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EXAMINER
HAKOMAKI, JAMES R

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Please find below and/or attached an Office communication concerning this application or proceeding.

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STATEMENT OF THE CASE

This is a decision on appeal, under 35 U.S.C. § 134(a) from the Examiner’s final rejection of claims 1–19. Final Act. 1 (Office Action Summary). We have jurisdiction under 35 U.S.C. § 6(b). For the reasons explained below, we find error in the Examiner’s rejections of these claims. Accordingly, we REVERSE the Examiner’s rejections.

1 “The real party in interest is the assignee of the present application, MiniPumps, LLC.” App. Br. 2. We thus proceed on the basis that, for purposes of this appeal, MiniPumps, LLC is the “Appellant.”
CLAIMED SUBJECT MATTER

The disclosed subject matter “relates to refill systems incorporating a refill needle, reservoirs, a system of passive check valves of known cracking pressures, a pressure actuation pump used to refill drug pump devices, and various sensors throughout the system.” Spec. ¶ 6. Apparatus claim 1 and method claim 13 are independent. Claim 1 is representative of the claims on appeal and is reproduced below.

1. Apparatus for refilling a reservoir, the apparatus comprising:
   a plurality of reservoirs;
   a plurality of reservoir fluid channels each associated with one of the reservoirs;
   an outlet fluid channel fluidically connected to the reservoir fluid channels;
   a plurality of valves, each having a cracking pressure, for fluidically sealing the reservoir fluid channels and the outlet fluid channel;
   at least one pressure sensor for monitoring pressure in the reservoir fluid channels and the outlet fluid channel;
   at least one actuation mechanism;
   a needle having a lumen in fluid communication with the outlet fluid channel, the needle being configured for insertion into a drug-delivery port of an implantable medical device; and
   a controller for actuating the at least one actuation mechanism and various ones of the valves in accordance with the monitored pressure and a protocol comprising a sequence of steps whereby fluidic pathways are opened between different ones of the reservoirs and the needle in a washing and filling sequence, each of the steps being associated with an expected pressure level.

REFERENCES

Frazier et al.    US 2004/0176732 A1    Sept. 9, 2004
Shih et al.     WO 2009/137777 A2    Nov. 12, 2009
THE REJECTIONS ON APPEAL

Claims 1–5 and 7–19 are rejected under 35 U.S.C. § 102(a)(2) as being anticipated by Shih.

Claim 6 is rejected under 35 U.S.C. § 103 as being unpatentable over Shih and Frazier.

ANALYSIS

The Rejection of Claims 1–5 and 7–19 as being anticipated by Shih

The Examiner finds that Shih discloses an apparatus and method for refilling a reservoir having all of the limitations recited. Final Act. 5. More particularly, the Examiner finds that:

Shih discloses an apparatus (400) for refilling a reservoir (108), the apparatus comprising: a plurality of reservoirs (428, 420, 436); a plurality of reservoir fluid channels (408, 404, 412) each associated with one of the reservoirs; an outlet fluid channel fluidically connected to the reservoir fluid channels; [and] at least one sensor (442) for monitoring pressure in the reservoir fluid channels and the outlet fluid channel.

Final Act. 5; see also Ans. 8 (citing Shih ¶ 78).

Appellant disagrees, stating that Shih’s element 442 is a “bubble detector” that “merely serves to detect the presence of gas in a fluid channel” and “has no ability to monitor pressure in the reservoir fluid channels as required by appealed claims 1 and 13.” App. Br. 9; see also Shih ¶ 66.

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2 In the Final Office Action, the drawings are objected to for failure to comply with 37 C.F.R. § 1.121(d). See Final Act. 2–3. However, this objection is not within the jurisdiction of the Board. See 37 C.F.R. § 1.181.

3 The Examiner has withdrawn the 35 U.S.C. § 112(d) rejection of claims 2, 7–9, and 12. See Ans. 7; see also Final Act. 4.
Appellant’s contentions are persuasive. Shih’s Figure 10 illustrates a plurality of bubble detectors 442 residing within tool 400. See Shih Fig. 10. Shih discloses that “the bubble detector 442 serves to detect gas.” Shih ¶ 66. The Examiner states, “Shih’s detector can measure differences in pressure in that a bubble can exert a different pressure depending upon its size of the bubble(s) and the location of the sensor.”4 Final Act. 10; see also App. Br. 9–11. However, the Examiner does not explain, or provide any supporting evidence to show, how Shih discloses “monitoring pressure” in the recited channels based on the mere detection of bubbles therein.

Nevertheless, the Examiner states, “Shih does teach the use of pressure sensors.” Ans. 8 (replicating a portion of Shih ¶ 78). Appellant again disagrees arguing, “Shih does not describe, teach or suggest implementing a pressure sensor in the refilling tool for monitoring pressure in the reservoir fluid channels” as recited. App. Br. 12 (emphasis added).

Appellant’s contention is again persuasive. However, as an initial matter, we note that apparatus claim 1 recites a refilling tool having “at least one pressure sensor for monitoring pressure in the [tool’s] reservoir fluid channels and the [tool’s] outlet fluid channel.” App. Br. 16 (Claims App.). Method claim 13, on the other hand, recites “providing a refill apparatus” and “monitoring a pressure level.” App. Br. 18 (Claims App.). Thus, in contrast to claim 1, claim 13 does not expressly recite what pressure level is being monitored (i.e., that found in the refill apparatus or that of the

4 The Examiner’s statement “a bubble can exert a different pressure depending upon its size” is indicative of the well-known Boyle’s Law (P₁V₁ = P₂V₂) which compares “the same [bubble] under two different sets of conditions.” See https://en.wikipedia.org/wiki/Boyle's_law.
implanted device being refilled). However, claim 13 also recites “providing a refill apparatus comprising at least one pump, a plurality of reservoirs, a plurality of reservoir fluid channels each associated with one of the reservoirs, a plurality of valves, each having a cracking pressure...” App. Br. 18 (Claims App.) (emphasis added).

Appellant’s Specification discloses that “[t]he controller [of the refill apparatus] may be configured to control the pump so as to maintain a pressure through the outlet lumen below a pressure causing damage to an implantable device,” “[t]he controller may be configured to control the pump so as to maintain, during a filling or aspiration step, a pressure through the outlet lumen above a cracking pressure of check valves in the fluid lines operatively used during the filling or aspiration step,” and “[t]he controller may be configured to monitor the at least one pressure sensor and, upon detection of an expected pressure level following an expected interval, to initiate or terminate a protocol step.” Spec. ¶ 11 (emphasis added); see also Spec. ¶ 12. We thus understand, consistent with Appellant’s Specification, that the claimed step “monitoring a pressure level” in claim 13 is directed to the “pressure level” within the refill apparatus itself, rather than a pressure found within the implanted device being refilled.

Referring once again to paragraph 78 of Shih relied on by the Examiner (see supra), it is not disputed that Shih discloses an “implantable drug-delivery device 100” comprising a “chamber 108” as part of this implantable device. See Shih ¶ 39; see also Figs. 1A–1B. Paragraph 78 of Shih specifically discloses circuitry, and that “the governing circuitry 444 may monitor or track the pressure in the drug chamber 108, as described above, to prevent it from surpassing a critical value.” Shih ¶ 78; emphasis
added. This passage evidences that Shih monitors or tracks a pressure within the implantable drug delivery device, i.e., within chamber 108, not within any tool (i.e., 400) used to refill that chamber. See Shih ¶ 64. The Examiner does not direct us to any disclosure where a reservoir in Shih’s refill tool 400 (as contrasted with Shih’s implanted device 100) is tracked or monitored. Thus, Appellant’s contention that “Shih does not describe, teach or suggest implementing a pressure sensor in the refilling tool for monitoring pressure in the reservoir fluid channels,” is also persuasive. App. Br. 12 (emphasis added).

In summation, and based on the record presented, we do not sustain the stated rejection of claims 1–5 and 7–19 because the Examiner has not established by a preponderance of the evidence that Shih anticipates any of independent claims 1 and 13.

**The Rejection of Claim 6 as being obvious over Shih and Frazier**

Claim 6 depends from claim 1. App. Br. 16 (Claims App.). The Examiner’s rejection of claim 6 as unpatentable over Shih and Frazier is based on the same unsupported findings in Shih as those discussed above. See Final Act. 8–9. The Examiner relies on Frazier as disclosing a biosensor and does not rely on Frazier to remedy the deficiencies of Shih. Final Act. 8–9. Accordingly, for reasons similar to those discussed above, we do not sustain the rejection of claim 6 over Shih and Frazier.

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5 The Examiner reproduced this passage in the Answer but “108” was omitted. See Ans. 8
DECISION

The Examiner’s rejections of claims 1–19 are reversed.

REVERSED