800 (9th Cir. 1974), is to the same effect. There, the Secretary of Labor brought an action to set aside a union election in which Baffone had been elected union president. *Id.* at 802-03. Baffone sought to intervene under Rule 23 [now Rule 24] of the Federal Rules of Civil Procedure. *Id*. Baffone met the standard for intervention as of right under the Federal Rules. *Id*. at 804. However, a substantive labor law statute generally barred intervention on the side of a union in suits brought by the Secretary of Labor. *Id*. (citing 29 U.S.C. § 482(b)). Quoting the Rules Enabling Act, the Ninth Circuit held that Rule 23 [now Rule 24] could not trump the rights created by substantive federal labor law. *Id*. Accordingly, Baffone could not intervene unless he met the statutory labor law requirements. *Id*. at 805. *See also John Hancock Life Ins. Co. v. J.P. Morgan Chase & Co.*, 938 F. Supp. 2d 440, 448 (S.D.N.Y. 2013) (under the Rules Enabling Act, Rule 23's equitable tolling principles are trumped by the statute of repose of the Securities Act of 1933).

In sum, the instant Petition is barred under the plain and unambiguous text of 35 U.S.C. § 315(a)(1).

III. BACKGROUND

A. Overview Of The '197 Patent

The '197 Patent is directed to an innovative water chamber design for the humidifier of a CPAP device. The inventors of the '197 Patent recognized two problems with prior humidifier water chambers: (1) the noise level in the chamber resulting from the blower delivering air directly to the chamber and (2) the possibility of spillage from the water chamber inlet port into the CPAP machine blower. Ex. 1001 at 1:10-35. The inventions described in the '197 Patent solve these problems.

As seen in Figure 2 of the patent (below), the water chamber comprises a horizontally oriented gas inlet 2 that fits over the blower outlet nozzle of a CPAP machine (not shown). *Id.* at 2:20-22.

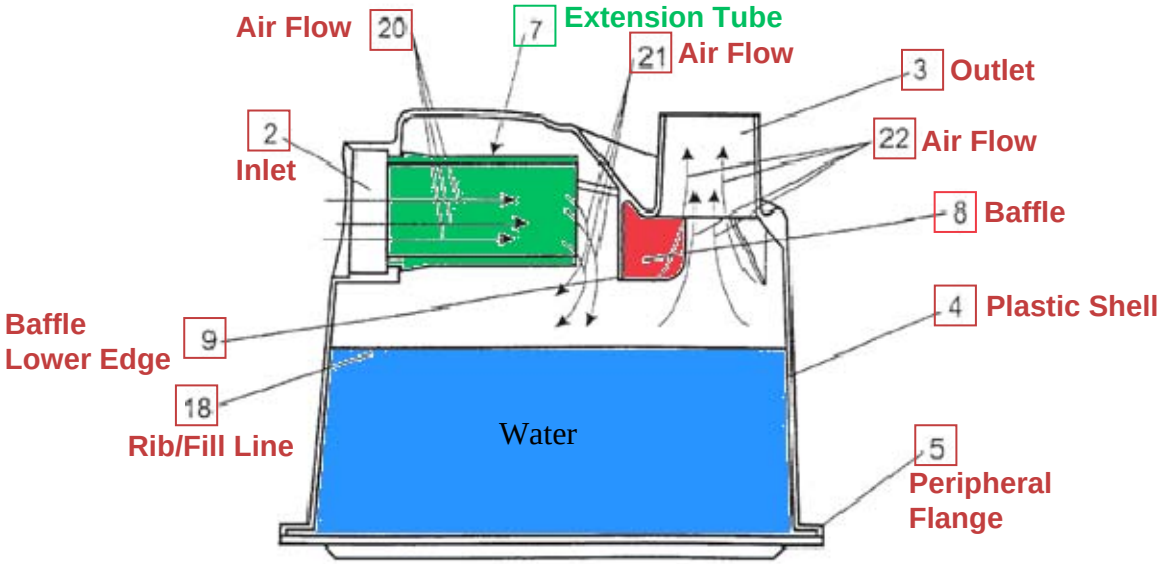


FIGURE 2

Id. at Fig. 2 (color and annotations added). An extension tube 7 "extend[s] inwardly into the chamber interior from the periphery of the gases inlet 2." *Id.* at 2:27-28. Air flow 20 enters the chamber 4 through the gas inlet 2 and passes through the extension tube 7, which results in a more controlled laminar flow pattern than is provided by the blower. *Id.* at 2:44-53. By creating an improved air-flow pattern, the inlet extension tube significantly reduces the noise level caused by air flowing through the humidifier chamber. *Id.* at 2:54-57.

After exiting the extension tube 7, the air flow 21 circulates within the chamber, where it is humidified. *Id.* at 2:25-36. Water in the chamber is heated by the transfer of heat from a heater plate on a CPAP machine to a conductive base 6 on the water chamber. *See, e.g., id.* at 2:15-20. The heated water interacts with the

air flow 21, causing the air to become humidified. Once the air is humidified, it exits the chamber through an outlet 3. *Id.* at 2:52-53. In some configurations, such as Figure 2 (above), a baffle 8 is provided to prevent the air from exiting the extension tube 7 and flowing directly through the outlet tube 3 without being sufficiently humidified. *Id.* at 2:29-38.

The extension tube 7 not only reduces the noise from air flowing into the humidifier, it also reduces the chance of water spilling out of the air inlet if the chamber is tipped. *Id.* at 2:59-61. As seen in Figure 6 (below), the extension tube 7 prevents water from flowing out of the inlet if or when the chamber is tipped.

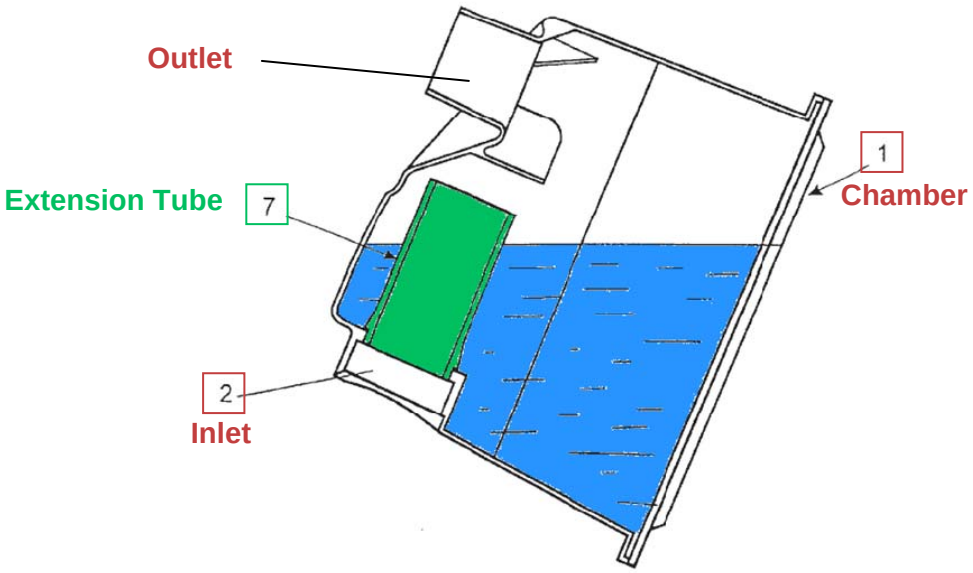


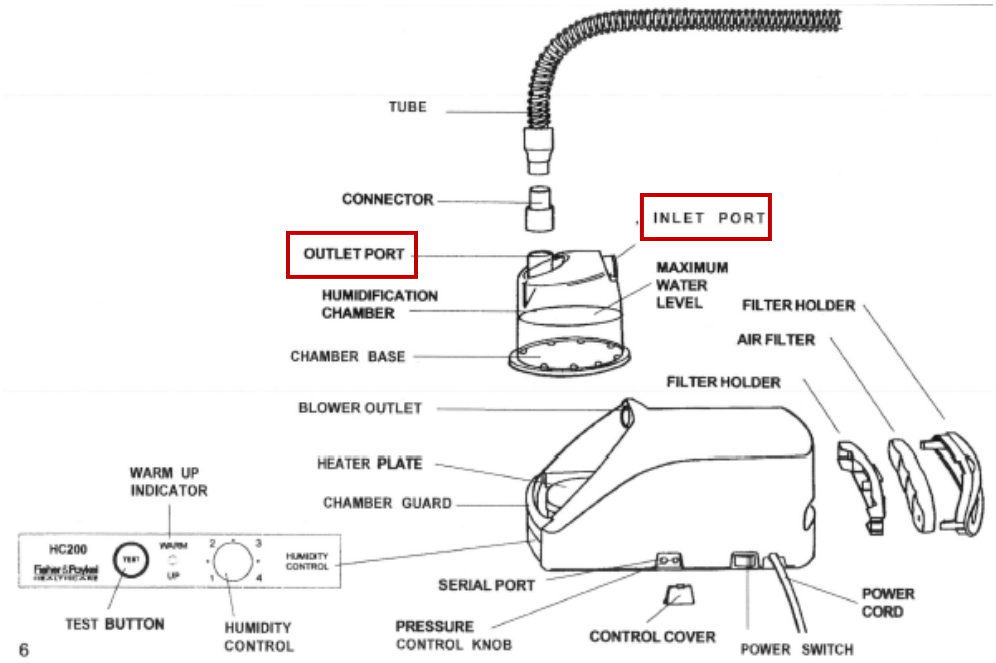
FIGURE 6

Id. at Fig. 6 (annotations and color added).

B. Overview Of The Alleged Prior Art

1. Overview of the HC200 Manual

The HC200 Manual shows a CPAP device having a humidifier for the treatment of sleep apnea. Ex. 1015. An image from the HC200 Manual is reproduced below.



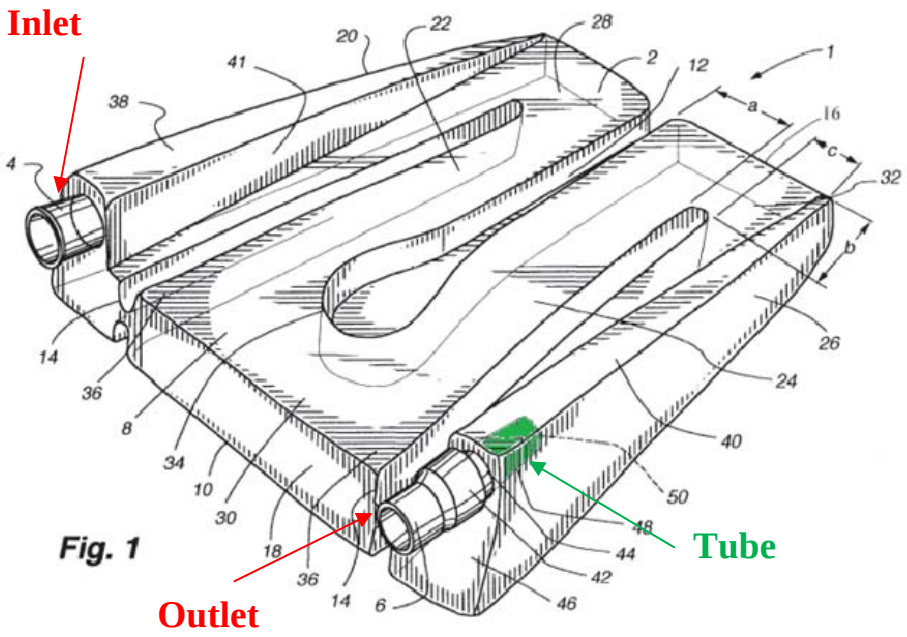
Id. at 7 (annotated).[2] The HC200 Manual shows a humidifier water chamber with an inlet port located on the sidewall of the chamber near the top of the chamber. *Id.* The manual also shows a heater plate that, in use, is positioned at the base of

[2] Citations to exhibit page numbers are to the page numbers that have been added to the exhibits by the parties and not to the original page numbers.

the chamber. *Id.* Air flows into the chamber through the inlet port and out of the chamber through a vertically oriented outlet port located at the top of the chamber. *Id.* As Petitioners acknowledge, the HC200 Manual does not teach the flow tube claimed in the '197 Patent.

2. Overview of Hebblewhite

U.S. Patent No. 6,135,432 ("Hebblewhite") teaches an auxiliary humidifier for a CPAP device. Ex. 1004 at Abstract. Hebblewhite's humidifier has a "low profile" to allow the CPAP device to be placed on top of it. *Id.* at 1:28-32, 4:6-7, Fig. 1. As shown in Figure 1 (below), air enters Hebblewhite's humidifier from the inlet 4, passes through a series of passageways 20, 22, 24, and 26, and exits through the outlet 6.

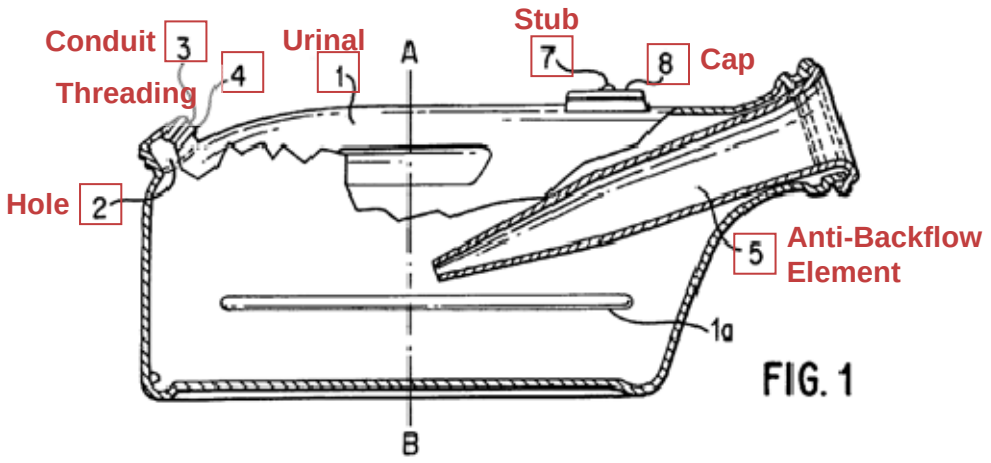


Id. at Fig. 1 (annotations and color added), *see also* 1:52-60.

Hebblewhite teaches that one disadvantage of low profile humidifiers is the formation of waves that can splash through the ***outlet*** of the humidifier. *Id.* at 3:34-38, 5:9-16. Air flow pushes waves away from the inlet and towards the outlet. Because of Hebblewhite's low profile, the outlet is located near the surface of the water. As a result, waves can splash into the outlet. *Id.* To avoid waves splashing through the ***outlet***, Hebblewhite includes a tube 48 extending from the outlet 6 away from the surrounding wall and into the humidifier chamber. *Id.* at 4:63-5:8. Hebblewhite makes no reference to potential spillage from tipping and does not teach that the outlet tube is useful for preventing the outflow of water that occurs from causes other than waves. Moreover, because the CPAP unit is positioned on top of the humidifier unit, tipping of the humidifier is unlikely to occur.

3. Overview of Gouget

U.S. Patent No. 5,953,763 ("Gouget") is titled "Safety Urinal" and describes a urinal receptacle. Ex. 1006. As shown in Figure 1 of Gouget (below), an anti-backflow element 5 extends to the volumetric center of the urinal.

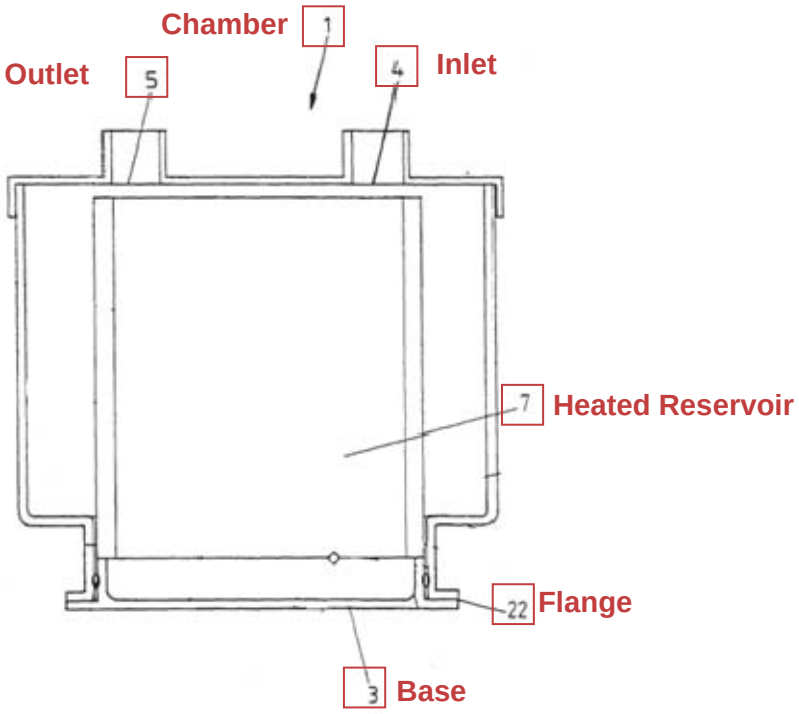


Id. at Fig. 1 (annotations added), *see also id.* at 8:37-42. A patient urinates into the chamber through the anti-backflow element. *Id.* at 8:56-67.

Gouget teaches that placing the outlet of the anti-backflow element at the volumetric center of the chamber prevents spilling regardless of the angle at which the urinal is positioned. *Id.* at 7:46-8:13. Gouget does not teach locating the end of the anti-backflow element anywhere except the volumetric center. Gouget also does not teach that the disclosed design is useful for devices other than safety urinals.

4. Overview of Smith

U.S. Patent No. 5,588,423 ("Smith") describes a humidifier water chamber. Ex. 1009 at Abstract. The inlet 4 and outlet 5 of the water chamber are vertically oriented, as shown in Figure 1 from Smith (below).

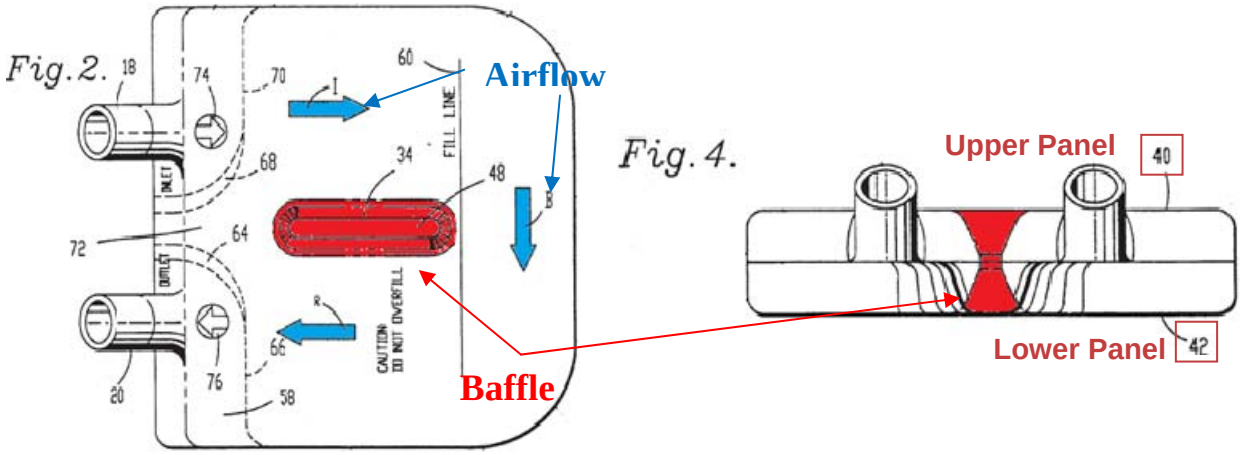


Id. at Fig. 1 (annotations added). Smith's water chamber includes a heater base for heating the water. *Id.* at 2:39-46. Smith does not teach a flow tube as claimed in the '197 Patent.

5. Overview of Rose

U.S. Patent No. 5,231,979 ("Rose") describes a CPAP humidifier with a baffle 34 located near the center of the water chamber and that extends between an upper panel 40 and lower panel 42 of the chamber (i.e., from the top to the bottom of the chamber). Ex. 1008 at 3:28-32, Figs. 2-3. Rose teaches that this baffle promotes a U-shaped flow pattern, as depicted, for example, in Figure 2 of the patent (which shows a top plan view of the humidifier). *Id.* at 4:22-30. The baffle also serves as support for the upper and lower panels 40 and 42, as illustrated, for

example, in Figure 4 of the patent (which shows an end view of the humidifier). *Id.* at 2:9-17. Figures 2 and 4 are shown below.



Id. at Figs. 2 and 4 (annotations and color added).

6. Overview of Netzer

PCT Publication WO 98/04311 ("Netzer") discloses a gas supply device for sleep apnea. Ex. 1010 at 2. Gas flows from a gas source into a water chamber 9 where it is humidified. *Id.* at 9. The humidified gas then flows back into the device and to the patient through an outlet. *Id.* at 8-9.

The water chamber 9 includes a drainage spout 20 and discharge line 21, as shown in Figure 3 below.

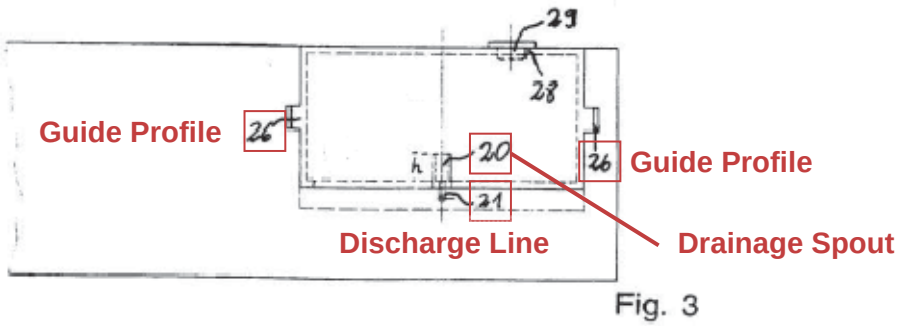


Fig. 3

Id. at Fig. 3 (annotations added), *see also* p. 9. These features prevent the water chamber from being overfilled. *Id.* at 9. Netzer teaches: "When the liquid container 9 is overfilled, the excess liquid is diverted out of the gas humidifier 5 via the drainage spout 20 and a discharge line 21. The maximum filling state level is thus determined by the height h of the drainage spout." *Id.* Netzer further explains that because the container inlet and outlet are located above and spaced apart from the maximum fill level, liquid cannot be carried along by the respiratory gas out of the chamber and into the flow guiding element 3. *Id.* at 6-7, 9.

IV. TRIAL SHOULD NOT BE INSTITUTED

A. Legal Standard

The statutory threshold that must be met to institute an IPR reads as follows:

> (a) Threshold — The Director ***may not authorize*** an inter partes review to be instituted ***unless*** the Director determines that the ***information presented in the petition*** filed under section 311 and any response filed under section 313 ***shows*** that there is a reasonable likelihood that the Petitioners would prevail with respect to at least 1 of the claims challenged in the petition.

35 U.S.C. § 314(a) (emphasis added); *accord* 37 C.F.R. § 42.108(c).

All grounds of the IPR at issue here rely upon obviousness as the alleged grounds of unpatentability. For any IPR ground to prevail based on obviousness, it is not enough to simply show that a combination of references disclose the claim limitations; in addition, the petition must provide a reason to modify and combine the reference. *See, e.g.*, *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418-19 (2007) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. . . . [I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.") (internal quotation marks and citations omitted). Moreover, Petitioners cannot rely on conclusory attorney argument and expert testimony to establish a reason to combine the prior art. *See, e.g.*, *In re: Nuvasive, Inc*., No. 2015-1670, 2016 WL 7118526, at *4, *6 (Fed. Cir. Dec. 7, 2016) (vacating Board's finding of a motivation to combine the prior art references that "relied on only one conclusory statement by [Petitioner]'s expert" and "conclusory statements" by Petitioner's attorneys).

Several principles also signal when a motivation to make a proposed combination is lacking. *See, e.g.*, M.P.E.P. § 2143.01. For example, "[i]f [the]

proposed modification would render the prior art invention being modified ***unsatisfactory for its intended purpose***, then there is no suggestion or motivation to make the proposed modification." *Id.* (emphasis added) (*citing In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984) (explaining that if a reference's device "were turned upside down, it would be rendered inoperable for its intended purpose.")). Likewise, "[i]f the proposed modification or combination of the prior art would ***change the principle of operation*** of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." M.P.E.P. § 2143.01 (emphasis added) (*citing In re Ratti*, 270 F.2d 810, 813 (C.C.P.A. 1959)). Moreover, "when the prior art ***teaches away*** from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." *KSR*, 550 U.S. at 416 (emphasis added) (*citing United States v. Adams*, 383 U.S. 39, 51-52 (1966)).

B. Procedural Deficiencies In The Petition Preclude Institution

1. Petitioners Do Not Properly Identify the Prior Art Relied Upon for Grounds 1-4

The Petition identifies in the Table of Grounds various combinations of five references for Grounds 1-4: the HC200 Manual (Ex. 1015), Hebblewhite (Ex. 1004), Gouget (Ex. 1006), Rose (Ex. 1008), and/or Smith (Ex. 1009). Pet. at 6.

On the next page of the Petition, the "HC200 Manual" is identified as Exhibit 1015. *Id.* at 7.

However, Petitioners then rely upon other references not identified in the Table of Grounds, including Exhibit 1007 (File History of Gouget parent application) and Exhibit 1012 (***Second*** HC200 Manual). *See, e.g.*, Pet. at 26-27, and 46-47) (identifying Ex. 1007) and Pet. at 3, 20, 21, 25, 30, and 31 (identifying Ex. 1012). Mr. Virr also includes an analysis of the Second HC200 Manual in his declaration, (Ex. 1003 ¶¶ 42-46), and relies upon it to support his invalidity analysis of the claims (*see, e.g.*, *id.* ¶¶ 69-76).

Petitioners' failure to identify the Second HC200 Manual in the Table of Grounds constitutes a failure to identify the art relied upon as required by 37 C.F.R. § 42.104(b)(2). Consequently, because Grounds 1-4 proceed to rely in part on the Second HC200 Manual, the Board should decline to institute any of those grounds.

2. Petitioners Fail to Show that the HC200 Manual or Second HC200 Manual Are Prior Art

Petitioners bear the burden of demonstrating that each reference they rely upon is prior art. *See Duncan Parking Techs., Inc. v. IPS Grp., Inc.*, IPR 2016-00070, 2016 WL 5662134 (P.T.A.B. Apr. 1, 2016) ("the burden being on Petitioner to show adequately that [a reference] is prior art"). Petitioners have not

met that burden for either HC200 Manual. For example, Petitioners have not submitted a declaration or other evidence establishing that the HC200 Manuals upon which they rely were, in fact, publicly available prior to the critical date of the '197 Patent.

Petitioners rely on a variety of evidence purportedly showing that the HC200 ***device*** existed before the critical date in an effort to show the HC200 ***Manual*** is prior art. Pet. at 7-8. However, none of this evidence shows that Exhibit 1015, the specific HC200 Manual upon which Petitioners rely, was distributed with the HC200 device or otherwise qualifies as prior art.[3] Thus, Petitioners have not shown that the HC200 Manual (Ex. 1015) is prior art.

With respect to the Second HC200 Manual (Ex. 1012), Petitioners assert that the manual is "believed to have been distributed . . . in the US in April 1999." Pet.

[3] Petitioners assert that the HC200 Manual was submitted in an IDS in January 1999. Pet. at 7. However, Petitioners provide no evidence showing that IDS was publicly available and cite no law establishing that submission of a document in an IDS renders the document a prior art printed publication under section 102(b). Moreover, Petitioners do not submit any evidence that the document referred to in the IDS is Ex. 1015.

at 9. However, Petitioners' belief is not evidence that the Second HC200 Manual is, in fact, prior art.

In addition, none of the evidence cited by Petitioners shows that the Second HC200 Manual is prior art. The Petition characterizes the Second HC200 Manual as an "updated" (and thus later) version of the HC200 Manual. *Id.* Petitioners present no evidence substantiating that assertion and, in fact, the two manuals display different part numbers. *Cf.* Ex. 1012 at 1 (Part Number 185042118), *with* Ex. 1015 at 17 (Part Number 185041244). Petitioners also present no evidence that the Second HC200 Manual was distributed with the HC200 device in 1999 as they allege.

Petitioners have failed to satisfy their burden of showing that the HC200 Manual or Second HC200 Manual are prior art. Accordingly, the Board should decline to institute Grounds 1-4 of the Petition because those grounds depend upon the manuals as part of the alleged obviousness combinations.

C. The Opinions Of Petitioners' Declarant, Mr. Virr, Should Be Given Little Or No Weight

ResMed relies upon a declaration by one of its former employees, Mr. Alexander Virr, to support the Petition. The claim charts in Mr. Virr's declaration are essentially a verbatim copy of the Petition. *Cf., e.g.,* Ex. 1003 ¶¶ 83, 88, 93, 112, 117, *with* Pet. at 19-26, 26-30, 30-33, 37-45, and 46-50. Moreover, Mr. Virr

admits that he did not prepare the claim charts; Petitioners did. Ex. 1003 ¶¶ 83, 88, 93, 112, 117 (all stating in part: "I understand that Petitioners have prepared the following claim chart …."). The cut-and-paste nature of the claim charts is evident from the fact that the charts refer throughout to Mr. Virr's declaration as if it were a different document. *See, e.g., id.* at p. 53 ("The reasons for modifying the HC200 water chamber in this manner are described in detail in Expert Alexander Virr's declaration."); *see also id.* at pp. 51-53, 59, 61, 66, 83, 86, 92, 93.

"Merely repeating an argument from the Petition in the declaration of a proposed expert does not give that argument enhanced probative value." *Kinetic Techs., Inc. v. Skyworks Sols., Inc.*, IPR2014-00529, Paper No. 8 at 15 (P.T.A.B. Sept. 23, 2014); *see also InfoBionic, Inc. v. Braemer Mfg., LLC*, IPR2015-01704, Paper No. 11 at 6 (P.T.A.B. Feb. 16, 2016) (finding expert declaration unpersuasive when it "repeats the Petitioner's arguments and offers little or no elaboration"). Accordingly, Mr. Virr's declaration does not provide additional support for the arguments contained in the Petition and the Board should accord it little, if any, probative weight.

D. Petitioners Have Not Established A Reasonable Likelihood Of Prevailing On Ground 1 (Alleged Obviousness Of Claim 1 By HC200 Manual / Hebblewhite)

Ground 1 asserts that the combination of the HC200 Manual and Hebblewhite renders Claim 1 obvious. Ground 1 fails because neither reference

discloses or renders obvious a flow tube extending into a water chamber from a gas inlet and because a person of ordinary skill in the art ("POSITA") would not have combined the HC200 Manual and Hebblewhite.[4] The asserted motivation for the combination relies on hindsight, the combination does not solve the asserted problem, and the combination creates an inoperable device as explained below.

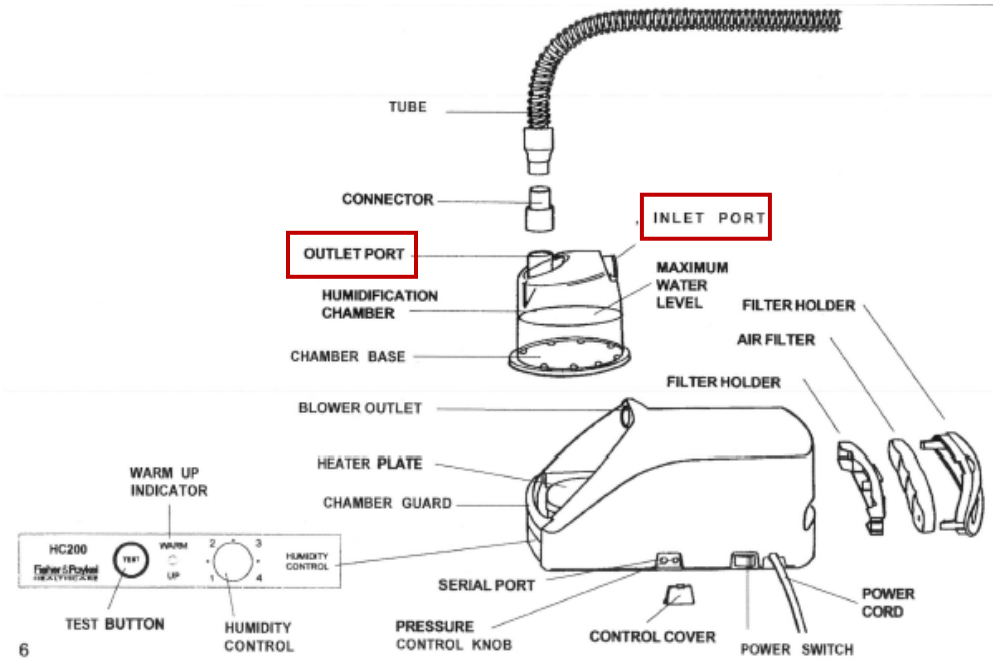
1. Differences Between Claim 1 and the Cited Art

Neither the HC200 Manual nor Hebblewhite teaches a flow tube extending from the gas ***inlet*** of the water chamber as required by Claim 1. Even Petitioners' declarant agrees that this feature is not present in the references. Ex. 1003 ¶ 71. Thus, Claim 1 is not merely a combination of known elements as Petitioners assert.

a. The HC200 Manual Does Not Teach or Suggest a Flow Tube

The HC200 Manual illustrates a CPAP device that includes a humidification chamber. Ex. 1015 at 7. An image from the HC200 Manual is shown below.

[4] The Petition defines the level of ordinary skill in the art on page 17. This Preliminary Response applies Petitioners' definition in the interest of streamlining factual disputes at this stage of the proceeding. FPH believes the Board can resolve this IPR at the preliminary stage also applying that definition. FPH reserves the right to revisit the definition should the Board institute trial.

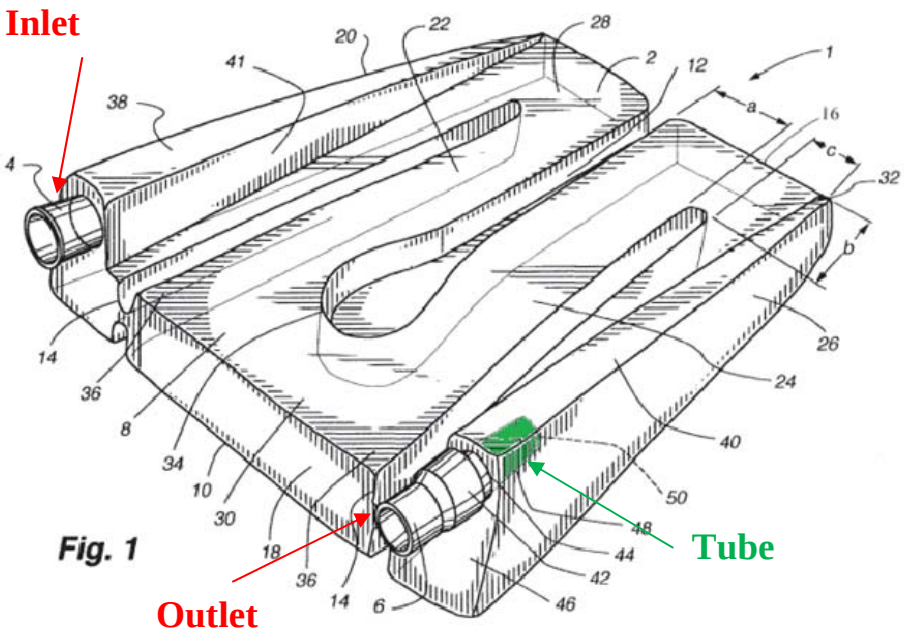


Id. at 7 (annotated). As shown in the figure above, the chamber includes an inlet port and an outlet port. However, no tube extends from the inlet port into the chamber. Petitioners concede that the HC200 Manual does not teach the flow tube limitation of the '197 Patent, and Petitioners do not rely on the HC200 Manual for that limitation. Pet. at 22.

b. <u>Hebblewhite Does Not Teach or Suggest a Flow Tube Extending from an Inlet Opening</u>

Hebblewhite describes a humidifier for a CPAP device. Ex. 1004 at Abstract. The humidifier has a "low profile" so that it can form "a low, generally flat base for supporting the CPAP device." *Id.* at 1:28-32, Fig. 1. The water chamber has a series of elongate passageways 20, 22, 24, 26. *Id.* at 4:10-14. As

shown in Figure 1 (below), air enters the humidifier from the inlet 4, passes over the four passageways, and exits through the outlet 6.



Id. at Fig. 1 (annotations and color added).

Hebblewhite teaches that one disadvantage of this humidifier construction is the formation of waves that can splash through the ***outlet*** of the humidifier. *Id.* at 1:33-45, 3:34-40, 5:9-16. To avoid waves splashing through the ***outlet***, the humidifier includes a tube 48 that extends into passageway 26 from the outlet. *Id.* at 4:63-5:16.

The outlet tube described in Hebblewhite is substantially different than the flow tube claimed in the ’197 Patent. The ’197 Patent claims a flow tube at the air inlet and claims, in use, that the flow tube receives gases supplied to a gas inlet and

that the gases pass through and exit the flow tube at an outlet end. Ex. 1001 at Claim 1 (claiming in part "an elongate flow tube extending into the water chamber from the inner periphery of said gases inlet" and "said flow tube in use receiving, at said inlet end, gases supplied to said gases inlet, said gases passing through said flow tube and exiting said flow tube at said outlet end distant from said wall"). The tube described in Hebblewhite is the opposite of what is claimed in the '197 Patent. The tube is located at the outlet and receives air flowing out of the water chamber. Ex. 1004 at 4:63-5:16.

Further, Hebblewhite describes that the outlet tube helps solve a different problem than addressed in the '197 Patent, namely waves created by air passing over the water surface splashing into the outlet. *Id.* Hebblewhite does not teach or suggest that waves are a problem at the air inlet. There is no suggestion anywhere in Hebblewhite that moving the outlet tube to the inlet is desirable. Even Hebblewhite's supposed "general applicability" statement is limited to the air outlet of the humidifier. *Id.* at 5:17-21 ("It should be appreciated that the idea of spacing ***the outlet aperture***, in this case the aperture 50 of the tube 48, away from the walls of the humidifier is of general applicability ….") (emphasis added). Moreover, the only section of Hebblewhite that addresses potential spilling at the inlet teaches a different solution to the problem—locating the inlet (and outlet) higher above the water. *Id.* at 4:45-51.

Hebblewhite also does not teach that the outlet tube is useful for preventing the outflow of water if the humidifier is tipped.[5] In fact, Hebblewhite does not mention tipping as a problem. Given the low profile construction of the water chamber and the location of outlet tube close to the water surface, the outlet tube would provide little, if any, protection against water spilling through the outlet if the device were tipped. *See, e.g.*, *id.* at Fig. 1.

2. It Would Not Have Been Obvious to Combine the HC200 Manual and Hebblewhite

a. Petitioners Use Improper Hindsight to Identify and "Solve" a Problem

Petitioners assert that a POSITA would have been motivated to combine the HC200 Manual and the outlet tube shown in Hebblewhite "in order to reduce the danger of water spilling into the air ***inlet*** and entering the blower of the HC200." Pet. at 24 (emphasis added). Mr. Virr cites the same motivation. Ex. 1003 ¶ 72. However, this purported motivation is not supported by the HC200 Manual,

[5] Mr. Virr contends otherwise in his declaration. Ex. 1003 ¶ 74. However, Mr. Virr references in support a passage from Hebblewhite (Ex. 1004 at 3:34-40) that is addressing waves created by airflow over the water surface and is not addressing potential spillage from tipping.

Hebblewhite, or the knowledge of a POSITA. Instead, it is based on improper hindsight.

As explained above, the HC200 Manual and Hebblewhite do not teach a flow tube extending from the air inlet of the humidifier chamber. Mr. Virr opines that it would have been obvious to move the outlet tube of Hebblewhite to the inlet of the device shown in the HC200 Manual. *Id.* Mr. Virr identifies the asserted problem using a tenuous interpretation of a statement in the HC200 Manual regarding not moving the device while the water chamber is full. *Id.* (*citing* Ex. 1015 at 9).

Contrary to Petitioners' assertions, the HC200 Manual does not describe the problem of "water spilling into the air inlet and entering the blower of the HC200." Pet. at 24-25. The HC200 Manual merely cautions the user to "[a]void moving or tilting the HC200 when the Humidification Chamber is full of water." Ex. 1015 at 9. The HC200 Manual does not say why moving or tilting the device would be problematic. Nor does the HC200 Manual instruct the user what to do if water enters the blower. The HC200 Manual lacks any identification of the problem that Petitioners assert is the motivation to combine the HC200 Manual and Hebblewhite.

Mr. Virr also cites to a separate statement in the Second HC200 Manual that describes what the user should do "[i]n the unlikely event that you tip water into

the blower outlet . . . ." Ex. 1003 ¶ 72 (*citing* Ex. 1012 at 1). However, that manual does not identify how the user could "tip water into the blower unit." It also states that such an event is "unlikely." Thus, it does not provide a reason to incorporate the outlet tube of Hebblewhite into the device shown in the manual. Moreover, as explained above, Petitioners have failed to make any showing that the Second HC200 Manual is prior art.

Additionally, the inlet and outlet of the device shown in the HC200 Manual are located at the upper portion of the chamber. Ex. 1015 at 7. The HC200 Manual has a "maximum water level" indicator at or below the vertical midpoint of the water chamber. *Id.* Given the positioning of the inlet well above the maximum fill line, spillage through the inlet is unlikely, just as the Second HC200 Manual states.

Mr. Virr also attempts to create a reason to combine Hebblewhite with the HC200 Manual by asserting that Hebblewhite addresses a general spilling problem. Ex. 1003 ¶ 73. However, Hebblewhite's "spillage" statements are limited to a very specific issue—waves. For example, Hebblewhite explains:

> When air flow within the passageway creates ***waves*** on the surface of the water, it has been found that the water has a tendency to ***splash*** against the end wall of the passageway, resulting in a danger of water ***spilling*** into the ***air outlet***. It has been found that by spacing the air

> outlet aperture away from the end wall, the danger of water ***spilling*** into the ***air outlet*** is greatly reduced.

Ex. 1004 at 3:34-41 (emphases added). Hebblewhite is clearly discussing spillage resulting from waves generated by airflow within the water chamber and is not describing a problem of spillage caused by tipping the water chamber. Likewise, the other portions of Hebblewhite cited by Petitioners and Mr. Virr also discuss the problem of water spillage from waves, not tipping. *Id*. at 2:26-3:3, 5:3-22.

Spillage resulting from waves as described in Hebblewhite also cannot create the problem that results in a need to reduce the danger of water spilling into the air ***inlet*** because spillage from waves as described in Hebblewhite is only a problem at the air ***outlet***. The air flow in Hebblewhite pushes the waves away from the inlet and towards the outlet. No statement in Hebblewhite suggests a danger of spillage into the inlet from waves. Moreover, as Petitioners acknowledge, waves are not a problem with the device shown in the HC200 Manual. Ex. 1003 ¶ 75 ("[T]he humidifier chamber in the HC200 Manual is taller than the Hebblewhite chamber and therefore suffers more from the danger of tipping (and less from the danger of wave action…."), ¶ 85 ("Indeed, the HC200 water chamber inlet appears to have been located . . . high enough above the water level to protect against wave action."). Also, the CPAP machine is positioned on top of the humidifier chamber in Hebblewhite. Ex. 1004 at 1:28-32.

Consequently, the problem of water spilling out of the inlet and entering into and damaging the CPAP machine (which the water must flow upward to reach) is diminished.

Thus, neither the HC200 Manual nor Hebblewhite teach or suggest the asserted motivation of alleviating the danger of water spilling into the chamber ***inlet***. Instead, this alleged motivation appears to come only from the teachings of the '197 Patent and is improper hindsight. *See Graham v. John Deere Co.*, 383 U.S. 1, 36 (1966); *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1327 (Fed. Cir. 2012); *Mintz v. Dietz & Watson Inc.*, 679 F.3d 1372, 1378 (Fed. Cir. 2012).

b. <u>Hebblewhite Does Not Solve the Identified Problem</u>

Even if the combination of the HC200 Manual and Hebblewhite did not rely upon hindsight, the combination would not have been obvious because the outlet tube described in Hebblewhite does not solve the problem identified by Petitioners—"the danger of water spilling into the air ***inlet*** and entering the blower of the HC200 …." Pet. at 24 (emphasis added).

First and foremost, Hebblewhite's tube is located at the outlet. Ex. 1004 at Fig. 1. The tube does not address or solve a potential problem of spillage at the inlet. Further, as explained above, the outlet tube would not prevent spillage through the outlet if the water chamber were tipped. *See also, e.g.*, Ex. 1003 ¶ 84

(acknowledging that: "The Hebblewhite reference does not describe how long to design tubes when those tubes are used to prevent against spilling that results from tipping instead of the less-severe waves that are created when air flows through a water chamber, ….."). Instead, the outlet tube described in Hebblewhite helps prevent water from splashing into the outlet caused by waves generated by airflow through the water chamber. *See, e.g.*, Ex. 1004 at 3:34-41. A POSITA would not look to Hebblewhite to solve the problem of spilling at an inlet caused by tipping the humidifier chamber because Hebblewhite does not teach a solution to that problem.

Moreover, Hebblewhite does not teach or suggest that the outlet tube is useful for noise reduction. Hebblewhite also does not otherwise address the issue of noise caused by air flowing through the humidifier chamber. Thus, a POSITA also would not look to Hebblewhite to solve the problem of high noise levels in humidifier chambers.

c. <u>The Identified Combination Creates a New Problem</u>

Given the orientation of the inlet and outlet openings in the device shown in the HC200 Manual, adding a flow tube at the inlet would direct airflow from the flow tube to the outlet. *See, e.g.*, Ex. 1015 at 7. Consequently, air circulation within the water chamber would be impeded and air humidification would be diminished. Petitioners even acknowledge this potential problem in Ground 2,

although they do not address it in Ground 1.[6] *See* Pet. at 28-29. Mr. Virr appears to recognize this air circulation problem as well. *See, e.g.*, Ex. 1003 ¶ 86. Because the asserted combination of the HC200 Manual and Hebblewhite identified by Petitioners would negatively impact air humidification, which is the primary function of a humidifier, the combination would not have been obvious. *See, e.g.*, *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1354 (Fed. Cir. 2001) (citing *In re Sponnoble*, 405 F.2d 578, 587 (C.C.P.A. 1969)) (combinations that create a "seemingly inoperative device" are not obvious); *In re Gordon*, 733 F.2d at 902 (same).

E. Petitioners Have Not Established A Reasonable Likelihood Of Prevailing On Ground 2 (Alleged Obviousness Of Claims 2 And 3 By HC200 Manual, Hebblewhite, Gouget, And Rose)

Ground 2 asserts that the combination of the HC200 Manual, Hebblewhite, Gouget, and Rose renders Claims 2 and 3 obvious. Claim 2 requires that the flow tube extends at least a quarter of the diameter of the water chamber. Claim 3 requires that the flow tube is aligned radially with the water chamber inlet and extends approximately to the middle of the chamber.

[6] As discussed below in connection with Ground 2, Petitioners' "solution" (adding a baffle) to the problem they create relies on hindsight and is improper for that and other reasons.

Ground 2 relies on the same base combination of the HC200 Manual and Hebblewhite recited in Ground 1. This combination fails for the reasons discussed above. Ground 2 also fails to meet the threshold for institution because it relies on non-analogous prior art—Gouget—from a completely different field that addresses a different problem. Additionally, Petitioners' purported combination creates an inoperable combination that Petitioners then attempt to remedy improperly using hindsight.

1. Hebblewhite Does Not Teach or Make Obvious the Flow Tube of Claims 2 and 3

As described above, Hebblewhite does not teach or make obvious a flow tube located at an inlet opening. Moreover, Hebblewhite describes a low profile humidifier in which the roof of the humidifier slopes in a downward direction from the inlet and outlet openings. Ex. 1004 at 4:45-48, Fig. 1. As is evident from Figure 1 of Hebblewhite, the sloped roof configuration limits the length that the outlet tube could extend into the water chamber because the outlet tube would contact the roof if it were extended further. The chamber design makes it impossible for the outlet tube to extend a distance that is a quarter, let alone one-half, the length of the chamber. Thus, Hebblewhite does not teach or make obvious a flow tube having the length as recited in Claims 2 and 3.

2. Gouget Is a Urinal and Is Not Analogous Art

To be prior art, a reference must be analogous to the claimed invention. *Innovention Toys LLC v. MGA Entm't, Inc.*, 637 F.3d 1314, 1321 (Fed. Cir. 2011); *In re Klein*, 647 F.3d 1343, 1348 (Fed. Cir. 2011); *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004). A reference is analogous art if (1) the reference is from the same field of endeavor as the claimed invention or (2) the reference is not from the same field of endeavor but is reasonably pertinent to the inventor's problem. *Bigio*, 381 F.3d at 1325.

Determining whether art is in the same field of endeavor requires analyzing "the 'circumstances' of the application—the full disclosure—and weigh[ing] those circumstances from the vantage point of the common sense likely to be exerted by one of ordinary skill in the art in assessing the scope of the endeavor." *Id.* at 1326.

A prior art reference in a separate field of endeavor will not be analogous art unless it is pertinent to the problem being solved by the challenged patent. *See Klein*, 647 F.3d at 1348. A reference is considered "reasonably pertinent," only if it would have logically commended itself to an inventor's attention in considering the problem at issue. *Circuit Check Inc. v. QXQ Inc.*, 795 F.3d 1331, 1335-36 (Fed. Cir. 2015); *In re ICON Health & Fitness, Inc.*, 496 F.3d 1374, 1379-80 (Fed. Cir. 2007); *In re Clay*, 966 F.2d 656, 659 (Fed. Cir. 1992). Mere use of the same

general principles does not make a reference analogous art. *In re Van Wanderham*, 378 F.2d 981, 988 (C.C.P.A. 1967).

Petitioners bear the burden of showing Gouget is prior art. *See Schott Gemtron Corp. v. SSW Holding Co.*, IPR2014-00367, Paper No. 62, at 62 (P.T.A.B. May 26, 2015). Here, Petitioners' prior art analysis merely consisted of examining the date of publication. *See* Pet. at 7; *see also* Ex. 1003 ¶ 51 (Mr. Virr assumes Gouget is prior art). But such an analysis is insufficient to meet Petitioners' burden when the reference is not in the same field of endeavor.

a. Gouget Is Not in the Same Field of Endeavor as a CPAP Humidifier

Petitioners appear to argue that the field of the endeavor for the '197 Patent is "liquid containers." Pet. at 26. Using Petitioners' reasoning, a swimming pool would be from the same field of endeavor. However, the '197 Patent does not merely describe and claim a "liquid container." Rather, the field of invention of the patent describes that the invention "relates to water chambers for gases humidification and in particular to water chambers for 'slide on' humidifiers and CPAP machines." Ex. 1001 at 1:6-8. The humidifier is configured for gas flow and humidification. *Id.* at 2:12-36. Claim 1 is directed to "a water chamber adapted for use in conjunction with a heater base and having a horizontally oriented gases inlet" and further claims, *inter alia*, gases passing through a flow

tube. *Id.* at Claim 1. Thus, the field of endeavor of the '197 Patent is not "liquid containers" in general.

The proper analysis is whether a ***urinal*** and a ***humidifier*** are within the same field of endeavor. They are not. The portable urinal described in Gouget also would not have logically commended itself to an inventor trying to reduce noise problems and tipping problems in a humidifier. Gouget does not humidify air. It is neither advantageous nor desirable to have air flow through Gouget's device. Liquid, not air, flows into the anti-backflow element of Gouget. The device described in Gouget stores urine, not water. Thus, Gouget is not in the same field of endeavor as the inventions described and claimed in the '197 Patent.

b. <u>Gouget Is Not Reasonably Pertinent to the Problem Solved by the '197 Patent</u>

Petitioners also fail to show that Gouget is reasonably pertinent to the problem being solved by the '197 Patent. *See ICON Health & Fitness, Inc.*, 496 F.3d at 1379-80; *Bigio* 381 F.3d at 1325-26. Mr. Virr states that he ***assumes*** Gouget is prior art. Ex. 1003 ¶ 51. The remainder of Mr. Virr's declaration is premised on this assumption, and Mr. Virr simply analyzes the disclosure of Gouget without ever explaining why a POSITA would have looked to it as prior art. *Id.* ¶¶ 84-88.

The Petition fares no better. The Petition bases its conclusions on Mr. Virr's assumptions and contains no explanation for why a POSITA would have looked to Gouget. Pet. at 26-29, 46-50.

The Petition generalizes that because Gouget and the '197 Patent are both directed (in part) to spillage prevention using a tube structure, a POSITA would have considered Gouget. Pet. at 26-27. But that is hindsight driven. And further, merely addressing similar scientific principles is not enough to make a reference analogous. *See Van Wanderham*, 378 F.2d at 388. Gouget must be reasonably pertinent to the particular problem solved by the '197 Patent. Gouget is not.

As described above, Gouget describes a portable urinal with an anti-backflow element 5 that allows ***liquid*** to enter the urinal without allowing the liquid to exit the urinal. Ex. 1006 at 8:21-55. In contrast, the '197 Patent is directed to a humidifier water chamber having a ***gas*** inlet and flow tube that allows proper gas inflow and circulation while lowering the noise level of the humidifier and preventing water outflow if the chamber is tipped. *See, e.g.*, Ex. 1001 at 2:54-65. Gouget also has no teachings related to noise reduction. Further, Gouget has no disclosure related to ***gas inflow***. Each of these elements are important features in CPAP humidifiers and the problems solved by the '197 Patent.

c. Gouget Does Not Teach or Make Obvious the Flow Tube of Claims 2 and 3

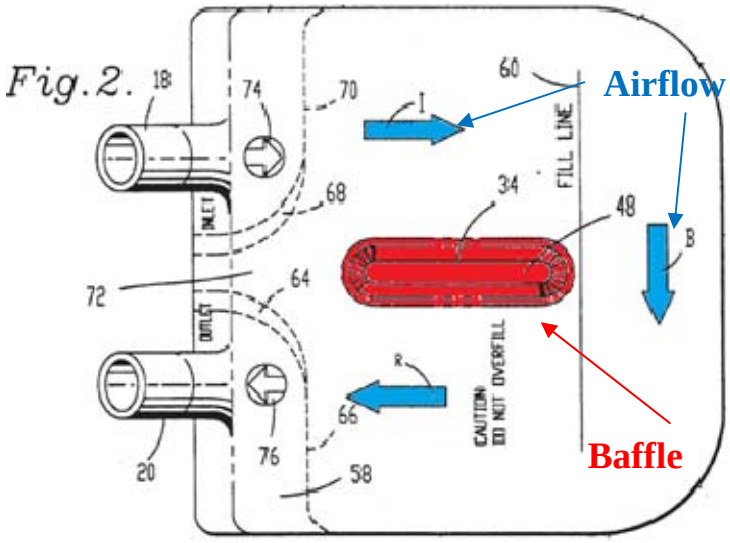
Even if Gouget were analogous prior art (which it is not), it does not teach or make obvious the flow tube of Claims 2 and 3 of the '197 Patent. Gouget teaches placing the end of an anti-backflow element at the volumetric center of the chamber. Ex. 1006 at 8:37-42. Petitioners purport to modify the device shown in the HC200 Manual in view of Gouget's volumetric center teaching. Pet. at 27. But the device as modified by Petitioners does not extend the flow tube to the volumetric center, despite Petitioners' characterization to the contrary. Pet. at 27 (describing modified device of HC200 Manual as having a "tube near the volumetric center"). The tube in Petitioners' modified design terminates at the top of the water chamber, far from its volumetric center. *Id.* Thus, Petitioners have not even applied Gouget's teachings in arriving at their modified design, and Gouget does not render the flow tube of Claims 2 and 3 obvious.

3. The Combination with Rose Relies on Improper Hindsight

Petitioners concede that their proposal to add a tube to the inlet of the water chamber shown in the HC200 Manual may cause some air that enters the chamber to exit through the outlet without circulating through the chamber. Pet. at 28. As shown in Petitioners' modified figure from the HC200 Manual, the end of the flow tube and the outlet port are located in close proximity. *Id.* Consequently, air may

leave the flow tube and travel directly to the outlet without being sufficiently humidified.

Petitioners seek to fix the air circulation problem they have created by further adding a baffle. Petitioners assert that it was "traditionally known to implement a baffle between an inlet and outlet in CPAP humidifiers" in order to "ensure additional circulation of air." *Id.* Petitioners cite to a baffle shown in Rose. *Id.* at 28-29. Figure 2 of Rose is shown below.



Ex. 1008 at Fig. 2 (annotations and color added). The baffle shown above extends between an upper and lower panel of the water chamber. *Id.* 3:28-32. Rose does not teach placing a baffle in a downwardly extending configuration directly between the inlet and outlet as in Petitioners' proposed combination. Instead, these teachings come directly from the '197 Patent.

The ’197 Patent states that “the chamber further includes a curved downwardly extending baffle 8 located between the gases outlet 3 and the termination of the inlet extension tube 7 to ensure against gases short circuiting the chamber by flowing directly from the extension 8 to the outlet 3.” Ex. 1001 at 2:29-34. A comparison of the suggested modification to the HC200 Manual device from the Petition and Figure 2 of the ’197 Patent further highlight this hindsight.

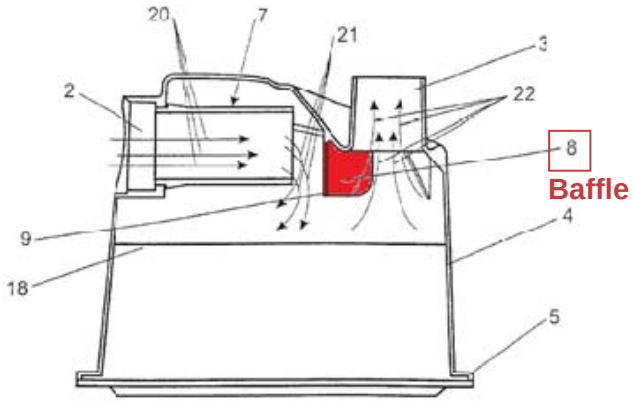
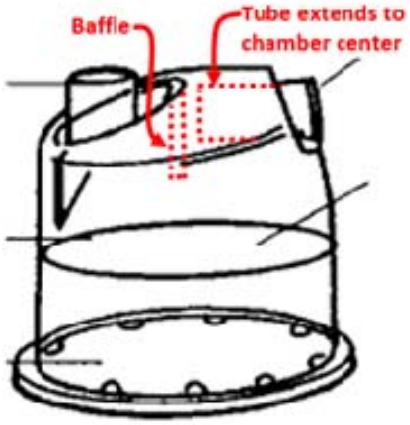


FIGURE 2

Ex. 1001 at Fig. 2
(annotations and color added)



Pet. at 28

As seen above, Petitioners have not simply moved Rose’s baffle to the HC200 Manual device. Petitioners instead used an entirely different type of baffle—a downwardly extending baffle directly between the inlet and outlet as taught by the ’197 Patent. Such a baffle would provide none of the support

features that Rose taught were important (Ex. 1008 at 2:9-17) and would direct air in an entirely different manner than the baffle described in Rose.

Mr. Virr asserts that a POSITA would have "general knowledge . . . regarding baffles, as evidenced by the Rose reference." Ex. 1003 ¶ 86. However, Rose shows only a single type of baffle, and Petitioners present no evidence of other baffle types except the baffle described in the '197 Patent.

Mr. Virr also asserts that it would have been obvious to modify and implement the baffle described in Rose into Petitioners' proposed combination "because Rose's chamber is made by blow molding, which is a process that requires that form of baffle construction, whereas the HC200 water chamber is injection molded, permitting a simple baffle in the form of a rib." *Id.* ¶ 87. But the HC200 Manual does not state that its device is injection molded. Petitioners are limited to the disclosure within the relied upon references in an IPR proceeding, and this portion of Mr. Virr's opinion should be disregarded. *See* 35 U.S.C. § 311(b).

F. In Sum, The Petition Fails To Demonstrate A Reasonable Likelihood That The Combination In Grounds 2 And 3 Renders Any Claim Obvious.Petitioners Have Not Established A Reasonable Likelihood Of Prevailing On Ground 3 (Alleged Obviousness Of Claim 6 By HC200 Manual, Hebblewhite, And Smith)

Ground 3 asserts that Claim 6 is obvious in view of the HC200 Manual, Hebblewhite, and Smith. Claim 6 depends from Claim 1 and recites additional

structure of the water chamber such as a transparent plastic shell enclosed at the bottom by a heat conductive plate. Ground 3 uses the same base combination as Ground 1, with the addition of Smith (Ex. 1009). Ground 3, therefore, fails for all the same reasons as Ground 1.

G. Petitioners Have Not Established A Reasonable Likelihood Of Prevailing On Ground 4 (Alleged Obviousness Of Claim 13 By HC200 Manual, Hebblewhite, Gouget, Rose, And Smith)

Ground 4 asserts that Claim 13 is obvious in view of the HC200 Manual, Hebblewhite, Gouget, Rose and Smith. Claim 13 depends indirectly from Claim 1, via Claims 2 and 3. Claim 13 recites additional structure of the water chamber such as a transparent plastic shell enclosed at the bottom by a heat conductive plate. Ground 4 uses the same base combination as Grounds 1 and 2, with the addition of Smith. Ground 4, therefore, fails for all the same reasons as Grounds 1 and 2.

H. Petitioners Have Not Established A Reasonable Likelihood Of Prevailing On Ground 5 (Alleged Obviousness Of Claims 1 And 6 By Netzer, Hebblewhite, And Smith)

Ground 5 asserts that Claims 1 and 6 are obvious in view of Netzer, Hebblewhite, and Smith. Ground 5 fails because the motivation to combine Netzer and Hebblewhite is based on hindsight and does not properly take into account Netzer's existing solution to the alleged problem to be solved. Additionally, the proposed combination of Netzer, Hebblewhite, and Smith would not have been

obvious because it does not account for the features of Netzer that would preclude the combination proposed by Petitioners.

1. Netzer, Hebblewhite, and Smith Do Not Teach or Make Obvious the Claimed Flow Tube

As previously explained, Hebblewhite does not teach an extension tube at the gas ***inlet***. Instead, the tube described in Hebblewhite is located at the gas outlet. *See*, *e.g.*, Ex. 1004 at Fig. 1. For all of the reasons previously provided in connection with Ground 1, it would not have been obvious in view of Hebblewhite to locate the extension tube at a gas inlet.

Netzer and Smith do not cure this deficiency. Netzer describes a humidifier in which the water level is controlled using a drainage spout located at the base of the water chamber. Ex. 1010 at 9. Smith describes a water chamber with a heater located at the base of the chamber. Ex. 1009 at 2:14-17. Neither Netzer nor Smith teach or suggest a flow tube as claimed in the '197 Patent and Petitioners do not contend otherwise.

2. There Would Have Been No Reason to Combine Netzer and Hebblewhite

The combination of Netzer and Hebblewhite is based on impermissible hindsight. Similar to the HC200 Manual-Hebblewhite combination, Petitioners assert that a POSITA would have combined Netzer and Hebblewhite "to limit the ability of water to spill out of the container through inlet 22 and outlet 23" of

Netzer's water chamber. Pet. at 42. As discussed in detail above, Hebblewhite contains no discussion of spillage through the inlet (or outlet) from tipping. Hebblewhite describes the use of an outlet tube to prevent spillage due to waves created by air movement across the water surface. Ex. 1004 at 3:34-40. There is no discussion in Netzer of spillage due to waves.

Petitioners assert that a POSITA would have added tubes to the inlet and outlet of Netzer in view of Hebblewhite. Pet. at 42. However, Hebblewhite only describes an extension tube located at the outlet of the humidifier. *See, e.g.*, Ex. 1004 at Fig. 1. As explained above, Hebblewhite does not teach locating the extension tube at an air inlet, and it would have been obvious in view of Hebblewhite to do so.

Mr. Virr asserts that it would have been obvious to include extension tubes at the inlet and outlet of the water chamber described in Netzer "in order to ensure that 'no water drops are carried over into the respiratory has lines,' which is a concern that is expressed in Netzer." Ex. 1003 ¶ 99 (citing and quoting in part Ex. 1010 at 6-7). However, in the portion of Netzer cited by Mr. Virr, Netzer explains that the overflow element described therein already solves the potential problem of water drops entering the respiratory line:

> It can also be advantageous if the liquid level in the liquid container is limited by means of an overflow element, and if the container inlet

> and the container outlet, which can be connected to the bypass, are preferably disposed at a spacing above the maximum liquid level. ***By this means***, it is ensured that the respiratory gas supplied through the gas humidifier is only combined with water vapor, and no water drops are carried over into the respiratory gas line.

Ex. 1010 at 6-7 (emphasis added).

Thus, Netzer is not merely discussing a potential problem. It is stating how the design disclosed by Netzer solves that problem. There would have been no reason to modify Netzer to include an extension tube at the gas inlet and outlet when Netzer already provides a solution to the identified problem of water droplets entering the respiratory line. Using both solutions, as Petitioners suggest, would simply increase the cost and complexity of the device.

Mr. Virr further asserts that a POSITA would have recognized that the overflow element described in Netzer "only addresses the problem of excess water in the gas lines due to overfilling, but would not address the ability of water to enter the gas lines if tipped or bumped by the user." Ex. 1003 ¶ 99. However, Netzer does not discuss the possibility of spillage of water into the inlet or outlet due to tipping, or identify this as a potential problem. Petitioners also fail to acknowledge that because Netzer includes an overflow element that prevents overfilling the water chamber, any problem associated with spillage from tipping is

diminished because the water is maintained at a level that is spaced apart from the inlet and outlet openings.

In sum, neither Netzer nor Hebblewhite disclose the supposed problem of water splashing into an inlet or the problem of water spilling into an opening due to tipping. As discussed above, this problem, and its solution, are found only in the '197 Patent. The Petition improperly uses hindsight to identify the asserted problem and arrive at a reason for combining Netzer and Hebblewhite. *See Graham*, 383 U.S. at 36; *ActiveVideo*, 694 F.3d at 1327; *Mintz*, 679 F.3d at 1378.

3. It Would Not Have Been Obvious to Add the Base Heater of Smith to the Combination of Netzer and Hebblewhite

Claim 1 requires "a water chamber adapted for use in conjunction with a heater base." Ex. 1001 at Claim 1. Petitioners concede that Netzer does not teach a "heater base." Pet. at 38. Netzer mentions the use of a heater, but only in very general terms, referring to "a heating unit, ***not shown in greater detail***, disposed ***in the region*** of the liquid container 9 for generating steam." Ex. 1010 at 10 (emphasis added). Petitioners argue that it would have been obvious to modify Netzer to include a heater base in view of Smith. Pet. at 38. But Petitioners fail to address Netzer as a whole, including its drainage system that precludes the use of a heater base.

The water chamber described in Netzer includes a "filling limiter" that prevents fluid from "being carried along during the humidifying of the respiratory gas." Ex. 1010 at 9. The filling limiter is "formed by a drainage spout 20 disposed on the base 19 of the liquid container 9." *Id.* The base of the housing includes a corresponding discharge line 21 beneath the drainage spout. *Id.*

Because the discharge spout drains to a drainage line in the base of the humidifier housing, a heater cannot be placed at the base of the water chamber. A base heating unit would interfere with Netzer's drainage system, which serves an important purpose in Netzer.

A POSITA would not place the heater at a location where water is being drained from the liquid container for other, additional reasons. The draining water could potentially cause a short circuit in an electrical heater. Additionally, any draining water contacting the heater would take away heat from the heating unit meant for humidifying the gases in the liquid container, resulting in a waste of energy used to power the heating unit. Such arrangement of the heating unit, like "a humidifier in permanent use," would "result[] in a high power consumption." *Id.* at 2. Any modification of Netzer's device that could increase power consumption would frustrate one of the objectives of Netzer, which is to reduce the power consumption of the device. *Id.* at 2, 10. As such, this proposed

modification would render Netzer inoperable for its intended purpose and would not have been obvious. *Gordon*, 733 F.2d at 902.

Petitioners also argue that the heater would be placed at the base because the lateral guide profiles of Netzer keep "the liquid reservoir in firm contact with a heating base." Pet. at 38. However, these same lateral guide profiles would keep the liquid reservoir in firm contact with a heat source located on the side of the chamber. Thus, the existence of the lateral guide profiles does not indicate the heater must be located at the base of the water chamber.[7]

In sum, Petitioners have not shown a reasonable likelihood that Claims 1 or 6 would have been obvious in view of Netzer, Hebblewhite, and Smith. Accordingly, the Petition should not be instituted as to Ground 5.

I. Petitioners Have Not Established A Reasonable Likelihood Of Prevailing On Ground 6 (Alleged Obviousness Of Claims 2, 3, And 13 By Netzer, Hebblewhite, Smith, Gouget, And Rose)

Ground 6 asserts that Claims 2, 3, and 13 are obvious in view of Netzer, Smith, Hebblewhite, Gouget, and Rose. Claims 2 and 3 depend from Claim 1, and Claim 13 depends from Claim 3. Ground 6 uses the same base combination as

[7] Even if a base heater was known in the prior art as a result of the format of Claim 1, Petitioners still must show a usable combination with that element. As explained above, Petitioners have not done so.

Ground 5—Netzer, Smith, and Hebblewhite, and adds Gouget and Rose. Consequently, Ground 6 fails to meet the threshold for all the same reasons as Ground 5.

Moreover, as explained above, Gouget is not analogous prior art. For this additional reason, Ground 6 fails to meet the threshold. Additionally, Hebblewhite does not provide any reason or motivation to extend the outlet tube described therein to a length required by Claims 2 and 3, as also discussed above. Thus, the IPR should not be instituted as to Ground 6 for all of these reasons.

V. CONCLUSION

For all these reasons, the Petition fails to establish a reasonable likelihood that any claim of the '197 Patent is unpatentable. The Board therefore should not institute trial in this proceeding.

Respectfully submitted,

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Dated: December 16, 2016

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CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), Counsel for Patent Owner Fisher & Paykel Healthcare Limited hereby certifies that this document complies with the type-volume limitation of 37 C.F.R. § 42.24(b). According to Microsoft Office Word 2010's word count, this document contains approximately 11,725 words, including any statement of material facts to be admitted or denied in support, and excluding the table of contents, table of authorities, mandatory notices under § 42.8, exhibit list, certificate of service or word count, or appendix of exhibits or claim listing.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, pursuant to 37 C.F.R. § 42.6(e)(1) and agreement of the parties, a true and correct copy of **PATENT OWNER PRELIMINARY RESPONSE** is being served via email on December 16, 2016, to counsel for ResMed Limited, ResMed Inc., and ResMed Corp at the email addresses below:

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