

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BMC MEDICAL CO. LTD., 3B PRODUCTS, L.L.C., and
3B MEDICAL INC.,
Petitioner,

v.

RESMED LIMITED,
Patent Owner.

Case IPR2014-01196
Patent RE 44,453 E

Before MEREDITH C. PETRAVICK, BARRY L. GROSSMAN, and
CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

PAULRAJ, *Administrative Patent Judge*

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. BACKGROUND

BMC Medical Co. Ltd., 3B Products, L.L.C., and 3B Medical Inc. (collectively “Petitioner”) filed a Petition for *inter partes* review of claims 1–7 of U.S. Patent No. RE 44,453 E (Ex. 1001, “the ’453 patent”) pursuant to 35 U.S.C. §§ 311–319 and 37 C.F.R. §§ 42.1–42.123. Paper 2 (“Pet.”). ResMed Limited (“Patent Owner”) filed a Preliminary Response. Paper 6. Taking into account the Petition and Patent Owner’s Preliminary Response, we determined that there was a reasonable likelihood that challenged claims 1–7 are unpatentable. Pursuant to 35 U.S.C. § 314, we instituted *inter partes* review, on January 21, 2015, as to claims 1–7 of the ’453 patent. Paper 7 (“Dec.”).

After institution, Patent Owner filed a Patent Owner Response (Paper 12, “PO Resp.”). Petitioner filed a reply to the Patent Owner Response. Paper 13 (“Pet. Reply”). Additionally, Petitioner filed a Motion to Exclude Evidence (Paper 14), to which Patent Owner filed an Opposition (Paper 18). Petitioner filed a Reply in Support of its Motion to Exclude (Paper 20).

A hearing was held on September 16, 2015, a transcript of which appears in the record. Record of Oral Hearing, Paper 24 (“Tr.”).

We have jurisdiction under 35 U.S.C. § 6(c). This decision is a final written decision under 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73 as to the patentability of the challenged claims. For the reasons discussed below, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–7 are unpatentable. Petitioner’s Motion to Exclude Evidence is dismissed as moot.

A. Related Proceedings

In addition to this proceeding, we have instituted an *inter partes* review of claims 9–19, 23–36, 40, and 63 of the '453 patent based on a separate petition filed by the same Petitioner. *See* Case IPR2014-01363, Decision on Institution of *Inter Partes* Review (PTAB Jan. 21, 2015) (Paper 7).

A separate petition for *inter partes* review challenging claims 1–7 of the '453 patent was filed by Apex Medical Corp. in Case IPR2014-00551. That proceeding was terminated based on settlement prior to our decision on institution. *See* Case IPR2014-00551, Judgment (PTAB Sept. 12, 2014) (Paper 11).

The '453 patent is a reissue of U.S. Patent No. 7,614,398 (“the '398 patent”). The '398 patent was initially asserted in an investigation before the U.S. International Trade Commission (ITC), *In the Matter of Certain Sleep-Disordered Breathing Treatment Systems and Components Thereof*, ITC Investigation No. 337-TA-890, but was later substituted with the '453 patent. Pet. 2; Ex. 1007; Ex. 1022. Patent Owner has also asserted the '398 patent in *ResMed Inc. v. BMC Medical Co., Ltd., et al.*, 313-cv-01246 (S.D. Cal), and *ResMed Inc. et al v. Apex Medical Corporation et al.*, 8:13-cv-00498 (C.D. Cal), which have been stayed pending the outcome of the ITC investigation and the Board’s *inter partes* review. Pet. 2; Ex. 1008; Ex. 1009.

B. The '453 Patent

The '453 patent relates to a humidifier for use with a continuous positive airway pressure (CPAP) device. Ex. 1001, 1:25–28. As the '453 patent explains, humidification of air delivered to CPAP patients may

increase comfort. *Id.* at 1:31–33. To this end, manufacturers often supply humidifiers which may be attached in the air circuit between the blower outlet and the patient interface of a CPAP device. *Id.* at 1:33–35.

In describing the prior art, the '453 patent explains that “[t]ypically, the blower and humidifier are separate components connected via a flexible conduit” wherein “[a]n air delivery conduit connects the humidifier outlet to a patient interface mask,” or “[a]lternatively, the blower and humidifier may be rigidly-connected together” wherein “[a]ir from the blower outlet passes into the humidifier inlet where it is humidified and then passes to the air delivery conduit.” *Id.* at 1:40–46. However, “[a] potential problem with either arrangement is that if the humidifier is tilted relative to its normal orientation, water may run or spill from the humidifier into the blower outlet which may damage the electrical circuits of the blower and potentially cause infection control problems.” *Id.* at 1:46–50.

The '453 patent seeks to address this problem with the humidifier embodiments disclosed therein. For example, one embodiment of a humidifier in a non-working, upright orientation is shown in Figure 10, reproduced below:

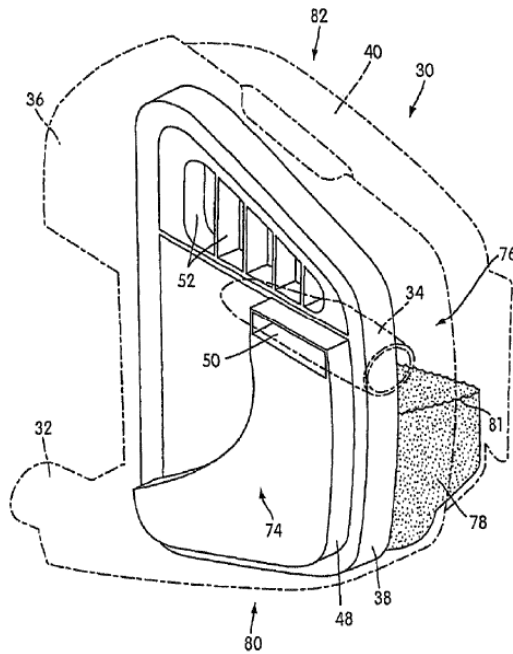


Figure 10 shows a humidifier 30 for a CPAP apparatus that “is rotated to an angle about 90° from the working upright orientation, such that a side 80 thereof corresponding to the side of the humidifier 30 adjacent the inlet 32, is oriented below a side 82 thereof corresponding to the side of the humidifier 30 adjacent the outlet 34.” *Id.* at 8:29–34. “Because the raised portion 48 of the gasket 38 increases the volume of the second chamber 76, the body of liquid 78 remains only in the second chamber 76 and the level 81 of the liquid body 78 remains below the first aperture 50. Thus, the liquid will not exit through the inlet 32.” *Id.* at 8:34–38.

The '453 patent contemplates that the humidifier “may be used as a retrofit or add-on component for a CPAP apparatus.” *Id.* at 9:25–26. To facilitate this usage, the '453 patent also discloses the use of “a connecting structure 100 that is configured to connect between the CPAP apparatus and humidifier 30.” *Id.* at 9:26–29. In certain embodiments illustrated in the patent,

the connecting structure 100 includes a housing 102, which provides a generally horizontally extending receptacle 104 within which the humidifier 30 may be disposed. The housing 102 provides a base portion 106 that is configured to support the humidifier 310 thereon and a retaining portion 108 configured to secure the humidifier 30 in position.

Id. at 9:30–35.

C. Illustrative Claims

Claims 1 and 2 of the '453 patent are illustrative, and reproduced below:

1. A humidifier assembly for a CPAP apparatus, comprising
a humidifier including
a base configured to retain a body of liquid therein, at least a portion of the base being constructed of a heat conducting material,
a top cover, and
a seal disposed between the top cover and the base; and
a connecting structure configured to connect between the CPAP apparatus and humidifier and allow communication of an outlet of the CPAP apparatus with [the] *an* inlet of the humidifier, the connecting structure including
a housing providing a base portion to support the humidifier thereon, and
a retaining mechanism configured to secure the connecting structure to the CPAP apparatus,
wherein the base portion includes a heating element in contact with the heat conducting material of the base of the humidifier.

2. A humidifier assembly according to claim 1, wherein the top cover defines both an inlet and an outlet communicated with an interior of the base, the inlet configured to receive pressurized breathable gas and the outlet configured to deliver the pressurized breathable gas with added humidity.

D. Grounds for Unpatentability

We instituted *inter partes* review of the '453 patent based upon the following grounds of unpatentability:

- A. Anticipation of claims 1 and 4–7 by Schätzl;¹
- B. Obviousness of claim 3 over Schätzl and Daniell;²
- C. Obviousness of claims 1 and 2 over Prime,³ Schätzl, and Dobson.⁴

Dec. 9.

II. DISCUSSION

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012). Claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

¹ German Pub. No. DE 199 36 499 A1, pub. Feb. 8, 2001 (Ex. 1002).

² U.S. Pat. No. 6,050,260, iss. Apr. 18, 2000 (Ex. 1017).

³ PCT Publication No. WO 00/21602, pub. Apr. 20, 2000 (Ex. 1018).

⁴ U.S. Pat. No. 5,673,687, iss. Oct. 7, 1997 (Ex. 1019).

We determine that no explicit claim construction is necessary for this decision.

B. Anticipation of Claims 1 and 4–7 by Schätzl

Schätzl discloses a humidifier for a CPAP device. Ex. 1002, 1:3–6. According to Petitioner, Schätzl’s “tub element 1” corresponds to the claimed base, “pot part 2” corresponds to the claimed top cover, and “seal structure 6” corresponds to the claimed seal disposed between the base and top cover. Pet. 15–16. Also according to Petitioner, Schätzl’s mountable housing 4 corresponds to the claimed connecting structure, including a base that supports the mountable housing 4, heating device 14, and fastening appliance 20. *Id.* at 16–17. Petitioner asserts that fastening appliance 20 couples the humidifier to the CPAP apparatus and corresponds to the claimed retaining mechanism. *Id.* Petitioner also argues that tub element 1 is disclosed as having heat-conducting material in its bottom area 15 that is in contact with heating device 14. *Id.* at 17 (citing Ex. 1002, 5:13–21).

Patent Owner has not directed any arguments to this anticipation challenge. As we indicated in our Scheduling Order, “any arguments for patentability not raised in the [Patent Owner’s] response will be deemed waived.” Paper 8, 5. Indeed, during the oral hearing, Patent Owner’s counsel admitted that Schätzl anticipates claim 1 of the ’453 patent. Tr. 45:6–15. Upon consideration of the arguments and evidence made of record in this proceeding, we determine that Petitioner has demonstrated by a preponderance of the evidence that Schätzl anticipates claims 1 and 4–7.

C. Obviousness of Claim 3 over Schätzl and Daniell

Claim 3 requires that “the connecting structure includes a control knob to control a heat setting of the heating element.” Petitioner has shown

that Schätzl discloses switching means 27 for controlling heating of water in the humidifier. Pet. 20. Petitioner has further shown that Daniell discloses a humidified CPAP system in which a dial controls heating of a heater plate to heat water in a humidification chamber. *Id.* at 21. Petitioner has also demonstrated that the substitution of Daniell's control knob for Schätzl's switching means would have been an obvious design choice to provide patients with easy temperature control. *Id.* (citing Ex. 1004 ¶ 52).

Patent Owner also does not direct any arguments to this obviousness challenge. Upon consideration of the arguments and evidence made of record in this proceeding, we determine that Petitioner has demonstrated by a preponderance of the evidence that claim 3 is unpatentable for obviousness over Schätzl and Daniell.

D. Obviousness of Claims 1 and 2 over Prime, Schätzl, and Dobson

Petitioner has asserted that Prime discloses all the limitations of claim 1 except the connecting structure. Pet. 42–43. In particular, Petitioner has shown that Prime's "base 3" corresponds to the claimed base, "dome 2" corresponds to the claimed top cover, and "adhesive means or glue 12" corresponds to the claimed seal disposed between the base and top cover. *Id.* at 47–49 (citing Ex. 1018, 1:5–7, 4:7–10, 3:19–26, Abstract, Figs. 1–2). Petitioner has also demonstrated that, to the extent Prime does not disclose the claimed connecting structure, Schätzl discloses this structure. *Id.* at 49–50 (citing Ex. 1002, 5:26–33, 5:58–6:3). Petitioner also asserts that a rationale for combining Prime's humidifier with Schätzl's connecting structure is provided by Dobson, which describes the undesirability of connecting a home-use humidifier to a ventilator using a flexible hose, due

to the risk of mishandling and to the extra cleaning burden. *Id.* at 50 (citing Ex. 1019, 1:24–38).

Claim 2 requires that “the top cover defines both an inlet and an outlet communicated with an interior of the base, the inlet configured to receive pressurized breathable gas and the outlet configured to deliver the pressurized breathable gas with added humidity.” Petitioner asserts that Prime’s inlet 4 and outlet 5 are defined by dome 2 and communicate with the interior of base 3, thereby rendering this dependent claim obvious when combined with Schätzl’s structure. Pet. 51–52 (citing Ex. 1018, 3:28–30). Patent Owner’s only arguments directed to the instituted grounds in this proceeding are with respect to claim 2. We do not find them persuasive.

As an initial matter, Patent Owner argues that the ITC, in Investigation No. 337-TA-890, previously rejected Petitioner’s argument that Schätzl and Dobson render claim 2 obvious. PO Resp. 17–21. We disagree that that the ITC’s determination has any bearing on the appropriate result here.⁵ First, the ITC did not consider a validity defense based on a combination that included Prime’s teachings, as presented here. Indeed, the ITC’s determination only addressed whether it would have been obvious to modify Schätzl’s “birdfeeder” humidifier design so as to move the inlet and outlet to the top cover as required by claim 2, but did not address whether it would have been obvious to modify the humidifier taught by Prime, which already contains inlet 4 and outlet 5 in the top cover (dome 2), to accommodate a connecting structure as taught by Schätzl. Ex. 2017, 137–

⁵ As noted by Patent Owner, the ITC’s determination of validity based on Schätzl and Dobson has not been appealed to the Federal Circuit. PO Resp. 21–22.

43.⁶ Second, even if we were to take the ITC's determination into account, it was decided based on the clear and convincing evidentiary standard that is not applicable to us. *Id.* at 142. In an *inter partes* review, we are entrusted with an independent statutory authority under 35 U.S.C. § 316(e) to determine patentability based on a preponderance of the evidence, and do so in light of the evidence and arguments made of record in this proceeding.

Patent Owner further argues that Petitioner has failed to show how the teachings of Schätzl and Dobson could be applied to Prime so that the inlet and outlet of Prime's humidifier are maintained in the top cover. PO Resp. 22–34. We disagree. Petitioner has articulated a specific rationale for using a connecting structure, as taught by Schätzl, rather than a hose connection that “can easily be accidentally snagged or struck by the patient” and “cut or torn in use.” Pet. 50 (citing Ex. 1019, 1:29–38).

Patent Owner's arguments are largely premised upon the ability to physically combine the structures disclosed in Prime and Schätzl. For example, Patent Owner argues that “the obvious problem with using *Prime's* humidifier in *Schätzl's* connecting structure is that the humidifier inlet 4 and outlet 5 are provided in completely different locations (i.e., the upper surface 6 of the humidification chamber 1) than the inlet and outlet openings in *Schätzl's* connecting structure (mountable housing 4).” PO Resp. 28–29. It is well established, however, that the criterion for obviousness is “not whether the references could be physically combined but whether the claimed inventions are rendered obvious by the teachings of the prior art as a whole.” *In re Etter*, 756 F.2d 852, 859 (Fed. Cir. 1985); *see also In re Keller*, 642 F.2d 413, 425 (CCPA 1981) (“The test for obviousness is not

⁶ We refer herein to the page numbers added to the very bottom of Ex. 2017.

whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference”). Here, even though the locations of the inlets and/or outlets may need to be modified in order to utilize Schätzl’s connecting structure with Prime’s humidifier, the record establishes that a skilled artisan would have been able and motivated to do so.

Thus, for the foregoing reasons, we determine that Petitioner has demonstrated by a preponderance of the evidence that claims 1 and 2 are rendered obvious by the combination of Prime, Schätzl, and Dobson.

III. PETITIONER’S MOTION TO EXCLUDE EVIDENCE

Petitioner moves to exclude certain portions of the Declarations submitted by Patent Owner (Ex. 2008; Ex. 2009), as well as Exhibits 2012–2018. Paper 14. Because our decision does not rely on any of the challenged exhibits, we dismiss Petitioner’s Motion to Exclude Evidence as moot.

IV. CONCLUSION

We conclude that Petitioner has demonstrated by a preponderance of the evidence that claims 1 and 4–7 are anticipated under 35 U.S.C. § 102 by Schätzl, that claim 3 is rendered obvious under 35 U.S.C. § 103 by Schätzl and Daniell, and that claims 1 and 2 are rendered obvious under 35 U.S.C. § 103 by Prime, Schätzl, and Dobson.

This is a final written decision of the Board under 35 U.S.C. § 318(a). Parties to the proceeding seeking judicial review of this decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

V. ORDER

Accordingly, it is

ORDERED that claims 1–7 of U.S. Patent RE 44,453 E are held to be unpatentable;

FURTHER ORDERED that Petitioner’s Motion to Exclude Evidence is dismissed as moot; and

FURTHER ORDERED that because this is a Final Written Decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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