# RESMED LIMITED, RESMED INC., AND RESMED CORP. v. FISHER & PAYKEL HEALTHCARE LIMITED

Cases IPR2016-01716, -01717, -01719, -01725, -01727, -01729, -01730, -01731

U.S. Patent Nos. 6,398,197; 7,111,624; 8,091,547; 8,550,072

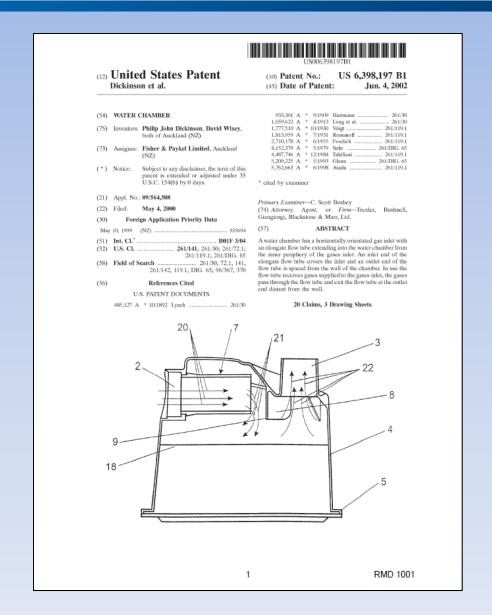
# Fisher & Paykel Healthcare Ltd.'s Demonstratives For Oral Hearing

Judge Hyun J. Jung Judge Carl M. DeFranco Judge Michael L. Woods

December 6, 2017

FPH EX. 2005 ResMed v. Fisher & Paykel IPR2016-01719

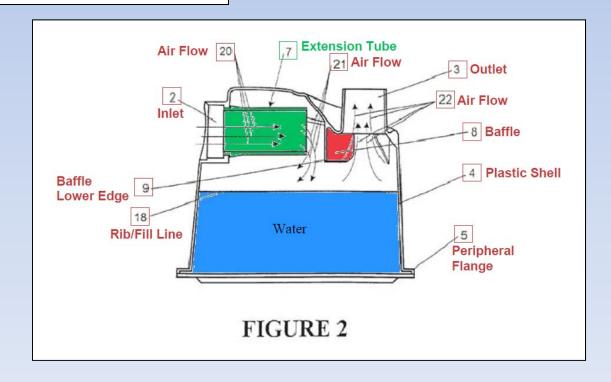
## U.S. Patent No. 6,398,197



## '197 Patent

#### **Noise Reduction**

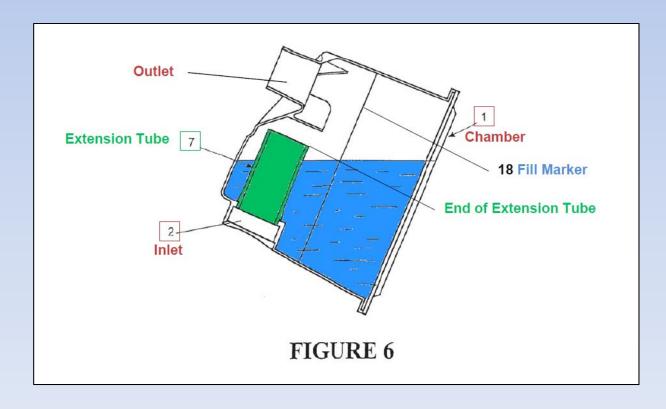
By providing the inlet extension tube 7 and therefore imparting an improved flow pattern to the inlet flow, it has been found that the noise level of the humidifier chamber has been significantly reduced, and, in conjunction with the curved baffle 8, effective operation of the water chamber 1 has been maintained.



## '197 Patent

#### **Spillage Prevention When Chamber Is Tipped**

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.



## '197 Patent - Claim 1

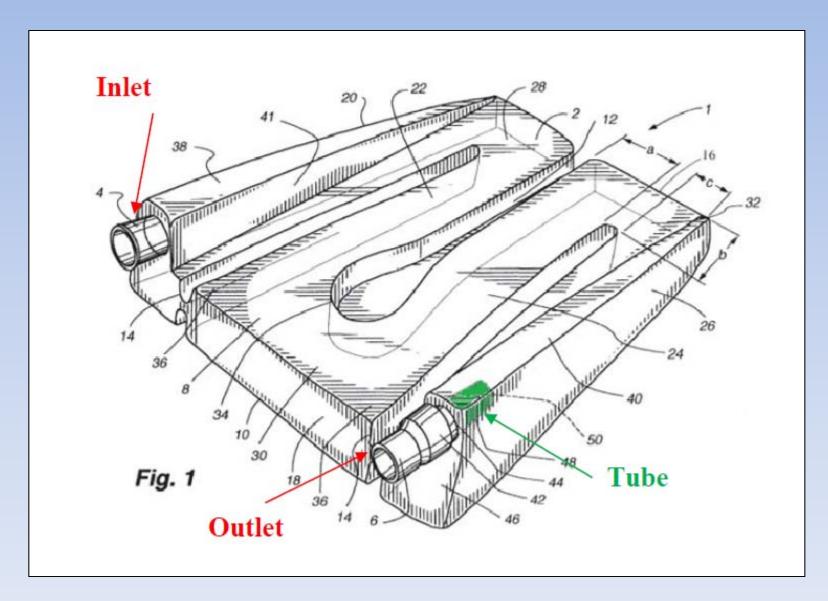
1. In a water chamber adapted for use in conjunction with a heater base and having a horizontally oriented gases inlet in a wall thereof the improvement comprising an elongate flow tube extending into said water chamber from the inner periphery of said gases inlet, an inlet end of said elongate flow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

# U.S. Patent No. 6,135,432 to Hebblewhite

#### **All Grounds Rely Upon Hebblewhite**

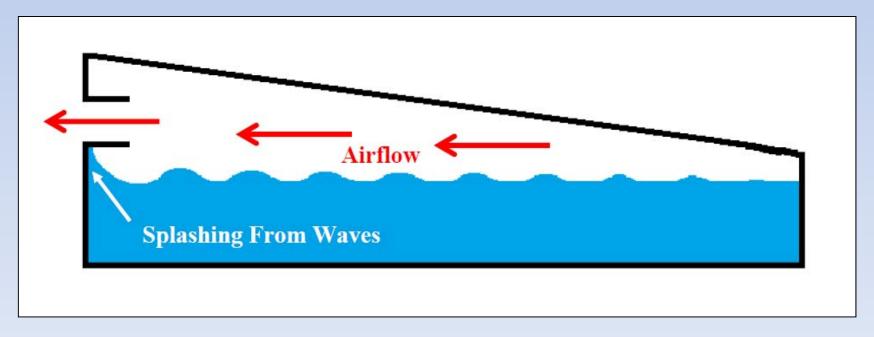
Ground	Claims	Combination
1	<u>1</u>	HC200 Manual + Hebblewhite
2	2 and 3	HC200 Manual + <b>Hebblewhite</b> + Gouget + Rose
3	6	HC200 Manual + Hebblewhite + Smith
4	13	HC200 Manual + <b>Hebblewhite</b> + Gouget + Rose + Smith
5	<u>1</u> & 6	Netzer + Smith + <b>Hebblewhite</b>
6	2, 3, & 13	Netzer + Smith + <b>Hebblewhite</b> + Gouget + Rose

# Hebblewhite: No Flow Tube Extending Into The Water Chamber From A *Gases Inlet*



# Hebblewhite: The Short Outlet Tube Addresses A Specific Wave Splashing Issue In Low-Profile Humidifiers

When water waves are formed within the fourth subpassageway 26, the waves have a particular tendency to splash against the end wall 46, resulting in the danger of water spilling into the air outlet 6. It has been found that spacing the aperture 50 of the air outlet 6 away from the end wall 46 overcomes this problem since the water is less turbulent away from the end wall 46. The aperture 50 should preferably be spaced at least 2 cm away from the end wall 46.



## Hebblewhite

#### <u>Petitioners – "Spillage" In General</u>

"Indeed, the prior art Hebblewhite reference shows a water chamber for a CPAP device that includes such a tube at an opening in order to prevent water from spilling through the opening (see tube 48 in Figure 1)."

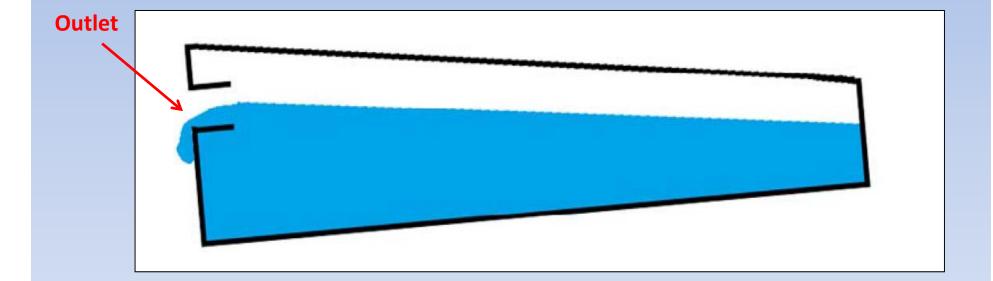
#### **Hebblewhite – Spillage Caused By Wave Splashing**

When water waves are formed within the fourth subpassageway 26, the waves have a particular tendency to splash against the end wall 46, resulting in the danger of water spilling into the air outlet 6. It has been found that spacing the aperture 50 of the air outlet 6 away from the end wall 46 overcomes this problem since the water is less turbulent away from the end wall 46. The aperture 50 should preferably be spaced at least 2 cm away from the end wall 46.

# Hebblewhite: Spillage Caused By Tipping Was Not A Problem

- No discussion in Hebblewhite of tipping
- Tipping was unlikely due to the low-profile humidifier design.
   Ex. 2001 (Schneider Decl.) at ¶ 62.
- The CPAP device rests on top of the humidifier, making tipping unlikely. *Id.*
- Petitioners do not contend that tipping was a problem in Hebblewhite. Ex. 1026 (Virr Decl.) at ¶ 11 ("...my previous declaration never discussed tipping Hebblewhite's chamber or extending the tube within Hebblewhite's chamber.").

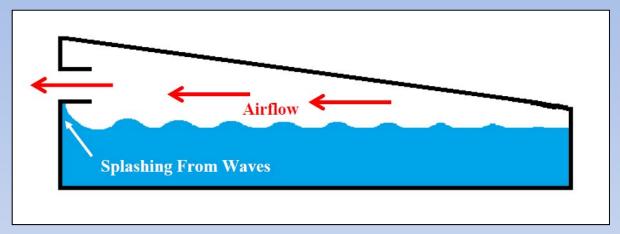
# Hebblewhite: The Outlet Tube Would Not Prevent Spillage Even If The Water Chamber Were Tipped



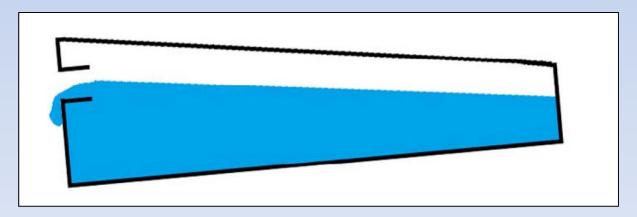
IPR2016-01719: Paper 14 (Patent Owner Response) at 26; Ex. 2001 (Schneider Decl.) at ¶ 61

## **Wave Splashing And Tipping Are Not The Same Issue**

## **Waves**



## **Tipping**



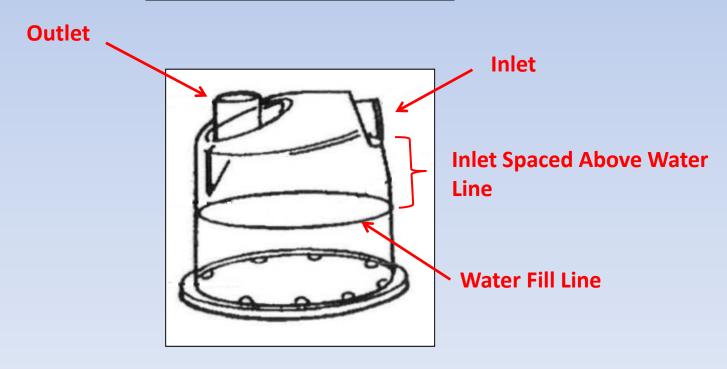
IPR2016-01719: Paper 14 (Patent Owner Response) at 20, 25-26; Ex. 2001 (Schneider Decl.) at ¶¶ 44-45, 61, 68

# Petitioners: Splashing From Waves Was Not A Problem In The HC200 Manual Water Chamber

#### Mr. Virr

"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."

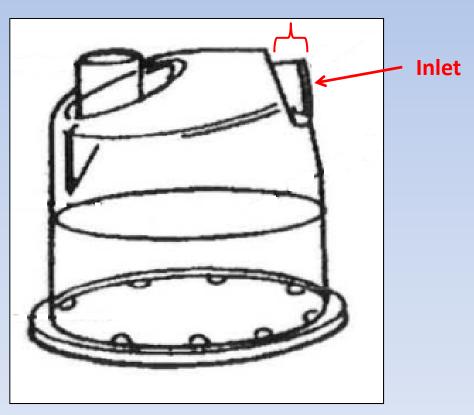
#### **HC200 Manual Water Chamber**



# Combining Hebblewhite With The HC200 Manual Would Not Have Provided Any Benefit

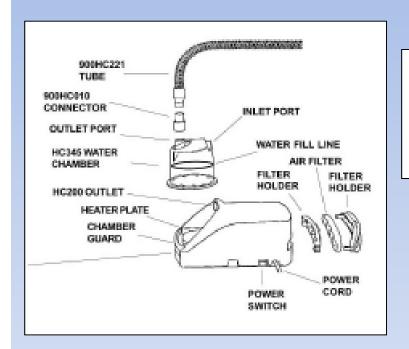
# The HC200 Manual Water Chamber Already Included an Offset Air Inlet

#### Offset



IPR2016-01719: Paper 14 (Patent Owner Response) at 23; Ex. 2001 (Schneider Decl.) at ¶ 65

# Spillage From Tipping Was Not A Recognized Problem In The HC200

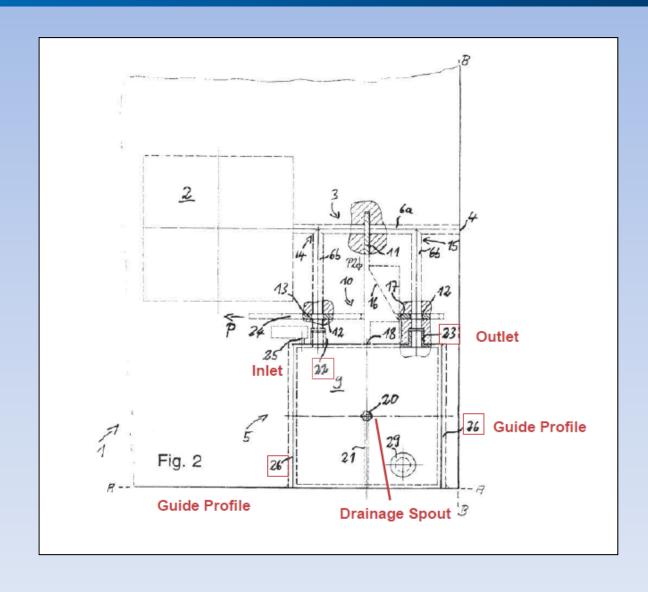


In the unlikely event that you tip water into the blower outlet:
Remove air filter and chamber
Shake excess water out of the back of the unit
Turn unit on and run at prescribed pressure for 5 minutes
Re-assemble and use as directed

#### CAUTION

Avoid moving or tilting the HC200 when the Humidification Chamber is full of water.

## Netzer

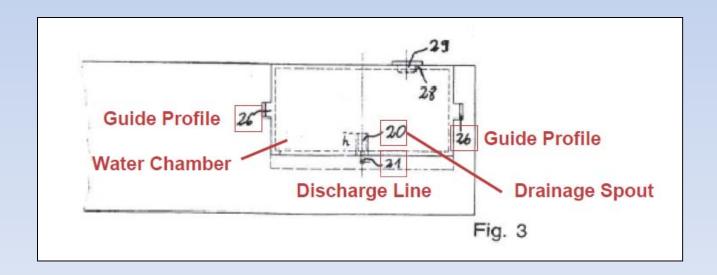


# Netzer: Spillage From Waves Or Tipping Was Not A Problem

- No discussion in Netzer of waves or tipping. IPR2016-01719: Ex. 2001 (Schneider Decl.) at ¶¶ 102-103.
- Inlet and outlet are spaced above water fill level of chamber. *Id.*
- Unlike Hebblewhite, airflow does not direct waves along passageways to the air outlet. *Id.* at ¶ 102. Open design of Netzer's water chamber would dissipate any waves. *Id.*
- Lateral guide profiles on water chamber ensure water chamber remains level during insertion. *Id.* at ¶ 105; IPR2016-01719: Ex. 1010 (Netzer) at 10 and Fig. 3.

# Netzer: Drainage System Prevents Overfilling And Mitigates Any Potential Spillage

It can also be advantageous if the liquid level in the liquid container is limited by means of an overflow element, and if the container inlet and the container outlet, which can be connected to the bypass, are preferably disposed at a spacing above the maximum liquid level. By this means, it is ensured that the respiratory gas supplied through the gas humidifier is only combined with water vapor, and no water drops are carried over into the respiratory gas lines.

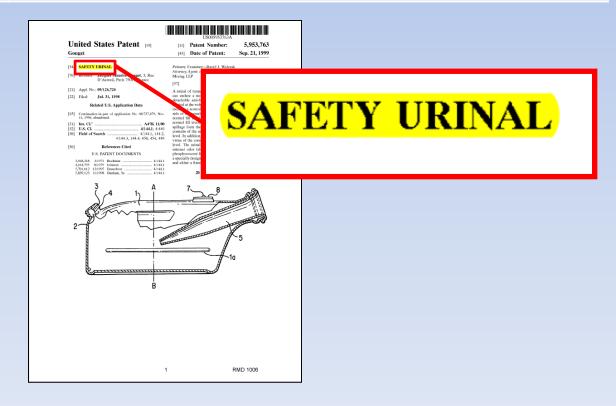


IPR2016-01719: Ex. 1010 (Netzer) at 6-7 and Fig. 3 (annotated); Ex. 2001 (Schneider Decl.) at ¶¶ 52-53, 104

## '197 Patent - Claims 2 & 3

### **Petitioners Rely Upon Gouget**

Ground	Claims	Combination
2	2 & 3	HC200 Manual +Hebblewhite + Gouget + Rose
6	2, 3, & 13	Netzer + Smith + Hebblewhite + Gouget + Rose



## '197 Patent - Claims 2 & 3

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.

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.

## **Analogous Art**

- Petitioners bore the burden of showing that prior art is analogous
- Petitioners merely assumed that Gouget was prior art
  - 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.

IPR2016-01719: Ex. 1003 (Virr. Decl.) at ¶ 51

## **Analogous Art**

- A reference is analogous art if:
  - The reference is from the same field of endeavor as the claimed invention, or
  - The reference is not from the same field of endeavor but is reasonably pertinent to the inventor's problem

In re Bigio, 381 F.3d 1320, 1325 (Fed. Cir. 2004)

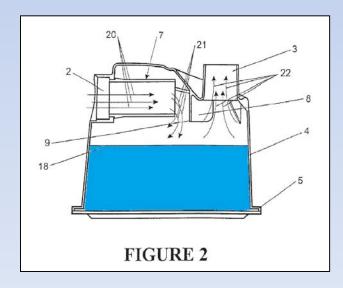
# Gouget Is Not From The Same Field Of Endeavor As The '197 Patent

#### '197 Patent – CPAP Humidifier

#### **Gouget – Urinal**

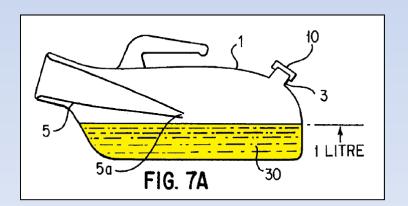
#### i) Field of the Invention

The present invention relates to water chambers for gases humidification and in particular to water chambers for "slide-on" humidifiers and CPAP machines.



#### FIELD OF THE INVENTION

The present invention relates to the field of safety urinals. In particular, the present invention describes features for a transparent or translucent plastic material urinal with a maximum fill indicator that is able to withstand sterilization temperature above 130° C., has an anti-backflow system that includes a screw-type release, in which the interior end of the system is located at the volumetric center of the urinal, such that the urinal may be tilted in any direction without spillage so long as the urinal is not filled beyond the fill indicator level, and an improved feature for quick emptying that prevents release of odors.



IPR2016-01719: Ex. 1001 ('197 patent) at 1:5-8 and Fig. 2 (annotated); Ex. 1006 (Gouget) at 1:9-20 and Fig. 7A (annotated); Ex. 2001 (Schneider Decl.) at ¶¶ 81-82

# Gouget Is Not Reasonably Pertinent To The Problems Solved By The '197 Patent

'197 Patent	Gouget
Preventing water from spilling if a humidifier is tipped while also allowing proper gas inflow and circulation through the humidifier and reducing noise. Ex. 1001 at 2:54-65.	Use of anti-backflow element to allow urine to enter a urinal without allowing the urine to exit accidentally if the urinal is tipped. Ex. 1006 at 8:21-55.

# Petitioners' Proposed Modification Would Not Have Been Obvious In View Of Gouget

#### Gouget

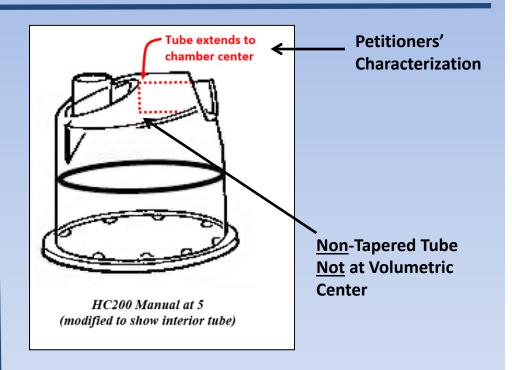
# FIG. 7A 10 3 1 LITRE

Tapered Anti-Backflow Element with Opening at Volumetric Center

#### SUMMARY OF THE INVENTION

It is an object of the present invention to solve the problems of the existing art by providing a safety urinal of transparent or translucent plastic material with a fill indicator that can endure a sterilization temperature of 130° C. having a removable anti-backflow element having its interior end located at the volumetric center and a "quick emptying" feature that dispenses with the necessity of removing the anti-backflow element for emptying. It is a

#### **Petitioners' Proposed Design**



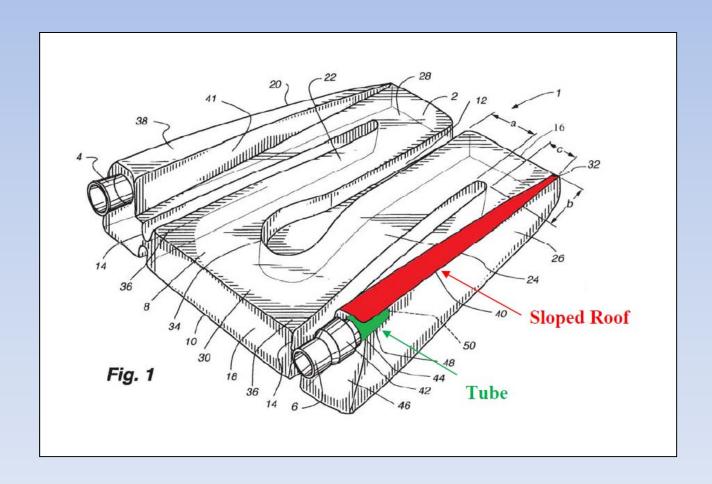
IPR2016-01719: Ex. 1006 (Gouget) at 2:29-36, Fig. 7A (annotated); Paper 4 (Pet.) at 27 (annotated); Paper 14 (Patent Owner Response) at 41-42

# Extending The Outlet Tube Would Have Been Contrary To Teachings Of Hebblewhite

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

# Hebblewhite Does Not Teach Or Suggest A Tube Of The Length Recited In Claims 2 and 3

#### **Sloped Roof Prevents the Outlet Tube from Extending Further**

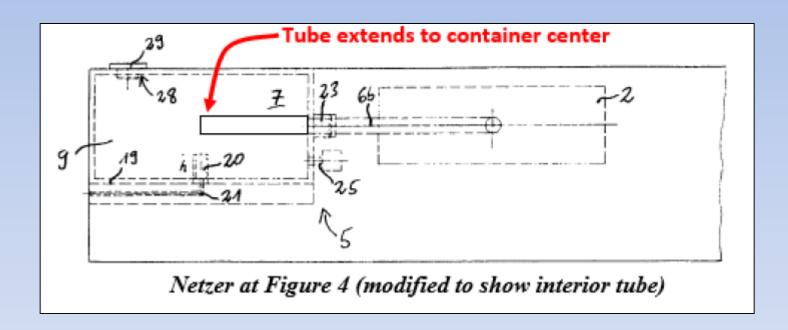


# Adding An Inlet Tube To The HC200 Manual Water Chamber Would Impede Humidification



## **Adding Tubes To Netzer Would Impede Humidification**

#### **Petitioners' Proposed Modified Design**

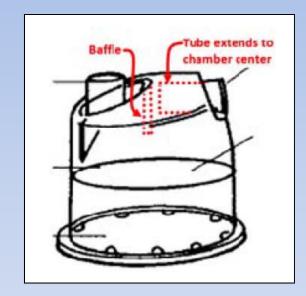


# Petitioners' Solution Of Adding A Baffle Is Based Upon Improper Hindsight

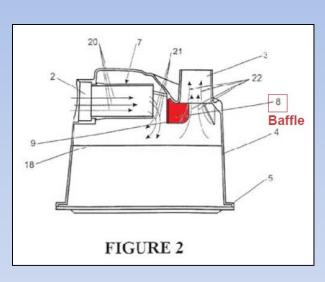
#### Rose

# Fig. 2. 18 74 70 60 Airflow 34 114 48 B

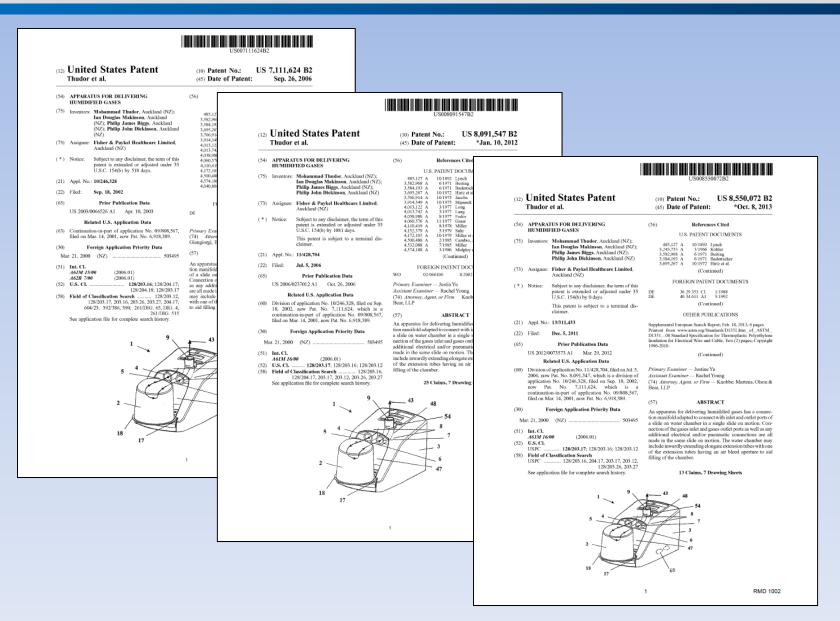
**Petitioners' Design** 



'197 Patent



## U.S. Patent Nos. 7,111,624; 8,091,547; 8,550,072



## **Overview Of Issues**

- Single motion of engagement urging the base of the humidifier chamber adjacent and in contact with the chamber heater '547 patent: Claims 1, 5, 11-14; '624 patent: Claims 3, 7; '072 patent: Claim 7
- Auxiliary electrical connection plug or socket or pneumatic connection plug or port – '547 patent: Claim 5; '624 patent: Claim 7; '072 patent: Claim 11
- Extension tube(s) extending inward into the humidifier chamber from gases inlet/outlet '547 patent: Claims 6, 9, 22-23
- Kenyon does not teach a single motion of connection '072 patent: Claims
   7, 11-13
- Gas return and patient outlet separable from the apparatus '072 patent: Claims 12-13

# "Urges" / "Urging"

#### <u>'072 Patent – Claim 7</u>

7. An apparatus for use in humidified gases delivery treatment as claimed in claim 6 wherein said apparatus includes a chamber heater and said single motion also <u>urges</u> a base of said chamber in contact with said heater.

#### '624 Patent - Claim 3

3. An apparatus for use in humidified gases delivery treatment as claimed in claim 2 wherein said water chamber has a base, and said water chamber is engagable with said humidifier engagement via a single motion, and said single motion of engagement urges the base of said water chamber adjacent and in contact with said chamber heater and makes a first fluid connection between said pressurised gases outlet and said humidifier inlet, and makes a second fluid connection between said humidifier outlet, with said first and second fluid connections being made in the direction of said single motion.

# "Urges" / "Urging"

#### '547 Patent - Claim 1

- An apparatus for use in humidified gases delivery treatment comprising:
  - a housing,
  - a removable humidification chamber with a base,
  - a gases line inlet in said housing to receive pressurised gases from a pressurised gases source, said gases line inlet adapted to make a separable fluid connection with a breathing conduit,
- a gases outlet in said housing in fluid connection with said gases line inlet, adapted to make a separable fluid connection with an inlet of said humidification chamber in order to provide gases flow into said humidification chamber.
- a humidified gases return in said housing, adapted to make a separable fluid connection with an outlet of said humidification chamber in order to receive humidified gases from said humidification chamber,
- a gases line outlet in said housing, in fluid connection with said humidified gases return, adapted to make fluid connection with or in fluid connection with a breathing conduit for delivery of humidified gases to a patient,
- a chamber heater in said housing for vaporising liquid water in said humidification chamber in order to provide water vapour to gases flow passing through said humidification chamber.
- said housing adapted to accommodate a humidification chamber, said humidification chamber being removable and engagable with said housing via a single motion, said single motion of engagement urging the base of said humidification chamber adjacent and in contact with said chamber heater, said single motion also making or breaking said separable connections between said gases outlet and said humidification chamber inlet, and said humidified gases return and said humidification chamber outlet.

said single motion of engagement <u>urging</u> the base of said humidification chamber adjacent and in contact with said chamber heater,

34 Ex. 1003

# "Urges" / "Urging"

IPR	Ground	Patent	Claims	Combination
-01729	1	'547	<u>1</u> ,11-14	Netzer + Levine
-01729	2	'547	5	Netzer + Levine + Bahr
-01730	1	'547	<u>1</u> , 11-14	HC200 Manual + Netzer
-01731	2	'547	5	HC200 Manual + Netzer + Bahr
-01725	3	'624	3	Netzer + Levine
-01725	4	'624	7	Netzer + Levine + Bahr
-01727	1	'624	3	HC200 Manual + Netzer
-01727	2	'624	7	HC200 Manual + Netzer + Bahr
-01716	3	'072	7	Netzer + Levine
-01717	3	'072	7	HC200 Manual + Kenyon

IPR2016-01729: Paper 4 (Pet.) at 16-49; IPR2016-01730: Paper 4 (Pet.) at 13-31; IPR2016-01731: Paper 4 (Pet.) at 48-60; IPR2016-1725: Paper 4 (Pet.) at 25-46; IPR2016-01727: Paper 4 (Pet.) at 14-51; IPR2016-01716: Paper 4 (Pet.) at 28-36; IPR2016-01717: Paper 4 (Pet.) at 33-51

# "Urges" / "Urging" – Construction

Claim Language	Construction
"said single motion of engagement urging the base of said humidification chamber adjacent and in contact with the chamber heater" ('547 patent – Claim 1)	A single motion of engagement that moves the chamber base in a direction so as to both move the chamber base adjacent the chamber heater and also press the chamber base against the chamber heater.
"said single motion of engagement urges the base of said water chamber adjacent and in contact with said chamber heater" ('624 patent – Claim 3)	

Claim Language	Construction
"said single motion also urges a base of said chamber in contact with said heater" ('072 patent – Claim 7)	The single motion of engagement moves the chamber base in a direction so as to press the chamber base against the chamber heater.

### "Urges" / "Urging" v. "Disposes"

#### '547 Patent - Claim 1

said single motion of engagement urging the base of said humidification chamber adjacent and in contact with said chamber heater,

#### '547 Patent - Claim 6

wherein said single motion <u>disposes</u> said heat conductive base adjacent a heater in said humidified gases delivery apparatus.

#### <u>'547 Patent – Claim 24</u>

wherein said single motion of engagement disposes the base of said humidification chamber adjacent said heater,

### "Urges" / "Urging" - Prosecution History

#### **Amendment to Issued Claim 6 of the '547 Patent**

- 7. (Currently Amended) A humidifier chamber for use with a gases humidification apparatus, the humidifier chamber comprising:
  - a container defining a water chamber having an aperture in the bottom, with a surrounding wall and top,
  - a heat conductive base enclosing said aperture in the bottom of said water chamber.

wherein said single motion urging disposes said heat conductive base adjacent and

in contact with a heater of said humidified gases delivery apparatus.

now or gases out or said container,

said gases inlet and said gases outlet being <del>parallel and</del> aligned, such that said humidifier chamber may make operable engagement with a humidified gases delivery apparatus in a single motion, and

at least one extension tube extending horizontally inward into said humidifier chamber from an inner periphery of said gases inlet and/or gases outlet,

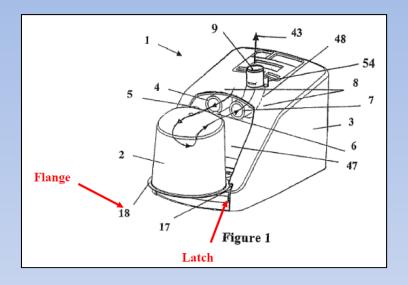
wherein said single motion <u>urging</u> <u>disposes</u> said heat conductive base adjacent <del>and</del> in contact with a heater of said humidified gases delivery apparatus.

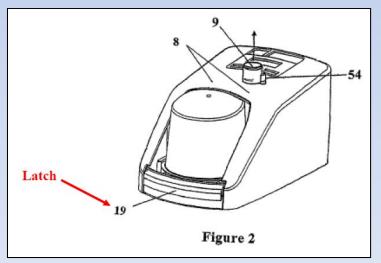
# "Urges" / "Urging" – Patents Describe Angled Slide-In Direction

It is envisaged that other configurations of the present invention are possible where the slide-on direction employed to fit the water chamber is not horizontal but at an angle from the horizontal or vertical. In such cases, the gases inlet 27 and outlet 28, are preferably parallel and aligned with the direction of the intended slide-on motion to allow mating of the chamber inlet/outlet ports and the connection manifold.

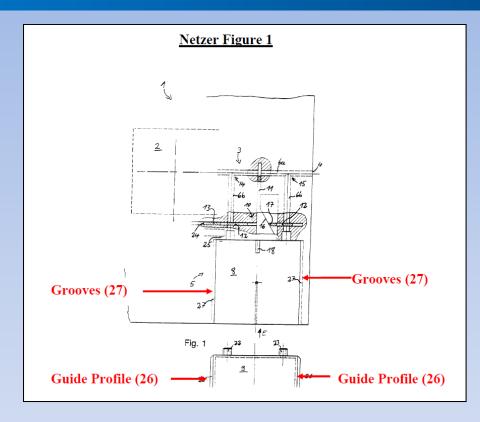
### "Urges" / "Urging"

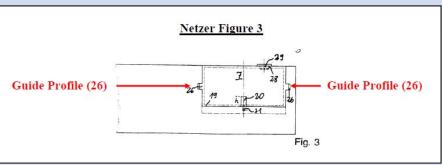
The latch 19, having a locking position and a release position, is biased toward the locking position which prevents removal of the chamber from the CPAP machine. The front face of the latch is shaped such that during the single slide-on motion employed to fit the water chamber to the CPAP machine the flange 18 urges the securing latch 19 into the release position and allows the water chamber to be properly fitted. Once the water chamber is properly seated on the heater base and the inlet 5 and outlet 6 is properly engaged with the connection manifold 8, the flange 18 and base of the chamber will no longer be in contact with the securing latch 19. This allows the securing latch biasing means to urge the latch into the locking position and prevent the water chamber from being removed as shown in FIG. 2.





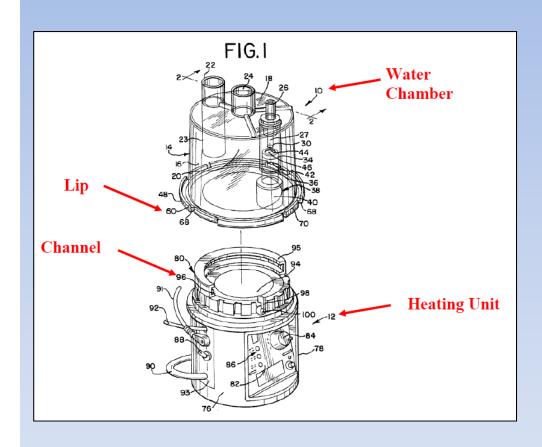
# Netzer Does Not Disclose The "Urges" / "Urging" Limitations





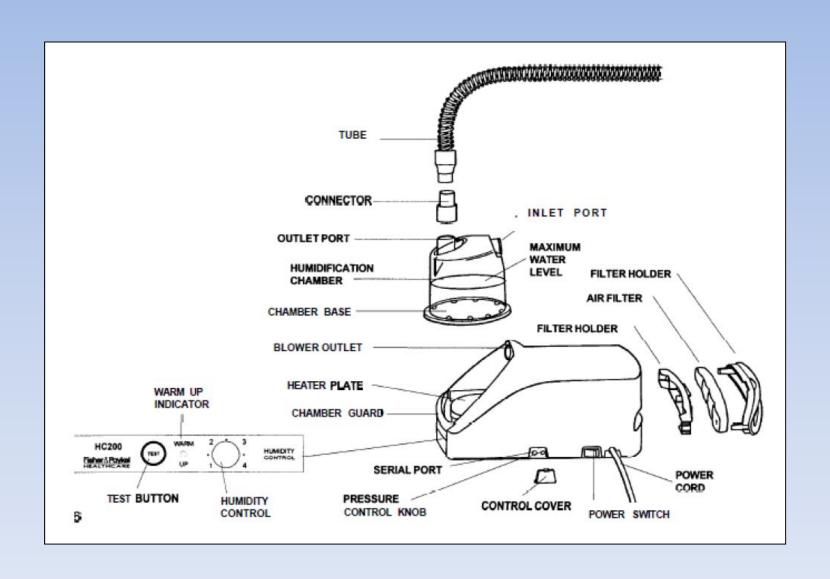
- Netzer does not teach that inserting the water chamber presses the base of the chamber against a heater
- Netzer describes guide profiles that would ensure the water chamber slides into the housing along a horizontal plane

# Levine Does Not Disclose The "Urges" / "Urging" Limitations



- Levine describes that lip (60) of the water chamber is inserted into channel (96) of heating unit
- The water chamber would slide horizontally over the heating surface and would not be urged into contact with the heater

# The HC200 Manual Does Not Disclose The "Urges" / "Urging" Limitations



#### <u>'624 Patent – Claim 7</u>

7. An apparatus for use in humidified gases delivery treatment as claimed in any one of claims 1–6 wherein said patient outlet includes a connector for receiving a breathing hose and at least one auxiliary electrical connection plug or socket or pneumatic connection plug or port, for a simultaneous connection when connecting a breathing circuit having complementary electrical or pneumatic connectors.

#### <u>'072 Patent – Claim 11</u>

11. An apparatus for use in humidified gases delivery treatment as claimed in claim 6, wherein said patient outlet includes a connector for receiving a breathing hose and at least one auxiliary electrical connection plug or socket or pneumatic connection plug or port, for a simultaneous connection when connecting a breathing circuit having complementary electrical or pneumatic connectors.

#### '547 Patent - Claim 5

5. An apparatus for use in humidified gases delivery treatment as claimed in claim 1 wherein said gases line outlet includes a connector for receiving a breathing hose and at least one auxiliary electrical connection plug or socket or pneumatic connection plug or port, for a simultaneous connection when connecting a breathing circuit having complementary electric or pneumatic connectors.

IPR	Ground	Patent	Claims	Combination
-01729	2	'547	5	Netzer + Levine + Bahr
-01731	2	'547	5	HC200 Manual + Netzer + Bahr
-01725	4	'624	7	Netzer + Levine + Bahr
-01727	2	'624	7	HC200 Manual + Netzer + Bahr
-01716	4	'072	11	Netzer + Bahr
-01717	4	'072	11	HC200 Manual + Kenyon + Bahr

## "auxiliary electrical connection plug or socket" – Construction

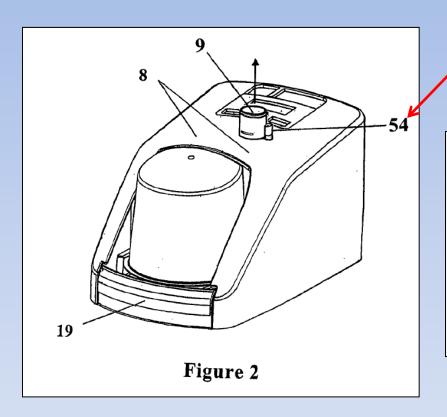
Claim Language	Construction
"auxiliary electrical connection plug or socket or pneumatic connection plug or port"	"an electrical connection plug or socket or pneumatic connection plug or port that is separate and distinct from the connection formed between the patient outlet and the breathing hose"

## Plug/Port/Socket Connote Structures Distinct from the Connection Formed Between the Patient Outlet and Breathing Hose

plug /pləg/ ▶n. 1 a piece of solid material fitting tightly into a hole and blocking it up. ■ a circular piece of metal, rubber, or plastic used to stop the drain of a bathtub or basin. ■ informal a baby's pacifier. ■ a mass of solidified lava filling the neck of a volcano. ■ (in gardening) a young plant with a small mass of soil protecting its roots. 2 a device for making an electrical connection, consisting of an insulated casing with metal pins that fit into holes in a socket.

port<sup>4</sup> ▶n. an aperture or opening, in particular: ■ a socket in a computer network into which a device can be plugged.

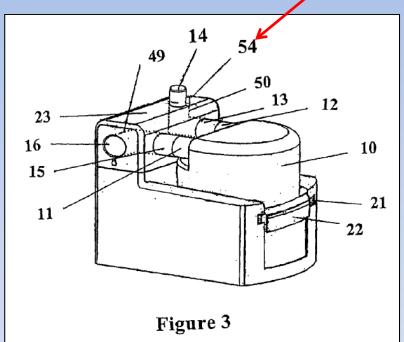
socket /'säkit/ ▶n. 1 a natural or artificial hollow into which something fits or in which something revolves: the eye socket. ■ a hollow, cylindrical part or piece, constructed to receive some part or thing fitting into it. ■ the part of the head of a golf club into which the shaft is fitted. 2 an electrical device receiving a plug or light bulb to make a connection.



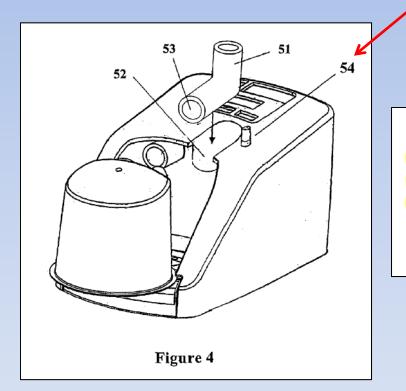
## electrical/pneumatic connection (54)

A further advantage is obtained when additional electrical or pneumatic connections are required. The use of heated conduits requires electrical wiring connectors between the conduit and humidified air source while an additional pneumatic connection may be used for pressure feedback or measurement. In the present invention the connector which includes an additional electrical and/or pneumatic connection 54 for the conduit is integral to the connection manifold of the CPAP machine 8 and therefore allows the disposable water chamber to remain as simple as possible.

## electrical/pneumatic connection (54)



In a similar manner to the first preferred embodiment of a CPAP machine, a further advantage obtained from the configuration of the second preferred embodiment, arises when an additional electrical or pneumatic connection is required. The inlet and/or outlet connectors including an electrical and/or pneumatic connection 54 for the conduit are integral to the connection manifold of the humidifier and therefore allow the disposable water chamber to remain as simple as possible.

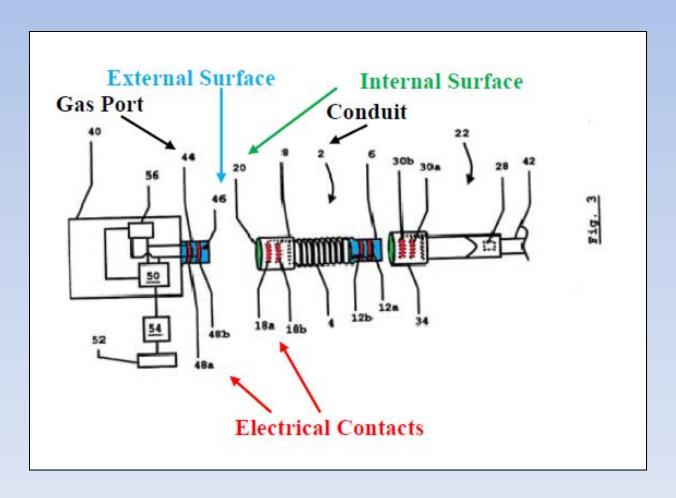


electrical/pneumatic connection (54)

This embodiment may also include additional electrical or pneumatic connections 54 for making a connection between the CPAP machine and a conduit connector, enabling this alternative to retain the advantages of the previously described embodiments.

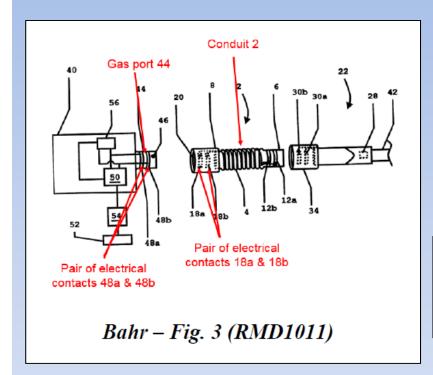
## Bahr Does Not Disclose an "auxiliary electrical connection plug or socket"

Bahr's Electrical Contacts Are Placed "on an external mating surface 46"
of the Hose Connector (gas port 44)



Ex. 1011 (Bahr) at Fig. 3 (annotated), ¶ [0022]; Ex. 2004 (Schneider Decl.) at ¶¶ 73, 94-95

#### The Petition



The ventilator 40 depicted in Figure 3 includes a gas port 44 to which conduit 2 connects to establish a fluid connection. RMD1011 at ¶¶ 21-22. An external mating surface 46 of the gas port 44 includes a pair of electrical contacts 48a, 48b.

Bahr discloses that said gases line outlet (gas port 44) includes at least one auxiliary electrical connection plug or socket as electrical contacts 48a, 48b.

# It Would Not Have Been Obvious To Combine Bahr With Any Reference Cited By Petitioners

#### Bahr:

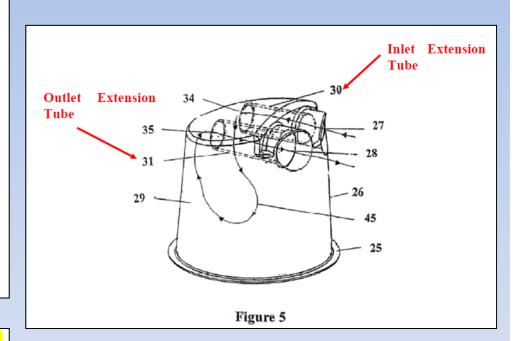
- Describes a ventilator. Used by trained professionals in hospitals. Ex. 1011 (Bahr) at ¶ [0022]; Ex. 2004 (Schneider Decl.) at ¶ 103.
- Does not describe use with a humidifying device. Ex. 2004 (Schneider Decl.) at ¶ 98.
- Conduit would be used with a single patient and then discarded or sterilized and reinstalled by trained clinician.
   Id. at ¶ 103.

### It Would Not Have Been Obvious To Combine Bahr With Any Reference Cited By Petitioners

- Bahr's electrical connections would be unsuitable for use in a CPAP device:
  - Connections would be exposed to water due to positioning on the mating surface of the gas port. Risk compounded by ring-shape of connections. Ex. 2004 (Schneider Decl.) at ¶¶ 98, 102.
  - Risk of damage to CPAP device (short circuits, corrosion). *Id.* at ¶¶ 99-100.
  - Risk of patient injury (inaccurate sensor measurement readings, electrical shock). Id. at ¶ 99.
  - Increase cost/complexity of device (additional circuitry for protecting against electrical discharge, detector for confirming electrical connection required). *Id.* at ¶¶ 101, 104-105.

### '547 Patent - Claims 6 & 9 (Extension Tube)

- **6.** A humidifier chamber for use with a gases humidification apparatus, the humidifier chamber comprising:
  - a container defining a water chamber having an aperture in the bottom, with a surrounding wall and top,
  - a heat conductive base enclosing said aperture in the bottom of said water chamber,
  - a gases inlet to said container adapted to receive a substantially horizontal flow of gases into said container,
  - a gases outlet from said container adapted to deliver a substantially horizontal flow of gases out of said container,
  - said gases inlet and said gases outlet being parallel and aligned, such that said humidifier chamber may make operable engagement with a humidified gases delivery apparatus in a single motion, and
  - at least one extension tube extending horizontally inward into said humidifier chamber from an inner periphery of said gases inlet and/or gases outlet,
  - wherein said single motion disposes said heat conductive base adjacent a heater in said humidified gases delivery apparatus.
- 9. A humidifier chamber as claimed in claim 6, wherein the at least one extension tube comprises an elongate inlet extension tube extending into said humidifier chamber from an inner periphery of said gases inlet, and an elongate outlet extension tube extending into said humidifier chamber from the inner periphery of said gases outlet.

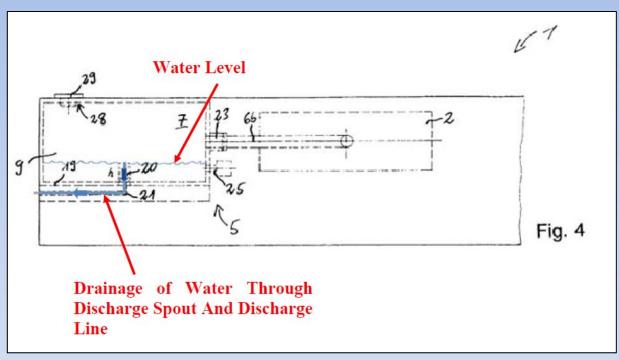


55 Ex. 1003

### **'547 Patent – Claims 6, 9, 22-23 (Extension Tube)**

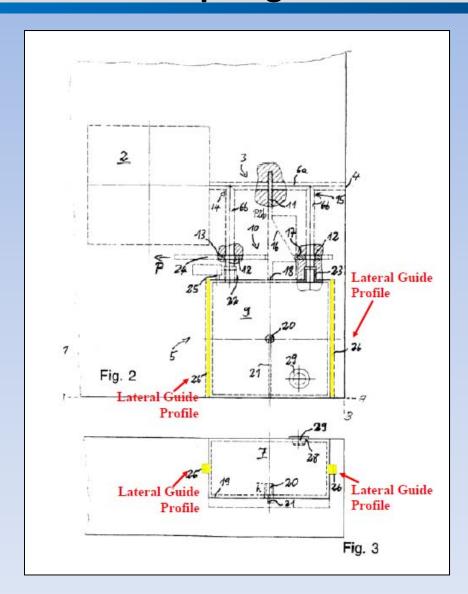
IPR	Ground	Patent	Claims	Combination
-01729	3	'547	<u>6</u> , 9, 22-23	Netzer + Levine + Dickinson
-01731	1	'547	<u>6</u> , 9, 22-23	HC200 Manual + Netzer + Dickinson

# No Reason To Combine – Spillage Was Not An Issue In Netzer



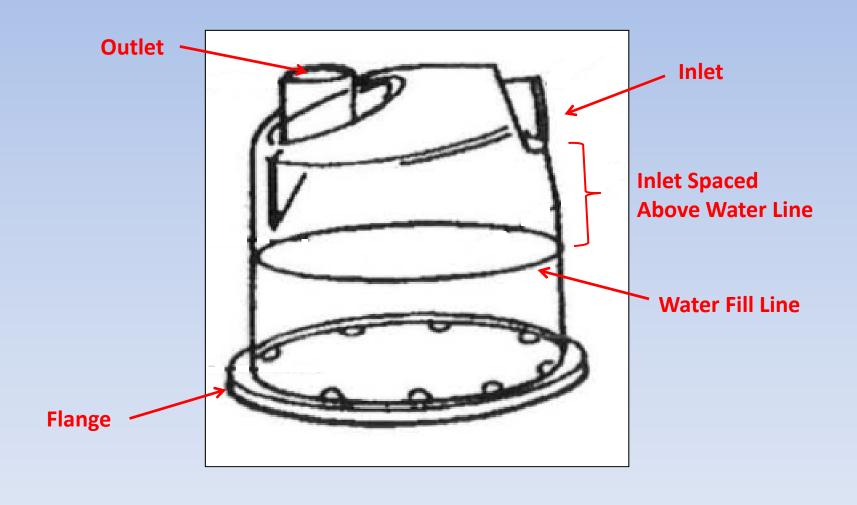
 Drainage system prevents overfilling and maintains water level a distance below the inlet and outlet openings

# No Reason To Combine – Spillage Was Not An Issue In Netzer



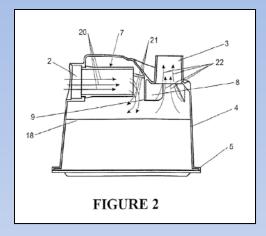
 Guide profiles help prevent the water chamber from tilting

### No Reason To Combine – Spillage Was Not A Recognized Problem In The HC200



## No Reason To Combine Dickinson With Netzer Or The Modified HC200 Manual Design

• Dickinson describes an extension tube at an air inlet. Ex. 1016 (Dickinson) at Fig. 2.



- Spillage through air outlet of Netzer or the modified HC200 design would not have been a problem. Ex. 2004 (Schneider Decl.) at ¶ 161.
- No reason to add extension tubes to achieve noise reduction. Id. at ¶¶ 151-152.
- Adding extension tubes would increase cost and complexity of manufacturing. *Id.* at ¶ 159.
- Adding extension tubes to Netzer would degrade humidification performance. *Id.* at ¶ 158.

### **Connections Made By A Single Motion**

IPR	Ground	Patent	Claims	Combination
-01717	1	'072	<u>6</u> (disclaimed)	Kenyon
-01717	2	'072	12-13	<b>Kenyon</b> + Wickham
-01717	3	'072	6 (disclaimed) and 7	HC200 Manual + Kenyon
-01717	4	'072	11	HC200 Manual + <b>Kenyon</b> + Bahr
-01717	5	'072	12-13	HC200 Manual + <b>Kenyon</b> + Wickham

### **Connections Made By A Single Motion: The Petition**

#### Claim 6 (Ground 1)

Kenyon discloses that said humidified gases return (connection outlet 24) is adjacent to, and aligned with said pressurized gases outlet (connection inlet 22), such that both said separable connections are made by a single motion. RMD1010 at 4:17-24 ("A connection

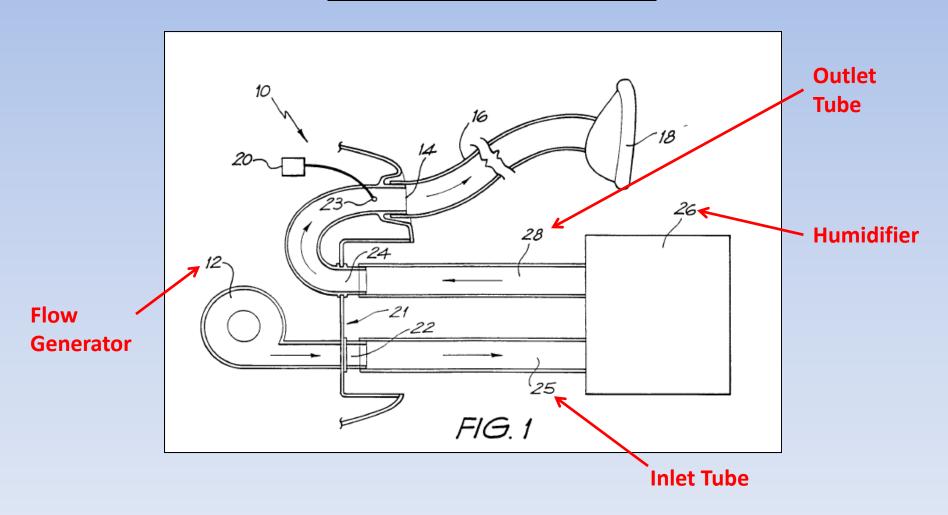
#### Claim 6 (Ground 3)

[6.5] and being adjacent to, and aligned with said pressurized gases outlet, such that both said separable connections are made by a single motion, and

Kenyon discloses that said humidified gases return (connection outlet 24) is adjacent to, and aligned with said pressurized gases outlet (connection inlet 22), such that both said separable connections are made by a single motion. RMD1010 at 4:17-24, 4:32-34, Fig. 1; RMD1012 at ¶¶ 62-67; see, supra, Sec. VII.F.2 at [6.5].

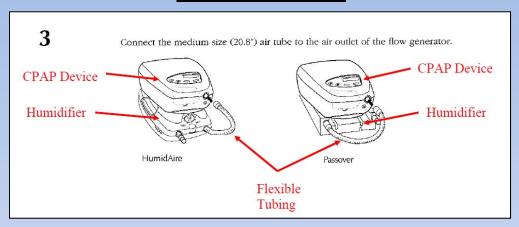
## **Kenyon Does Not Disclose The Claimed Single Motion Limitation**

#### Kenyon Discloses an External Humidifier Connected to a Flow Generator by Flexible Tubes

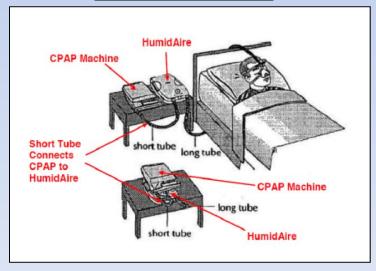


## It Was Conventional To Use Flexible Tubes To Connect External Humidifiers

#### **AutoSet T Device**



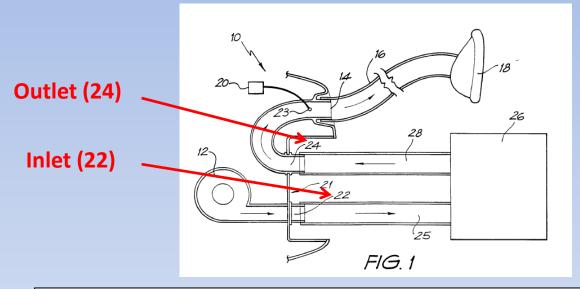
#### **HumidAire Device**

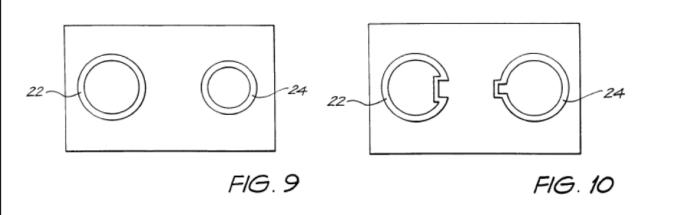


Ex. 2009 (AutoSet T) at 12 (annotated); Ex. 1027 (HumidAire) at 4 (annotated); Ex. 2004 (Schneider Decl.) at ¶ 111

### **Kenyon Discloses Flexible Inlet And Outlet Tubes**

## <u>Different Inlet and Outlet Connections to Avoid Incorrect Installation Necessary</u> <u>Because Inlet and Outlet Tubes are Flexible</u>



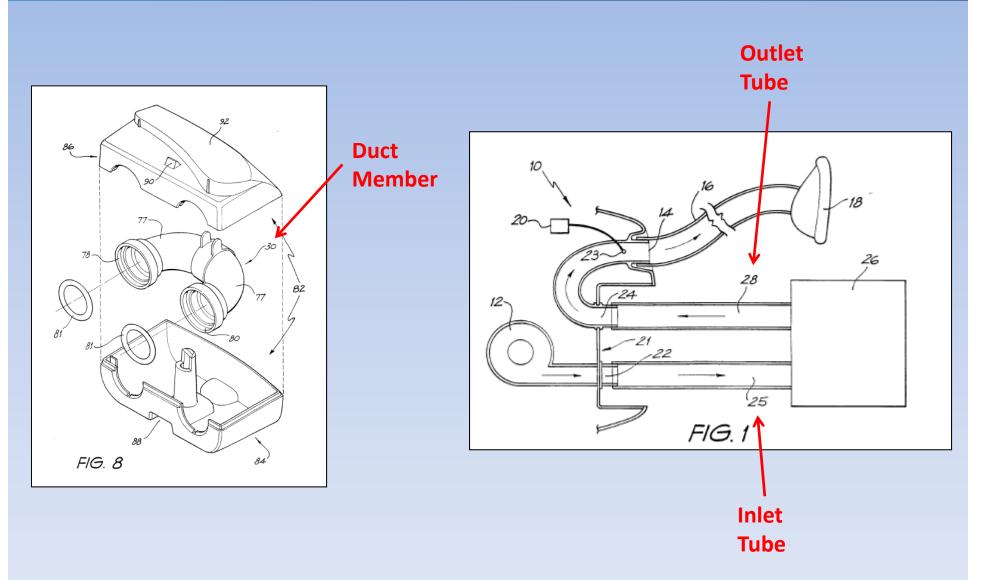


Ex. 1010 (Kenyon) at Figs. 1, 9-10 and p. 8, Ins. 11-17; Ex. 2004 (Schneider Decl.) at ¶¶ 109-110

### **Kenyon Discloses Flexible Inlet And Outlet Tubes**

- A POSITA would understand Kenyon's inlet and outlet tubes are flexible:
  - Rigid tubes would undesirably increase footprint of device. Ex. 2004 (Schneider Decl.) at ¶ 112.
  - Rigid tubes would cause movement of CPAP device to be translated to humidifier (and vice versa) and potentially cause problems (accidental disconnection, breakage). Id. at ¶¶ 113, 115.
  - Rigid tubes would make it difficult to connect the humidifier to the CPAP device. *Id.* at ¶ 114.

### **Duct Member Is Different From Inlet And Outlet Tubes**



Ex. 1010 (Kenyon) at Figs. 1 and 8 (annotated); Ex. 2004 (Schneider Decl.) at ¶ 117

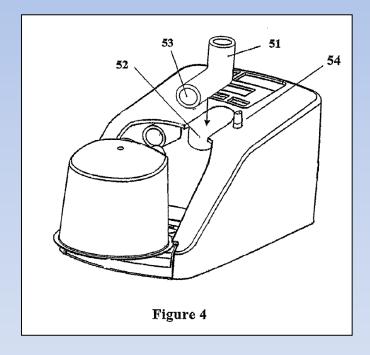
# '072 Patent – Claims 12 & 13 (Separable Gases Return And Patient Outlet)

12. An apparatus for use in humidified gases delivery treatment as claimed in claim 6, wherein said gases return and said patient outlet are separable from said apparatus.

13. An apparatus for use in humidified gases delivery treatment as claimed in claim 12, wherein said apparatus further comprises an elbow tube having a first inlet end and a second outlet end; and

said first inlet end of said elbow tube comprises said gases return, and

said second outlet end of said elbow tube comprises said patient outlet.

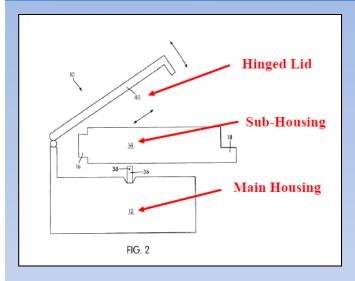


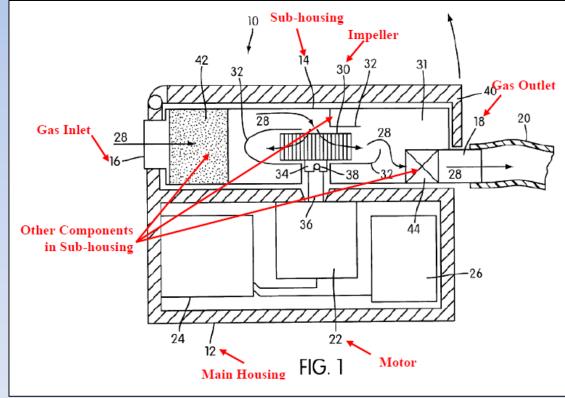
68 Ex. 1002

## '072 Patent – Claims 12 & 13 (Separable Gases Return And Patient Outlet)

IPR	Ground	Patent	Claims	Combination
-01717	2	′072	12 and 13	Kenyon + Wickham
-01717	5	'072	12 and 13	HC200 Manual + Kenyon + Wickham

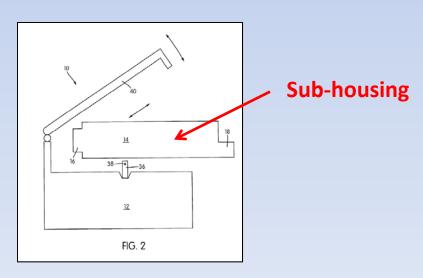
### Wickham Teaches Removing The Entire Gas Flow Path





## Wickham Emphasizes The Importance Of Removing The Entire Gas Flow Path

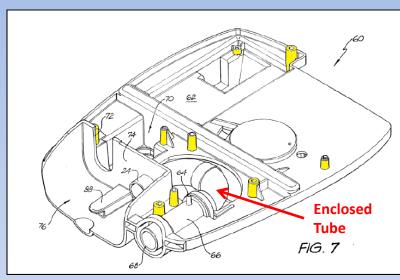
The removability of the sub-housing 14 represents a major improvement over prior art devices as the sub-housing 14 contains most of the "gas flow path" components of the breathable gas supply apparatus 10 that can come into contact with airborne particles from atmosphere or from the patient being treated and it can easily be removed, disposed and replaced with a clean, sterile or disinfected sub-housing 14. Alternatively, the sub-housing 14 can be removed, cleaned, sterilised or disinfected and then reinstalled.



Ex. 1029 (Wickham) at 4:26-34 and Fig. 2 (annotated); Ex. 2004 (Schneider Decl.) at ¶¶ 122-123

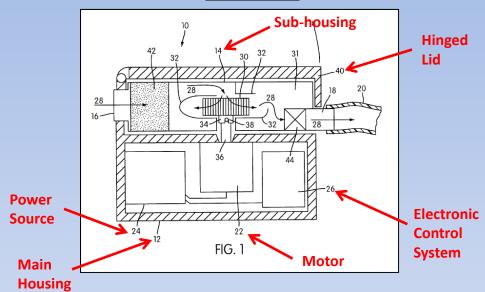
# It Would Not Have Been Obvious To Make Kenyon's U-Shaped Tube Removable

#### **Kenyon**



- Tube enclosed in screwenclosed housing
- Housing not intended to be opened by patient – includes electrical components

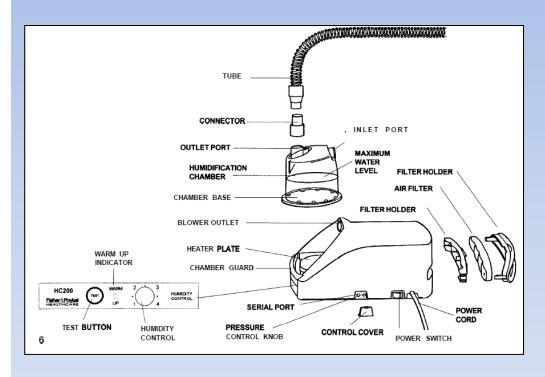
#### **Wickham**



- Contains hinged top allowing sub-housing to be removed
- Electrical components located in separately enclosed compartment

## It Would Not Have Been Obvious To Include A Removable Gases Return And Patient Outlet In The HC200 Device

#### **HC200 Manual**



- Sealed housing
- Does not teach that the housing can or should be opened by a user
- Making housing removable would expose electrical components and would be prohibited by safety standards

## It Would Not Have Been Obvious To Include A Removable Gases Return And Patent Outlet In The HC200 Device

## <u>Virr Declaration – Tube Embedded in Housing of</u> <u>Modified HC200 Design</u>

