



ResMed Limited, ResMed Inc., and
ResMed Corp.
v.
Fisher & Paykel Healthcare Limited

Case Nos. IPR2016-01716, -01717, -01719, -01725, -01727,
-01729, -01730, and -01731

December 6, 2017 Oral Hearing
Petitioner's Presentation

Undisputed that a POSITA would have an engineering degree and at least five years of relevant product design experience

E. Person of Ordinary Skill in the Art

In view of the subject matter of the '547 patent, a person of ordinary skill in the art ("POSITA") as of any of the claimed priority dates as early as March 2000 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. See RMD1012 ¶¶ 22-23. This level of knowledge and skill is applied throughout the Petition.

E.g., IPR2016-01729 Petition at 15; RMD1012 (First Virr Declaration) ¶¶ 22-23.

Test for obviousness does not require structures from secondary references be “bodily incorporated” into the primary reference

Ultimately, “[t]he test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference. . . . Rather, the test is what the combined teachings of the references **would have suggested** to those of ordinary skill in the art.”

MCM Portfolio LLC v. Hewlett-Packard Co., 812 F.3d 1284, 1294 (Fed. Cir. 2015) (emphasis added).

Issues to be addressed – '072, '547, '624 Patents

- 1) **Moving patient outlet to CPAP housing is the only purportedly novel feature in the claims**
- 2) “Urging...adjacent and in contact with” does not require a pressing force
- 3) “Auxiliary electrical connection” need not be “separate and distinct” from the patient outlet
- 4) Evidence shows motivation to combine Bahr with other references
- 5) Kenyon teaches a single slide on motion
- 6) Wickham teaches air path removal for cleaning, sterilizing, or disinfecting a gas flow path
- 7) Evidence shows motivation to combine Dickinson with other references

Only difference between claims and admitted prior art is moving the patient outlet to the CPAP housing

1. An apparatus for use in humidified gases delivery treatment comprising:

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,

RMD1003 ('547 Patent) at 9:48-60 (cited in IPR2016-01729 Petition at 9-11).

ii) Summary of the Prior Art

Humidifier chambers of this type are also now used in compact and portable ventilation machines, for example machines intended for the home treatment of obstructive sleep apnoea (CPAP machines). Where the humidifier base is adapted for use with slide-on humidifier chambers, and the connection of the chamber to the machine is accomplished with a single sliding movement, the inlet air port is provided horizontally through the side of the chamber. Air enters the humidifier chamber through the inlet air port and the humidified air leaves the humidifier chamber into a breathing conduit through an exit port in the top of the humidifier chamber.

RMD1003 ('547 Patent) at 1:34-44 (cited in IPR2016-01729 Petition at 9-11).

FISH.

The only difference between the prior art discussed in the background

section and what is claimed in the '547 patent (claim 1) is that the patient outlet is

on the housing of the CPAP machine rather than the humidifier chamber,

RMD1012 at ¶ 46. For example, the prior art humidification chamber referenced in the background section of the '547 patent appears to be shown in U.S. Patent No. 6,398,197¹ ("Dickinson"), also assigned to F&P. RMD1016. A side-by-side illustration of the prior art chamber from Dickinson and the chamber disclosed in the '547 patent is provided below for comparison:

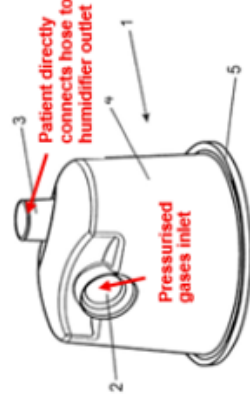


Fig. 1 – '197 Patent (RMD1016)

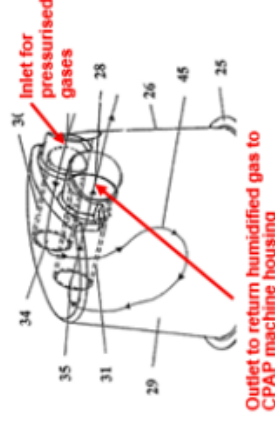


FIG. 5 – '547 Patent (RMD1003)

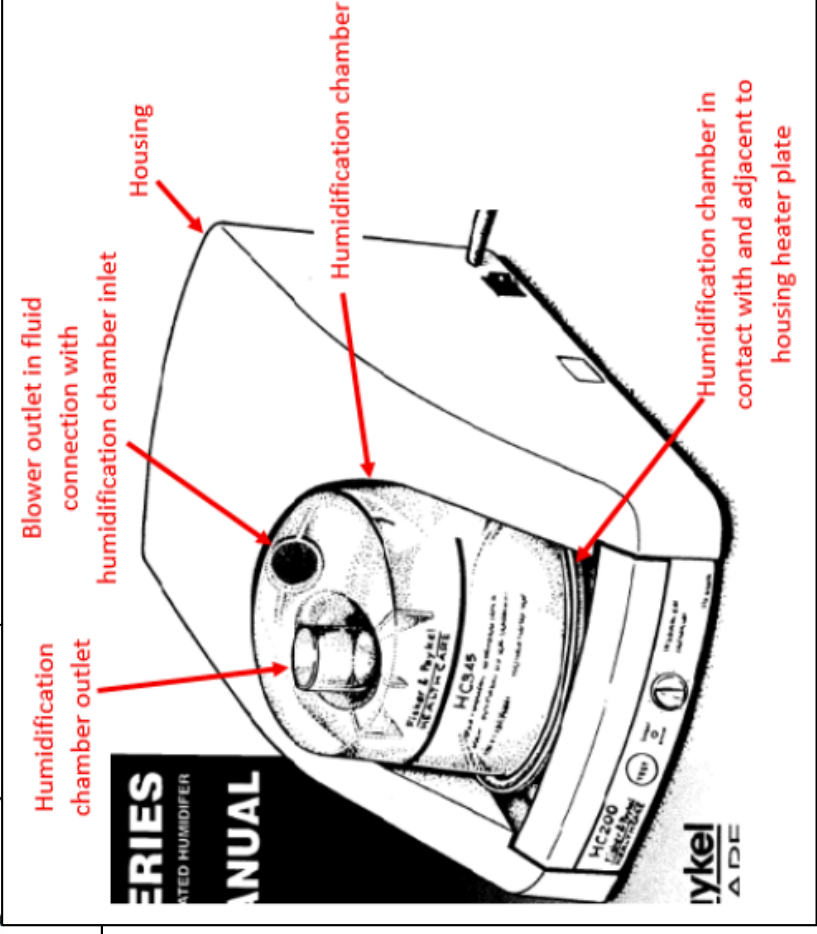
E.g., IPR2016-01729 Petition at 9-10 (citing RMD1012 (First Virr Declaration) ¶¶ 45-46; RMD1003 ('547 Patent) at FIG. 5 (annotated); RMD1016 (Dickinson) at FIG. 1 (annotated)).

Undisputed that HC200 discloses the admitted prior art described in the patents

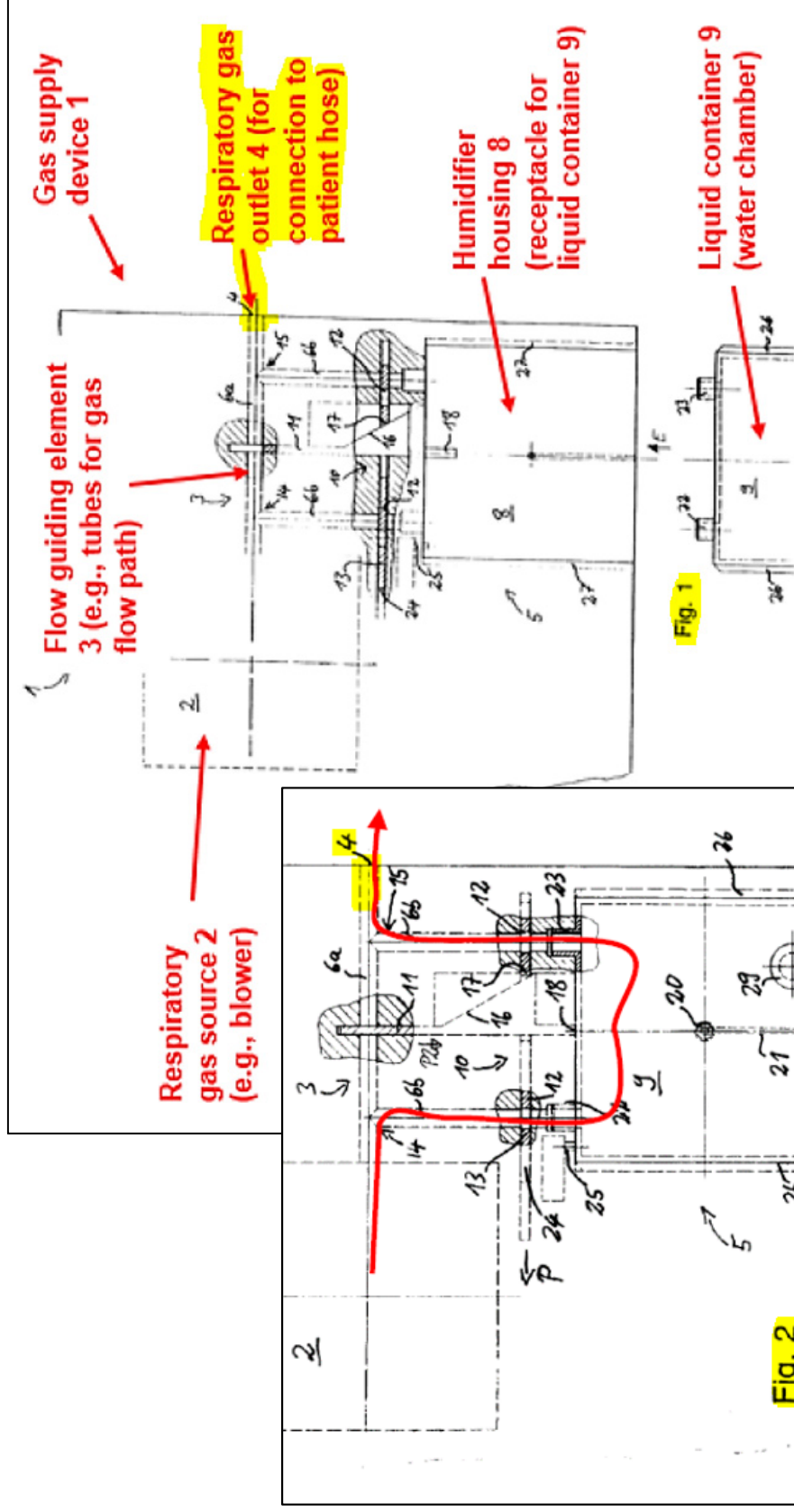
To install the Humidification Chamber:

1. Fill the clean Humidification Chamber through the Outlet Port to the Maximum Water Level with cold distilled water.
2. Press down the spring loaded Chamber Guard and **slide the Humidification Chamber onto the Heater Plate**, ensuring that the Inlet Port on the Chamber fits securely over the Blower Outlet. The Chamber Guard should spring back up to completely surround the chamber base.
3. Switch the HC200 on.

RMD1017 (HC200) at 8 (cited in IPR2016-01730 Petition at 14).

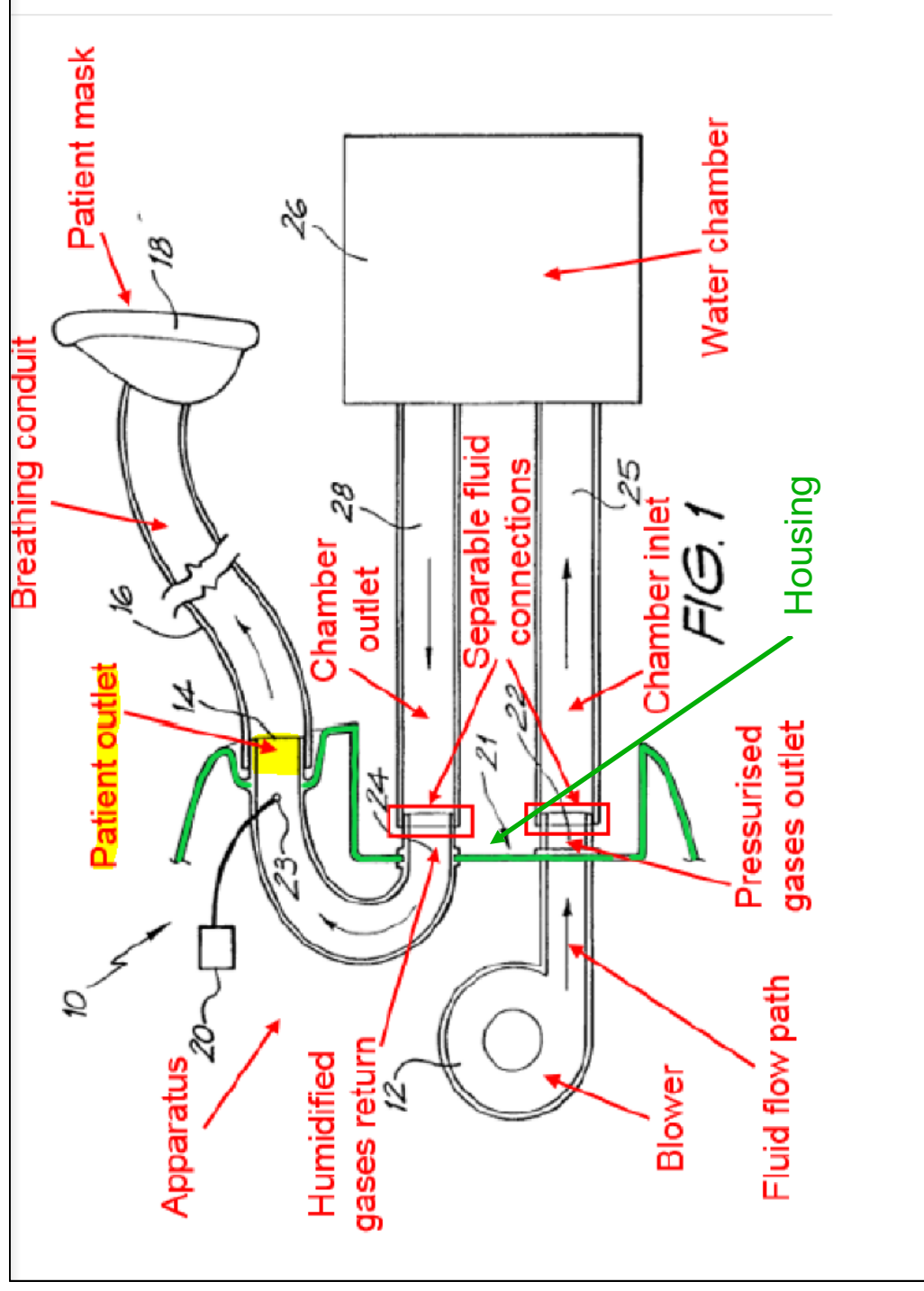


Netzer discloses the patient outlet on the housing – the purported improvement in the claims



E.g., IPR2016-01729 Petition at 18 (citing RMD1008 (Netzer) at Fig. 1 (annotated)).

Kenyon also discloses the patient outlet on the housing –
the purported improvement in the claims



E.g., IPR2016-01717 Petition at 17 (citing RMD1010 (Kenyon) at Fig. 1 (annotated)).

Patent Owner conceded several claims because the prior art discloses the patents' purported point of novelty

- Patent Owner disclaimed:
 - '072 patent - claim 6
 - '547 Patent - claims 24 and 25
 - '624 Patent - claims 1 and 2
- Grounds that are now moot:
 - IPR2016-01716 - Grounds 1 and 2
 - IPR2016-01717 - Grounds 1 and 3 (as applied to claim 6)
 - IPR2016-01725 - Grounds 1 and 2
 - IPR2016-01725 - Ground 3 (as applied to claim 2)
 - IPR2016-01727 - Ground 1 (as applied to claims 1 and 2)
 - IPR2016-01729 - Ground 1 (as applied to claims 24 and 25)
 - IPR2016-01730 - Ground 1 (as applied to claims 24 and 25)

IPR2016-01716 Patent Owner Response at 5; IPR2016-01717 Patent Owner Response at 5;
IPR2016-01725 Patent Owner Response at 1; IPR 2016-01727 Patent Owner Response at 1;
IPR2016-01729 at RMD2007 (Statutory Disclaimer); IPR2016-01730 at RMD2006 (Statutory Disclaimer).

Issues to be addressed – '072, '547, '624 Patents

- 1) Moving patient outlet to CPAP housing is the only purportedly novel feature in the claims
- 2) **“Urging...adjacent and in contact with” does not require a pressing force**
- 3) “Auxiliary electrical connection” need not be “separate and distinct” from the patient outlet
- 4) Evidence shows motivation to combine Bahr with other references
- 5) Kenyon teaches a single slide on motion
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“urging...adjacent and in contact with” covers an intended use that is entitled to no patentable weight under the BRI standard

1. An apparatus for use in humidified gases delivery treatment comprising:

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 breaking said separable connections between outlet and said humidification chamber humidified gases return and said humidifier outlet.

RMD1003 ('547 patent), Claim 1.

“urging” recited in:

- '072 patent, claim 7
- '547 patent, claim 1
- '624 patent, claim 3

Even if the Board adopts FPH’s narrow construction (which would be

legally erroneous), the Board should confirm the unpatentability of claims 1 and

11-14 because the limitation “single motion of engagement urging...” is a mere

functional recitation/recitation of intended use within an apparatus claim, which is

entitled to no patentable weight under the law. This phrase is not entitled to

patentable weight because a “clause that merely states the result of the limitations

in the claim adds nothing to the patentability or substance of the claim.” *Texas*

Instruments Inc. v. U.S. Int’l Trade Comm’n, 988 F.2d 1165, 1172 (Fed. Cir. 1993);

see also *Israel v. Cresswell*, 166 F.2d 153, 156 (C.C.P.A. 1948) (“adds nothing to

the patentability of a claim.”); *Minton v. Nat’l Ass’n of Sec. Dealers, Inc.*, 336 F.3d

1373, 1381 (Fed. Cir. 2003).

Plain language of the claims does not require an “urging” force specifically pressing the chamber base against the heater

1. An apparatus for use in humidified gases delivery treatment comprising:

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.

RMD1003 ('547 patent), Claim 1.

chamber heater. Response, 20-21. However, pressing is not required by the claims and is never even mentioned in the specification. RMD1028, ¶7. For example, a

E.g., IPR2016-01729 Reply at 2 (citing RMD1028 (Second Virr Declaration) at ¶ 7).

Nothing in the patents requires an “urging” force pressing the chamber base against the heater

- The only mention of “urge” in the patents relates to securing latches used to lock the water chamber into position.
- The latch discussion is unrelated to the engagement between the water chamber and the heater base.
- The patents never describe any sort of urging force required to press the water chamber base against the heater.

E.g., IPR2016-01729 Reply at 2-5; RMD1028 (Second Virr Declaration) ¶¶ 7, 8, 11.

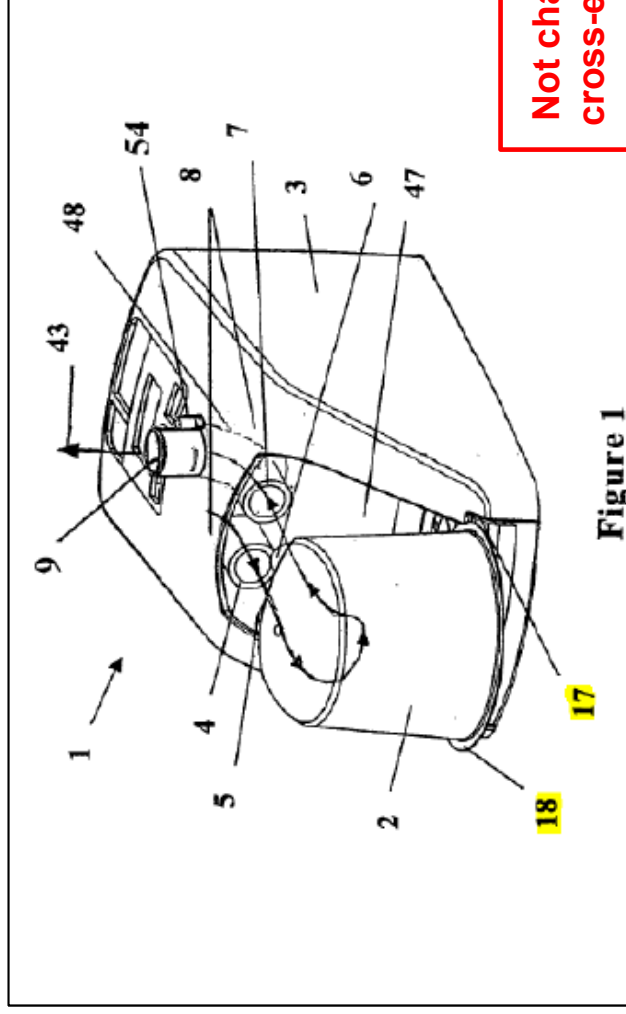
The latch 19, having a locking position and a release position, is biased toward the locking position which prevents removal of the chamber from the CPAP machine. The front face of the latch is shaped such that during the single slide-on motion employed to fit the water chamber to the CPAP machine the 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.

E.g., RMD1003 ('547 patent) at 4:43-56 (cited in IPR2016-01729 Petitioner's Reply at 2-7).

on motion. The latch 22, having a locking position and a release position, is biased toward the locking position which prevents removal of the chamber from the humidifier. The front face of the latch 22 is shaped such that during the single slide-on motion employed to fit the water chamber to the humidifier the flange urges the securing latch 22 into the release position and allows the water chamber 10 to be properly fitted. Once the water chamber is properly seated on the heater base and the inlet 11 and outlet 12 is properly engaged with the connection manifold 23, the flange and base of the water chamber will no longer be in contact with the securing latch 22. This allows the securing latch biasing means to urge the latch into the locking position and prevent the water chamber from being removed.

E.g., RMD1003 ('547 patent) at 5:64-6:10 (cited in IPR2016-01729 Petitioner's Reply at 2-7).

Unchallenged expert testimony confirms patents do not describe a “force pressing” the chamber base against the heater



‘624 patent at Fig. 1; 4:11-18. A POSITA would have understood that the patents at issue simply describe and contemplate the water chamber being slid onto the heater plate using the groove/flange structures depicted in Figure 1, and that the patents at issue do not contemplate any sort of force pressing the chamber base against the chamber heater—and certainly not a spring bias force that was implied by the Patent Owner’s arguments.

Patent Owner's own declarant agrees the patents do not describe pressing the water chamber onto the heater

Q. And then Claim 3 you use the word "urges," and that's the -- this idea of pushing the base of the water chamber in contact with the chamber heater; correct?

A. Correct.

Q. With force?

A. With force.

Q. Yes. Okay. And you can envision -- and we've talked about some of those. You can envision multiple ways that that urging could be accomplished?

A. I can envision that, yes.

Q. Okay. And the patent doesn't describe any specific way of causing that. Is that true?

A. I have not seen that, yes.

RMD1029 (Schneider Transcript) at 72:19-73:7
(cited in e.g., IPR2016-01731 Reply at 2).

A. I can envision there a gel, that when you put something on top of it, it creates something that forces the heater plate to go up. There's other ways to force the heater plate up. It could be several springs, for instance. There could be one spring. There could be -- the spring could be different forms. I have no idea how the engineers based on in that age, 2000, have envisioned how to urge the content because it's not displayed here. Spring-like system could be possible. Is it a spring like that that you move down, and it circles -- I don't know. There's several ways to do it.

RMD1029 (Schneider Transcript) at 58:24-59:1
(cited in e.g., IPR2016-01731 Reply at 2).

A. There's several ways I can consider that depending on the mechanism that creates the urge, the force. Now, in this patent there's nowhere that means how they do the urging. So the answer to your question might be different between the mechanisms that creates the urge or not.

RMD1029 (Schneider Transcript) at 57:16-17
(cited in e.g., IPR2016-01731 Reply at 2).

Functional recitation of “urges... in contact with” merely requires a motion that provides **contact**, not a “pressing force”

1. An apparatus for use in humidified gases delivery treatment comprising:

said housing adapted to accommodate a humidification chamber, said humidification chamber being removable and engageable 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.

6. A humidifier chamber for use with a gases humidification apparatus, the humidifier chamber comprising:

wherein **said single motion disposes said heat conductive base adjacent a heater in said humidified gases delivery apparatus.**

RMD1003 ('547 patent) at Claims 1, 6.

- **Claim 1 of the '547 patent:**
“urging...in contact with” merely requires positioning the water chamber base in **contact** with the chamber heater.

- **Claim 6 of the '547 patent:**
The term “adjacent” requires **adjacency** between the heater plate and chamber base (and does not require physical contact like claim 1).

*E.g., IPR2016-01729 Reply at 3:
RMD1028 (Second Virr Declaration) ¶ 12.*

Patent passages cited by Patent Owner merely describe an angled slide-on direction for the water chamber

Limited portion cited in Patent Owner's Response (e.g., IPR2016-01729 Response at 21).

Additional clarifying passage ignored by Patent Owner (e.g., IPR2016-01729 Reply at 3-4; RMD1028 (Second Virr Declaration) at ¶ 9).

The chamber as shown in FIG. 5 is constructed from an open bottomed plastic container enclosed by a heat conductive base 24, and includes a horizontally aligned gases inlet 27 and a parallel gases outlet 28. 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.

RMD1003 ('547 patent)

- Additional passage clarifies the patents envision an angled direction for sliding the water chamber into the blower unit.
- Nothing in these passages describes any sort of pressing forces applied between the chamber base and chamber heater.

E.g., IPR2016-01729 Reply at 3-4; RMD1028 (Second Virr Declaration) ¶ 9.

Patent Owner concedes invalidity if “urging” construction not adopted

FPH only raises arguments against Ground 1 for claims 1 and 11-14 (Response, 31-37) that rely on its improperly narrow construction of “urging . . . adjacent and in contact with,” which, as described above in Section II, should not be adopted. By failing to raise any other arguments, FPH has effectively conceded that, unless its narrow construction of “urging . . . adjacent and in contact with” is adopted, claims 1 and 11-14 are unpatentable. Scheduling Order, 3 (arguments “not raised . . . in the response will be deemed waived”). Accordingly, if the

E.g., IPR2016-01729 Reply at 13-15.

Issues to be addressed – '072, '547, '624 Patents

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- 3) **“Auxiliary electrical connection” need not be “separate and distinct” from the patient outlet**
- 4) Evidence shows motivation to combine Bahr with other references
- 5) Kenyon teaches a single slide on motion
- 6) Wickham teaches air path removal for cleaning, sterilizing, or disinfecting a gas flow path
- 7) Evidence shows motivation to combine Dickinson with other references

Nothing in the claims requires the “auxiliary electrical connection” be “separate and distinct” from the patient outlet

1. An apparatus for use in humidified gases delivery treatment comprising:

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,

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.

RMD1003 ('547 patent), Claims 1, 5 (discussed in IPR2016-01729 Reply at 7-13; RMD1028 (Second Virr Declaration) ¶¶ 14-17).

“Auxiliary electrical connection” limitations recited in:

- '072 patent, claim 11
- '547 patent, claim 5
- '624 patent, claim 7

Unchallenged expert testimony confirms “auxiliary electrical connection” can be part of a common structure with the patient outlet

14. Plain claim language for “auxiliary connection” (claim 5 of ’547 Patent, claim 11 of ’072 Patent, claim 7 of ’624 Patent). Responsive to Patent Owner’s proposed construction that “auxiliary electrical connection plug or socket” requires a separate and distinct auxiliary connection from the patient outlet

onse at 22-26; ’072-2 Response at 27-31; ’547-1 Response at 26-30; use at 26-30; ’624-1 Response at 22-26; ’624-2 Response at 22-26), I disagree. In particular, the plain meaning of the claim language does not require that the “auxiliary connection plug or socket” be a separate and distinct structure from the patient outlet, but instead indicates that the “auxiliary connection plug or socket” can be part of the common structure with the patient outlet. For example,

Not challenged by
cross-examination

RMD1028 (Second Virr Declaration) ¶14 (cited in e.g., IPR2016-01729 Reply at 7-8).

Patent Owner’s “separate and distinct” requirement is inconsistent with plain meaning of “auxiliary”

aux·il·ia·ry \ôg-'zil-yə-rē, -'zil-rē, -'zi-lə-\ *adj* [*L auxiliarius*, fr. *auxilium* help; akin to *L augēre* to increase — more at *EKE*] (15c) **1 a** : offering or providing help **b** : functioning in a subsidiary capacity <an ~ branch of the state university> **2 of a verb** : accompanying another verb and typically expressing person, number, mood, or tense **3 a** : SUPPLEMENTARY **b** : constituting a reserve <an ~ power plant> **4** : equipped with sails and a supplementary inboard engine

Patents use “additional” to mean a second auxiliary connection, something not required by the claims

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.

RMD1003 ('547 patent) at 5:18-23 (cited in IPR2016-01729 Reply at 8-9).

Not challenged by cross-examination

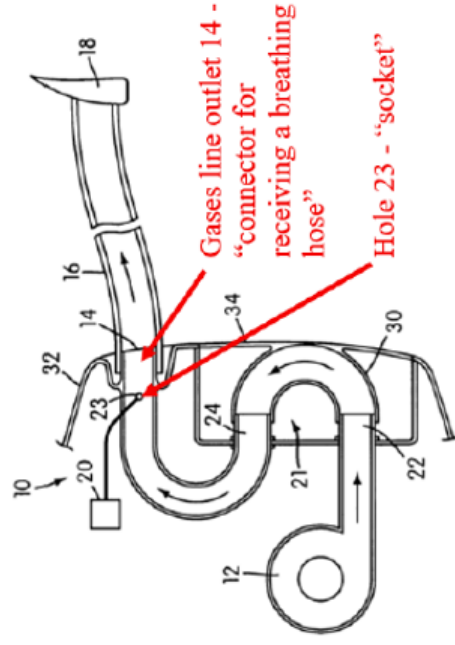
Instead of using the word “additional” to describe a separate and distinct structure, as Patent Owner incorrectly alleges, the patents at issue actually use the word “additional” to refer to a second auxiliary electrical/pneumatic connection in embodiments with multiple electrical/pneumatic connections (as opposed to embodiments with a single electrical/pneumatic connection). For

RMD1028 (Second Virr Declaration) ¶14 (cited in IPR2016-01729 Reply at 7-8).

Reference relied on by Patent Office during prosecution showed “auxiliary connection” in common structure

construction. In particular, during prosecution the Examiner asserted that the Kenyon reference (RMD1032) satisfied the requirements of claim 5 by having a hole 23 (alleged to be “a socket for a pressure sensor (20)”) in the sidewall of a gases line outlet 14 (alleged to be a connector for receiving a breathing hose).

RMD1006, 115; RMD1032, Fig. 1. This hole 23 is integrally formed in the same structure as the gases line outlet 14 and is not separate and distinct from the gases outlet 14, as depicted below:



RMD1032, Fig. 1 (annotated). FPH did not contest or otherwise disagree with this assertion regarding the Examiner’s interpretation of claim 5. RMD1006, 99. This

E.g., IPR2016-01729 Reply at 9-10 (citing RMD1006 ('547 prosecution history) at 99; RMD1032 (Kenyon) at Fig. 1 (annotated)).

Issues to be addressed – '072, '547, '624 Patents

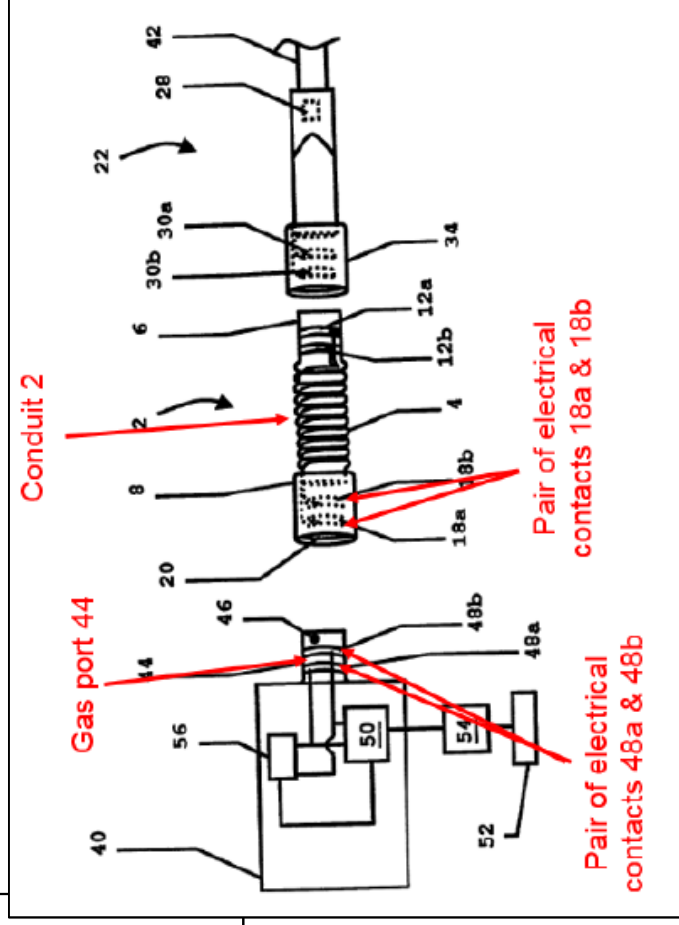
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Even if “separate and distinct” structures are required, a POSITA would have understood that Bahr discloses an auxiliary electrical connection plug/socket

‘624-1 Response at 34-35; ‘624-2 Response at 33). Bahr describes that its electrical contacts 48a-b are separate and distinct components “on an external mating surface 46” of the gas port 44, and that electrical contacts 18a-b are separate and distinct components “provided on the inside of the female interface 8.” Bahr at 0022. A POSITA would have understood the electrical contacts 48a-b and 18a-b to be a “plug or socket,” as recited by claim 11 of the ‘072 patent, claim 7 of ‘624 patent, and Claim 5 of the ‘547 patent. Alternatively, a POSITA would have understood that the gas port 44 and the female interface 8 would be considered to be two different components, with a distal end of the gas port 44 (without the contacts 48a-b) being the patient outlet and the proximate end of the gas port 44 (with the contacts 48a-b) being the “auxiliary electrical connection plug or socket.”

RMD1028 (Second Virr Declaration) ¶ 18
(cited in e.g., IPR2016-01729 Reply at 16).

**Not challenged by
cross-examination**



E.g., IPR2016-01729 Petition at 45-46 (citing RMD1011 (Bahr) at Fig. 3 (annotated)).

Bahr contemplates use in humidified environments and a “gas tight connection” is water tight

[0004] Very often a fluid transfer device which is used in patient care, such as a liquid ventilator which transfers a breathing liquid to and from a patient, a gas ventilator or respirator which transfers gas to and from a patient, or a dialysis machine which transfers blood to and from a patient, needs to communicate with external elements such as sensors or valves connected to a fluid flow path linking the device to the interior of a patient.

RMD1011 (Bahr) ¶ 4 (cited in e.g., IPR2016-01729 Reply at 18).

proximal end of the flexible tubing 4. The contacts 48a and 48b, and 18a and 18b, are disposed on their respective surfaces 46, 20 such that when the female interface 8 is pushed over the port 44 to thereby form a gas tight connection, the contacts 48a and 48b and 18a and 18b will establish an electrical connection. Preferably one or both sets of contacts

RMD1011 (Bahr) ¶ 22 (cited in e.g., IPR2016-01729 Reply at 18).

Not challenged by cross-examination

factual errors. Bahr explicitly describes (a) its device is designed to be used with highly humidified/moist fluids, like blood, (b) the electrical contacts establish an electrical connection when the flexible tubing forms a “gas tight connection” with the gas port, and (c) the tubing is “formed of a flexible rubber material to form a gas seal when push-fit with” the gas port. Bahr at 0004, 0019, 0022-0023. A POSITA would have understood that Bahr contemplates use in a humidified environment, and that such a “gas tight connection” would also be water tight, and thus capable of preventing the mating surfaces from being exposed to water.

RMD1028 (Second Virr Declaration) ¶ 19 (cited in e.g., IPR2016-01729 Reply at 18).

A “separate and distinct” electrical connection of the type shown in the patent would have many of the same alleged disadvantages as Bahr

POSITA would have understood that the “electrical and/or pneumatic connection 54 for the [patient breathing gas] conduit” could also be exposed to water, e.g., during cleaning or as a result of water being splashed on the housing (such as from a patient spilling water from the water chamber onto the housing as the water chamber is being slid into the housing), as illustrated below (with annotation):

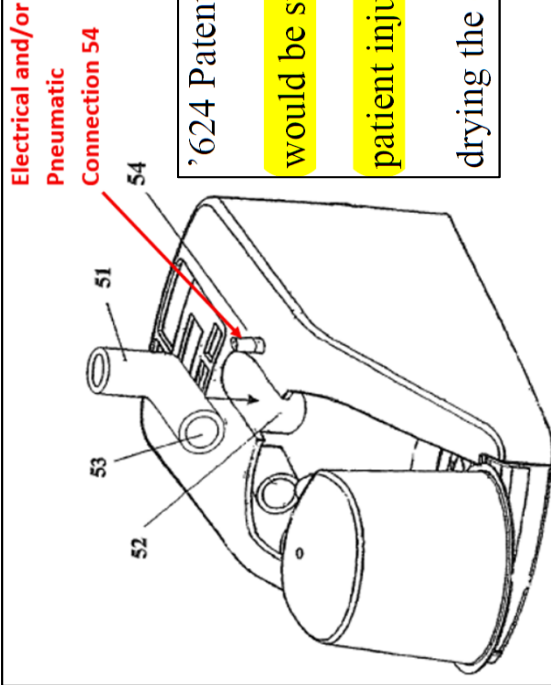


Figure 4

RMD1028 (Second Virr Declaration) ¶ 20
(cited in e.g., IPR2016-01729 Reply at 18-19).

’624 Patent, Fig. 4, 6:13-21. A POSITA would understand that the connector 54 would be susceptible to the same risks of electrical short, device malfunction, or patient injury if, for example, “the patient reconnected the breathing hose without drying the electrical contacts,” as asserted by Patent Owner against Bahr’s device.

RMD1028 (Second Virr Declaration) ¶ 20
(cited in e.g., IPR2016-01729 Reply at 18-19).

A POSITA would not have been deterred from combining Bahr with the other references because of cost and complexity

Response at 35-38; '624-2 Response at 34-37), I disagree. First, a POSITA would have recognized that the widely known practice of using conventional circuitry to confirm that a proper electrical connection was established would not have added meaningful cost/complexity to the resulting system, especially given the additional safety/performance benefits achieved from receiving confirmation that the proper connection is established. Second, a POSITA would have understood that, like Bahr, the patents at issue would have typically employed the then-conventional circuitry to confirm that a proper electrical connection was established even though the specification does not describe this feature. Patent Owner's arguments are flawed because they conflate visual confirmation of a physical connection established with signal-based confirmation of an electrical connection being established.

**Not challenged by
cross-examination**

Issues to be addressed – '072, '547, '624 Patents

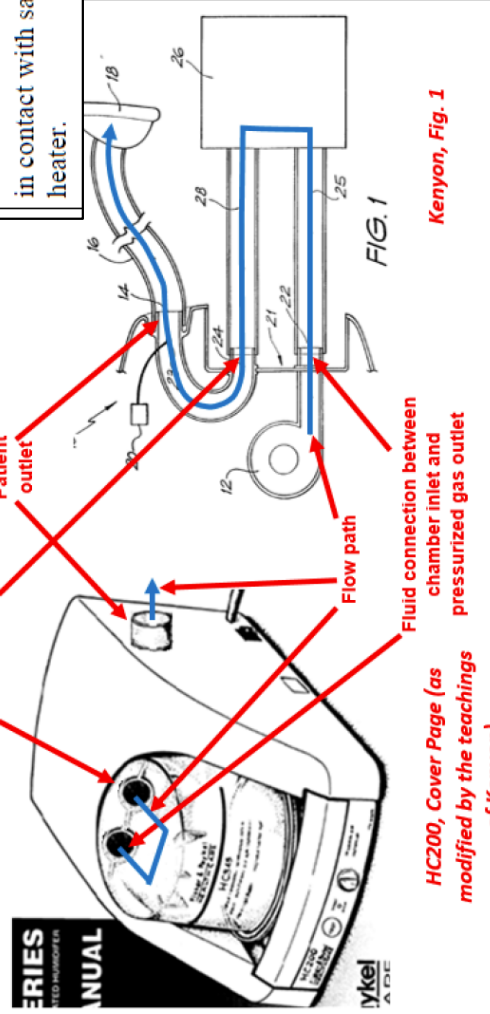
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- 7) Evidence shows motivation to combine Dickinson with other references

A POSITA would have understood that Kenyon teaches the “single motion” limitation

(’072-2 Response at 33-34, 41-42), I disagree. As discussed in greater detail, there are several similarities between the humidifier 26 and duct member 30 that demonstrate that the humidifier 26 would have also been made of rigid material, similar to the duct member 30, which is made from “ABS plastic.” Kenyon at 5:30-32. ¹ For example, Kenyon describes that a “connection means” on the flow generator permits “selective connection to either a duct member . . . or to a humidifier” and that this selective connection permits the CPAP device to be “quickly and easily converted between including, or not including, a humidifier in the gas supply path.” Kenyon at 2:33-36; 4:32-34. ² In another example, Kenyon describes that the flow generator includes a differently shaped/size inlet 22 and outlet 24 that are designed to ensure that *both* “the duct member and the humidifier inlet and outlet are provided with corresponding engaging formations to avoid incorrect installation.” Kenyon at 6:11-16 (emphasis added); *see also* 3:7-9. In another example, Kenyon uses the term “flexible” to describe other tubing (“flexible gas supply tube 16 to a face mask 18”), but does not use it to describe either the humidifier 26 or the duct member 30 (or their sub-components). Kenyon at 4:15-17; *see also* 4:22-29. Based on these similarities, a POSITA would have

Not challenged by cross-examination

Patent Owner fails to address Petitioner’s argument that the combination of HC200 and Kenyon discloses the “single motion” limitation

4. A POSITA Would Have Combined <i>HC200</i> with <i>Kenyon</i>. A person of ordinary skill in the art at the time of the '072 patent would have been motivated to modify the <i>HC200</i> to move the patient outlet tube from the humidifier chamber to the housing, as taught by <i>Kenyon</i>, so that the humidifier chamber could slide in and out of the housing without requiring the patient to disconnect the outlet tube and mask every time he needed to fill or clean the humidifier. RMD1012 at ¶¶ 91-101.	IPR2016-01717 Petition at 34-46 (citing RMD1012 (First Virr Declaration) ¶¶ 64, 67, 73, 99-101). Exemplary Disclosure of <i>HC200 Manual</i> and/or <i>Kenyon</i> Chamber onto the Heater Plate,” describing “The ideal humidity setting for your HC200 depends on room temperature and humidity. The aim is to maximise comfort at the mask while preventing excess condensation in the Tube. Initially, a setting of 2 is recommended”, 10 (instructing “Allow the heater plate to cool for about 15 minutes before removing the chamber”); RMD1012 at ¶¶ 73-75. <i>HC200 Manual</i> discloses said chamber (humidification chamber) has a base. <i>HC200 Manual</i> also discloses that said single motion also urges the base of said chamber (humidification chamber) in contact with said heater. RMD1017 at 7 (depicting a “Chamber Base” for the
[7.3] said single motion also urges a base of said chamber in contact with said heater.	IPR2016-01717 Petition at 50.  The diagram shows a humidifier unit on the left and a patient interface on the right. Red arrows and text annotations highlight specific connections and components. The annotations include: 'Fluid connection between chamber outlet and humidified gases return' pointing to a connection on the humidifier; 'Patient outlet' pointing to a tube on the patient interface; 'Flow path' pointing to a tube connecting the two; 'Fluid connection between chamber inlet and pressurized gas outlet' pointing to another connection on the humidifier; and 'HC200, Cover Page (as modified by the teachings of Kenyon)' pointing to the humidifier unit. The patient interface is labeled 'FIG. 1' and 'Kenyon, Fig. 1'. The humidifier unit has a label 'SERIES HC200' and 'ANALOG'.

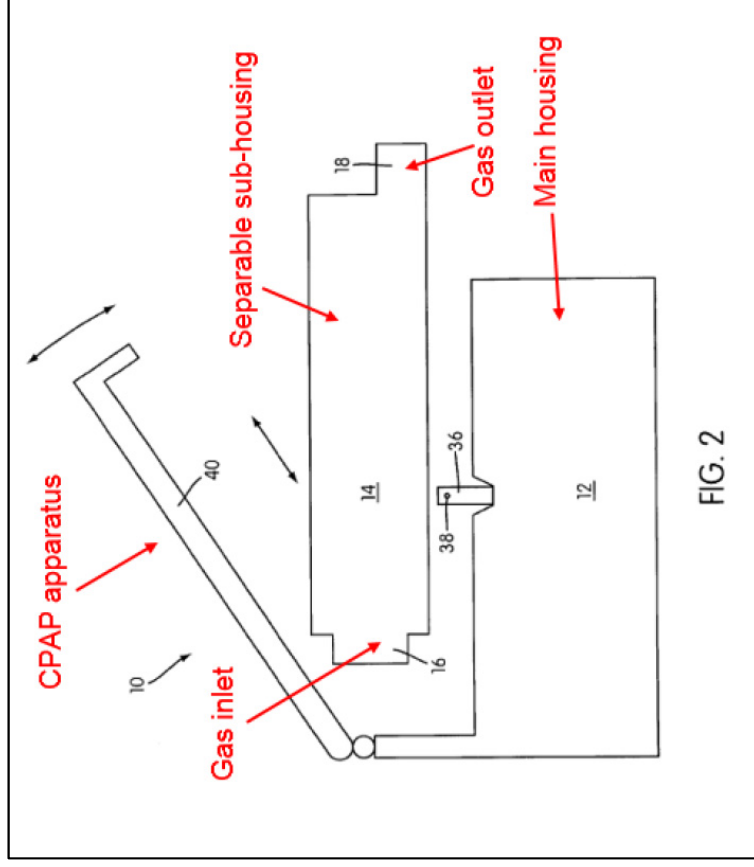
Issues to be addressed – '072, '547, '624 Patents

- 1) Moving patient outlet to CPAP housing is the only purportedly novel feature in the claims
- 2) “Urging...adjacent and in contact with” does not require a pressing force
- 3) “Auxiliary electrical connection” need not be “separate and distinct” from the patient outlet
- 4) Evidence shows motivation to combine Bahr with other references
- 5) Kenyon teaches a single slide on motion
- 6) **Wickham teaches air path removal for cleaning, sterilizing, or disinfecting a gas flow path**
- 7) Evidence shows motivation to combine Dickinson with other references

Wickham teaches a separable gas inlet and 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.

RMD1002 ('072 Patent), Claim 12.



Wickham and patents agree that air path components should be removable so they can be cleaned

Wickham

14. Alternatively, the sub-housing 14 can be removed, cleaned, sterilised or disinfected and then reinstalled.

RMD1029 (Wickham) at 4:33-34 (cited in IPR2016-01717 Reply at 19).

In a second aspect, the present invention discloses a method of cleaning, sterilising or disinfecting the gas flow path of the breathable gas supply apparatus of the first aspect, said method comprising the steps of:

- (a) removing the sub-housing from the main housing, and
- (b) cleaning, sterilising, disinfecting or replacing the sub-housing; and
- (c) connecting the sub-housing to the main housing.

RMD1029 (Wickham) at 3:1-9 (cited in IPR2016-01717 Reply at 19).

'072 Patent

Preferably the connection manifold 23 includes a passage 49 which receives airflow from the inlet conduit through inlet port 16 and directs it into the water chamber inlet port 11 through manifold outlet port 15. Preferably the connection manifold 23 also includes a passage 50 which receives airflow from the water chamber outlet port 12, via manifold inlet port 13 and directs it to the manifold patient outlet port 14. The connection passages 49 and 50 are shown in hidden in FIG. 3. Preferably the connection manifold 23 of the present invention is removable to aid cleaning and/or sterilization of the passages. Preferably the connection passages are internal to the connection manifold 23.

RMD1002 ('072 Patent) at 5:47-58 (cited in IPR2016-01717 Reply at 19).

A POSITA would have been motivated to modify Kenyon or HC200+Kenyon in view of Wickham

(’072-2 Response at 47-49), I disagree. Particularly, as described in the previous paragraph (*supra* ¶ 27), a POSITA would have understood from Wickham’s disclosure that it is advantageous to adapt a flow generator’s housing so that the flow path (whether in whole or in part) can be accessed, removed, and cleaned. Additionally a POSITA would have understood that the part of the air path most in need of removal for cleaning was that which was downstream of the humidifier and thus wet.

↑ RMD1038 (Second Virr Declaration) ¶ 28
(cited in IPR2016-01717 Reply at 18-19).

**Not challenged by
cross-examination**

be removed. A POSITA would have appreciated that the teachings of Wickham could have been readily applied to the CPAP device resulting from the combination of the HC200 and Kenyon to provide access and removability of the gases return and patient outlet so that it could be cleaned and sterilized.

RMD1038 (Second Virr Declaration) ¶ 31
(cited in IPR2016-01717 Reply at 18-19).

Particularly, a POSITA would have understood that Wickham’s teaching of a hinged housing permitting access to a removable tube within the housing could have readily been applied to Kenyon. Additionally, a POSITA would have readily

RMD1038 (Second Virr Declaration) ¶ 30
(cited in IPR2016-01717 Reply at 18-19).

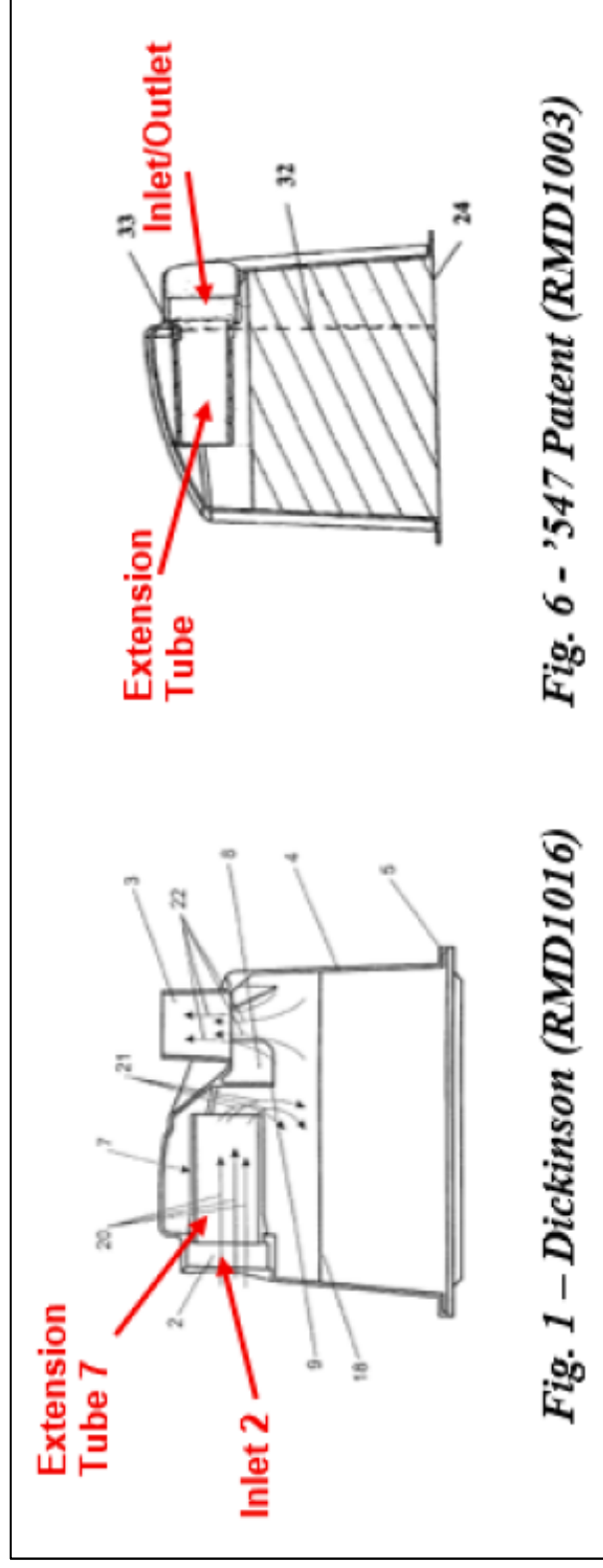
Issues to be addressed – '072, '547, '624 Patents

- 1) Moving patient outlet to CPAP housing is the only purportedly novel feature in the claims
- 2) “Urging...adjacent and in contact with” does not require a pressing force
- 3) “Auxiliary electrical connection” need not be “separate and distinct” from the patient outlet
- 4) Evidence shows motivation to combine Bahr with other references
- 5) Kenyon teaches a single slide on motion
- 6) Wickham teaches air path removal for cleaning, sterilizing, or disinfecting a gas flow path
- 7) **Evidence shows motivation to combine Dickinson with other references**

Dickinson teaches the use of extension tubes like those claimed in the patents

6. A humidifier chamber for use with a gases humidification apparatus, the humidifier chamber comprising: at least one extension tube extending horizontally inward into said humidifier chamber from an inner periphery of said gases inlet and/or gases outlet,

RMD1003 ('547 Patent), Claim 6.



E.g., IPR2016-01729 Petition at 53 (citing RMD1016 (Dickinson), Fig. 1 (annotated); RMD1003 (547 Patent), Fig. 6 (annotated)).

A POSITA would have been motivated to add Dickinson's extension tubes to Netzer or HC200

chamber.” *Id.* at 2:54-57. Accordingly, these advantages would have been readily

understood by and prompted a person of ordinary skill in the art at the time of the

’547 patent to add extension tubes, as suggested by *Dickinson*, to the inlet and

outlet in the *HC200 Manual*’s humidification chamber, as modified based on the

teachings of *Netzer* (as discussed above), to prevent water from flowing out of the

inlet and outlet, which both have a horizontal orientation (like *Dickinson*’s inlet 2),

when the humidification chamber is tilted. A person of ordinary skill in the art

would have understood that water flowing back through either the *HC200*

Manual’s inlet or outlet, as modified based on the teachings of *Netzer*, would pose

potential risks. For example, water flowing back through the inlet may

understood by and prompted a

RMD1012 (First Virr Declaration) ¶ 91 (cited in e.g., IPR2016-01729 Petition at 53-55).

Not challenged by cross-examination

Accordingly, these advantages would have been readily

understood by and prompted a person of ordinary skill in the art at the time of the

’547 patent to add extension tubes, as suggested by *Dickinson*, to the inlet 22 and

outlet 23 in *Netzer*’s water container 9 to prevent water from flowing out of the

inlet 22 and outlet 23, which both have a horizontal orientation (like *Dickinson*’s

inlet 2) along the same sidewall of the container 9, when the container 9 is tilted.

A person of ordinary skill in the art would have understood that water flowing

back through either *Netzer*’s inlet 22 or outlet 23 would pose potential risks. *Id.* at

¶ 116. For example, water flowing back through the inlet 22 may potentially

RMD1012 (First Virr Declaration) ¶ 104 (cited in e.g., IPR2016-01729 Petition at 53-55).

Netzer's drainage system would not have discouraged a POSITA from adding Dickinson's extension tubes

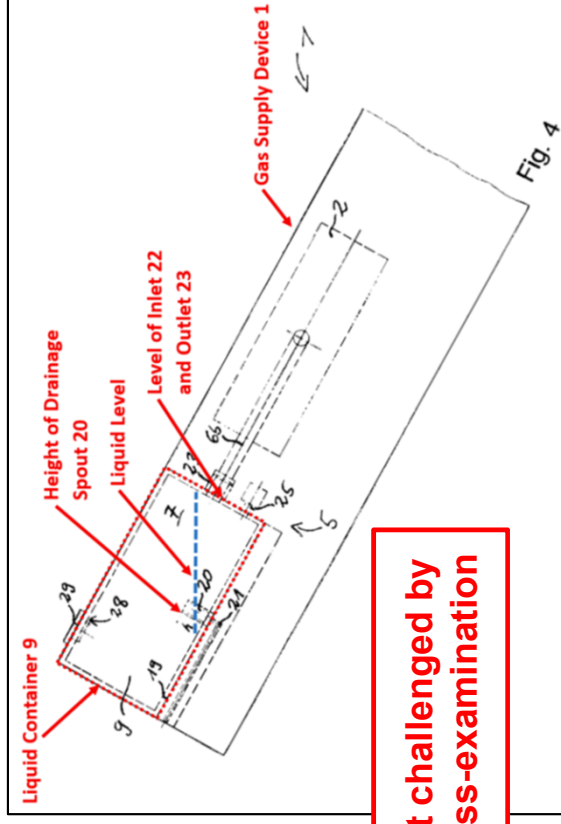
Netzer

Even in situations when the Netzer device was not in use, a POSITA would have understood that with many combinations of water levels and tilt angles, Netzer's drainage spout would not have been able to prevent any spillage. Specifically, as depicted in Netzer's Figure 4 (annotated below with rotation) if Netzer's container 9 were tilted similar to the angle shown in Dickinson Fig. 6 (see above), the liquid level would bypass the drain 20 and could reach the inlet 22 and outlet 23:

RMD1028 (Second Virr Declaration) ¶ 34
(cited in e.g., IPR2016-01729 Reply at 21-23).

I Response at 46-48), I disagree. A POSITA would have understood that Netzer's "drainage system" addresses a different problem and solution addressed from Dickinson's "inlet extension tube." Specifically, Netzer's drainage spout prevents chamber overfilling – meaning that the chamber is filled with more than a recommended amount of liquid. Netzer at pp. 6-7. In contrast, Dickinson's inlet extension tube 7 is designed to address spillage issues by preventing water backflow when there are sudden changes in the water chamber's orientation (e.g., tipping the water chamber). Dickinson at 2:59-61. A POSITA would have understood that Netzer's drain spout is not designed to accommodate issues related to a water chamber being tilted or tipped, which can cause spillage. A POSITA

RMD1028 (Second Virr Declaration) ¶ 33
(cited in e.g., IPR2016-01729 Reply at 21-23).



Not challenged by cross-examination

E.g., IPR2016-01729 Reply at 21-23 (citing RMD1008 (Netzer), Fig. 4 (annotated)).

the respiratory gas is located in this region. In order to prevent liquid drops from being carried along during the humidifying of the respiratory gas, a filling limiter is provided in the liquid container 9. This is formed by a drainage spout 20 disposed on the base 19 of the liquid container 9. When the liquid container 9 is overfilled, the excess liquid is diverted out of the gas humidifier 5 via the drainage spout 20 and a discharge line 21. The maximum filling state level is thus determined by the height h of the drainage spout 20.

RMD1008 (Netzer) at 9 (cited in e.g., IPR2016-01729 Reply at 20-21).

Patent Owner fails to acknowledge that HC200 and Netzer would benefit from extension tubes to prevent accidental tipping and spillage

baseless. Instead, a POSITA would have understood that Netzer's device would have been capable of tipping, such as in the event of an accident (e.g., device falling/being pulled off of a surface) or the device being moved. A POSITA would

RMD1034 (Second Virr Declaration) ¶ 35 (cited in e.g., IPR2016-01731 Reply at 13).

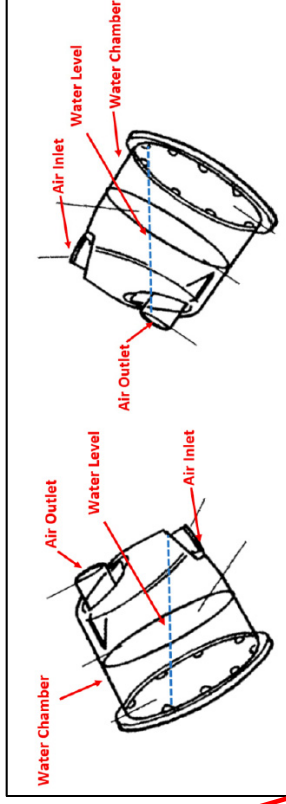
at 33-35), I disagree. A POSITA would have understood that tipping of the HC200 could have occurred while the water chamber is disconnected from the base portion (e.g., patient carrying the chamber by itself, such as when refilling the chamber) and also could have occurred while the chamber is attached to the base portion (e.g., accident causing the base and connected water chamber to tip over, such as the base and chamber being pulled off of a surface). Patent Owner also

RMD1034 (Second Virr Declaration) ¶ 37 (cited in e.g., IPR2016-01731 Reply at 13).

35), a POSITA would have understood that with many combinations of water levels and tilt angles, HC200 would not have been able to prevent any spillage.

RMD1034 (Second Virr Declaration) ¶ 39 (cited in e.g., IPR2016-01731 Reply at 13).

HC200



E.g., IPR2016-01731 Reply at 16 (citing RMD1017 (HC200) at 7 (annotated)).

Not challenged by cross-examination

IPR2016-01719

'197 Patent

Issues to be addressed – '197 patent

- I. **HC200 – A POSITA would have understood that water entering the sidewall inlet was a concern**
- II. HC200 – Hebblewhite shows a tube that prevents water from entering the opening
- III. HC200 – Selecting a tube that extends “to approximately the middle” would have been obvious
- IV. Netzer – A POSITA would have understood the concern of water entering Netzer’s gas lines due to tipping
- V. Netzer – Hebblewhite shows a tube that keeps water from spilling through the opening

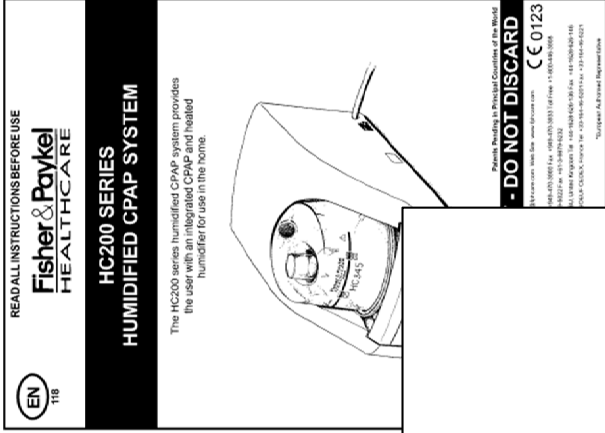
HC200 – The HC200 Manuals CAUTION that tipping may cause water to enter the inlet



CAUTION

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

RMD1015 (HC200 Manual, Rev. A) at 9 (cited by Petition at 25).



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

If you feel that your HC200 is not operating correctly, consult your homecare dealer.
Do not attempt to repair the HC200 yourself.

RMD1012 (HC200 Manual, Rev. B) at 1 (cited by Petition at 25).

In sum, neither the HC200 Manual nor Hebblewhite teach or suggest the problem identified in the '197 Patent of water spilling through a chamber inlet when the chamber is tipped. Instead, this alleged problem and Petitioners'

Patent Owner error

Response at 28.

HC200 – A POSITA would have understood that water entering the inlet was the concern

the device again). A skilled artisan would have understood that the HC200 Manual caution against moving or tilting the HC200 when the chamber is full of water is because doing so could allow water to spill through the horizontal inlet port out of the water chamber and into the HC200 blower unit, which can damage the blower or at least require the user to take multiple steps to remove water from the HC200 blower unit.

RMD1003 (First Virr Declaration) at ¶¶ 69-79 (cited in Petition at 25).

The HC200 Manual clearly states “CAUTION ... Avoid moving or tilting the HC200 when the Humidification Chamber is full of water.” This statement is clear that moving or tilting the chamber is only a concern when the chamber is “full of water” which, together with the illustrations of the chamber in the figures, would have indicated to a POSITA that moving or tipping the water chamber can cause water to splash through its sidewall opening into the blower. Patent Owner did not

RMD1026 (Second Virr Declaration) at ¶ 12 (cited in Reply at 8-9).

HC200 – Patent Owner's expert acknowledged that water entering the inlet was a concern

Q. -- is that a machine that a patient might pull off of their nightstand?

A. Absolutely, yes. Yes.

Q. Okay. And if -- so in that case, is there a possibility of the water flowing back into the flow generator?

A. Yes. In this design that was very well possible that under two conditions. First, you see the design of this device is that the outlet hose leaves the humidification chamber on top. And there was a good reason for that. As we discussed already, we could have accumulation of fluid when there was

particular U shape in the tubing. And the easiest part here was to just put your hose on top of your humidifier, and the fluid went back where it came from in the humidification chamber. There was no problem with that. That was the purpose on the top, to catch excess fluid back in there.

Now, the chamber here, I don't know the internal of the chamber. It's not given here. But let's just assume it's just an empty -- an empty house; right? There's no interior design. Of course, the lightness of the machine would easily bring back the fluid into the machine. That happened quite often with this machine.

RMD1027 (Schneider Deposition Transcript) at 158:19-161:2; see 173:3-174:2; 179:2-17 (cited in Reply at 9).

Issues to be addressed – '197 patent

I. HC200 – A POSITA would have understood that water entering the sidewall inlet was a concern

II. HC200 – Hebblewhite shows a tube that prevents water from entering the opening

III. HC200 – Selecting a tube that extends “to approximately the middle” would have been obvious

IV. Netzer – A POSITA would have understood the concern of water entering Netzer’s gas lines due to tipping

V. Netzer – Hebblewhite shows a tube that keeps water from spilling through the opening

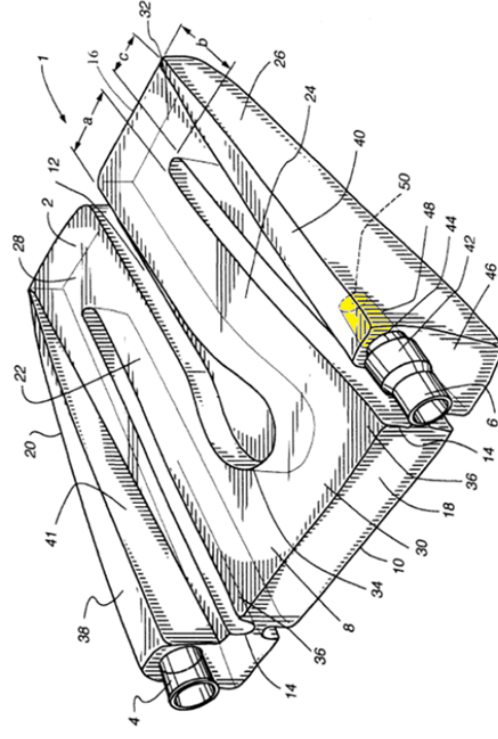
HC200 – Hebblewhite shows a tube that prevents water from entering the opening

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.)

Petition at 22-23.

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.

RMD1004 (Hebblewhite) at 5:9-16; see also 3:33-39 (cited by Petition at 24, 26).



Hebblewhite at Figure 1.

HC200 – Experts agree that humidification can be adjusted by increasing temperature

Given the orientation of the inlet and outlet openings in the water chamber shown in the HC200 Manual, adding an elongated tube at the inlet would direct airflow from the tube to the outlet. Ex. 2001 ¶ 72. Air circulation within the water

Patent Owner argument

Response at 34-35.

Hebblewhite). Selecting a balance between spillage protection and humidification is a design choice and at least some designers would have deemed a relatively short tube to provide enough protection from spillage (e.g., protection up to approximately 45 degrees, as shown by the illustration in Patent Owner's response). In fact, Patent Owner stated that the HC200's integrated "offset" protects the inlet from a modest amount of tipping, which is an admission that a tube of similar or greater length would also protect the inlet from at least as much tipping. In fact, humidification levels can be readily adjusted by increasing the temperature of the water, as controlled by the heater plate, so long as the water temperature does not exceed safety limits. Simply put, a POSITA would have

RMD1026 (Second Virr Declaration) at ¶ 14; see Petition at 28-29.

Q. And so in a device like the HC200 that is taller and has a smaller diameter than water chambers before, how would you go about maximizing the air flow over the surface area of the water?

MR. BELLINGER: Objection. Form.

THE WITNESS: On a heated humidifier it's no longer that much an issue because that's the purpose of the heated. The warmer the water, the easier is it to expel molecules into the air. So what we said the principle said before is very important and true for cold pass-over humidifiers. As soon as you have heated humidifiers, you can reduce the surface area because you can increase the temperature, and by that you can create air and humidification, vaporizing molecules. That's what the purpose is of humidification.

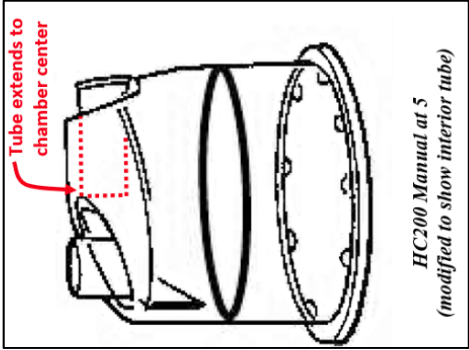
RMD1027 (Schneider Deposition Transcript)
at 183:20-184:10 (cited by Reply at 11).

Issues to be addressed – '197 patent

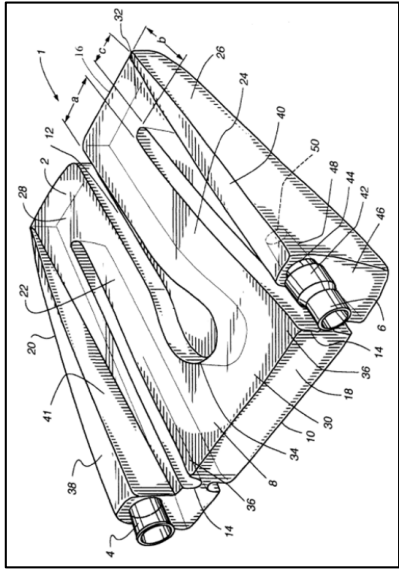
- I. HC200 – A POSITA would have understood that water entering the sidewall inlet was a concern
- II. HC200 – Hebblewhite shows a tube that prevents water from entering the opening
- III. HC200 – Selecting a tube that extends “to approximately the middle” would have been obvious**
- IV. Netzer – A POSITA would have understood the concern of water entering Netzer’s gas lines due to tipping
- V. Netzer – Hebblewhite shows a tube that keeps water from spilling through the opening

HC200 – Selecting a tube length “to approximately the middle” would have been obvious

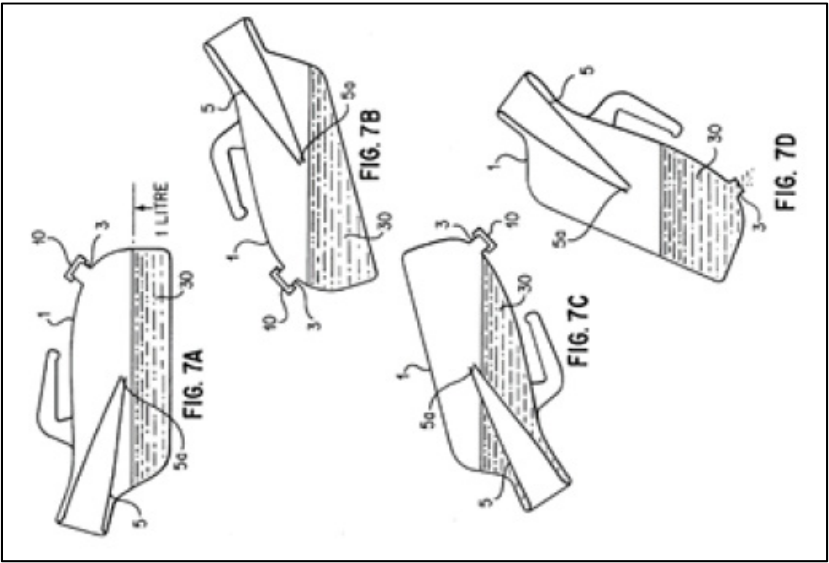
It would have been apparent to a skilled artisan, in view of the teachings of Gouget, to have designed the tube at the inlet of the HC200 water chamber (an obvious modification, as already explained with regard to claim 1) to extend to the middle of the water chamber, because extending the tube to the 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



Petition at 27.



RMD1004 (Hebblewhite) at Fig. 1.



RMD1007 (Gouget) at Figs. 7A-D

HC200 – A POSITA would have considered Gouget for its tube length teachings

as having a “tube near the volumetric center”). The tube in Petitioners’ modified design terminates at the top of the water chamber, far from its volumetric center. *Id.*; Ex. 2001 ¶ 47. Thus, Petitioners have not even applied Gouget’s teachings in arriving at their modified design.

Response at 41-42.

Patent Owner argument

chamber.” The Hebblewhite reference does not describe how long to design tubes when those tubes are used to prevent against spilling that results from tipping instead of the less-severe waves that are created when air flows through a water chamber, but I believe that it was a typical design process to select a length of tube that minimized the possibility of water spilling out of a liquid chamber, as shown by the Gouget reference. Gouget describes a liquid chamber in which it is also

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

Gouget to protect against wave action, by locating the added tube a reasonable distance above the water, for example, at the height at which the inlet was originally designed. Since chambers were designed to hold a good amount of

RMD1003 (First Virr Declaration) at ¶¶ 84-85
(cited by Petition at 27, Reply at 12-13);
see RMD1026 (Second Virr Declaration) at ¶ 18.

HC200 – Gouget’s tube length teachings are “reasonably pertinent” to the problem

Petitioners also fail to show that Gouget is reasonably pertinent to the problems being solved by the '197 Patent. See *ICON Health & Fitness, Inc.*, 496

Response at 39-40.

Patent Owner error

Gouget illustrates the basic principle that liquid in a container is less likely to enter an inlet tube the closer that tube’s opening is to the container center. Petition, 26-30; RMD1003, ¶¶ 84-85. Indeed, FPH’s expert admitted that “[t]he

Reply at 12.

Finally, the cases FPH cited predate *KSR*, and FPH ignores that test was “broadened by the Supreme Court in *KSR*.” *Ex parte Leimkuhler*, Appeal 2010-003914 (BPAL, 2012) (“[A] prior art reference is analogous under 35 U.S.C. § 103(a) if it is reasonably pertinent to any problem with which one of ordinary skill in the art is concerned.”); see also *KSR*, 505 U.S. at 417 (“[w]hen a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one.” (emphasis

Reply at 15.

that results from tipping. *In re Clay*, 966 F.2d 656, 659 (Fed. Cir. 1992). A POSITA would have recognized that Gouget’s primary focus is not the type of liquid contained, but instead a solution to prevent liquid from spilling from a container. RMD1026, ¶ 17. Indeed, Gouget is clear that its “invention” is a container that “may be tilted in any direction without spillage.” RMD1006, 1:9-20.

Reply at 14.

humidification chamber. As I explained in my initial declaration and throughout this declaration, it is clear that a POSITA seeking to solve the HC200’s spillage problem using a tube (as suggested by Hebblewhite) would have logically considered the size of the HC200 chamber, basic engineering principles, and other containers such as the Gouget container to identify an appropriate tube length. See Ex. 1003, ¶¶ 84-88.

RMD1026 (Second Virr Declaration) at ¶ 15
(cited in Reply at 11-12).

FISH.

HC200 – Expert Virr aptly summarized a POSITA's consideration of Gouget

Q Isn't it fair to say that a person of skill in the art designing a CPAP humidifier would not have looked to a urinal?

MR. KANE: Object to the form.

A I think that's how the process works. So we're not talking about a person who's just wandering around and one day decides to go looking for urinal patents. So the particular individual we're describing here has been tasked with redesigning HC200 to try and overcome spill-back issues. And what we're suggesting is that that person has looked at Hebblewhite and has said, here is a tube which appears to be useful for preventing water leaving from a side opening of a container. And under those circumstances, that person would be looking for guidance on the optimum length of that tube.

And when -- and that process of seeking guidance would have many parts, but usually that would include a patent search, and the search would not necessarily be limited -- in fact, it really shouldn't at all be limited to respiratory devices. It's a search about how long to make tubes that are intended to prevent water leaving a side opening of a water chamber or a chamber.

So under those circumstances, I don't find it at all hard to believe that that person would have come across Gouget.

Ex. 2004 (Virr Deposition Transcript) at 83:6-84:22 (cited in Petitioner Response to Motion for Observations at 4).

HC200 – Using baffles to ensure sufficient humidification was well known

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.)

Petition at 28-29.

rates one or more baffles. The baffle promotes the flow of air therethrough in a U-shaped or other appropriate indirect path, as well as providing rigidity and struc-

RMD1008 (Rose) at 2:9-11 (cited by Petition at 29).

Moreover, the baffle in Rose creates a U-shaped flow path, as shown in the figure above. The baffle that Petitioners seek to add to the HC200 Manual water chamber would not create such a flow path. The baffle that Petitioners seek to incorporate

**Patent Owner
argument**

Response at 45-46.

HC200 – A POSITA would have known how to implement baffles

RMD1008, 2:7-11; RMD1026, ¶¶ 21-23. In Rose, the inlet and outlet are on the same wall and placing the baffle between the openings to force an “indirect path” results in a parallel arrangement. A POSITA would have readily recognized that the HC200’s inlet and outlet are on different, orthogonal walls, and placing a baffle between the openings to force the “indirect path” results in a perpendicular arrangement. *Id.* Indeed, when Rose discusses an alternative design in which the inlet and outlet are on “opposite ends of the humidifier,” Rose suggests perpendicular baffles to force a “serpentine airflow path.” *Id.*; RMD1008, 4:52-63. Thus, the resulting combination is consistent with the law, especially in the context of both HC200 and Rose. *MCM*, 812 F.3d at 1294 (“what the combined teachings of the references would have suggested”).

Reply at 16-17.

Although the particular humidifier heretofore described is especially adapted for use in CPAP devices, the invention is not so limited. Broadly speaking, the principles of the invention can be used in the fabrication of humidifiers for virtually any breathing device where humidification is in order. In addition, while a single, central, integral baffle has been shown, which effectively defines a U-shaped airway path through the humidifier, other alternatives are possible. For example, a pair of spaced apart baffle walls, together with an inlet and an outlet on opposite ends of the humidifier body, could be employed. This would generate an essentially S-shaped or serpentine airflow path through the humidifier. A unit could also be fabricated without any baffles

RMD1008 (Rose) at 4:50-63 (cited by Reply at 16).

Issues to be addressed – '197 patent

- I. HC200 – A POSITA would have understood that water entering the sidewall inlet was a concern
- II. HC200 – Hebblewhite shows a tube that prevents water from entering the opening
- III. HC200 – Selecting a tube that extends “to approximately the middle” would have been obvious

IV. Netzer – A POSITA would have understood the concern of water entering Netzer’s gas lines due to tipping

- V. Netzer – Hebblewhite shows a tube that keeps water from spilling through the opening

Netzer – A POSITA would have understood that water in the gas lines was a concern

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

Petition at 40.

the respiratory gas is located in this region. In order to prevent liquid drops from being carried along during the humidifying of the respiratory gas, a filling limiter is provided in the liquid container 9. This is formed by a drainage spout 20 disposed on the base 19 of the liquid

RMD1010 (Netzer) at 6-7, 9 (cited by Petition at 40-43).

Netzer – A POSITA would have known that water could enter gas lines from tipping/bumping

Netzer also does not describe any potential problem from spillage due to tipping or bumping. Ex. 2001 ¶ 103. Instead, that alleged problem, and its

Response at 52.

Patent Owner
argument

in addition to through the outlet 23. See RMD1010 at 6-7 and 9. Skilled artisans would have recognized that water entering inlet 22 could flow back into the “respiratory gas source 2 . . . formed by a blower” (RMD1010 at 7) and harm the blower if the device was tipped while the blower was off. Further, if the device

RMD1003 (First Virr Declaration) at ¶ 100 (cited by Petition at 42).

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

RMD1026 (Second Virr Declaration) at ¶ 24 (cited by Reply at 18-19); see Ex. 1003 (First Virr Declaration) at ¶ 99-102.

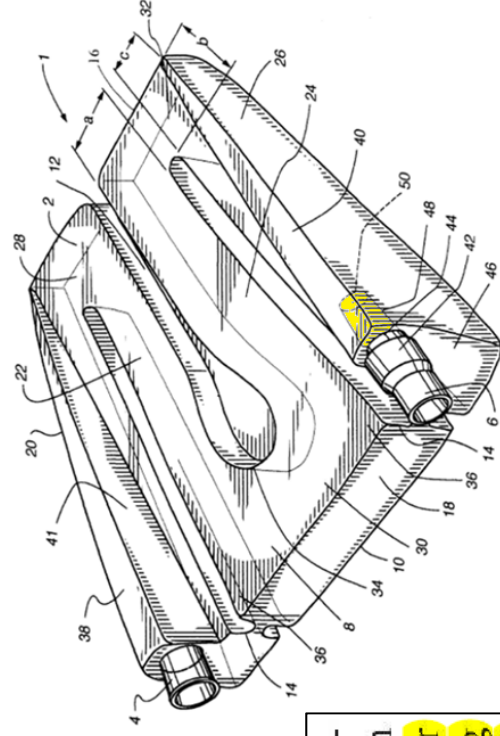
Issues to be addressed – '197 patent

- I. HC200 – A POSITA would have understood that water entering the sidewall inlet was a concern
- II. HC200 – Hebblewhite shows a tube that prevents water from entering the opening
- III. HC200 – Selecting a tube that extends “to approximately the middle” would have been obvious
- IV. Netzer – A POSITA would have understood the concern of water entering Netzer’s gas lines due to tipping
- V. Netzer – Hebblewhite shows a tube that keeps water from spilling through the opening**

Netzer – Hebblewhite shows a tube that keeps water from spilling through the opening

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

Petition at 40-41.



Hebblewhite at Figure 1.

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.

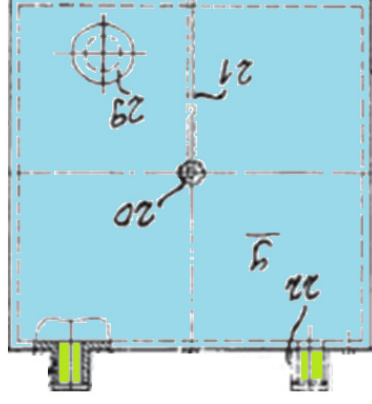
RMD1004 (Hebblewhite) at 5:9-16; see also 3:33-39 (cited by Petition at 42).

Netzer – Air short circuits from inlet to outlet in Netzer’s original design

degrade humidification performance. Ex. 2001 ¶ 109. Air would not travel over portions of the surface of the water because of the two extension tubes, which would reduce humidification. *Id.* Consequently, a POSITA would not have been

Response at 55.

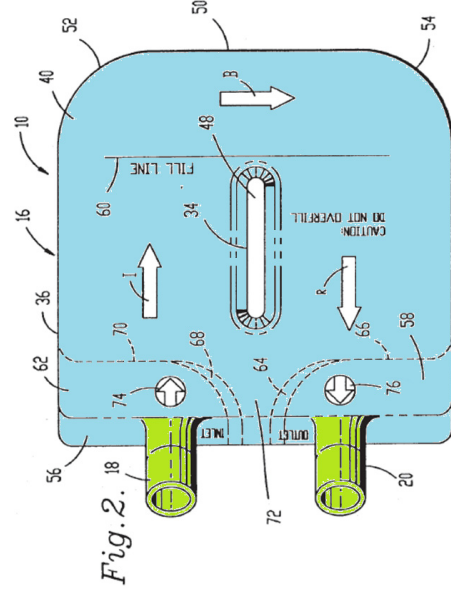
Patent Owner error



Ex. 1010 (Netzer) at Fig. 2
(rotated and portions omitted)

Indeed, Netzer’s humidification chamber configuration, in which the inlet and outlet are located on the same wall, is the same as that in Rose, for which Rose is clear that a baffle is necessary to ensure sufficient humidification. *See* Ex. 1008, FIG. 2, 2:3-13. As such, even if air short circuited directly from Netzer’s inlet to Netzer’s outlet after tubes have been added, as the Patent Owner and Dr. Schneider suggest, a POSITA would have recognized that this was already the case in Netzer’s design and adding tubes would not necessarily make the air flow worse.

RMD1026 (Second Virr Declaration) at ¶ 30; (cited by Reply at 21-22).



Ex. 1008 (Rose) at Fig. 2.

Netzer – Experts agree that humidification can be adjusted by increasing temperature

are advantageous. Resp., 53. A POSITA would have considered any such minimal humidification reduction worthwhile to protect the patient, and would have further recognized that one could have compensated for modest humidification reductions by increasing heater plate temperature. RMD1026, ¶¶ 30-31; *Winner*, 202 F.3d at 1349 n.8; RMD1027, 183:20-184:10 (admitting that “you can increase the temperature, and by that you can create air and humidification”). Third, even if a POSITA would have implemented significant

Reply at 22 (citing Schneider Deposition Transcript, RMD1027).

31. Second, even if adding tubes reduced humidification, humidification levels can be readily adjusted by increasing the temperature of the water, as controlled by the heater plate, so long as the temperature does not exceed safety limits. Simply put, a POSITA may have considered a modest reduction in

Q. And so in a device like the HC200 that is taller and has a smaller diameter than water chambers before, how would you go about maximizing the air flow over the surface area of the water?

MR. BELLINGER: Objection. Form.

THE WITNESS: On a heated humidifier it's no longer that much an issue because that's the purpose of the heated. The warmer the water, the easier is it to expel molecules into the air. So what we said the principle said before is very important and true for cold pass-over humidifiers. As soon as you have heated humidifiers, you can reduce the surface area because you can increase the temperature, and by that you can create air and humidification, vaporizing molecules. That's what the purpose is of humidification.

RMD1027 (Schneider Deposition) at
183:20-184:10 (cited by Reply at 27-29).

RMD1026 (Second Virr Declaration) at ¶ 31 (cited by Reply at 27-29).

Netzer – Adding a baffle to Netzer increases humidification over original design

2001 ¶ 115. Neither Petitioners nor Mr. Virr propose any other baffle design that would promote circulation through the space located beneath the added tubes. *Id.*

Response at 57-58.

 **Patent Owner
argument**

Ground 5. For example, air already flowed directly from Netzer’s inlet to its outlet in the original design and therefore, even if FPH’s suggestion that air would flow directly from the inlet to the outlet when tubes were added was true, the modified design would have the same level of humidification as the original design. RMD1026, ¶ 35. Even if there were reduced humidification, increasing the temperature would compensate for any reduced humidification. *Id.* ¶¶30-31; RMD1027, 183:20-184:10.

the “dead space.” But, as already explained, air flowed directly from the inlet to the outlet in the original design, and adding a baffle to ensure that air flows in an “indirect path” between the inlet and outlet (as disclosed by Rose) would increase humidification over the original design, even if the air still did not flow beneath the tubes. RMD1008, 2:9-13; RMD1026, ¶ 36. This obvious modification was surely

Reply at 24; see Petition at 48-49.