

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent of: Dickinson et al.  
U.S. Patent No.: 6,398,197 Attorney Docket No.: 36784-0046IP1  
Issue Date: June 4, 2002  
Appl. Serial No.: 09/564,508  
Filing Date: May 4, 2000  
Title: WATER CHAMBER

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**PETITION FOR *INTER PARTES* REVIEW**  
**OF UNITED STATES PATENT NO. 6,398,197**  
**PURSUANT TO 35 U.S.C. §§ 311–19, 37 C.F.R. § 42**

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## **EXHIBIT LIST**

<b>EX. #</b>	<b>Exhibit Description</b>
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
RMD1003	Declaration of Mr. Alexander Virr
RMD1004	U.S. Patent No. 6,135,432 to Hebblewhite et al. (“Hebblewhite”)
RMD1005	File History of Hebblewhite and parent app. no. 08/633,413
RMD1006	U.S. Patent No. 5,953,763 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 U.S. Patent No. 6,006,748 (App. No. 08/951,357)
RMD1012	Fisher & Paykel Healthcare, “HC200 Series Humidified CPAP System” Instruction Sheet, (Rev. B)
RMD1013	Fisher & Paykel Healthcare, SEC Form-1 Registration Statement
RMD1014	Stuff.co.nz, “Sleeping beautifully” article
RMD1015	Fisher & Paykel Healthcare, “HC200 Series Nasal CPAP Blower & Heated Humidifier User’s Manual,” (Rev. A)
RMD1016	Fisher & Paykel, Correspondence regarding FDA 510(k) submission
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”)

## **EXHIBIT LIST**

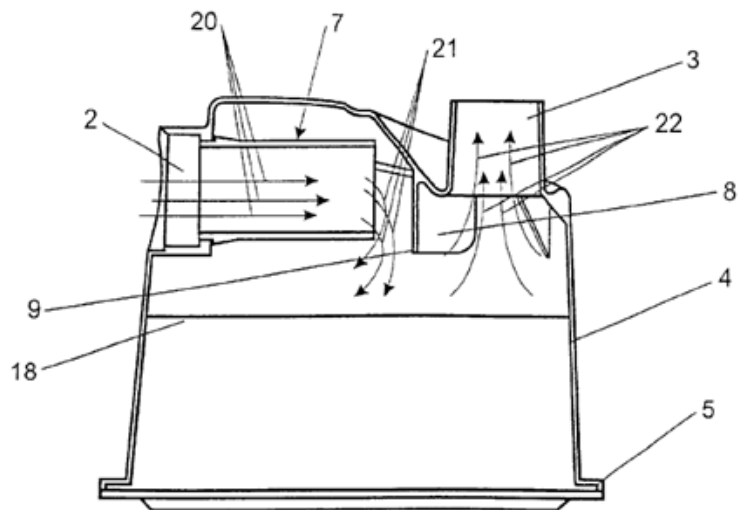
RMD1020	Patent Owner's Complaint for <i>Fisher &amp; Paykel Healthcare Ltd. v. ResMed Corp.</i> , Case No. 3:16-cv-02068-GPC-WVG (S.D. Cal.)
RMD1021	Patent Owner's Complaint for <i>Fisher &amp; Paykel Healthcare Ltd. v. ResMed Corp.</i> , Case No. 2:16-cv-06099-R-AJW (C.D. Cal.)
RMD1022	Patent Owner's Notice of Voluntary Dismissal Without Prejudice for <i>Fisher &amp; Paykel Healthcare Ltd. v. ResMed Corp.</i> , Case No. 2:16-cv-06099-R-AJW (C.D. Cal.)
RMD1023	Petitioners' Complaint for <i>ResMed Inc., et al. v. Fisher &amp; Paykel Healthcare Corp. Ltd., et al.</i> , Case No. 3:16-cv-02072-JAH-MDD (S.D. Cal.)
RMD1024	Petitioners' Notice of Voluntary Dismissal Without Prejudice for <i>ResMed Inc., et al. v. Fisher &amp; Paykel Healthcare Corp. Ltd., et al.</i> , Case No. 3:16-cv-02072-JAH-MDD (S.D. Cal.)

## I. INTRODUCTION

ResMed Inc., ResMed Corp, and ResMed Limited (collectively “ResMed” or “Petitioners”) petition for *inter partes* review (“IPR”) of claims 1-3, 6, and 13 of U.S. Pat. 6,398,197, assigned to Fisher & Paykel Healthcare Limited (“F&P”).

The ’197 patent relates to a “slide on” water humidification chamber for a continuous positive airway pressure (CPAP) device, in which the CPAP device blows pressurized air into a mask that a patient wears while asleep to treat obstructive sleep apnoea (OSA). Slide-on water chambers for such devices have been known in the art, but the ’197 patent explains that its “improvement” was adding an “inlet extension tube

7” to the horizontal gas inlet in order to prevent water from flowing back through the horizontal inlet if the CPAP device was tipped. (RMD1001 at 1:44; 2:54-65.)



*'197 Patent at Figure 2*

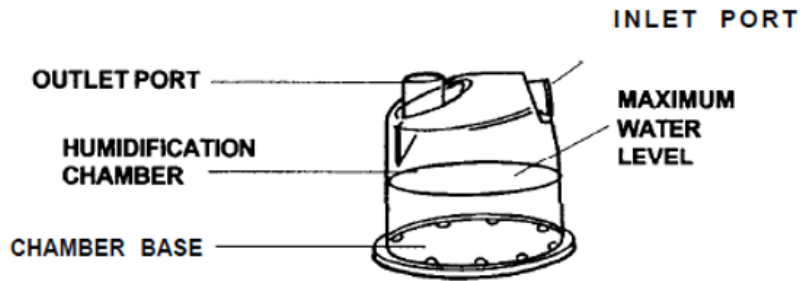


water.” (RMD1015 at 9;

*see also* RMD1012 at 1.)

It would have been obvious  
in view of the teachings in

Hebblewhite to have



*HC200 Manual at page 7 (portions omitted)*

modified the HC200 water chamber to add a tube to the horizontal inlet port, in order to protect the blower outlet from water. (RMD1003 at ¶¶ 69-79.)

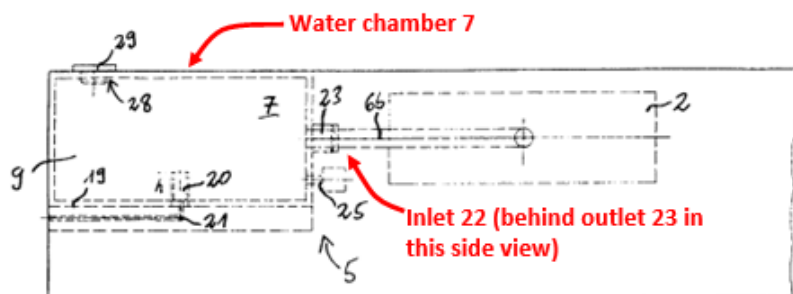
For Grounds 5 and 6, the Petition relies on Netzer (RMD1010), which also shows a CPAP device that includes a slide-on water chamber. In Figure 4 of

Netzer, the water chamber

slides into the CPAP

device from left to right,

and includes a horizontal



*Netzer at Figure 4*

inlet 22 that slides into a corresponding port of the CPAP device. As described below, it would have been obvious in view of Hebblewhite’s teachings for a skilled artisan to modify Netzer’s water chamber to add a tube to the inlet, so that “it is ensured that the respiratory gas supplied through the gas humidifier is only combined with water vapor, and no water drops are carried over into the respiratory gas lines,” which Netzer describes as a design goal of its water chamber. (RMD1010 at 6-7.)



## **II. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8**

### **A. Real Party-In-Interest Under 37 C.F.R. § 42.8(b)(1)**

ResMed Inc., ResMed Corp, and ResMed Limited are the Real Parties-in-Interest.

### **B. Related Matters Under 37 C.F.R. § 42.8(b)(2)**

ResMed Corp is currently a defendant in a pending litigation in the Southern District of California involving the '197 patent. *See Fisher & Paykel Healthcare Ltd. v. ResMed Corp.*, Case No. 3:16-cv-02068-GPC-WVG (S.D. Cal.). Patent Owner filed the complaint in this case on August 16, 2016, and alleges that ResMed infringes the '197 patent. RMD1020.

On August 15, 2016, Patent Owner both filed and dismissed (without prejudice) a complaint in the Central District of California also alleging that ResMed infringes the '197 patent. RMD1021; RMD1022.

Petitioners have also filed and dismissed (without prejudice) a complaint related to the '197 patent. On August 16, 2016, Petitioners filed a complaint in the Southern District of California alleging infringement of several patents held by Petitioners, and seeking declaratory judgment on non-infringement and invalidity of the '197 patent. RMD1023. Petitioners voluntarily dismissed this complaint without prejudice on August 18, 2016. RMD1024.

Petitioners' withdrawn action for declaratory judgment regarding the invalidity of the '197 patent has no effect under 35 U.S.C. § 315(a) because it was voluntarily dismissed without prejudice. *See Macuato U.S.A. v. BOS GmbH & KG*, IPR2012-00004, Paper No. 18 at pp. 15-16 (PTAB Jan. 24, 2013); *see also Oracle Corp., et al. v. Click-to-Call Techs. LP*, IPR2013-00312, Paper No. 52 at pp. 12-13 (PTAB Oct. 28, 2014). Additionally, Patent Owner's pending suit against Petitioners regarding the '197 patent has no effect under 35 U.S.C. § 315(b) since it was filed less than a year ago.

**C. Lead And Back-Up Counsel Under 37 C.F.R. § 42.8(b)(3)**

Petitioners provide the following designation of counsel.

LEAD COUNSEL	BACK-UP COUNSEL
Stephen R. Schaefer, Reg. No. 37,927 3200 RBC Plaza, 60 South Sixth Street Minneapolis, MN 55402 Tel: 612-337-2508 / Fax 612-288-9696 <a href="mailto:schaefer@fr.com">schaefer@fr.com</a>	Michael J. Kane, Reg. No. 39,722 3200 RBC Plaza, 60 South Sixth Street Minneapolis, MN 55402 Tel: 612-337-2502 / Fax: 612-288-9696 <a href="mailto:kane@fr.com">kane@fr.com</a>

**D. Service Information**

Please address all correspondence and service to both counsel listed above. Petitioners consent to electronic service by email at IPR36784-0046IP1@fr.com (cc'ing [schaefer@fr.com](mailto:schaefer@fr.com) and [kane@fr.com](mailto:kane@fr.com)).

### **III. PAYMENT OF FEES – 37 C.F.R. § 42.103**

Petitioners authorize charging Deposit Account 06-1050 for the petition fee specified in 37 C.F.R. § 42.15(a) and for any other required fees.

### **IV. REQUIREMENTS FOR IPR UNDER 37 C.F.R. § 42.104**

#### **A. Grounds for Standing Under 37 C.F.R. § 42.104(a)**

Petitioners certify that the '197 patent is available for IPR and that  
Petitioners are not barred or estopped from requesting IPR.

#### **B. Challenge Under 37 C.F.R. § 42.104(b) and Relief Requested**

Petitioners request IPR of claims 1-3, 6, and 13 of the '197 patent on the grounds listed below. These references and other evidence cited in this Petition, including testimony of expert Alexander Virr (RMD1003), demonstrate invalidity of the claims.

<b>Ground</b>	<b>Claims</b>	<b>Basis for Rejection</b>
<b>Ground 1</b>	<b>1</b>	§ 103 – HC200 Manual, Hebblewhite
<b>Ground 2</b>	<b>2, 3</b>	§ 103 – HC200 Manual, Hebblewhite, Gouget, Rose
<b>Ground 3</b>	<b>6</b>	§ 103 – HC200 Manual, Hebblewhite, Smith
<b>Ground 4</b>	<b>13</b>	§ 103 – HC200 Manual, Hebblewhite, Gouget, Rose, Smith
<b>Ground 5</b>	<b>1, 6</b>	§ 103 – Netzer, Smith, Hebblewhite
<b>Ground 6</b>	<b>2, 3, 13</b>	§ 103 – Netzer, Smith, Hebblewhite, Gouget, Rose

Hebblewhite (RMD1004) was filed in August 1997 and claims priority to an application filed in June 1996, almost three years before the earliest claimed

priority date of the '197 patent (May 1999), and is prior art under at least § 102(e).  
(See prosecution history of Hebblewhite and parent application, RMD1005.)

Gouget (RMD1006) was filed in July 1998, and is therefore prior art under at least § 102(e). Moreover, Gouget is a continuation-in-part of US App. No. 08/737,879 (filed November 1996, abandoned), and is a § 102(e) reference as of that date because the relevant portions in Gouget are supported by the '879 application, as explained by Expert Virr in his declaration. (RMD1007 at 13-36; RMD1003 at ¶ 51.) Even further, because that earlier application is a translation of WO 96/29972 (published October 1996), the subject matter in Gouget is also § 102(b) prior art. (RMD1007 at 37-58.)

Rose (RMD1008) issued as a US patent in August 1993, and is prior art under at least § 102(b).

Smith (RMD1009) issued as a US patent in December 1996, and is prior art under at least § 102(b).

Netzer (RMD1010) published as a PCT publication in February 1998, and is prior art under at least § 102(b).

The HC200 Manual (RMD1015) is dated May 1998, and was submitted by Petitioners to the USPTO in a January 1999 information disclosure statement, which is at least three months before the earliest claimed priority date of the '197 patent. (See RMD1011 at 101-103, showing information disclosure statement

from prosecution of US Pat. No. 6,006,748.) Thus, the HC200 Manual was publicly available before May 1999 and therefore is prior art to the '197 patent. This "User's Manual" would have been distributed with the HC200 device, which was available before May 1999, as evidenced by the following:

- Patent Owner's 2001 SEC Form 1 Registration Statement refers to "the launch of our first integrated flow generator-humidifier, the HC200 series, in the U.S. in April 1999." (RMD1013 at 46-47.)
- An article by Stuff.co.nz states that the HC200 was released in 1998. (RMD1014 at 4.)
- Patent Owner submitted, in August 1997, its 510(k) application requesting FDA approval to market the HC200 in the US. (RMD1016 at 1 and 2.)
- The FDA granted Patent Owner approval in July 1998 to market the HC200 in the US. (RMD1016 at 3-4.)
- The "Summary of the Prior Art" section of the '197 patent describes a prior art slide-on humidification chamber with features that were present in the HC200. (RMD1001 at 1:9-34.)
- The claims of the '197 patent admit that features of the HC200 were present in the prior art. (RMD1001 at claim 1.)

Public distribution of the HC200 Manual before the May 1999 date renders the HC200 Manual 102(b) prior art, because the distribution would have been at least

one year before the May 4, 2000 US filing date of the '197 patent.

An updated “Rev B” version of the HC200 Manual (herein “Revised HC200 Manual”) shows similar subject matter. (RMD1012.) While the Revised HC200 manual is not dated, it is believed to have been distributed with HC200 devices that were sold in the US in April 1999. Petitioners submit that it would be improper for Patent Owner to argue that the HC200 Manual (RMD1015) is not prior art if Patent Owner in fact knows that it is prior art, or if Patent Owner knows that the Revised HC200 Manual (RMD1012) or similar HC200 manuals are prior art.

## **V. BACKGROUND: '197 PATENT AND PROSECUTION HISTORY**

### **A. Overview of the '197 Patent**

The '197 patent describes a “slide on” water humidification chamber for use with a Continuous Positive Airway Pressure (CPAP) system. (RMD1001 at 1:6-8.) As some background, CPAP systems deliver pressurized air to a patient’s airway, and can be used to treat obstructive sleep apnea (OSA) by helping keep the patient’s airway open during sleep. (RMD1003 at ¶ 24.) The idea of using CPAP therapy for OSA was invented nearly thirty-five years ago in June 1980 by Dr. Colin Sullivan, whose early inventions formed the basis of Petitioners’ business. (RMD1003 at ¶ 24.) As was well-known, CPAP systems typically include a mask for a patient’s mouth and/or nose, a ventilator that blows air to the mask through a

tube, and an optional humidifier that adds moisture to the air. (RMD1001 at 1:13-24; RMD1003 at ¶ 24.)

The '197 patent explains in several places that its water chamber design was known, and that the innovation was the addition of the “tube.” For example, the '197 patent admits in its “Summary of the Prior Art” section that CPAP machines with “slide-on humidifier chambers” that are “fitted onto the heater base” were well known. (RMD1001 at 1:10-29.) In such systems, a user connects the humidification chamber to the CPAP machine with a “single sliding movement” and the “inlet air port is consequently provided horizontally through a side of the chamber.” (RMD1001 at 1:24-34.) Indeed, the detailed description further explains that the purportedly innovative “benefits have been achieved while maintaining, in the design shown, S [sic] equivalent external appearance and size . . . as earlier chambers.” (RMD1001 at 2:62-65 (emphasis added).)

The preamble of claim 1 (the only independent claim) also recognizes that slide-on water chambers that include horizontal gas inlets and that are used with heater bases were known in the art:

1. In a water chamber adapted for use in conjunction with a heater base and having a horizontally oriented gases inlet in a wall thereof the improvement comprising an elongate flow tube extending into said water chamber from the inner periphery of said gases inlet, an inlet end of said elongate flow tube covering said inlet and an outlet

end of said flow tube being spaced from the wall of said chamber, said flow tube in use receiving, at said inlet end, gases supplied to said gases inlet, said gases passing through said flow tube and exiting said flow tube at said outlet end distant from said wall.

(Emphasis added.) Claim 1 is written in the Jepson format, in which the preamble portion of the claim before the “improvement comprising” language is admitted to be prior art, as explained by Patent Office rules:

[I]n the case of an improvement, any independent claim should contain in the following order: (1) A preamble comprising a general description of all the elements or steps of the claimed combination which are conventional or known, (2) A phrase such as ‘wherein the improvement comprises,’ and (3) Those elements, steps, and/or relationships which constitute that portion of the claimed combination which the applicant considers as the new or improved portion.

37 C.F.R. § 1.75(e); *see also* MPEP 2129; *In re Fout*, 213 USPQ 532, 535-56

(CCPA 1982) (“Valid prior art may be created by the admissions of the parties ... .

We hold that Appellants’ admission that they had actual knowledge of the prior [technology] described in the preamble constitutes an admission that it is prior art to them. . . . [T]he implied admission that the Jepson format preamble of claim 1 describes prior art has not been overcome.”).

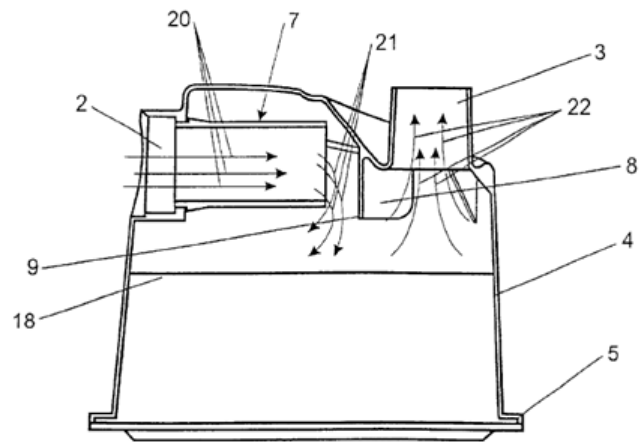
The background of the ’741 patent explains that water can spill through the opening in the side of the water chamber:



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 1:29-34.)

The '197 patent describes that the likelihood of such a water spill can be reduced by adding an “inlet extension tube 7 extending inwardly into the chamber interior from the periphery of the gases inlet 2.”



*'197 Patent at Figure 2*

(RMD1001 at 2:26-28.) 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.” (RMD1001 at 2:29-34.)

The '197 patent explains 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.” (RMD1001 at 2:54-61.)

## **B. Overview of Prosecution History**

The application that matured into the ’197 patent began with a provisional application filed in New Zealand on May 10, 1999. (RMD1002 at 16-23.) The New Zealand provisional did not include any claims. (*Id.*) Almost a year later, on May 4, 2000, Applicant filed that application in the United States. (RMD1002 at 1-15.) The US application added Jepson-style claims, and changed the “Summary of the Invention” section to specify that the “elongate flow tube extending into said water chamber” is “the improvement,” as shown below:

It is therefore an object of the present invention to provide a water chamber which at least goes some way towards overcoming the above disadvantages or which will at least provide the public with a useful choice.

In a first aspect the invention may broadly be said to consist in a water chamber adapted for use in conjunction with a heater base and having a horizontally oriented gases inlet characterised by an elongate flow tube extending into said water chamber from the inner periphery of said gases inlet.

(RMB1002 at 19.)

It is therefore an object of the present invention to provide a water chamber which at least goes some way towards overcoming the above disadvantages or which will at least provide the public with a useful choice.

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

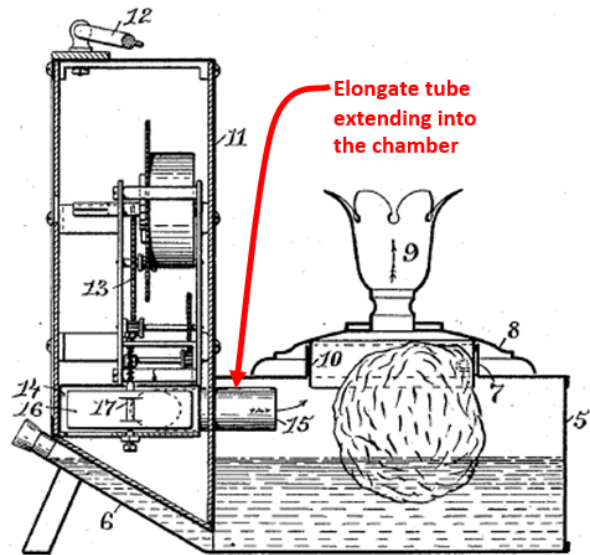
(RMD1002 at 4 and 5.)

The US Patent Office mailed an office action in July 2001, rejecting claims 1-3 over prior art and objecting to claims 6 and 13 as being dependent upon a rejected base claim.<sup>1</sup> (RMD1002 at 24-30.) Claims 1 and 2 were rejected as being unpatentable over Lynch (RMD1017), and claims 1, 2, and 4 were alternatively rejected as anticipated by Romanoff (RMD1019). (RMD1002 at 24-30.) Claim 3 was rejected over Lynch in view of Hartmann (RMD1018), and was alternatively rejected over Romanoff in view of Hartmann. (RMD1002 at 24-30.)

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<sup>1</sup> This section omits discussion of unchallenged claims and their rejections.

Lynch is a patent that issued in 1892 that relates to “improvements in 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



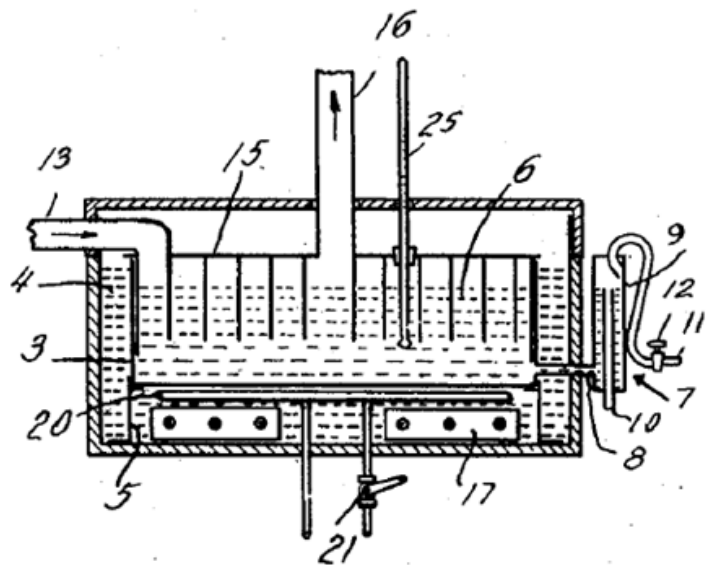
*Lynch at Figure 2*

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 2:60-67.) Lynch discloses the “elongate tube” feature that the ’197 patent application identified as an “improvement.”

In its response, Applicant did not dispute that Lynch's tube disclosed 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's reservoir holds "disinfectants in solid or liquid form" and therefore does not disclose the "water chamber" feature 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 simply argued that "[t]he inlet pipe 13 . . . does not show any extension within the water reservoir 3." (RMD1002 at 33.)



*Romanoff at Figure 2*

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.)

Shortly thereafter, the Office issued a Notice of Allowance that identified no reasons for allowance. (RMD1002 at 37-39.)

**C. Person of Ordinary Skill in the Art**

In view of the subject matter of the '197 patent, a person of ordinary skill in the art as of any of the claimed priority dates (as early as May 1999) 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. This level of knowledge and skill is applied throughout the Petition.

**VI. CLAIM CONSTRUCTION UNDER 37 C.F.R. § 42.104(B)(3)**

For *inter partes* review, a claim in an unexpired patent is given its broadest reasonable construction in light of the specification in which it appears. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142-46 (2016).

Claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Constructions offered in the Petition are intended to aid this proceeding, and do not waive any arguments concerning indefiniteness or claim breadth in proceedings applying different construction standards.

## **VII. THE CHALLENGED CLAIMS OF THE '197 PATENT ARE UNPATENTABLE**

The “Summary of the Prior Art” section and the language of Jepson claim 1 in the '197 patent show that Applicant knew that its “improvement” was only adding a tube at the horizontal opening to its prior art water chamber. Indeed, when the Examiner found such a tube in the Lynch reference, Applicant simply argued that Lynch’s disinfectant reservoir was not a water chamber and that Lynch’s device did not heat the reservoir. *See supra*, Section V.B (“Overview of Prosecution History”). But the water chamber and heater features were known in the art, as explained not only by the '197 patent but as also shown by the HC200 Manual, which relates to the Fisher & Paykel CPAP device that is described in the background section of the '197 patent. The HC200 Manual shows a water chamber that includes all of the features of claim 1 except for the “tube,” but the tube feature was known in the art, as evidenced not only by Lynch but also by the Hebblewhite reference. Hebblewhite describes a CPAP humidifier that uses a tube to space an opening in a horizontal wall of a water chamber away from the wall so that “the danger of water spilling into the air outlet is greatly reduced.” (RMD1004 at 3:38-40.) As described below, it would have been obvious to modify the water chamber that is shown in the HC200 Manual to include a tube at the inlet, rendering at least claim 1 invalid.

**A. [GROUND 1] – Obviousness of claim 1 by the HC200 Manual in view of 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 ’197 patent acknowledges that these features were known. In particular (and 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.) Even further, the HC200 Manual discloses these features, as explained below.

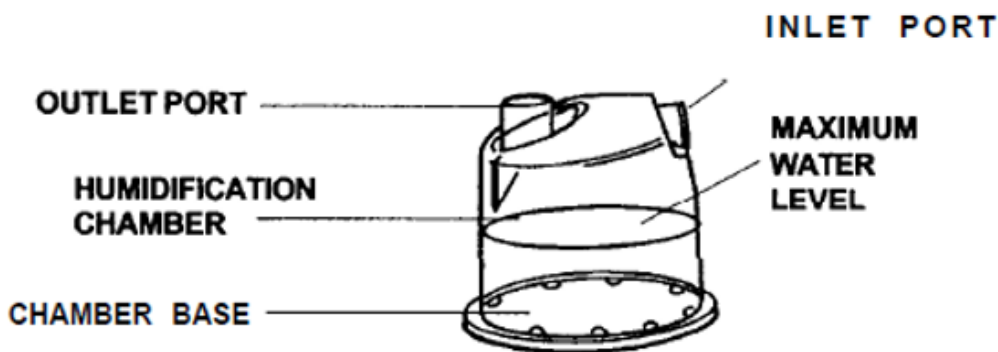
Water chamber. The HC200 Manual discusses the “HC200 Series Nasal CPAP Blower & Heated Humidifier,” which uses the HC345 water chamber. A perspective view of the HC200 device with the water chamber placed therein is



*HC200 Manual at page 1*



shown on page 1 of the HC200 Manual.<sup>2</sup> 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 full of water.” (RMD1015 at 8 (emphasis added).)

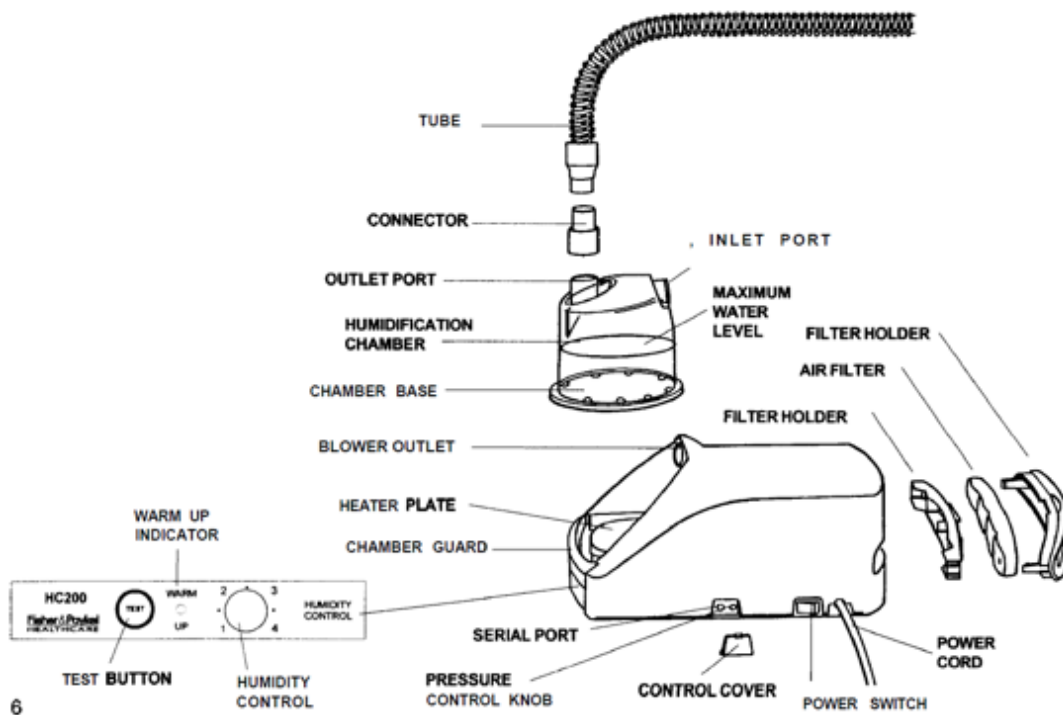


*HC200 Manual at page 7 (portions omitted)*

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<sup>2</sup> Pages numbers refer to exhibit page numbering, not source document numbers.

Heater base. 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*

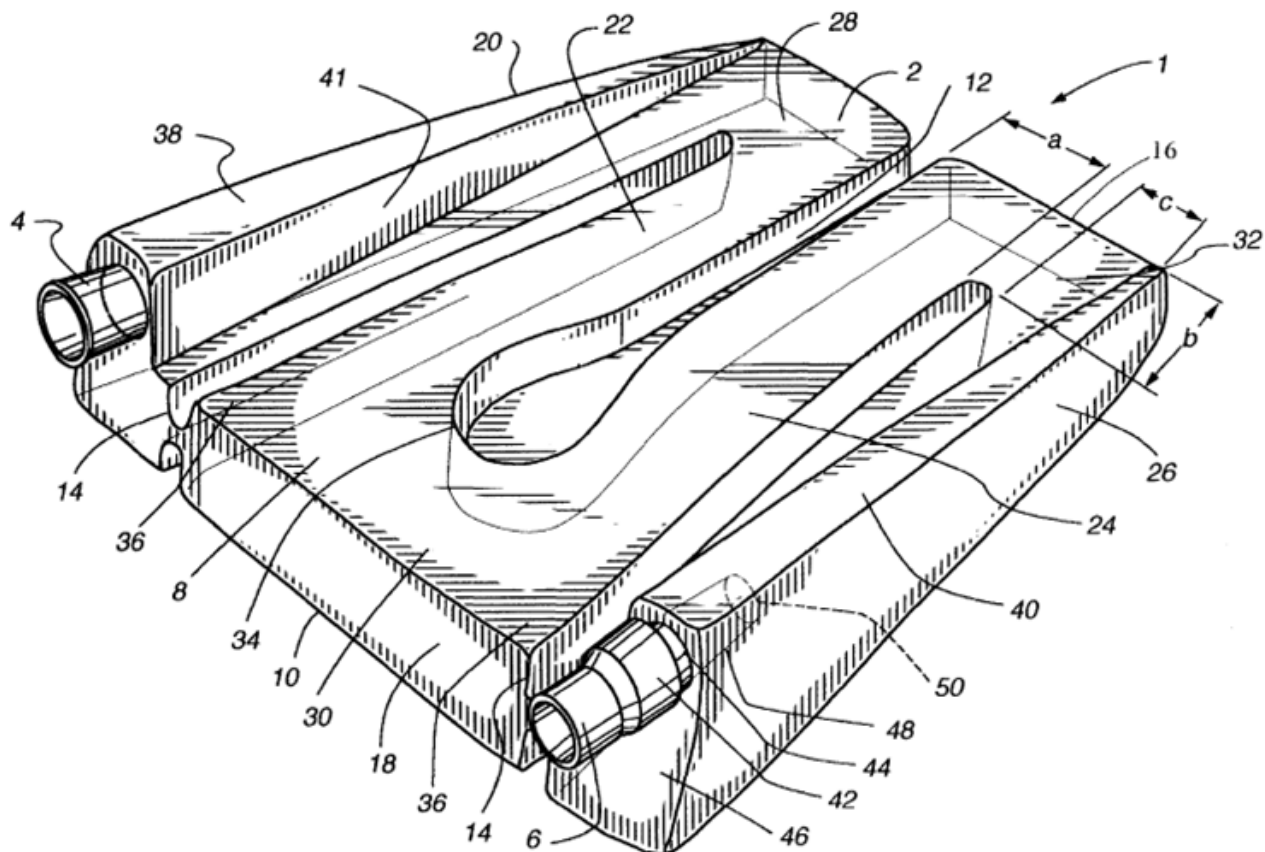
Horizontally oriented gases inlet in a wall thereof. The two figures copied above show a horizontally oriented gases inlet (labeled as “Inlet Port” in the figures) in a wall of the water chamber. It is apparent from the figures that the inlet is horizontally oriented, but the horizontal configuration is further supported by the description at page 8, which explains 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.)

***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.”*** The HC200 Manual does not disclose the above-recited elongate flow tube, but skilled artisans would have been prompted to modify the HC200 Manual water chamber to disclose this feature as construed under a broadest reasonable interpretation standard in either of at least two ways: (1) By inserting an initially-detached tube into the HC200 water chamber’s inlet port, and (2) By molding the HC200 water chamber to have a tube extend inward from what was initially the HC200 water chamber’s inlet port. Indeed, having a tube at an aperture of a humidifier chamber was traditionally known in the art. For

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.)

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.)

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 HC200 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 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.

**B. [GROUND 2] – Obviousness of claims 2 and 3 by HC200 Manual in view of 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

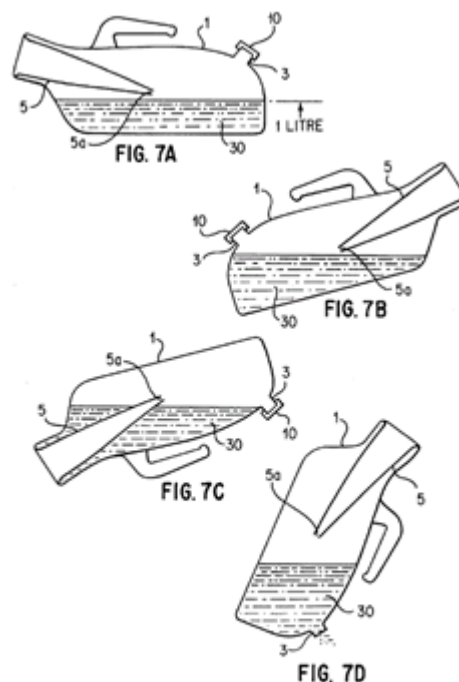
should space the aperture “at least 2 cm away from the end wall” to protect the aperture from waves created by air moving within the chamber, but does not explain how long a tube should be to protect against other types of waves, such as those that result when the water chamber is tipped. (RMD1004 at 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

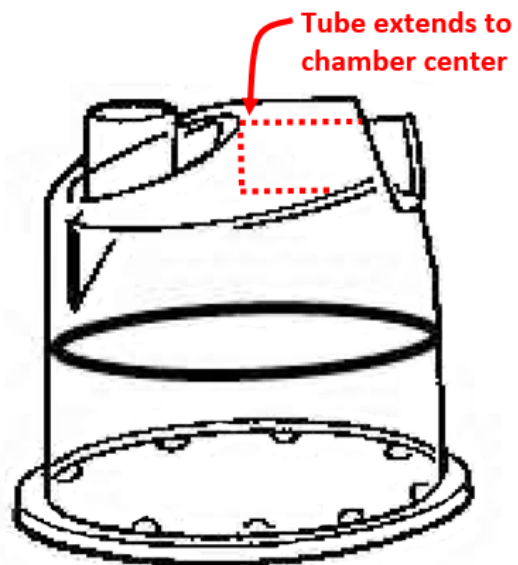
Gouget, it is an “object of the present invention to prevent spillage from the urinal



***Gouget at Figures 7A-D***

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).

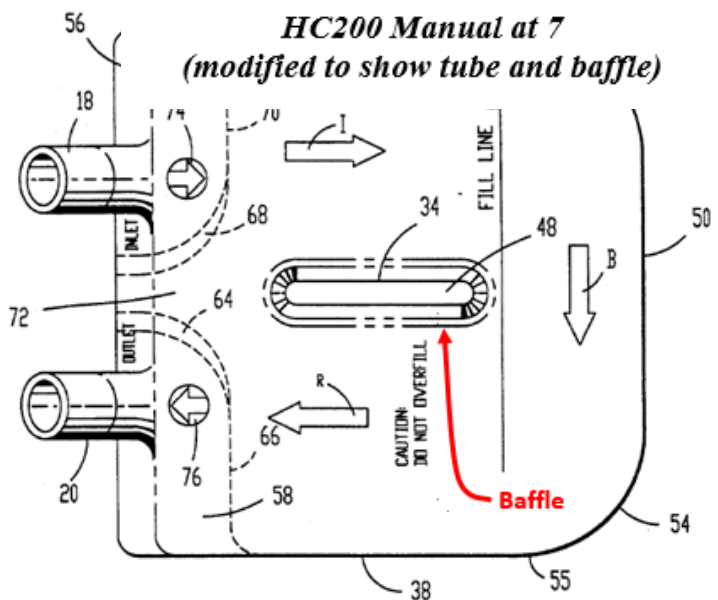
It would have been apparent to a skilled artisan, in view of the teachings of Gouget, to have designed the tube at the inlet of the HC200 water chamber (an obvious modification, as already explained with regard to claim 1) to extend to the middle of the water chamber, because extending the tube to the 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.) Even though claim 2 only recites that the tube extend “at least a quarter of the diameter of said water chamber,” the



*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 because the modified chamber may have the tube outlet located closer to the chamber outlet, 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



*Rose at Figure 2*

inlet and an outlet in CPAP humidifiers for this purpose. Indeed, 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.)

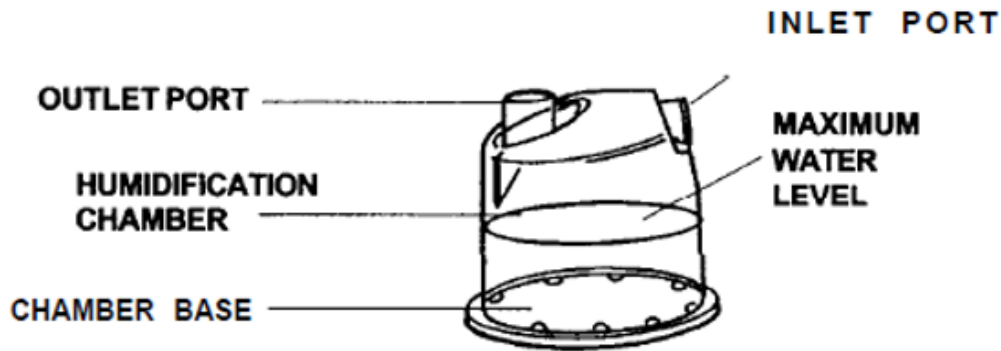
***Claim 3: “A water chamber as claimed in claim 2 wherein said gases inlet and said flow tube are aligned radially and said flow tube extends to approximately the middle of said chamber.”*** The modification to the HC200 water chamber to design the inlet tube to extend to the middle of the chamber (as

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 because a tube that slide into an inlet or that is integrally formed with the inlet port would be aligned radially with the inlet under the broadest reasonable interpretation standard.

**C. [GROUND 3] – Obviousness of claim 6 by HC200 Manual in view of 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).)



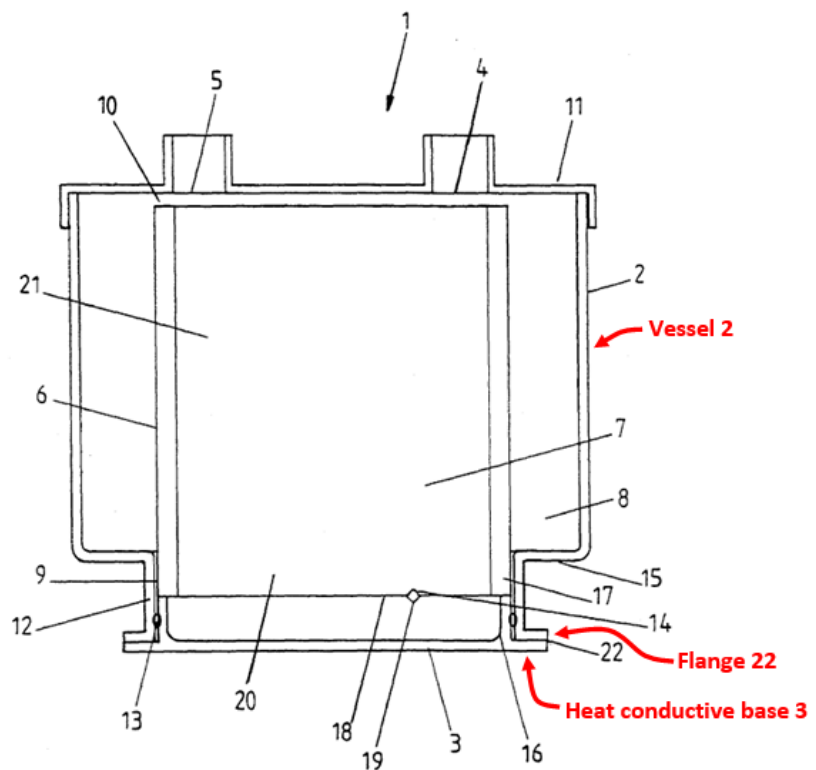
*HC200 Manual at page 7 (portions omitted)*

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 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 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 2:12-15.) 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



*Smith at Figure 1*

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 Fisher & 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.)

**D. [GROUND 4] – Obviousness of claim 13 by HC200 Manual in view of Hebblewhite, Gouget, Rose, and Smith**

***Claim 13: “A water chamber as claimed in claim 3 wherein said water chamber comprises a transparent plastic shell open at the bottom and having a peripheral flange, a heat conductive plate enclosing said bottom of said shell and sealed at its periphery to said flange, and said elongate flow tube comprises a tubular extension tube member fitted at said gases inlet.”*** 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 HC200 water chamber to disclose the subject matter of claim 13.

**E. [GROUND 5] Obviousness of claim 1 and 6 by Netzer in view of Smith and Hebblewhite**

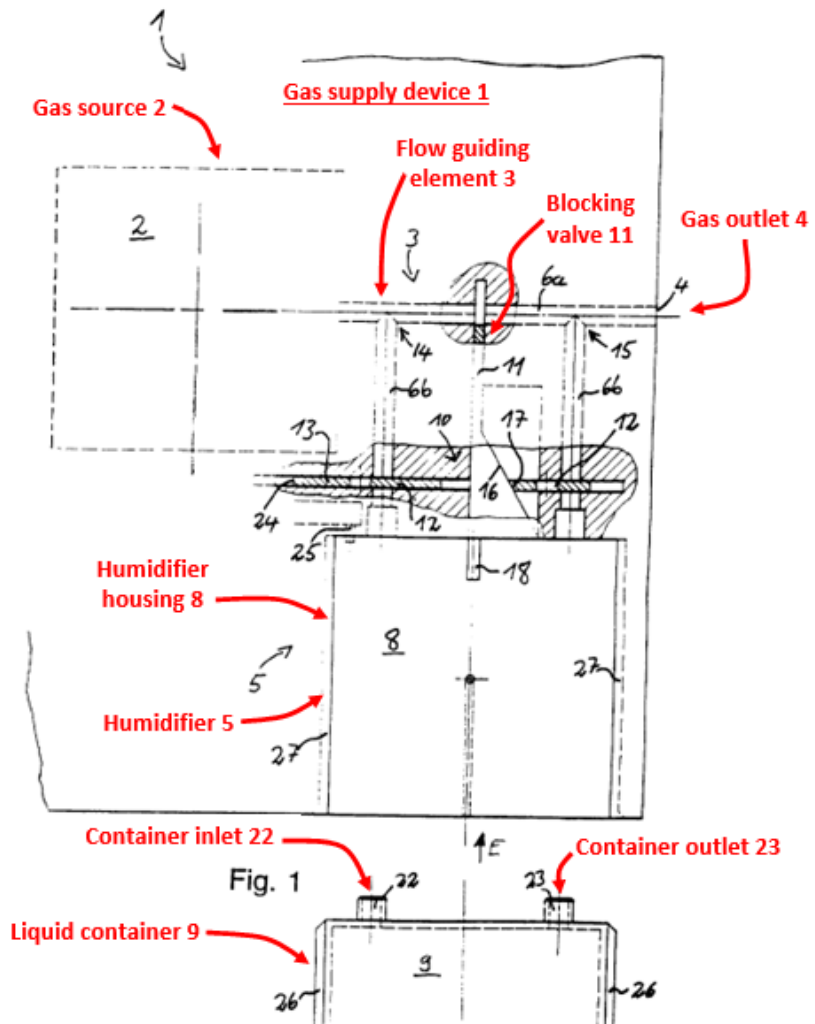
Grounds 5 and 6 describe an additional set of rejections that render claims 1-3, 6, and 13 invalid. These grounds rely on Netzer as a primary reference rather than the HC200 Manual.

Before addressing the claim language, this section briefly provides an overview of the Netzer primary reference, which describes a “gas supply device for sleep apnea” that is similar to that described in the HC200 Manual and that described by the ’197 patent. (RMD1010 at 2.) Netzer shows an overhead “top view” illustration of its device in Figure 1, and describes the overhead view as follows:

The embodiment example of a gas supply device 1 for sleep apnea depicted in the figures has, aside from the respiratory gas source 2, the flow guiding element 3 and the respiratory gas outlet 4, a humidifier housing 8 for receiving a liquid container 9. This liquid container 9 can be removed from and replaced in the humidifier housing 8. Fig. 1 shows the device 1 with the liquid container 9 removed.

(RMD1010 at 8; Fig. 1.)

Netzer describes how the gas source 2 (a “blower”) introduces air into the “flow guiding element 3.” Depending on whether a “blocking valve 11” is open or closed, the air goes directly to the “gas outlet 4” (which is connected to a patient’s face mask through a hose), or is routed through the “humidifier 5” before going to the “gas outlet 4.” Additional



Netzer at Figure 1

description of these components is provided below:

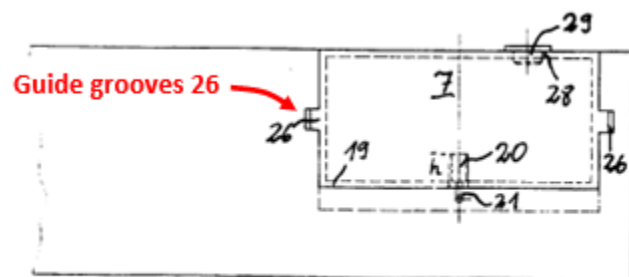
- Gas source 2: Netzer describes that the “respiratory gas source 2 is formed by a blower in the figures.” (RMD1010 at 7.)
- Flow guiding element 3: Netzer describes that “ambient air . . . is transported in the flow guiding element 3.” (RMD1010 at 7.) “The flow guiding element 3 is connected to a gas humidifier 5 and has two flow paths



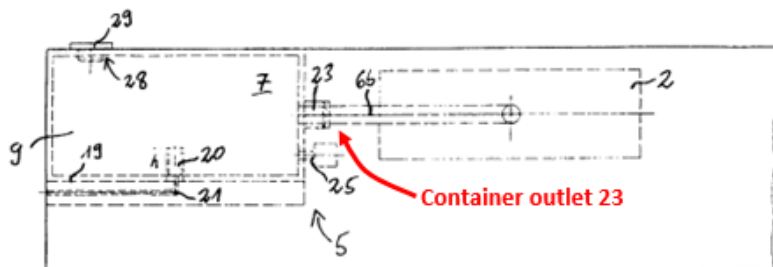
6a, 6b. The first flow path 6a leads to the respiratory gas outlet 4, bypassing the gas humidifier 5, and the second flow path 6b leads to the respiratory gas outlet 4 via an admixing point 7 . . . which is connected to the gas humidifier 5.” (RMD1010 at 8.)

- Liquid container 9: Netzer describes that the removable liquid container includes a “container inlet 22” and a “container outlet 23.” (RMD1010 at 9.)
- Gas outlet 4: Netzer describes that an “air hose, not shown in detail, can be connected to the respiratory gas outlet 4, connecting the device 1 to a, likewise not shown in detail, face mask, which can be placed on the nasal region of a patient.” (RMD1010 at 8.)

Netzer describes that the liquid container 9 is a slide-on container that has a horizontal gas inlet and horizontal gas outlet that mate with flow path 6b once the chamber has been slid into place. For example, Figure 4, which is “a cutaway side view of the device, cut along the line B-B in Fig. 2,” shows how outlet 23 horizontally



*Netzer at Figure 3*



*Netzer at Figure 4*

protrudes from the chamber to connect to the second flowpath 6b. Moreover, Netzer discusses how “[l]ateral guide profiles 26 are provided on the liquid container 9, which engage in corresponding guide grooves 27 in the humidifier housing 8. By this means the insertion of the liquid container in the humidifier housing 8 is facilitated . . . .” (RMD1010 at 10.) Netzer shows the guide grooves 27 in Figure 3, which is “a cutaway side view of the device cut along the line A-A in Fig. 2.” (RMD1010 at 7.)

***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).) ~

A skilled artisan would have seen a reason to design Netzer’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 firm 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).

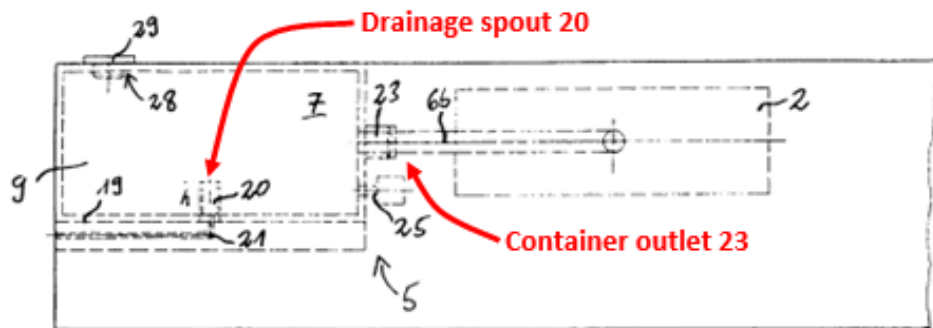
The ’197 patent acknowledges that these features were known. As described previously, the above features are listed in the preamble of the Jepson-style claim 1, and thus were admitted by Applicant to be prior art features. *See* 37 C.F.R. § 1.75(e); *In re Fout*, 213 USPQ 532, 534 (CCPA 1982). Moreover, 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.)

***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 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

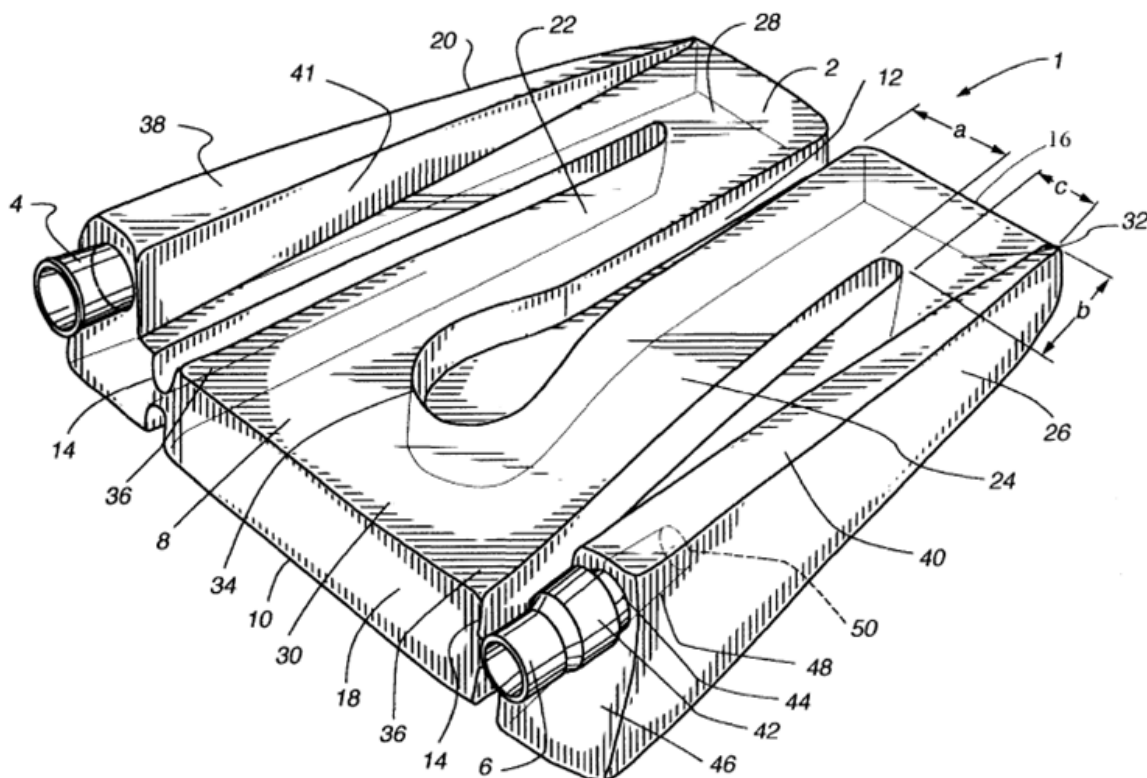


*Netzer at Figure 4*

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 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.)

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.)

***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,<sup>3</sup> 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

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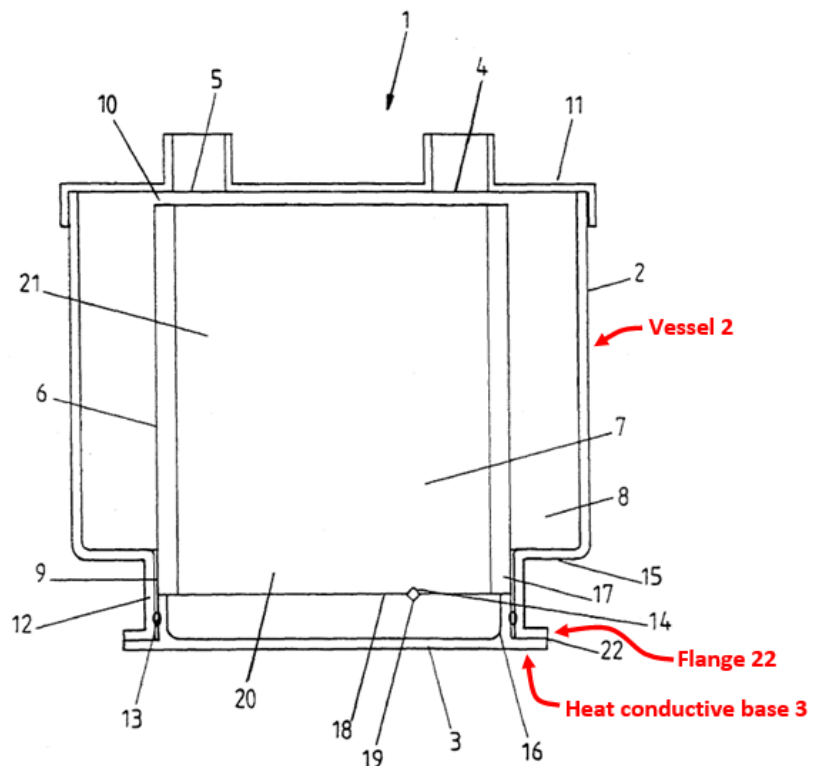
<sup>3</sup> Figure 1 (top view with container detached); Figure 2 (top view with container attached); Figure 3 (side view); and Figure 4 (other side view).



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.)

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.)

A skilled artisan would have seen a reason to have designed Netzer's water



*Smith at Figure 1*

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), 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.)

**F. [GROUND 6] Obviousness of claims 2, 3, and 13 by Netzer in view of Smith, 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 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 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

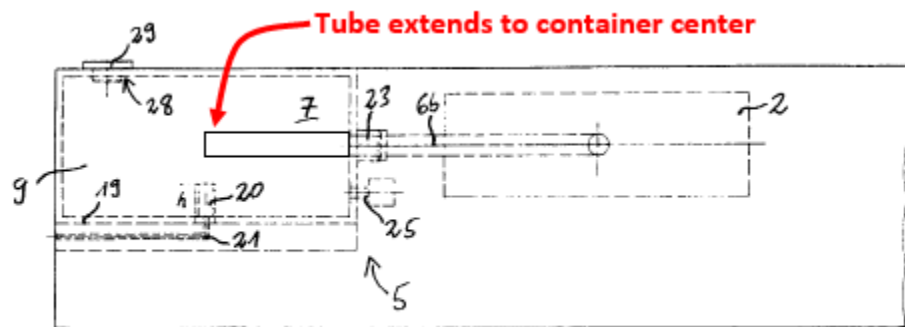
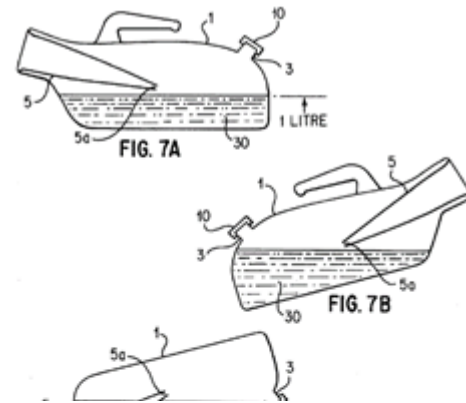
chamber so that

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.)

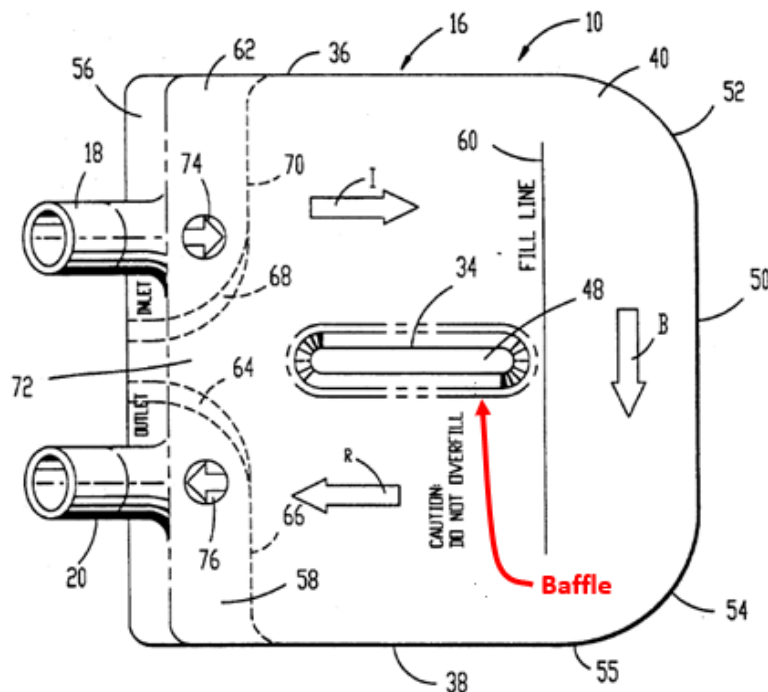
It would have been apparent to a skilled artisan, in view of the teachings of Gouget, to have designed the length of the tubes added at Netzer’s inlet 22 and outlet 23 to extend to the middle of the container, because extending the tubes to the middle places the tubes near the volumetric center and thus would help ensure that “no water drops are carried over into the respiratory gas lines” (RMD1010 at



*Netzer at Figure 4 (modified to show interior tube)*

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.)

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



*Rose at Figure 2*

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 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 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.”*** 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.

#### **VIII. GROUNDS 1-4 AND 5-6 ARE NOT REDUNDANT**

Petitioner submits that Grounds 1-4 are not redundant in view of Grounds 5-6. The primary reference for Grounds 1-4 (the HC200 Manual) is advantageous over the primary reference for Grounds 5-6 (Netzer), at least because the HC200 Manual shows the prior art Fisher & Paykel slide-on water chamber that is discussed in the background section of the '197 patent. As such, the HC200 Manual helps explain the prior art being discussed in the '197 patent (especially because Applicant did not cite a reference that illustrated the prior art water chamber). On the other hand, while Petitioner submits that the HC200 Manual is

102(b) prior art because it was publicly available at least one year before the US filing date of the '197 patent, this manual is Patent Owner's own manual. Should Patent Owner be able to show that the manual is not prior art, the Netzer reference is available as a 102(b) publication.

The HC200 Manual and Netzer are also advantageous with respect to each other for various other reasons. For example, the HC200 Manual includes computer-generated figures, some of which show the claim features in three-dimension representation, while Netzer includes hand-drawn figures that are only two-dimensional, which can involve reading the specification to help understand what is shown by the figures. Moreover, the HC200 Manual discloses claim 1 in combination with only a single secondary reference (see Ground 1), while the Netzer is combined with two secondary references to disclose claim 1 (see Ground 5). On the other hand, the rejection of dependent claim 6 requires fewer secondary references when Netzer is used as the primary reference than when the HC200 Manual is used as the primary reference (compare Ground 5 with Ground 3). Using Netzer as the primary reference also involves fewer separate grounds of rejection and therefore fewer modifications than when the HC200 Manual is used as the primary reference (compare Grounds 5-6 for Netzer with Grounds 1-4 for the HC200 Manual). For at least these reasons, Grounds 1 and 2 present issues that



are substantively different from each other, and IPR should be instituted on both Grounds.

## **IX. CONCLUSION**

Claims 1-3, 6, and 13 of the '197 patent are not patentable under 35 U.S.C. § 103 as set forth above. Accordingly, Petitioners request *inter partes* review of all the challenged claims.

Respectfully submitted,

Dated: September 7, 2016

/ Stephen R. Schaefer, Reg. No. 37,927/  
Stephen R. Schaefer, Reg. No. 37,927

Dated: September 7, 2016

/ Michael J. Kane, Reg. No. 39,722/  
Michael J. Kane, Reg. No. 39,722

(Case No. IPR2016-01719)

Both above signers of:  
Fish & Richardson P.C.  
3200 RBC Plaza  
60 South Sixth Street  
Minneapolis, MN 55402  
*Attorneys for Petitioners*

**CERTIFICATION UNDER 37 CFR § 42.24(d)**

Under the provisions of 37 CFR § 42.24(d), the undersigned hereby certifies that the word count for the foregoing Petition for Inter Partes Review totals 10,258, which is less than the 14,000 allowed under 37 CFR § 42.24(a)(1)(i).

Respectfully submitted,

Date: Sep. 7, 2016

/Stephen R. Schaefer, Reg. No. 37,927/

Stephen R. Schaefer, Reg. No. 37,927  
Fish & Richardson P.C.  
3200 RBC Plaza  
60 South Sixth Street  
Minneapolis, MN 55402  
*Attorneys for Petitioners*

(Case No. IPR2016-01719)

## CERTIFICATE OF SERVICE

Pursuant to 37 CFR §§ 42.6(e)(1) and 42.105, the undersigned certifies that on September 7, 2016, a complete and entire copy of this Petition for *Inter Partes* Review, and all supporting exhibits, were provided via FedEx to the Patent Owner by serving the correspondence address of record as follows:

Trexler Bushnell Giangiorgi & Blackstone LTD  
105 W Adams Street  
Chicago, IL 60603

/Edward G. Faeth/  
Edward G. Faeth  
Fish & Richardson P.C.  
3200 RBC Plaza  
60 South Sixth Street  
Minneapolis, MN 55402  
(202) 626-6420