UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

Petitioners,

v.

FISHER & PAYKEL HEALTHCARE LIMITED,

Patent Owner.

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

DECLARATION OF DR. HARTMUT SCHNEIDER IN SUPPORT OF PATENT OWNER RESPONSE TO PETITION FOR *INTER PARTES* REVIEW

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I, Dr. Hartmut Schneider, declare and state as follows:

I. BACKGROUND AND QUALIFICATIONS

1. I have been retained by Knobbe, Martens, Olson & Bear, LLP, counsel for Fisher & Paykel Healthcare Limited ("Fisher & Paykel"). I have been asked by counsel to review relevant materials and render my expert opinion in connection with technical matters related to Fisher & Paykel's response to ResMed's ("Petitioners") petition for *inter partes* review of U.S. Patent 6,398,197 ("the '197 Patent"). I have been asked to provide opinions regarding the patentability of Claims 1-3, 6, and 13 (the "Challenged Claims") of the '197 Patent.

2. Exhibit 2002 is my current curriculum vitae, which includes a listing of my patents and work in obstructive sleep apnea medical research and related product development. The following paragraphs briefly summarize my relevant experience.

3. I hold an M.D. from Philipps University in Marburg Germany, which I received in 1987. I also obtained a Ph.D. from Philipps University, which I received in 1999. I am currently an Associate Professor of Medicine at Johns Hopkins School of Medicine, Division of Pulmonary and Critical Care Medicine in Baltimore, Maryland with joint appointments as the Privatdozent for Internal

Medicine at Philipps University and the Medical Director at the American Sleep Clinic in Frankfurt, Germany.

4. From 1987 to 1991, I worked as an M.D. and post-doctoral research fellow in the sleep disorders center of Philipps University. During this period, I was responsible for the clinical and technical sleep laboratory operations and oversaw expansion of the sleep center from one to six beds. I was also involved in developing diagnostic devices for the early diagnosis and treatment of sleep apnea, including home sleep testing devices and much larger bedside diagnostic units for hospitals and sleep disorder centers. During this time, I collaborated directly with several Durable Medical Equipment companies (DMEs) that provided CPAP machines for treating sleep apnea using CPAP therapy. These DMEs included SEFAM, based in France, Respironics, based in the United States, a German DME and distributer called Stimotron, and later a start-up German CPAP manufacturer called MAP, GmbH. ("MAP"). This early experience with patients using CPAP treatment made me a medical pioneer in the field of sleep apnea and CPAP treatment in Germany and I became a consultant medical advisor for MAP from 1993 to 2000. During this time, I worked with MAP's device engineers and software designers to develop several commercial CPAP machines, including machines used with humidifiers, as discussed further below.

5. From 1991-2000, I worked as a physician in the Interdisciplinary Center of Internal Medicine of Philipps University Marburg. During these nine years I gained experience in disciplines such as cardiology (one year), pulmonary and sleep disorders (three years), oncology (one year), nephrology (one year), and gastroenterology (one year). I also continued working a few days per week in a clinical outpatient care center (Poliklinik) for patients with sleep apnea for at least five of these years. I also co-directed the clinical and research operations of the Sleep Disorders Center and was responsible for several research projects focused on the effect of sleep apnea and treatment on cardiovascular function. This research, together with my experience in internal medicine, established me as a renowned researcher in the field of pathophysiology of respiratory and sleep medicine. For my achievements, I was awarded the title of "Privatdozent of Internal Medicine" by the state of Hessia, a title that is essentially equivalent to Associate Professor of Medicine in the United States.

6. As mentioned above, I was a consulting scientific advisor for MAP from 1993 until 2000, at which time MAP was purchased by ResMed, Inc. Through my time consulting with MAP, I gained substantial experience in the design and development of CPAP devices, including CPAP devices used in conjunction with humidifiers. This work also resulted in multiple patents across

the world, as detailed in my C.V. (Ex. 2002). My work for MAP included assisting with the development of several CPAP devices, as well as other research and diagnostic devices for sleep apnea. For example, in conjunction with engineers from MAP, I developed and tested a Pcrit machine (a modified CPAP machine that provides positive and negative pressure), an AutoSet CPAP machine for laboratory use, and finally an AutoCPAP device for in-home use. All these machines either were or remain in clinical or research use across Germany, Europe, the U.S. and/or Australia.

7. As two examples of my particular experience related to humidifier design, the development of the proprietary algorithms for both the auto-adjusted CPAP devices (Autoset and AutoCPAP) required extensive knowledge of humidifier function and design. In principle, all auto-adjusted CPAP devices use some input signal derived from patients' breathing to adjust the CPAP machine. These input signals can be received as data into software algorithms used to recognize breathing abnormalities and adjust the CPAP machine's blower to modify pressure and/or flow of air to a patient during treatment. However, it was found that the addition of a humidifier between the patient and the blower created signal noise that impacted the software algorithms for detecting breathing abnormalities, thereby affecting the performance of the CPAP machine and the

efficacy of therapy. To better understand and control for this type of noise, the MAP engineers and I tested various humidification chamber designs for their effects on signal noise and ultimately on the efficacy of the algorithms to detect and adjust based on patient breathing abnormalities. In the end, we developed our own humidifier chambers and integrated these into MAP's CPAP machines. The approach we developed was eventually adopted by all CPAP manufacturers working on AutoCPAP.

8. In 2001, I joined the Johns Hopkins Division of Pulmonary and Critical Care Medicine and became the Laboratory Director of the Johns Hopkins Bayview Sleep Disorders Center, which conducts more than 1,500 sleep studies annually. In this role I have overseen all technical developments over the last 17 years relating to diagnosing patients with sleep apnea and treating patients using CPAP therapy, and have worked extensively with CPAP devices. During these years I have extended my expertise to treat nocturnal breathing problems in patients with COPD (chronic obstructive pulmonary disease) and asthma. One of my major research activities is to develop and test a nasal high flow therapy for treating these patients during sleep.

9. In 2009, I founded a clinical sleep center in Frankfurt, Germany, called the American Sleep Clinic, at which I serve as the Medical Director

responsible for all medical and operational affairs. Since 2009, I have seen more than 2,000 patients and initiated CPAP treatment in over 1,000 patients. I have worked with several DME companies in Germany, all of which provide a spectrum of CPAP devices to patients.

10. From 2001 to 2010, I also worked on developing a nasal high-flow system that is tailored to use during sleep and targeted to treat snoring and mild sleep apnea. I am a named inventor on U.S. and foreign patents for this development work. The technology was developed by TNI Medical, who is manufacturing and distributing these devices in Europe and Asia. As the main inventor of this treatment concept, I was involved in all technical aspects in producing a clinically viable product. One of the greatest challenges in the development process was to provide both high levels of airflow and high levels of humidification without "rain out" of condensed water and without producing noise that could interfere with the sleep continuity. Through this development and closely collaborative work, I gained further experience in aerodynamics and humidification as it relates to medical devices to assist ventilations.

11. Since 2006, I have also served as a consultant for Fisher & Paykel Healthcare. Initially, I was asked to give feedback to the clinical applications and future directions for using CPAP in children and patients with milder forms of

upper airway obstruction. I was also asked to evaluate the design, hardware and software properties and to give advice on how to develop strategies for High Flow Therapy ("HFT"). HFT is a concept where warm and humidified air is delivered through a small nasal cannula (similar to a standard oxygen cannula) to a patient.

12. In 2014, I became a co-founder of a Johns Hopkins start-up company, RespEQ. This company was founded based on one of my inventions that was initially targeted to be an adjunct to conventional CPAP devices. It consisted of a low resistance, low dead space flow sensor that would not affect the outflow of the CPAP devices or humidification profiles of conventional CPAP devices. It also became apparent that such a technique also would not affect drug dispensing properties of asthma inhalers. I worked on developing both the technical and business models for a start-up company. I serve as RespEQ's Chief Medical Operator and am involved in technical and medical development as well as in the patent application process.

13. I am a named inventor on 6 U.S. Patents and 2 international patents that resulted from my design work described above.

14. I am also a named author on more than 50 publications, many of which relate to the use of respiratory devices, such as CPAP machines, for medical treatments.

15. I am being compensated for my time in connection with this proceeding at $450 per hour. My compensation is not dependent on the outcome of this proceeding. I have no personal or financial stake or interest in the outcome of this proceeding.

16. In the event that additional relevant information becomes available to me, I reserve the right to review and consider that information in further developing or refining my opinions.

II. INFORMATION AND MATERIALS CONSIDERED

17. I have reviewed the specification and claims of the '197 Patent. I have been informed that the '197 Patent was filed on May 4, 2000 and claims priority to New Zealand Provisional Application No. 335694 filed on May 10, 1999.

18. I have also reviewed the following materials:

- the Petition for *Inter Partes* Review (Dkt. No. 4) in IPR2016-01719;
- the Exhibits cited in the Petition, including the declaration of Alexander Virr;
- Fisher & Paykel's Preliminary Response (Dkt. No. 9);
- the Decision by the Patent Trial and Appeal Board to Institute *Inter Partes* Review (Dkt. No. 12).

19. The above referenced materials are in addition to any other materials referenced directly or indirectly in this declaration.

III. RELEVANT LEGAL STANDARDS

A. Obviousness

20. I have been asked to opine as to whether the Challenged Claims of the '197 Patent would have been obvious to a person of ordinary skill in the art at the time of the alleged inventions described in the '197 Patent, in view of the art identified by Petitioners.

21. I have been informed and understand that a patent claim can be found to be unpatentable if the claim would have been obvious in view of the prior art at the time the claimed invention was made. I understand that this determination is made from the perspective of a person having ordinary skill in the art who is presumed to be aware of all prior art.

22. I have been informed that 35 U.S.C. § 103 governs the determination of obviousness. According to 35 U.S.C. § 103:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such

> that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

23. I have been informed that the factors to be considered in an obviousness inquiry include: the scope and content of the prior art; the differences between the prior art and the claimed invention; the level of ordinary skill in the pertinent art; and any evidence of "objective indicia of nonobviousness." I understand that those objective indicia may include considerations such as whether a product covered by the claims is commercially successful and whether there was a long-felt-but-unmet need in the field for the claimed invention, among other things.

24. In determining the scope and content of the prior art for purposes of assessing obviousness, I have been informed that a reference qualifies as prior art only when it is analogous to the claimed invention of the challenged patent. I understand that two separate tests define the scope of analogous art: (1) whether the art is from the same field of endeavor as the challenged patent, regardless of the problem addressed, and (2) if the art is not within the same field of endeavor as the challenged patent, whether it is still reasonably pertinent to the particular

problem with which the inventor of the challenged patent was involved. I understand that a reference is reasonably pertinent if, because of the subject matter with which it deals, the reference logically would have commended itself to an inventor's attention in considering his or her problem.

25. To assess the differences between prior art and the claimed subject matter, it is my understanding that the law requires the claimed invention to be considered as a whole. I understand that this assessment requires showing that one of ordinary skill in the art at the time of invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would have selected the elements from the prior art and combined them in the claimed manner.

26. I also understand that hindsight-driven motivation is improper for determining obviousness. That is, it is improper to use knowledge gleaned only from the patent at issue as a motivation for combining references or modifying a reference to show obviousness of the claimed subject matter. It is my further understanding that the law recognizes several rationales for combining references or modifying a reference to show obviousness of the claimed subject matter. I understand that some of these rationales include: combining prior art elements according to known methods to yield predictable results; simple substitution of one

known element for another to obtain predictable results; a predictable use of prior art elements according to their established functions; applying a known technique to a known device (method or product) ready for improvement to yield predictable results; choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; and some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

B. Claim Construction

27. I understand that the first step in analyzing the patentability of a patent claim begins with an analysis of the wording of the claim itself, also referred to as "claim construction." I understand that the proper standard for claim construction in an IPR proceeding is the broadest reasonable interpretation in light of the specification to one having ordinary skill in the art at the time the claimed invention was made. As the basis for my opinions and conclusions herein, claim terms are presumed to take on their ordinary and customary meaning, based on the broadest reasonable interpretation in light of the specification of the '197 Patent.

IV. PERSON OF ORDINARY SKILL IN THE ART

28. I have been informed that for purposes of assessing the obviousness of patent claims, the level of skill possessed by the hypothetical person of ordinary skill in the art ("skilled artisan") is informed by several factors. I understand these factors include the type of problems encountered in the relevant art, the prior art solutions to those problems, the rapidity with which innovations are made in the relevant art, the sophistication of the relevant technology, and the educational level of active workers in the field.

29. The relevant field for the '197 Patent includes respiratory therapy devices and related humidifiers. I consider myself to be an expert in the relevant field, both now and as of 1999, when the first application leading to the '197 Patent was filed.

30. It is my opinion that 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. 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. My opinions are thus based on the perspective of a person of ordinary skill in the art having this level of knowledge and skill at the time of the effective filing dates of the applications that led to the '197 Patent. Therefore, my opinions are based on the perspective of a person of ordinary skill in the art near the time of May 1999. While Mr. Virr has offered a different definition of a person of ordinary skill in the art (Ex. 1003 ¶ 22), my opinions expressed herein would not change even if Mr. Virr's proposed level of ordinary skill in the art were applied.

V. OVERVIEW OF THE '197 PATENT AND OTHER BACKGROUND

31. The '197 Patent relates to a humidifier used in conjunction with a CPAP (continuous positive airway pressure) device used to supply pressurized air into the airways of a patient, such as for the treatment of sleep apnea. Ex. 1001 at 1:6-8.

32. In a typical CPAP system, air is directed by a blower into a tube leading to a patient interface (such as a mask) and into the airways of the patient. Depending on the humidity of the airflow, providing the airflow to the patient can have the effect of drying out the patient's mouth, nose, or throat. This drying out can result in patient discomfort and poor compliance with CPAP therapy. A

solution to this problem is to provide a humidifier for use in conjunction with the CPAP machine for increasing the humidity of the airflow.

33. The ’197 Patent describes a water chamber design for use with a CPAP device. The inventors of the ’197 Patent recognized two problems with prior humidifier water chambers: (1) the noise level in the chamber resulting from the blower delivering air directly to the chamber and (2) the possibility of tipping that may result in spillage from the water chamber inlet port into the CPAP machine blower. Ex. 1001 at 1:10-35.

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

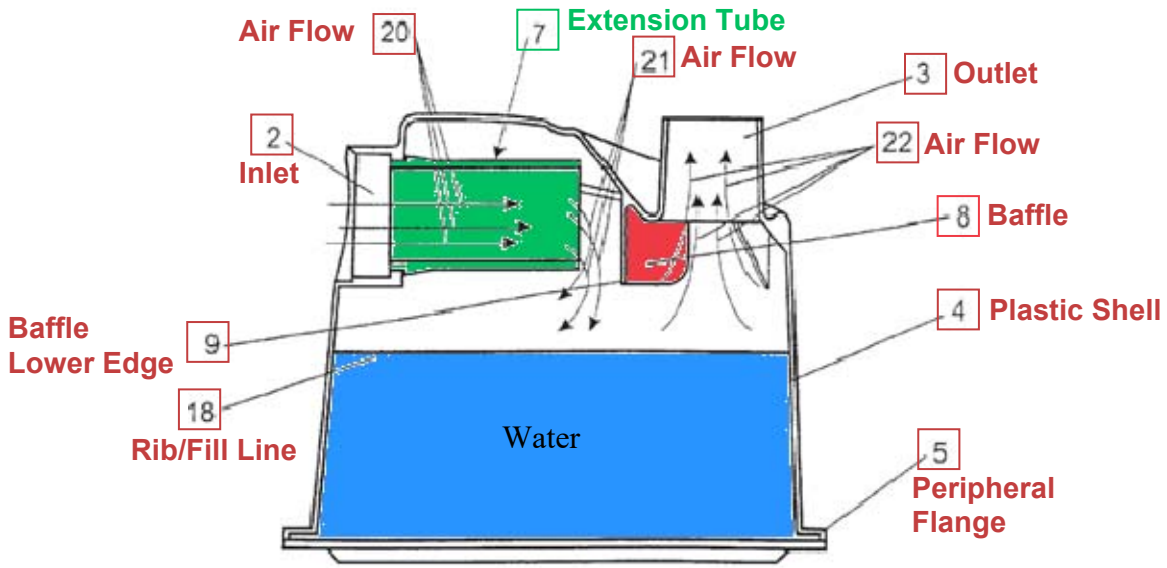


FIGURE 2

Id. at Fig. 2 (color and annotations added).

35. 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 leaves the blower in a turbulent flow state from its interaction with the blower and enters the chamber 4 through the gas inlet 2 and passes through the extension tube 7. The patent explains that passing the airflow through the extension tube results in a more controlled laminar flow than the turbulent flow 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.

36. Noise reduction is an important benefit of a CPAP machine because CPAP machines are used during sleep. Loud noise levels can prevent a patient from falling asleep or wake the patient during the night. A hose typically connects the CPAP machine with a patient interface on the face or head of a patient. Sound generated by the CPAP machine can travel through the hose and reach the patient's head and ears. The noise reduction benefit described in the '197 Patent is therefore an important one.

37. After exiting the extension tube 7, the airflow 21 circulates turbulently within the chamber. *Id.* at 2:25-36. Water in the chamber is heated by the transfer of heat from a heater plate on a CPAP machine to a conductive base 6 on the water chamber. *Id.* at 2:15-20. Liquid water molecules at the surface of the heated water evaporate into water vapor and are dispersed into the surrounding air, causing it to become humidified. As the airflow circulates through the chamber, it becomes humidified and eventually exits the chamber through an outlet 3. *Id.* at 2:52-53.

38. Figure 2 of the '197 Patent also shows a baffle 8 that extends downward from the top of the water chamber. The baffle abruptly redirects the airflow and prevents the airflow from exiting the extension tube 7 and flowing directly out of the chamber through the outlet 3. *Id.* at 2:29-38. The baffle causes air to flow throughout the chamber and improves humidification performance. *Id.*

39. The extension tube 7 also reduces the chance of water spilling out of the air inlet if the chamber is tipped. *Id.* at 2:59-61. Spillage through the air inlet is particularly problematic because water can potentially reach the blower that generates the airflow. The blower is an electrical component and can be damaged if exposed to water. Because the air outlet is oriented near the top of the chamber, water spilling through the outlet is not an issue. As shown in Figure 6 (below), the extension tube 7 prevents water from spilling 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).

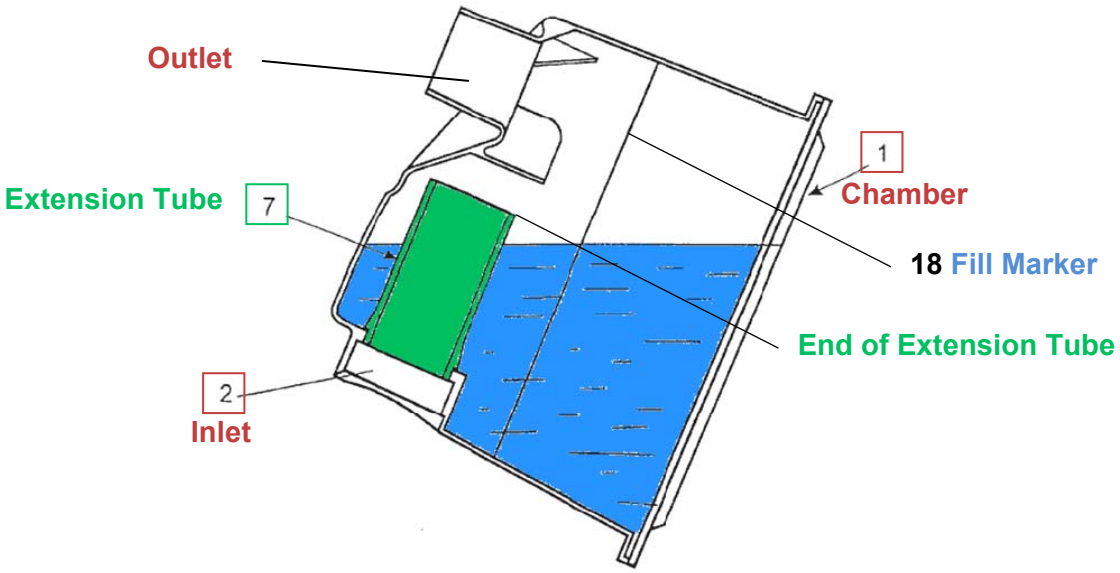
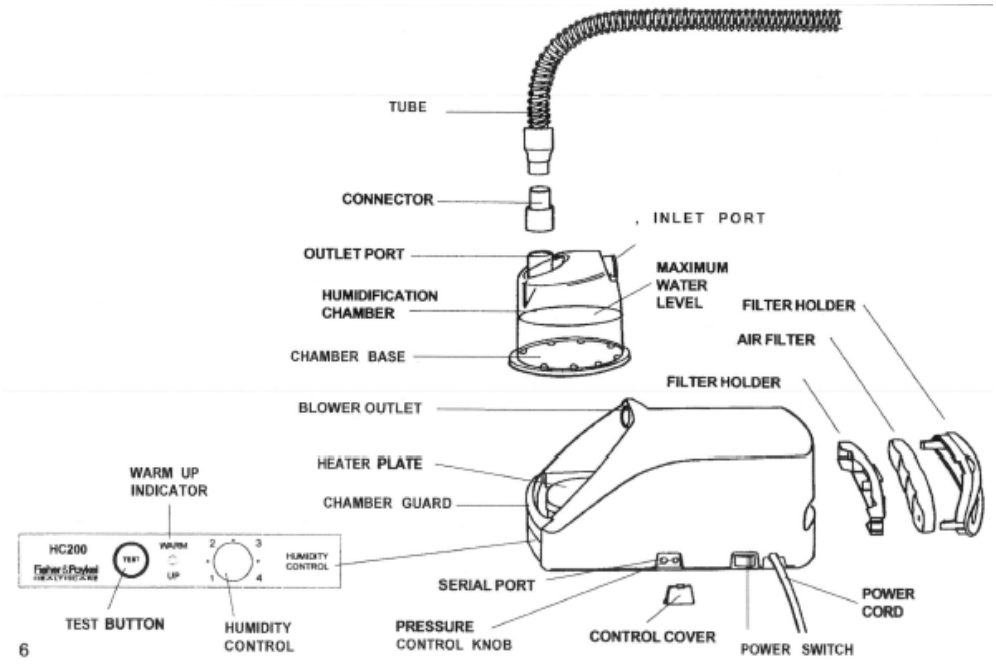


FIGURE 6

VI. OVERVIEW OF THE ART

A. Overview of the HC200 Manual

40. The HC200 Manual shows a high-profile CPAP device for the treatment of sleep apnea that includes a humidifier. Ex. 1015. An image from the HC200 Manual is reproduced below.



Id. at 7.

41. The HC200 Manual shows a humidifier water chamber with a horizontally oriented inlet port located near the top of the chamber. *Id*. A vertically oriented outlet port is located in the roof of the chamber. The manual also shows a heater plate that is positioned at the base of the chamber when the chamber is inserted. *Id*. Air flows into the chamber through the inlet port and out

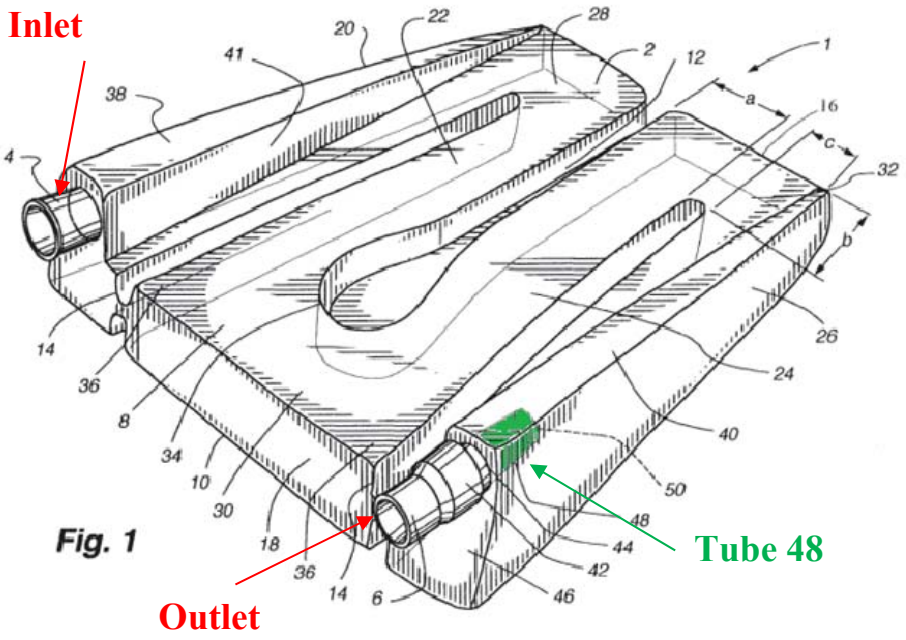
of the chamber through the outlet port. *Id*. The HC200 Manual does not show an extension tube extending into the water chamber from the inlet. The HC200 Manual also does not illustrate a baffle between the inlet and the outlet. Moreover, because the outlet port is vertically oriented well above the water line, water splashing through the outlet port is not a problem in the design shown.

B. Overview of Hebblewhite

42. U.S. Patent No. 6,135,432 ("Hebblewhite") teaches a low-profile humidifier for a CPAP device. Ex. 1004 at Abstract. Hebblewhite describes using a long passageway to direct air from the inlet to the outlet in a single path to ensure each portion of the surface area of the water contributes equally to the humidifying of the airflow. *Id*. at Fig. 1; 1:67-2:3. Hebblewhite also stresses the importance of maximizing water surface area. *Id*. at 1:40-41; 2:3-9. Hebblewhite explains that "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." *Id*. at 1:42-45.

43. Low-profile humidifiers are of low height and are placed under and support a connected CPAP device. *Id*. at 1:28-30. Due to their low height, Hebblewhite explains that low-profile humidifiers suffer from the problem of entrainment of water droplets at the output airflow to the patient. *Id*. at 1:33-36. Hebblewhite describes several ways to reduce entrainment of water droplets at the

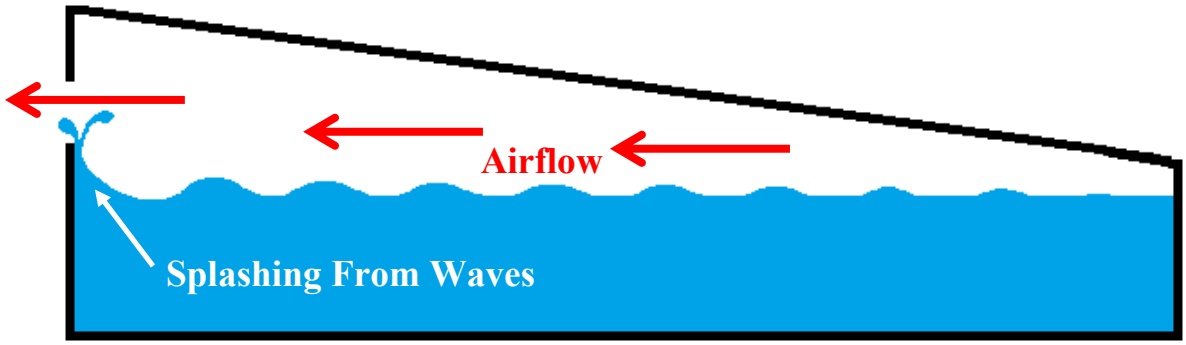
output airflow including reducing turbulence through an enlarged passageway and spacing the air outlet away from the chamber walls. *Id.* at 3:1-3, 35-40. Hebblewhite illustrates the spaced air outlet 48 in Figure 1 below:



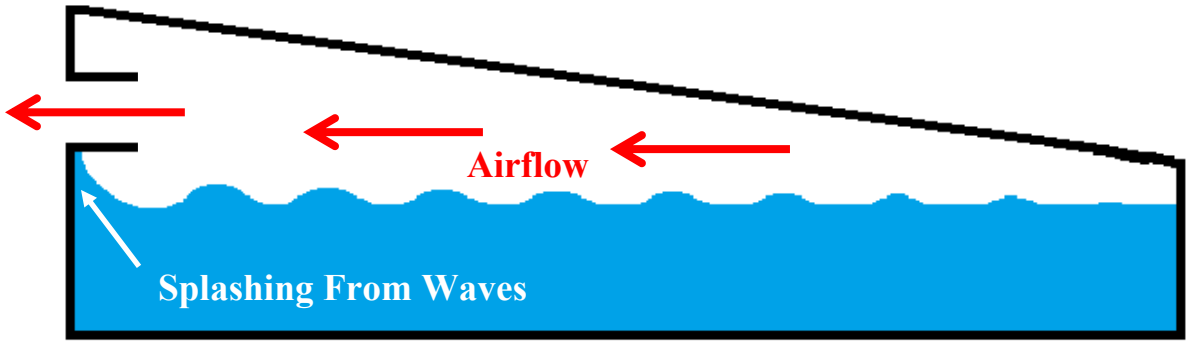
Id. at Fig. 1 (annotations and color added), *see also* 1:52-60.

44. Hebblewhite explains that low profile humidifiers are susceptible to wave formation caused by normal airflow from the inlet to the outlet that can splash through the outlet of the humidifier. *Id.* at 3:34-38, 5:9-16. The waves are created due to the close proximity of the airflow to the water surface, which results from the low-profile humidifier design. As the waves reach the end of the chamber, the waves strike the end wall of the chamber beneath the air outlet,

which, similar to waves hitting a sea wall, can cause the waves to rise above a normal height and splash up and into the outlet. *Id.* at 3:34-38. I provide the following graphic depicting the last elongate passageway to illustrate this issue:

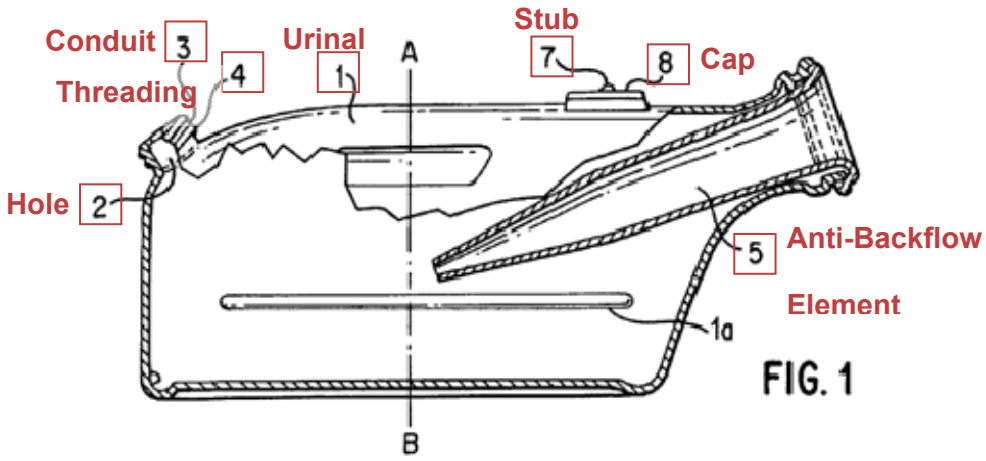


45. To avoid water from splashing through the outlet when waves splash against the end wall of the water chamber, Hebblewhite includes a short tube 48 extending from the outlet 6 away from the surrounding wall and into the humidifier chamber. *Id*. at 4:63-5:8. By spacing the opening at the end of the tube a short distance away from the end wall of the chamber, water caused by splashing waves cannot reach the opening and will not splash into the tube. I provide the following drawing to illustrate how this works:



C. Overview of Gouget

46. U.S. Patent No. 5,953,763 ("Gouget") is titled "Safety Urinal" and describes a urinal receptacle. Ex. 1006. Gouget includes an anti-backflow element through which a patient urinates into the chamber. *Id.* at 8:56-67. As shown in Figure 1 of Gouget (below), the anti-backflow element 5 extends to the volumetric center of the urinal chamber (and nowhere else).

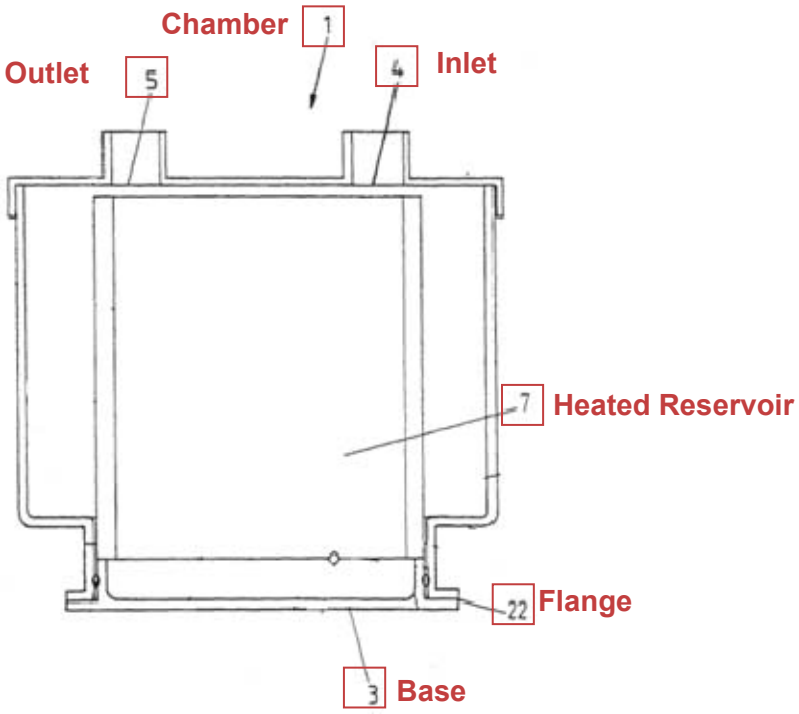


Id. at Fig. 1 (annotations added), *see also id.* at 8:37-42.

47. Gouget explains that positioning the outlet of the anti-backflow element at the volumetric center of the chamber prevents urine from spilling out of the chamber regardless of the angle at which the urinal is positioned. *Id.* at 7:46-8:13. Gouget does not teach that the disclosed design is useful for devices other than safety urinals.

D. Overview of Smith

48. 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).

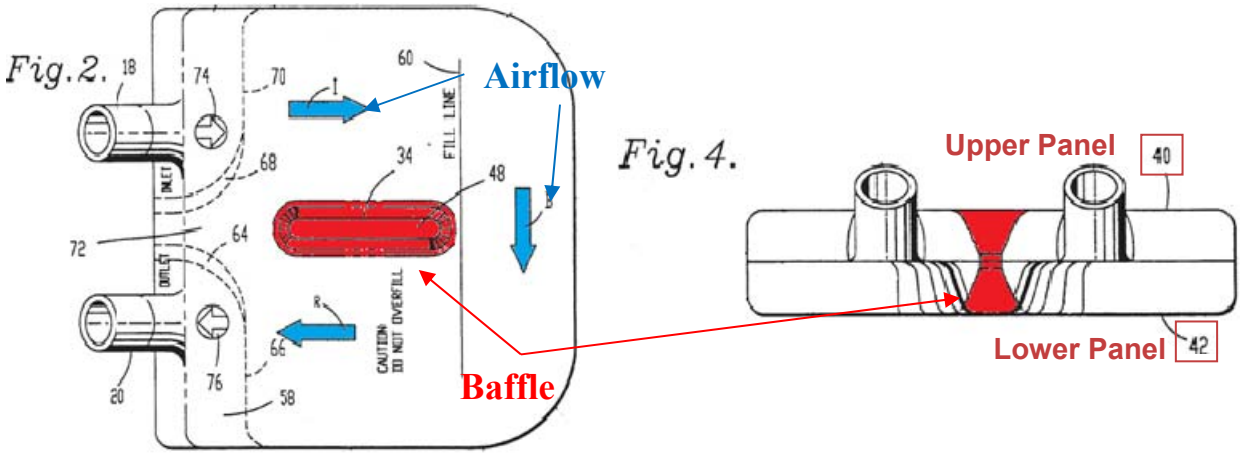


Id. at Fig. 1 (annotations added). The water chamber includes a heater base for

heating the water. *Id.* at 2:39-46. Smith does not describe an extension tube that extends from the air inlet into the water chamber.

E. Overview of Rose

49. U.S. Patent No. 5,231,979 ("Rose") describes a CPAP humidifier that has a baffle 34 located near the center of the chamber. The baffle is shown in Figures 2 and 4 of Rose (below).



Ex. 1008 at Figs. 2 and 4 (annotations and color added).

50. The baffle extends between an upper panel 40 and lower panel 42 of the chamber. *Id.* at 3:28-32, Figs. 2-3. Rose explains that the baffle promotes a U-shaped flow pattern. *Id.* at 4:22-30, Fig. 2 (showing U-shaped flow pattern). The baffle also provides support for the upper and lower panels 40 and 42, as shown, for example, in Figure 4 of the patent. *Id.* at 2:9-17.

F. Overview of Netzer

51. PCT Publication WO 98/04311 ("Netzer") describes a CPAP device designed to be used with or without a humidifier. Ex. 1010 at 2. When used with a humidifier, gas flows out of the CPAP device and into a water chamber 9 through inlet 22 where it is humidified. *Id.* at 9. The humidified gas then exits the chamber through outlet 23 and flows back into the CPAP device and to the patient through an outlet. *Id.* at 8-9. Figure 2 of Netzer is shown below.

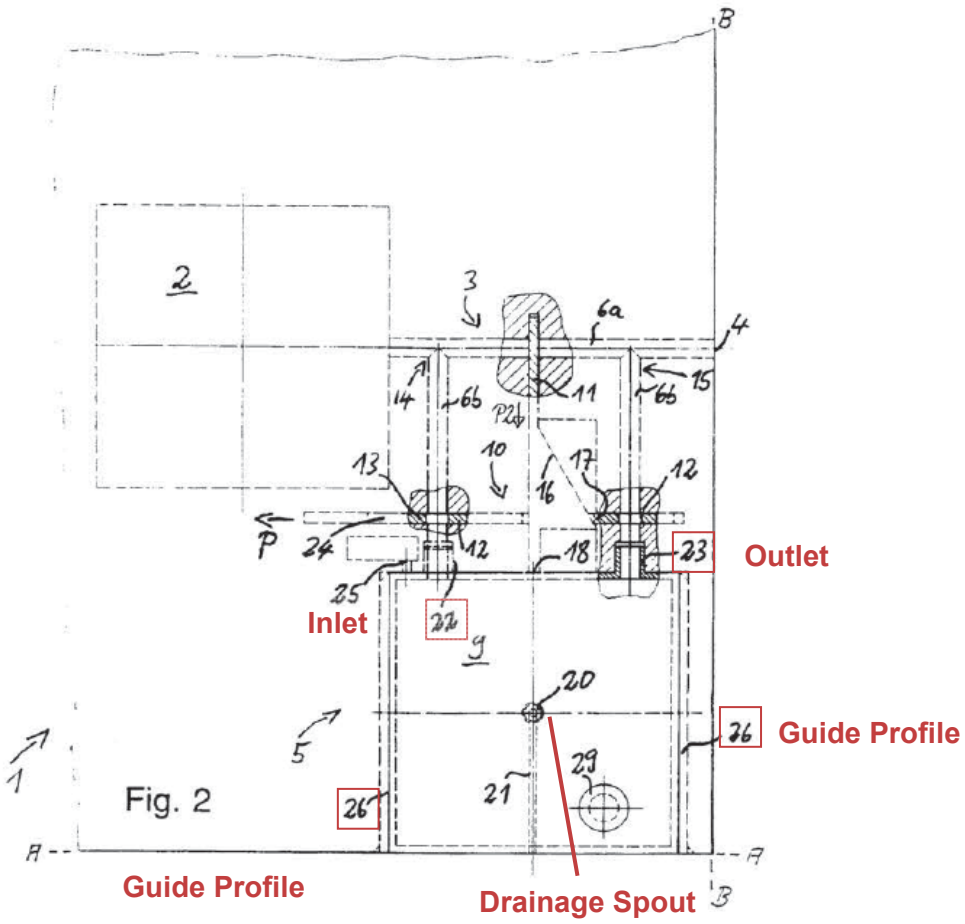


Fig. 2

Id. at Fig. 2 (annotations added).

52. As shown above in Figure 2, Netzer also describes a drainage spout 20 located in the water chamber. The drainage spout and associated discharge line are further shown in Figure 3 of Netzer below (annotations added).

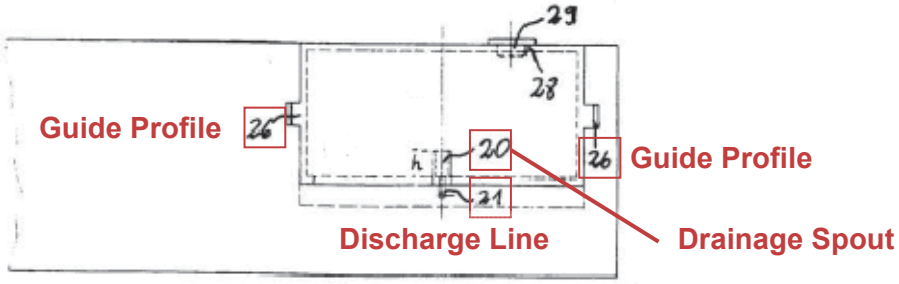


Fig. 3

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

VII. GROUND 1: CLAIM 1 WOULD NOT HAVE BEEN OBVIOUS OVER THE COMBINATION OF THE HC200 MANUAL AND HEBBLEWHITE

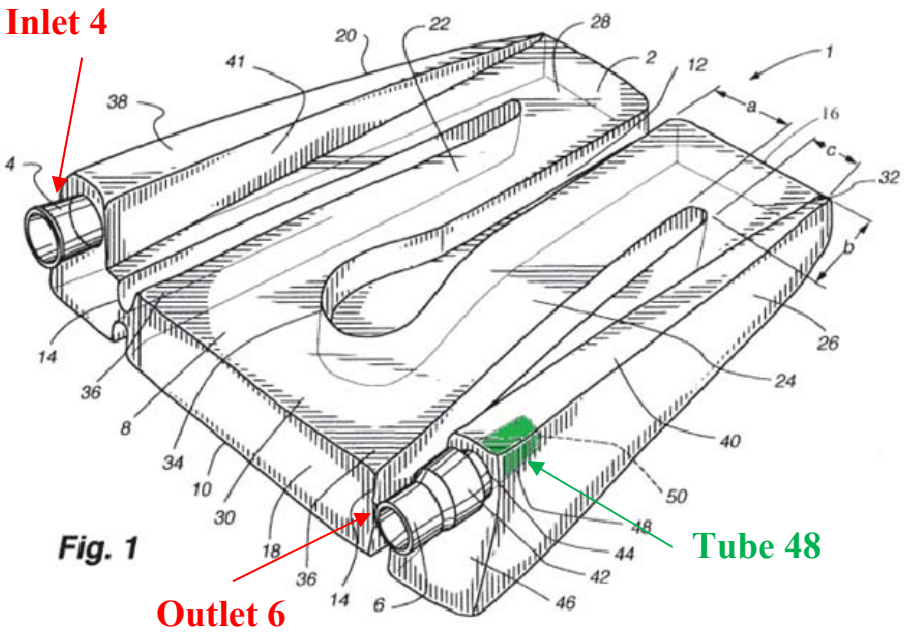
54. In Ground 1 of the Petition, Petitioners argue that Claim 1 of the '197 Patent would have been obvious over the combination of the HC200 Manual and Hebblewhite. I disagree.

55. Claim 1 of the '197 Patent states:

> In a water chamber adapted for use in conjunction with a heater base and having a horizontally oriented gases inlet in a wall thereof the improvement comprising an elongate flow tube extending into said water chamber from the inner periphery of said gases inlet, an inlet end of said elongate flow tube covering said inlet and an outlet end of said flow tube being spaced from the wall of said chamber, said flow tube in use receiving, at said inlet end, gases supplied to said gases inlet, said gases passing through said flow tube and exiting said flow tube at said outlet end distant from said wall.

56. It would not have been obvious to a skilled artisan at the time of the invention of the '197 Patent to modify the device shown in the HC200 Manual in view of Hebblewhite to include an elongate flow tube extending into the water chamber from the gases inlet for many reasons, as described below.

57. Neither the HC200 Manual nor Hebblewhite disclose a flow tube extending from the gas inlet of a water chamber. No tube extends from the inlet or outlet port of the chamber shown in the HC200 Manual. Ex. 1015 at 7. Hebblewhite discloses a short tube located at the outlet of the water chamber, as shown Figure 1 (below).



Ex. 1004 at Fig. 1 (annotations and color added), 4:63-5:8. Hebblewhite does not describe any tube that extends from the air inlet and into the water chamber.

58. The short outlet tube described in Hebblewhite is not an elongate flow tube as claimed in the '197 Patent. It is located at the outlet of the water chamber, instead of extending into the water chamber from the air inlet as claimed in the

'197 Patent. The tube of Hebblewhite receives air flowing out of the chamber, rather than into the chamber. *Id.* at 4:63-5:16. Hebblewhite contains no teachings about using a tube on the air inlet.

59. A skilled artisan would not have understood the outlet tube described in Hebblewhite to have any applicability to the air inlet of the water chamber. Hebblewhite describes that the short tube is located at the air outlet to address a specific problem resulting from the low-profile design of Hebblewhite's water chamber: spillage from wave action. Hebblewhite explains that one potential disadvantage of the low-profile humidifier design is the formation of waves that can splash through the outlet of the humidifier. *Id.* at 1:33-45, 3:34-40, 5:9-16. As explained above, this potential splashing problem is caused by waves that are created by air passing over the surface of the water. These waves may splash into the outlet as they strike the end wall of the humidifier. *Id.* at 3:34-40.

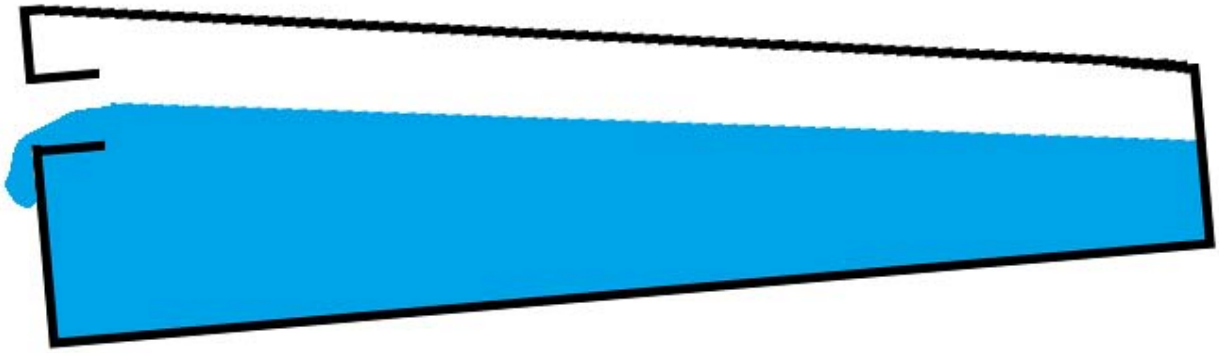
60. Hebblewhite solves this problem by including a tube at the air outlet. *See, e.g., id.* at Fig. 1. Only a short tube length is required to prevent water from splashing through the outlet because the splashing issue is localized at the end wall of the water chamber. Hebblewhite explains that a tube of at least 2 cm in length (less than one inch) is sufficient. *Id.* at 5:15-16 ("The aperture 50 should preferably be spaced at least 2 cm away from the end wall 46."). In contrast to an

air outlet, spillage due to wave action is not a problem at an air inlet because the waves are only created in the direction of the airflow (towards the outlet). Nothing in Hebblewhite suggests and a skilled artisan would not have understood that it would have been desirable to move or utilize the short outlet tube of Hebblewhite in conjunction with an air inlet.

61. A skilled artisan also would not have understood the outlet tube described in the Hebblewhite to have any applicability to the potential problem of spillage resulting from the water chamber being tipped and would not have combined the outlet tube of Hebblewhite with the water chamber shown in the HC200 Manual to address any potential problem of spillage due to tipping. This is because Hebblewhite does not teach that the outlet tube is useful to prevent the outflow of water if the humidifier is tipped; nor would the short outlet tube described in Hebblewhite be useful to prevent the outflow of water if the water chamber were tipped. Given the low-profile construction of the water chamber and the location of the short outlet tube 48 close to the water surface, the outlet tube would provide little, if any, protection against water spilling through the outlet if the device were tipped, even slightly. Figures A and B illustrate schematically the final elongated passageway of Hebblewhite when filled with water (Figure A) and show what would happen if the water chamber were slightly tipped (Figure B).

Figure A

Figure B



As these figures show, even slight tipping would cause water to spill out of the outlet tube.

62. Spillage from tipping was also not a major concern for the water chamber described in Hebblewhite and it would not have been obvious to utilize the outlet tube described in Hebblewhite to address any problems of spillage

resulting from tipping. Due to the low-profile construction of the water chamber, which has a wide base and is short in height, it would be difficult to tip the chamber. Also, the CPAP device is designed to be located on top of the low-profile water chamber and connected therewith through a tube extending from the inlet. *See* Ex. 1004 at 1:28-32, Fig. 1. Because the water chamber is located beneath the CPAP device, the likelihood that the water chamber will be tipped is further reduced due to the added weight of the CPAP device on top of the chamber. Also, if the CPAP device were tipped, the movement of the CPAP device is unlikely to be transferred to the water chamber, which in use would be attached to the CPAP device with a flexible hose. Also, any spillage of water into the air inlet of the water chamber, even if it were to occur, would be unlikely to reach the CPAP device or its blower because of its location on top of the humidifier chamber – *i.e.,* water would not spill upward and into the CPAP device.

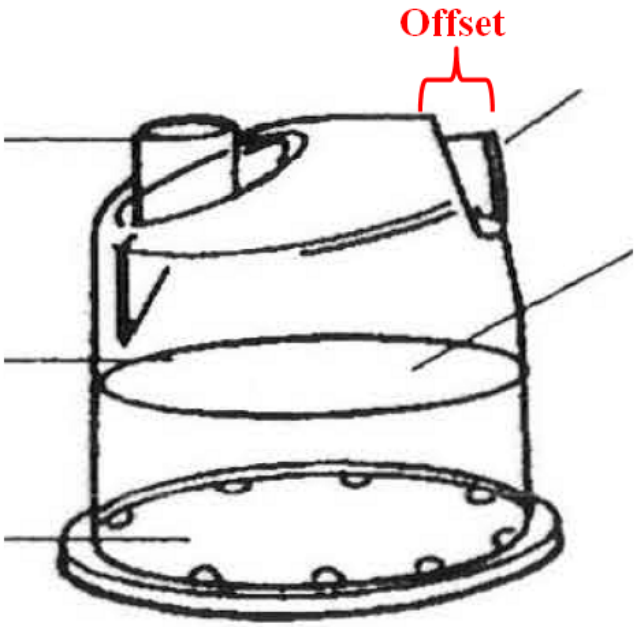
63. The water chamber shown in the HC200 Manual included features to reduce the likelihood of spillage from tipping the chamber. The HC200 Manual chamber is designed with an inlet and outlet located on an upper portion of the chamber and a "maximum water level" indicator at or below the vertical midpoint of the water chamber. Ex. 1015 at 7. Because the inlet is positioned well-above

the maximum fill line, water is unlikely to reach the inlet even if the device is tipped and the risk of spillage through the inlet is reduced.

64. The HC200 Manual water chamber was also designed to be removable from its base on the CPAP device for filling, cleaning, transporting, or emptying, while leaving the CPAP device in place. The HC200 Manual indicates that this removable water chamber can be slid into place on a base portion of the CPAP device. Ex. 1015 at 8. The HC200 Manual instructs users to "press down the spring-loaded Chamber Guard and slide the Humidification Chamber onto the Heater Plate," which results in the chamber being securely locked into place. *Id.* This slide-in feature reduces the likelihood that spillage that might occur while attaching the water chamber.

65. A skilled artisan would not have been motivated to incorporate the outlet tube of Hebblewhite, which is intended to prevent the potential problem of waves splashing through the air outlet, into the HC200 Manual water chamber. The water chamber shown in the HC200 Manual does not have a low-profile design and does not have the same potential problems with waves described in Hebblewhite. Unlike the water chamber design shown in Hebblewhite, air is not directed across the water surface from the air inlet to the air outlet and waves are not generated that travel toward the air outlet. The air outlet of the HC200 Manual

water chamber is located on the roof of the chamber and is spaced well-above the water fill level of the water chamber. Ex. 1015 at 7. The air inlet is also located well-above the water fill level. Due to the positioning of the air inlet and outlet, any waves that may possibly be formed in the water chamber could not splash through the outlet or inlet. Moreover, the inner portion of the air inlet in the HC200 Manual water chamber is already offset from the chamber sidewall, as illustrated below:



Id. (annotations added). The short tube described 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.

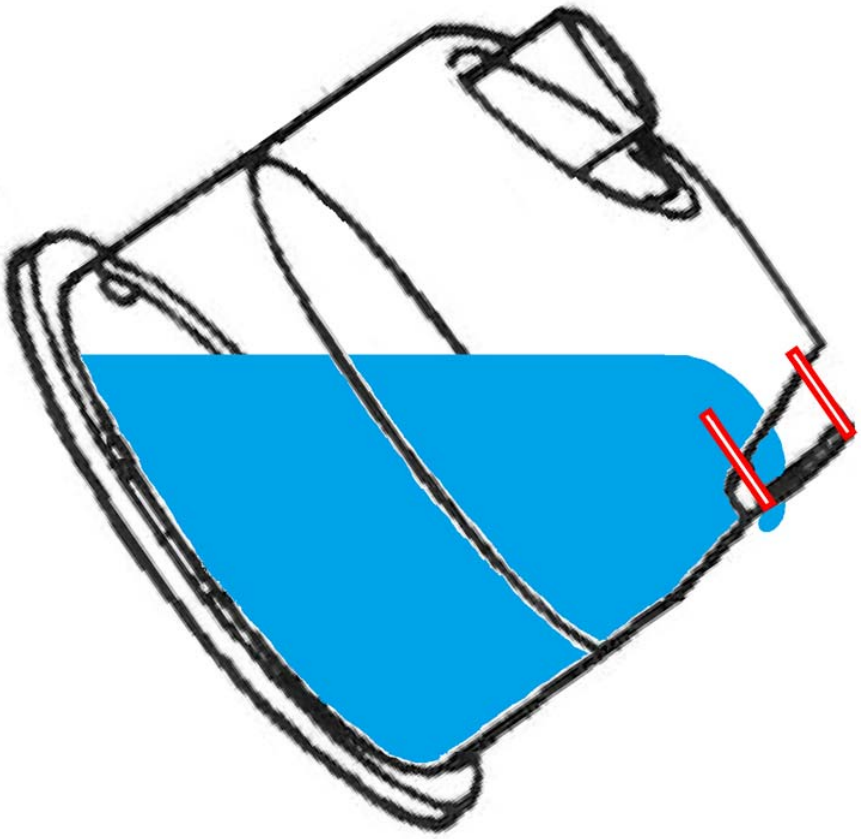
66. The water chamber in the HC200 Manual operates in a different way from the low-profile humidifier of Hebblewhite. Unlike the airflow in Hebblewhite's low-profile water chamber, air that enters the HC200 Manual water chamber is not directed along a specific path through the chamber and instead swirls throughout the water chamber along multiple paths over the heated water in order to become humidified. As noted above, Hebblewhite criticizes this humidifier design, in which airflow can take a number of different paths between the air inlet and outlet. 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. Thus, the HC200 Manual water chamber utilizes the airflow arrangement that Hebblewhite criticizes.

67. In addition, even if the short outlet tube of Hebblewhite was attached at the air inlet of the HC200 Manual water chamber, the resulting combination would provide minimal protection against spilling if the chamber were tipped. As

illustrated below, water would still spill out of the air inlet of the HC200 Manual water chamber, even if modified with the short outlet tube from Hebblewhite, if the water chamber were tipped.



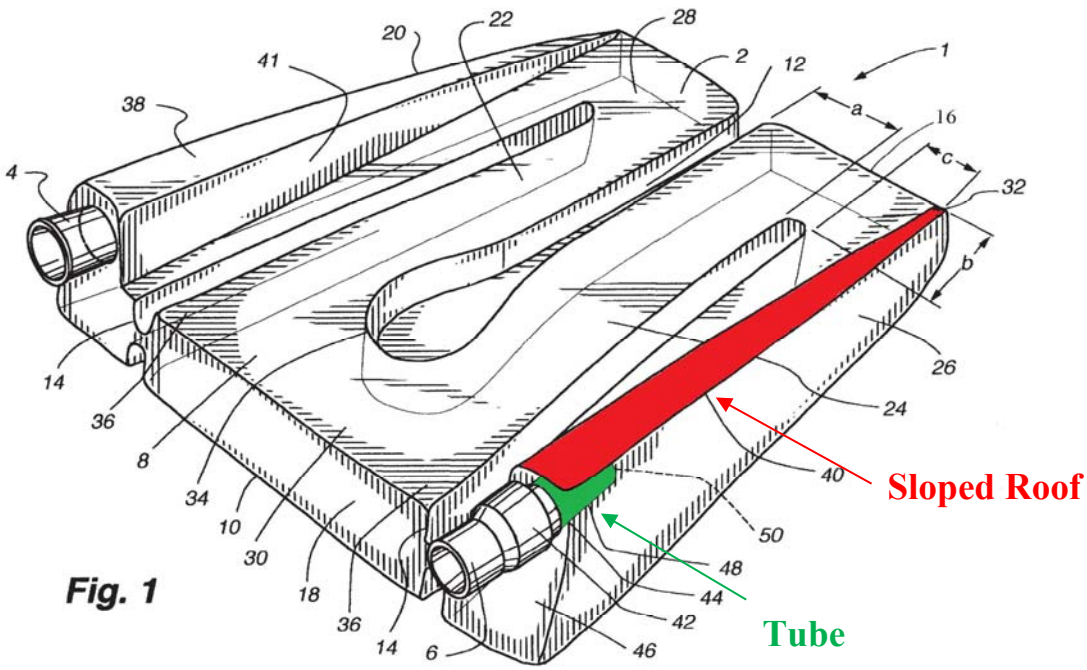
Ex. 1015 at 7 (modified to show short tube at air inlet). A skilled artisan would not have viewed the short outlet tube described in Hebblewhite as having applicability to preventing spillage when the water chamber is tipped and would not have been motivated to make this combination.

68. A skilled artisan also would not have incorporated the outlet tube of Hebblewhite into the HC200 Manual water chamber to address any potential problem from spillage through the air inlet due to tipping because splashing from waves (which is the issue the outlet tube of Hebblewhite is intended to address) is a substantially different problem than spillage due to tipping. The potential wave splashing problem described in Hebblewhite involves only a small amount water splashing upward from the end of wall of the water chamber and potentially entering the chamber outlet. The problem of spillage from tipping a humidifier involves a large amount of water being directed to the water chamber inlet opening and potentially pouring through the opening. The problems are thus not the same and require different solutions. For example, as explained above, the outlet tube described in Hebblewhite would be ineffective at preventing spillage caused by tipping the water chamber.

69. To prevent the wave splashing problem at the outlet, Hebblewhite's tube only needs to be of sufficient length to prevent waves that contact the end wall of the chamber from splashing upward and into the outlet opening. To be effective at spillage prevention from tipping, the short outlet tube of Hebblewhite would need to be extended by a significant length. To be effective at preventing spillage out of the air outlet when the chamber was tipped, the outlet tube of Hebblewhite

would need to extend approximately half the length of the final elongated passageway. For example, if the chamber were tipped toward the outlet opening, water would flow toward the outlet end of the water chamber and would reach the opening at the end of the outlet tube unless the tube extended approximately half of the length of the final passageway of the water chamber closest to the outlet opening.

70. It would not have been possible to extend the length of the outlet tube of Hebblewhite to a length that would provide meaningful protection against spillage through the chamber outlet if the water chamber was tipped. For this additional reason, a skilled artisan would not have understood the outlet tube of Hebblewhite to have any potential applicability to preventing spillage caused by tipping the water chamber. As shown below in Figure 1 of Hebblewhite, the final passage of the water chamber has a roof that slopes downward from the air outlet.



Ex. 1004 at Fig. 2 (color and annotations added); 3:21-23 ("Ideally, the roof of the last subpassageway rises gradually along substantially the whole length of the last subpassageway."). This sloped roof design prevents the outlet tube from extending much further into the chamber (and certainly not half the length of the final passage of the chamber) because the outlet tube would contact the roof if the length of the tube was extended.

71. Moreover, the disclosure of Hebblewhite does not suggest and would also have discouraged a skilled artisan from extending the length of the outlet tube. The amount of water vapor evaporated from a volume of water is related to the

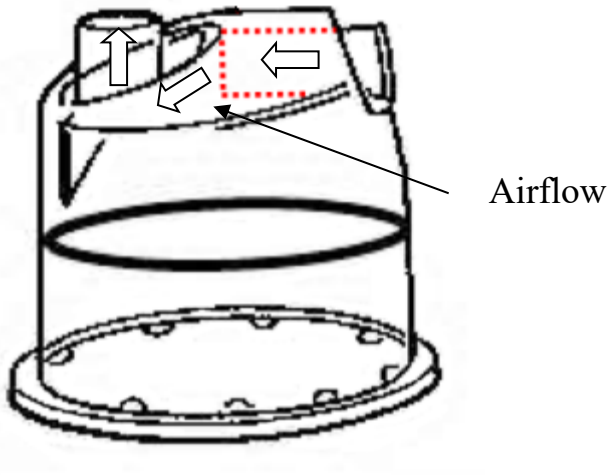
surface area of the water. The more surface area, the more evaporation. The humidifier chamber described in Hebblewhite is designed to maximize the surface area of the water that the air passes over between the inlet and the outlet to humidify the air. For example, Hebblewhite explains:

> 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.

Id. at 1:40-45. Extending the outlet tube further into the chamber would be contrary to this teaching. Extending the outlet tube would cause gas to exit the tube a further distance away from the end of the final passageway of the chamber without travelling over the entire surface of the water. Airflow over the surface of the water located beneath the tube would be diminished and this water would provide diminished humidification of the airflow. For these additional reasons, a skilled artisan would not have understood the outlet tube of Hebblewhite to have any applicability to the problem of spillage from tipping.

72. It also would not have been obvious to add an elongate tube to the inlet of the HC200 Manual water chamber in view of Hebblewhite because adding

the elongate tube to the HC200 Manual chamber would hamper humidification performance. Given the orientation of the inlet and outlet openings of the water chamber shown in the HC200 Manual, adding an elongate flow tube at the inlet would direct airflow from the flow tube to the outlet, as illustrated below from a modified drawing from the Petition.



HC200 Manual at 5
(modified to show interior tube)

Pet. at 27 (modified to show airflow). As a result, air circulation within the water chamber would be impeded and air humidification would thus be diminished.

73. Hebblewhite also does not teach or suggest that its outlet tube is useful for noise reduction. Hebblewhite does not describe any problems relating to noise. Also, the short tube located at the outlet of Hebblewhite's water chamber would not impart a more laminar flow pattern to air entering the water chamber

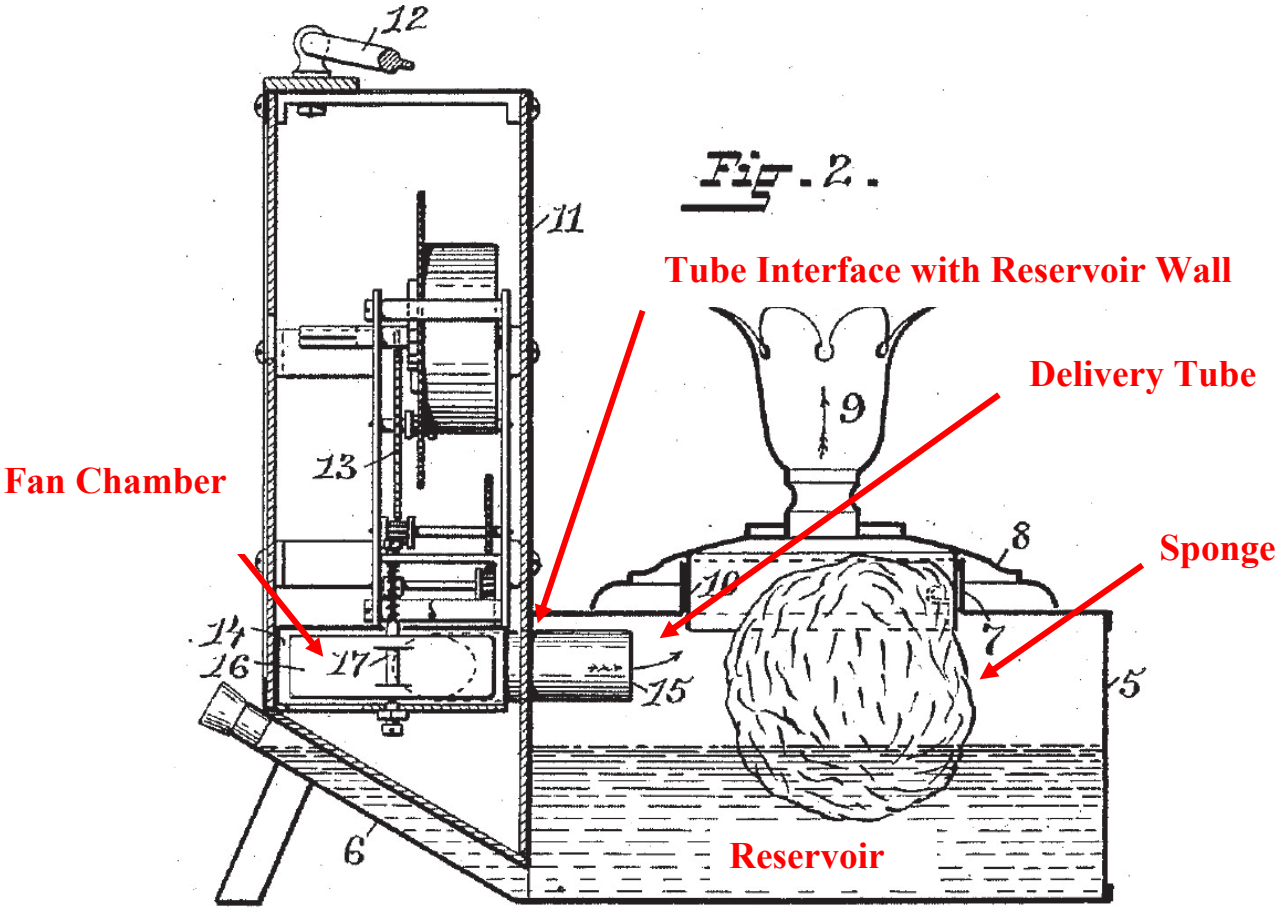
and would not provide a noise reduction benefit. Consequently, it would not have been obvious in view of Hebblewhite to add a tube at the inlet of the HC200 Manual water chamber to address any potential issues relating to noise and a skilled artisan would not have looked to Hebblewhite for this purpose.

74. Mr. Virr also points to the Sullivan HumidAire water chamber, U.S. Patent No. 485,127 ("Lynch") (Ex. 1017), and Gouget as allegedly supporting using an extension tube located at a humidifier chamber inlet. Ex. 1003 ¶ 78. However, a skilled artisan would not have combined the tube of Hebblewhite with the chamber of the HC200 Manual in view of any of these references.

75. The Sullivan HumidAire brochure appears to disclose a low-profile humidifier similar to Hebblewhite and including tubes external to the water chamber. However, Mr. Virr provides no reason why a skilled artisan viewing the HumidAire water chamber would have been motivated modify the water chamber of the HC200 Manual in view of the HumidAire brochure. A skilled artisan would not have been motivated to modify the inlet of the HC200 Manual chamber to include the outlet tube of Hebblewhite in view of the HumidAire brochure.

76. Lynch describes a vaporizer for disinfecting or perfuming a passing airflow, rather than a humidifier for humidifying air. Ex. 1017. The Patent Office expressly considered Lynch during prosecution of the '197 Patent and concluded

that all of the claims were patentable over Lynch. Ex. 1002 at 34, 38. Lynch illustrates a delivery pipe 15 that extends into a reservoir. Ex. 1017 at Fig. 2. The only function of the delivery pipe appears to be to direct air through an unspecified heating device and to deliver air into the reservoir.



Id. at Fig. 2, 34-38, 40-59. Lynch does not address any problems related to noise and does not discuss any problems relating to spillage. There is no indication in Lynch that the interface between the tube and reservoir wall is sealed such that it would prevent spillage into the fan chamber if the reservoir were somehow tipped.

Furthermore, even if the ventilator in Lynch was tipped towards the delivery pipe, it would be much too short to prevent spillage from the tipping. *See id.* at Fig. 2. Given these differences in purpose and function, a skilled artisan would not have had any motivation to modify the inlet of the HC200 Manual chamber to include the outlet tube of Hebblewhite in view of the delivery pipe of Lynch.

77. Lastly, Gouget (Ex. 1006) discloses a urinal and would not have been understood or looked to by a skilled artisan as containing teachings pertinent to a humidifier. As such, a skilled artisan would not have been motivated to combine the urinal described in Gouget, including the anti-backflow element 5 of the urinal, with either the HC200 Manual or Hebblewhite, as explained in more detail below in Ground 2.

VIII. GROUND 2: CLAIMS 2 AND 3 WOULD NOT HAVE BEEN OBVIOUS OVER THE COMBINATION OF THE HC200 MANUAL, HEBBLEWHITE, GOUGET AND ROSE

78. Claims 2 of the ’197 Patent depends from independent Claim 1. Claim 2 requires: “A water chamber as claimed in claim 1 wherein said flow tube extends for a distance of at least a quarter of the diameter of said water chamber.” Claim 3 depends from Claim 2. Claim 3 further requires: “A water chamber as claimed in claim 2 wherein said gases inlet and said flow tube are aligned radially and said flow tube extends to approximately the middle of said chamber.”

79. As explained above, it is my opinion that it would not have been obvious to modify the device shown in the HC200 Manual in view of Hebblewhite to include a flow tube extending from the air inlet of the HC200 Manual water chamber. It also would not have been obvious to further modify the water chamber in the HC200 Manual in view of Gouget and Rose.

80. I understand that, to be prior art, a reference must be analogous to the claimed invention. I understand that 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. I also understand that determining whether art is in the same field of endeavor requires analyzing the circumstances of the application – the full disclosure – and weighing 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. I understand that a prior art reference in a separate field of endeavor will not be analogous art unless it is pertinent to the problem being solved by the challenged patent. I understand that 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.

81. The field of invention of the '197 Patent is humidifiers, and particularly humidifiers for CPAP or similar devices that are configured with a water chamber for humidification of a gas flow as it passes through the chamber. The field of invention of the '197 Patent describes that the invention "relates to water chambers for gases humidification and in particular to water chambers for 'slide on' humidifiers and CPAP machines." Ex. 1001 at 1:6-8. The '197 Patent further describes details of a water chamber for use with a CPAP device. *See*, *e.g.*, *id.* at 2:12-16 ("Referring to FIGS. 1 and 2 a water chamber is illustrated particularly for use in a portable CPAP machine adapted to receive slide-on chambers and which makes the gases inlet connection to the chamber in the same slide-on motion."). Claim 1, the only independent claim in the patent, is also directed to "a water chamber adapted for use in conjunction with a heater base and having a horizontally oriented gases inlet" and further claims gases passing through a flow tube. Ex. 1001 at Claim 1.

82. Gouget, which describes a urinal receptacle, is not analogous art to the '197 Patent. A skilled artisan would not have looked at Gouget when seeking to design or solve a problem with a humidifier, including a humidifier for use with a CPAP device. Gouget is in a different field than the '197 Patent. The receptacle described in Gouget stores urine, while the inventions described in the '197 Patent

facilitate the humidification of an airflow using liquid water. Gouget lacks any design features that would facilitate the humidification of an airflow. Liquid, not air, flows into the mouth of the anti-backflow element of Gouget and into the chamber for storage. Ex. 1006 at 8:56-67. Air does not flow through the urinal described in Gouget in the manner air flows through a humidifier. The only airflow described in Gouget is air escaping from the chamber in Gouget through the liquid inlet (anti-backflow element) as the chamber fills with urine. *Id.* 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." *See id.*

83. Furthermore, the problems addressed in the '197 Patent pertained to reducing noise caused by air flowing into the humidifier chamber and preventing water from spilling out of the air inlet of the humidifier chamber if the chamber were tipped. A skilled artisan would not have found Gouget to be reasonably pertinent to either of those problems.

84. Gouget does not address any issues relating to noise. Gouget does not address airflow entering the urinal chamber or suggest any solutions to noise caused by airflow. Urine, not air, is designed to flow through the chamber inlet of

the urinal receptacle described in Gouget. Gouget also does not identify any issues with noise caused by urine entering the chamber.

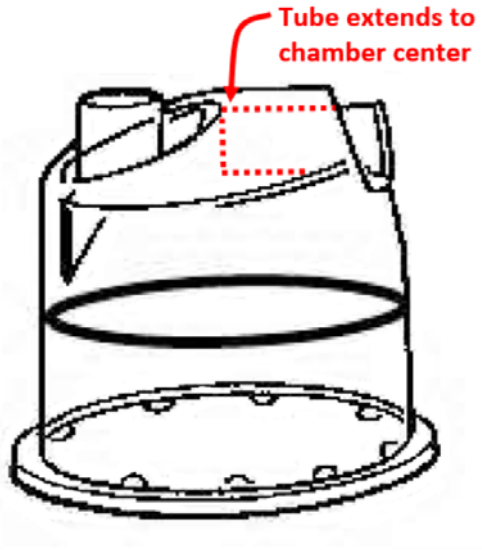
85. It would also be undesirable in a humidifier to pass air into or out of the humidifier chamber through a tapered inlet tube as shown in Gouget. A tapered tube as shown in Gouget at either an inlet or an outlet to a water chamber would restrict the airflow into or out of a humidifier chamber. As a result, the blower of a CPAP device would be required to operate at a higher speed to push air through the tapered tube and sustain the desired airflow through the chamber. This is undesirable because it would reduce the life of the blower, the blower would generate additional noise, and the CPAP device would limit pressure range performance or consume more energy and be more expensive to operate because of the associated pressure drop that would result from the tapered shape of the Gouget tube. Passing air into a humidifier chamber through a tapered tube as shown in Gouget would cause the air to accelerate as it passes through the tube would also create an undesirable whistling noise that is disruptive to the patient. The noise would be directed from the humidifier to the patient interface, such as a mask, through the attached hose. Any such noise is undesirable for patients being treated using CPAP because it can prevent the patient from falling asleep or potentially

wake the patient from sleep. For these additional reasons, a skilled artisan would not look to a tapered tube like shown in Gouget when designing a humidifier.

86. The portable urinal described in Gouget also would not have logically commended itself to an inventor trying to reduce spillage problems in a humidifier. As explained above, none of the design considerations that must be taken into account when designing a humidifier is present in Gouget. For example, Gouget does not take into account airflow patterns through the chamber, the effective humidification rate of the airflow, turbulence of the airflow, or wave action. To prevent spillage, Gouget teaches a device with the same opening for both entering liquid and for escaping air. Ex. 1006 at 8:56-67. This arrangement would not be suitable for a humidifier that requires both an air inlet and an air outlet. As such, Gouget's solution to preventing urine from spilling out of the container is not reasonably pertinent to a humidifier because it is incompatible with a humidifier design.

87. Even if Gouget were analogous prior art (which it is not), a skilled artisan would not combine the teachings of Gouget with Hebblewhite, the HC200 Manual or Rose to position a tube at the inlet of the HC200 Manual chamber to extend at least a quarter of the diameter of the water chamber as required by Claim 2 of the '197 Patent or extend to approximately the middle of the chamber as

required by Claim 3 of the '197 Patent. Adding a tube of such lengths at the air inlet of the HC200 Manual water chamber would direct air to the outlet opening. This is shown by Petitioners' modified figure from the HC200 Manual, in which the end of the tube added by the Petitioners to the HC200 Manual water chamber and the chamber outlet port are located in close proximity.



HC200 Manual at 5
(modified to show interior tube)

Pet. at 27. As a result, a large amount of air would travel directly from the inlet tube to the air outlet without circulating through the water chamber. Humidification performance would be diminished, which would be undesirable.

88. As explained above in Paragraph 85, utilizing a tapered tube as shown in Gouget at the air inlet of the HC200 Manual water chamber would also restrict airflow and cause the CPAP blower to operate at a higher speed to prevent a significant pressure drop between the inlet and the inside of the humidification

chamber. A higher blower speed would result in increased noise from the blower and also may result in a whistling noise as air passes through the tapered tube at a higher speed, both of which would be undesirable in a CPAP device. The tapered tube would also create a resistance that would limit the detection of a patient's respiratory pressure fluctuations, which are needed to determine the patient's breathing pattern while using CPAP. Moreover, an additional resistance between the blower and the patient's interface (nasal mask) would impair the algorithms for delivering constant pressures throughout the night, particularly in case of mask leaks or mouth breathing, both of which conditions are common when patients use CPAP. In addition, an increased resistance together with limitations in detecting breathing patterns of a patient make it particularly difficult to use Auto-CPAP algorithms which depend on an accurate assessment of breathing patterns and inspiratory flow contours of a patient on CPAP. Finally, it also would make it difficult to generate a compliance report, which reports abnormalities in breathing pattern (apneas and hypopneas), leakage and other parameters that are necessary to determine whether delivered CPAP is effective on a night by night basis. For all these additional reasons, a skilled artisan would not have combined the tapered tube of Gouget with the water chamber shown in the HC200 Manual.

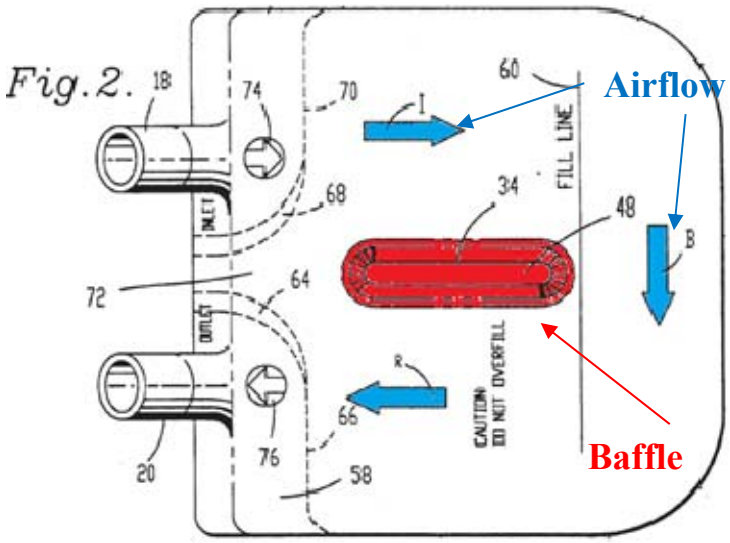
89. Moreover, it would not have been obvious to extend the length of the outlet tube described in Hebblewhite further into a humidifier chamber. The outlet tube described in Hebblewhite requires only a short length to function for its intended purpose of preventing splashing into the outlet from waves, as discussed above. The tube need only be of a sufficient length to prevent waves that splash against the end wall of the final humidifier passageway from splashing upward into the outlet opening. Hebblewhite also describes other features that minimize waves at the outlet. Hebblewhite describes widening the final bend in the elongate passageway and sloping the roof of the passageway upward toward the outlet to reduce air turbulence and minimize the formation of waves. Ex. 1004 at 2:64-3:23. Given these solutions, the potential problem of splashing from waves at the outlet would be reduced and only a short outlet tube would be needed to address any splashing that may occur. Indeed, Hebblewhite states that the opening of the tube should preferably be placed at least 2 cm away from the end wall 48, which illustrates the relatively short length of the tube. *Id.* at 5:15-16. Thus, Hebblewhite already includes features that make elongating the short outlet tube to address the problem of spillage from unnecessary.

90. Hebblewhite also does not teach that a longer outlet tube would be desirable. As described above in Paragraph 70, it is not possible to extend the

length of the outlet tube of Hebblewhite much further due to the sloped roof design of the humidifier. As also described above in Paragraph 71, Hebblewhite emphasizes the importance of maximizing the water surface area over which air travels within the humidifier chamber. Extending the length of the outlet tube would be inconsistent with that teaching.

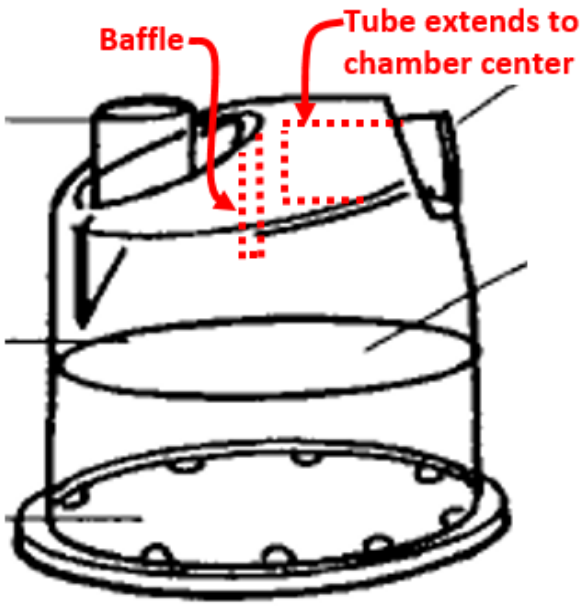
91. Mr. Virr asserts that a skilled artisan would have been motivated to fix the air circulation problem created by adding a tube at the air inlet of the HC200 Manual water chamber by further adding a baffle as disclosed by Rose. Ex. 1003 ¶¶ 86-87. I disagree.

92. In Rose, the baffle extends floor-to-ceiling between an upper and lower panel of the water chamber and creates a horizontal U-shaped path for the airflow that runs parallel to the airflow of the inlet and outlet, as shown in Figure 2 below.



Ex. 1008 at Fig. 2 (annotations and color added). Similar to the humidifier in Hebblewhite (Ex. 1004 at 1:42-45), the water chamber of Rose maximizes the absorption of water vapor into the airflow by ensuring that the airflow passes over the largest surface area of the water as practicable as it passes between the inlet and the outlet.

93. The baffle that Mr. Virr and Petitioners incorporate into the modified HC200 Manual water chamber is substantially different from the baffle described in Rose, and it would not have been obvious to incorporate such a baffle in view of Rose. The baffle added by Petitioners extends down from the ceiling perpendicular to the flow of air at the inlet and outlet and terminates in a free end as shown in the image below from the Petition.



HC200 Manual at 7
(modified to show tube and baffle)

Pet. at 28. Rose, however, does not teach the use of a downwardly extending baffle or the principle of placing a baffle directly between the inlet and outlet and perpendicular to the airflow to direct air downward and away from the outlet. The baffle in Rose creates a horizontal and elongate flow path over the surface of the water in the chamber, while the baffle added by Petitioners to the modified HC200 Manual water chamber obstructs the airflow from swiftly exiting through the outlet. Nothing in Rose suggests that the downwardly extending baffle added by Petitioners would adequately humidify the airflow. In view of the foregoing, a skilled artisan would not have made the modification proposed by Petitioners because it requires a different structure and creates a different airflow pattern than

any described in Rose. Mr. Virr further states that a skilled artisan would have "general knowledge . . . regarding baffles, as evidenced by the Rose reference." Ex. 1003 ¶ 86. However, Rose shows only a single type of baffle – a floor-to-ceiling baffle running parallel to the flow of gases.

IX. GROUND 3: CLAIM 6 WOULD NOT HAVE BEEN OBVIOUS OVER THE COMBINATION OF THE HC200 MANUAL, HEBBLEWHITE, AND SMITH

94. 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. Claim 6 states: "A water chamber as claimed in claim 1 wherein said water chamber comprises a transparent plastic shell open at the bottom and having a peripheral flange, a heat conductive plate enclosing said bottom of said shell and sealed at its periphery to said flange, and said elongate flow tube comprises a tubular extension tube member fitted at said gases inlet."

95. Ground 3 uses the same base combination as Ground 1, with the addition of Smith (Ex. 1009). Claim 6 would not have been obvious for all of the reasons provided above in connection with Ground 1. Smith also does not describe a tube extending into water chamber from the air inlet (or air outlet) or otherwise suggest that it would have been desirable to add such a tube.

X. GROUND 4: CLAIM 13 WOULD NOT HAVE BEEN OBVIOUS OVER THE COMBINATION OF THE HC200 MANUAL, HEBBLEWHITE, GOUGET, ROSE, AND SMITH

96. 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 states: "A water chamber as claimed in claim 3 wherein said water chamber comprises a transparent plastic shell open at the bottom and having a peripheral flange, a heat conductive plate enclosing said bottom of said shell and sealed at its periphery to said flange, and said elongate flow tube comprises a tubular extension tube member fitted at said gases inlet."

97. Ground 4 uses the same base combination as Grounds 1 and 2, with the addition of Smith. Claim 13 would not have been obvious for all of the reasons provided above in connection with Grounds 1 and 2. As noted above, Smith also does not describe a tube extending into its water chamber from the air inlet (or air outlet) or otherwise suggest that it would have been desirable to add such a tube.

XI. GROUND 5: CLAIMS 1 AND 6 WOULD NOT HAVE BEEN OBVIOUS OVER THE COMBINATION OF NETZER, HEBBLEWHITE, AND SMITH

98. Ground 5 asserts that the combination of Netzer, Hebblewhite, and Smith renders Claims 1 and 6 obvious. I do not believe that it would have been obvious to combine Netzer, Hebblewhite, and Smith to arrive at the invention of

Claims 1 and 6 for many of the same reasons provided above in connection with Ground 1 and for the additional reasons described below.

99. For all of the reasons previously provided in connection with Ground 1 (*see* Paragraphs 57-71), Hebblewhite does not teach or otherwise suggest repositioning the disclosed outlet tube to the air inlet of a water chamber or extending the length of the outlet tube to address a potential problem of spillage out of the outlet or inlet of the water chamber caused by tipping the chamber. For at least those reasons, Claims 1 and 6 also would not have been obvious over the combination of Hebblewhite, Netzer, and Smith. Further, Netzer and Smith do not teach or suggest the elongate flow tube as claimed in Claim 1 of the '197 Patent. Netzer and Smith do not disclose any tube extending from the air inlet (or outlet) of the water chamber and into the chamber.

100. A skilled artisan also would not have combined Netzer and Hebblewhite as proposed by Petitioners for other reasons. Hebblewhite does not teach or suggest that its outlet tube is useful for noise reduction, as explained above. Netzer likewise does not describe any potential problems with noise in the disclosed water chamber. Thus, a skilled artisan would not have looked to Hebblewhite to solve any noise problem in Netzer's water chamber and would not

have located a tube at the air inlet or outlet of the water chamber for the purpose of reducing noise.

101. As explained in Paragraphs 59-70 above, Hebblewhite also does not teach a general solution to the problem of spillage through the inlet or outlet of a water chamber. Hebblewhite instead teaches a solution to one specific problem, namely potential spillage caused by waves splashing at an outlet in a low-profile humidifier. Waves or spillage through the inlet or outlet openings of the water chamber would not have been a problem in Netzer.

102. Splashing from 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 of the chamber. Ex. 1010 at Fig. 4 and pp. 6-7 and 9 (explaining that the inlet and outlet openings are spaced above the maximum water level in the water chamber). As a result, any splashing caused by waves that may be generated by airflow through the water chamber would be unlikely to reach the outlet or inlet openings. Moreover, any waves would tend to dissipate in the water chamber shown in Netzer due to the open configuration of the chamber and significant splashing caused by waves would be unlikely to occur. Finally, the drainage system of Netzer (described in more detail below) would dissipate any waves because the waves passing over drainage system would drain out of the chamber.

In light of these differences in function between Hebblewhite and Netzer, a skilled artisan would have no reason to incorporate Hebblewhite's outlet tube in Netzer's water chamber.

103. Netzer also does not describe any potential problem from spillage through the inlet or outlet that may result if the water chamber is tipped. Spillage due to the tipping also would not have been a problem in Netzer's water chamber for the reasons provided below. Thus, it would not have been obvious to add extension tubes to the inlet or outlet of Netzer's water chamber to address any such spillage problem.

104. Netzer includes a drainage system that would help prevent water from spilling through the inlet or outlet of the water chamber. 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 lines.

Ex. 1010 at 6-7. The drainage system in Netzer prevents overfilling and ensures that the water level is located a set distance beneath the inlet and outlet openings. Because the water chamber cannot be overfilled, spillage from tipping (or from

waves) is substantially mitigated because the water level is maintained a sufficient distance beneath the inlet and outlet openings of the water chamber. If the chamber were tipped, water also could pour out of the drain instead of pouring out of the inlet or outlet opening.

105. The device described in 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.* 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 tilting once connected to the base, thereby also preventing spillage resulting from tipping.

106. In view of the features already present in Netzer that would prevent spillage, a skilled artisan would have seen no reason to modify Netzer's water chamber to include extension tubes at the gas inlet and outlet. Doing so would simply increase the cost and complexity of the device without any countervailing benefits.

107. Even if a short outlet tube as described in Hebblewhite were added to the air inlet (or air outlet) in Netzer, it would not provide meaningful protection against spillage from tipping the reservoir during use and a skilled artisan would not combined the teachings of Hebblewhite and Netzer. A short tube would space

the inlet or outlet openings only a short distance into the water chamber. If the water chamber was somehow tipped and water did not drain through the drainage system described in Netzer, water could spill through the tubes and out of the chamber.

108. To provide meaningful protection against spillage from tipping (in the event water did not exit through Netzer's drainage system if the water chamber was tipped), extension tubes would need to extend from the inlet and outlet openings to near the center of the water chamber. However, as described above in Paragraphs 70-71, Hebblewhite does not teach or suggest extending the length of the disclosed outlet tube. Thus, a skilled artisan would not have been motivated in view of Hebblewhite to modify Netzer's water chamber to include tubes at the inlet and outlet of the water chamber and also significantly extend the length of the tubes.

109. It also would not have been obvious to add extension tubes to the inlet and outlet of Netzer's water chamber as proposed by Petitioners because doing so would impair the functionality of the device. As described in more detail above in Paragraphs 70-71 adding the extension tubes would degrade humidification performance because air would not travel fully over the surface of the water located beneath the two extension tubes. As such a skilled artisan 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.

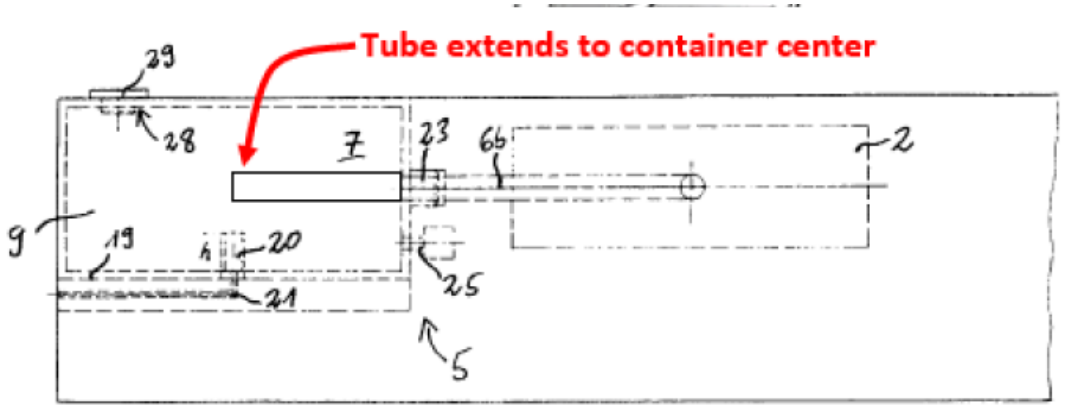
XII. GROUND 6: CLAIMS 2, 3, AND 13 WOULD NOT HAVE BEEN OBVIOUS OVER THE COMBINATION OF NETZER, HEBBLEWHITE, SMITH, GOUGET, AND ROSE

110. Ground 6 uses the same base combination as Ground 5 (Netzer, Smith, and Hebblewhite) and also adds Gouget and Rose. It would not have been obvious to combine these references to arrive at the inventions of Claims 2, 3, and 13 for many of the same reasons provided above in connection with Grounds 2 and 5, and for the additional reasons described below.

111. For the reasons provided above in Paragraphs 98-109 it would not have been obvious in view of Netzer and Hebblewhite to add extension tubes to the inlet or outlet of Netzer's water chamber, let alone an extension tube having the lengths required by Claims 2 and 3 (and Claim 13, which depends from Claim 3).

112. As explained above in Paragraphs 81-87, Gouget is not analogous art to the '197 Patent. In addition, a skilled artisan would not have combined the teachings of Gouget and Hebblewhite to position an elongated tube at the inlet (or outlet) of a humidifier chamber, such as Netzer's water chamber, for the reasons provided above in Paragraphs 88-94.

113. It also would not have been obvious to add extension tubes to the inlet and outlet of Netzer's water chamber as proposed by Petitioners because doing so would impair the functionality of the device. Mr. Virr contends that "a skilled artisan would have been prompted to design the tubes that are attached to inlet 22 and outlet 23 to extend to the midpoint of the reservoir 7." Ex. 1003 ¶ 114. Petitioners include the following modified illustration from Netzer.



Netzer at Figure 4 (modified to show interior tube)

Pet. at 47. As a motivation for the 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' (RMD1010 at 6-7), either due to waves caused by airflow or waves caused by tipping." Pet. at 47-48; Ex. 1003 ¶¶ 113-114.

114. A skilled artisan would not have been motivated to add the short outlet tube described in Hebblewhite to the inlet and outlet openings of Netzer's

water chamber and extend the tubes to "near the volumetric center" of the chamber because doing so would degrade humidification performance. By extending both of the tubes in Netzer to the center of the chamber as proposed by Petitioners, air circulation within the chamber would be diminished. Airflow over the water surface, particularly in the corners of the chamber next to the inlet and outlet, would be reduced. The resulting dead air space would contribute very little to the humidification of the passing airflow, thereby significantly limiting the efficiency of the humidifier in Netzer. As a result, humidification performance would be negatively impacted.

115. Indeed, Petitioners appear to recognize this problem because they further propose adding a baffle to the modified water chamber to improve air circulation. Ex. 1003 ¶ 115. However, a central baffle located between the inlet and outlet tubes Petitioners propose adding would do little to promote the flow of air over the water located along the length of the extended tubes and improve humidification performance.

XIII. CONCLUSION

116. For these reasons, it is my opinion that the Challenged Claims of the '197 Patent would not have been obvious to a person of ordinary skill in the art.

117. I declare that all statements made herein of my own knowledge are true and further that all 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.

Executed on June 15, 2017 at Baltimore, Maryland.

Dr. Hartmut Schneider