

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

FISHER & PAYKEL HEALTHCARE LIMITED
Patent Owner

Case IPR2016-01719
Patent 6,398,197

PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE

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EXHIBIT LIST

EX. #	Exhibit Description
RMD1001	U.S. Patent No. 6,398,197 to Dickinson et al. (“the ’197 patent”)
RMD1002	Relevant portions of the file history of the ’197 patent
RMD1003	First Declaration of Mr. Alexander Virr
RMD1004	U.S. Patent No. 6,135,432 to Hebblewhite et al. (“Hebblewhite”)
RMD1005	File History of Hebblewhite and parent app. no. 08/633,413
RMD1006	U.S. Patent No. 5,953,763 to Gouget (“Gouget”)
RMD1007	File History of Gouget parent app. no. 08/737,879
RMD1008	U.S. Patent No. 5,231,979 to Rose et al. (“Rose”)
RMD1009	U.S. Patent No. 5,588,423 to Smith (“Smith”)
RMD1010	PCT Pub. WO 98/04311 to Netzer and a certified translation thereof (“Netzer”)
RMD1011	File History of U.S. Patent No. 6,006,748 (App. No. 08/951,357)
RMD1012	Fisher & Paykel Healthcare, “HC200 Series Humidified CPAP System” Instruction Sheet, (Rev. B)
RMD1013	Fisher & Paykel Healthcare, SEC Form-1 Registration Statement
RMD1014	Stuff.co.nz, “Sleeping beautifully” article
RMD1015	Fisher & Paykel Healthcare, “HC200 Series Nasal CPAP Blower & Heated Humidifier User’s Manual,” (Rev. A)
RMD1016	Fisher & Paykel, Correspondence regarding FDA 510(k) submission

RMD1017	U.S. Patent No. 485,127 to Lynch (“Lynch”)
RMD1018	U.S. Patent No. 933,301 to Hartmann (“Hartmann”)
RMD1019	U.S. Patent No. 1,813,959 to Romanoff (“Romanoff”)
RMD1020	Patent Owner’s Complaint for <i>Fisher & Paykel Healthcare Ltd. v. ResMed Corp.</i> , Case No. 3:16-cv-02068-GPC-WVG (S.D. Cal.)
RMD1021	Patent Owner’s Complaint for <i>Fisher & Paykel Healthcare Ltd. v. ResMed Corp.</i> , Case No. 2:16-cv-06099-R-AJW (C.D. Cal.)
RMD1022	Patent Owner’s Notice of Voluntary Dismissal Without Prejudice for <i>Fisher & Paykel Healthcare Ltd. v. ResMed Corp.</i> , Case No. 2:16-cv-06099-R-AJW (C.D. Cal.)
RMD1023	Petitioners’ Complaint for <i>ResMed Inc., et al. v. Fisher & Paykel Healthcare Corp. Ltd., et al.</i> , Case No. 3:16-cv-02072-JAH-MDD (S.D. Cal.)
RMD1024	Petitioners’ Notice of Voluntary Dismissal Without Prejudice for <i>ResMed Inc., et al. v. Fisher & Paykel Healthcare Corp. Ltd., et al.</i> , Case No. 3:16-cv-02072-JAH-MDD (S.D. Cal.)
RMD1025	Transcript of Telephone Conference between Board and Parties on January 25, 2017
RMD1026	Second Declaration of Mr. Alexander Virr
RMD1027	Transcript of August 30, 2017 Deposition of Dr. Schneider

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The Board should find all of the challenged claims unpatentable. It is undisputed that the Jepsen-style independent claim of the '197 patent admits that the only feature of the claimed water chamber that was different from the prior art was a tube extending from the sidewall opening, but this so-called “improvement” was not new or innovative. The Petition showed that it was common to implement tubes at sidewall openings, and that a POSITA would have understood from Hebblewhite’s suggestion that such a tube would be advantageous in the HC200 and Netzer humidification chambers. Patent Owner (“FPH”) attempts to obscure the ordinary nature of this modification (and the known benefits achieved therefrom) with dozens of flawed arguments identifying irrelevant differences between Hebblewhite and the primary references, but those arguments lose sight of the forest for the trees. The Board must not do so. All claims 1-3, 6, and 13 are unpatentable upon the instituted grounds.

I. [GROUND 1] Obviousness of claim 1 by the HC200 Manual in view of Hebblewhite

The only feature in claim 1 that the HC200 Manual does not disclose is a tube at the humidification chamber’s sidewall opening. Adding that tube would have been obvious for the reasons cited in the Institution Decision. Inst. Dec., 8. Indeed, the Virr Declaration explained that a POSITA would have understood the HC200’s “CAUTION” to “[a]void moving or tilting the HC200 when the

Humidification Chamber is full of water” as an indication that such movement would spill water through the sidewall opening into the blower, which would have prompted a POSITA to modify the HC200 (as suggested, for example, by Hebblewhite). RMD1015, 9; RMD1003, ¶¶ 72-73. A second HC200 manual confirmed this fact, stating in its “Troubleshooting” section that users must disassemble and dry the humidifier if user “tip water into the blower outlet.” RMD1012, 1.

The evidence shows that a POSITA would have recognized (certainly before May 1999) that such water-spillage concerns were resolved by Hebblewhite’s suggestion for using a tube that prevents water from entering a sidewall opening. RMD1003, ¶¶ 71-80. Indeed, FPH’s expert admitted that a tube would have prevented water from flowing back into a blower outlet. RMD1027, 174:3-176:1. FPH’s Response does not directly dispute this fact, but instead identifies minor differences between the HC200 and Hebblewhite devices—differences that do not detract from Hebblewhite’s broader suggestion of using a tube or from the predictable benefit achieved by the cited combination. This obvious modification was surely “rational” and was expressly “articulated” in the Petition. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418-419 (2007).

FPH’s flawed arguments are addressed below.

The location of Hebblewhite’s tube. FPH assumed that a POSITA was an

automaton rigidly bound by the direction air flowed through Hebblewhite's tube ("inlet" vs. "outlet"). Resp., 18-19. To the contrary, the POSITA was a person of "ordinary creativity" that would have recognized Hebblewhite's broad suggestion for using a tube to reduce spillage through a sidewall opening, regardless whether that opening served as an "inlet" or "outlet." *KSR*, 550 U.S. at 421; *see also* Petition, 22-25; RMD1003, ¶¶ 71-83. Indeed, Hebblewhite's teaching was not so limited, and the tube's spillage-reducing benefit was a result of its shape and proximity to water, regardless which direction air flowed through the tube. RMD1026, ¶ 5.

The length of Hebblewhite's tube. FPH mistakenly assumed (pp. 20-21) that Hebblewhite only suggests using short (2cm) tubes, but Hebblewhite plainly suggests no upper limit for tube length. RMD1004:5:15-16 ("spaced at least 2 cm away from the end wall") (emphasis added). Again, a POSITA was not an automaton, and would have recognized that such a tube predictably implemented in the HC200 design would not have been limited to 2cm. RMD1026, ¶ 4. In fact, Hebblewhite suggests a lower bound on tube length, thereby indicating that a designer should opt towards increased length—contrary to FPH's false assumption and its arguments based upon the false assumption. *Id.*

The blower above Hebblewhite's humidification chamber. FPH contends (p. 21) that Hebblewhite does not need an inlet tube because its blower is unlikely

to be damaged by water because it is on top of the humidification chamber, but this contention is not relevant to the HC200 or the predictable modification thereto. *In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) (“[Prior art] must be read, not in isolation, but for what it fairly teaches in combination with the prior art as a whole.”). Again, the HC200 had a sidewall opening proximate to water and was subject to spillage concerns, and Hebblewhite suggested an improvement to protect against spillage. Petition, 22-25; RMD1003, ¶¶ 71-83. FPH’s arguments are misplaced and ignore the law. *MCM Portfolio LLC v. Hewlett-Packard Co.*, 812 F.3d 1284, 1294 (Fed. Cir. 2015) (“The test for obviousness is not whether the features of a secondary reference may be bodily incorporated.... Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art.”).

Hebblewhite’s teaching also cuts against FPH’s position. A POSITA would have understood that Hebblewhite’s lack of an inlet tube was not due to fundamental problems with inlet tubes, but that Hebblewhite did not need one because harm would not occur if water flowed through the inlet. RMD1026, ¶ 6. Hebblewhite’s treatment of the outlet and inlet would have plainly indicated to a POSITA that spillage-protection tubes should be placed at any sidewall opening where water flowing through would be detrimental. *Id.*

Waves vs. tipping. FPH assumes (pp. 19-27) that Hebblewhite’s tube only

protected its outlet from waves, that the tube would not help with tipping, and that the HC200 did not have a wave problem and therefore did not need a tube, but these arguments ignore the law and critical facts. FPH's contentions do not disprove the straightforward fact that the HC200 would have been improved by a tube at the sidewall opening (as suggested by Hebblewhite)—regardless of whether the spillage-protection function protected from tipping, waves, or both.

RMD1015, 9; RMD1003, ¶¶ 72-73. Contrary to FPH's contention, Petitioners were not required to show that Hebblewhite discussed "tipping spillage" for the predictable improvement to be recognized. It is sufficient that a POSITA would have known that the HC200 would be *improved* with the predictable addition of a tube (as suggested by Hebblewhite). *DyStar Textilfarben GmbH & Co.*

Deutschland KG v. C.H. Patrick Co., 464 F.3d 1356, 1366 (Fed. Cir. 2006).

Indeed, a POSITA is one of "ordinary creativity" and would have plainly recognized the benefits of reducing "tipping spillage" based on Hebblewhite's discussion that "the chances of water spillage ... are greatly reduced" with a tube at a sidewall opening (especially in light of the HC200's spillage concerns).

RMD1004, 2:64-67; RMD1026, ¶ 7.

The HC200 slide-in feature. FPH states (p. 29) that the "slide-in feature reduces the likelihood that any spillage ... might occur," but this argument cuts against FPH's position. First, FPH's statement explicitly concedes that spillage

still occurs. Second, the abrupt endwall stop that occurs during slide-in installation would likely create more waves than lowering the chamber into place. RMD1026, ¶ 13. Further, the slide-in feature couples the water chamber and humidifier body together, so that water flows into the blower when tipped rather than the components detaching. *Id.*; see RMD1027, 158:19-164:7. FPH's arguments here are fatally flawed.

Hebblewhite's elongate passageways. FPH cites (p. 22) Hebblewhite's discussion regarding purported benefits of its elongate-passageway design (RMD1004, 2:1-9), but FPH's argument is a strawman. Once again, this contention is not relevant to the HC200 or the suggested known improvement thereto. RMD1003, ¶¶ 71-83; *Merck*, 800 F.2d at 1097 ("what it fairly teaches in combination with the prior art as a whole."). Also, it is sufficient that a POSITA would have known that the HC200 would have been improved (as suggested by Hebblewhite) by remedying the spillage concern—regardless of whether other modifications (elongate passageways) might have further increased humidification. *Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349 n.8 (Fed. Cir. 2000); RMD1026, ¶ 8.

Advantages of the added tube. As an initial point, FPH misrepresents the modification proposed in the Petition by assuming the added tube replaces the HC200's "offset" to provide nearly the same structure, rather than the added tube

extending beyond the existing “offset.” Response, 28; Petition, 27; RMD1026, ¶ 10. Additionally, FPH engages in doublespeak regarding the tube, inconsistently arguing that (1) a tube is unnecessary because the “offset” already protects from spills (p. 23), and (2) a tube would not protect from spills even if added (pp. 27-28). FPH cannot have it both ways. Its admission that the “offset” would protect from spills is evidence that a tube would do the same (if not more). Lastly, FPH’s illustration of the HC200 spilling water (p. 28) is itself evidence that a short tube would advantageously protect from tipping that was less severe than the approximately 45-degree tipping in the illustration. RMD1026, ¶ 10. This illustrative admission from FPH is consistent with the Petition and known benefits achieved from the combination. Petition, 22-25; RMD1003, ¶¶ 71-83.

Tipping Hebblewhite’s chamber. FPH argues (pp. 25-27) that Hebblewhite would have required a longer tube to protect from tipping, and that Hebblewhite’s angled ceiling would not permit a longer tube, but this argument is another strawman. The Petition never suggested lengthening the tube in Hebblewhite’s chamber, and FPH’s arguments here ignore the HC200 and the suggested modification thereto. *Merck*, 800 F.2d at 1097; RMD1026, ¶ 11.

The Petition did not mention noise. FPH relies upon legal error (p. 34) by arguing that Hebblewhite does not explain that its tube reduces noise (a problem that the ’197 patent was trying to solve). *KSR*, 550 U.S. at 420 (holding it was

“error” to “look only to the problem the patentee was trying to solve”). Regardless of whether the obvious “tube” modification to the HC200 would reduce noise (which it would have done), FPH’s arguments here do not dispute the evidence that the suggested modification would have predictably resolved the HC200’s known spillage problem. *Id.* (“there existed ... a known problem for which there was an obvious solution”).

The HC200 Manual suggests the tipping problem. FPH states (pp. 28-29) that “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.” This statement is incorrect. The HC200 Manual plainly explains that a user should “[a]void moving or tilting the HC200 when the Humidification Chamber is full of water” (RMD1015, 9), and FPH did not address Mr. Virr’s testimony explaining that a POSITA would have understood the HC200’s “CAUTION” to indicate that tipping would spill water into the inlet. RMD1003, ¶¶ 72-73.

Notably, FPH never provided an alternative reason for HC200’s “CAUTION.” Rather, FPH ignores it and instead contends the HC200 “already includes features to reduce the risk of spillage from tipping.” Response, 28. Those features, however, are simply the water fill line and the inlet position above the water fill line. Ex. 2001, ¶¶ 61-63. Of course, those “features” were already

present in the HC200 and therefore HC200's "CAUTION" plainly refers to a problem not solved by those features. RMD1026, ¶ 12. HC200's water fill line and inlet position "features" undermine FPH's position because they illustrate that there was a known problem with water spillage. *Id.* Indeed, FPH's expert admitted that water would flow back through the HC200 inlet if a user pulled the humidifier off their nightstand, knocked the humidifier with excessive force, or carried an overfilled humidifier. RMD1027, 158:19-161:2; 168:24-169:16; 173:3-174:2; 179:2-17. Finally, FPH never addressed that the HC200's "CAUTION" was confirmed by the Second HC200 Manual. RMD1012, 1 ("tip water into the blower outlet").

Hebblewhite's tube is generally applicable to "other humidifiers."

Hebblewhite is clear that "the idea of spacing the outlet aperture, in this case the aperture 50 of the tube 48, away from the humidifier is of general applicability, and may be used in other humidifiers, regardless of whether the humidifiers are formed with elongate passageways." RMD1004, 5:17-22. FPH once again assumes (p. 20) that a POSITA was an automaton and would rigidly limit this suggestion to "outlets," but a POSITA having "ordinary creativity" would have understood that Hebblewhite's suggestion broadly applied to any sidewall humidifier opening in proximity to water. RMD1026, ¶ 9. Indeed, waves would not have been as significant a problem in humidifiers without elongate

passageways, but Hebblewhite explains that tubes can be used in such humidifiers. RMD1004, 1:32-36; 4:6-10; 5:17-21; RMD1026, ¶ 9.

Other devices have sidewall tubes. FPH critiques (pp. 30-33) Mr. Virr’s citation to other references that corroborate the background knowledge of a POSITA at the time (commonly using tubes at sidewall openings). RMD1003, ¶¶ 78-79. Those critiques are misplaced because they simply flag minor differences between the structures while ignoring Virr’s pertinent testimony that these references confirm his understanding of the background knowledge of a POSITA—that sidewall tubes were common and provided known benefits. *Id.* Mr. Virr’s testimony is sufficient, and the citation of corroborating references reinforces his accuracy.

Purported new problem. FPH argues (pp. 33-34) that a tube would diminish humidification, but its arguments are unpersuasive and ignore the law. First, even if the tube reduced humidification, claim 1 does not require a particular tube length and FPH’s alleged short tube (e.g., that illustrated at page 28 of the Response) would protect against spillage in many cases while only minimally affecting (if any) humidification. RMD1026, ¶ 14. Indeed, FPH’s argument (p. 23) that HC200’s “offset” protects against tipping confirms that a short tube is advantageous. A POSITA would have considered such minimal humidification reduction worthwhile to protect the blower and to keep users from needing to

disassemble the humidifier. *Id.*; *Winner*, 202 F.3d at 1349 n.8 (“The fact that the motivating benefit comes at the expense of another benefit ... should not nullify its use as a basis to modify the disclosure.”). Moreover, any humidification reduction was readily compensated by increasing heater temperature, and a small reduction in peak humidification would not have been a concern because the HC200 was known as a powerful humidifier. RMD1026, ¶ 14; RMD1027, 183:20-184:10 (FPH’s expert acknowledging that “you can increase the temperature, and by that you can create air and humidification”). Second, even if a POSITA would have implemented significant spill protection using a longer tube, the Petition proved a POSITA would have added a baffle to force air through an “indirect path.” Petition, 28-29; RMD1003, ¶¶ 86-87.

II. [GROUND 2] Obviousness of claims 2-3 by HC200 Manual in view of Hebblewhite, Gouget, and Rose

As discussed above and in the Petition, Hebblewhite’s suggestion to add a tube at a sidewall opening of a humidifier would have led to a predictable improvement of the HC200. Hebblewhite describes a lower limit for the tube length (“at least 2 cm”), but is silent regarding the upper limit. RMD1004, 5:15-16. Before 1999, of course, a POSITA would have logically considered the size of the HC200 chamber, basic engineering principles, and other containers in identifying an appropriate tube length. RMD1026, ¶ 15.

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 longer the tube, the more it will prevent spillage." RMD1027, 191:23-25. FPH's arguments against Gouget are flawed—mistakenly focusing on irrelevant elements of Gouget while ignoring Gouget's general suggestion for tube length. FPH's focus on the secondary references in isolation was error. *MCM*, 812 F.3d at 1294.

The following sections address FPH's flawed arguments.

Gouget's volumetric center endpoint. FPH contends (p. 41) that the proposed modification ignores that Gouget's tube ends at the volumetric center, but FPH overlooked Mr. Virr's explanation regarding why a POSITA would have ended the tube above the volumetric center. The Virr Declaration explained that ending the tube at the horizontal mid-point (but above the volumetric center) would advantageously maximize spill resistance as suggested by Gouget, while still accounting for the pre-existing height and horizontal orientation of the "offset" (as selected by the original HC200 designer to minimize wave production and maximize water capacity). RMD1003, ¶¶ 84-85; RMD1026, ¶ 18. Indeed, angling the tube downward to the volumetric center would place end of the tube underwater when water was at the fill line, and would intensify waves when water fell below the fill line, which Hebblewhite indicates to be undesirable. RMD1004,

1:36-40; 2:64-3:1; RMD1026, ¶ 18.

Gouget's tapered tube. FPH suggests (pp. 41-42) that a POSITA would not have used Gouget's tapered tube in the HC200 because it would whistle and cause other problems, but the Petition and Virr Declaration never suggested incorporating Gouget's "tapered" tube into the HC200. Petition, 26-30; RMD1003, ¶¶ 84-85. FPH erroneously imports a "bodily incorporation" test into the obviousness analysis, which is legal error. *MCM*, 812 F.3d at 1294; RMD1026, ¶ 19.

Lengthening Hebblewhite's tube. FPH suggests (pp. 42-44) that a POSITA would not have lengthened Hebblewhite's tube because it would hit Hebblewhite's chamber ceiling, but the Petition never suggested lengthening the tube *in Hebblewhite's chamber*. Petition, 26-30; RMD1003, ¶¶ 84-85. Yet again, FPH is improperly reading Hebblewhite in "isolation," rather than properly "in combination with the prior art as a whole." *Merck*, 800 F.2d at 1097; *MCM*, 812 F.3d at 1294 (error to import a "bodily incorporation" test).

Gouget is permissible in an obviousness determination. FPH suggests that Gouget is non-analogous art, but its arguments are based on mischaracterizations of the facts and law. Even if Gouget's type of container does not fall within the "same field," Gouget remains meaningful under the law because Gouget is "reasonably pertinent to the particular problem with which the inventor is

involved.” *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004). The background of the ’197 patent is clear that there were at least two different problems with existing “slide-on” humidifiers: (1) noise from air delivery (RMD1001, 1:17-42), and (2) spillage from tipping (RMD1001, 1:24-34).

Gouget “would have commended itself to [the ’197 patent] inventor’s attention in considering his problem,” because Gouget addresses container spillage 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.

FPH assumes (pp. 39-40) the ’197 patent is directed toward a single, overly narrow problem, but FPH’s articulation is flawed for at least two reasons. First, although the ’197 patent discusses two distinct problems (as acknowledged by FPH’s expert), FPH’s characterization improperly bundles both problems into one. RMD1026, ¶ 16; Ex. 2001, ¶ 33. If FPH’s narrow view of the law were correct, a POSITA/examiner would be precluded from considering any reference that did not address every problem mentioned in a patent. Second, FPH’s “problem” characterization is more specific than its “field of endeavor” characterization, effectively eviscerating the “reasonably pertinent” test. *Bigio*, 381 F.3d at 1325;

RMD1026, ¶ 16.

Moreover, the case law FPH cites does not support their overly-narrow articulation of the problem. FPH cited *Pure Fishing Inc.*, but ignored the different facts in which a petitioner broadened the problem beyond that originally set forth by the Board's institution decision. IPR2015-01252, Paper No. 30 at 10-11. FPH further cited *Van Wanderham*, but that case deals with wildly different technologies/solutions. *In re Van Wanderham*, 378 F.2d 981, 988 (CCPA 1967) (“cryogenic liquid propellant flow system” and “cutlery art”). Here, the first paragraph of Gouget states that its “invention” enables containers to be “tilted in any direction without spillage,” which is a specific problem to which the '197 patent is directed. RMD1006, 1:10-20.

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 (BPAI, 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 added)). Fatally, FPH never addresses this mandate under *KSR*. For the reasons described above, Gouget is pertinent to the problem of selecting a tube length.

Rose teaches benefits to baffles. The claims do not recite a baffle, but the Petition and Virr Declaration were clear that a POSITA would have considered it obvious to add a baffle to the HC200 chamber in view of Rose's teachings. Petition, 28-29; RMD1003, ¶¶ 86-87. FPH argues (pp. 41-47) that two differences in the proposed baffle design (in the Petition) show improper hindsight, but they do not. Instead, FPH's arguments ignore both the law and the level of ordinary skill.

A first difference is that Rose's baffle is parallel to air flowing from its inlet, while the proposed baffle is perpendicular to air flowing from the HC200's inlet. Of course, FPH ignores that Rose expressly suggests the HC200 perpendicular design. For example, Rose teaches that a baffle should be placed between the inlet and outlet to force air through an "indirect path" between the inlet and outlet. 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”).

A second difference is that Rose’s baffle extends floor-to-ceiling, while the proposed baffle extends only from the ceiling. Rose’s chamber is blow molded which requires the sizable floor-to-ceiling design illustrated by Rose, and a POSITA would have understood that the HC200 chamber is injection molded and does not require as sizable a feature. RMD1003, ¶¶87. Further, the HC200 chamber has a metal chamber bottom that is heated, making a plastic floor-to-ceiling baffle undesirable. RMD1026, ¶¶ 21-23.

In sum, FPH erroneously imports a “bodily incorporation” test into the obviousness analysis, which is a legal error. *MCM*, 812 F.3d at 1294. The evidence shows that Rose broadly suggested using a baffle in a humidification chamber (e.g., inserting a baffle between the inlet and outlet to force air through an “indirect path”), and that a POSITA would have recognized the known benefits of applying Rose’s suggestion to implement a baffle in the HC200 humidification chamber. RMD1008, 2:7-13; Petition, 28-29; RMD1003, ¶¶ 86-87. Finally, the claims do not require any “baffle” at all, so FPH’s arguments regarding specific shapes/configurations of a “baffle” are misplaced.

III. [GROUND 3] Obviousness of claim 6 by HC200 Manual in view of Hebblewhite and Smith

FPH does not present additional arguments regarding claim 6, and that claim is therefore invalid for the reasons discussed for Ground 1. Response, 57-58.

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

FPH does not present additional arguments regarding claim 13, and that claim is therefore invalid for the reasons discussed for Ground 1. Response, 58.

V. [GROUND 5] Obviousness of claims 1 and 6 by Netzer in view of Smith and Hebblewhite

The only feature in claim 1 that Netzer does not disclose is the sidewall tube, and adding that tube would have been obvious for the reasons cited in the Institution Decision. Inst. Dec., 10. Netzer discusses that there should be “no water drops ... carried over into respiratory gas lines,” and the Virr Declaration explained that water could enter the respiratory gas lines through either the inlet or outlet due to waves or tipping. Petition, 39-43 (citing RMD1010, 6-7); RMD1003, ¶¶ 99-100; RMD1026, ¶ 24. The evidence shows that a POSITA would have recognized (certainly before May 1999) that such a concern with water spilling into the respiratory lines through sidewall openings was resolved by Hebblewhite’s suggestion for using a tube mechanism that prevents water from entering a sidewall opening. RMD1003, ¶¶ 101-102. Indeed, Hebblewhite explicitly states

that “the idea of spacing the outlet aperture ... away from the humidifier ... is of general applicability and may be used in other humidifiers.” RMD1004, 5:17-22. This obvious modification was “rational” and was expressly “articulated” in the Petition. *KSR*, 550 U.S. at 418-419.

FPH’s flawed arguments are addressed below.

Netzer’s drain does not prevent water from entering the inlet/outlet. FPH suggests (pp. 50-53) that tubes are unnecessary because Netzer’s drain “solves” the splashing and spilling problem, but this statement is incorrect. The drain prevents overfilling, and would have to close upon chamber installation or else air would escape through the drain and destroy pressurization. RMD1026, ¶¶25-26; RMD1010, 9, FIGS. 1-4. Even if the drain could remain open, it simply would not drain water fast enough to remove a large wave resulting from an impact before that wave spilled into the inlet/outlet. *Id.* Moreover, if the water chamber tipped towards the inlet/outlet, the water level (already below the drain opening) would lower at the chamber center as it pooled at the sidewall with the inlet/outlet. *Id.* Indeed, FPH’s statements explicitly concede that tipping would spill water into the inlet/outlet. Resp., 52-53 (“spilling from tipping is substantially mitigated”). As such, FPH’s arguments are flawed.

The tubes would help with splashing and spilling. FPH suggests (pp. 50-51) that there would be no motivation to modify Netzer because its drain solves

Netzer's stated problem of water droplets in the air flow. But FPH fails to acknowledge that a POSITA would have recognized the additional problem of spilling due to bumping/tipping/etc., and that the drain would not address the spilling problem (as explained above). RMD1003, ¶¶ 98-105; RMD1026, ¶ 24; Petition, 39-43; RMD1010, 9, FIGS. 1-4. The law does not require Netzer to expressly mention "tipping" or "spilling" to support its combination with Hebblewhite. *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1276 (Fed. Cir. 2004).

Netzer's guides. FPH states (p. 53) that Netzer's lateral guides would minimize spilling but, as explained above for Ground 1, the abrupt endwall stop that occurs during slide-in installation would likely create more waves than lowering the chamber into place. RMD1026, ¶ 27. Moreover, the guides would couple the water chamber to the humidifier body, so that water flows into Netzer's respiratory gas lines when tipped rather than the components detaching. *Id.*

Human health is more important than tube cost. FPH states (p. 53) that adding tubes would "needlessly increase the cost and complexity," but the potential to harm patients would outweigh any minimal cost or complexity. RMD1026, ¶ 29. Moreover, FPH ignores the law here. *Winner*, 202 F.3d at 1349 n.8 ("the motivating benefit comes at the expense of another benefit"); *In re Dance*, 160 F.3d 1339, 1344 (Fed. Cir. 1998) ("Simplicity of the prior art...").

Advantages of the added tube. FPH states (p. 53) that a short tube would

not help because “[i]f the water chamber were somehow tipped substantially, water could spill through the tube,” but FPH’s statement explicitly concedes that a short tube would help with tipping that was less “substantial,” such as when the humidifier is rocked but does not tip over (a common circumstance). RMD1026, ¶ 28.

The Petition did not discuss noise. FPH relies upon legal error (p. 54) by arguing that Hebblewhite and Netzer do not address noise problems (which the ’197 patent was trying to solve). *KSR*, 550 U.S. at 420 (holding it was “error” to “look only to the problem the patentee was trying to solve.”). Regardless of whether the obvious modification to Netzer would reduce noise, FPH’s arguments here do not dispute the evidence that the suggested modification would have remedied the bumping/tipping concerns. *Id.* (“there existed ... a known problem for which there was an obvious solution”); RMD1027, 174:3-176:1 (admitting that tubes prevent flowback).

Purported new problem. FPH argues (p. 55) that adding tubes would reduce humidification because air would purportedly flow directly from the inlet to the outlet without circulating under the tubes, but FPH’s arguments are unpersuasive and ignore the law. First, Netzer’s original design locates the inlet and outlet near each other on the same sidewall, such that air would flow directly from the inlet to the outlet without circulating in the chamber, which is the problem that Rose

identifies in chambers that have their inlet and outlet on the same sidewall.

RMD1008, 1:57-61; 2:9-13; RMD1026, ¶¶ 30-31; *see* Response, 33-34, 55-58.

Accordingly, even if air continued to flow directly from the inlet to outlet when tubes were added, as FPH suggests, there would be no reduction in humidification because air would still take the same path as in the original design (just spaced apart from the wall). RMD1026, ¶¶ 30-31.

Second, even if adding the tubes reduced humidification, claim 1 does not require a particular tube length, and a short tube would protect against spillage in many cases while only minimally (if at all) affecting humidification. RMD1026, ¶¶ 30-31. Indeed, FPH's concession that, if short tubes were added, water would only spill out the chamber if the tipping was substantial confirms that short tubes 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 spill protection using a longer tube, a POSITA would have added a baffle to force air through an "indirect path" in such circumstances. Petition, 48-49; RMD1003, ¶

115.

VI. [GROUND 6] Obviousness of claims 2, 3, and 13 by Netzer in view of Smith, Hebblewhite, Gouget, and Rose

As discussed above and in the Petition, Hebblewhite's suggestion to add a tube at a humidifier sidewall opening would have led to a predictable improvement in Netzer. Hebblewhite describes a lower limit for tube length ("at least 2 cm"), but is silent regarding the upper limit. RMD1004, 5:15-16. Before 1999, of course, a POSITA would have logically considered the size of Netzer's chamber and basic engineering principles and other containers with tubes in identifying an appropriate a tube length. RMD1026, ¶ 32; KSR, 550 U.S. at 421 ("ordinary creativity", not an "automaton").

As shown in the Petition, 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, 46-50; RMD1003, ¶¶ 113-117. FPH provides only two substantive arguments regarding Gouget, and both are unpersuasive.

First, FPH argues (pp. 55-56) that Gouget is not analogous prior art, but Gouget is analogous art for the same reasons described above with respect to Ground 2. RMD1026, ¶¶ 33-34.

Second, FPH argues that adding tubes that extend to the middle of Netzer's chamber would have reduced humidification due to "dead space" under the tubes,

but this argument is not convincing for the reasons discussed with respect to 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.

Moreover, even though the claims do not recite a baffle, the Petition and Virr Declaration were clear that a POSITA would have considered it obvious to add a baffle to Netzer in view of Rose's teachings. Petition, 48-49; RMD1003, ¶115. FPH (pp. 57-58) does not dispute that it would have been obvious to add a baffle, and only argues that the baffle would not have promoted airflow through 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 "rational" and was expressly "articulated" in the petition. *KSR*, 550 U.S. at 418-419.

VII. CONCLUSION

For the reasons discussed above, Petitioners request that this Board find all claims at issue unpatentable upon the instituted grounds.

Respectfully submitted,

Dated: September 15, 2017

(Trial No. IPR2016-01719)

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CERTIFICATE UNDER 37 CFR § 42.24(d)

Under the provisions of 37 CFR § 42.24(d), the undersigned hereby certifies that the word count for the foregoing Petitioner's Reply to Patent Owner's Response totals 5,552, which is less than the 5,600 allowed under 37 CFR § 42.24(c)(1).

Respectfully submitted,

Dated: September 15, 2017
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CERTIFICATE OF SERVICE

Pursuant to 37 CFR §§ 42.6(e)(4) and 42.205(b), the undersigned certifies that on September 15, 2017, a complete and entire copy of this Petitioner's Reply to Patent Owner's Response to Petition with supporting exhibits were provided via email to the Patent Owner by serving the correspondence email address of record as follows:

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