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

Patent 6,398,197

DECLARATION OF ALEXANDER VIRR

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

I. ASSIGNMENT

1. I have been retained on behalf of ResMed Inc., ResMed Corp., and ResMed Limited ("ResMed"). I understand that ResMed is requesting that the Patent Trial and Appeal Board ("PTAB" or "Board") institute an *inter partes* review ("IPR") proceeding of Fisher & Paykel Healthcare Limited's ("Patent Owners") U.S. Patent No. 6,398,197 ("the '197 patent") (RMD1001).

2. I have been asked to opine on the subject of the validity of certain claims of the '197 patent in light of the Grounds of rejection at issue in ResMed's *inter partes* review Petition.

3. My findings, as explained below, are based on my study, experience, and background in the fields discussed below, informed by my education in Mechanical Engineering, and my extensive experience in the field of medical devices and respiratory therapy. I have also relied on my review and analysis of the prior art, information provided to me in connection with this case, and information I have independently reviewed.

4. I am being compensated for my work as an expert with respect to the aforementioned *inter partes* review Petitions, but my compensation is not contingent in any way on the content of my opinions or the outcome of this proceeding.

II. QUALIFICATIONS

5. I received my Bachelor of Arts degrees in History and Political Science from the Australian National University in 1987. I also received a Bachelor of Mechanical Engineering degree from New South Wales University in 1993.

6. From approximately April 1996 to November 2009, I was employed by ResMed Limited in Sydney, Australia. During my time at ResMed, I held positions as Senior Engineer, Mechanical Engineering Manager, and Engineering Section Leader.

7. I am no longer an employee of ResMed. I am now employed as Chief Technology Officer at PAFtec, where we develop and manufacture respirators for dusty and otherwise inhospitable environments. I also own my own consulting firm, Virtex Innovation.

8. I began my career at ResMed as a Senior Engineer in the Technology Development Group. The Technology Development Group was a specialized engineering department within ResMed that focused on advanced research and development projects. My work in the Technology Development Group focused on the development of various aspects of flow generator products. Generally, flow generators are machines that produce a pressurized flow of breathable gas. The pressurized gas flow can be delivered to a patient for the treatment of various

ailments. For example, much of my work at ResMed related to Continuous Positive Airway Pressure ("CPAP") machines, which were flow generators designed for the treatment of sleep apnea. Within the Technology Development Group, I worked on fans for flow generator products, and also worked on a new type of flow meter that ResMed would eventually incorporate into its products.

9. Around the year 2000, I transitioned from the Technology Development Group to working on a product team that was focused on the development of a new CPAP platform. That CPAP platform would later be released around late 2001 as ResMed's S7 product line. The S7 line was released as several different products with slightly different configurations, although the core structure of the products was largely the same (particularly with respect to the humidifiers and connecting structures). For example, some higher-end models included software algorithms in the flow generators for automatically adjusting the flow of pressurized air based on feedback received from the patient. Other models did not include this feature.

10. My specific role in the development of the S7 platform was leading the design and engineering effort of the humidifier. This humidifier was marketed as the H2i humidifier. In my later years at ResMed, I would also lead or be heavily involved in the development of subsequent generations of humidifier products,

including the H3i humidifier, the H4i humidifier, and the H5i humidifier and climate control system.

III. LEGAL STANDARDS

11. In preparing my analysis, I have applied the legal standards described below, which were provided to me by counsel for the Petitioners.

12. It is my understanding that assessing the validity of a U.S. patent based on a prior art analysis requires two essential steps. First, one must construe the terms of the patent claims to understand what meaning one of ordinary skill in the art would have given the terms as of the effective priority date(s) of the claims. Second, after the claim terms have been construed, one may then assess validity by comparing a patent clam to the "prior art." For the purpose of my independent analysis herein, I have assumed that each of the references applied in the Grounds of the '197 Petition constitutes prior art.

13. I understand that the '197 patent has not expired. As such, I have been informed that the "broadest reasonable interpretation" standard of construction applies in these proceedings. Under this standard, claims are to be interpreted according to their broadest reasonable construction in light of the specification as it would be interpreted by one of ordinary skill in the art as of the time of the respective claims of the '197 patent. I understand that under the broadest reasonable interpretation, words of the claim are given their plain

meaning, unless such meaning is inconsistent with the specification. The plain meaning of a term means the ordinary and customary meaning given to the term by those of ordinary skill in the art at the time of the invention. I have been informed that the broadest reasonable interpretation standard that applies in *inter partes* review proceedings involving unexpired patents is different than the standard applied by courts and in some other forums in which issued patents are litigated.

14. I understand that the teaching of the prior art is viewed through the eyes of a person of ordinary skill in the art at the time the invention was made. To assess the level of ordinary skill in the art, I understand that one can consider the types of problems encountered in the art, the prior solutions to those problems found in prior art references, the rapidity with which innovations are made, the sophistication of the technology, and the level of education of active workers in the field. My opinion as to what constitutes a relevant person of ordinary skill in the art is set forth further below.

A. *Anticipation*

15. I understand that, for a claim to be anticipated by a prior art reference, the reference must disclose each element of the claim in the manner that the elements are arranged according to the language of the claim. When a claim element is not expressly disclosed by a prior art reference, the reference may still anticipate a claim if the element is inherently disclosed. I understand that an

inherent disclosure requires that the missing descriptive matter from a reference necessarily be present in the thing described in the reference.

B. ***Obviousness***

16. I understand that a patent claim is invalid as obvious if the subject matter "as a whole" of the claimed invention would have been obvious to a person of ordinary skill in the field at the time the invention was made. In determining the differences between a prior art reference (or a proposed combination of prior art references) and the claims, the question of obviousness is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious.

17. I understand that a patent claim composed of several elements is not proved obvious merely by demonstrating that each of its elements was independently known in the prior art. In evaluating whether any claim of the '197 patent would have been obvious, I have further considered and set forth articulated reasons that would have prompted a person of ordinary skill in the field to combine the elements or concepts from the prior art in the same way as in the claimed invention.

18. I understand that there is no single way to define the line between true inventiveness on one hand (which is patentable) and the application of common sense and ordinary skill to solve a problem on the other hand (which is not

patentable). For example, market forces or other design incentives may be what produced a change, rather than true inventiveness. It is my understanding that the decision-maker may consider whether the change was merely the predictable result of using prior art elements according to their known functions, or whether it was the result of true inventiveness. And, the decision-maker may also consider whether there is some teaching or suggestion in the prior art to make the modification or combination of elements recited in the claim at issue. Also, the decision-maker may consider whether the innovation applies a known technique that had been used to improve a similar device or method in a similar way. The decision-maker may also consider whether the claimed invention would have been obvious to try, meaning that the claimed innovation was one of a relatively small number of possible approaches to the problem with a reasonable expectation of success by those skilled in the art. I understand that the decision-maker must be careful not to determine obviousness using the benefit of hindsight, and that the decision-maker should consider obviousness from the position of a person of ordinary skill in the relevant field at the time the claimed invention was made.

19. I understand that in order to determine whether a patent claim is obvious, one is to make certain factual findings regarding the claimed invention and the prior art. Specifically, I understand that the following factors are to be evaluated to determine whether a claim is obvious: (1) the scope and content of the

prior art; (2) the difference or differences, if any, between the claim of the patent and the prior art; (3) the level of ordinary skill in the art at the time the claimed invention was made; and (4) the objective indicia of non-obviousness, also known as "secondary considerations."

20. I understand that the secondary considerations include:

(a) commercial success of a product due to the merits of the claimed invention;

(b) a long felt need for the solution provided by the claimed invention;

(c) unsuccessful attempts by others to find the solution provided by the claimed invention;

(d) copying of the claimed invention by others;

(e) unexpected and superior results from the claimed invention;

(f) acceptance by others of the claimed invention as shown by praise from others in the field or from the licensing of the claimed invention;

(g) teaching away from the conventional wisdom in the art at the time of the invention;

(h) independent invention of the claimed invention by others before or at about the same time as the named inventor thought of it; and

(i) other evidence tending to show obviousness.

21. I have been informed that, in order to establish a secondary consideration, the evidence must demonstrate a nexus between that secondary consideration and the claimed invention.

IV. PERSON OF ORDINARY SKILL IN THE ART

22. 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 at least five years of relevant product design experience in the field of medical devices or respiratory therapy, or an equivalent advanced education. 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.

V. MATERIALS CONSIDERED

23. In preparing this declaration, I have considered the claims, specifications, and prosecution histories of the '197 patent. I have also read and considered ResMed's Petition for *inter partes* review of this patent, the various documents referenced in my declaration, and additional background materials. Among the materials that I have reviewed in preparing this declaration are:

- **RMD1001:** U.S. Patent No. 6,398,197 to Dickinson et al. ("the '197 patent")

- **RMD1002:** Relevant portions of the file history of the ’197 patent
- **RMD1004:** U.S. Patent No. 6,135,432 to Hebblewhite et al. (“Hebblewhite”)
- **RMD1005:** File history of Hebblewhite and parent application
- **RMD1006:** U.S. Patent No. 6,953,763 to Gouget (“Gouget”)
- **RMD1007:** File History of Gouget parent app. no. 08/737,879
- **RMD1008:** U.S. Patent No. 5,231,979 to Rose et al. (“Rose”)
- **RMD1009:** U.S. Patent No. 5,588,423 to Smith (“Smith”)
- **RMD1010:** PCT Pub. WO 98/04311 to Netzer and a certified translation thereof (“Netzer”)
- **RMD1011:** File history of US Pat. No. 6,006,748 to Hollis
- **RMD1012:** Fisher & Paykel Healthcare, “HC200 Series Humidified CPAP System” Instruction Sheet, (Rev. B)
- **RMD1015:** Fisher & Paykel Healthcare, “HC200 Series Nasal CPAP Blower & Heated Humidifier User’s Manual,” (Rev. A)
- **RMD1017:** U.S. Patent No. 485,127 to Lynch (“Lynch”)
- **RMD1018:** U.S. Patent No. 933,301 to Hartmann (“Hartmann”)
- **RMD1019:** U.S. Patent No. 1,813,959 to Romanoff (“Romanoff”)
- **RMD1020:** ResMed, “Sullivan HumidAire” brochure (1997)

VI. SUMMARY OF THE '197 PATENT

24. I have reviewed the specification, claims, and file histories of the '197 patent. The '197 patent relates to devices used in the delivery of humidified gases to a patient, including humidifier arrangements for continuous positive airway pressure ("CPAP") devices, respiratory support devices, and mechanical ventilation devices. RMD1001 at 1:5-8; 1:17-20. As background, CPAP therapy delivers pressurized air to a patient's airway to help keep the patient's airway open. The idea of using CPAP therapy to treat obstructive sleep apnea (OSA) was invented thirty-five years ago in June 1980 by Dr. Colin Sullivan, whose early inventions formed the basis of Petitioners' business. As was well-known, a CPAP system has three main parts: a mask that delivers pressurized air to the mouth and/or nose; a tube that connects the mask to a motor; and a housing with a motor (typically referred to as a flow generator) that blows air into the tube. RMD1001 at 1:13-24. Optionally, a humidifier may be used with the flow generator to humidify the air before it is blown into the hose and delivered to the patient via the mask.

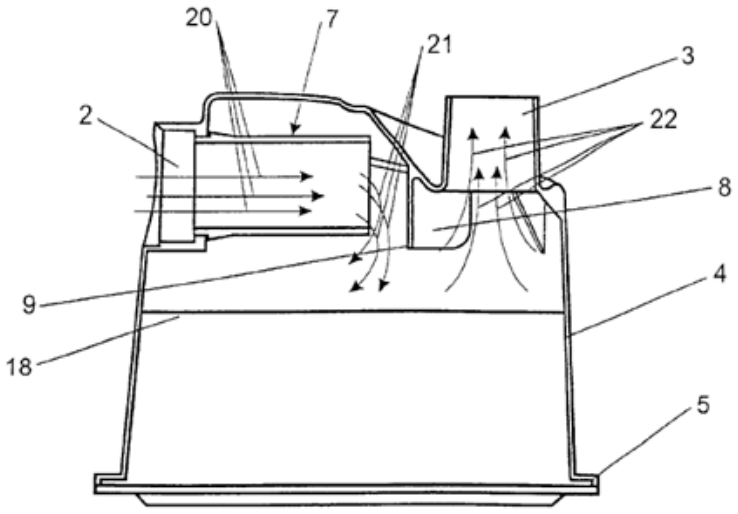
25. The '197 patent focuses on features of a water chamber for "slide-on" humidifiers and CPAP machines. *Id.* at 1:6-8. The '197 patent describes that it was well known for CPAP machines with "slide-on humidifier chambers" to have the humidifier chamber "fitted onto the heater base." *Id.* at 1:10-29. Such known

systems allow the humidification chamber to be connected to the CPAP machine with a "single sliding movement," such that the "inlet air port is consequently provided horizontally through a side of the chamber." *Id.* at 1:24-34. As further background, the '197 patent describes that an inlet port on the side of a chamber "significantly increases the likelihood of water spillage from the chamber if the chamber is tilted with water therein," and in such a scenario "water may flow out through the inlet port and into the air blower of the CPAP machine." *Id.* at 1:29-34.

26. The '197 patent's alleged improvement over the prior art appears to be the addition of an "elongate flow tube extending into said water chamber from the inner periphery of the gases inlet" of the chamber. *Id.* at 1:44-46. The '197 patent explains, with reference to FIG. 6, that "the inlet extension tube 7 acts as a weir against water flow back through gases inlet 2 upon tilting of the chamber 1." *Id.* at 2:59-61. The '197 patent further explains how "[i]n the most preferred embodiment the chamber further includes a curved downwardly extending baffle 8 located between the gases outlet 3 and the termination of the inlet extension tube 7 to ensure against gases short circuiting the chamber by flowing directly from the extension 7 to the outlet 3." *Id.* at 2:29-34. The '197 patent suggests that "[b]y providing the inlet extension tube 7 and therefore imparting an improved flow pattern to the inlet flow, it has been found that the noise level of the humidifier

chamber has been significantly reduced, and, in conjunction with the curved baffle 8, effective operation of the water chamber 1 has been maintained. Additionally, with reference to FIG. 6, the inlet extension tube 7 acts as a weir against water flow back through gases inlet 2 upon tilting of the chamber 1." *Id.* at 2:54-61.

27. Figure 2 of the '197 patent depicts the chamber. This chamber has a "transparent plastic shell 4 and a heat conductive base 6" (base 6 identified in Figure 3) that are "connected at a peripheral flange 5 which also serves as a securing flange in the slide-on connection with the CPAP machine." *Id.* at 2:15-20. The '197 patent further describes an "inlet extending tube 7 extending inwardly into the chamber interior from the periphery of the gases inlet 2," and a "curved downwardly extending baffle 8 located between the gases outlet 3 and the termination of the inlet extension tube 7 to ensure against gases short circuiting the chamber by flowing directly from the extension 7 to the outlet 3." *Id.* at 2:26-34.



'197 Patent at Figure 2

VII. PROSECUTION HISTORY

A. *The '197 Patent*

28. On May 10, 1999, the application that matured into the '197 patent began as a provisional patent application that was filed in New Zealand. RMD1002 at 16-23. The New Zealand application did not include any claims. *Id.*

29. On May 4, 2000, Applicant filed an application in the United States that claimed priority to the New Zealand provisional patent application. RMD1002 at 1-15. The US Application added the claims. *Id.*

30. On July 10, 2001, the United States Patent and Trademark Office (the "Office") mailed an office action. RMD1002 at 24-30. The office action rejected claims 1 and 2 as unpatentable over Lynch (RMD1017). Claims 1, 2, and 4 were alternatively rejected as anticipated by Romanoff (RMD1019). Claim 3 was rejected as being unpatentable over Lynch in view of Hartmann (RMD1018), and was alternatively rejected over Romanoff in view of Hartmann. (RMD1002 at 24-30.) Lynch is a patent that describes "mechanical air-purifying devices." (RMD1017 at 1:11-12.) In Lynch's device, "the air is drawn in through the inlet of the fan-chamber and forced through the reservoir, where it comes in contact with the disinfectant or other contents thereof, being finally driven through the perforation in the reservoir-cover and the hollow ornament into the room to be ventilated or disinfected." (RMD1017 at 2:20-67.)

31. On January 8, 2002, Applicant submitted its response. The response did not dispute that Lynch's tube 15 discloses claim 1's "improvement comprising an elongate flow tube extending into said water chamber from the inner periphery of said gases inlet." Rather, Applicant simply argued that Lynch describes a reservoir that holds "disinfectants in solid or liquid form" and therefore does not disclose the "water chamber" of claim 1. (RMD1002 at 34.) Applicant also argued that Lynch does not provide "any suggestion of heating the reservoir." (RMD1002 at 34.) Regarding Romanoff, Applicant argued that the inlet pipe did not enter the water chamber in the recited manner. (RMD1002 at 33.) Regarding the rejections of dependent claim 3, Applicant argued that "adopting a pipe structure similar to that in Hartmann in either Romanoff or Lynch would leave the gases exit from an inlet pipe in the immediate vicinity of the gases exit form [sic] the relevant reservoir or chamber providing only limited opportunity for contact with either the water in Romanoff or the cleansing materials of Lynch." (RMD1002 at 36.)

32. On February 28, 2002, the Office issued a Notice of Allowance that identified no reasons for allowance. (RMD1002 at 37-39.)

VIII. CLAIM INTERPRETATION

33. I understand that the broadest reasonable interpretation should be applied to the claim terms of the '197 patent.

IX. DISCUSSION OF PROPOSED GROUNDS OF UNPATENTABILITY

A. *Teachings of the Prior Art*

1. Admitted Prior Art

34. The background section of the '197 patent admits that prior art humidifier devices included most of the features of the devices described and claimed in the patents. For example, the Summary of the Prior Art section explains that that humidified gases delivery treatments that use a "heater base" and "slide-on humidifier chambers" in which the "inlet air port is consequently provided horizontally through a side of the chamber" were well-known in the art:

> *Summary of the Prior Art*
>
> *In the prior art humidification systems are well known which include a heater base and a disposable humidifier chamber which is fitted onto the heater base and within which a supply of water can be heated by the heater base. Air passing through the chamber from an inlet to an outlet is humidified by the evaporation of water from the water supply.*
>
> *Humidifier chambers of this type are also now used in compact and portable ventilation machines, for example machines intended for the home treatment of obstructive sleep apnoea (CPAP machines). These machines pose a particular difficulty as the air flow is delivered directly to the humidifier chamber from the air blower of the CPAP machine and this can generate an annoying noise level within the humidifier chamber. Furthermore where the CPAP machine is adapted for use with slide-on humidifier chambers, and the connection of the chamber to the machine is accomplished within the single sliding movement, the inlet air port is consequently provided horizontally through a side of the chamber. Locating the inlet port in the side of the chamber significantly increases the likelihood of water spillage from the chamber if the chamber is tilted with water therein.*

This can be of particular disadvantage where the water may flow out through the inlet port and into the air blower of the CPAP machine.

RMD1001 at 1:10-34.

35. Based on my review of this admission in the patent application, it is my opinion that the only real difference between the prior art discussed in the background section and the apparatus recited by claim 1 of the '197 patent is that claim 1 recites an elongate flow tube extending into said water chamber from the inner periphery of said gases inlet. For example, the prior art humidification chamber referenced in the background section of the '197 patent appears to be shown by the humidification chamber in the HC200 Manual (Rev. A) (RMD1015) and the HC200 Manual (Rev. B) (RMD1012), which describe a water chamber used in the HC200 CPAP device marketed by Fisher & Paykel. The figures of the '197 patent appear to show the water chamber from the HC200 manuals with the "elongate flow tube" and "baffle" features added. Indeed, the '197 patent explains that the tube can reduce noise and act "as a weir against water flow back through gases inlet 2 upon tilting of the chamber 1" and that such "benefits have been achieved while maintaining, in the design shown, S [sic] equivalent external appearance and size, and the same ease of use and simplicity to the user, as earlier chambers." RMD1001 at 2:54-65 (emphasis added). Indeed, claim 1 of the '197 patent recites in the beginning of the claim, before the "improvement comprising"

language, the "water chamber," "heater base," and "horizontally oriented gases inlet" features that are present in the water chamber used with the HC200 device.

36. Given the admission that these features were known prior art and the knowledge of one of ordinary skill in the art at the relevant time, it is my opinion that adding a tube to an opening in a water chamber to prevent water from leaving the chamber through that opening would have been an obvious modification. In fact, as I opine below, water chambers with tubes to prevent undesired water spillage were known well before the time of the '197 patent.

2. Overview of the HC200 Manual (RMD1015)

37. For the purpose of this declaration, I have been told to assume that Fisher & Paykel Healthcare, "HC200 Series Nasal CPAP Blower & Heated Humidifier" User's Manual, (Rev. A) (RMD1015) is prior art to the claims of the '197 patent.

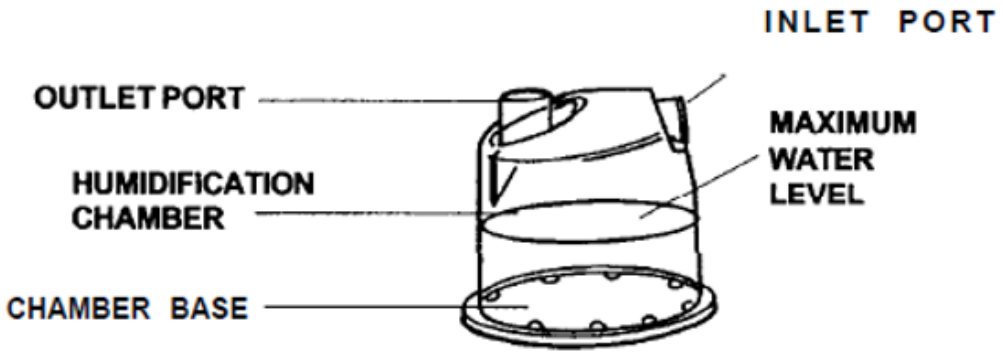
38. Based on my review of the HC200 Manual and my knowledge and skill in the art, I offer the following overview of the HC200 Manual's disclosure and teachings. This overview relates to particular portions of the reference, but it should be understood that the HC200 Manual also provides additional disclosure and teachings that may not be mentioned in the following paragraphs.

39. The HC200 Manual describes an "integrated Continuous Positive Airway Pressure generator and Heated Humidifier, designed for the treatment of Obstructive Sleep Apnoea in adult patients." RMD1015 at 6. The HC200 device, including the humidification chamber for use with the HC200, is shown on page 1 of the HC200 Manual.[1] The manual also provides a side view of the humidification chamber at page 7. RMD1015 at 7. The humidification chamber is shown to have a horizontally oriented inlet port connectable with the blower outlet, and a "metal base." RMD1015 at 5 and 11. The HC200 manual also cautions to

HC200 Manual at page 1

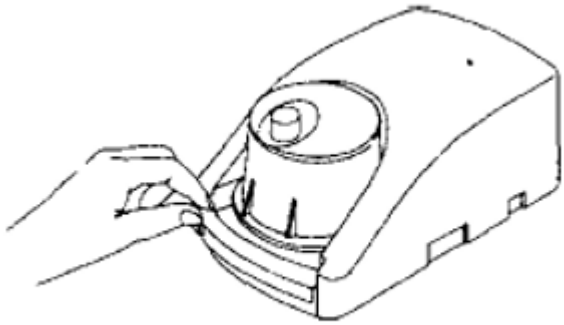
[1] Pages numbers refer to exhibit page numbering, not source document numbers.

"[a]void moving the HC200 when the Humidification Chamber is full of water." *Id* at 9.



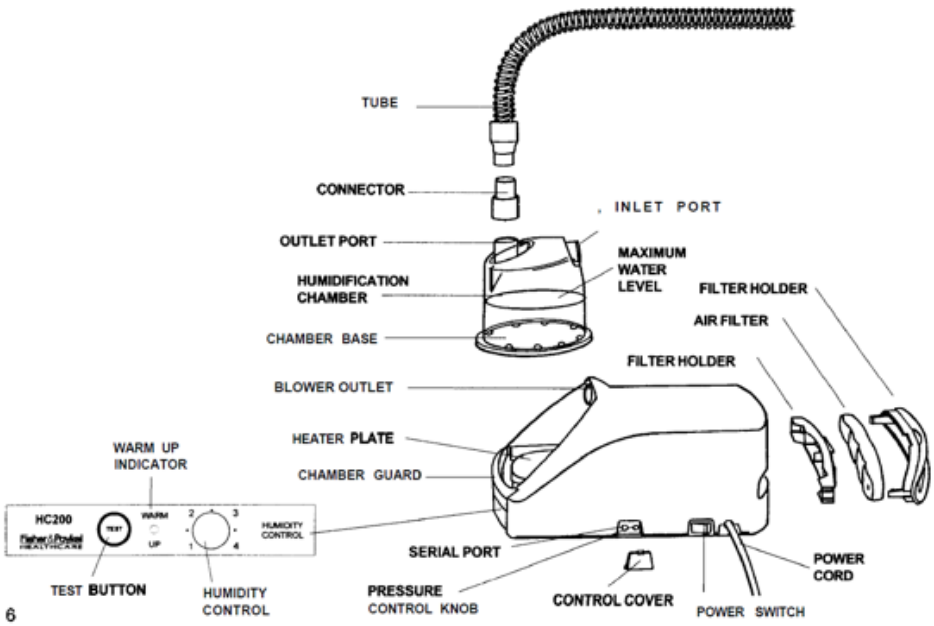
HC200 Manual at page 7 (portions omitted)

40. The HC200 Manual provides instructions for slidably installing the humidification chamber with the HC200 device, which connects the chamber inlet port to the blower outlet. *Id.* at 8 ("Press down the spring loaded Chamber Guard and slide the Humidification Chamber onto the Heater Plate, ensuring that the Inlet Port on the Chamber fits securely over the Blower Outlet.").



HC200 Manual at page 8

41. The HC200 Manual further describes that the HC200 device provides a heated humidifier and identifies that the water chamber sits on a "heater plate." RMD1015 at. 7.



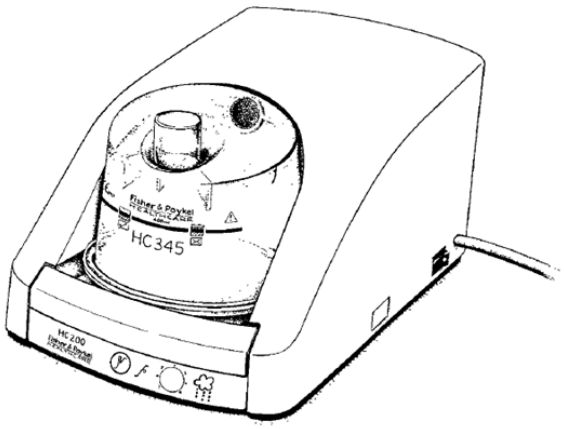
HC200 Manual at page 7

3. Overview of the HC200 Manual, Rev B (RMD1012)

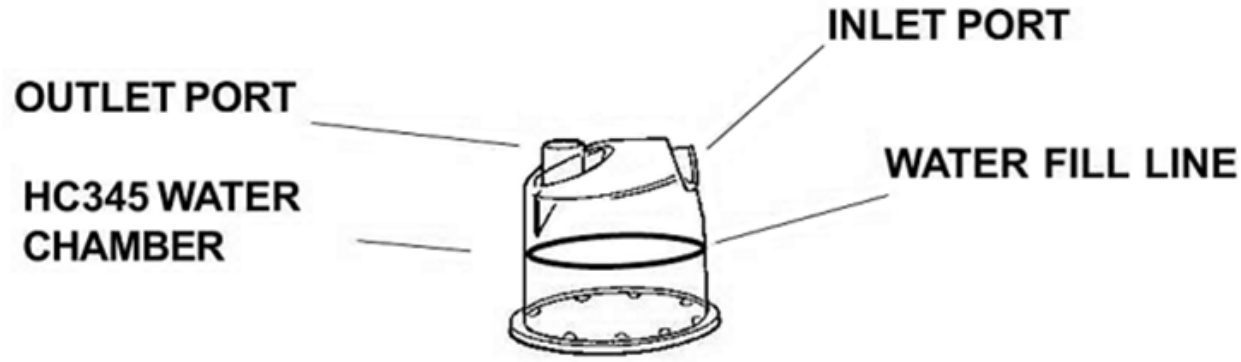
42. For the purpose of this declaration, I have been told to assume that Fisher & Paykel Healthcare, "HC200 Series Humidified CPAP System" Instruction Sheet, (Rev. B) ("Second HC200 Manual") (RMD1012) is prior art to the claims of the '197 patent.

43. Based on my review of the Second HC200 Manual and my knowledge and skill in the art, I offer the following overview of the Second HC200 Manual's disclosure and teachings. This overview relates to particular portions of the reference, but it should be understood that the Second HC200 Manual also provides additional disclosure and teachings that may not be mentioned in the following paragraphs.

44. The Second HC200 Manual describes a "humidified CPAP system" that "provides the user with an integrated CPAP and heated humidifier for use in the home." *Id.* at 1. The Second HC200 device and its HC345 water chamber, is shown on page 1 of the Second HC200 Manual. The manual also provides a side view of the water chamber. The water chamber is shown to have a horizontally oriented inlet port that can be connected to the HC200 blower outlet. (*Id.* at 5.) The Second HC200 manual identifies that a patient can accidentally "tip water into the blower outlet" of the HC200 device. *Id.* at 1.

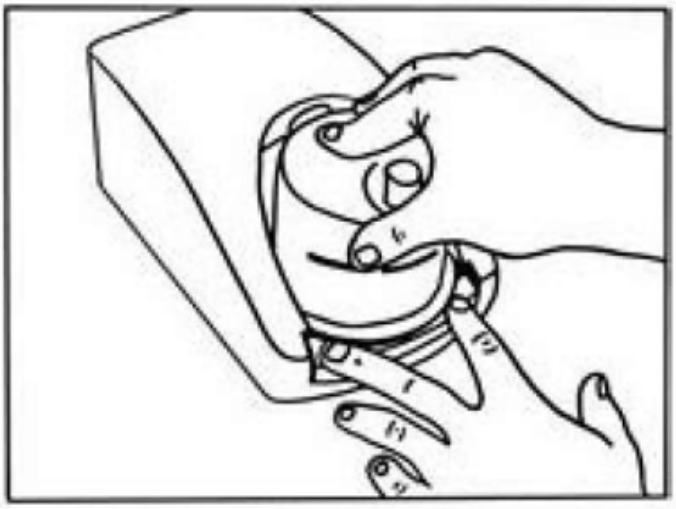


HC200 Manual at page 1



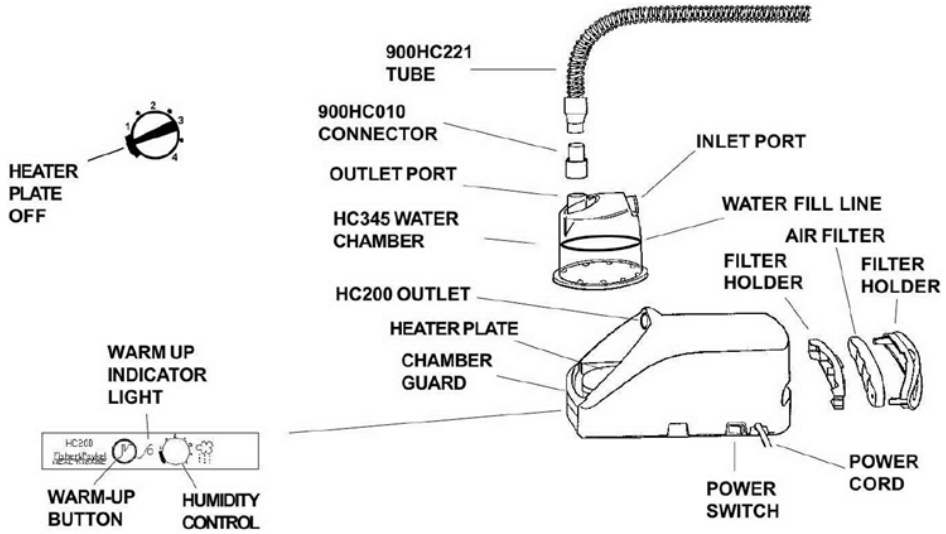
HC200 Manual at page 5 (portions omitted)

45. The Second HC200 Manual provides instructions for slidably attaching the water chamber to the HC200 device to connect the water chamber inlet port to the HC200 outlet. "To attach the water chamber to the HC200, press down on the finger guard and slide the chamber on." *Id.* at 6.



HC200 Manual at page 6

46. The Second HC200 Manual further describes that the device provides a "heated humidifier" and identifies a "heater plate" and a switch with a "heater plate off" position. *Id* at. 5. The HC200 Manual further explains that there is a "temperature selected by the temperature control knob," and that "some users prefer not to use heated humidification." *Id.* at 1 and 3.



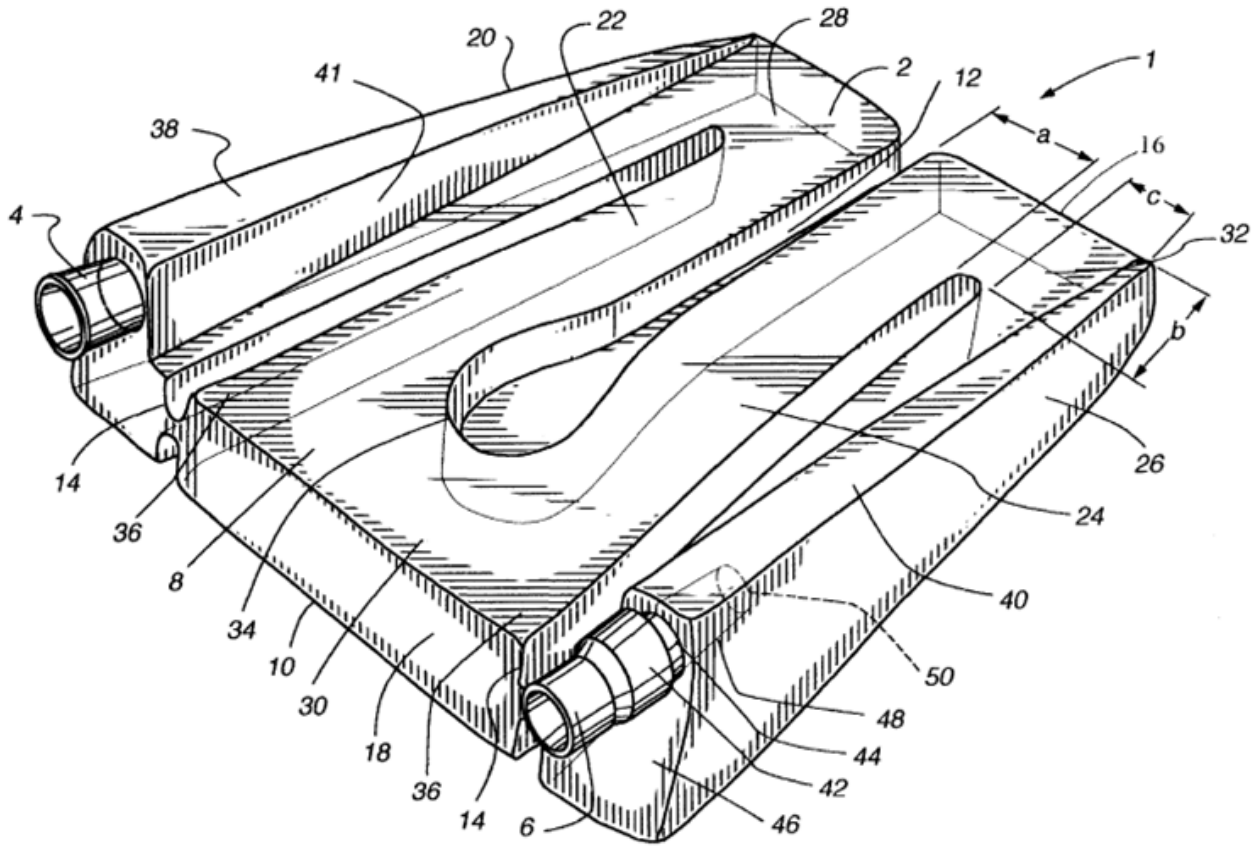
HC200 Manual at page 5

4. Overview of the Hebblewhite Reference

47. For the purpose of this declaration, I have been told to assume that U.S. Patent No. 6,135,432 to Hebblewhite et al. ("Hebblewhite") (RMD1004) is prior art to the claims of the '197 patent.

48. Based on my review of Hebblewhite and my knowledge and skill in the art, I offer the following overview of Hebblewhite's disclosure and teachings. This overview relates to particular portions of the reference, but it should be understood that Hebblewhite also provides additional disclosure and teachings that may not be mentioned in the following paragraphs.

49. Hebblewhite describes a "humidifier for use with a Continuous Positive Airway Pressure (CPAP) device" and that has a tube extending from an aperture in its water chamber in order to prevent water from entering the opening. RMD1004 at 1:7-10; FIG. 1. The humidifier described by Hebblewhite includes "an elongate passageway, extending between the air inlet and air outlet, . . . the passageway being adapted to be partially filled with water so that air passing along the passageway becomes humidified as it passes over the water from the air inlet to the air outlet," as shown in Figure 1 below. *Id.* at 1:52-59.



Hebblewhite at Figure 1

50. A tube 48 is provided at an air outlet of Hebblewhite's humidifier. Hebblewhite describes the tube 48 as reducing the amount of water that spills into the air outlet. For example, Hebblewhite describes that when the "air flow within the passageway creates waves on the surface of the water, it has been found that the water has a tendency to splash against the end wall of the passageway, resulting in a danger of water spilling into the air outlet." *Id* at. 3:33-38. Hebblewhite explains that "by spacing the air outlet aperture away from the end wall, the danger of water spilling into the air outlet is greatly reduced." *Id* at. 3:38-40. Hebblewhite also notes that "[i]t should be appreciated that the idea of spacing the

outlet aperture, in this case the aperture 50 of the tube 48, away from the humidifier is of general applicability, and may be used in other humidifiers, regardless of whether the humidifiers are formed with elongate passageways." *Id*. at 5:17-22.

5. Overview of the Gouget Reference

51. For the purpose of this declaration, I have been told to assume that U.S. Patent No. 5,953,763 to Gouget ("Gouget") (RMD1006) is prior art to the claims of the '197 patent. I note that Gouget claims priority to App. No. 08/737,879 (RMD1007 at 13-36), and believe that my analysis regarding Gouget is fully supported by the disclosure in the prior '879 application. Indeed, Figures 1-4 are substantially similar between Gouget and the prior '879 application (RMD1007 at 33), and the prior '879 application refers to how "[i]ts anti-backflow system . . . permit[s] turning said urinal in any direction when normally filled without its contents escaping" (RMD1007 at 25), which I understand to support description in Gouget explaining the benefits to placing the interior end of the anti-backflow device 5 at the volumetric center of the chamber. RMD1007 at 25. I also understand that the prior '879 application is a translation of a PCT application that published as WO 96/29972 in French in October 1996 (and which I have been told is prior art under § 102(b)). RMD1007 at 37-58.

52. Based on my review of Gouget and my knowledge and skill in the art, I offer the following overview of Gouget's disclosure and teachings. This overview relates to particular portions of the reference, but it should be understood that Gouget also provides additional disclosure and teachings that may not be mentioned in the following paragraphs.

53. Gouget describes a "urinal . . . with a detachable anti-backflow element having an interior end located at the volumetric center of the urinal." RMD1006 at Abstract. Gouget explains it is an "object of the present invention to prevent spillage from the urinal at any angle of tilt when the contents of the urinal are below the fill indicator level." RMD1006 at 2:36-39; RMD1007 at 25 ("[i]ts anti-backflow system . . . permit[s] turning said urinal in any direction when normally filled without its contents escaping."). With reference to FIGS. 7A-7D, Gouget describes anti-backflow device 5 having an interior end 5a positioned near a center of the chamber such that fluid contents below the volumetric center of the chamber are prevented from spilling out through the anti-backflow device 5. *See* RMD1006 at 9:51-10:13; *see also* RMD1007 at 25, 27, FIG. 1.

6. Overview of the Rose Reference

54. For the purpose of this declaration, I have been told to assume that U.S. Patent No. 5,231,979 to Rose et al. ("Rose") (RMD1008) is prior art to the claims of the '197 patent.

55. Based on my review of Rose and my knowledge and skill in the art, I offer the following overview of Rose's disclosure and teachings. This overview relates to particular portions of the reference, but it should be understood that the Rose also provides additional disclosure and teachings that may not be mentioned in the following paragraphs.

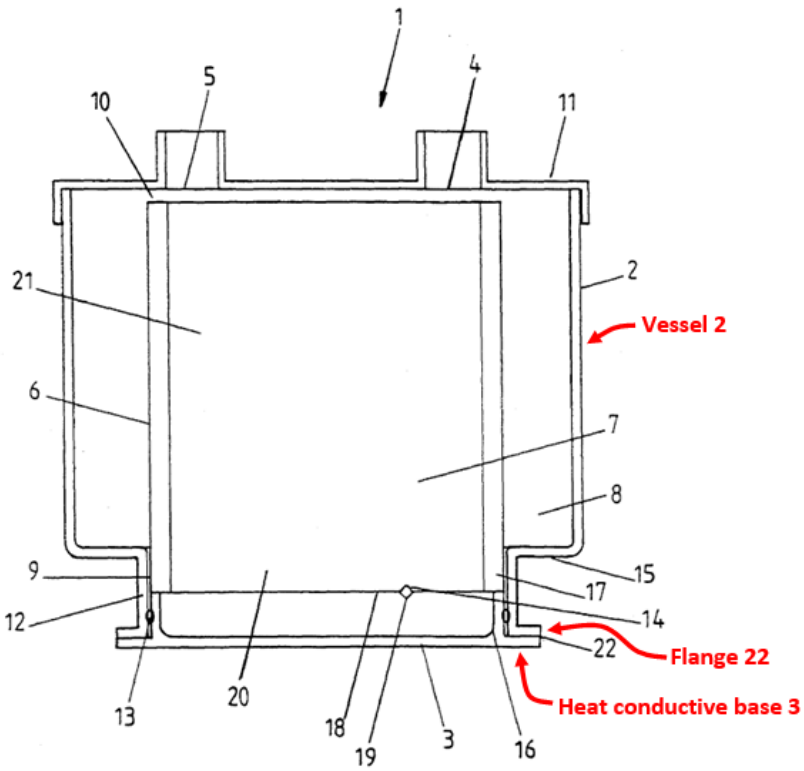
56. Rose describes a "humidifier for a CPAP device" that includes an "internal baffle integrally formed" with the humidifier. RMD1008 at 1:6-10. "Pressured air from the CPAP device 12" is described as "circulated through the humidifier 10 for subsequent delivery to the patient through air hose 26 to mask 28." *Id*. at 3:1-4. The humidifier 10 includes an "inlet 18," an "outlet 20," and a "baffle 34." Rose describes that the "baffle promotes the flow of air therethrough in a U-shaped or other indirect path," as shown in FIG. 2. *Id.* at 2:7-11; *see also* 3:17-22; 4:24-30; 4:55-66.

7. Overview of the Smith Reference

57. For the purpose of this declaration, I have been told to assume that U.S. Patent No. 5,588,423 to Smith ("Smith") (RMD1009) is prior art to the claims of the '197 patent.

58. Based on my review of Smith and my knowledge and skill in the art, I offer the following overview of Smith's disclosure and teachings. This overview relates to particular portions of the reference, but it should be understood that Smith also provides additional disclosure and teachings that may not be mentioned in the following paragraphs.

59. Smith describes "humidifier chambers for use with heated humidifier bases." RMD1009 at 1:6-8. Smith discusses that a "humidification chamber 1 is formed as a closed watertight vessel 2 with a heat conductive base 3, for conducting heat from the heater base to liquid placed in the humidification chamber 1." *Id.* at 2:12-15. Smith's "watertight vessel 2" includes an "outwardly extending flange 22." Smith further explains that "a seal 13 is provided between the heat conductive base 3 and the vessel 2," to "ensure that the chamber is watertight with the heated conductive base 3 in place." *Id.* at 3:3:23-6.



Smith at Figure 1

8. Overview of the Netzer Reference

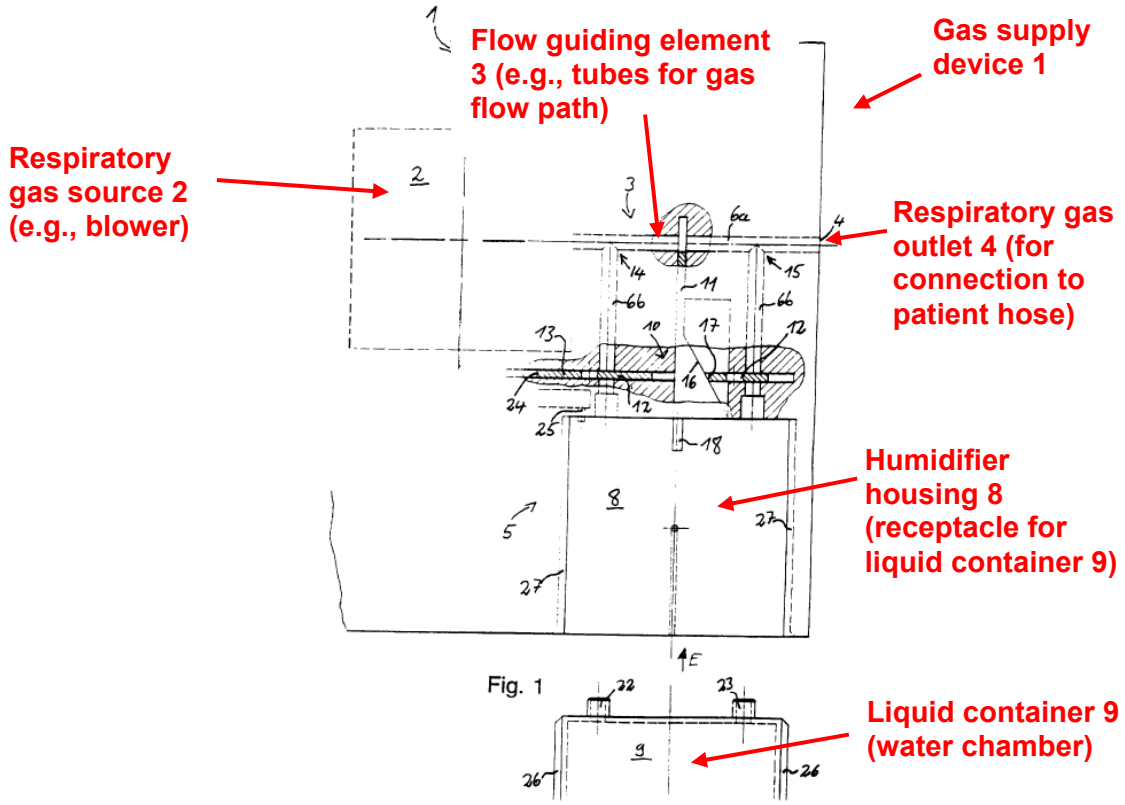
60. For the purpose of this declaration, I have been told to assume that PCT Pub. WO 98/04311 to Netzer ("Netzer") (RMD1010) is prior art to the claims of the '197 patent.

61. Based on my review of Netzer and my knowledge and skill in the art, I offer the following overview of Netzer's disclosure and teachings. This overview relates to particular portions of the reference, but it should be understood that Netzer also provides additional disclosure and teachings that may not be mentioned in the following paragraphs.

62. Netzer generally describes a gas supply device and humidifier for respiratory gas treatment, such as for the treatment of sleep apnea. RMD1010 at 1:1-4. In some embodiments, Netzer's device may be a continuous positive airway pressure ("CPAP") device that provides a pressurized flow of gases to a patient during sleep. The pressurized flow of gases can prevent closure of the patient's airways that would otherwise interrupt normal breathing cycles during sleep. In other embodiments, Netzer's device may be implemented as a mechanical ventilation device or other form of respiratory assist device.

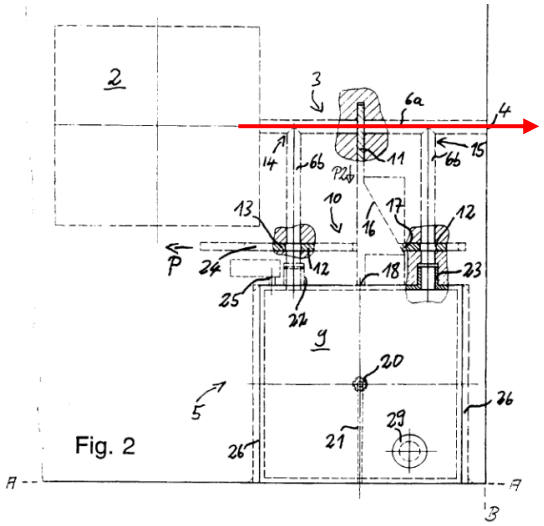
63. With reference to the drawings, Figure 1 is a top view of the gas supply device 1. The larger box at the top of the figure depicts an outline of the housing of the gas supply device 1. Within the device housing is a respiratory gas

source 2 (e.g., a blower, pump, or gas cylinder), a flow guiding element 3, and a humidifier housing 8. RMD1010 at 7:8-11. At bottom, a liquid container 9 is shown removed from the device. *Id.* at 6:14-16. The liquid container 9 holds water for the humidifier. Figure 1 is reproduced and annotated below.

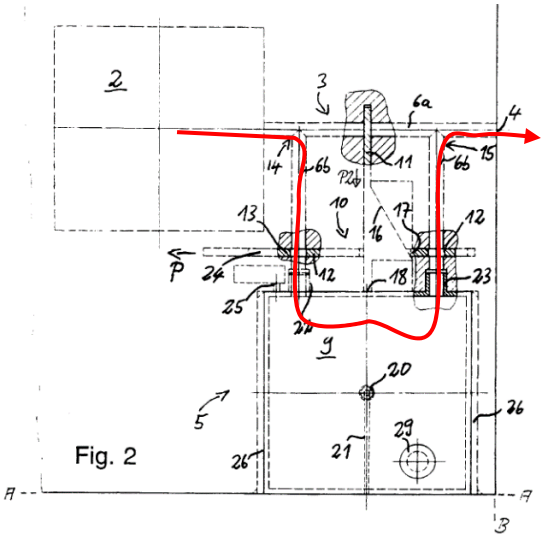


64. Netzer's gas supply device 1 is adapted to operate with or without the humidifier 5 activated. *Id.* at 6:4-8. Depending on whether the humidifier is being used, the device 1 directs the flow of gas from respiratory gas source 2 to one of two flow paths (illustrated below) to gas outlet 4. *Id.* at 7:1-6. The first flow path 6a bypasses the humidifier 5, and instead leads straight to gas outlet 4 for delivery to the patient. *Id.* The second flow path 6b runs through the humidifier 5 so that the flow of gases from respiratory gas source 2 enter and exit liquid container 9 for

humidification before flowing to gas outlet 4. *Id.* A valve assembly 10 in the device 1, comprising a main flow blocking valve 11 and a pair of bypass flow blocking valves 12, are operable to open or close different sections of flow guiding element 3 to form either the first gas flow path 6a or the second gas flow path 6b. *Id.* at 7:8-20.



First Gas Flow Path 6a (Bypassing Humidifier 5)



Second Gas Flow Path 6b (Through Humidifier 5)

65. The design of Netzer's device 1 allows the patient to insert and remove the liquid container 9 via a single motion. For insertion, the patient slides the liquid container 9 into the humidifier housing 8, and in a single slide-on motion (i) switches on a humidifier heating unit, (ii) establishes a first fluid connection between an inlet 22 of the liquid container 9 and a gases outlet opening of the flow guiding element 3, (iii) establishes a second fluid connection between an outlet 23 of the liquid container 9 and a gases return opening of the flow guiding element 3,

and (iv) actuates the valve assembly 10 to close the first gas flow path 6a and to open the second gas flow path 6b. *Id. at* 6-9.

66. To facilitate insertion of the liquid container 9, Netzer provides lateral guide profiles 26 on the liquid container 9, and corresponding guide grooves 27 in

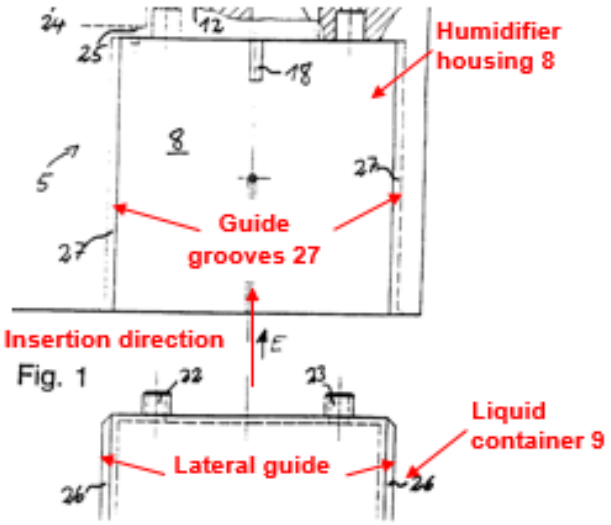


Fig. 1

the humidifier housing 8. *Id.* at 9:12-15, FIG. 1. When the patient inserts liquid container 9 into the device 1, the guide profiles 26 engage their corresponding grooves 27 in the humidifier housing 8. *Id.* This structure, along with an inlet 22 and an outlet 23 of the liquid container 9 that fit into corresponding connectors in the humidifier housing 8, permit Netzer's container 9 to be engageable with the housing 8 in a single motion. *Id*.

67. Netzer's liquid container 9 is designed to hold water that, when the container 9 is heated by a heater in the humidifier housing 8, will create water vapor expelled through the outlet 23 and along the gas flow path 6b. RMD1010 at

1-2, 8-9, Figs. 1, 4. To do this, Netzer's container 9 has sidewalls, a top, a base 19, a horizontally oriented inlet 22, and a horizontally oriented outlet 23, which provide a horizontal flow of gases into and out of the container 9 along the flow path 6b, as depicted in Netzer's Figure 4, which provides a side view of the container 9 inserted into the housing 8. *Id.* at 8-9, Fig. 4.

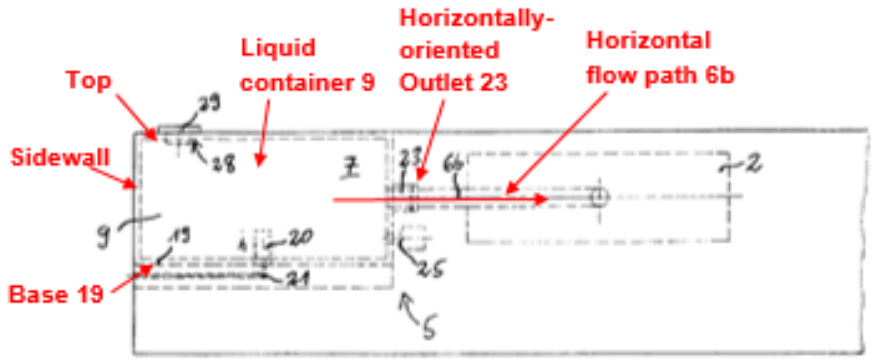


Fig. 4

68. Regardless of which flow path 6a or 6b is open, or whether the humidifier is in use, the device 1 includes a single gas outlet 4, for connection to a patient conduit (e.g., a flexible hose that leads to a mask or nasal pillow). *Id.* at 7:1-3, Figs. 1-2.

B. *The HC200 Manual in view of Hebblewhite renders obvious claim 1*

69. I understand that claim 1 recites "a water chamber adapted for use in conjunction with a heater base and having a horizontally oriented gases inlet in a wall," and believe that these features are disclosed by the HC200 Manual. Almost every page of that manual shows or describes the water chamber, and multiple pages show how the water chamber is used with a heater base. For example, the

illustration at page 7 (all page numbers refer to exhibit page numbers) labels the heater plate, and the illustrations at pages 1 and 8 show how the water chamber rests on the heater plate. *See also* RMD1012 at 5 and 6.

70. Moreover, I believe that a skilled artisan would have understood that the inlet port was horizontally oriented, because page 7 of the HC200 Manual shows how both the water chamber inlet port and the blower outlet port are horizontally oriented, and the manual describes how the water chamber and its inlet port are slid into engagement with the HC200 and its outlet port. RMD1015 at 8; *see also* RMD1012 at 5. For example, page 8 explains that a user has to "slide the Humidification Chamber onto the Heater Plate" and shows that a user must hold down the "Chamber Guard" to slide the water chamber into place. RMD1015 at 8; *see also* RMD1012 at 6.

71. I understand that claim 1 further recites a water chamber "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." Skilled artisans would have recognized that this claim feature is shown by tube 48 in the Hebblewhite

reference, except that tube 48 is positioned on the gases outlet rather than the gases inlet, as described by the claim. RMD1004 at Fig 1. Indeed, Hebblewhite discloses that "tube 48" spaces aperture 50 away from end wall 46 of the water chamber in order to reduce "the danger of water spilling into the air outlet 6." RMD1004 at 5:3-16; *see also* 3:33-40; 3:47-50; 5:5-8; 5:5-22.

72. I believe 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, in order to prevent water from spilling into the blower outlet of the HC200 device and potentially harming the fan and electronics of the HC200 device, for at least the reasons that I describe below. As an initial matter, the HC200 Manual cautions at page 9 to "[a]void moving or tilting the HC200 when the Humidification Chamber is full of water." *See also* RMD1012 at 1 (explaining that a user could "tip water into the blower unit" and, if water enters the blower unit, the patient is supposed to remove the air filter and chamber, shake excess water out of the back of the unit, and turn the unit on and run at the prescribed pressure for 5 minutes before using the device again). A skilled artisan would have understood that the HC200 Manual caution against moving or tilting the HC200 when the chamber is full of water is because doing so could allow water to spill through the horizontal inlet port out of the water chamber and into the HC200 blower unit, which can damage the blower

or at least require the user to take multiple steps to remove water from the HC200 blower unit.

73. Hebblewhite explains how using tube 48 (and therefore spacing aperture 50 away from the side wall) would reduce the danger that water could spill into the aperture that is protected by the tube. RMD1004 at 3:38-40 ("It has been found that by spacing the air outlet aperture away from the end wall, the danger of water spilling into the air outlet is greatly reduced."); *see* 2:64-3:3; 3:33-40; 5:3-22. Indeed, Hebblewhite is clear 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." RMD1004 at 5:17-22. Given the problem of water entering the blower that could result from "moving or tilting the HC200 when the Humidification Chamber is full of water" (RMD1015 at 9; *see also* RMD1012 at 1), and the explanation in Hebblewhite that a tube can prevent water from spilling through an opening and that the tube solution is of "general applicability" (RMD1004 at 5:17-22), I believe that a skilled artisan would have been prompted to add a tube to the inlet port of the water chamber that is shown by the HC200 Manual.

74. Although Hebblewhite discusses how tube 48 prevents water from spilling into the outlet aperture due to waves that are created by air flowing

through the chamber, I believe that skilled artisans would have understood the tube technology to prevent water from spilling into the outlet aperture due to other types of water movements, such as water movement due to a user moving or tilting the CPAP device. Indeed, Hebblewhite is clear that with tube 48, "the danger of water spilling into the air outlet is greatly reduced," and there is simply no indication in Hebblewhite that the tube would only work on waves that were created by air rather than waves that were created due to mechanical movements of the water chamber.

75. Indeed, a reason that water spillage due to airflow-created waves was more of an issue than tipping in Hebblewhite's design was due to the low profile of Hebblewhite's water chamber, but as previously described, Hebblewhite is clear 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." RMD1004 at 5:17-22. A skilled artisan would have understood that the humidifier chamber in the HC200 Manual is taller than the Hebblewhite chamber and therefore suffers more from the danger of tipping (and less from the danger of wave action), as noted by the HC200 manual's caution against "moving or tilting" the chamber when full of water. RMD1015 at 9; *see also* RMD1012 at 1. Given the problem stated by the HC200 Manual, and the tube

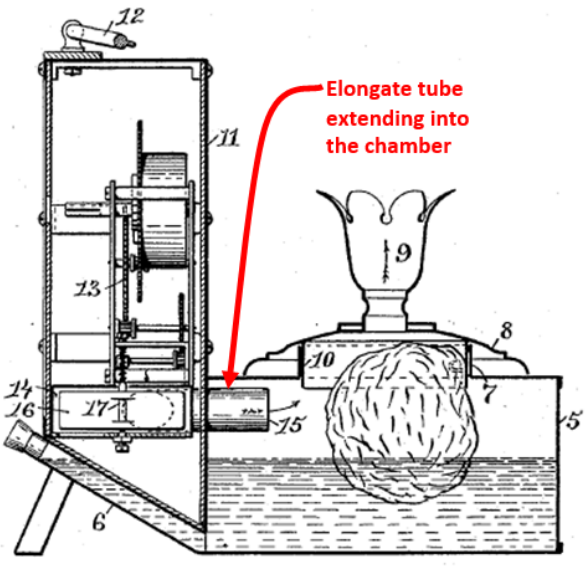
solution of "general applicability" shown in Hebblewhite, I believe that a skilled artisan would have been prompted to add a tube to the inlet port of the water chamber shown in the HC200 Manual, despite Hubblewhite not expressly mentioning that the tube prevented water spillage due to tipping.

76. Moreover, although Hebblewhite's tube 48 is on the water chamber's outlet rather than its inlet, I do not believe that this difference in application would have affected a skilled artisan from recognizing that the tube would prevent spills at any type of horizontal opening in a water chamber. Indeed, the portions of Hebblewhite that discuss the concerns with water spillage focus on how the tube spaces the "aperture" away from the water chamber wall to prevent a water spill, and there is little difference between the HC200 water chamber inlet and the Hebblewhite water chamber outlet, except that air is going in one and out the other when the devices are operating (but both openings would be free of airflow when the devices are off, and yet tipping would remain a concern). I do not believe that a skilled artisan would have considered spacing an aperture away from a wall using a tube to be a technology that applies to air outlets and not air inlets.

77. In any event, Hebblewhite's humidifier does not suffer from the same dangers as the HC200 device if water enters Hebblewhite's air inlet, because Hebblewhite's CPAP device is placed "on top of the humidifier." RMD1004 at 1:28-45. With such a design (rather than a slide-on chamber design in which the

blower is to the side of the water chamber, as shown by the HC200 Manual), there is less danger of water that enters the inlet making its way into the CPAP blower, because the blower is positioned above the water chamber (the two are often connected with a tube). As such, there was simply not a great motivation for Hebblewhite's designers to include the tube 48 on Hebblewhite's water chamber's inlet, as there was to include the tube on the water chamber outlet.

78. I further believe that skilled artisans would have seen a reason to have modified the water chamber in the HC200 Manual to include a tube (as shown by Hebblewhite), because it was known that a tube at the inlet of a liquid chamber could prevent liquid from spilling out of the chamber, as shown by multiple additional references that I describe herein. As a first example, Figure 2 of the Lynch reference that was cited during prosecution shows such an inlet tube 15. As a second example, the Gouget reference describes a portable urinal chamber that includes an "anti-backflow element" that can "prevent spillage from the urinal at any angle of tilt when the contents of the urinal are below the fill indicator level." RMD1006 at 2:29-39; *see also* RMD1007 at 25, 27,



***Lynch* at Figure 2**

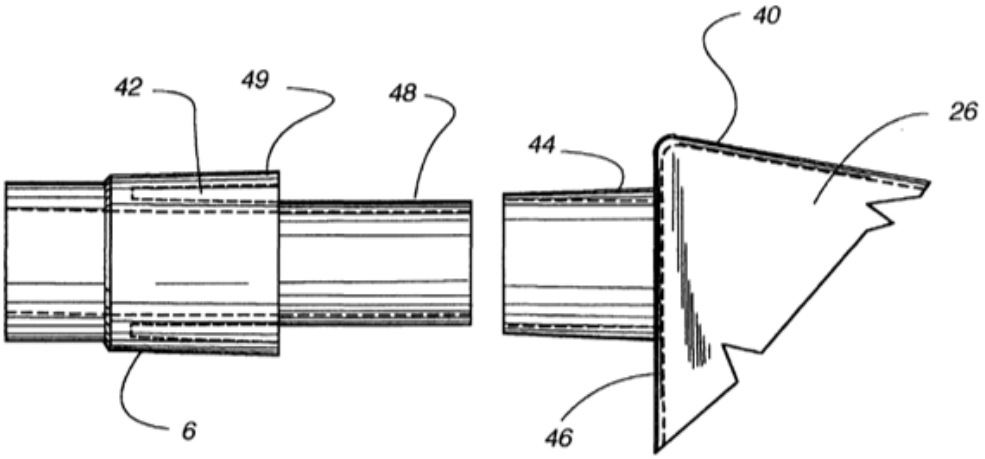
FIG. 1. As a third example, skilled artisans would have known that the inlet and outlet ports of the Sullivan HumidAire water chamber included tubes that extended to the interior of the water chamber, as shown in a 1997 brochure of the HumidAire product. *See* RMD1020 at 2 and 3 (showing the transparent water chamber at the bottom right of each page).

HumidAire Brochure at 3

79. These teachings demonstrate that skilled artisans would have readily recognized how Hebblewhite's tube could have been applied to an inlet of a water chamber, either because the teachings show such a tube on a water chamber or because the teachings explain that such a tube prevents liquid from leaving the chamber, which further solidifies my opinion that skilled artisans would have been motivated to add a flow tube to the inlet port in the water chamber that is shown by the HC200 Manual.

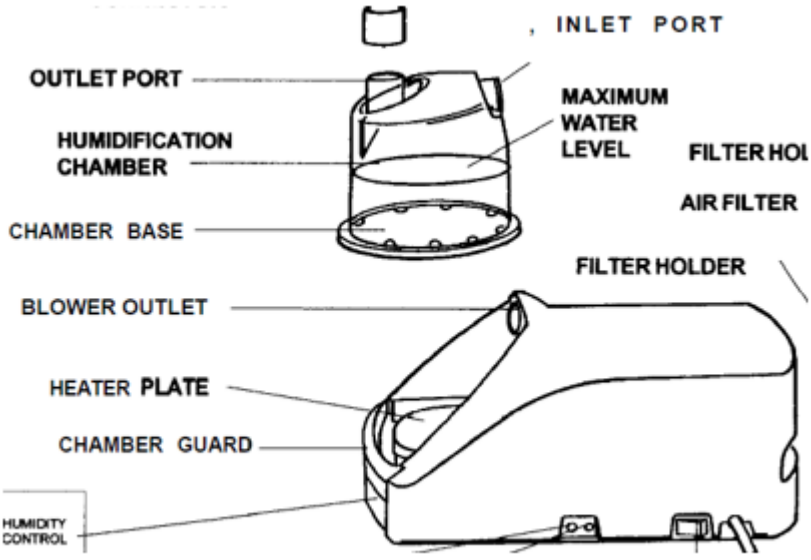
80. Given the reasons that I described above to add a tube to the inlet of the water chamber that is shown by the HC200 Manual, I believe that skilled artisans would have seen reasons to add the tube in at least two ways. First, I

believe that skilled artisans would have seen reasons to include the tube as an attachment that is inserted into the inlet from the outside, because Hebblewhite shows such an attachment. Figure 2 of Hebblewhite shows that the attachment includes, in addition to tube 48, a mechanism that retains the tube 48 in place (e.g., so that tube 48 does not slide all the way into the chamber and end up floating in the water). RMD1005 at Fig. 2. Hebblewhite describes the entire attachment device (including tube 48 and the retaining mechanism) "as an outlet attachment 42 which is attached to a circular tube 44 which projects outwardly from the end wall 46 of the fourth subpassageway 26. The outlet attachment 42 is provided with a tube 48 which projects through the circular tube 44 and into the fourth subpassageway 26, the tube 44 being gripped between the outer surface of the tube 48 and the inner surface of an outer skirt portion 49." RMD1004 at 4:63-5:8; Fig. 2.



Hebblewhite at Figure 2

Hebblewhite's outwardly-facing circular tube 44 is similar to the outwardly-projecting feature that extends out from the water chamber shown in the HC200 Manual. *See also* RMD1012 at 5.



HC200 Manual at page 7 (portions omitted)

As such, I believe that skilled artisans being motivated to modify the HC200 water chamber based on Hebblewhite's teachings would have designed an inlet tube

attachment that was similar to Hebblewhite's outlet attachment 42. Still, the HC200 water chamber attachment would not need to include a tube that extended away from the water chamber (as shown by the unlabeled left-most part of the attachment 42 in Hebblewhite's Figure 2), because skilled artisans would have understood that Hebblewhite's attachment 42 needed an outwardly-extending tube so that a hose could connect to the humidifier chamber outlet, while the HC200 water chamber has no such need for a hose attachment at its inlet. Rather the HC200 Manual shows that the HC200 device includes a blower outlet (shown in the above figure), that would abut against or go into the HC200 water chamber inlet. To the extent that the tube attachment for the HC200 water chamber affected the dimensions of the inlet port (with the attachment inserted therein) so that the HC200 outlet did not properly abut against or fit within the water chamber inlet, I believe that skilled artisans would have considered it an obvious and standard design modification to change the dimensions of the inlet port and the tube attachment so that the HC200 blower outlet and the water chamber inlet (with the tube attachment) joined together in the same manner as before the addition of the attachment.

81. I believe that skilled artisans would have seen a reason to add a tube to the HC200 water chamber in a second way, by integrally forming the tube with the water chamber. Stated another way, I believe that skilled artisans would have

considered molding the HC200 water chamber to have an inlet port tube that was integrally formed with the chamber, at least because the outlet port tube is already shown to be integrally formed with the remaining portion of the chamber, and at least because integral construction would ensure that there was no risk of water leaking at a junction of the inlet port and the tube. Designing a mold to form a chamber with two integrally-formed tubes rather than one integrally-formed tube would have been within the skill level of skilled artisans at the time.

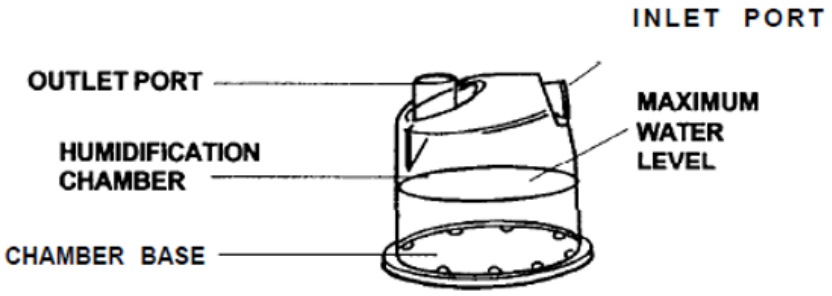
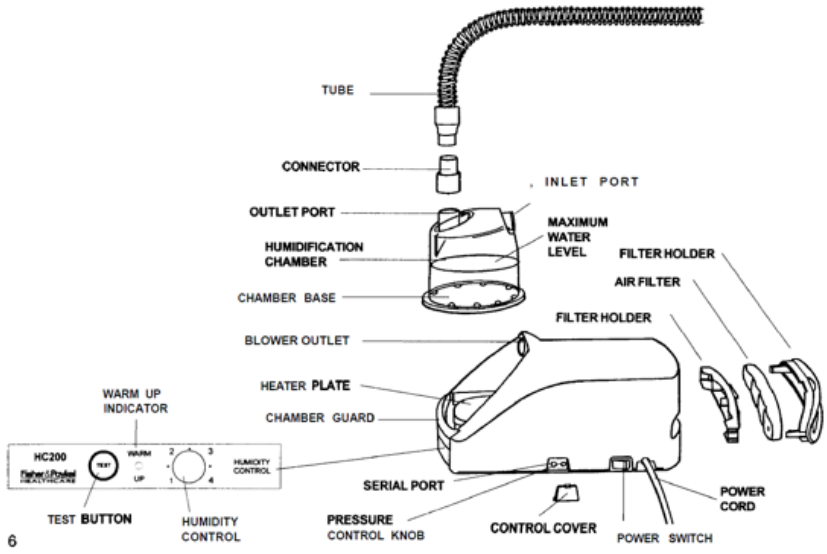
82. I believe that both of the above-described modifications to the HC200 water chamber would have disclosed under the broadest reasonable interpretation standard the claim feature of an "improvement comprising an elongate flow tube extending into said water chamber from the inner periphery of said gases 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." As such, I believe that it would have been obvious to have modified the teachings of the HC200 Manual in view of the Hebblewhite reference to disclose the features of claim 1 of the '197 patent.

83. I understand that Petitioners have prepared the following claim chart for the '197 Petition to show how each element of claim 1 is disclosed by the

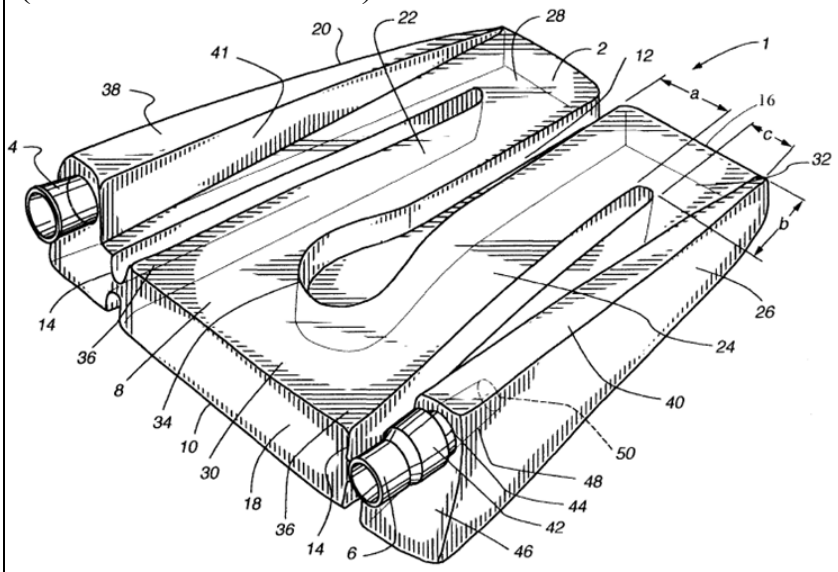
HC200 Manual in view of Hebblewhite. Based on my review of the HC200 manual and Hebblewhite, the '197 patent and file history, I agree that each element of claim 1 of the '197 patent is disclosed by the HC200 Manual and Hebblewhite, and further agree that Petitioners' claim chart accurately demonstrates the correspondence between the elements of claim 1 and exemplary disclosure from the HC200 manual and Hebblewhite. As demonstrated by my analysis concerning the HC200 manual and Hebblewhite, it is my opinion that the HC200 manual in view of Hebblewhite renders obvious claim 1 of the '197 patent.

'197 Patent Claims	**Exemplary Disclosure of HC200 Manual and Hebblewhite**
Claim 1 (first limitation): 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 HC200 Manual discloses these features, as explained below. Water chamber. The HC200 Manual discusses the "HC200 Series Nasal CPAP Blower & Heated Humidifier," which uses the HC345 water chamber. A perspective view of the HC200 device with the water chamber placed therein is shown on page 1 of the HC200 Manual.[2] The manual also includes (at page 5) a side view of the water chamber (shown below). (*See* RMD1015 at 1-12; *see also* RMD1012 at 1-6.) The manual describes that "the Humidification Chamber is

[2] Pages numbers refer to exhibit page numbering, not source document numbers.

'197 Patent Claims	Exemplary Disclosure of HC200 Manual and Hebblewhite
	full of <u>water</u>." (RMD1015 at 8 (emphasis added).)  *HC200 Manual at page 7 (portions omitted)* <u>Heater base</u>. The HC200 Manual describes a "Heated Humidifier" (page 1), and shows (at page 7) an illustration that identifies a "heater plate." (RMD1015 at 1, 7; *see also* RMD1012 at 1, 5.)  *HC200 Manual at page 7* <u>Horizontally oriented gases inlet in a wall thereof</u>. The two figures copied above show a horizontally oriented gases inlet in a wall of the water chamber. It is apparent from the figures that the inlet is horizontally oriented, but the horizontal configuration is further supported by the description at page 8, which explains

’197 Patent Claims	Exemplary Disclosure of HC200 Manual and Hebblewhite
	that to install the chamber, a user may “[p]ress down the spring loaded Chamber Guard and slide the Humidification Chamber onto the Heater Plate, ensuring that the Inlet Port on the Chamber fits securely over the Blower Outlet.” (RMD1015 at 8; *see also* RMD1012 at 6.) As Mr. Virr explains in his declaration, “a skilled artisan would have understood that the inlet port was horizontally oriented, because page 7 of the HC200 Manual shows how both the water chamber inlet port and the blower outlet port are horizontally oriented, and the manual describes how the water chamber and its inlet port are slid into engagement with the HC200 and its outlet port.” (RMD1003 at ¶ 70.) The ’197 patent acknowledges that these features were known. As described previously, the above-described features are listed in the preamble of a Jepson-style claim, and thus were admitted by Applicant to be prior art features. *See* 37 C.F.R. § 1.75(e); *In re Fout*, 213 USPQ 532, 534 (CCPA 1982). Moreover, the “Summary of the Prior Art” section of the ’197 patent explains that humidification systems with a “heater base,” “slide-on humidifier chambers,” and an “inlet air port . . . consequently provided horizontally through a side of the chamber” were prior art features. (RMD1001 at 1:10-29.)
Claim 1 (second limitation): 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	The HC200 Manual does not disclose the above-recited elongate flow tube, but this feature was traditionally known in the art. As an example, Hebblewhite discloses a “humidifier for use with a Continuous Positive Airway Pressure (CPAP) device” that has a tube extending from an aperture in its water chamber in order to prevent water from entering the opening, just like the tube in the ’197 patent. (RMD1004 at 1:7-10.)

’197 Patent Claims	Exemplary Disclosure of HC200 Manual and Hebblewhite
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	In greater detail, Hebblewhite discloses a humidifier with “an elongate passageway, extending between the air inlet and air outlet, . . . the passageway being adapted to be partially filled with water so that air passing along the passageway becomes humidified as it passes over the water from the air inlet to the air outlet.” (RMD1004 at 1:52-59.)  ***Hebblewhite at Figure 1*** Hebblewhite includes a tube 48 at its air outlet and explains that the addition of tube 48 reduces the amount of water that spills into the air outlet: > When the air flow within the passageway creates waves on the surface of the water, it has been found that the water has a tendency to splash against the end wall of the passageway, resulting in a danger of water spilling into the air outlet. It has been found that by spacing the air outlet aperture away from the end wall, the danger of water spilling into the air outlet is greatly reduced. (RMD1004 at 3:33-39; *see also* 3:47-50; 5:5-22.)

’197 Patent Claims	Exemplary Disclosure of HC200 Manual and Hebblewhite
	A skilled artisan would have been motivated to modify the HC200 water chamber to include a tube that spaces the aperture in the side wall away from the side wall, in order to reduce the danger of water spilling into the air inlet and entering the blower of the HC200, as Expert Alexander Virr explains in his declaration. (*See* RMD1003 at 71-79.) Although Hebblewhite’s tube 48 is positioned at the outlet of the water chamber (rather than the inlet), and is described as preventing water spills that result from waves created by airflow (rather than waves created by user tipping), a skilled artisan would have recognized that the addition of a tube to a horizontal opening would have prevented water from spilling through the horizontal opening, regardless whether the opening was an inlet or an outlet, and regardless whether the water movement was caused by air flow or by physical movement of the chamber. (RMD1003 at ¶¶ 71-79.) A skilled artisan would have understood that adding a tube to the inlet of the H200 water chamber would have addressed the HC200 Manual’s concern that “moving or tilting the HC200 when the Humidification Chamber is full of water” could result in water entering the blower. (RMD1015 at 9; RMD1003 at 71-79; *see also* RMD1012 at 1.) Indeed, Hebblewhite expressly states that “[i]t should be appreciated that the idea of spacing the outlet aperture, in this case the aperture 50 of the tube 48, away from the humidifier is of general applicability, and may be used in other humidifiers, regardless of whether the humidifiers are formed with elongate passageways.” (RMD1004 at 5:17-22.) The reasons for modifying the HC200 water chamber in this manner are described in detail in Expert Alexander Virr’s declaration. (RMD1003 at ¶¶ 69-79.) As described in additional detail by Expert Virr in his declaration, a skilled artisan would have been

'197 Patent Claims	Exemplary Disclosure of HC200 Manual and Hebblewhite
	prompted to modify the HC200 water chamber to include a tube in at least one of two ways: (1) as an attachment that includes a tube portion that slides into the water chamber inlet port from outside, and that also includes a lip to engage the outside of the inlet port, to keep the tube portion from sliding all of the way into the chamber (similar to the design shown in Hebblewhite), and (2) as a tube that is integrally formed to the inlet port of the water chamber, similar to how the tube at the outlet of the HC200 water chamber is integrally formed with the water chamber. (RMD1003 at ¶¶ 80-83.) The modified HC200 chambers disclose the claim language under the broadest reasonable interpretation standard.

C. *HC200 Manual in view of Hebblewhite, Gouget, and Rose renders claims 2 and 3 obvious*

84. I understand that claim 2 recites that "said flow tube extends for a distance of at least a quarter of the diameter of said water chamber" and that claim 3 recites that "said flow tube extends to approximately the middle of said chamber." The Hebblewhite reference does not describe how long to design tubes when those tubes are used to prevent against spilling that results from tipping instead of the less-severe waves that are created when air flows through a water chamber, but I believe that it was a typical design process to select a length of tube that minimized the possibility of water spilling out of a liquid chamber, as shown by the Gouget reference. Gouget describes a liquid chamber in which it is also undesirable for liquid to spill out of the chamber (in this case because the chamber

is a portable urinal), and Gouget explains that the tube should be designed to terminate near the "volumetric center" of the chamber so that no matter which way the chamber is tipped, water is unlikely to enter the tube (assuming that the chamber is not filled to the volumetric center in the first place). RMD1006 at Figures 1; 7A-D; 1:10-20; 2:36-39; 3:36-52; 5:53-59; 8:37-42; *see also* RMD1007 at 25, 27, FIG. 1. I believe that a skilled artisan would understand Gouget's "volumetric center" teachings to mean that the tube should extend to the middle of a chamber if the chamber is generally symmetrically shaped.

85. Given these teachings, I believe that a skilled artisan would have been prompted to design the tube that is attached to the inlet port in the modified HC200 water chamber so that the tube extends to the horizontal mid-point of the water chamber. Gouget's "volumetric center" language suggests that the end point of the tube should terminate at the vertical midpoint in the chamber, and this makes sense for a urinal as it maximizes the container's resistance to spill. But in a humidifier, dropping the inlet tube to the volumetric center of the container is not sensible due to the wave action it would promote (as taught by Hebblewhite). Indeed, the HC200 water chamber inlet appears to have been located by its designers high enough above the water level to protect against wave action. As such, a humidifier designer that adds a tube that extends to the middle of the water chamber may be forced to accept less complete protection against spill back than is taught by

Gouget to protect against wave action, by locating the added tube a reasonable distance above the water, for example, at the height at which the inlet was originally designed. Since chambers were designed to hold a good amount of water, this places the horizontal tube near the top of the water chamber. Furthermore, a skilled artisan may view the greater water capacity permitted with a high inlet port a beneficial tradeoff to placing the end of the tube at the vertical midpoint.

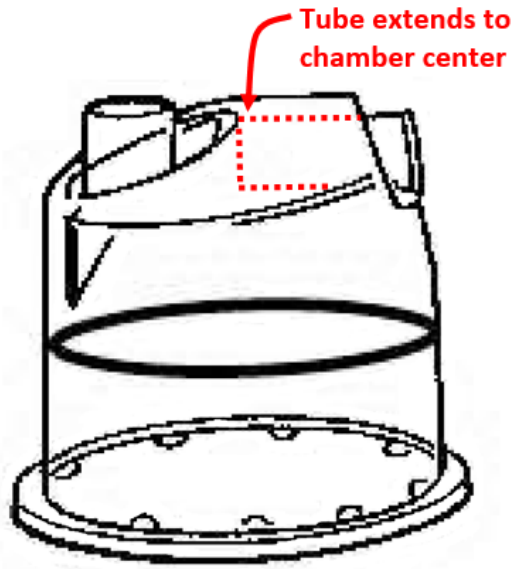
86. I believe that skilled artisans would have understood that there was a benefit to encouraging air passing from the inlet port to the outlet port in humidification chambers to flow over as much of the surface of the water as possible to encourage humidification, and believe that skilled artisans would have been familiar with the common practice of including one or more baffles in humidification chambers to encourage such mixing. Indeed, the Rose reference describes that its baffle 34 "promotes the flow of air therethrough in a[n] . . . indirect path." RMD1008 at 2:7-11; *see also* 3:17-22; 4:24-30; 4:55-66. Given the general knowledge and skill of those in the art regarding baffles, as evidenced by the Rose reference, I believe that a skilled artisan would have seen a reason to have included at least one baffle in the HC200 Manual's modified water chamber between the inlet tube and the outlet port, so that the air takes an "indirect path" from the inlet tube to the outlet port.

87. Rose explains that its baffle may be "formed integrally with the body" and I believe that skilled artisans would have seen a reason to design a baffle in the modified HC200 Manual's chamber in the same manner, at least because of Rose's teaching and because the HC200 outlet port is already formed integrally with the plastic shell of the chamber. RMD1008 at 2:9-17. Moreover, while Rose's baffle "extends between the upper and lower panels" from ceiling to floor, one skilled in the art would have appreciated that it is only thus formed in Rose because Rose's chamber is made by blow molding, which is a process that requires that form of baffle construction, whereas the HC200 water chamber is injection molded, permitting a simple baffle in the form of a rib. Designing the HC200 water chamber to include this feature would promote an indirect air path between the inlet tube and the outlet port.

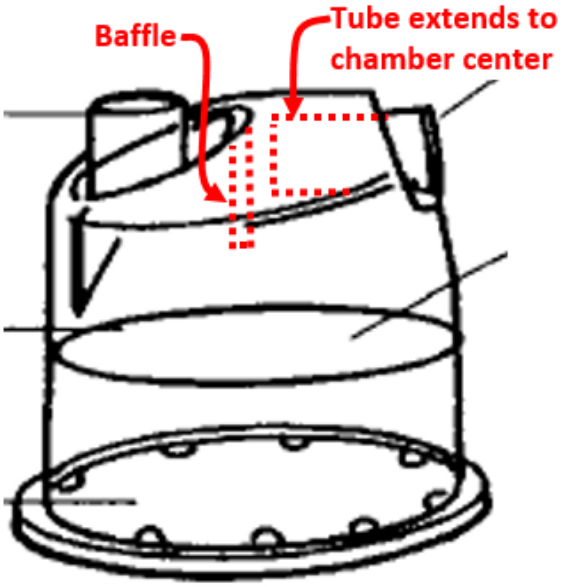
88. I understand that the Petitioners have prepared the following claim chart for the '197 Petition to show how each element of claims 2 and 3 is disclosed by the HC200 manual in view of Hebblewhite, Gouget, and Rose. Based on my review of the HC200 Manual, Hebblewhite, Gouget, Rose, and the '197 patent and file history, I agree that each element of claims 2 and 3 of the '197 patent is disclosed by the HC200 Manual, Hebblewhite, Gouget, and Rose. I further agree that the Petitioners' claim chart accurately demonstrates the correspondence between the elements of claims 2 and 3 and exemplary disclosure from these

references. As demonstrated by my analysis concerning the HC200 Manual, Hebblewhite, Gouget, and Rose, it is my opinion that these references render obvious claims 2 and 3 of the '197 patent.

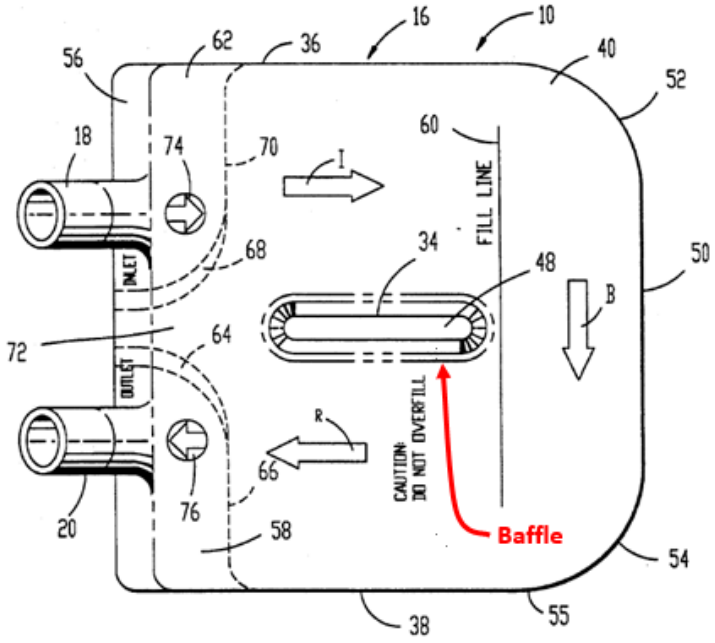
'197 Patent Claims	**Exemplary Disclosure of HC200 Manual, Hebblewhite, Gouget, and Rose**
Claim 2: A water chamber as claimed in claim 1 wherein said flow tube extends for a distance of at least a quarter of the diameter of said water chamber	Hebblewhite discloses that the tube at the water chamber aperture should space the aperture "at least 2 cm away from the end wall" to protect the aperture from waves created by air moving within the chamber, but does not explain how long a tube should be to protect against other types of waves, such as those that result when the water chamber is tipped. (RMD1004 at 5:15-16.) Selecting the length of a tube to protect an opening from water entry due to tipping, however, was traditionally known in the design of liquid containers. For example, Gouget discloses a "urinal . . . with a detachable anti-backflow element having an interior end located at the volumetric center of the urinal." (RMD1006 at Abstract; *see also* RMD1007 at 25, 27, FIG. 1.) In Gouget, it is an "object of the present invention to prevent spillage from the urinal at any angle of tilt when the contents of the urinal are below the fill indicator level." (RMD1006 at 2:36-39; RMD1007 at 25 ("Its anti-backflow system . . . permit[s] turning said urinal in any direction when normally filled without its contents escaping"); *id* at 13-36.) In other words, Gouget teaches that it is advantageous to design the tube so that the end of the tube is near the center of the chamber so that fluid cannot enter the tube no matter how the chamber is positioned (as long as the chamber was not filled to the tube in the first place). It would have been apparent to a skilled artisan, in view of the teachings of Gouget, to have designed the tube at the inlet of the HC200 water chamber (an obvious modification, as already explained with regard

’197 Patent Claims	Exemplary Disclosure of HC200 Manual, Hebblewhite, Gouget, and Rose
	to claim 1) to extend to the middle of the water chamber, because extending the tube to the middle places the tube near the volumetric center while still maintaining the maximum water fill level, and also maintaining the tube-to-water spacing that was designed into the HC200 water chamber in order to prevent undue wave action, as Expert Alexander Virr explains in his Declaration. (*See* RMD1003 at ¶¶ 84-85.) The modification to the HC200 water chamber to design the inlet tube to extend to the middle of the chamber discloses that “said flow tube extends for a distance of at least a quarter of the diameter of said water chamber.”  ***HC200 Manual at 5 (modified to show interior tube)***

Moreover, to the extent that some of the air that enters the chamber through the inlet tube would exit through the outlet without circulating through the chamber, a skilled artisan would have considered it an obvious modification to have added a baffle between the inlet tube and the outlet, to ensure additional circulation of air, at least because it was traditionally known to implement a baffle between an inlet and an outlet in CPAP humidifiers for this purpose. Indeed, Rose



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



Rose at Figure 2

’197 Patent Claims	Exemplary Disclosure of HC200 Manual, Hebblewhite, Gouget, and Rose
	describes a CPAP humidification chamber in which “pressured air from the CPAP device 12 is thus circulated through the humidifier 10 for subsequent delivery to the patient through air hose 26 to mask 28.” (RMD1008 at 3:1-4.) Rose’s humidification chamber 10 includes an inlet 18, an outlet 20, and an “elongate baffle 34” that “promotes the flow of air therethrough in a U-shaped or other indirect path.” (RMD1008 at 2:7-11; *see also* 3:17-22; 4: 24-30; 4:55-66 (emphasis added).) A skilled artisan would have understood from Rose that it was desirable to add a baffle that “promotes the flow of air therethrough in a[n] . . . indirect path,” and therefore would have been motivated to add a baffle that limited the amount of air that could flow from the inlet tube directly to the outlet, as Expert Alexander Virr explains in his declaration. (RMD1008 at 2:7-11; *see* RMD1003 at ¶¶ 86-87.) Given Rose’s teaching that the “baffle is formed integrally with the body” (RMD1008 at 2:13-17), a skilled artisan would have seen a reason to integrally form the baffle to the water chamber ceiling, as Expert Alexander Virr explains in his Declaration. (*See* RMD1003 at ¶¶ 86-87.)
Claim 3: 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	The modification to the HC200 water chamber to design the inlet tube to extend to the middle of the chamber (as discussed above with regard to claim 2) discloses that “said flow tube extends to approximately the middle of said chamber.” Regarding the “said gases inlet and said flow tube are aligned radially” language, this feature is disclosed under the BRI standard regardless whether the added tube is an attachment that slides into the inlet, or is a tube that is integrally formed with the inlet port.

D. *HC200 Manual in view of Hebblewhite and Smith renders claim 6 obvious*

89. I understand that claim 6 recites "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." A skilled artisan would have understood that the HC200 water chamber disclosed a transparent plastic shell that was open at the bottom, because the manual shows at pages 1 and 7 that the chamber is transparent and explains at page 12 that the chamber is made of "plastic" and has a "metal base." RMD1015 at 1, 7 and 12; *see also* RMD1012 at 1, 2, 5, 6.

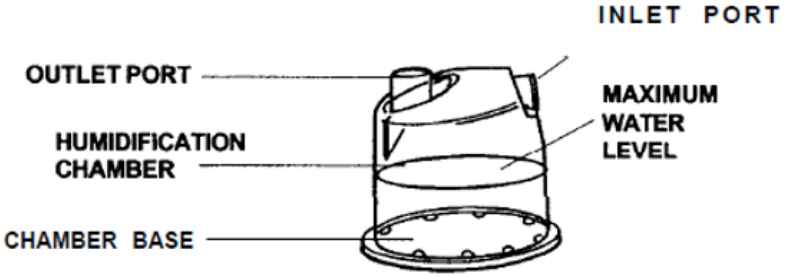
90. It further would have been apparent to skilled artisans that the bottom of the chamber is a heat conductive plate that is sealed at its periphery to the flange, because the HC200 Manual shows at page 5 that the water chamber sits on a "heater plate" and explains that the chamber has a "metal base." RDM1015 at 12; *see also* RMD1012 at 2 and 5. Regardless, the Smith reference shows such features in greater detail. For example, Smith describes a chamber that is formed as a "watertight vessel 2 with a heat conductive base 3," where the side walls of the vessel have a "flange 22" to which the sidewalls are mounted to the base 3. RMD1009 at 2:9-17. Smith describes that a "seal 13 is provided between the heat conductive base 3 and the vessel 2."

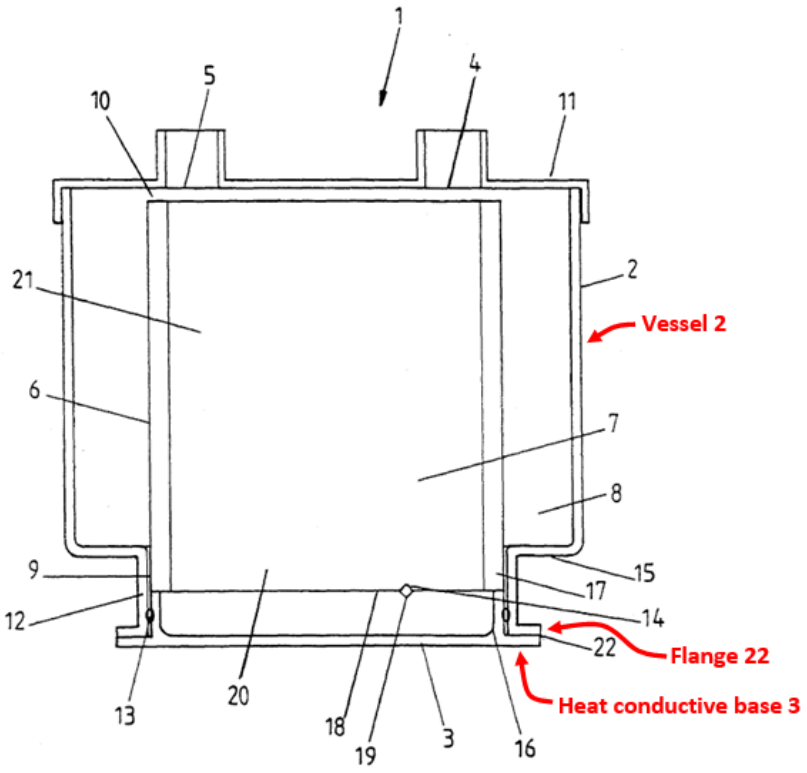
91. I believe that skilled artisans would have seen a reason to have designed the water chamber that is shown in the HC200 manual so that the plastic shell was open at the bottom and had a peripheral flange, and also so that a heat conductive plate enclosed the bottom of said shell and was sealed at its periphery to the flange, because this is what the HC200 manual reasonably shows, because the Smith reference shows any features that may not be presented in as detailed of a manner in the HC200 manual, because Smith is also describing a Fisher & Paykel water chamber, and because Smith expressly notes that its design provides a watertight seal between the plastic shell and heater base in a water chamber and a watertight seal is a desirable feature in a water chamber.

92. I further believe that the HC200 water chamber that has been modified to include the tube attachment (as described above) discloses that the tube attachment is fitted at the inlet, because the tube attachment would be sized to the dimensions of the inlet, in order to provide a secure fit with the HC200 outlet and in order to prevent water from leaking between the exterior of the tube and the periphery of the inlet.

93. I understand that the Petitioners have prepared the following claim chart for the ’197 Petition to show how each element of claim 6 is disclosed by the HC200 manual in view of Hebblewhite and Smith. Based on my review of the HC200 manual, Hebblewhite, Smith, and the ’197 patent and file history, I agree

that each element of claim 6 of the ’197 patent is disclosed by these references, and I further agree that the Petitioners’ claim chart accurately demonstrates the correspondence between the elements of claim 6 and exemplary disclosure from the HC200 manual, Hebblewhite, and Smith. As demonstrated by my analysis concerning the HC200 manual in view of Hebblewhite and Smith, it is my opinion that the HC200 manual in view of Hebblewhite and Smith renders obvious claim 6 of the ’197 patent.

’197 Patent Claims	Exemplary Disclosure of HC200 Manual, Hebblewhite, and Smith
Claim 6: 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	The HC200 Manual discloses that the water chamber comprises a transparent plastic shell. (*See* RMD1003 at ¶ 89.) For example, the illustration on page 5 (shown below), shows how the chamber is transparent. Moreover, the HC200 Manual describes that the chamber is made of “plastic.” (RMD1015 at 12; *see also* RMD1012 at 2 (emphasis added).)  *HC200 Manual at page 7 (portions omitted)* The HC200 Manual does not discuss that the plastic shell is “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,” but a skilled artisan would have understood that the plastic shell was open at the bottom because the HC200 Manual indicates that the bottom is not plastic

'197 Patent Claims	Exemplary Disclosure of HC200 Manual, Hebblewhite, and Smith
	but is a "metal base." (RMD1015 at 12; *see also* RMD1012 at 2; RMD1003 at ¶¶ 89-90.) The illustrations at pages 1 and 5 further show how the bottom of the water chamber is flanged. To the extent that additional disclosure regarding this style of water chamber construction is helpful, other prior art references show that it was traditionally known for a water chamber shell to be open at the bottom, have a peripheral flange, and have a heat conductive plate that encloses the bottom of the shell and that is sealed at its periphery to the flange. For example, the Smith reference discusses "humidifier chambers for use with heated humidifier bases." (RMD1009 at 1:6-8.) Smith  ***Smith at Figure 1*** discusses that "humidification chamber 1 is formed as a closed watertight vessel 2 with a heat conductive base 3, for conducting heat from the heater base to liquid placed in the humidification chamber 1." (RMD1009 at 2:12-

'197 Patent Claims	Exemplary Disclosure of HC200 Manual, Hebblewhite, and Smith
	15.) Smith notes that the vessel 2 includes an "outwardly extending flange 22" and explains that "[t]o ensure that the chamber is watertight with the heated conductive base 3 in place, a seal 13 is provided between the heat conductive base 3 and the vessel 2." (RMD1009 at 2:14-15; 3:23-26.) A skilled artisan would have seen a reason to have designed the HC200 water chamber so that the plastic shell had a peripheral flange, so that a heat conductive plate enclosed the bottom of the plastic shell, and so that it was sealed at its periphery to the flange (all disclosed by Smith) in order to implement the water chamber flange that is shown is lesser detail in the HC200 Manual, and in order to provide a mechanism to "ensure that the chamber is watertight with the heated conductive base" (RMD1009 at 3:23-26; *see* RMD1003 at ¶ 91.) Indeed, a skilled artisan would have understood that the Smith reference was assigned to Fisher & Paykel Limited, and therefore would have been a particularly relevant reference to consider when designing a water chamber that was based on the disclosure of the Fish &Paykel HC200 Manual. (*See* RMD1003 ¶ at 91.) The reasons for a skilled artisan to have modified the HC200 water chamber to include the chamber design disclosed by Smith (at least for the exterior portion of the chamber, to the extent any modification is needed) are described in detail in Expert Alexander Virr's declaration. (*See* RMD1003 at ¶ 91.) Finally, the HC200 Manual's modified water chamber discloses that "said elongate flow tube comprises a tubular extension tube member fitted at said gases inlet." Indeed, the HC200 water chamber would have a tubular extension tube attachment inserted into and fitted at the inlet. (RMD1003 at ¶ 92.)

E. *The HC200 Manual in view of Hebblewhite, Gouget, Rose, and Smith renders claim 13 obvious*

94. I understand that claim 13 includes the same language as claim 6, but that claim 13 depends from claim 3 instead of claim 1. For substantially the same reasons discussed above in connection with claim 6, I believe that it would have been obvious in view of the listed combination of references to modify the water chamber shown by the HC200 manual to disclose the subject matter of claim 13.

F. *Netzer in view of Smith and Hebblewhite renders claims 1 and 6 obvious*

95. I understand that claim 1 recites a water chamber adapted for use in conjunction with a heater base and having a horizontally oriented gases inlet in a wall thereof, and believe that Netzer expressly discloses all of these features except the heater being a "base." Regarding the water chamber feature, Netzer describes a humidifier that includes a "liquid container functioning as a liquid reservoir" and in which "a water supply is gradually vaporized." RMD1010 at 2 and 3. Regarding the horizontally oriented gases inlet feature, Netzer shows how the liquid reservoir includes a horizontally oriented gas inlet. For example, the figures show the container inlet 22 and container outlet 23 (which receive and provide gas through "flow path 6b") as being horizontally oriented. Specifically, Figure 4

shows outlet 23 as being horizontally oriented and obscuring outlet 22, which would therefore also be horizontally oriented.

96. Regarding the heater base feature, Netzer describes that the "base humidifier has a heating unit, not shown in greater detail, disposed in the region of the liquid container 9 for generating steam." RMD1010 at 10. I believe that a skilled artisan would have understood Netzer to be referring to a heater base unit, because Netzer's disclosure of "lateral guide profiles 26" (shown in the side view in Figure 3) indicate a mechanism for retaining the liquid reservoir in firm contact with a heating base, which was typically employed in humidifiers with heater bases so that adequate heat transfer between the base and chamber occurred.

97. Regardless, the Smith reference shows a heater base for a CPAP humidifier (see at least 1:6-8 and 2:9-16 of RMD1010), and I believe that a skilled artisan would have seen a reason to have modified Netzer's teachings so that the heated humidifier described in Netzer used a heater base, and so that the water chamber had a heat conductive base to transfer heat from the heater base to the water in the chamber, at least because heater bases were typically used at the time to warm water in CPAP humidifiers, because Netzer's sideways-insertion design would have indicated to a skilled artisan that it used a heater base, and because Netzer describes how such a design provide a mechanism "for conducting heat

from the heater base to liquid placed in the humidification chamber." RMD1010 at 2:9-16.

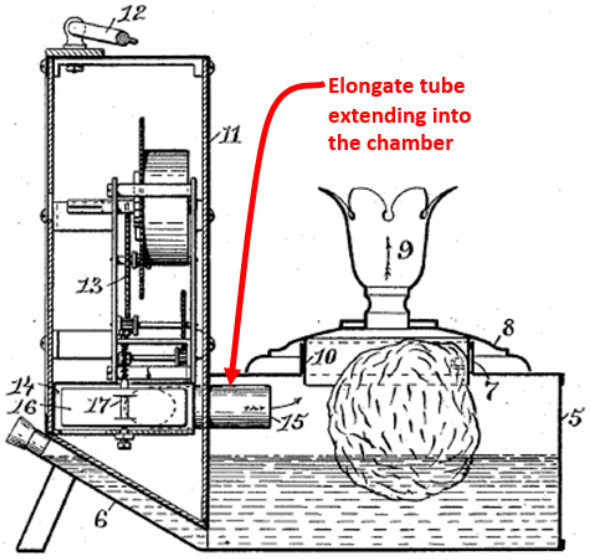
98. I understand that claim 1 further recites "the improvement comprising an elongate flow tube extending into said water chamber from the inner periphery of said gases inlet, an inlet end of said elongate flow tube covering said inlet and an outlet end of said flow tube being spaced from the wall of 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." Skilled artisans would have recognized that this claim feature is shown by tube 48 in the Hebblewhite reference (although tube 48 is positioned on the outlet rather than the inlet, as recited by the claim). Indeed, Hebblewhite discloses that a "tube 48" spaces aperture 50 away from end wall 46 of the water chamber in order to reduce "the danger of water spilling into the air outlet 6." RMD1004 at 5:3-16; *see also* 3:33-40; 3:47-50; 5:5-8; 5:5-22.

99. I believe that a skilled artisan would have been motivated to modify Netzer's water chamber so that it included in its water chamber a tube at inlet 22 and a tube at outlet 24, in order to ensure that "no water drops are carried over into the respiratory gas lines," which is a concern that is expressed by Netzer. RMD1010 at 6-7. Indeed, although Netzer is worried about water drops entering the gas lines, I believe that skilled artisans would have recognized that Netzer's

solution to its concern (a drainage spout 20) only addresses the problem of excess water in the gas lines due to overfilling, but would not address the ability of water to enter the gas lines if tipped or bumped by a user.

100. As explained earlier, it is undesirable for water drops to enter the respiratory gas lines, and water can enter the respiratory gas lines through inlet 22 in addition to through the outlet 23. *See* RMD1010 at 6-7 and 9. Skilled artisans would have recognized that water entering inlet 22 could flow back into the "respiratory gas source 2 . . . formed by a blower" (RMD1010 at 7) and harm the blower if the device was tipped while the blower was off. Further, if the device was tipped while the blower was off and the "second flow path 6b" was open, water could fill the flow guiding element 3 and then, if the user opened the "first flow path 6a," the CPAP device would supply gas (and the water in the gas lines) down the "first flow path 6a" to the mask that is worn by the user.

101. I further believe that skilled artisans would have seen a reason to have modified Netzer's water chamber to include tubes at the water chamber openings (as shown by Hebblewhite), because it was known that adding a tube at the inlet of a liquid chamber could prevent liquid from spilling out of the chamber. As a first example, Figure 2 of the Lynch reference cited during prosecution shows such an inlet tube 15. RMD1017 at Fig. 2. As another example, the Gouget reference describes a portable urinal chamber that includes an "anti-backflow element" that can "prevent spillage from the urinal at any angle of tilt when the contents of the urinal are below the fill indicator level." RMD1006 at 2:29-39; *see also* RMD1007 at 25. As a third example, skilled artisans would have known that the inlet and outlet ports of the Sullivan HumidAire water chamber included



***Lynch* at Figure 2**

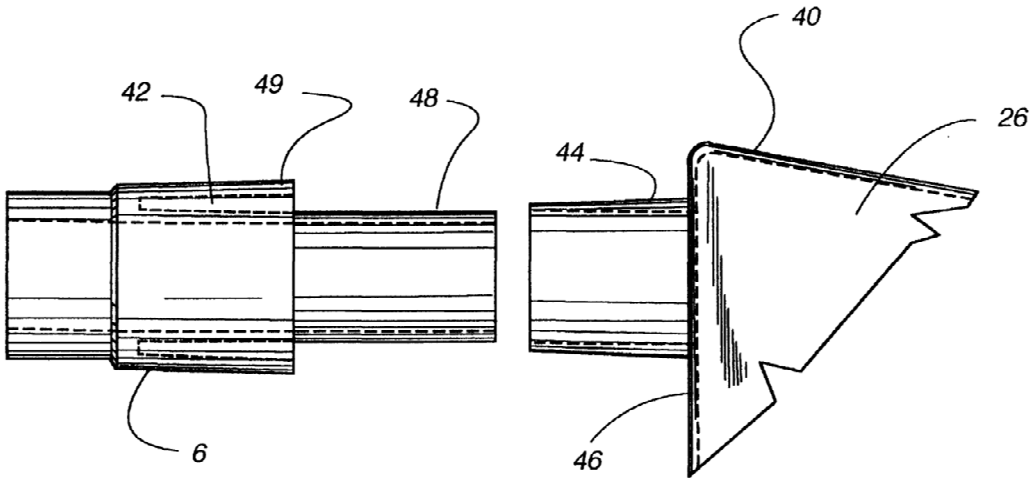
tubes that extended to the interior of the water chamber, as shown in a 1997 brochure of the HumidAire product. *See* RMD1020 at 2 and 3 (showing the transparent water chamber at the bottom right of each page).

HumidAire Brochure at 3

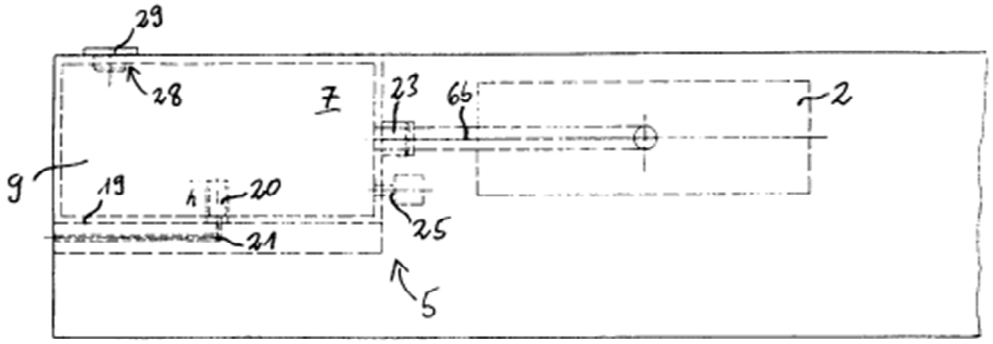
102. These teachings demonstrate that skilled artisans would have readily recognized how Hebblewhite's tube could have been applied to an inlet of a water chamber in order to prevent water from leaving the water chamber when the device was tipped, which further solidifies my opinion that skilled artisans would have been motivated to add a flow tube to the inlet port in the water chamber shown by Netzer.

103. Given the reasons that I previously described to add a tube to the inlet and outlet of Netzer's water container, I believe skilled artisans would have seen reasons to add the tubes in at least two ways. First, I believe that skilled artisans would have seen reasons to include the tubes as attachments that were inserted into the inlet 22 and outlet 23 from the outside, because Hebblewhite shows such an attachment mechanism. For example, Figure 2 of Hebblewhite shows a close up of

the attachment that includes tube 48 and the mechanism that retains the tube 48 in place. Hebblewhite describes the entire attachment (including tube 48 and the retaining mechanism) "as an outlet attachment 42 which is attached to a circular tube 44 which projects outwardly from the end wall 46 of the fourth subpassageway 26. The outlet attachment 42 is provided with a tube 48 which projects through the circular tube 44 and into the fourth subpassageway 26, the tube 44 being gripped between the outer surface of the tube 48 and the inner surface of an outer skirt portion 49." (RMD1004 at 4:63-5:8.)



RMD1004 at Figure 2. Hebblewhite's outwardly-extending circular tube 44 (through which the attachment is inserted) is similar to Netzer water container's outwardly-projecting inlet 22 and outlet 23, as shown in the below figure.



RMD1010 at FIG. 4. As such, I believe that skilled artisans motivated to add an tubes to the interior of humidification chambers openings due to Hebblewhite's teachings would have seen a reason to implement the tubes using an attachment mechanism that was similar to that illustrated by Hebblewhite's attachment 42. Skilled artisans would have considered it unnecessary for the attachment to Netzer's water chamber to include a hose-connecting portion of the attachment (as shown by the left-most unlabeled portion of Hebblewhite's attachment 42 in the above picture). Skilled artisans would have understood that Hebblewhite's attachment 42 included the left-most portion of attachment 42 so that a hose could connect to the humidifier chamber, but Netzer's device does not require such tubes to connect the humidification chamber to the rest of the CPAP device. I believe that skilled artisans would have considered designing the dimensions of the inlet 22 or outlet 23 and the attachments added thereto so that the inlet 22 and outlet 23 (with the added tube attachments) adequately sealed with other components of flow path 6b.

104. As a second way to add tubes to Netzer's water chamber inlet and outlet, I believe that skilled artisans would have seen a reason to have molded Netzer's water chamber so that the tubes at the inlet 22 and the outlet 23 were integrally formed with the rest of the chamber, at least because the outwardly-facing protrusions at inlet 22 and outlet 23 are already shown to be integrally formed with the chamber, and at least because integral construction would ensure that there was no risk of water leaking at a junction of the attachments and inlet 22 and outlet 23. Molding the chamber so that the tubes at the inlet 22 and outlet 23 extended into the chamber, rather than just out of the chamber (as shown in the figures), would have been within the skill level of skilled artisans at the time.

105. I believe that both of the above-described modifications to the Netzer water container would have disclosed under the broadest reasonable interpretation standard the claim feature of an "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." As such, I believe that it would have been obvious to have modified

the teachings of Netzer in view of Smith and Hebblewhite to disclose the features of claim 1 of the '197 patent.

106. I understand that claim 6 recites "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." Netzer describes a liquid container 9, but does not specify the materials of which it is made. As I previously discussed, I believe that skilled artisans would have recognized that liquid container 9 would have been heated by a heat plate and thus that the container would include a heat conductive base.

107. The Smith reference describes a chamber with a heat conductive base and describes how a heat conductive base may be formed to the rest of the chamber. Specifically Smith describes that the chamber is formed as a "watertight vessel 2 with a heat conductive base 3," where the side walls of the vessel have a "flange 22" to which the sidewalls are mounted to the base 3. RMD1009 at 2:9-17. Smith describes that a "seal 13 is provided between the heat conductive base 3 and the vessel 2." RMD1009 at 3:24-26.

108. I believe that skilled artisans would have seen reasons to have designed the water chamber that is shown by Netzer to include a shell that was

open at the bottom and that had a peripheral flange, to include a heat conductive plate enclosing the bottom of the shell, and so that it was sealed at its periphery to the flange, because Smith shows a suitable water chamber that is able to be heated by a heater plate, and because Smith expressly notes that its design provides a watertight seal between the plastic shell and heater base in a water chamber, and a watertight seal is a desirable feature in a water chamber.

109. While the Netzer and Smith references do not expressly mention whether the water chamber shell is made of plastic, I believe that skilled artisans would have understood that plastic was often employed in the construction of water chambers and would have been a reasonable design choice. Indeed, using a transparent plastic allowed patients to view the water level and see whether the chamber needed to be refilled. Further, Smith discloses that an interior wall of Smith's chamber is made of Plexiglass, and skilled artisans would have understood that Plexiglass is a type of plastic and that the exterior chamber walls could also have been made of Plexiglass or a similar type of plastic. RMD1009 at 3:15-17.

110. I believe that a skilled artisan would have understood that the water chamber that is shown by the Netzer reference could have incorporated aspects of Smith's heat conductive plate and its sealing with the flange of the plastic shell without affecting the placement or functioning of inlet 22, outlet 23, or the drainage spout. Moreover, Smith's flange 22 (which seals the heat conductive

base 3 to the sides of the water chamber) provides a mechanism to guide Netzer's liquid container 9 into the humidifier housing 8, and I believe that a skilled artisan would have understood that it would have been a simple design choice to use the flanges 22 instead of or in addition to Netzer's guide profiles 26, so that "the insertion of the liquid container 9 in the humidifier housing 8 is facilitated." RMD1010 at 10.

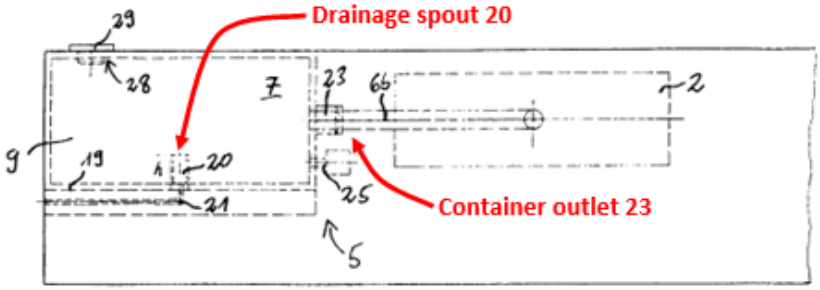
111. I further believe that the modified Netzer water chamber (with the tube attachments inserted into the inlet 22 and outlet 23, as described above) discloses that a tube attachment would be fitted at the inlet, because the tube attachment would be sized to the dimensions of the inlet in order to prevent water from leaking between the exterior of the tube and the periphery of the inlet.

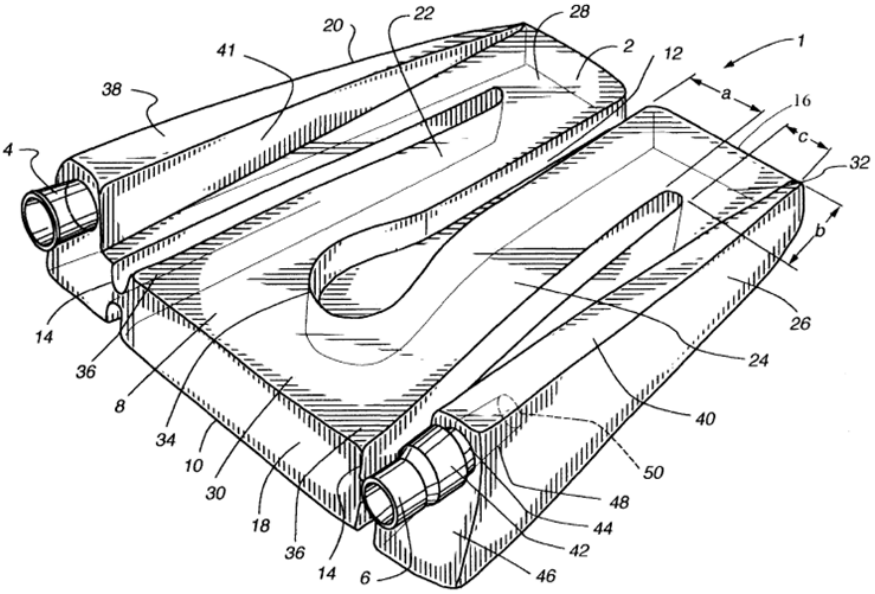
112. I understand that the Petitioners have prepared the following claim chart for the '197 Petition to show how each element of claims 1 and 6 is disclosed by Netzer in view of Smith and Hebblewhite. Based on my review of Netzer, Smith, Hebblewhite, and the '197 patent and file history, I agree that each element of claims 1 and 6 of the '197 patent is disclosed by Netzer in view of Smith and Hebblewhite, and I further agree that the Petitioners' claim chart accurately demonstrates the correspondence between the elements of claims 1 and 6 and exemplary disclosure from Netzer, Smith, and Hebblewhite. As demonstrated by

my analysis concerning these references, it is my opinion that Netzer in view of Smith and Hebblewhite renders obvious claims 1 and 6 of the '197 patent.

'197 Patent Claims	Exemplary Disclosure of Netzer, Smith, and Hebblewhite
Claim 1 (first limitation): In a water chamber adapted for use in conjunction with a heater base and having a horizontally oriented gases inlet in a wall thereof	Netzer's liquid container 9 is adapted for use in conjunction with a heater base and has a horizontally oriented gases inlet in a wall thereof, as described below. Water chamber: Netzer explains that its humidification container 7 holds water. (RMD1010 at 2 ("Because the humidifier has a heating unit, by means of which a water supply is gradually vaporized.").) Horizontally oriented gases inlet: As described above, Netzer shows in Figure 4 how outlet 23 is horizontally oriented in a wall of the liquid container 9. The inlet 22 is hidden behind the outlet 23 in Figure 4, but Figure 1 shows how inlet 22 is horizontally oriented in the wall of the liquid container 9. (RMD1010 at Figs 1, 2, and 4.) Heater base: Netzer explains that "[t]he base humidifier has a heating unit, not shown in greater detail, disposed in the region of the liquid container 9 for generating steam." (RMD1010 at 10; *see also id.* at 2.) Netzer does not explicitly describe its "heating unit" as a "heater base," but it is likely that the "heating unit" was a heater base because heater bases were traditionally employed in prior art CPAP devices, as evidenced by the Smith reference, which relates to "humidifier chambers for use with heated humidifier bases." (RMD1009 at 1:6-8 (emphasis added).) Smith discusses that its "humidification chamber 1 is formed as a closed watertight vessel 2 with a heat conductive base 3, for conducting heat from the heater base to liquid placed in the humidification chamber 1." (RMD1009 at 2:9-16 (emphasis added).)

’197 Patent Claims	Exemplary Disclosure of Netzer, Smith, and Hebblewhite
	A skilled artisan would have seen a reason to design Nezter’s CPAP device so that its “heating unit” was a “heater base” (and so that the bottom of the water chamber had a heat conductive base) as disclosed by Smith, because Netzer’s sideways-insertion design would have indicated to a skilled artisan that it used a heater base (because the lateral guide profiles 26 indicate a mechanism for retaining the liquid reservoir in frim contact with a heating base), and because Smith describes how such a design provides a mechanism “for conducting heat from the heater base to liquid placed in the humidification chamber.” (RMD1009 at 2:9-16 (emphasis added); *see* RMD1003 at ¶¶ 96-97). Netzer is silent on the heating feature that it utilizes and a skilled artisan designing a CPAP device based on Netzer’s teachings would necessarily be prompted to select an appropriate heating mechanism from the prior art, and Smith describes an appropriate heating mechanism. Indeed, because this combination of features “‘simply arranges old elements with each performing the same function it had been known to perform’ and yields no more than one would expect from such an arrangement, the combination is obvious.” *KSR Int’l v. Teleflex Inc.*, 550 U.S. 398, 417 (2007). The ’197 patent acknowledges that these features were known. As described previously, the above features are listed in the preamble of the Jepson-style claim 1, and thus were admitted by Applicant to be prior art features. *See* 37 C.F.R. § 1.75(e); *In re Fout*, 213 USPQ 532, 534 (CCPA 1982). Moreover, the “Summary of the Prior Art” section of the ’197 patent explains that humidification systems were already known to include a “heater base,” “slide-on humidifier chambers,” and an “inlet air port . . . consequently provided horizontally through a side of the chamber.” (RMD1001 at 1:10-29.)

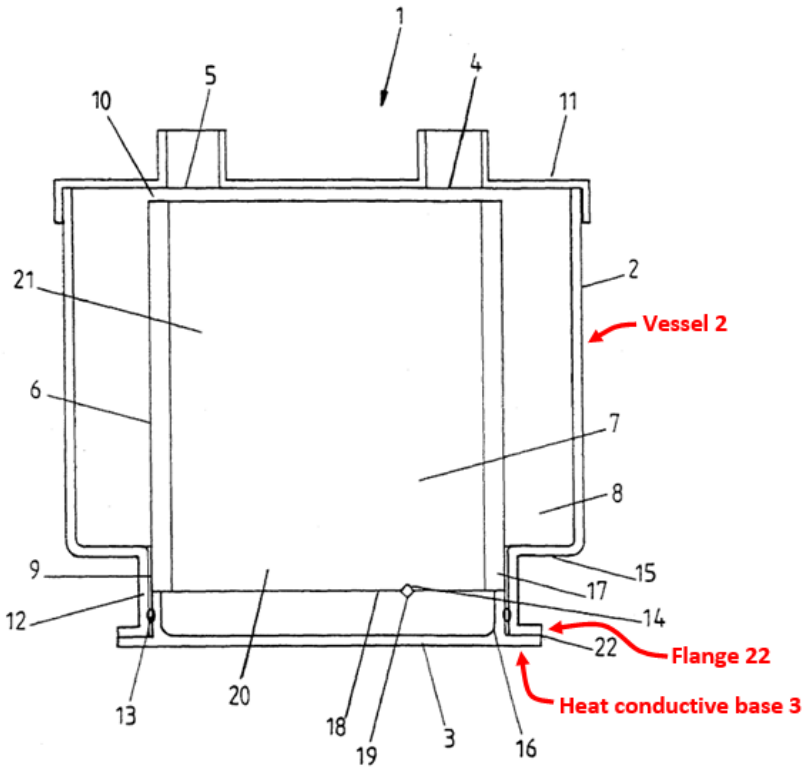
’197 Patent Claims	Exemplary Disclosure of Netzer, Smith, and Hebblewhite
Claim 1 (second limitation): the improvement comprising an elongate flow tube extending into said water chamber from the inner periphery of said gases inlet, an inlet end of said elongate flow tube covering said inlet and an outlet 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	Because Netzer expresses concerns that water could exit the horizontal opening in its water chamber, and because it was traditionally known to add a tube to a horizontal opening to prevent water from spilling out of that opening (as shown by the Hebblewhite reference), it would have been obvious to modify Netzer to include a horizontal tube at its inlet. First some background regarding Netzer’s concerns with water leaving the water chamber. Netzer explains that “the container inlet and the container outlet . . . are preferably disposed at a spacing above the maximum liquid level. By this means, it is ensured that  *Netzer at Figure 4* 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.” (RMD1010 at 6-7.) To keep the water level from exceeding the maximum liquid level, Netzer explains that liquid container 9 includes a “filling limiter” so that “excess liquid is diverted out of gas humidifier by a draining spout 20 disposed on the base 19 of the liquid container 9.” (RMD1010 at 9.) With this configuration, “liquid can thus not be carried along by the respiratory gas into the flow guiding element 3.” (RMD1010 at 9.) As mentioned above, the Hebblewhite reference discloses a CPAP humidifier with a tube at a horizontal opening in order to keep water from spilling through the horizontal opening. In greater detail, Hebblewhite

’197 Patent Claims	Exemplary Disclosure of Netzer, Smith, and Hebblewhite
	discloses a humidifier with “an elongate passageway, extending between the air inlet and air outlet, . . . the passageway being adapted to be partially filled with water so that air passing along the passageway becomes humidified as it passes over the water from the air inlet to the air outlet.” (RMD1004 at 1:52-59.)  ***Hebblewhite at Figure 1*** Hebblewhite includes a tube 48 at its air outlet and explains that the function of tube 48 is to reduce the amount of water that spills into the air outlet: > When the air flow within the passageway creates waves on the surface of the water, it has been found that the water has a tendency to splash against the end wall of the passageway, resulting in a danger of water spilling into the air outlet. It has been found that by spacing the air outlet aperture away from the end wall, the danger of water spilling into the air outlet is greatly reduced. (RMD1004 at 3:33-40; *see also* 3:47-50; 5:5-22.)

'197 Patent Claims	Exemplary Disclosure of Netzer, Smith, and Hebblewhite
	A skilled artisan would have been motivated to modify Netzer's reservoir 9 to include tubes at the inlet 22 and outlet 23, in order to limit the ability of water to spill out of the container through inlet 22 and outlet 23 of the CPAP device. (RMD1003 at ¶¶ 98-102.) Adding tubes would be a simple and inexpensive measure to make sure that "liquid can thus not be carried along by the respiratory gas into the flow guiding element 3" if the CPAP device was bumped or tipped. (RMD1010 at 9; RMD1003 at ¶¶ 98-102.) Indeed, Hebblewhite expressly states that "[i]t should be appreciated that the idea of spacing the outlet aperture, in this case the aperture 50 of the tube 48, away from the humidifier is of general applicability, and may be used in other humidifiers, regardless of whether the humidifiers are formed with elongate passageways." (RMD1004 at 5:17-22.) As described in additional detail by Expert Virr in his declaration, a skilled artisan would have been prompted to modify Netzer's water chamber to include tubes at its inlet 22 and outlet 23 in at least one of two ways: (1) as attachments that included a tube portion that was slid through the inlet 22 or outlet 23 from the outside and that extended into the interior of the chamber (with a protrusion or lip on the end of the attachment to keep the tube from sliding entirely into the chamber, as shown by Hebblewhite), and (2) as tubes that are integrally formed to inlet 22 and outlet 23, just as how the exterior-facing tubes on the Netzer's inlet 22 and outlet 23 are integrally formed with the chamber. (RMD1003 at ¶¶ 103-105; Figs. 1, 2, and 4.)

’197 Patent Claims	Exemplary Disclosure of Netzer, Smith, and Hebblewhite
Claim 6: 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	Netzer shows the liquid container 9 in all four figures,[3] but does not discuss the construction of the container in great detail. Given the lack of detail about the construction of the chamber, a skilled artisan would have been prompted to look to references that described other prior art heated humidification chambers to identify a suitable construction for Netzer’s water chamber. One such reference that discloses “humidifier chambers for use with heated humidifier bases” is Smith, which was discussed in detail with reference to claim 1 for Smith’s disclosure of a “heater plate” and a corresponding heat conductive base on the water chamber. (RMD1009 at 1:6-8.)

[3] Figure 1 (top view with container detached); Figure 2 (top view with container attached); Figure 3 (side view); and Figure 4 (other side view).

’197 Patent Claims	Exemplary Disclosure of Netzer, Smith, and Hebblewhite
	Smith discusses that its “humidification chamber 1 is formed as a closed watertight vessel 2 with a heat conductive base 3, for conducting heat from the heater base to liquid placed in the humidification chamber 1.” (RMD1009 at 2:12-15.) Smith’s watertight vessel 2 includes an “outwardly extending flange 22” to help seal the watertight vessel 2 to the heat conductive base 3, and explains this by noting that “[t]o ensure that the chamber is watertight with the heated conductive base 3 in place, a seal 13 is provided between the heat conductive base 3 and the vessel 2.” (RMD1009 at 3:23-26.)  *Smith at Figure 1* A skilled artisan would have seen a reason to have designed Netzer’s water container 9 to include a plastic shell that is open at the bottom, a bottom having a heat conductive plate, the heat conductive plate enclosing the bottom of the plastic shell, and the heat conductive plate sealing at a flange of the shell (all disclosed by Smith),

'197 Patent Claims	Exemplary Disclosure of Netzer, Smith, and Hebblewhite
	because Netzer is silent regarding the construction of its chamber and heat conductive plate (including how they would be joined) and a skilled artisan would have had to look to other references to implement a water chamber that was adapted to sit on a heater base, and because Smith describes a suitable mechanism that uses a flange to "ensure that the chamber [top portion] is watertight with the heated conductive base." (RMD1009 at 3:23-26.) Reasons for a skilled artisan to have designed Netzer's water chamber to include the above-described features are described in detail in Expert Alexander Virr's declaration. (*See* RMD1003 at ¶¶ 106-111.) Finally, Netzer's modified water chamber discloses that "said elongate flow tube comprises a tubular extension tube member fitted at said gases inlet," as recited by claim 6. Specifically, this feature is disclosed by the modified water chamber that is already described with respect to independent claim 1, which would have tubular extension tube members inserted into inlet 22 and outlet 23. (RMD1003 at ¶ 111.)

G. *Netzer in view of Smith, Hebblewhite, Gouget, and Rose renders claims 2, 3, and 13 obvious*

113. I understand that claim 2 recites that "said flow tube extends for a distance of at least a quarter of the diameter of said water chamber" and that claim 3 recites that "said flow tube extends to approximately the middle of said chamber." The Hebblewhite reference does not describe how long to design tubes when those tubes are used to prevent against spillage that results from tipping, instead of mild waves that are created when air flows through a water chamber, but

I believe that it was a typical design process to select a length of tube that minimized the possibility of water incidentally entering the tube, as shown by the Gouget reference. Gouget describes another scenario in which a patient does not want fluid to escape a liquid reservoir through an inlet (in this case a portable urinal), and Gouget explains that the tube should be designed to terminate near the "volumetric center" of the chamber so that no matter which way the chamber is turned the tube should not get water in its end (assuming that the chamber is not filled to the volumetric center in the first place). (RMD1009 at Figures 1; 7A-D; 1:10-20; 2:36-39; 3:36-52; 5:53-59; 8:37-42; *see also* RMD1007 at 25, 27, FIG. 1.)

114. A skilled artisan would understand this to mean that the tube extends to the middle of the chamber if the chamber is generally symmetrically shaped. Given these teachings, I believe 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 mid-point of the reservoir 7. Gouget indicates that the end point of the tubes should also be located at the vertical midpoint in the chamber, but I believe that a skilled artisan would not have considered lowering the vertical orientation of the inlet 22 and the outlet 23, because the designer of the Netzer reference already selected a suitable height for placing the inlet 22 and outlet 23 above the surface of the water, and because lowering the vertical orientation of the inlet 22 and outlet 23 may increase the wave action on the water. Therefore I believe that a skilled artisan

would have focused on placing Gouget's tube end points near the horizontal midpoint in the chamber.

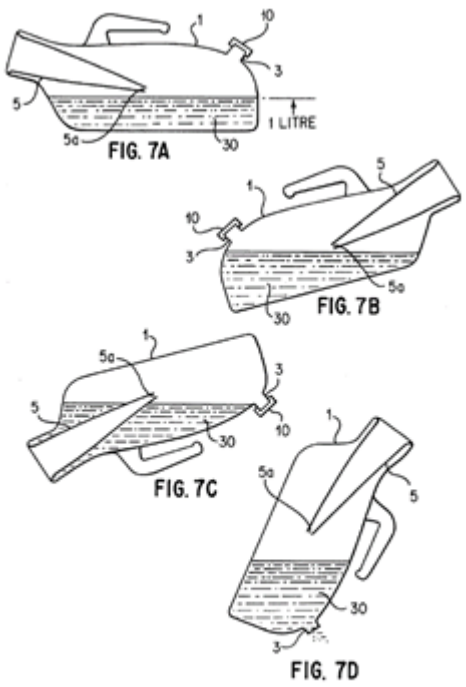
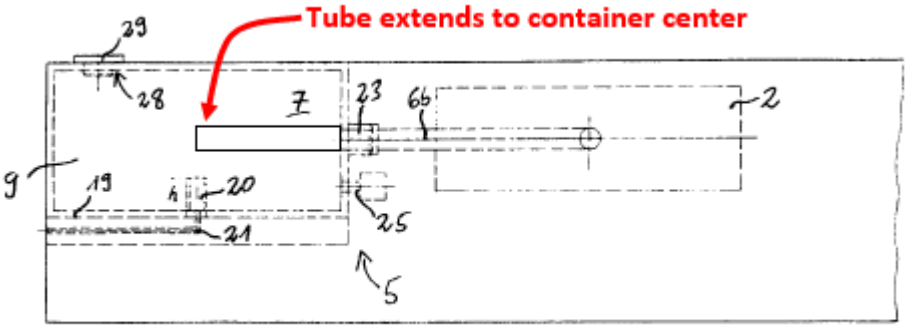
115. In Netzer's unmodified water chamber, some of the air that entered the chamber through the inlet port may flow directly to the outlet port without sufficiently circulating, but I believe that skilled artisans would have recognized that this direct flow may provide sufficient humidification due to the distance between the inlet and outlet ports, because the tubes are relatively close to the water level to encourage humidification, and because Netzer is designed already designed with this configuration. The larger size of the humidification chamber, even if not all to maximize humidification, would be beneficial because of the amount of water that could be stored. I further believe that skilled artisans would have recognized that a similar level of humidification would be achieved in the modified chamber, in which the tubes extended from the inlet and outlet to the middle of the chamber. Regardless Netzer's baffle-less design, I believe that skilled artisans would have been familiar with the common practice of including one or more baffles in humidification chambers to encourage additional humidification. Indeed, the Rose reference describes that its humidifier 10 has a baffle 34 that "promotes the flow of air therethrough in a U-shaped or other indirect path." RMD1008 at 2:7-11; *see also* 3:17-22; 4: 24-30; 4:55-66. Given the general knowledge and skill of those in the art regarding baffles, as evidenced

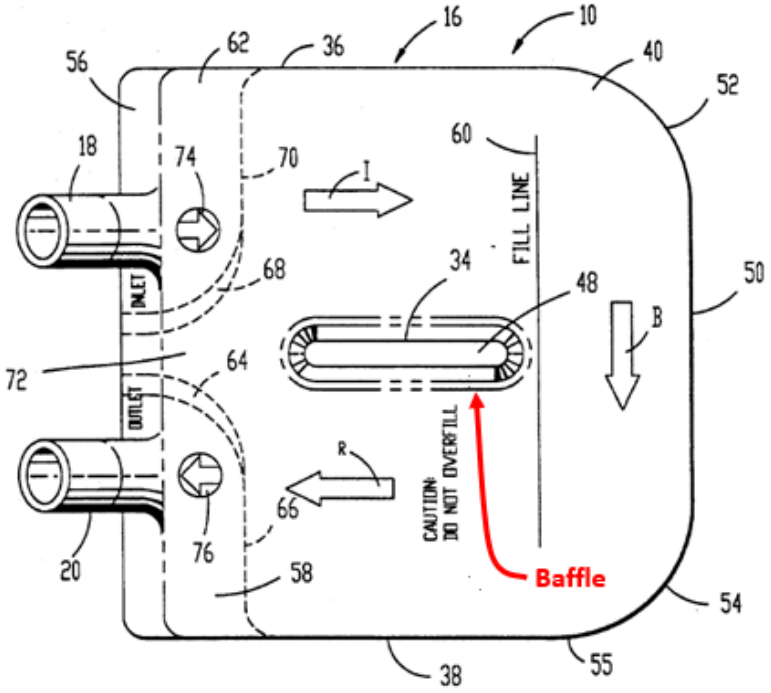
by the Rose reference, I believe that skilled artisans would have seen reasons to have included at least one baffle in Netzer's modified water chamber between the inlet tube and the outlet tube, so that the air coming in through the inlet tube takes an "indirect path" to the outlet port, as explained by Rose to be a benefit to using a baffle. Rose shows that its baffle 34 extends from the ceiling to the floor to create a rib that extends lengthwise between the inlet opening and the outlet opening, and I believe that skilled artisans would have recognized that a similar baffle design would work adequately in Netzer's modified water chamber to provide for sufficient humidification. Moreover, I believe that selecting a baffle design, whether it would be that shown in Rose or another baffle design, would have been a simple matter of design and testing to achieve sufficient humidification, given Rose's teachings that the air is to flow in an "indirect path" to ensure sufficient humidification.

116. Claim 13 includes language that is similar to that in claim 6, and the features recited in claim 13 are disclosed by at least Netzer, Smith, and Hebblewhite, as described above with respect to claim 6. Claim 13 depends on claim 3, and therefore believe that skilled artisans would have considered the combination of features recited in claim 13 (and 3, 2, and 1) to have been disclosed by Netzer in view of Smith, Hebblewhite, and Gouget.

117. I understand that the Petitioners have prepared the following claim chart for the ’197 Petition to show how each element of claims 2, 3, and 13 is disclosed by Netzer in view of Smith, Hebblewhite, and Gouget. Based on my review of these references and the ’197 patent and file history, I agree that each element of claims 2, 3, and 13 of the ’197 patent is disclosed by Netzer in view of Smith, Hebblewhite, and Gouget. I further agree that the Petitioners’ claim chart accurately demonstrates the correspondence between the elements of claims 2, 3, and 13 and exemplary disclosure from Netzer, Smith, Hebblewhite, and Gouget. As demonstrated by my analysis concerning these references, it is my opinion that Netzer in view of Smith, Hebblewhite, and Gouget renders obvious claims 2, 3, and 13 of the ’197 patent.

’197 Patent Claims	Exemplary Disclosure of Netzer, Smith, Hebblewhite, and Gouget
Claim 2: 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	Hebblewhite describes that a tube should space the end of the aperture “at least 2 cm away from the end wall” to protect against waves that are created by air moving within the chamber, but does not explain how long a tube should be to protect against other types of waves, such as those that result when the water chamber is tipped. (RMD1004 at 5:15-16.) Selecting the length of tube to protect an opening from water entry due to tipping, however, was traditionally known in the design of liquid reservoirs with inlet tubes. For example, the Gouget reference discloses a “urinal . . . with a detachable anti-backflow element having an interior end located at the volumetric center of the urinal.” (RMD1006 at Abstract; *see also* RMD1007 at 25, 27, FIG. 1.) Gouget describes that is an “object of the present invention to prevent spillage from the urinal at any angle of

'197 Patent Claims	Exemplary Disclosure of Netzer, Smith, Hebblewhite, and Gouget
	tilt when the contents of the urinal are below the fill indicator level." (RMD1006 at 2:36-39; RMD1007 at 25 ("Its anti-backflow system . . . permit[s] turning said urinal in any direction when normally filled without its contents escaping"); *id* at 13-36.) In other words, Gouget teaches that it is advantageous to position the end of the tube near the center of the chamber so that fluid cannot reach the end of the tube no matter which position the chamber is tipped (as long as the chamber is not initially filled so that the fluid reaches the tube). (RMD1003 at ¶¶ 113-114.)  *Gouget at Figures 7A-D*  *Netzer at Figure 4 (modified to show interior tube)* It would have been apparent to a skilled artisan, in view of the teachings of Gouget, to have designed the length of the tubes added at Netzer's inlet 22 and outlet 23 to extend to the middle of the container, because 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

'197 Patent Claims	Exemplary Disclosure of Netzer, Smith, Hebblewhite, and Gouget
	into the respiratory gas lines" (RMD1010 at 6-7), either due to waves caused by airflow or waves caused by tipping, as Expert Alexander Virr explains in his Declaration. (RMD1003 at ¶¶ 113-16.)  *Rose at Figure 2* Netzer's water chamber presumably achieves sufficient humidification even though some air may be able to flow directly from the inlet to the outlet (e.g., because the inlet and outlet are spaced far apart), and a similar, presumably-adequate level of humidification would result when tubes are added to the inlet and outlet as described above, because the spacing between the inlet and outlet would not change. (RMD1003 at ¶ 115.) To the extent that additional humidification is desirable, a skilled artisan would have considered it an obvious modification to have added a baffle between the inlet and outlet tubes, to ensure additional circulation of air, at least because it was traditionally known to implement a baffle between an inlet and an outlet in CPAP humidifiers for this purpose. Indeed, the Rose reference describes a CPAP humidification chamber in which "pressured air from the CPAP device 12 is thus circulated

'197 Patent Claims	Exemplary Disclosure of Netzer, Smith, Hebblewhite, and Gouget
	through the humidifier 10 for subsequent delivery to the patient through air hose 26 to mask 28." (RMD1008 at 3:1-4.) Rose's humidification chamber 10 includes an inlet 18, an outlet 20, and an "elongate baffle 34" that "promotes the flow of air therethrough in a U-shaped or other indirect path." (RMD1008 at 2:7-11; *see also* 3:17-22; 4:24-30; 4:55-66 (emphasis added).) A skilled artisan would have understood from Rose that it was desirable to add a baffle that "promotes the flow of air therethrough in a[n] . . . indirect path," and therefore would have been motivated to add a baffle that limited the amount of air that could flow from the inlet tube directly to the outlet tube, either as a floor-to-ceiling rib as shown in Rose, or as some other baffle design, as explained by Expert Alexander Virr in his declaration. (RMD1008 at 2:7-11; *see* RMD1003 at ¶ 115.)
Claim 3: 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	The modification to the Netzer water chamber to extend the inlet tube to the middle of the chamber (as discussed with regard to claim 2) discloses that "said flow tube extends to approximately the middle of said chamber." Regarding the "said gases inlet and said flow tube are aligned radially" language, this feature is disclosed under the BRI standard by the added tubes (either as an attachment that slides into the inlet 22, or as a tube that is integrally formed with the inlet).
Claim 13: A water chamber as claimed in claim 3 wherein said water chamber comprises a transparent plastic shell open	Claim 13 includes the same language as claim 6, but it depends from claim 3 instead of claim 1. For substantially the same reasons discussed above in connection with claim 6, it would have been obvious in view of the listed combination of references to modify the Netzer water chamber to disclose the subject matter of claim 13.

’197 Patent Claims	Exemplary Disclosure of Netzer, Smith, Hebblewhite, and Gouget
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	

H. *CONCLUSION*

118. 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. 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: 14 APRIL, 2016 /s/