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Filed on behalf of:

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UNITED STATES PATENT AND TRADEMARK	OFFICE
BEFORE THE PATENT TRIAL AND APPEAL	BOARD
RESMED LIMITED, RESMED INC., and RESMEI	O CORP.,
Petitioners,	
v.	
FISHER & PAYKEL HEALTHCARE LIMIT	ED,
Patent Owner.	

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

PATENT OWNER RESPONSE

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Exhibit No.	Description
2001	Expert Declaration of Dr. Hartmut Schneider
2002	C.V. of Dr. Hartmut Schneider

I. <u>INTRODUCTION</u>

Patent Owner Fisher & Paykel Healthcare Limited ("FPH") is a world leader and innovator in respiratory therapy devices for critical care and home care use. FPH's 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.

The '197 Patent claims recite an *elongate flow* tube, also referred to as an extension tube, extending from the horizontal *inlet* of a humidification chamber. Ex. 1001 at 2:25-28, Fig. 2 (reproduced below).

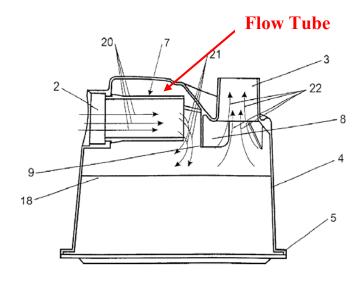
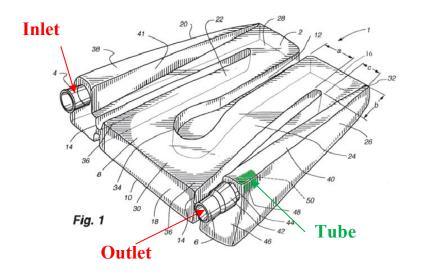


FIGURE 2

In its Institution Decision, the Board only addressed the parties' arguments regarding Grounds 1 and 5, which challenged Claim 1 as obvious over the HC200 Manual/Hebblewhite and Netzer/Hebblewhite combinations respectively. The

Board then exercised its discretion to institute on the remaining grounds raised in the Petition.

All of the instituted grounds rely on Hebblewhite, which describes a low-profile humidifier having a short tube on the *outlet* of the humidifier chamber. *See* Ex. 1004 at Fig. 1, item 50 (reproduced below with color annotations).



The purpose of the tube is to address a specific problem at the air outlet that results from the low-profile chamber design. Airflow through the low-profile chamber creates waves that are directed toward the air outlet, which is located only a short distance above the water surface. Ex. 2001 ¶ 59. The outlet tube prevents splashing water caused by waves hitting the wall at the end of the chamber from entering the air outlet. Ex. 1004 at 4:63-5:8. Only a short tube length is required to address that splashing problem. Ex. 2001 ¶ 60. Splashing caused by waves is not

a problem at the air inlet, and Hebblewhite does not teach or suggest an extension tube at the inlet. *Id*.

Hebblewhite also teaches away from using an "elongate" tube of any kind. Hebblewhite's low-profile humidifier design relies upon directing air within the chamber along a controlled flow path over a large surface area of water so that the air becomes sufficiently humidified. *Id.* at 1:42-45. Utilizing an elongate outlet tube would be contrary to that teaching because it would reduce the water surface area over which the air travels. Ex. 2001 ¶ 71. The low-profile humidifier design, which includes a roof that slopes downward from the outlet opening, also prevents the outlet tube from extending further into the water chamber. *Id.* ¶ 70.

Petitioners seek to combine Hebblewhite with the HC200 Manual or Netzer in all asserted grounds. The HC200 Manual and Netzer water chambers operate in different ways compared to Hebblewhite. *Id.* ¶¶ 41, 44-45, 53. Splashing through the inlet or outlet caused by waves striking the inner wall of the water chambers were not problems in the HC200 Manual device or Netzer. *Id.* ¶¶ 65, 102. Thus, a person having ordinary skill in the art ("POSITA") would have had no reason to combine Hebblewhite's short outlet tube with either the HC200 Manual or Netzer. *Id.* ¶¶ 54-77, 110-115.

Petitioners contend that a POSITA would have added Hebblewhite's outlet tube to the HC200 Manual device or Netzer to prevent water from pouring out

through the air inlet or outlet if the water chambers were tipped. The purported spillage from tipping problem that Petitioners create—in which a wall of water is directed into an opening and pours through the opening—is fundamentally different from the splashing problem described in Hebblewhite. *Id.* ¶ 68. Hebblewhite's short outlet tube would provide no protection against spilling from tipping. Ex. 2001 ¶ 61. Thus, a POSITA would not have looked to Hebblewhite's outlet tube to address any problem of spillage caused by tipping the water chambers described in the HC200 Manual or Netzer. *Id.* ¶ 68.

Hebblewhite also makes no mention that the outlet tube has any impact on noise, which is one of the key advantages of the inlet flow tube described in the '197 Patent. Thus, a POSITA also would not have looked to Hebblewhite's outlet tube to address any potential noise problem. *Id.* ¶ 73.

Grounds 2, 4, and 6 of the Petition also fail because the asserted combinations rely on Gouget, which describes a portable urinal that is not analogous art to the '197 Patent. Ex. 1006 at 1:9. Neither Petitioners nor their expert, Mr. Virr, provide any explanation as to why Gouget is allegedly analogous art.

Petitioners add yet another reference (Rose – Ex. 1008) to their combination in Grounds 2 and 4 in an attempt to remedy the non-analogous nature of Gouget. Because Gouget is not analogous art, it creates serious performance problems in

combination with the other cited references. Petitioners improperly use hindsight in an attempt to engineer away the problems they create.

In sum, none of the challenged claims of the '197 Patent would have been obvious in view of the cited references. The Board should therefore confirm the validity of the challenged claims.¹

II. BACKGROUND

A. Overview of the '197 Patent

The '197 Patent is directed to an innovative water chamber design for an integrated humidifier and CPAP machine. 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 tipping that may result in spillage through the water chamber

The question of whether *inter partes* review violates the Constitution by extinguishing private property rights through a non-Article III forum without a jury is currently being decided by the Supreme Court in *Oil States Energy Services*, *LLC v. Greene's Energy Group, LLC*, Case No. 16-712. FPH therefore reserves all rights in view of *Oil States*, including the right to object to this *inter partes* review as unconstitutional.

inlet port and 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.

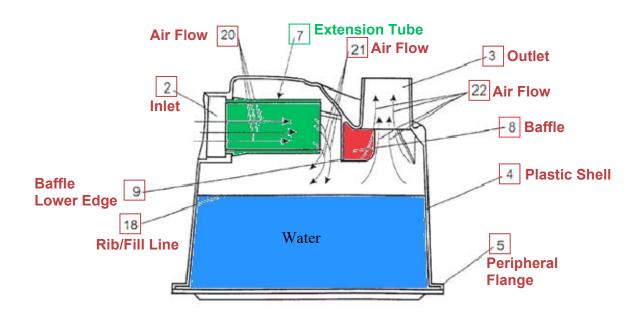


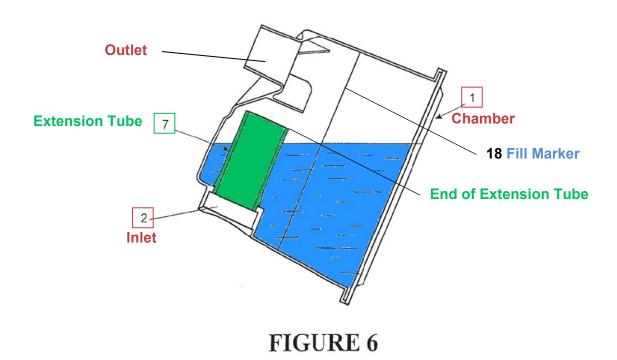
FIGURE 2

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. Airflow 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 airflow pattern through the chamber inlet, the inlet extension tube significantly

reduces the noise level caused by air flowing through the chamber. *Id.* at 2:54-57. This is an important benefit, as CPAP machines are used during sleep and loud noise levels can prevent a patient from falling asleep or wake the patient during the night. Ex. 2001 ¶ 36.

After exiting the extension tube 7, the airflow 21 circulates within the chamber. Ex. 1001 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. Water molecules at the surface of the heated water evaporate into water vapor causing the airflow to become humidified. Ex. 2001 ¶ 37. Once the air is humidified, it exits the chamber through an outlet 3. Ex. 1001 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 also has the added benefit of reducing the chance of water spilling out of the air inlet if the chamber is tipped. *Id.* at 2:59-61. For example, as seen in Figure 6 (below), the extension tube 7 prevents water from flowing out of the inlet when the chamber is tipped on its side in the direction of the inlet.



Id. at Fig. 6 (annotations and color added). Because the outlet is oriented near the top of the chamber, water spilling through the outlet is not an issue. Ex. 2001 ¶ 39.

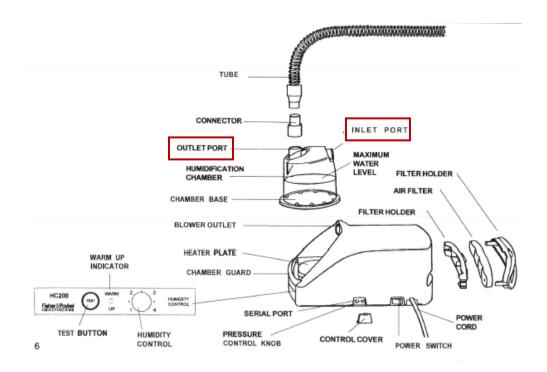
B. Overview of the Alleged Prior Art

1. Overview of the HC200 Manual

The HC200 Manual shows Fisher & Paykel's HC200 CPAP device. Ex. 1015 at 1.2 An image from the HC200 Manual is reproduced below.

² The page numbers in citations refer to the page numbers added by FPH or Petitioners to the exhibits at the bottom of the page.

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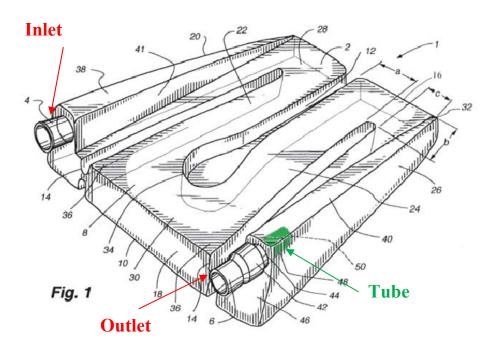


Id. at 7 (annotated).³ The HC200 Manual shows a humidifier water chamber with an inlet port located on the sidewall of the chamber near the top of the chamber. Id. Air flows into the chamber through the inlet port and out of the chamber through a vertically oriented outlet port located at the top of the chamber. Id. As Petitioners acknowledge, the HC200 Manual does not teach the flow tube claimed in the '197 Patent. Moreover, because the outlet port is vertically oriented well above the water line, splashing at the outlet port is not a problem. Ex. 2001 ¶ 65.

³ Citations to exhibit page numbers are to the page numbers that have been added to the exhibits by the parties (if any) and not to the original page numbers.

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" shape 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.

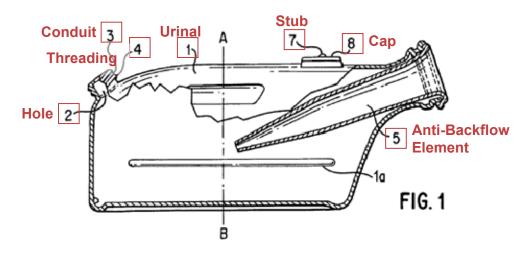
Hebblewhite teaches that one disadvantage of *low-profile* humidifiers is the formation of waves that can splash through the *outlet* of the humidifier. *Id.* at 3:34-38, 5:9-16. Airflow pushes waves in one direction: away from the inlet and

towards the outlet. *Id.*; Ex. 2001 ¶¶ 59-60. Because of Hebblewhite's *low-profile*, the outlet is located near the surface of the water. Ex. 1004 at Fig. 2. When waves splash against the end wall 46 of the chamber beneath the outlet opening, some of the splashing water may potentially travel into the air outlet. *Id.* at 3:34-38, 5:9-16.

To prevent water from splashing through the *outlet*, Hebblewhite includes a relatively short outlet tube 48 extending from the outlet 6 away from the surrounding wall and into the humidifier chamber. *Id.* at 4:63-5:8; Ex. 2001 ¶ 60. Hebblewhite explains that the tube need only be at least 2 cm in length. Ex. 1004 at 5:15-16 ("The aperture 50 should preferably be spaced at least 2 cm away from end wall 42.").

3. Overview of Gouget

U.S. Patent No. 5,953,763 ("Gouget") is not within the field of CPAP machines or humidifiers. Ex. 2001 ¶¶ 82-86. Instead, Gouget is titled "Safety Urinal" and describes a urinal receptacle. Ex. 1006 at 1:9. As shown in Figure 1 of Gouget (below), an anti-backflow element 5 extends to the volumetric center of the urinal.

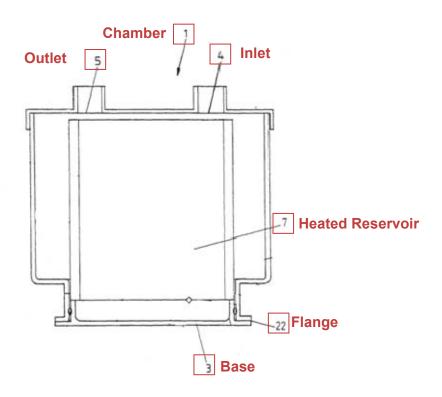


Id. at Fig. 1 (annotations added), *see also id.* at 8:37-42. A patient urinates into the chamber through the anti-backflow element. *Id.* at 8:56-67.

Gouget does not address issues relating to airflow through the urinal, humidification, or problems pertaining to noise. Ex. 2001 ¶¶ 82-86. Instead, Gouget deals with the problem of capturing and retaining urine. Gouget teaches that placing the outlet of the anti-backflow element at the volumetric center of the chamber prevents spilling of captured urine regardless of the angle at which the urinal is positioned. Ex. 1006 at 7:46-8:13. Gouget does not teach locating the end of the anti-backflow element anywhere except the volumetric center. Ex. 2001 ¶ 47.

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. Ex. $2001 \, \P \, 48$.

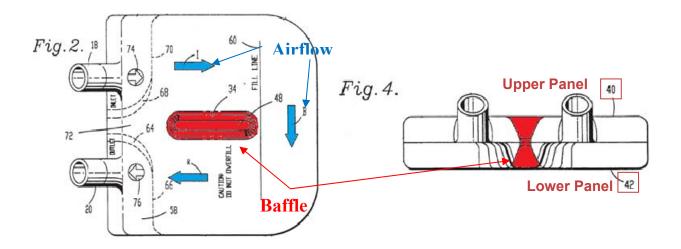
5. Overview of Rose

U.S. Patent No. 5,231,979 ("Rose") describes a CPAP humidifier with a baffle 34 located near the center of the water chamber. Ex. 1008 at 3:28-32, Figs. 2-3. The baffle extends between an upper panel 40 and lower panel 42 of the chamber (i.e., from the top to the bottom of the chamber). *Id.* at Fig. 4. The baffle also serves as support for the upper and lower panels 40 and 42. *Id.* at 2:9-17.

Rose teaches that this baffle promotes a U-shaped airflow pattern, as depicted in Figure 2 of the patent. *Id.* at 4:22-30, Fig. 2. Figure 2 (which shows a

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top plan view of the humidifier) and Figure 4 (which shows an end view of the humidifier) are shown below.

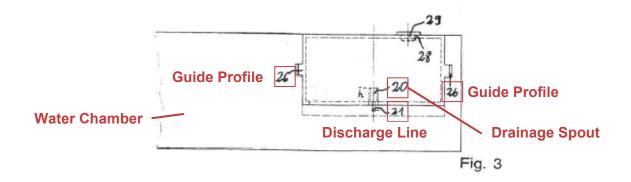


Id. at Figs. 2 and 4 (annotations and color added).

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 by absorbing water vapor within the chamber 9. *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.



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 20." 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 outlet of the chamber and into the flow guiding element 3. Id. at 6-7, 9.

C. <u>Level of Ordinary Skill in the Art</u>

A person of ordinary skill in the art at the time of the effective filing dates of the application that led to the '197 Patent would have had a bachelor's degree in mechanical engineering, biomedical engineering or a related discipline and a sufficient amount of product design or development experience to obtain a level of competence in the field of respiratory therapy devices, including humidifiers, or an equivalent advanced education. Ex. 2001 ¶ 30. For individuals with different

educational backgrounds, a person could still be of ordinary skill in the art provided that person's additional experience compensates for any differences in that person's education as stated above. While the level of skill in the art proposed by FPH differs from that proposed by Petitioners (Pet. at 17), FPH believes the difference is immaterial to deciding the issues raised by the Petition. *Id*.

III. <u>LEGAL STANDARD FOR OBVIOUSNESS</u>

The instituted grounds rely upon obviousness as the alleged grounds of unpatentability. For any ground to prevail based on obviousness, it is not enough to simply show that a combination of references discloses 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.*, 842 F.3d 1376, 1382-1384 (Fed. Cir. 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 "was turned upside down it would be 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, Moreover, "when the prior art teaches away from 813 (C.C.P.A. 1959)). 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)).

IV. ARGUMENT

A. Ground 1: Claim 1 is Patentable over the HC200 Manual in View of Hebblewhite

Ground 1 asserts that the combination of the HC200 Manual and Hebblewhite renders Claim 1 obvious. The Board instituted as to Ground 1 based on the record at the time of its decision. FPH now supplements the record and submits the declaration of Dr. Hartmut Schneider (Ex. 2001), which further explains why Claim 1 would not have been obvious over the HC200 Manual and Hebblewhite.

1. The HC200 Manual and Hebblewhite Do Not Disclose a Flow Tube Located at an Inlet Opening

The HC200 Manual and Hebblewhite do not teach a flow tube of any length extending from the gas *inlet* of the water chamber as required by Claim 1. No flow tube extends into the water chamber of the HC200 Manual device from either the inlet or outlet port. Ex. 1015 at 7. Hebblewhite discloses a short tube located at the *outlet* of the water chamber. Ex. 1004 at Fig. 1, 4:63-5:8; Ex. 2001 ¶¶ 57-58. Petitioners also concede that the elongate flow tube of Claim 1 is not present in either the HC200 Manual or Hebblewhite. Pet. at 22 ("[t]he HC200 Manual does not disclose the above-recited elongate flow tube"); Ex. 1003 ¶ 71 (discussing Hebblewhite and stating that "tube 48 is positioned on the gases outlet rather than

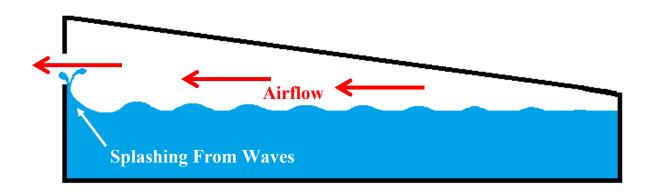
the gases inlet"). Thus, the combination of the HC200 Manual and Hebblewhite does not teach all of the elements of Claim 1.

2. There Would Have Been No Reason to Modify the Inlet of the HC200 Manual Water Chamber to Include the Outlet Tube of Hebblewhite

Petitioners argue that it would have been obvious to relocate the outlet tube of Hebblewhite to the air inlet of the HC200 Manual water chamber. Pet. at 22, 24-25. However, as described below, that proposed modification would not have been obvious for multiple reasons. Ex. 2001 ¶¶ 56-72.

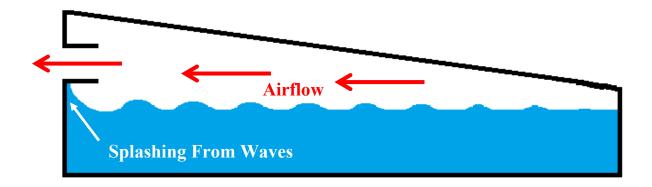
a. <u>Hebblewhite's Outlet Tube Addresses a Specific Wave</u> Splashing Issue Associated with Low-Profile Humidifiers

Hebblewhite describes a solution to a specific splashing issue that results from the low-profile design of the humidifier. *Id.* ¶¶ 44-45, 59. Hebblewhite explains that low-profile humidifiers are susceptible to wave formation caused by the close proximity of turbulent air flowing over the surface of the water. Ex. 1004 at 2:64-65; Ex. 2001 ¶ 60. The waves travel away from the air inlet and toward the outlet of the humidifier chamber. *See*, *e.g.*, Ex. 1004 at 3:34-40, 5:9-16; Ex. 2001 ¶ 44. The waves splash against the wall at the end of the water chamber, similar to small waves splashing against a sea wall, which cause water to splash upward. Ex. 1004 at 3:34-37; Ex. 2001 ¶ 44. As illustrated below, the water could splash through the outlet if the short outlet tube was not present.



Ex. 2001 ¶ 45; see also Ex. 1004 at 2:64-3:1.

Hebblewhite teaches adding a short tube 48 that extends into the water chamber from the air outlet to prevent water from splashing into the outlet. Ex. 1004 at 4:63-5:16. The tube prevents splashing water at the end wall of the water chamber from spilling out of the chamber, as illustrated below.



Ex. 2001 ¶ 45; Ex. 1004 at 3:34-40. Only a short tube length is required to prevent water from splashing through the outlet because the splashing issue is localized at

the end wall of the water chamber. Ex. 2001 ¶ 60. Hebblewhite explains that a tube of at least 2 cm in length (less than one inch) is sufficient. Ex. 1004 at 5:15-16 ("The aperture 50 should preferably be spaced at least 2 cm away from the end wall 46.").

Splashing caused by reflected waves is not a problem at the air inlet. Ex. 2001 ¶ 60. Consequently, Hebblewhite's outlet tube has no applicability to the inlet opening. *Id.* Moreover, because the CPAP device is designed to be located on top of the water chamber in Hebblewhite, any spillage of water into the air inlet of the water chamber, even if it were to occur, would not reach the CPAP device and would not pose a significant issue. *Id.* ¶ 62. Even Hebblewhite's supposed "general applicability" statement is limited to the air outlet. Ex. 1004 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). For all of the foregoing reasons, a POSITA would not have understood that statement, or any of Hebblewhite's disclosure, to suggest locating a tube at the air inlet. Ex. 2001 ¶ 57-60.

b. <u>Splashing and Spillage Caused By Waves Was Not a</u> Problem with the HC200 Manual Humidifier

There would have been no reason for a POSITA to combine Hebblewhite with the HC200 Manual. *Id.* ¶¶ 65-73. The water chamber in the HC200 Manual

operates in a different way from the low-profile humidifier of Hebblewhite. Hebblewhite criticizes humidifier designs in which airflow can take multiple different paths between the air inlet and outlet. *Id.* Hebblewhite explains:

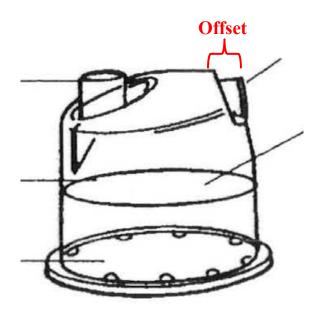
In an arrangement where the air flow can take a number of different paths between the air inlet and the air outlet, there is a danger that certain paths will contribute more greatly to the humidifying process than others, for example because the air is flowing at different speeds along different paths. Such an arrangement does not make maximum use of the available water surface area.

Ex. 1004 at 2:3-9. The HC200 Manual water chamber utilizes the airflow arrangement that Hebblewhite criticizes. Ex. 2001 ¶ 66. Unlike the airflow in Hebblewhite's low-profile water chamber, air that enters the HC200 Manual water chamber is not directed along a specific path through the chamber. *Id.* Instead, air swirls throughout the water chamber along multiple paths over the heated water in order to become humidified. *Id.*

Splashing from waves was also not a problem in the HC200 Manual water chamber, and a POSITA would have no reason to incorporate Hebblewhite's outlet tube. Ex. 2001 ¶ 65. Unlike Hebblewhite, airflow in the HC200 Manual water chamber does not create waves that are pushed directly toward the air outlet. *Id.* Unlike the low-profile water chamber design of Hebblewhite, the air outlet and

inlet of the HC200 Manual humidifier are spaced well above the fill level of the water chamber. Ex. 1015 at 7. Any waves that may be created in the water chamber would not result in splashing that could reach and spill through the air inlet or outlet. Ex. 2001 ¶ 65. Petitioners also agree that splashing from wave action was not an issue in the HC200 Manual device. Ex. 1003 ¶ 85 ("Indeed, the HC200 water chamber inlet appears to have been located by its designers high enough above the water level to protect against wave action.").

Moreover, the inner portion of the air inlet in the HC200 Manual water chamber is already offset from the chamber sidewall, as illustrated below:



Ex. 1015 at 7 (annotations added); Ex. 2001 ¶ 65. The short tube in Hebblewhite would provide no added benefit over this offset, and thus there would have been no reason to add Hebblewhite's tube to the HC200 Manual water chamber. *Id*.

c. <u>A POSITA Would Not Have Looked to Hebblewhite's</u> Outlet Tube to Address Any Problem of Spillage Caused by Tipping in the HC200 Manual Water Chamber

Petitioners argue that a POSITA would have understood that Hebblewhite teaches a general solution to the problem of "prevent[ing] water from spilling through [a] horizontal opening" when the water movement is caused by physical movement (i.e., tipping) of the entire water chamber. Pet. at 24-25. However, because Hebblewhite does not teach or suggest a solution to the problem of spillage caused by tipping the water chamber, a POSITA would not have incorporated Hebblewhite's outlet tube into the HC200 Manual to address any such problem. Ex. 2001 ¶¶ 61-64.

i. <u>Tipping Was Not a Problem in Hebblewhite</u>

As an initial matter, Hebblewhite does not mention any potential problem with tipping. *Id.* ¶ 62. The water chamber has a low-profile and a wide base. Ex. 1004 at Fig. 1, 4:6-7 ("The humidifier is a low-profile humidifier, and is of generally flat, rectangular box-like construction."). As a result of this wide and flat construction, it is unlikely that the water chamber could be easily tipped. Ex. 2001 ¶ 62. The water chamber is also designed so that that the CPAP device rests on top of it. Ex. 1004 at 1:30-32 ("In this case, it is desirable that the humidifier is designed so as to form a low, generally flat base for supporting the CPAP device."). Accidental movement of the water chamber is unlikely because the

weight of the CPAP device helps prevent the underlying water chamber from moving or tipping. *Id.* \P 62.

ii. The Wave Splashing Issue Described in Hebblewhite Is Different from the Problem of Spillage Caused by Tipping

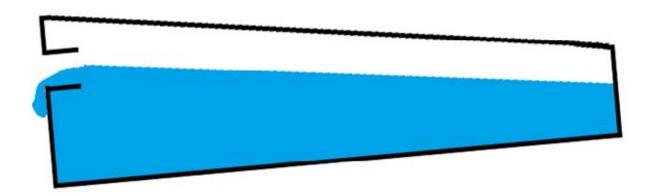
The problem described in Hebblewhite of splashing caused by waves is also fundamentally different from the problem of spillage caused by tipping a water chamber. Id. ¶ 68. The potential splashing problem described in Hebblewhite involves a small amount of splashing water caused by waves at the end of wall of the water chamber. Id. The problem of spillage from tipping involves a large volume of water that is directed to an opening of the water chamber and pours through the opening. Id. The problems are not the same, require different solutions, and a POSITA would not have viewed the short outlet tube described in Hebblewhite as having applicability to preventing spillage when the water chamber is tipped. Id.

The images below illustrate the final elongated passageway of Hebblewhite when filled with water (Figure A) and show what would happen if the water chamber were tipped (Figure B).

Figure A



Figure B

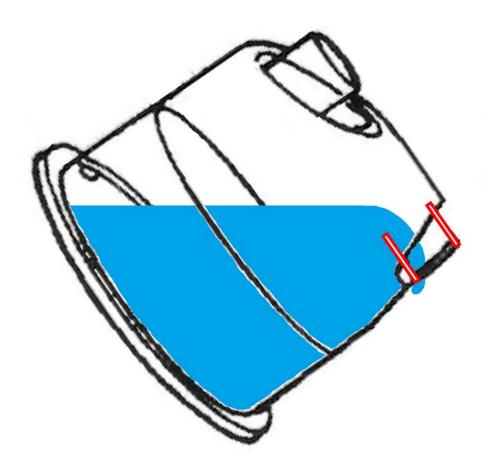


Id at 61. As the figures above illustrate, even slight tipping of the water chamber would cause water to spill out of the outlet tube. Id. The contrary assertion of Petitioners' expert, Mr. Virr, that "there is simply no indication in Hebblewhite that the tube would only work on waves that were created by air rather than waves that were created due to mechanical movements of the water chamber" (Ex. 1003 ¶ 74) is incorrect and unsupported.

To provide meaningful protection against spillage from tipping, Hebblewhite would need to include a tube extending nearly half the length of the final passageway of the water chamber. Ex. 2001 ¶ 69. However, Hebblewhite does not teach or suggest extending the length of the tube. *Id.* at ¶ 71. As described further in Section IV.B.2 below, it is not possible to extend Hebblewhite's outlet tube and Hebblewhite teaches away from extending the tube. *Id.* ¶¶ 70-71. For this additional reason, a POSITA would not have understood the outlet tube of Hebblewhite to have any applicability to the problem of spillage from tipping. *Id.* ¶ 71.

iii. Incorporating Hebblewhite's Outlet Tube Into the HC200 Manual Device Would Not Have Provided Any Benefit

Incorporating Hebblewhite's tube into the HC200 Manual water chamber would not protect against spilling if the chamber were tipped, and thus a POSITA would not have added the tube to the HC200 Manual water chamber to address any issue of spillage caused by tipping. *Id.* ¶ 67. The tube would space the inlet only a short distance into the water chamber. *Id.* As the illustration below demonstrates, water could spill through the tube and out of the chamber if the water chamber were somehow tipped.



Id. Consequently, a POSITA would have had no reason to incorporate Hebblewhite's outlet tube into the HC200 Manual water chamber. *Id.*

Petitioners also have not shown that spillage from tipping was a recognized problem in the HC200 Manual water chamber that a POSITA would have had reason to address. Petitioners rely on an interpretation of a statement in the HC200 Manual regarding not moving the device while the water chamber is full as justification for further modifying the HC200 Manual device itself. Ex. 1003 ¶ 72 (citing Ex. 1015 at 9). However, the HC200 Manual CPAP device already includes features to reduce the risk of spillage from tipping. Ex. 2001 ¶¶ 61-63.

The removable water chamber design enables patients to remove the water chamber for filling, cleaning, transporting, or emptying, while leaving the CPAP machine in place. *Id.* ¶ 64. The HC200 Manual instructs users to "press down the spring-loaded chamber guard and slide the humidification chamber onto the heater plate," thus securely locking the chamber in place for use. *Id.* This slide-in feature reduces the likelihood that any spillage that might occur while assembling the water chamber with its base portion. *Id.* The chamber guard also maintains the water chamber firmly in place once inserted, and thereby minimizes the likelihood that the water chamber will be inadvertently tipped. *Id.*

Moreover, the inlet and outlet located on an upper portion of the chamber and a much lower "maximum water level" indicator that is at or below the vertical midpoint of the water chamber also makes spillage from tipping the chamber an unlikely event. Ex. 1015 at 7; Ex. 2001 ¶ 63. The second HC200 Manual (Ex. 1012) cited by Petitioners also confirms that such spillage is "unlikely." Ex. 1012 at 1. Without a meaningful motivation to combine, a POSITA would have had no reason to incorporate Hebblewhite's outlet tube into the HC200 Manual water chamber. Ex. 2001 ¶¶ 63-66.

In sum, neither the HC200 Manual nor Hebblewhite teach or suggest the problem identified in the '197 Patent of water spilling through a chamber inlet when the chamber is tipped. Instead, this alleged problem and Petitioners'

purported 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).

d. None of the Other Art Identified by Petitioners Provides a Reason to Combine Hebblewhite and the HC200 Manual

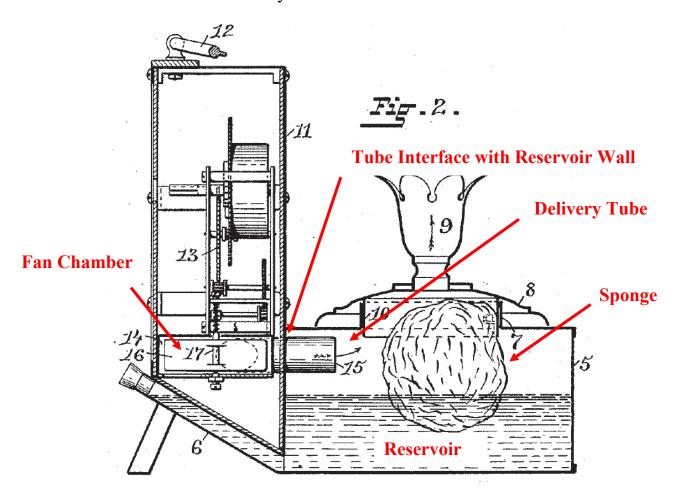
ResMed's expert also points to the Sullivan HumidAire water chamber, U.S. Patent No. 485,127 ("Lynch") (Ex. 1017), and Gouget as allegedly showing extension tubes located at a liquid chamber inlet. Ex. 1003 ¶ 78. However, none of those references provide any support for combining Hebblewhite and the HC200 Manual or for any of Petitioners' obviousness assertions. Ex. 2001 ¶¶ 74-77.

The HumidAire water chamber shown in Mr. Virr's declaration appears to disclose a low-profile humidifier similar to Hebblewhite. *Id.* ¶ 75.4 Mr. Virr presents no evidence that the tubes shown extending outward from the water chamber were intended to prevent spillage. As such, Mr. Virr provides no reason why a POSITA viewing the HumidAire water chamber would have been motivated

⁴ Mr. Virr's declaration cites to Exhibit 1020 as containing a HumidAire brochure. Ex. 1003 at ¶ 78. However, Exhibit 1020 is actually a copy of a complaint filed by FPH.

to add an elongate flow tube extending into the water chamber of the HC200 Manual.

Lynch is directed to a vaporizer for disinfecting or perfuming a passing airflow, rather than a humidifier. Ex. 1017. The Patent Office expressly considered Lynch during prosecution of the '197 Patent and was distinguished by the applicant. Ex. 1002 at 34. Lynch illustrates a delivery pipe 15 that extends into a reservoir chamber. Ex. 1017 at Fig. 2. The only function of the delivery pipe appears to be to direct air through a fan chamber and towards a sponge located in the reservoir, as illustrated below:



Id. at Fig. 2, 34-38, 40-59 (annotations and color added); Ex. 2001 \P 76. There is no indication in Lynch that the interface between the tube and reservoir wall is sealed such that it would prevent liquid from entering into the fan chamber if the reservoir were somehow tipped. Id. \P 76.

Lynch does not teach or suggest that the disclosed vaporizer addresses or solves any problems related to noise or spillage, nor would it be effective to prevent spillage. *Id.* Given the size and structure of the vaporizer shown in Lynch, it is unlikely the device would be tipped and cause any spillage of fluid from the

reservoir. *Id.* For all of these reasons, a POSITA would not have viewed Lynch as providing any reason to locate an elongate flow tube at the air inlet of the HC200 Manual water chamber. *Id.*

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

Given the orientation of the inlet and outlet openings in the water chamber shown in the HC200 Manual, adding an elongated tube at the inlet would direct airflow from the tube to the outlet. Ex. 2001 ¶ 72. Air circulation within the water chamber would be impeded and air humidification would be diminished. *Id.* Because the asserted combination urged by Petitioners would negatively impact air humidification, which is the primary function of a humidifier, a POSITA would not have positioned the outlet tube of Hebblewhite at the inlet of the HC200 Manual chamber. *Id.*; *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).

⁵ Petitioners even acknowledge this potential problem in Ground 2, although they do not address it in Ground 1. *See* Pet. at 28-29; Ex. 1003 ¶ 86. 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.

Indeed, the '197 Patent illustrates significant changes beyond the elongate tube to provide proper flow and ensure "adequate humidification during [the airflow's] journey through the chamber." Ex. 1001 at 2:35-36. For example, the patent described "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 7 to the outlet 3." *Id.* at 2:30-34.

f. Hebblewhite Does Not Teach or Suggest a Solution to the Problem of Noise Caused by Airflow through the Water Chamber

Lastly, one of the important benefits recognized by the '197 Patent inventors of locating the elongate flow tube at the inlet opening of the water chamber was that it provided a significant reduction in noise levels. Ex. 1001 at 2:44-59. Hebblewhite does not teach or suggest that its outlet tube is useful for noise reduction. Ex. 2001 ¶ 73. The outlet tube of Hebblewhite also would provide no noise reduction benefits. *Id.* Thus, a POSITA would not have looked to Hebblewhite to solve the problem of high noise levels in humidifier chambers. *Id.*

B. Ground 2: Claims 2 and 3 are Patentable over the HC200 Manual in View of Hebblewhite, Gouget, and Rose

In Ground 2, Petitioners argue that Claims 2 and 3 would have been obvious over four unrelated references – the HC200 Manual, Hebblewhite, Gouget, and Rose. 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. The Board exercised its discretion to institute on Ground 2 but did not address the merits of the ground in its Institution Decision.

Ground 2 relies in part on the combination of the HC200 Manual and Hebblewhite. Thus, this combination fails for at least the reasons discussed above in connection with Ground 1.

Petitioners acknowledge that Hebblewhite does not disclose an elongated flow tube having a length as recited in Claims 2 and 3. Ex. 1003 ¶ 84 ("[t]he 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"). Petitioners instead rely upon Gouget as allegedly disclosing a tube having a length as recited in Claims 2 and 3. Gouget describes a portable urinal and is not analogous art. Even if Gouget were considered as prior art, the cited combination still would not have rendered Claims 2 and 3 obvious.

1. 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.

In the first step, 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 requires consideration of a second step. Under this second step, a prior art reference will not be analogous art unless it is reasonably 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).

Whether a reference is analogous art is a question of fact. *Circuit Check*, 795 F.3d at 1335 (Fed. Cir. 2015) (citing *Wang Labs., Inc. v. Toshiba Corp.*, 993 F.2d

858, 864 (Fed. Cir. 1993). In *inter partes* review, Petitioners bear the burden of showing prior art is analogous. *See Schott Gemtron Corp. v. SSW Holdings Co.*, *Inc.*, IPR2014-00367, 2015 WL 3430088, at *15 (P.T.A.B. May 26, 2015).

Here, Petitioners did not even attempt to explain why Gouget is allegedly analogous prior art to the '197 Patent. Instead, 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. *See, e.g., Pure Fishing Inc., v. Globeride, Inc.*, IPR2015-01252, Paper No. 30 at 15-16 (P.T.A.B. October 31, 2016) (concluding that "Petitioner's briefs and evidence fail establish that one skilled in the art would have considered [the prior art] reasonably pertinent to the problem" addressed in the patent at issued); *see also Schott Gemtron Corp.*, 2015 WL 3430088, at *23.

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 section 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; Ex. 2001 ¶ 81. A humidifier is configured for gas flow through a chamber and humidification of that gas flow as it passes through the chamber. Ex. 2001 ¶ 81. 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. Ex. 1001 at Claim 1. Thus, the field of endeavor of the '197 Patent is not "liquid containers" in general. Ex. 2001 ¶ 81.

The proper analysis is whether a *urinal* and a *humidifier* are within the same field of endeavor. They are not. *Id.* ¶ 82. Gouget does not humidify air. *Id.* Gouget is concerned with capturing and storing inflowing urine.⁶ *Id.*; Ex. 1006 at 8:56-67. It is neither advantageous nor desirable to have air flow into, through and out of Gouget's device. Ex. 2001 ¶¶ 82, 85-86. Gouget is also not designed for

⁶ Air escapes from the chamber in Gouget through the anti-backflow element as the chamber fills with urine. Ex. 1006 at 8:56-67. Thus, the only design consideration related to airflow in Gouget is selecting the diameter of the smaller end of the anti-backflow element to allow a backflow of escaping air and to ensure the smaller end "cannot be completely obstructed by liquid flow." *Id.*; Ex. 2001 ¶ 82.

noise reduction because, again, there is no airflow through Gouget. *Id.* ¶¶ 83-84. Thus, Gouget is not in the same field of endeavor as the inventions described and claimed in the '197 Patent and a POSITA would not have looked to Gouget to solve any of the problems addressed in the '197 Patent. *Id.* ¶¶ 81-86.

b. Gouget Is Not Reasonably Pertinent to the Problem Solved by the '197 Patent

Petitioners also fail to show that Gouget is reasonably pertinent to the problems being solved by the '197 Patent. See ICON Health & Fitness, Inc., 496 F.3d at 1379-80; Bigio 381 F.3d at 1325-26. Petitioners generalize 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 as prior art. Pet. at 26-However, Petitioners' contentions are based on an overly broad 27. characterization of the problem addressed in the '197 Patent. See Pure Fishing Inc., IPR2015-01252, Paper No. 30 at 10-15 (rejecting Petitioner's characterization of the problem addressed by the patent at issue as being overly broad). Moreover, 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. Ex. 2001 ¶¶ 83-87.

As described above, Gouget describes an anti-backflow element 5 that allows *liquid* to enter the urinal without allowing the liquid to exit accidentally. Ex. 1006 at 8:21-55. Thus, the problem addressed in Gouget is limited to preventing liquid spills from tipping a urinal. Ex. 2001 ¶ 86. In contrast, the problem addressed in the '197 Patent is preventing liquid spills from tipping a humidifier while also allowing proper gas inflow and circulation through the humidifier and lowering the noise level of the humidifier. *See*, *e.g.*, Ex. 1001 at 2:54-65. None of the basic design considerations relevant to designing a humidifier is present in Gouget. Ex. 2001 ¶ 86. For example, Gouget does not take into account airflow patterns through the chamber or the rate of the airflow for effective humidification. *Id*.

Furthermore, even if air could be passed through the inlet of Gouget against the backflow of escaping air, it would be undesirable to pass air through the tapered tube shown in Gouget. Ex. 2001 ¶¶ 85, 88. The tapered shape would accelerate and disrupt air flowing through the tube and into the chamber. *Id.* If the tapered tube were located at the inlet of a humidifier, it would reduce humidification performance and likely create an undesirable whistling noise that would be disruptive to the patient. *Id.* If the tapered tube were located at the outlet of a humidifier, it would impede airflow out of the humidification chamber and result in diminished performance of the humidifier. *Id.*

2. The Identified Combination Does Not Teach or Make Obvious the Flow Tube of Claims 2 and 3

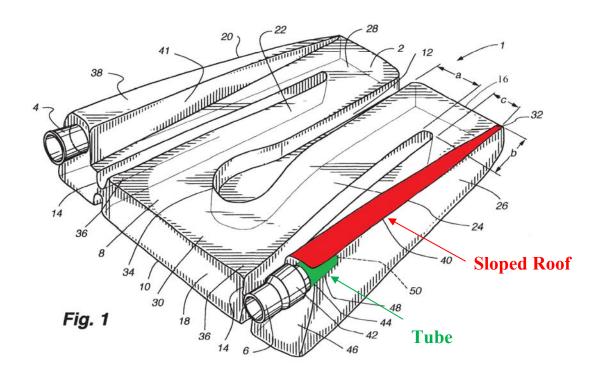
Ignoring that Gouget is non-analogous art, the combination relied upon by Petitioners still would not have rendered Claims 2 and 3 obvious. Petitioners purport to modify the device shown in the HC200 Manual in view of Gouget's teaching of positioning the outlet of an anti-backflow element at the volumetric center of the urine chamber. 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. *Id.* (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.*; Ex. 2001 ¶ 47. Thus, Petitioners have not even applied Gouget's teachings in arriving at their modified design.

In addition, adding a tube at the air inlet of the HC200 Manual in the manner urged by Petitioners would direct air to the outlet opening. Ex. 2001 ¶ 87. Air would travel from the inlet tube to the air outlet without adequate circulation and humidification. *Id.* Moreover, utilizing a tapered tube as shown in Gouget at the air inlet of the HC200 Manual water chamber would create a pressure drop that would require the blower to operate at a higher speed and would create a number of problems, such creating an undesirable whistling sound, interfering with the

necessary detections of a patient's breathing function, and impairing the ability of the CPAP device to deliver constant pressures to the patient throughout the night, among other problems. *Id.* ¶ 88. For these additional reasons, a POSITA would not have combined the tapered tube of Gouget with the water chamber shown in the HC200 Manual because it would render the HC200 Manual water chamber inoperable for its intended purpose. *Id.* ¶¶ 87-88.

Any suggestion by Petitioners that it would have been obvious to extend the outlet tube of Hebblewhite in view of Gouget is also unsupported. As explained above in Section IV.A.2.a, Hebblewhite discloses a short tube located at the outlet of the water chamber. Hebblewhite does not teach that a longer outlet tube would be desirable. Ex. 2001 ¶ 90. Moreover, Hebblewhite teaches away from extending the length of the tube in two manners. *Id.* ¶ 89.

First, the configuration of the low-profile water chamber described in Hebblewhite prevents the short outlet tube from extending further into the water chamber. Ex. 2001 ¶ 70. The roof of the water chamber slopes downward from the outlet opening, as shown below.



Ex. 1004 at Fig. 2 (annotations and color added). The sloping roof prevents the outlet tube from extending further into the water chamber. Ex. 2001 ¶ 70.

Second, Hebblewhite's disclosure regarding effective humidification teaches away from extending the outlet tube. *Id.* ¶ 71. Hebblewhite's water chamber is designed to maximize the surface area of the water that the air passes over between the inlet and the outlet so that the air is sufficiently humidified. *See* Ex. 1004 at 1:40-45; Ex. 2001 ¶ 71. Hebblewhite teaches:

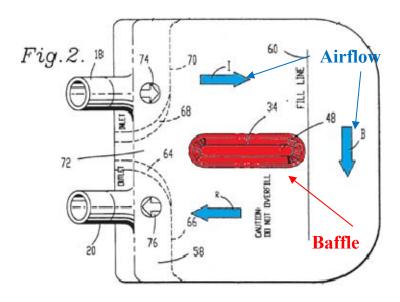
It is also important when designing a low-profile humidifier to ensure that maximum use is made of the available water surface area. For example, there is no point in providing a large surface area of water within the humidifier if the air flow passes over only a small portion of this area.

Ex. 1004 at 1:40-45. Extending the short outlet tube of Hebblewhite further into the water chamber would be directly contrary to this teaching because it would cause gas to exit through the tube before traveling the full length of the passageway. Ex. 2001 ¶ 71. Air would not travel over the surface of the water located beneath the tube and the water located beneath the elongated tube would provide little to no humidification benefit. *Id*.

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

In Rose, the baffle extends floor-to-ceiling between an upper and lower panel of the water chamber parallel to the direction of flow from the inlet and outlet, as shown in Figure 2 below.



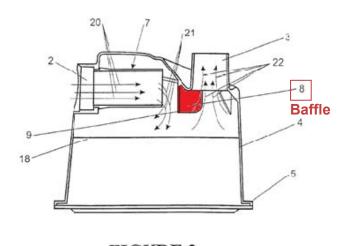
Ex. 1008 at Fig. 2 (annotations and color added). In contrast to the baffle in Rose, Petitioners propose modifying the HC200 Manual chamber to include a downwardly extending baffle directly between the inlet and the outlet and perpendicular to the flow of gases from the inlet and outlet that terminates in a free end. Pet. at 18.

Rose, however, does not teach either a downwardly extending baffle or placing a baffle directly between the inlet and outlet. Ex. 2001 ¶¶ 91-92. Moreover, the baffle in Rose creates a U-shaped flow path, as shown in the figure above. The baffle that Petitioners seek to add to the HC200 Manual water chamber

would not create such a flow path. The baffle that Petitioners seek to incorporate into the HC200 Manual water chamber is not supported by Rose and a POSITA would not have been motivated to modify the HC200 Manual water chamber to include such a baffle. Ex. 2001 ¶ 93.

Instead of coming from Rose, the proposed downwardly extending baffle suggested by Petitioners comes 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 7 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 reconstruction.

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Baffle Chamber center

FIGURE 2

Pet. at 28

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

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 perpendicular to the inflow of gases and 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. Ex. 2001 ¶ 93. Moreover, Rose does not teach that this type of baffle would result in an adequate amount of humidification of the passing air. *Id.*

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. Mr. Virr, however, does not explain how a change in the molding process would necessarily lead to the specific baffle design disclosed in the '197 Patent. The baffle in Rose runs parallel to the flow of air, whereas the baffle shown in Mr. Virr's hindsight-based drawings runs perpendicular to the flow of air, identical to the '197 Patent disclosure. Mr. Virr provides no explanation for how this significant change is suggested by the prior art.

C. <u>Ground 3: Claim 6 is Patentable over the HC200 Manual in View of Hebblewhite, Gouget, Rose, and Smith</u>

Ground 3 asserts that Claim 6 would have been 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.

D. <u>Ground 4: Claim 13 is Patentable over the HC200 Manual in View of Hebblewhite, Gouget, Rose, and Smith</u>

Ground 4 asserts that Claim 13 would have been 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.

E. <u>Ground 5: Claims 1 and 6 are Patentable over Netzer in View of</u> Hebblewhite and Smith

Ground 5 asserts that the combination of Netzer, Hebblewhite, and Smith renders Claims 1 and 6 obvious. Ground 5 fails for many of the same reasons as Ground 1 and for the additional reasons described below.

1. <u>Netzer, Hebblewhite, and Smith Do Not Teach or Make Obvious a</u> Flow Tube at an Inlet Opening

For the reasons previously provided in connection with Ground 1 (see Sections IV.A.2.a), Hebblewhite does not teach or suggest that it would be useful to reposition the disclosed outlet tube at a gas inlet because the outlet tube is used

to address splashing from waves that are not present at a gas inlet. Ex. 2001 ¶¶ 58-59. 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. Ex. 2001 ¶ 99. Petitioners also do not contend otherwise.

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

Petitioners argue that it would have been obvious to relocate the short outlet tube of Hebblewhite to the air inlet and air outlet of Netzer's water chamber. Pet. at 42. However, as described below, that proposed modification would not have been obvious for multiple reasons.

a. <u>Splashing and Spillage Caused by Waves Was Not a</u> Problem in Netzer

There would have been no reason for a POSITA to combine Hebblewhite with Netzer. Ex. 2001 ¶¶ 98-109. Netzer does not describe any potential problem with waves. *Id.* ¶ 102. Splashing into the inlet or outlet from waves would not be a problem in Netzer's water chamber because the inlet and outlet openings are located a sufficient distance above the water fill level of the chamber. *Id.*; Ex. 1010 at Fig. 4 and pp. 6-7 and 9 (explaining that the inlet and outlet openings are

spaced above the maximum fill level of the water chamber). Moreover, unlike Hebblewhite, airflow in Netzer's water chamber does not create waves that are directed toward the air outlet. Ex. 2001 ¶ 102. The open square design of the reservoir chamber in Netzer would also dissipate waves, rather than allowing them to concentrate at either the inlet or the outlet. *Id.* In light of these differences, a POSITA would have no reason to incorporate Hebblewhite's outlet tube, which is intended to address the issue of splashing from waves, into Netzer's water chamber. *Id.*

b. A POSITA Would Not Have Looked to Hebblewhite's Outlet Tube to Address Any Problem of Spillage Caused by Tipping in Netzer's Water Chamber

Petitioners argue that it would have been obvious to include tubes at the inlet and outlet openings of Netzer's water chamber "in order to limit the ability of water to spill out of the container through inlet 22 and outlet 23 of the CPAP device." Pet. at 42. In particular, Petitioners assert it would have been obvious to add extension tubes "to make sure that 'liquid can thus not be carried along by the respiratory gas into the flow guide element 3' if the CPAP device were bumped or tipped." Pet. at 42, *quoting* Ex. 1010 at 9 and *citing* Ex. 1003 ¶¶ 98-102.

Netzer describes a drainage system and inlet/outlet positioning that prevents water drops from being carried into the respiratory line. For example, Netzer teaches:

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, Netzer also solves that problem, leaving a POSITA no further motivation to solve that same problem. Ex. 2001 ¶ 104.

Netzer also does not describe any potential problem from spillage due to tipping or bumping. Ex. 2001 ¶ 103. Instead, that alleged problem, and its solution, are found only in the '197 Patent. Petitioners improperly use 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.

Furthermore, spillage from tipping would not have been a problem in Netzer. Ex. 2001 ¶ 104. The drainage system in Netzer prevents overfilling and ensures that the water level is located a set distance beneath the inlet and outlet openings. *Id.* Because the water chamber cannot be overfilled, the risk of spillage

from tipping is substantially mitigated because the water level is maintained a sufficient distance beneath the inlet and outlet openings of the water chamber. *Id.* Even if the chamber were tipped, water also could pour out of the drain instead of pouring out of the inlet or outlet opening. *Id.* Netzer also includes lateral guide profiles on the reservoir and corresponding guide grooves in the humidifier housing that further minimize the risk of spillage. *Id.* ¶ 105; Ex. 1010 at 10. The guide profiles ensure that the water chamber remains level as it slides into the humidifier base and prevent the water chamber from titling once connected to the base. Ex. 2001 ¶ 105.

In view of the features already present in Netzer that would prevent spillage, a POSITA would have seen no reason to modify Netzer's water chamber to include extension tubes at the gas inlet and outlet. *Id.* ¶ 106. The addition of such extension tubes would needlessly increase the cost and complexity of the device and a POSITA would not have been motivated to incorporate the extension tubes. *Id.*

Moreover, adding a short outlet tube as described in Hebblewhite to the air inlet (or air outlet) of Netzer's water chamber would not prevent spillage if the water chamber was tipped. Ex. 2001 ¶ 107. A short tube would space the inlet only a short distance into the water chamber. *Id.* If the water chamber were somehow tipped substantially, water could spill through the tube and out of the

chamber. *Id.* Thus, a POSITA would have had no reason to incorporate Hebblewhite's short outlet tube into Netzer's water chamber to prevent spillage from tipping. *Id.*

Furthermore, as discussed above in Section IV.B.2, Hebblewhite also does not teach or suggest that the length of the outlet tube could be extended and, in fact, Hebblewhite teaches away from extending the tube. *Id.* ¶¶ 70-71. A POSITA would have had no reason in view of Hebblewhite to relocate the outlet tube to the inlet of Netzer's water chamber and significantly extend the length of the tube, which would be necessary to provide effective protection from spillage due to tipping. *Id.* ¶¶ 108-109.

c. <u>Hebblewhite and Netzer Do Not Teach or Suggest a Solution to the Problem of Noise Caused by Airflow through the Water Chamber</u>

As previously explained, Hebblewhite does not teach or suggest that its outlet tube is useful for noise reduction. Ex. 2001 ¶ 73. Netzer likewise does not disclose any potential problems with noise in the water chamber. *Id.* ¶ 100. Thus, a POSITA would not have had any reason to incorporate the outlet tube of Hebblewhite into Netzer's water chamber to address potential issues with noise caused by airflow through the chamber. *Id.*

d. The Identified Combination Creates a New Problem

As described in more detail below in connection with Ground 6, adding elongate extension tubes at the inlet and outlet of Netzer's water chamber would degrade humidification performance. Ex. 2001 ¶ 109. Air would not travel over portions of the surface of the water because of the two extension tubes, which would reduce humidification. *Id.* Consequently, a POSITA would not have been motivated to add extension tubes to the inlet and outlet openings of Netzer as Petitioners propose because it would adversely affect performance. *Id.*

F. Ground 6: Claims 2, 3, and 13 are Patentable over Netzer in View of Hebblewhite, Smith, Gouget, and Rose

Ground 6 asserts that Claims 2, 3, and 13 would have been obvious in view of Netzer, Smith, Hebblewhite, Gouget, and Rose. Ground 6 uses the same base combination as 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.

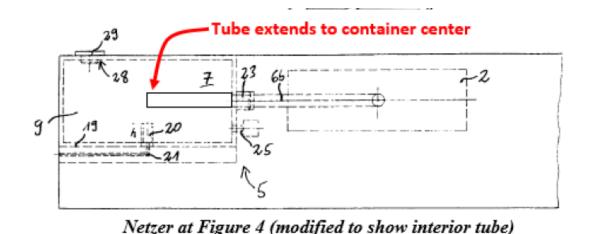
Moreover, as explained above, Gouget is not analogous prior art. In addition, a POSITA would not be motivated to extend the length of the outlet tube described in Hebblewhite and position an elongated tube at the inlet and outlet of Netzer because doing so would render Netzer inoperable for its intended purpose.

1. Gouget Is Not Analogous Art

As discussed above in Section IV.B.1, Gouget is not analogous art. Ex. 2001 ¶¶ 81-86, 112. As was the case for Ground 2, Petitioners do not even attempt to explain how Gouget is analogous art. Because Ground 6 relies upon Gouget as part of the identified combination, Ground 6 fails for at least this reason.

2. <u>The Identified Combination Does Not Teach or Make Obvious the</u> Flow Tube of Claims 2 and 3

Ignoring that Gouget is non-analogous art, the combination relied upon by Petitioners still would not have rendered Claims 2 and 3 obvious. *Id.* ¶¶ 112-115. Petitioners assert that a POSITA would have been motivated to "position the end of the tube towards the center of the chamber" and include the following illustration in the Petition.



Pet. at 47. As a motivation for this modification of Netzer, Petitioners rely on

Gouget and argue that "extending the tubes to the middle places the tubes near the

volumetric center and thus would help ensure that 'no water drops are carried over into the respiratory gas lines' (Ex. 1010 at 6-7), either due to waves caused by airflow or waves caused by tipping." Pet. at 47-48.

A POSITA would not have been motivated to extend tubes from the inlet and outlet of Netzer's water chamber to "near the volumetric center" of the chamber. Ex. 2001 ¶¶ 113-114. As described above, one principle of humidifier design is to increase humidification by ensuring that the airflow passes over the maximum surface area of the available water. *Id.* By adding tubes to Netzer's inlet and outlet openings that extend to the center of the chamber as Petitioners propose, some of the available surface area would be bypassed by the airflow, creating dead air spaces and thereby reducing humidification performance. *Id.*

Petitioners also assert that "presumably" Netzer's reservoir achieves sufficient humidification. Pet. at 48. Nevertheless, Petitioners also argue that "[t]o the extent that additional humidification is desirable," a POSITA would have further modified Netzer to include the central baffle of Rose. *Id.* According to Petitioners, this modification would promote the flow of air through a U-shaped or indirect path between the inlet and outlet tubes. *Id.* at 49.

The addition of a central baffle like in Rose, however, would do nothing to promote the flow of air through dead air space created by the extended tubes. Ex. 2001 ¶ 115. Neither Petitioners nor Mr. Virr propose any other baffle design that

would promote circulation through the space located beneath the added tubes. Id.

As such, a POSITA would not have been motivated to extend the lengths of the

inlet and outlet tubes in Netzer, as proposed by the Petitioners. Id.

Moreover, as explained in Section IV.B.2 above, any suggestion by

Petitioners that it would have been obvious to extend the outlet tube of

Hebblewhite in view of Gouget is also unsupported. Ex. 2001 ¶¶ 78-90.

V. CONCLUSION

For the foregoing reasons, the Petition fails to establish that any of the

challenged claims of the '197 Patent would have been obvious. The Board should

therefore confirm the patentability of the challenged claims.

Respectfully submitted,

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Dated: June 16, 2017

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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-

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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 RESPONSE AND EXHIBITS 2001-2002** are being served via email on June 16, 2017, to counsel for ResMed Limited, ResMed Inc., and ResMed Corp at the email addresses below:

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