UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ResMed Inc., ResMed Corp., and ResMed Limited
Petitioners

v.

Fisher & Paykel Healthcare Limited
Patent Owners

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

SECOND DECLARATION OF ALEXANDER VIRR

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I, Alexander Virr, of New South Wales, Australia, declare that:

1. On April 14, 2016, I provided an initial Declaration in the IPR2016-01719 proceeding. *See* Ex. 1003. I provide this Second Declaration in response to statements made in the June 16, 2017 Patent Owner's Response ("Response") and the accompanying June 15, 2017 Declaration of Dr. Harmut Schneider ("Schneider Declaration"; Ex. 2001) submitted in this proceeding.

2. In the course of preparing my initial declaration in this proceeding (Ex. 1003) and again while preparing this responsive declaration, I considered my own knowledge and experience, including my work experience in the field of medical devices and respiratory therapy. Additionally, in the course of preparing both my initial declaration and this responsive declaration, I have analyzed the following publications and materials:

- **Ex. 1001:** U.S. Patent No. 6,398,197 to Dickinson et al. ("the '197 patent")
- **Ex. 1002:** Relevant portions of the file history of the '197 patent
- **Ex. 1004:** U.S. Patent No. 6,135,432 to Hebblewhite et al. ("Hebblewhite")
- **Ex. 1005:** File history of Hebblewhite and parent application
- **Ex. 1006:** U.S. Patent No. 6,953,763 to Gouget ("Gouget")
- **Ex. 1007:** File History of Gouget parent app. no. 08/737,879

- **Ex. 1008:** U.S. Patent No. 5,231,979 to Rose et al. ("Rose")
- **Ex. 1009:** U.S. Patent No. 5,588,423 to Smith ("Smith")
- **Ex. 1010:** PCT Pub. WO 98/04311 to Netzer and a certified translation thereof ("Netzer")
- **Ex. 1011:** File history of US Pat. No. 6,006,748 to Hollis
- **Ex. 1012:** Fisher & Paykel Healthcare, "HC200 Series Humidified CPAP System" Instruction Sheet, (Rev. B)
- **Ex. 1015:** Fisher & Paykel Healthcare, "HC200 Series Nasal CPAP Blower & Heated Humidifier User's Manual," (Rev. A)
- **Ex. 1017:** U.S. Patent No. 485,127 to Lynch ("Lynch")
- **Ex. 1018:** U.S. Patent No. 933,301 to Hartmann ("Hartmann")
- **Ex. 1019:** U.S. Patent No. 1,813,959 to Romanoff ("Romanoff")
- **Ex. 1020:** ResMed, "Sullivan HumidAire" brochure (1997)
- Other background references, of which I had previously been aware, not cited herein, that a person of ordinary skill in the art at the time of the alleged invention ("POSITA") would have recognized as being related to the subject matter of the '197 patent.

3. I have also reviewed my initial Declaration signed on April 14, 2016 (Ex. 1003), the March 13, 2017 Board Decision in this proceeding, the Patent Owner's Response submitted on June 16, 2017, the accompanying Schneider

Declaration (Ex. 2001), and the transcript of the August 30, 2017 Deposition of Dr. Schneider (Ex. 1027).

A. ***The HC200 Manual in view of Hebblewhite (claim 1)***

4. **Length of Hebblewhite's tube.** Responsive to at least page 21 of the Patent Owner's Response and paragraph 60 of the Schneider Declaration, I disagree with statements which suggest that Hebblewhite suggests only a short tube. For example, the Response and Schneider Declaration both state that "[o]nly a short tube length is required…. Hebblewhite explains that a tube of at least 2 cm in length (less than one inch) is sufficient." Response, 21; Ex. 2001, ¶ 60. The cited portion of Hebblewhite, however, is clear that "[t]he aperture 50 should preferably be spaced at least 2 cm away from the end wall 46," which suggests only a lower bound on length and no upper bound. Ex. 1004, 5:15-6. A POSITA would have understood this portion of Hebblewhite to suggest that a designer should opt towards a lengthy tube, and not that short tubes were preferred as Patent Owner and Dr. Schneider imply. Furthermore, a POSITA seeking to address the HC200's spillage problem with a tube would have understood that the tube would not have to be the exact same size and shape of the tube that is disclosed in Hebblewhite, and would have considered at least characteristics of the HC200 and basic engineering principles, in addition to Hebblewhite's teachings, in selecting a tube shape and size. *See* Ex. 1003, ¶¶ 71-79.

5. **Hebblewhite's tube being at its outlet.** Responsive to at least page 21 of the Patent Owner's Response and paragraph 60 of the Schneider declaration, I disagree with statements which suggest that a POSITA would not have considered adding a tube to the HC200's inlet because Hebblewhite tube is located at Hebblewhite's outlet and not its inlet. A POSITA would have understood that that the spillage-prevention characteristics of Hebblewhite's tube were not due to the direction in which air flowed through the tube, but were instead related to the shape of the tube and its proximity and orientation to water that may contact the tube. Indeed, the HC200 inlet is structurally similar to the Hebblewhite outlet, with both being circular openings in sidewalls of humidification chambers through which water may flow due to splashing or tipping. *See* Ex. 1003, ¶¶ 71-79.

6. **Hebblewhite's blower.** Responsive to at least page 21 of the Patent Owner's Response and paragraph 62 of the Schneider Declaration, I disagree with statements which suggest that Hebblewhite's blower being located on top of its humidification chamber would have motivated a POSITA to <u>not</u> place a tube at an inlet to a different type of humidification chamber. I agree with Dr. Schneider that "any spillage of water into the air inlet of [Hebblewhite's] water chamber … would be unlikely to reach the CPAP device or its blower because of its location on top of the humidifier chamber" (Ex. 2001, ¶ 62), but believe that POSITAs would have actually understood this disclosure to indicate that a tube should be placed at the

HC200 air inlet. Specifically, a POSITA would have understood that a tube was not necessary at Hebblewhite's inlet due to Hebblewhite disclosing a stand-alone humidifier with the blower being above the blower, and not due to fundamental disadvantages with inlet tubes. The tube/no-tube disparity between Hebblewhite's outlet and inlet would have indicated to a POSITA that it was important to have a tube at any sidewall opening at which damage could occur if water flowed through that sidewall opening. Indeed, POSITAs would have recognized that the HC200 was an integrated humidifier in which harm could occur if water flowed through its inlet. As such, the fact that a tube is not located at Hebblewhite's inlet (because water would not cause harm if it flowed from the inlet of his non-integrated humidifier) actually supports the conclusion that I presented in my initial Declaration—that it would have been obvious to add a tube to the HC200 inlet in view of Hebblewhite's teachings, because adding a tube to the HC200 inlet would prevent harm/damage just as adding a tube to Hebblewhite's outlet was to prevent harm/damage. *See* Ex. 1003, ¶¶ 71-79.

7. **Waves and tipping in Hebblewhite and the HC200.** Responsive to at least pages 21 and 24 of the Patent Owner's Response and paragraphs 59-62 of the Schneider Declaration, I disagree with statements which suggest that a POSITA would not have added a tube to the HC200 because Hebblewhite discusses waves being created by moving air (without discussing a concern with

tipping), while the HC200 discusses a concern with tipping (without discussing waves crated by moving air). As I already stated above, a POSITA would have understood that the spillage-prevention characteristics of Hebblewhite's tube were related to its shape and its proximity and orientation to water that may contact the tube, and a POSITA would not have focused on whether water contacted the tube due to tipping, bumping, or waves created by moving air. *See* Ex. 1003, ¶¶ 71-79.

8. Hebblewhite's discussion of airflow paths. Responsive to at least page 22 of the Patent Owner's Response and paragraph 66 of the Schneider Declaration, I disagree with statements which suggest that Hebblewhite's criticism of humidifier designs in which air can flow through a number of different paths would have affected a POSITA's decision to modify the HC200 to include a tube. A POSITA with the HC200 design in hand would have been prompted to address the HC200's spillage problem and would have seen Hebblewhite's tube as a way to address that problem, and a POSITA would have considered Hebblewhite's suggestion that elongate passages are preferred over designs without elongate passages irrelevant to the teachings of a structure that addresses spillage. Whether or not a POSITA would have further modified the HC200 to route air through elongate passages (a recognizable option at the time) was distinct from, and supplemental to, the known benefits of resolving the HC200's spillage problem. *See* Ex. 1003, ¶¶ 71-79.

9. **Hebblewhite's statement of "general applicability."** Responsive to at least page 21 of the Patent Owner's Response, I disagree with statements which suggest that a POSITA would not have considered Hebblewhite's teachings to have "general applicability" to both outlets and inlets because the "general applicability" discussion in Hebblewhite at column 5 used the term "outlet aperture." *See* 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, and may be used in other humidifiers, regardless of whether the humidifiers are formed with elongate passageways."). It is clear that a POSITA would have understood that Hebblewhite referred to the "outlet aperture" in column 5 simply to identify the structure that "is of general applicability" to different types of humidifiers. Indeed, Hebblewhite is clear that its tube structure may be used in humidifiers that do not include elongate passageways, and a main reason that Hebblewhite included the tube on the outlet was to protect the outlet from waves that were created as a result of air moving through narrow elongate passageways, with the size of waves being large at least partially due to the passageway being long and permitting the waves to increase in size. Ex. 1004, 1:32-36; 2:58-3:3; 4:6-10; 5:9-22. As such, the fact that Hebblewhite indicates that its tube feature may be used in chambers without elongate passageways (and therefore without the same concern from waves) would

have supported a POSITA's understanding that tube mechanisms could protect sidewall openings from water that splashes due not only to wave action but also to tipping. Finally, a POSITA simply would have had enough skill and creativity to conclude that a tube which protects against water spillage created by waves would also protect against water spillage created by tipping. The protective mechanism is the same in both cases. Water which normally would have splashed into the sidewall opening instead hits the cylindrical walls of a tube that surrounds the sidewall opening. *See* Ex. 1003, ¶¶ 71-79.

10. **The HC200's offset.** Responsive to at least pages 23 and 27 of the Patent Owner's Response and paragraphs 65-67 of the Schneider Declaration, I disagree with statements which suggest that adding a short tube to the HC200 would have provided no benefits over the "offset" already present in the HC200. As an initial point, I never suggested simply replacing the HC200's "offset" with a tube of the same length, as the Patent Owner's Response and Schneider Declaration imply. Rather, I was clear that "a skilled artisan would have been motivated to modify the water chamber that is shown by the HC200 Manual to include a tube that extends inward from the inner periphery of the water chamber inlet." Ex. 1003, ¶ 72 (emphasis added). Moreover, to the extent that Patent Owner and Dr. Schneider suggest that a short tube would not provide any benefit, even if it extended past the "offset," their acknowledgement that the HC200's

"offset" already protects from tipping is an admission that a tube would also protect from tipping (even more so, due to the aperture in the tube being located further away from the sidewall than the aperture of the "offset"). Indeed, the illustration of the HC200 spilling water at page 28 of the Patent Owner's Response is evidence that even the relatively short tube that is shown in that illustration would protect against tipping, so long as the tipping was less severe than the approximately 45 angle at which the chamber is oriented in that illustration (the illustration shows water only starting to spill once the chamber has been tipped approximately 45 degrees). *See* Ex. 1003, ¶¶ 71-79.

11. **Tipping Hebblewhite.** Responsive to at least page 23 of the Patent Owner's Response and paragraph 65 of the Schneider Declaration, I disagree with statements which suggest that Hebblewhite's modest protection from tipping would have left a POSITA without motivation to add a tube to the HC200 to address tipping (e.g., because Hebblewhite's tube could not be extended to half length of the water chamber). I indicated in my previous declaration that a POSITA would have added a tube to the HC200 chamber to protect the inlet to that chamber from tipping based on the HC200's "CAUTION" against tipping and Hebblewhite's indication that a tube can protect a sidewall opening from water, and my previous declaration never discussed tipping Hebblewhite's chamber or extending the tube within Hebblewhite's chamber. *See* Ex. 1003, ¶ 72. No

humidifier can be absolutely protected against spillage by means only of modifications to its geometry. All the measures being discussed here are partial protections, and yet they have proved to be adequate.

12. **The HC200 Manual's discussion of tipping.** Responsive to at least page 28 of the Patent Owner's Response, I disagree with statements which suggest that the HC200 does not indicate that water spilling due to tipping was a problem. The HC200 Manual clearly states "CAUTION … Avoid moving or tilting the HC200 when the Humidification Chamber is full of water." This statement is clear that moving or tilting the chamber is only a concern when the chamber is "full of water" which, together with the illustrations of the chamber in the figures, would have indicated to a POSITA that moving or tipping the water chamber can cause water to splash through its sidewall opening into the blower. Patent Owner did not directly address my analysis of this phrase at paragraph 72 of my initial declaration (Ex. 1003, ¶ 72), and instead simply concluded that the HC200 does not indicate that tipping can cause water to spill through the inlet. The only support that Patent Owner provided for its conclusion, however, was to suggest that the HC200 "already includes features to reduce the risk of spillage from tipping," but these features are only the HC200's water line and the position of the HC200 inlet above that water line. *See* Ex. 2001, ¶¶ 61-63. These "features," however, were already included in the HC200 chamber and therefore a POSITA would have understood

that the manual's "CAUTION" refers to a problem that was not solved by the water line and inlet position "features." Indeed, a water line will not stop water from flowing through the inlet opening if the chamber is tipped to its side. The fact that the HC200 includes a water line and an inlet above that water line proves that the HC200 designer was concerned with water entering the inlet, which supports my conclusion in my initial declaration that a POSITA would have understood from the HC200's own statements that spillage due to tipping is a problem. *See* Ex. 1003, ¶¶ 71-79.

13. **Slide-in chamber.** Responsive to at least page 29 of the Patent Owner's Response and paragraph 64 of the Schneider Declaration, I disagree with statements which suggest that the slide-in nature of the HC200 chamber would have reduced spillage. As a first point, a POSITA would have recognized that having to push a chamber sideways into its humidifier base would have caused waves to form during the pushing and those waves to splash with force into the sidewall and potentially spill into the inlet when the chamber suddenly hits the blower wall and stops sliding. This is in contrast to chambers/humidifiers for which a user could place the chamber into the humidifier from above without such a lateral movement. As a second point, the features that create the slide-in chamber characteristics would retain the water chamber to the main body of the humidifier if the entire assembly was tipped, which would cause water to flow out

of the water chamber's sidewall opening into the blower, which is exactly the problem that a POSITA would be seeking to avoid. In contrast, the water chamber of at least some humidifiers that did not have slide-on installation would fall away from the humidifier base if the entire assembly was tipped over (such that water would not spill into the blower). As such, in many situations the slide-in features actually increase the possibility of spillage due to tipping. *See* Ex. 1003, ¶¶ 71-79.

14. **Reduced humidification.** Responsive to at least pages 33-34 of the Patent Owner's Response and paragraph 72 of the Schneider Declaration, I disagree with statements which suggest that a POSITA would not add a tube to the HC200 chamber because it would purportedly reduce humidification. I note that independent claim 1 does not require any particular length of tube, and believe that at least some POSITAs seeking to address the HC200's water spillage problem would have selected a relatively short tube (e.g., 2 cm long, as disclosed by Hebblewhite). Selecting a balance between spillage protection and humidification is a design choice and at least some designers would have deemed a relatively short tube to provide enough protection from spillage (e.g., protection up to approximately 45 degrees, as shown by the illustration in Patent Owner's response). In fact, Patent Owner stated that the HC200's integrated "offset" protects the inlet from a modest amount of tipping, which is an admission that a tube of similar or greater length would also protect the inlet from at least as much

tipping. In fact, humidification levels can be readily adjusted by increasing the temperature of the water, as controlled by the heater plate, so long as the water temperature does not exceed safety limits. Simply put, a POSITA would have considered a modest reduction in humidification for a given water temperature a worthwhile tradeoff to limit the chance that water would enter the blower, potentially making it unusable. Ex. 1012, 1. This is especially because humidifiers need only a certain level of performance, beyond which further increases in their ability to add moisture to the air will only result in water condensing out on the walls of the air delivery hose and in the mask ("rain out"). POSITAs knew that the HC200 was a powerful humidifier already, at least partially because Fisher & Paykel was known for its hospital humidifiers, which typically require more humidification than consumer devices. Thus it is very likely that a POSITA would have considered the level of humidification provided by the HC200 to already be more than most competing devices, while the level of spill-back protection was less and would therefore have considered the possible reduction in performance due to adding a tube to the inlet to be worthwhile in light of its improvements to spill protection. When water spills into a blower it is typically destroyed and the patient must report the fault to the manufacturer and wait for a replacement machine to be supplied. As such they are typically without

therapy for some days or weeks, which has a significant impact on their health and wellbeing. *See* Ex. 1003, ¶¶ 71-79.

B. ***The HC200 Manual in view of Hebblewhite, Gouget, and Rose (claims 2 and 3)***

15. Responsive to at least pages 45 and 46 of the Patent Owner's Response, I disagree with statements which suggest that a POSITA would not have considered Gouget's teachings when looking to solve a problem with a humidification chamber. As I explained in my initial declaration and throughout this declaration, it is clear that a POSITA seeking to solve the HC200's spillage problem using a tube (as suggested by Hebblewhite) would have logically considered the size of the HC200 chamber, basic engineering principles, and other containers such as the Gouget container to identify an appropriate tube length. *See* Ex. 1003, ¶¶ 84-88.

16. **The problems articulated in the '197 patent.** Responsive to at least page 40 of the Patent Owner's Response and paragraph 83 of the Schneider Declaration, I disagree with statements which suggest that the problem that the inventor of the '197 patent sought to address was "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." Rather, it is clear that a POSITA would have recognized that the '197 patent is directed to at least two problems which are less specific: (1) noise that results from air delivery to the

water chamber (Ex. 1001, 1:17-42), and (2) spillage from tipping the water chamber (Ex. 1001, 1:24-34). This is at least because the '197 patent refers to these problems separately, and because a POSITA would have recognized that these issues manifested themselves in different ways. Indeed, Dr. Schneider explicitly identified these two problems as being distinct from each other in his declaration. Ex. 2001, ¶ 33 ("The inventors of the '197 patent recognized two problems with prior humidifier water chambers: (1) the noise level … and (2) the possibility of tipping that may result in spillage…."). Moreover, Patent Owner stated that the "field of endeavor" includes "water chambers for gases humidification," but Patent Owner's articulation of the problem also requires a humidifier. As such, I believe that Patent Owner's articulation of the problem is narrower than the purported "field of endeavor," which supports my conclusion that the problem articulated by the Patent Owner is overly narrow. Response, pp. 37-38; *see* Ex. 1003, ¶¶ 84-88.

17. **Gouget's relevance to the problem.** Responsive to at least page 40 of the Patent Owner's Response and paragraphs 82-86 of the Schneider Declaration, I disagree with statements which suggest that a POSITA would not have considered Gouget's teachings when trying to identify how long a tube to implement at the HC200 sidewall opening. As discussed above, a POSITA would have already considered adding a tube to the HC200 based on the teachings of

Hebblewhite, and at that point would have been looking to identify a length of that tube because Hebblewhite only states that the tube should be "at least 2 cm" long. Patent Owner and Dr. Schneider emphasize that Gouget is a urinal, but it is clear that a POSITA would have understood from the disclosure and figures of Gouget that a primary focus of Gouget is not what type of liquid is within the container but is rather a design to keep that liquid from spilling out of an opening in the container, which is the same problem that was of concern to the inventors of the '197 patent and to a POSITA seeking to improve the HC200. *See* Ex. 1003, ¶¶ 84-88.

18. **Volumetric center.** Responsive to at least page 41 of the Patent Owner's Response, I disagree with statements which suggest that the modification to the HC200 that I discuss in my initial declaration does not account for Gouget's teachings because the tube configuration that I discuss in my initial declaration does not end at the volumetric center of the HC200 chamber. In particular, I explained in my initial declaration (at paragraphs ¶¶ 84-85) that angling the tube so that it ends at the volumetric center would promote waves. Indeed, with an angled tube, filling the chamber to approximately its water fill line would submerge the tip of the tube in water and lead to significant splashing and air flow resistance problems. As such, a POSITA would have extended the tube as close to the volumetric center as possible while remaining above the water level. In doing so

they would have arrived at a point near the horizontal mid-point of the chamber. Doing so would maximize the container's resistance to spill as Gouget suggests, while still taking into account the requirement to accommodate a certain volume of water and not route the air through that body of water. *See* Ex. 1003, ¶¶ 84-88.

19. **Tapered tube.** Responsive to at least page 42 of the Patent Owner's Response and paragraphs 85-88 of the Schneider Declaration, I disagree with statements which suggest that the modification to the HC200 that I discuss in my initial declaration does not account for the tapered shape of Gouget's tube, or that the tapered shape of Gouget's tube would have let a POSITA to ignore Gouget's teachings. Indeed, I never suggested in my initial declaration that a POSITA would have added a tapered tube to the HC200 chamber, as Patent Owner and Dr. Schneider suggest. Rather, I was clear that a POSITA would have simply looked to Gouget to determine how long of a tube should be used with the HC200 chamber after already implementing Hebblewhite's suggestion to add a tube to the HC200, and I do not believe that the tapered nature of the Gouget tube would have led a POSITA to look past Gouget's teachings. Gouget is clear that a main feature of its anti-spill technology was the position of the end of the tube, and a POSITA would have considered the taper a feature unrelated to the location of the end of the tube. Ex. 1003, ¶¶ 84-85. As a second point, it would be clear to a POSITA that all of the tubes being considered would be moulded from plastic and as such would all

be tapered to some degree. Tapering ("draft") is required of all tubes made by plastic injection moulding, to allow the steel core inside the tube to be withdrawn after the plastic has hardended. For instance, the outlet tube of the HC200 has some level of taper. So the taper shown in Gouget would not have deterred a POSITA from considering Gouget's disclosure in designing a mechanism to address the HC200 design's spillage problem.

20. **Extending Hebblewhite's tube.** Responsive to at least pages 43-44 of the Patent Owner's Response and paragraphs 70-71 of the Schneider Declaration, I disagree with statements which suggest that a POSITA would not have modified the HC200 to include a tube due to Hebblewhite's ceiling purportedly limiting the ability to extend the length of the tube that is already in Hebblewhite's chamber. I never concluded in my previous declaration that the tube should be extended in the embodiment depicted in Hebblewhite's chamber. Rather, I noted that a POSITA would have been prompted to implement a tube in the HC200 chamber to address spillage at a sidewall opening based on Hebblewhite's suggestion that a tube can protect a sidewall opening from spilling, and whether or not a tube could be extended in Hebblewhite's depicted embodiment does not change the fact that Hebblewhite would have suggested to a POSITA that a tube structure protects a sidewall opening from spillage. *See* Ex. 1003, ¶¶ 84-88.

21. **Baffle.** Responsive to at least page 47 of the Patent Owner's Response and paragraph 93 of the Schneider Declaration, I disagree with statements which suggest that POSITAs would not modified the HC200 to include a baffle, as I discussed in my initial declaration, because the proposed baffle is different from a baffle illustrated in Rose in two ways. A first difference is that Rose's baffle runs parallel to airflow that exits the inlet while the baffle that I discussed in the suggested HC200 modification is perpendicular to the airflow exiting the inlet. This difference, however, is explicitly taught by Rose. Rose is clear that a baffle should force air to move in an "indirect path" between the inlet and outlet, which a POSITA would have understood to mean that the baffle must be placed between the inlet and outlet to prevent air from shortcutting directly from the inlet to the outlet. Ex. 1008, 2:7-11. Rose's inlet and outlet are on the same wall, and a baffle placed between the inlet and outlet in such a configuration runs parallel to air coming out of the inlet. The HC200 has the inlet and the outlet on orthogonal walls, and employing Rose's teaching that the baffle should be placed between the inlet and the outlet to force air to move in an "indirect path" results in a baffle that is oriented perpendicular to the air leaving the inlet. The baffle orientation suggested for the HC200 is a direct result of Rose's teachings.

22. Moreover, Dr. Schneider is incorrect when he stated that "Rose shows only a single type of baffle…running parallel to the flow of gases." Ex. 2001, ¶

93. Rather, Rose explains that in chambers in which the inlet and outlet are on opposite walls, multiple baffles should be spaced apart to generate an "S-shaped or serpentine airflow path through the humidifier," and a POSITA would have recognized that implementing an S-shaped airflow path between an inlet and outlet on opposite walls could have been implemented in at least two predictable manners, one of which would have included the baffles being oriented perpendicular to the inlet and outlet. Ex. 1008, 4:55-63. As such, Rose clearly suggests using perpendicularly-orienting baffles when the inlet and outlet are located on different walls.

23. A second difference is that Rose's baffle extends from the floor to the ceiling and the baffle suggested for the HC200 extends downward from the ceiling without contacting the floor. This difference, however, also arises from teachings in Rose and differences between the HC200 and Rose humidification chambers. For example, as I explained in my initial declaration (at paragraph 87), Rose's chamber is made by blow molding, which requires the wide top-to-bottom baffle construction that is illustrated in Rose. The HC200 chamber is not blow molded, and a POSITA would therefore understand that the wide blow-molded design illustrated in Rose would have been unnecessary and that a thinner baffle that was not formed as a through-blown feature was more appropriate to injection moulding. Moreover, the bottom of the HC200 chamber was a heated metal plate,

and a POSITA would have readily recognized that a plastic baffle should not contact a heated metal plate and could not readily be joined to it. *See* Ex. 1003, ¶¶ 84-88.

C. ***Netzer in view of Smith and Hebblewhite (claims 1 and 6)***

24. **Identifying that tipping and bumping was a problem.** Responsive to at least page 52 of the Patent Owner's Response and paragraph 101 of the Schneider Declaration, I disagree with statements which suggest that I used hindsight to identify the tipping/bumping problem present in the design of the Netzer humidification chamber. As I explained at paragraphs 98-102 of my initial declaration, Netzer is clear that water should not enter its respiratory gas lines (Ex. 1010, 6-7), and a POSITA would have been skilled enough to recognize that water could enter the respiratory gas lines due to tipping or bumping. Indeed, water in the respiratory gas lines was a predominant concern at the time and was known to harm patients.

25. **Splashing from waves.** Responsive to at least pages 50-51 of the Patent Owner's Response and paragraph 102 of the Schneider Declaration, I disagree with Dr. Schneider's statement that splashing due to waves would not be a problem in Netzer's water chamber because the "inlet and outlet openings are located well-above the water fill level" and because the drainage system of Netzer would purportedly "dissipate any waves." Ex. 2001, ¶ 102. A POSITA would

have recognized that significant bumps (e.g., from a user striking the humidifier while reaching for it in the dark, tripping on the conduit connecting the humidifier to the patient mask, or running into a table on which the humidifier is resting) would create large waves that could readily splash into the water chamber's sidewall openings. The idea that the small drain opening in Netzer's water chamber would significantly dissipate a wave on its way towards the sidewall openings is unreasonable. As an initial note, the drain was designed to prevent overfilling before installation of the chamber, and Netzer's humidifier would have to include a mechanism to close the drain opening during operation, otherwise air would simply exit through the drain rather than the respiratory gas lines. Moreover, even if the drain were actually open during operation, at most a small amount of water from a wave could enter the relatively-small drain inlet as the wave rolled past the inlet on the way to the sidewall in which the inlet and outlet are located. That amount would be negligible in comparison to the volume of the wave and would not meaningfully affect whether or not water from that wave splashed into the sidewall openings. Indeed, the drain is located in the center of the chamber and therefore, even if it were open during operation, would at most drain some water from the center of the wave as it swept past the drain inlet, while the sidewall openings are offset from the center of the sidewall. *See* Ex. 1003, ¶¶ 95-102.

26. **Spillage from tipping.** Responsive to at least pages 52-53 of the Patent Owner's Response and paragraph 104 of the Schneider Declaration, I disagree with Patent Owner's statement that "spilling from tipping would not have been a problem in Netzer." Response, 52. The two arguments presented by Patent Owner and Dr. Schneider are flawed. Their first argument is that Netzer's drainage system prevents overfilling and therefore that water would not spill into the sidewall openings, but even if the drain set the water level at a very low level, a POSITA would have understood that water would still flow into Netzer's inlet and outlet if the chamber was significantly tipped toward the inlet and outlet. When a blower is destroyed or a patient injured by water spillage it is usually because the device has fallen off the bedside table or has been packed for transport with the water still in it or has been picked up and tipped while still connected to the patient. The angle of tipping is at least 90 degrees in some of these instances. So any level of water in the tank will result in spillage if the openings are unprotected. Devices such as Netzer's drainage system which seek only to limit fill level are entirely ineffective in preventing spillage of water into the gas delivery lines. Indeed, Patent Owner and Dr. Schenider statements that the risk from spilling would have been "substantially mitigated" by the added tubes are admissions that water could still spill into the inlet and outlet if the humidifier was tipped. Response, 50-51; Ex. 2001, ¶204. Their second argument is that water would flow

into the drain if tipped, but I wholly disagree that any water would enter the drain if the chamber were tipped towards the inlet and outlet. As an initial point, the drain would not be open during operation as this would allow the air to exit via the drain rather than flowing to the patient. Further, even if the drain was open, the water level would have lowered to the level of the drain opening (or below), and tipping the chamber at that point toward the inlet and the outlet would cause water to flow away from the location of the drain in the middle of the chamber and towards the wall in which the inlet and outlet are located. The water level would only rise near the side wall towards which the chamber was tipped, and a POSITA would have recognized that the height of the water at the mid-point of the chamber (the drain location) would have actually decreased as water flowed toward the side wall. *See* Ex. 1003, ¶¶ 95-102.

27. **Guide profiles.** Responsive to at least page 53 of the Patent Owner's Response and paragraph 105 of the Schneider Declaration, I disagree with the statement that the guide profiles would "prevent the water chamber from tilting once connected to the base, thereby also preventing spillage resulting from tipping." Ex. 2001, ¶ 105. As a first point, a POSITA would have recognized that having to push a chamber filled with water sideways into engagement with a humidification base would have caused waves to form during the pushing process and then ride up the end wall and potentially spill into the inlet and outlet when the

chamber abruptly stops. This is in contrast to humidifiers in which a user could lower a water chamber into place without such a lateral movement. A user may tip the water chamber during the lowering process, but the water would not spill into the gas humidification tubes at that time because the chamber and humidifier base would not yet be engaged. With a sideways water chamber installation, waves are directed directly into the gas humidification lines. As a second point, Dr. Schneider's statement that the guide profiles would "prevent the water chamber from tilting once connected to the base" is not correct. Ex. 2001, ¶ 105. While the guide profiles may prevent the water chamber from tilting independent of the base once the two are connected together, the guide profiles would retain the water chamber to the base. Thus, the water chamber is guaranteed to tip when the entire apparatus was tilted. The retention of these two components together would cause water flowing out of the water chamber's sidewall openings to flow directly into the respiratory gas lines, which is exactly the problem that a POSITA would be seeking to avoid. If there were not guide profiles, the water chamber may disengage from the humidifier base if the entire apparatus is tipped over and water would therefore not spill into the respiratory gas lines during such a tipping event. Indeed, a POSITA would have known that some humidification devices were decoupled in this manner when tipped. As such the guide profiles actually increase the possibility of spillage due to tipping. *See* Ex. 1003, ¶¶ 95-102.

28. **Short tube.** Responsive to at least pages 53-54 of the Patent Owner's Response and paragraphs 107-108 of the Schneider Declaration, I disagree with statements which suggest that adding a short tube to each of Netzer's sidewall openings would not protect against spillage. The Response and Schneider Declaration note that if the chamber was "substantially" tipped, that water would spill out of the chamber, but those statements are actually admissions that tubes would protect from any tipping that was not substantial. *See* Response, 53-54. Indeed, a POSITA would have recognized that a tube of "at least 2 cm" (as suggested by Hebblewhite) would provide significant protection from waves that are created from modest tipping in which waves would hit the side of the chamber and splash upward toward the inlet and outlet. A 2 cm tube would prevent that upwardly-directed water from spilling into a sidewall opening. As such, even 2 cm tubes (the minimum suggest by Hebblewhite, not the maximum) would protect the inlet and outlet from some tipping and from waves that result when a user carries, turns, or rocks a humidifier. While short tubes would not protect against high angles of tip they could provide a useful improvement in protection against wave action and moderate angles of tip, both of which can result in enough water entering the gas lines to harm or discomfort the patient. *See* Ex. 1003, ¶¶ 95-102.

29. **Cost and complexity.** Responsive to at least paragraph 106 of the Schneider Declaration, I disagree with Dr. Schneider's statement that adding tubes

"would simply increase the cost and complexity of the device without any countervailing benefits." Ex. 2001, ¶ 106. First, it is simply incorrect to state that there are no countervailing benefits because the additional protection from water that tubes would provide is a significant benefit. Second, adding a feature to any sort of consumer or medical device can involve additional cost and/or complexity and the relevant question that a designer is faced with is not whether the feature results in additional cost and/or complexity, but whether that additional cost and/or complexity is justified in view of any countervailing benefits. Here, the benefits to additional tubes are health related and therefore of great value. Indeed, water in respiratory lines was known to harm patients, and a POSITA would have been aware of these dangers. In view of the significant dangers that water in respiratory lines pose, it is clear that a POSITA may have considered such additional cost and/or complexity (if any) justified. *See* Ex. 1003, ¶¶ 95-102.

30. **Reduced humidification.** Responsive to at least page 55 of the Patent Owner's Response and paragraph 109 of the Schneider Declaration, I disagree with statements which suggest that a POSITA would not modify the HC200 chamber to add a tube because doing so would purportedly reduce humidification. First, Netzer's unmodified design shows the inlet and the outlet on the same wall of the humidification chamber and a POSITA would have recognized that air might flow directly from the inlet to the outlet without

sufficiently circulating through the chamber in this configuration. This is because there is no baffle forcing the air to take an "indirect path," as Rose teaches. Indeed, Netzer's humidification chamber configuration, in which the inlet and outlet are located on the same wall, is the same as that in Rose, for which Rose is clear that a baffle is necessary to ensure sufficient humidification. *See* Ex. 1008, FIG. 2, 2:3-13. As such, even if air short circuited directly from Netzer's inlet to Netzer's outlet after tubes have been added, as the Patent Owner and Dr. Schneider suggest, a POSITA would have recognized that this was already the case in Netzer's design and adding tubes would not necessarily make the air flow worse.

31. Second, even if adding tubes reduced humidification, humidification levels can be readily adjusted by increasing the temperature of the water, as controlled by the heater plate, so long as the temperature does not exceed safety limits. Simply put, a POSITA may have considered a modest reduction in humidification for a given water temperature a worthwhile tradeoff in exchange for protecting the respiratory gas lines from water entry, and limiting the potential that a patient could be harmed (as described above). This is especially because humidifiers need only a certain level of performance, beyond which further increases in their ability to add moisture to the air will only result in water condensing out on the walls of the air delivery hose and in the mask ("rain out"). Without knowing the dimensions or water temperature of Netzer's humidifier, it is

impossible for Patent Owner and Dr. Schneider to know its performance, but there is no reason to suppose it would be so poor as to rule out the addition of features to reduce spillage.

D. *Netzer in view of Smith, Hebblewhite, Gouget, and Rose (claims 2, 3, and 13)*

32. Responsive to at least page 82 of the Patent Owner's Response, I disagree with statements which suggest that a POSITA would not have looked to Gouget when seeking to solve a problem with spillage in a humidifier. Rather, as I explained in my initial declaration and throughout this declaration, it is clear that a POSITA seeking to solve Netzer's problem with water spillage using tubes at the inlet and outlet (as suggested by Hebblewhite) would have considered the size of Netzer's chamber, basic engineering principles, and other containers such as the Gouget container in identifying an appropriate length for the tube. *See* Ex. 1003, ¶¶ 113-117.

33. The problems articulated in the '197 patent. Responsive to at least pages 40 and 56 of the Patent Owner's Response and paragraphs 83 and 112 of the Schneider Declaration, I disagree that the problem articulated by the inventor of the '197 patent was "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." Response, 40. Rather, it is clear that a POSITA

would have recognized that the '197 patent was directed to at least two separate problems: (1) noise that results from air delivery to the water chamber (Ex. 1001, 1:17-42), and (2) spillage from tipping the water chamber (Ex. 1001, 1:24-34). This is at least because the '197 patent refers to these problems separately, and because a POSITA would have recognized that these problems manifested themselves in different ways. Indeed, Dr. Schneider acknowledges in his declaration that these two problems are distinct. Ex. 2001, ¶ 33 ("The inventors of the '197 patent recognized two problems with prior humidifier water chambers: (1) the noise level … and (2) the possibility of tipping that may result in spillage….").

Moreover, Patent Owner states that the "field of endeavor" includes "water chambers for gases humidification," but Patent Owner's articulation of this problem requires a humidifier and thus is narrower than the purported "field of endeavor." Response, pp. 37-38. *See* Ex. 1003, ¶¶ 113-117.

34. **Gouget's relevance to the problem.** Responsive to at least pages 40-56 of the Patent Owner's Response and paragraphs 82-86 and 112 of the Schneider Declaration, I disagree that a POSITA would not have looked to Gouget when trying to identify how long of a tube to implement at Netzer's sidewall openings. A POSITA here would have already considered adding a tube to the HC200 based on the teachings of Hebblewhite, and at that point would have been looking to identify a length of that tube, because Hebblewhite only states that the tube should

be "at least 2 cm" long. Patent Owner and Dr. Schneider emphasize that Gouget is a urinal, but a POSITA would have understood from the disclosure and figures of Gouget that a primary focus of that reference is not what type of liquid is contained within the chamber but keeping that liquid from spilling out of an opening in the container, which is the same problem that was of concern to the inventors of the '197 patent and to a POSITA seeking to improve Netzer's chamber using a tube. *See* Ex. 1003, ¶¶ 113-117.

35. **Extend to center.** Responsive to at least pages 56-57 of the Patent Owner's Response and paragraph 114 of the Schneider Declaration, I disagree with statements which suggest that there would be a humidification reduction if the tubes were extended to the middle of Netzer's chamber. Rather, as I discussed above with respect to the combination of Netzer, Smith, and Hebblewhite, a POSITA would have recognized that air would flow directly from the inlet to the outlet in Netzer's original configuration without sufficiently circulating through the chamber because there is no baffle forcing the air to take an "indirect path," as Rose discloses. As such, even if air flowed directly from the inlet to the outlet when Netzer's chamber includes tubes extending to the middle of the chamber, as the Patent Owner and Dr. Schneider suggest, a POSITA would recognize that such short-circuiting of air would be exactly what occurred before tubes were added. *See* Ex. 1003, ¶¶ 113-117.

36. **Baffle.** Responsive to at least pages 57-58 of the Patent Owner's Response and paragraph 115 of the Schneider Declaration, I disagree with statements which suggest that a baffle would not improve humidification performance. As I have explained above, absent a baffle, air would flow directly from the inlet to the outlet in Netzer's original configuration without sufficiently circulating through the chamber. A POSITA would have understood that adding a baffle would have increased humidification in comparison to the short-circuiting of air that would occur in the original Netzer design, even if circulating air did not contact the water that was under the tubes. As such a POSITA would have recognized that adding tubes that extended to the middle of the chamber, along with a baffle to prompt the circulation of air in an "indirect path" would have increased humidification in the chamber rather than decreased it. *See* Ex. 1003, ¶¶ 113-117.

CONCLUSION

37. I currently hold the opinions expressed in this declaration. However, my analysis may continue after the signing of this declaration. If and as my analysis continues, I may acquire additional information and/or obtain supplemental insights that result in added observations.

38. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Respectfully submitted,

Date: September 15, 2017

Alexander Virr